



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Board Meeting

November 18, 2015

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**NOTE:** Pursuant to the Open Meetings Law at La. R.S. 42:16, the Board may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, (4) discussions regarding personnel matters, or other purposes itemized at La. R.S. 42:17.



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## Table of Contents

1 – A.	Table of Contents	002
1 – B.	Agenda	004
1 – C.	Meeting Notice & Arrangements	006
1 – D.	Acronyms	007
2.	Invocation & Pledge of Allegiance	
3.	Quorum Call	
4.	Call for Additional Agenda Items & Adoption of Agenda	
5.	Consideration of Minutes from Previous Meetings ~ August 12, 2015	011
6.	Report on Action Items	034
7.	Confirmation of Acts	
8.	Opportunity for Public Comment	
**	Special Order of the Day – Presentation of Pharmacist Gold Certificates	
9.	Committee Reports	
A.	Finance – Mr. Pitre	035
	• Consideration of Interim Report for Fiscal Year 2015-2016	036
	• Consideration of Proposed Budget for Fiscal Year 2016-2017	045
B.	Application Review – Mr. Soileau	054
C.	Reciprocity – Ms. Hall	055
D.	Violations – Mr. Bond	056
	• Consideration of Proposed Voluntary Consent Agreements	057
E.	Impairment – Mr. Rabb	101
	• Consideration of Committee Recommendations re Applications	
F.	Reinstatement – Ms. Melancon	103
	• Consideration of Committee Recommendations re Applications	
G.	Tripartite – Mr. Burch	110
H.	Regulation Revision – Mr. McKay	111
	• Consideration of Comments & Testimony from Public Hearing re <i>Regulatory Project 2015-4 ~ Compounding for Office Use for Veterinarians</i>	112
I.	Executive Committee – Mr. Aron	148
	• Consideration of Committee Recommendations re Policies & Procedures	150
10.	Staff Reports	
J.	Assistant Executive Director – Mr. Fontenot	154
	• Consideration of Requests for Waivers from PMP Reporting Rule	166
K.	General Counsel – Mr. Finalet	194
	• Consideration of Proposed Voluntary Consent Agreements	195
L.	Executive Director – Mr. Broussard	243
	• Census Reports	248
	• Productivity Reports	254
	• Roster of Accredited Pharmacy Technician Training Programs	256
	• Exceptions Report	257
	• Examination Reports	260
	➤ MPJE	260
	➤ NAPLEX	296
	➤ PTCE	324
	• Legislative Auditor Report	330

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10.	Staff Reports (cont.)	
	• Proposal from CriticalPoint	384
	• Proposed Rule from EPA	387
	• Proposed Revision to Chapter 797 from USP	467
	• Proposed New Chapter 800 from USP	611
11.	Request to Delay Implementation of Requirement for National Accreditation of Pharmacy Technician Training Programs – Mr. Timothy Koch, WalMart Stores	643
12.	Announcements	651
13.	Adjourn	



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**NOTICE IS HEREBY GIVEN** that a meeting of the Board has been ordered and called for 9:30 a.m. on Wednesday, November 18, 2015 at the Board office, for the purpose to wit:

## AGENDA

NOTE: This agenda is tentative until 24 hours in advance of the meeting, at which time the most recent revision becomes official.

**Revised 11-16-2015**

1. Call to Order
2. Invocation & Pledge of Allegiance
3. Quorum Call
4. Call for Additional Agenda Items & Adoption of Agenda
5. Consideration of Minutes
6. Report on Action Items
7. Confirmation of Acts
8. Opportunity for Public Comment
- \*\*\*  
Special Order of the Day – Presentation of Pharmacist Gold Certificates  
PST.008941 – Charles Davis Trahan  
PST.009015 – Edward Charles Vocke, III  
PST.009016 – Karen Schell Vocke
9. Election of Board Officers
10. Committee Reports
  - A. Finance – Mr. Pitre
    - Consideration of Interim Report for Fiscal Year 2015-2016
    - Consideration of Proposed Budget for Fiscal Year 2016-2017
  - B. Application Review – Mr. Soileau
    - Consideration of Committee Recommendations re Applications
  - C. Reciprocity – Ms. Hall
    - Consideration of Committee Recommendations re Applications
  - D. Violations – Mr. Bond
    - Consideration of Proposed Voluntary Consent Agreements
  - E. Impairment – Mr. Rabb
    - Consideration of Committee Recommendations re Applications
  - F. Reinstatement – Ms. Melancon
    - Consideration of Committee Recommendations re Applications
  - G. Tripartite – Mr. Burch
  - H. Regulation Revision – Mr. McKay
    - Consideration of Comments & Testimony from Public Hearing re Regulatory Project 2015-4 ~ Compounding for Office Use for Veterinarians
  - I. Executive – Mr. Aron
    - Consideration of Committee Recommendations re Policies & Procedures

(continued)

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**NOTE:** Pursuant to the Open Meetings Law at La. R.S. 42:16, the Board may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, (4) discussions regarding personnel matters, or other purposes itemized at La. R.S. 42:17.

11. Staff Reports
  - J. Assistant Executive Director – Mr. Fontenot
    - Consideration of Requests for Waivers from PMP Reporting Requirement
  - K. General Counsel – Mr. Finalet
    - Consideration of Proposed Voluntary Consent Agreements
  - L. Executive Director – Mr. Broussard
12. Request to Delay Implementation of Requirement for National Accreditation of Pharmacy Technician Training Programs – Mr. Timothy Koch, WalMart Stores, Inc.
13. Announcements
14. Adjourn

## Acronyms

AACP	American Association of Colleges of Pharmacy
AAPS	American Association of Pharmaceutical Scientists
AAPT	American Association of Pharmacy Technicians
ACA	American College of Apothecaries
ACCME	Accreditation Council for Continuing Medical Education
ACCP	American College of Clinical Pharmacy
ACE	Advisory Committee on Examinations (NABP)
ACPE	Accreditation Council for Pharmacy Education
ADA	American Dental Association
ADC	automated dispensing cabinet
ADS	automated dispensing system
AFDO	Association of Food & Drug Officials
AFPE	American Foundation for Pharmaceutical Education
AIHP	American Institute of the History of Pharmacy
AMA	American Medical Association
AMCP	Academy of Managed Care Pharmacy
AMS	automated medication system
APEC	Australian Pharmacy Examining Council
APhA	American Pharmacists Association
APPE	advanced pharmacy practice experience
ASAE	American Society of Association Executives
ASAP	American Society for Automation in Pharmacy
ASCP	American Society of Consultant Pharmacists
ASHP	American Society of Health-System Pharmacists
ASPL	American Society for Pharmacy Law
AVMA	American Veterinary Medical Association
AWARxE	NABP consumer protection program
BNDD	Bureau of Narcotics and Dangerous Drugs
BPS	Board of Pharmacy Specialties
CAC	Citizen Advocacy Center
CCAPP	Canadian Council for Accreditation of Pharmacy Programs
CCGP	Commission for Certification in Geriatric Pharmacy
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDTM	collaborative drug therapy management
CDS	controlled dangerous substances
CE	continuing education
CFR	Code of Federal Regulations
CHPA	Consumer Healthcare Products Association
CLEAR	Council on Licensure, Enforcement and Regulation
CMI	consumer medication information
CMS	Centers for Medicare and Medicaid Services
CPD	continuing professional development
CPhA	Canadian Pharmacists Association
CPPA	Center for Pharmacy Practice Accreditation
CPSC	Consumer Product Safety Commission
DEA	Drug Enforcement Administration
DEQ	La. Department of Environmental Quality
DHH	La. Department of Health and Hospitals

DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DNV	Det Norske Veritas (Norwegian accreditation organization)
DSM	disease state management
EDK	emergency drug kit
ELTP	Electronic Licensure Transfer Program (NABP)
EPA	Federal Environmental Protection Agency
EPCS	Electronic Prescribing of Controlled Substances (DEA)
ETS	Educational Testing Service
EU	European Union
ExCPT	Examination for the Certification of Pharmacy Technicians
FARB	Federation of Associations of Regulatory Boards
FBI	Federal Bureau of Investigation
FD&C	Federal Food, Drug & Cosmetic Act
FDA	Federal Food & Drug Administration
FIP	Federation Internationale Pharmaceutique
FMI	Food Marketing Institute
FPGEC	Foreign Pharmacy Graduate Examination Committee (NABP)
FPGEE	Foreign Pharmacy Graduate Equivalency Examination (NABP)
FSBPT	Federation of State Boards of Physical Therapy
FSMB	Federation of State Medical Boards
FRC	Foreign Pharmacy Graduate Equivalency Examination Review Committee (NABP)
FTC	Federal Trade Commission
GPhA	Generic Pharmaceutical Association
GPO	US Government Printing Office
gTLD	generic top level domain (Internet addresses)
HCFA	Health Care Financing Administration
HDMA	Healthcare Distribution Management Association
HIPAA	Health Insurance Portability and Accountability Act (of 1996)
HIPDB	Healthcare Integrity and Protection Data Bank
HMO	health maintenance organization
IACP	International Academy of Compounding Pharmacists
ICANN	Internet Corporation for Assigned Numbers and Names
ICPT	Institute for the Certification of Pharmacy Technicians
IDOI	Internet Drug Outlet Identification (NABP)
INEOA	International Narcotic Enforcement Officers Association
IOM	Institute of Medicine
IPPE	introductory pharmacy practice experience
ISMP	Institute for Safe Medication Practices
JCPP	Joint Commission of Pharmacy Practitioners
LAMP	Louisiana Academy of Medical Psychologists
LANP	Louisiana Association of Nurse Practitioners
LAPA	Louisiana Academy of Physician Assistants
LBP	Louisiana Board of Pharmacy
LDA	Louisiana Dental Association
LIPA	Louisiana Independent Pharmacies Association
LPA	Louisiana Pharmacists Association
LPTA	Louisiana Physical Therapy Association
LPTB	Louisiana Physical Therapy Board
LSBD	Louisiana State Board of Dentistry
LSBME	Louisiana State Board of Medical Examiners

LSBN	Louisiana State Board of Nursing
LSBOE	Louisiana State Board of Optometry Examiners
LSBPNE	Louisiana State Board of Practical Nurse Examiners
LSBVM	Louisiana State Board of Veterinary Medicine
LSBWDD	Louisiana State Board of Wholesale Drug Distributors
LSHP	Louisiana Society of Health-System Pharmacists
LSMS	Louisiana State Medical Society
LSNA	Louisiana State Nurses Association
LTC	long term care
LTCF	long term care facility
LVMA	Louisiana Veterinary Medical Association
MPJE	Multistate Pharmacy Jurisprudence Examination (NABP)
MRC	MPJE Review Committee (NABP)
NABP	National Association of Boards of Pharmacy
NABP-F	National Association of Boards of Pharmacy Foundation
NABPLAW	National Association of Boards of Pharmacy – Law Database
NACDS	National Association of Chain Drug Stores
NAMSDL	National Alliance for Model State Drug Laws
NAPLEX	North American Pharmacist Licensure Examination (NABP)
NAPRA	National Association of Pharmacy Regulatory Authorities (Canada)
NASCSA	National Association of State Controlled Substance Authorities
NASPA	National Alliance of State Pharmacy Associations
NASPER	National All Schedules Prescription Electronic Reporting Act
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NCPA	National Community Pharmacists Association
NCPDP	National Council for Prescription Drug Programs
NCPIE	National Council on Patient Information and Education
NCPO	National Conference of Pharmaceutical Organizations
NCSBN	National Council of State Boards of Nursing
NCVHS	National Committee on Vital and Health Statistics
NDC	National Drug Code
NDMA	Nonprescription Drug Manufacturing Association
NIPCO	National Institute for Pharmacist Care Outcomes
NISPC	National Institute for Standards in Pharmacist Credentialing
NOCA	National Organization for Competency Assurance
NPA	National Pharmacy Association
NPC	National Pharmaceutical Council
NPDB	National Practitioner Data Bank
NPTA	National Pharmacy Technician Association
NRC	NAPLEX Review Committee (NABP) Federal Nuclear Regulatory Commission
OAL	Optometry Association of Louisiana
OBRA	Omnibus Budget Reconciliation Act
OIG	Office of Inspector General
ONDCP	Office of National Drug Control Policy
ONDD	Office of Narcotics and Dangerous Drugs
OSHA	Occupational Safety and Health Administration
PARE	Pharmacy Assessment, Remediation and Evaluation (NABP)
PBM	pharmacy benefit management
PCAB	Pharmacy Compounding Accreditation Board
PCCA	Professional Compounding Centers of America

PCMA	Pharmaceutical Care Management Association
PCOA	Pharmacy Curriculum Outcomes Assessment (NABP)
PDMA	Prescription Drug Marketing Act
PEBC	Pharmacy Examining Board of Canada
PhRMA	Pharmaceutical Research and Manufacturers of America
PMP	Prescription Monitoring Program
PMP-i	Prescription Monitoring Program Interconnect (NABP)
PTCB	Pharmacy Technician Certification Board
PTCE	Pharmacy Technician Certification Examination
PTEC	Pharmacy Technician Educators Council
RFID/EPC	Radio Frequency Identification / Electronic Product Code
SAMSHA	Federal Substance Abuse & Mental Health Services Administration
TJC	The Joint Commission
TOEFL	Test of English as a Foreign Language
TOEFL iBT	Test of English as a Foreign Language Internet-based Test
TSE	Test of Spoken English
URAC	Utilization Review Accreditation Commission
USP	United States Pharmacopeia / United States Pharmacopeial Convention
USP DI	US Pharmacopeia Dispensing Information
USP-NF	US Pharmacopeia – National Formulary
VAWD	Verified-Accredited Wholesale Distributors (NABP)
Vet-VIPPS	Veterinary-Verified Internet Pharmacy Practice Sites (NABP)
VIPPS	Verified Internet Pharmacy Practice Sites (NABP)
VPP	Verified Pharmacy Practice (NABP)
WHO	World Health Organization
WHPA	World Health Professions Alliance



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## Minutes

**Regular Meeting**

**&**

**Administrative Hearing**

Wednesday, August 12, 2015 at 10:00 a.m.

Thursday, August 13, 2015 at 8:30 a.m.

**Location:**

Louisiana Board of Pharmacy  
3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700

## Table of Contents

<u>Agenda Item No.</u>	<u>Description</u>	<u>Page No.</u>
<i>Wednesday, August 12, 2015</i>		
1.	Call to Order	04
2.	Invocation & Pledge of Allegiance	04
3.	Quorum Call	04
4.	Call for Additional Agenda Items & Adoption of Agenda	05
5.	Consideration of Minutes from Previous Meeting	05
6.	Report on Action Items	05
7.	Confirmation of Acts	05
8.	Opportunity for Public Comment	06
*	Statement of Purpose	06
**	Special Order of the Day	06
9.	Committee Reports	
	A. Finance	06
	B. Application Review	07
	C. Reciprocity	07
	D. Violations	07
	E. Impairment	08
	F. Reinstatement	09
	G. Tripartite	09
	H. Regulation Revision	10
	I. Executive	10
10.	Staff Reports	
	J. Assistant Executive Director	11
	K. General Counsel	12
	L. Executive Director	13
11.	Request for Interpretation of LAC 46:LIII.2745.C.2 and LAC 46:LIII.2747.B.4.b	14
12.	Announcements	14
13.	Recess	14

## Table of Contents

<u>Agenda Item No.</u>	<u>Description</u>	<u>Page No.</u>
<i>Thursday, August 13, 2015</i>		
A.	Call to Order	15
B.	Invocation & Pledge of Allegiance	15
C.	Quorum Call	15
D.	Call for Additional Agenda Items & Adoption of Agenda	15
E.	Opportunity for Public Comment	15
	Appearances	15
F.	Formal Hearings	16
G.	Adjourn	22

A regular meeting of the Louisiana Board of Pharmacy was held on Wednesday, August 12, 2015 in the Boardroom of the Board's office, located at 3388 Brentwood Drive in Baton Rouge, Louisiana. The meeting was held pursuant to public notice, each member received notice, and notice was properly posted.

*1. Call to Order*

Mr. Carl Aron, President, called the meeting to order at 10:05 a.m.

*2. Invocation & Pledge*

Mr. Aron called upon Mr. Brian Bond, and he delivered the invocation. Ms. Pam Reed then led the group in the recitation of the Pledge of Allegiance.

*3. Quorum Call*

Mr. Aron called upon the Secretary, Mr. Bond, to call the roll to establish a quorum.

**Members Present:**

Mr. Carl W. Aron  
Mr. Brian A. Bond  
Mr. Clovis S. Burch  
Mr. Ryan M. Dartez  
Ms. Jacqueline L. Hall  
Mr. Richard M. Indovina  
Mr. Marty R. McKay  
Ms. Chris B. Melancon  
Ms. Diane G. Milano  
Mr. Ronald E. Moore  
Mr. Blake P. Pitre  
Mr. T. Morris Rabb  
Ms. Pamela G. Reed  
Mr. Don L. Resweber  
Dr. Deborah H. Simonson  
Mr. Richard A. Soileau  
Mr. Rhonny K. Valentine

**Staff Present:**

Mr. Malcolm J. Broussard, Executive Director  
Mr. Carlos M. Finalet, III, General Counsel  
Mr. M. Joseph Fontenot, Assistant Executive Director  
Ms. Kelley L. Villeneuve, Office Manager

**Guests:**

Mr. Mohamad Salem – Wal-Mart Stores  
Mr. Aaron Nash  
Dr. Adam Chesler – PTCB  
Mr. Zachary Green – PTCB  
Mr. Deeb Eid – PTCB  
Mr. Earl Wattigny

Mr. Charles Morvant  
Mr. Edward Miller, Jr.  
Mr. Russell Champagne, CPA  
Ms. Penny Scruggins, CPA  
Mr. Ben Sims – Brookshire Pharmacy  
Mr. Justin Johnson – LIPA  
Mr. David Ruckman – Target Pharmacies  
Mr. Bud Courson – Courson & Nickel  
Mr. Russell Caffery – LIPA

Mr. Bond certified all 17 members were present, constituting a quorum for the conduct of official business.

#### *4. Call for Additional Agenda Items & Adoption of Agenda*

Mr. Aron asked if there were any additional agenda items, but none were offered. With no objection, the Board adopted the posted agenda dated August 10, 2015. Mr. Aron then requested authority from the Board to reorder the agenda as necessary for the purpose of accommodating certain guests. There were no objections to that request.

#### *5. Consideration of Minutes*

Mr. Aron reminded the members they had received the draft minutes from the Regular Board Meeting on May 27, 2015 held in Baton Rouge, Louisiana. With no objections, he waived the reading thereof. Hearing no requests for amendment or any objection to their approval, Mr. Aron declared the minutes were approved as presented. Mr. Bond reminded the members to sign the Minute Book.

#### *6. Report on Action Items*

Mr. Aron called on Mr. Broussard for the report. Mr. Broussard reviewed the rulemaking activities directed during the previous Board meeting, specifically in reference to the following items:

- Proposal 2015-D ~ Compounding for Office Use for Veterinarians
- Proposal 2015-E ~ Electronic Signature on Facsimile Prescription
- Proposal 2015-F ~ Telepharmacy Services
- Proposal 2015-G ~ Remote Processor Pharmacy Permit
- Proposal 2015-H ~ Remote Access to Medical Orders
- Project 2015-3 ~ Electronic Product Verification

#### *7. Confirmation of Acts*

Pursuant to Mr. Aron's declaration that the officers, committees, and executive director had attended to the business of the Board since the last meeting in accordance with policies and procedures previously approved by the Board, Mr. Rabb moved,

**Resolved**, that the actions taken and decisions made by the Board officers, Board committees, and Executive Director in the general conduct and transactions of Board business since May 27, 2015 are approved, adopted, and ratified by the entire Board.

The motion was adopted after a unanimous vote in the affirmative.

## 8. *Opportunity for Public Comment*

Mr. Aron reminded the members and guests the Open Meetings Law requires all public bodies to provide an opportunity for public comment at all meetings and for each agenda item upon which a vote is to be taken. He solicited general comments on non-agenda items from the guests present, but none were offered.

### *Statement of Purpose*

Mr. Aron reminded the members of the purpose and mission of the Board of Pharmacy by reciting the relevant portion of the Louisiana Pharmacy Practice Act. He urged the members to keep their mission in mind as they considered all the matters before them.

At this point, Mr. Aron exercised personal privilege to commend two members of the Board who had received awards at the recent meeting of the Louisiana Pharmacists Association. In particular, Mr. Pitre had been honored as the Independent Pharmacist of the Year, and Mr. Soileau as the Pharmacist of the Year. The rest of the members as well as the guests congratulated those two members with a generous round of applause.

### \*\* *Special Order of the Day – Presentation of Pharmacist Gold Certificates.*

Mr. Aron informed the members present that 134 pharmacists received their initial license from the Louisiana Board in 1965, and of that number, 51 were still actively licensed and qualified for their gold certificate, and further, that three of that number were present to receive their gold certificates. He then presented those certificates to:

PST.008994 – Edward Miller, Jr.

PST.008995 – Charles Lewis Morvant

PST.009017 – Earl Lawrence Wattigny

All of the members and guests congratulated each of the recipients with a round of generous applause.

## 9. *Committee Reports*

### A. *Finance Committee*

Mr. Aron recognized Mr. Russell Champagne and Ms. Penny Scruggins, both CPAs from Kolder, Champagne & Slaven, the accounting firm which assists the Board and staff. Mr. Aron noted that Mr. Champagne usually meets with the Board during its August meeting every year, to review the annual financial report for the previous fiscal year. Mr. Broussard directed the members to a copy of the report in their electronic meeting binder. Mr. Aron invited both guests to the witness table. Mr. Champagne then reviewed the annual report for Fiscal Year 2014-2015, including an explanation for the just-implemented GASB-68 accounting standard relative to net pension liability and its effect on the Board's financial status. He answered questions from several members. Upon the completion of his report, Mr. Pitre moved,

**Resolved**, to accept the Final Report for Fiscal Year 2014-2015, subject to legislative audit.

The motion was adopted after a unanimous vote in the affirmative. Mr. Pitre then directed the members to a copy of a proposed budget amendment for Fiscal Year 2015-2016. He reviewed the proposed changes, which included

performance adjustments for the staff to be implemented on October 1, 2015. He also indicated the Finance Committee had considered the proposal during their meeting the previous day and voted to recommend the approval of the proposed amendment. Mr. Pitre then moved,

**Resolved**, to adopt, *in globo*, Proposed Budget Amendment No. 1 for Fiscal Year 2015-2016.

The motion was adopted after a unanimous vote in the affirmative.

Finally, Mr. Pitre expressed his appreciation to the other members of the committee for their ongoing work, as well as Ms. Scruggins and Mr. Champagne.

*B. Application Review Committee*

Mr. Aron called upon Mr. Soileau for the committee report. Mr. Soileau reported the committee had not met since the previous Board meeting, but their next meeting had been scheduled for September 22, 2015.

*C. Reciprocity Committee*

Mr. Aron called upon Ms. Hall for the committee report. She reported the staff had evaluated 65 applications for pharmacist licensure by reciprocity and that none of them contained information that warranted a committee-level review. In conformance with policies and procedures previously approved by the Board, the staff approved the applications and issued the credentials.

Ms. Hall reported staff had referred one applicant to the committee, and the committee interviewed the applicant earlier that day. Following their interview and deliberation, the committee voted to issue the pharmacist license without restriction.

Finally, she closed her report with appreciation to the other committee members for their work earlier that day.

*D. Violations Committee*

Mr. Aron called upon Mr. Bond for the committee report. Mr. Bond reported the committee held an informal conference on June 17 to consider their posted agenda which included 10 cases: one pharmacist, 4 pharmacy technicians, 2 technician candidates, and 3 pharmacy permits. After interviews and deliberations, the committee took no action against two of the cases and then granted a re-hearing request from a respondent who did not appear at the conference. The committee offered proposed voluntary consent agreements for the 7 remaining cases. Of that number, four declined and are scheduled for an administrative hearing. Mr. Bond presented the three remaining agreements to the members for their consideration.

**Homer Memorial Hospital a/k/a Claiborne Memorial Medical Center (PHY.000469)** Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed the permit owner a fine of \$5,000 plus

administrative and investigative costs.

**NS3 Health, LLC d/b/a Commcare Pharmacy-FTL (PHY.006735)** Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed the permit owner a fine of \$50,000 plus administrative and investigative costs.

**Advantage Pharmacy, LLC d/b/a Advantage Pharmacy (PHY.006676)** Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand, and further, assessed the permit owner a fine of \$10,000 plus administrative and investigative costs.

Mr. Bond reported the committee will meet on September 2-3 to consider that docket of 35 cases, which includes 14 pharmacists, 6 pharmacy technicians, one pharmacy technician candidate, 13 pharmacy permits, and one CDS license for a physician.

Finally, Mr. Bond concluded his report with appreciation to the other committee members for their ongoing efforts.

*E. Impairment Committee*

Mr. Aron called upon Mr. Rabb for the committee report. Mr. Rabb reported the committee met the previous day to consider six referrals from the staff. Following their interviews and deliberations, the committee continued two of the cases, recommended the acceptance of both voluntary surrenders, and developed proposed voluntary consent agreements for the final two cases. He then presented the following files to the members for their consideration.

**Ginger Allen Teekell (PST.016606)** Mr. Rabb moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective June 19, 2015.

**William Coleman Honeycutt (PST.010643)** Mr. Rabb moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective June 19, 2015.

**Kim Cox Vines (PST.015475)** Mr. Rabb moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board approved the applicant's request for the reinstatement of the previously suspended license, contingent upon the satisfaction of certain requirements prior to December 31, 2016; and further,

upon completion of the stated requirements, the license shall be automatically reinstated, then suspended for fifteen years with execution of the suspension stayed, and then placed on probation for fifteen years, ending August 12, 2030, subject to certain terms enumerated in the consent agreement.

**Elizabeth Farrell Heard (PST.020284)** Mr. Rabb moved to approve the applicant's request for termination of the probationary period scheduled to conclude on February 5, 2018. The motion was adopted after a unanimous vote in the affirmative. The Board removed all probationary terms and restored the license to active and unrestricted status.

Finally, Mr. Rabb closed his report with appreciation to his fellow committee members for their work the previous day and for the ongoing staff support.

*F. Reinstatement Committee*

Mr. Aron called upon Ms. Melancon for the committee report. Ms. Melancon reported the committee had met the previous day to consider the three referrals from the staff. She then reported the following files to the members for their consideration.

**John Alan Smith (PST.016824)** Ms. Melancon moved to approve the application for reinstatement of the previously suspended license. The motion was adopted after a unanimous vote in the affirmative. The Board reinstated the license and restored it to active and unrestricted status.

**Taddese Tewelde (PST.011262)** Ms. Melancon moved to deny the request for reinstatement of the previously suspended license. The motion was adopted after a unanimous vote in the affirmative. The Board denied the request for reinstatement of the suspended license.

**Aaron Wayne Nash (PST.010983)** Ms. Melancon moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board approved the application for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of two years and stayed the execution of the suspension, then placed the license on probation for two years, effective August 12, 2015, subject to certain terms enumerated in the consent agreement.

Ms. Melancon closed the report with appreciation to the other committee members for their work the previous day.

*G. Tripartite Committee*

Mr. Aron noted the committee had not met since the last Board meeting.

#### *H. Regulation Revision Committee*

Mr. Aron called upon Mr. McKay for the committee report. Mr. McKay initiated a discussion on Act 261 of the 2015 Legislature, relative to the use of marijuana for therapeutic purposes. Although the legislation had not yet been formally referred to the Committee, the committee considered that topic during their August 6 meeting – from a conceptual level with no specific language yet offered. During the discussion, Mr. Aron recognized two representatives from the Louisiana Cannabis Association, who provided additional information about similar initiatives in other states.

Following an extensive discussion, Mr. McKay moved to refer Act 261 of the 2015 Legislature to the Regulation Revision Committee for the purpose of developing a regulatory proposal to implement the legislation for future consideration by the Board. The motion was adopted after a unanimous roll vote in the affirmative. President Aron referred the matter to the committee and requested priority consideration so as to comply with the deadlines included in the legislation.

At this point, Mr. Aron declared a luncheon recess. It was noted the members recessed at 11:50 a.m. and then reconvened in open session at 12:40 p.m.

#### *I. Executive Committee*

Mr. Aron indicated the committee met the previous day to consider their posted agenda. He then directed the members to the Final Legislative Brief prepared by staff. Mr. Broussard reviewed each of the measures in that report to report what action was required by either staff or the Board. By the end of that review, President Aron had referred the following items to the Board's Regulation Revision Committee for their development of regulatory proposals to be considered by the Board: (1) Act 391 (HB 319) relative to interchangeable biological products, (2) Act 409 (HB 568) relative to the use of independent marketing contractors by pharmacies, (3) Act 453 (SB 115) relative to Schedule II prescriptive authority for physician assistants and optometrists, as well as the previously-discussed (4) Act 261 (SB 143) relative to the use of marijuana for therapeutic purposes.

Mr. Aron informed the members of several ongoing questions relative to the requirement for practical experience for pharmacist licensure. The committee requested staff to research the prevalence of that requirement in other states; in reply, they provided an excerpt from the NABP Survey of Pharmacy Law, which was also provided to the members in their electronic meeting binder. At the committee's recommendation, Mr. Aron questioned the members whether they desired to maintain the requirement for additional practical experience beyond that provided during the academic professional experience program, or whether they were amenable to a reduction or elimination of that requirement. Mr. McKay moved to refer §705 of the Board's rules to the Regulation Revision Committee for their development of a regulatory proposal to amend that rule. The motion was adopted after a unanimous vote in the affirmative.

Mr. Aron then directed the members to two documents in the electronic meeting binder, both of which required approval. Mr. McKay then moved, **Resolved**, that the Board approve Amendment Three to the Memorandum of Understanding Between the National Association of Boards of Pharmacy and the State of Louisiana Relating to the Prescription Drug Monitoring Program.

The motion was adopted after a unanimous vote in the affirmative. Mr. McKay then moved,

**Resolved**, that the Board approve the Management Letter for the Legislative Auditor, in connection with their annual audit of the Board's operations, and further, authorize the Board's President and Executive Director to execute that document on our behalf.

The motion was adopted after a unanimous vote in the affirmative.

## 10. Staff Reports

### J. Report of Assistant Executive Director

Mr. Aron called upon Mr. Fontenot for his report. Mr. Fontenot then directed the members to a copy of the quarterly on the Prescription Monitoring Program (PMP) report in their electronic meeting binder. He reviewed the report and all of the reporting parameters.

Mr. Fontenot then directed the members to a copy of the PMP Annual Report for Fiscal Year 2014-2015. Since that report composed a portion of the Board's Annual Report, there was no action required for the PMP component since the full report was still pending.

Mr. Fontenot then directed the members to the requests for exemption – both partial and full – from the PMP reporting requirements. Mr. Rabb moved,

**Resolved**, to authorize the issuance of partial PMP reporting waivers to:  
> PHY.005087-IR – Community Pharmacy Service;  
once they have executed the standard consent agreement for that purpose.

The motion was adopted after a unanimous vote in the affirmative. Mr. McKay then moved,

**Resolved**, to authorize the issuance of PMP reporting waivers to:  
> PHY.007140-NR – Alegria Pharmacy Services (NY);  
> PHY.003045-HOS – Baton Rouge General Health Center Pharmacy (LA);  
> PHY.000054-HOS – Baton Rouge General Medical Center Pharmacy (LA);  
> PHY.000469-HOS – Claiborne Memorial Medical Center (LA);  
> PHY.007113-NR – Complete Medical Homecare (MO);  
> PHY.007133-HOS – Cornerstone Hospital of Bossier City (LA);  
> PHY.007131-NR – Cystic Fibrosis Services (MD);  
> PHY.007108-NR – Hemophilia Preferred Care of Memphis (TN);  
> PHY.002953-CH – Lafayette Community Healthcare Clinic Pharmacy (LA);

- > PHY.007135-NR – NuFactor Infusion Pharmacy (NC);
  - > PHY.006453-NR – Pegasus Express Pharmacy Services (TN);
  - > PHY.007139-NR – Pet360 Pharmacy (KY);
  - > PHY.006402-NR – Retail Pharmacy Customer Care Center (RI);
- and
- > PHY.007130-NR – Total Vein Pharmacy (TX)
- once they have executed the standard consent agreement for that purpose.

The motion was adopted after a unanimous vote in the affirmative.

Finally, Mr. Fontenot indicated completion of his report.

At this point, Mr. Aron declared a mid-afternoon recess. It was noted the members recessed at 2:50 p.m. and then reconvened in open session at 3:20 p.m. In Mr. Aron's temporary absence, Mr. Rabb resumed the meeting.

*K. Report of General Counsel*

Mr. Rabb called upon Mr. Finalet for the report. Mr. Finalet then presented the following files to the Board for its consideration.

**Danielle Joy Raines (CPT.011269)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board revoked the certificate, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board.

**Custom Meds, Inc. f/k/a McCully-Snyder Pharmacy d/b/a Custom Meds (PHY.006141)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board suspended the permit for a one year and five months and stayed the execution of the suspension, then placed the permit on probation for one year and five months, ending on January 8, 2017, subject to certain terms enumerated in the consent agreement.

**Jeremy John McCauley (CPT.012645)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board revoked the certificate, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or any application for any other credential issued by the Board.

It was noted Mr. Aron returned to the meeting at 3:30 p.m. and resumed the chair.

**Mitchell Morris Sonnier, DDS (CDS.027061-DDS)** Mr. McKay moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the CDS license for an

indefinite period of time, effective May 8, 2015.

**Barbara Ann Bruce, MD (CDS.034112-MD)** Mr. McKay moved to suspend the CDS license due to the voluntary surrender of respondent's DEA registration. The motion was adopted after a unanimous vote in the affirmative. The Board suspended the CDS license for an indefinite period of time, effective May 20, 2015.

**Martin Fleming Schreeder, MD (CDS.043861-MD)** Mr. McKay moved to suspend the CDS license due to the summary suspension of respondent's medical license. The motion was adopted after a unanimous vote in the affirmative. The Board suspended the CDS license for an indefinite period of time, effective June 25, 2015.

Finally, Mr. Finalet indicated the completion of his report.

*L. Report of Executive Director*

Mr. Aron called upon Mr. Broussard for the report. Mr. Broussard directed the members to his report which was posted in the Boardroom Library prior to the meeting; it was also included in the meeting binder. He reviewed the following topics:

- Meeting Activity
- Reports

Census Reports – Credentials & Compliance Divisions  
Production Reports – Credentials Division  
Exceptions Report  
Compliance Division Annual Summary  
Annual Report for Fiscal Year 2014-2015

Mr. McKay moved,

**Resolved**, to approve the *Annual Report for Fiscal Year 2014-2015.*

The motion was adopted after a unanimous vote in the affirmative.

- Examinations
  - MPJE
  - NAPLEX
  - PARE
  - PTCB
- Operations
  - Credentials Division
  - Compliance Division
  - Administrative Division
- State Activities
  - 2015 Regular Session of Louisiana Legislature
- National Activities
  - National Association of Boards of Pharmacy (NABP)
  - NABP-AACP District 6 Annual Meeting

MALTAGON

- International Activities

International Pharmaceutical Federation (FIP)

Finally, Mr. Broussard indicated the completion of his report.

11. *Request for Interpretation of LAC 46:LIII.2745.C.2 and 2747.B.4.b – Fred’s Pharmacies*

Mr. Aron requested Mr. Broussard to provide the relevant background about the request, which questioned whether the requirement for the patient’s address on a controlled substance prescription, if omitted by the prescriber, could be satisfied by the use of a ‘backtag’ in lieu of pharmacy personnel recording the address on the prescription form itself. Mr. Broussard directed the members to a copy of the request, a copy of the rules at issue, as well as a copy of the reply from the DEA. After reviewing all of the documents, the members noted the rules require the address to be recorded on the prescription form. Although the ‘backtag’ is an addendum to the form, it is not the prescription form since it was not present when the form was issued by the prescriber. A literal interpretation of the Board’s rules indicates the address shall be recorded on the form, and there is no provision in the Board’s rules for a ‘backtag.’ Further, the information from the DEA quotes the corresponding federal rules, indicating the pharmacist’s corresponding responsibility for ensuring the prescription form is complete before dispensing it. Further, the DEA suggests the verifying pharmacist should ensure the consistency between the address information on the ‘backtag’ compared to the address information on the prescription form.

Mr. Pitre moved the Board interpret LAC 46:LIII.2745.C.2 and 2747.B.4.b to require the patient’s address for a controlled substance prescription shall be written on the prescription form itself, and further, the use of a ‘backtag’ in lieu of recording the information on the prescription form itself is not compliant with the Board’s rules. The motion was adopted after a unanimous vote in the affirmative.

12. *Announcements*

Mr. Aron directed the members to the announcements in their meeting binder.

13. *Recess*

Having completed the tasks itemized on the posted agenda, with no further business pending before the Board, and without objection, Mr. Aron recessed the meeting at 4:15 p.m.

\* \* \* \* \*

An Administrative Hearing was convened on Thursday, August 13, 2015 in the Boardroom of the Board's office, located at 3388 Brentwood Drive in Baton Rouge, Louisiana. The hearing was held pursuant to public notice, each member received notice, each respondent received notice (unless specifically stated otherwise in the official transcript), and notice was properly posted.

*A. Call to Order*

Mr. Aron called the meeting to order at 8:35 a.m.

*B. Invocation & Pledge of Allegiance*

Mr. Aron called upon Mr. Bond for the invocation, then Ms. Milano led the group in the recitation of the Pledge of Allegiance

*C. Quorum Call*

Mr. Aron called upon Secretary Bond and he called the roll. After doing so, he certified all 17 members were present, constituting a quorum for the conduct of official business.

*D. Call for Additional Agenda Items & Adoption of Agenda*

Mr. Aron asked if there were any additional agenda items, and none were requested. With no objection, the Board adopted the posted agenda for the meeting. He then requested authority to re-order the agenda as may become necessary, and there was no objection to that request.

*E. Opportunity for Public Comment*

Mr. Aron reminded the members and guests the Open Meetings Law requires all public bodies to provide an opportunity for public comment at all meetings and prior to the vote on each agenda item. He solicited comments from the guests, but none were offered.

*Appearances*

Mr. Aron indicated he would serve as the Hearing Officer, Mr. Carlos Finalet as the Prosecuting Attorney, Mr. Mark LaCour as the Official Recorder, and Mr. Malcolm Broussard as the Hearing Clerk. Without objection, Mr. Aron waived the reading of the posted agenda and instead directed the insertion thereof into these minutes. The posted agenda is re-created here.

**A G E N D A**

NOTE: This agenda is tentative until 24 hours in advance of the meeting, at which time the most recent revision becomes official.  
Revised 08-03-2015

- A. Call to Order
- B. Invocation & Pledge of Allegiance
- C. Quorum Call
- D. Call for Additional Agenda Items & Adoption of Agenda
- E. Opportunity for Public Comment

- F. Formal Hearings
- |     |  |                  |
|-----|--|------------------|
| 01. | CPT.004786 – Kelly Brocato Suttles       | Case No. 14-0343 |
| 02. | PTC-A – Corsica Waynieca Northern        | Case No. 15-0047 |
| 03. | CPT.008217 – Chasity Danae Maddie        | Case No. 15-0045 |
| 04. | CPT.012350 – Christopher Captain Turnage | Case No. 15-0077 |
| 05. | PTC.022305 – Porcha Carnesha Aldredge    | Case No. 15-0055 |
| 06. | PTC.021055 – Christy Le’Ann Bourque      | Case No. 15-0111 |
- G. Adjourn

*F. Formal Hearings*

Mr. Aron asked Mr. Finalet if he was prepared, and he replied in the affirmative. Mr. Finalet then called the first case listed on the agenda.

**Corsica Waynieca Northern (PTC Applicant)** Mr. Finalet appeared for the Board and Ms. Northern appeared without counsel. At Mr. Aron’s question, Ms. Northern requested to hold the hearing in open session. Mr. Finalet presented an opening statement, one witness, and six exhibits. Ms. Northern responded to questions from the panel members. Mr. Finalet then offered a closing statement, proffered findings of fact, conclusions of law and board order, and then tendered the matter to the hearing panel for its consideration. Mr. Moore moved to enter into executive session for deliberating the disciplinary matter and discussing the respondent’s professional competency. The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered into executive session at 9:00 a.m. and then returned to open session at 9:40 a.m.

Ms. Hall moved,

**Resolved**, that the Board’s hearing panel, having heard the testimony, considered the evidence, observed the demeanor of the witnesses and weighed the credibility of each, accept the Findings of Fact as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Ms. Hall then moved,

**Resolved**, that the Board’s hearing panel accept the Conclusions of Law as proposed by the Prosecuting Attorney, modify them by deleting the first citation, adopt the amended conclusions as our own, and then enter them into the hearing record.

The motion was adopted after a majority vote in the affirmative; Mr. Pitre objected. Ms. Hall then moved,

**Resolved**, that the Board’s hearing panel enter the following order

at this time:

It is ordered, adjudged, and decreed that the Application for a New Louisiana Pharmacy Technician Candidate Registration from Corsica Waynieca Northern is hereby granted, and further, the registration shall be suspended with the execution thereof stayed, and then placed on probation for one year after the date of issue, subject to the following term: she shall not violate, or be found guilty of violating, any law or rule pertaining to the practice of pharmacy or to controlled substances..

The motion was adopted after a majority vote in the affirmative; Mr. Pitre objected.

**Kelly Brocato Suttles (CPT.004783)** Mr. Finalet appeared for the Board and noted the absence of the respondent or counsel. After verifying the absence of the respondent, Mr. Aron ruled the hearing would proceed as scheduled in the form of a default proceeding. Mr. Finalet presented an opening statement, no witnesses, and four exhibits. He then offered a closing statement, proffered proposed findings of fact, conclusions of law, and board order, and then tendered the matter to the hearing panel for its consideration. Mr. McKay moved to enter into executive session for the purpose of deliberating the disciplinary matter and discussing the respondent's professional competency. The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered executive session at 9:55 a.m. and then reconvened in open session at 10:10 a.m.

Ms. Hall moved,

**Resolved**, that the Board's hearing panel, having heard the testimony and considered the evidence, accept the Findings of Fact as proposed by the Prosecuting Attorney, modify them by amending Item 3 to delete the phrase "*two different controlled dangerous substances*" and replace it with the phrase "*one controlled dangerous substance and one prescription medication*", and by amending Item 6 to reflect the absence of the respondent from these proceedings, adopt the amended findings as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Ms. Hall then moved,

**Resolved**, that the Board's hearing panel accept the Conclusions of Law as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Ms. Hall then moved,

**Resolved**, that the hearing panel enter the following order at this time:

It is ordered, adjudged, and decreed that Louisiana

Pharmacy Technician Certificate No. 4783, held by Kelly Brocato Suttles, shall be and is hereby revoked, effective on the entry of this order, and further, the respondent shall pay the following assessments:

- (1) A fine of \$1,000;
- (2) The administrative hearing fee of \$250; and
- (3) The investigative and hearing costs, including the costs of the prosecuting attorney, and the official recorder; and

It is further ordered the acceptance of any future application for the reinstatement of this certificate, or any application for any other credential issued by the Board, shall be conditioned upon the satisfaction of the following terms:

- (1) Respondent shall have paid all assessments levied herein;
- (2) Respondent shall have no pending legal or disciplinary actions against her in any jurisdiction; and
- (3) Respondent shall have received a favorable recommendation for her return to the practice of pharmacy without posing a threat to the public's health, safety, or welfare pursuant to a medical evaluation from an addiction medicine specialist approved by the Board.

The motion was adopted after a unanimous vote in the affirmative.

**Chasity Danae Maddie (CPT.008217)** Mr. Finalet appeared for the Board and noted the absence of the respondent or counsel. After verifying the absence of the respondent, Mr. Aron ruled the hearing would proceed as scheduled in the form of a default proceeding. Mr. Finalet presented an opening statement, no witnesses, and five exhibits. He then offered a closing statement, proffered proposed findings of fact, conclusions of law, and board order, and then tendered the matter to the hearing panel for its consideration. Mr. Soileau moved to enter into executive session for the purpose of deliberating the disciplinary matter and discussing the respondent's professional competency. The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered executive session at 10:25 a.m. and then reconvened in open session at 10:45 a.m.

Ms. Hall moved,

**Resolved**, that the Board's hearing panel, having heard the testimony and considered the evidence, accept the Findings of Fact as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Ms. Hall then moved,

**Resolved**, that the Board's hearing panel accept the Conclusions of Law as proposed by the Prosecuting Attorney, modify them by deleting the citations relative to R.S. 40:968(A)(1) and R.S. 40:978(B), adopt the amended conclusions as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Ms. Hall then moved,

**Resolved**, that the hearing panel enter the following order at this time:

It is ordered, adjudged, and decreed that Louisiana Pharmacy Technician Certificate No. 8217, held by Chasity Danae Maddie, shall be and is hereby revoked, effective on the entry of this order, and further, the respondent shall pay the following assessments:

- (1) A fine of \$1,000;
- (2) The administrative hearing fee of \$250; and
- (3) The investigative and hearing costs, including the costs of the prosecuting attorney, and the official recorder; and

It is further ordered the acceptance of any future application for the reinstatement of this certificate, or any application for any other credential issued by the Board, shall be conditioned upon the satisfaction of the following terms:

- (1) Respondent shall have paid all assessments levied herein;
- (2) Respondent shall have no pending legal or disciplinary actions against her in any jurisdiction; and
- (3) Respondent shall have received a favorable recommendation for her return to the practice of pharmacy without posing a threat to the public's health, safety, or welfare pursuant to a medical evaluation from an addiction medicine specialist approved by the Board.

The motion was adopted after a unanimous vote in the affirmative.

**Christopher Captain Turnage (CPT.012350)** Mr. Finalet appeared for the Board and noted the absence of the respondent or counsel. After verifying the absence of the respondent, Mr. Aron ruled the hearing would proceed as scheduled in the form of a default proceeding. Mr. Finalet presented an opening statement, no witnesses, and five exhibits. He then offered a closing statement, proffered proposed findings of fact, conclusions of law, and board order, and then tendered the matter to the hearing panel for its consideration. Mr. Moore moved to enter into executive session for the purpose of deliberating the disciplinary matter and discussing the respondent's professional competency. The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered executive session at 10:55 a.m. and then reconvened in open session at 11:00 a.m.

Mr. McKay moved,

**Resolved**, that the Board's hearing panel, having heard the testimony and considered the evidence, accept the Findings of Fact as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Mr. McKay then moved,

**Resolved**, that the Board's hearing panel accept the Conclusions of Law as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Mr. McKay then moved,

**Resolved**, that the hearing panel enter the following order at this time:

It is ordered, adjudged, and decreed that Louisiana Pharmacy Technician Certificate No. 12350, held by Christopher Captain Turnage, shall be and is hereby revoked, effective on the entry of this order, and further, the respondent shall pay the following assessments:

- (1) A fine of \$1,000;
- (2) The administrative hearing fee of \$250; and
- (3) The investigative and hearing costs, including the costs of the prosecuting attorney, and the official recorder; and

It is further ordered the acceptance of any future application for the reinstatement of this certificate, or any application for any other credential issued by the Board, shall be conditioned upon the satisfaction of the following terms:

- (1) Respondent shall have paid all assessments levied herein; and
- (2) Respondent shall have no pending legal or disciplinary actions against him in any jurisdiction.

The motion was adopted after a unanimous vote in the affirmative.

**Porsha Carnesha Aldredge (PTC.022305)** Mr. Finalet appeared for the Board and noted the absence of the respondent or counsel. After verifying the absence of the respondent, Mr. Aron ruled the hearing would proceed as scheduled in the form of a default proceeding. Mr. Finalet presented an opening statement, no witnesses, and five exhibits. He then offered a closing statement, proffered proposed findings of fact, conclusions of law, and board order, and then tendered the matter to the hearing panel for its consideration. Mr. McKay moved to enter into executive session for the purpose of deliberating the disciplinary matter and discussing the respondent's professional competency. The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered executive session at 12:40 p.m. and then reconvened in open session at 12:50 p.m.

Ms. Hall moved,

**Resolved**, that the Board's hearing panel, having heard the testimony and considered the evidence, accept the Findings of Fact as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Ms. Hall then moved,

**Resolved**, that the Board's hearing panel accept the Conclusions of Law as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Ms. Hall then moved,

**Resolved**, that the hearing panel enter the following order at this time:

It is ordered, adjudged, and decreed that Louisiana Pharmacy Technician Candidate Registration No. 22305, held by Porsha Carnesha Aldredge, shall be and is hereby revoked, effective on the entry of this order, and further, the respondent shall pay the following assessments:

- (1) A fine of \$1,000;
- (2) The administrative hearing fee of \$250; and
- (3) The investigative and hearing costs, including the costs of the prosecuting attorney, and the official recorder; and

It is further ordered the acceptance of any future application for the reinstatement of this certificate, or any application for any other credential issued by the Board, shall be conditioned upon the satisfaction of the following terms:

- (1) Respondent shall have paid all assessments levied herein; and
- (2) Respondent shall have no pending legal or disciplinary actions against her in any jurisdiction.

The motion was adopted after a unanimous vote in the affirmative.

**Christy Le'Ann Bourque (PTC.021055)** Mr. Finalet appeared for the Board and noted the absence of the respondent or counsel. After verifying the absence of the respondent, Mr. Aron ruled the hearing would proceed as scheduled in the form of a default proceeding. Mr. Finalet presented an opening statement, no witnesses, and five exhibits. He then offered a closing statement, proffered proposed findings of fact, conclusions of law, and board order, and then tendered the matter to the hearing panel for its consideration. Ms. Melancon moved to enter into executive session for the purpose of deliberating the disciplinary matter and discussing the respondent's professional competency.

The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered executive session at 1:00 p.m. and then reconvened in open session at 1:05 p.m.

Mr. McKay moved,

**Resolved**, that the Board's hearing panel, having heard the testimony and considered the evidence, accept the Findings of Fact as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Mr. McKay then moved,

**Resolved**, that the Board's hearing panel accept the Conclusions of Law as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.

The motion was adopted after a unanimous vote in the affirmative. Mr. McKay then moved,

**Resolved**, that the hearing panel enter the following order at this time:

It is ordered, adjudged, and decreed that Louisiana Pharmacy Technician Candidate Registration No. 21055, held by Christy Le'Ann Bourque, shall be and is hereby revoked, effective on the entry of this order, and further, the respondent shall pay the following assessments:

- (1) A fine of \$1,000;
- (2) The administrative hearing fee of \$250; and
- (3) The investigative and hearing costs, including the costs of the prosecuting attorney, and the official recorder; and

It is further ordered the acceptance of any future application for the reinstatement of this certificate, or any application for any other credential issued by the Board, shall be conditioned upon the satisfaction of the following terms:

- (1) Respondent shall have paid all assessments levied herein;
- (2) Respondent shall have no pending legal or disciplinary actions against her in any jurisdiction; and
- (3) Respondent shall have received a favorable recommendation for her return to the practice of pharmacy without posing a threat to the public's health, safety, or welfare, pursuant to a medical evaluation from an addiction medicine specialist approved by the Board.

The motion was adopted after a unanimous vote in the affirmative.

Mr. Finalet indicated completion of the formal hearings scheduled for that day. Mr. Aron expressed his appreciation to Mr. LaCour for his services that day.

*G. Adjourn*

Having completed the tasks itemized on the posted agenda, with no further business pending before the Board, and without objection, Mr. Aron adjourned the meeting at 1:10 p.m.

Respectfully submitted,

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Brian A. Bond  
Secretary



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



November 18, 2015

## Agenda Item 6: Report on Action Items

During the staff report at your last meeting, you approved the Board's Annual Report for Fiscal Year 2014-2015 and directed its required distribution. We provided a copy to the Office of the Governor, the Louisiana State Library, and the Legislative Research Library. We also posted a copy on the Board's website.

On September 21, 2015, we re-issued the two emergency rules you originally issued on June 1, with no changes to the content and as you authorized during your May 27 meeting.

- With respect to *Regulatory Project 2015-4 ~ Compounding for Office Use for Veterinarians*, that proposal received comments and testimony during its August public hearing, and you will be considering those comments later during this meeting. We re-issued the emergency rule to keep it in place while you continue the formal rulemaking process. That emergency rule will expire on January 19, 2016 unless extended or cancelled sooner.
- With respect to *Regulatory Project 2015-5 ~ Electronic Signature on Facsimile Prescription*, that proposal did not receive any comments or testimony during the August public hearing. In the absence of any comments and with no need for further revision, President Aron directed the continuation of the rulemaking process. We prepared the required legislative report, and in the absence of any legislative intervention, the Board published the proposal as a Final Rule in the October 20, 2015 edition of the Louisiana Register. Since the Final Rule was effective that day, the emergency rule was cancelled.

Respectfully submitted,  
Malcolm J Broussard  
Executive Director



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Finance Committee

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**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



**NOTICE IS HEREBY GIVEN** that a meeting of the Finance Committee has been ordered and called for 4:00 p.m. on Tuesday, November 17, 2015 in the Board office, for the purpose to wit:

## AGENDA

NOTE: This agenda is tentative until 24 hours in advance of the meeting, at which time the most recent revision becomes final.

**Revised 10-31-2015**

1. Call to Order
2. Quorum Call
3. Call for Additional Agenda Items & Adoption of Agenda
4. Opportunity for Public Comment
5. Consideration of Interim Report for Fiscal Year 2015-2016
6. Consideration of Proposed Budget for Fiscal Year 2016-2017
7. Adjourn

---

**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.



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## Finance Committee

### Interim Report Fiscal Year 2015-2016

November 18, 2015

Blake P. Pitre  
Chair

Louisiana Board of Pharmacy  
 FY 2015-2016  
 Statement of Assets, Liabilities, Equity

	FY 14-15 Q4 06/30/2015 (A)	FY 15-16 Q1 09/30/2015
<b>ASSETS</b>		
> Current Assets		
* Cash		
General Operations		
Whitney Bank	160,513	160,554
Iberia Bank	928,695	644,811
Hurricane Relief Fund - Whitney Bank	83,221	83,242
Reserve Funds		
General Account	1,920,602	1,900,222
OPEB Account	<u>1,047,038</u>	<u>1,044,728</u>
* <i>Total Cash</i>	<u>4,140,069</u>	<u>3,833,557</u>
* <i>Prepaid Expenses</i>	3,000	3,000
<i>Total Current Assets</i>	4,143,069	3,836,557
> Fixed Assets		
Land: Lot 5-A, Towne Center Business Park	709,080	709,080
Land: Lot 1-A-2, Leonard Place Subdivision	295,860	295,860
Office Building - 3388 Brentwood Drive	1,057,861	1,057,861
Office Equipment	216,119	217,133
Furniture	154,198	155,493
Software: Licensure & Website	408,560	408,560
Accumulated Depreciation	<u>(762,358)</u>	<u>(779,011)</u>
<i>Total Fixed Assets</i>	<u>2,079,320</u>	<u>2,064,976</u>
<b>TOTAL ASSETS</b>	6,222,389	5,901,533
<b>DEFERRED OUTFLOWS OF RESOURCES</b>		
	644,896	644,896
<b><u>TOTAL ASSETS &amp; DEFERRED OUTFLOWS</u></b>	<b><u>6,867,285</u></b>	<b><u>6,546,429</u></b>
<b>LIABILITIES</b>		
> Current Liabilities		
Accrued salaries and benefits	82,372	0
Unemployment taxes payable	57	23
State taxes withheld	3,365	3,276
State retirement withheld	0	0
Accounts payable	2,225	0
Interest payable	2,469	0
Compensated absences (ST)	64,373	64,373
Building Loan @ Iberia Bank (ST)	<u>474,134</u>	<u>447,934</u>
<i>Total Current Liabilities</i>	<u>628,995</u>	<u>515,606</u>

Louisiana Board of Pharmacy  
 FY 2015-2016  
 Statement of Assets, Liabilities, Equity

	FY 14-15 Q4 06/30/2015 (A)	FY 15-16 Q1 09/30/2015
<b>LIABILITIES (cont.)</b>		
> Long Term Liabilities		
Compensated absences (LT)	53,962	53,962
Other Post Employment Benefits (OPEB) Payable	1,096,000	1,096,000
Net Pension Liability	<u>4,117,091</u>	<u>4,117,091</u>
<i>Total Long Term Liabilities</i>	<i>5,267,053</i>	<i>5,267,053</i>
<b>TOTAL LIABILITIES</b>	<b>5,896,048</b>	<b>5,782,659</b>
<b>DEFERRED INFLOWS OF RESOURCES</b>	<b>607,441</b>	<b>607,441</b>
<b>EQUITY</b>		
Fund Balance at End of Prior Fiscal Year	(2,408,224)	(1,424,342)
Fund Balance - designated	182,952	182,952
Invested in Fixed Assets	1,605,186	1,605,186
Net Income/Loss	<u>983,882</u>	<u>(207,467)</u>
<b>TOTAL EQUITY</b>	<b>363,796</b>	<b>156,329</b>
<b><u>TOTAL LIABILITIES, DEFERRED INFLOWS, &amp; EQUITY</u></b>	<b><u>6,867,285</u></b>	<b><u>6,546,429</u></b>

Louisiana Board of Pharmacy  
 FY 2015-2016  
 Statement of Revenue, Expenses, and Budget Performance  
**Revenue**

	FY 14-15 Q4 06/30/2015 (A)	FY 15-16 Q1 09/30/2015	FY 15-16 Budget (A#1)
<i>Licenses &amp; Permits</i>			
Pharmacist Renewals	782,525	4,150	770,000
New Pharmacist Licensing Fee	193,100	33,900	190,500
Technician Renewals	315,900	10,700	316,000
Technician Candidate Registrations	37,725	8,775	25,000
Lapsed Credential Fees	66,600	18,000	55,000
Student Registrations	3,050	1,500	3,000
Permits - Pharmacies	275,675	16,625	270,000
Permits - CDS	454,215	95,115	450,000
Permits - Emergency Drug Kits	13,400	625	12,500
Permits - Automated Medication Systems	23,250	1,200	20,000
Permits - Durable Medical Equipment	82,600	70,600	80,000
<i>Examinations</i>			
Reciprocity	54,600	13,650	50,000
Technicians	55,900	17,100	50,000
<i>Penalties</i>			
Licenses and Certificates	8,633	1,950	8,000
Permits	12,150	4,988	11,000
<i>Administrative Fees</i>			
Documents: Copies and Certification Fees	4,903	1,533	5,000
Duplicate Credentials	5,710	1,760	5,000
Silver Certificates	400	100	400
Original Certificates	8,700	3,075	7,500
NSF Fees	450	200	500
Handling & Mailing Fees	190	(203)	100
<i>Sale of Goods &amp; Services</i>			
Law Books	5,125	740	6,000
Official Lists of Licensees	10,800	1,800	7,500
USCPSC Inspection Fee	4,800	0	2,000
Disposal of Assets	300	0	0
<i>Enforcement Actions</i>			
Hearing Fees	21,000	2,500	22,000
Fines	631,500	65,000	200,000
Investigative Costs	30,320	736	30,000
<i>Prescription Monitoring Program</i>			
Assessments	482,225	98,500	475,000
Grants	0	0	0
<i>Miscellaneous</i>			
	940	830	1,000
<b>TOTAL REVENUE</b>	<b>3,586,686</b>	<b>475,449</b>	<b>3,073,000</b>

Louisiana Board of Pharmacy  
FY 2015-2016  
Statement of Revenue, Expenses, and Budget Performance  
**Expenses**

		FY 14-15	FY 15-16	FY 15-16
		Q4 06/30/2015 (A)	Q1 09/30/2015	Budget (A#1)
<i>Operations</i>	Rentals - Office & Equipment	14,535	1,137	17,000
	Equipment Maintenance	2,579	4,066	3,000
	Telephone	19,634	4,861	20,000
	Printing	22,443	7,276	25,000
	Postage	48,112	29,895	52,000
	Civil Service Assessment	6,074	6,323	6,400
	Office Insurance (ORM)	7,112	8,931	8,400
	Dues & Subscriptions	10,613	2,560	20,000
	Office Supply Expenses	21,175	4,436	21,000
	Financial Service Charges	47,541	2,487	50,000
	Depreciation of Fixed Assets	99,091	16,653	64,000
	Interest Payments on Building Loan	44,882	4,961	15,000
	Office Meeting Expenses	538	563	500
	Utilities	10,614	2,125	11,000
	Miscellaneous	0	0	0
<i>Acquisitions</i>		3,662	0	75,000
<i>Personal Services</i>	Salaries	1,477,054	285,696	1,357,400
	Payroll Taxes (FICA + FUTA)	22,117	4,910	28,000
	Retirement Contributions	185,294	102,988	505,000
	Health Insurance (SEGBP)	119,813	32,015	135,800
	Other Post Employment Benefits (OPEB)	79,132	0	156,000
	Board Member Per Diem	29,400	6,225	31,000
<i>Professional Services</i>	Accounting	22,519	9,680	25,000
	Legal	8,189	56	30,000
	Information Systems	93,011	86,820	128,000
	Property Management	20,350	5,161	42,000
	Temp. Labor	15,507	3,536	20,000
	Prescription Monitoring Program	77,300	0	80,000
<i>Staff Expenses</i>	ED - Travel	4,264	2,302	10,000
	GC - Travel	10,212	2,673	10,000
	AED - Travel	1,956	325	10,000
	CO - Travel	3,774	1,803	5,000
	CO - Rental Cars & Fuel	15,886	3,711	17,500
	CO - Education	8,514	3,580	10,000
	House Staff - Travel	199	0	1,000
	Mileage	15,327	2,482	20,000
<i>Board Expenses</i>	Meeting Expenses	12,070	4,171	15,000
	Committee Expenses	5,315	1,961	8,000
	Conventions	22,668	0	15,000
	Mileage	12,483	2,420	15,000
	President's Expenses	10,192	1,599	10,000
<b>TOTAL EXPENSES</b>		<b>2,631,151</b>	<b>660,388</b>	<b>3,073,000</b>

Louisiana Board of Pharmacy  
 FY 2015-2016  
 Summary of Income Fund Balance Changes

**Summary**

	FY 14-15 Q4 06/30/2015 (A)	FY 15-16 Q1 09/30/2015	FY 15-16 Budget (A#1)
<b>Income Statement</b>			
Total Revenue	3,586,686	475,449	3,073,000
Total Expenses	2,631,151	660,388	3,073,000
Net Ordinary Income	955,535	(184,939)	0
Other Income & Expenses			
Investment	28,347	(22,528)	0
Net Income	983,882	(207,467)	0

	FY 14-15 Q4 06/30/2015 (A)	FY 15-16 Q1 09/30/2015	FY 15-16 Budget (A#1)
<b>Fund Balance</b>			
Beginning Fund Balance	(620,086)	363,796	363,796
Total Income	3,615,033	452,921	3,073,000
Total Expenses	2,631,151	660,388	3,073,000
Ending Fund Balance	363,796	156,329	363,796
Reservations of Fund Balance	1,272,000	1,237,000	1,237,000
Unreserved Fund Balance	(908,204)	(1,080,671)	(873,204)

*Notes on Reservation of Fund Balance*

<b>FY 14-15</b>	Other Post-Employment Benefits Payable	572,000
	Debt Service Payable	450,000
	Continuing Payroll Obligations	150,000
	Homeland Maintenance	<u>100,000</u>
	<b>TOTAL</b>	<b>1,272,000</b>

<b>FY 15-16</b>	Other Post Employment Benefits Payable	572,000
	Debt Service Payable	465,000
	Continuing Payroll Obligations	150,000
	Homeland Maintenance	<u>50,000</u>
	<b>TOTAL</b>	<b>1,237,000</b>

Louisiana Board of Pharmacy  
 FY 2015-2016  
 Schedule A - Hurricane Katrina/Rita Pharmacy Relief Fund

**Statement of Assets, Liabilities & Equity**

	FY 14-15 Q4 06/30/2015 (A)	FY 15-16 Q1 09/30/2015
<b>ASSETS</b>		
Current Assets		
Hancock Bank - Checking Account	<u>83,221</u>	<u>83,242</u>
<b><u>TOTAL ASSETS</u></b>	<b><u>83,221</u></b>	<b><u>83,242</u></b>
<b>LIABILITIES</b>		
Current Liabilities	0	0
<b>EQUITY</b>		
Retained Earnings	83,137	83,221
Net Income	<u>84</u>	<u>21</u>
<b><u>TOTAL LIABILITIES &amp; EQUITY</u></b>	<b><u>83,221</u></b>	<b><u>83,242</u></b>

**Statement of Receipts & Disbursements**

	FY 14-15 Q4 06/30/2015 (A)	FY 15-16 Q1 09/30/2015
<b>RECEIPTS</b>		
FEMA - Funds for payment of claims	8,920,812	8,920,812
FEMA - Administrative allowance	81,103	81,103
Pharmacies - reversal of claims	430,138	430,138
Interest income	<u>22,146</u>	<u>22,167</u>
<b><u>TOTAL RECEIPTS</u></b>	<b><u>9,454,199</u></b>	<b><u>9,454,220</u></b>
<b>DISBURSEMENTS</b>		
Claims paid to pharmacies	8,920,812	8,920,812
Reversed claim funds returned	430,138	430,138
Reversed administrative allowance returned	7,338	7,338
Interest earned on reversed admin. allowance returned	<u>12,690</u>	<u>12,690</u>
<b><u>TOTAL DISBURSEMENTS</u></b>	<b><u>9,370,978</u></b>	<b><u>9,370,978</u></b>
<b>FUND BALANCE</b>	<b><u>83,221</u></b>	<b><u>83,242</u></b>

*Note:* These funds are held in an account separate and apart from the Board's operating funds. Further, all recordkeeping is kept separate from the Board's general fund records. At the conclusion of the audit exposure period, any funds remaining will be transferred to the Board's operating account.

Louisiana Board of Pharmacy  
FY 2014-2015  
Summary of Board Actions

<b>Date</b>	<b>Action</b>
11/12/2014	Original Budget - Finance Committee Approval
11/13/2014	Original Budget - Board Approval
8/11/2015	Budget Amendment #1 - Finance Committee Approval
8/12/2015	Budget Amendment #1 - Board Approval
	Budget Amendment #2 - Finance Committee Approval
	Budget Amendment #2 - Board Approval
Aug-16	Acceptance of Final Report



# Louisiana Board of Pharmacy

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## Finance Committee

### Proposed Budget for Fiscal Year 2016-2017

November 18, 2015

Blake P. Pitre  
Chair

Louisiana Board of Pharmacy  
FY 2016-2017 ~ Original Budget Worksheet

**Revenue**

	FY 14-15 Actual (A)	FY 15-16 9/30/2015	FY 15-16 Budget (A#1)	FY 16-17 Proposed	Notes
<i>Licenses &amp; Permits</i>					
4201 Pharmacist Renewals	782,525	4,150	770,000	780,000	1
4206 New Pharmacist Licensing Fee	193,100	33,900	190,500	195,000	2
4204 Technician Renewals	315,900	10,700	316,000	316,000	3
4208 Technician Candidate Registrations	37,725	8,775	25,000	25,000	4
4205 Lapsed Credential Fees	66,600	18,000	55,000	30,000	5
4350 Student Registrations	3,050	1,500	3,000	3,000	6
4301 Permits - Pharmacies	275,675	16,625	270,000	275,000	7
4302 Permits - CDS	454,215	95,115	450,000	455,000	8
4303 Permits - Emergency Drug Kits	13,400	625	12,500	13,000	9
4304 Permits - AMS	23,250	1,200	20,000	20,000	10
4306 Permits - Durable Medical Equipment	82,600	70,600	80,000	80,000	11
<i>Examinations</i>					
4153 Reciprocity	54,600	13,650	50,000	50,000	12
4152 Technicians	55,900	17,100	50,000	50,000	13
<i>Penalties</i>					
4252 Licenses and Certificates	8,633	1,950	8,000	9,000	14
4251 Permits	12,150	4,988	11,000	12,000	15
<i>Administrative Fees</i>					
4460+62 Documents: Copies & Certification Fees	4,903	1,533	5,000	5,000	16
4452 Duplicate Credentials	5,710	1,760	5,000	5,000	17
4453 Silver Certificates	400	100	400	400	18
4459 Original Certificates	8,700	3,075	7,500	7,500	19
4454 NSF Fees	450	200	500	500	20
4463 Handling & Mailing Fees	190	(203)	100	100	21
<i>Sale of Goods &amp; Services</i>					
4402 Law Books	5,125	740	6,000	6,000	22
4461 Official Lists of Licensees	10,800	1,800	7,500	7,500	23
4458 USCPSC Inspection Fee	4,800	0	2,000	0	24
4457 Disposal of Assets	300	0	0	0	25
<i>Enforcement Actions</i>					
4102 Hearing Fees	21,000	2,500	22,000	21,000	26
4501 Fines	631,500	65,000	200,000	200,000	27
4502 Investigative Costs	30,320	736	30,000	30,000	28
<i>Prescription Monitoring Program</i>					
4660 Assessments	482,225	98,500	475,000	482,000	29
4455 Miscellaneous	940	830	1,000	1,000	30
<b>TOTAL REVENUE</b>	<b>3,586,686</b>	<b>475,449</b>	<b>3,073,000</b>	<b>3,079,000</b>	<b>31</b>

Louisiana Board of Pharmacy  
FY 2016-2017 ~ Original Budget Worksheet

**Expenses**

<u>Operations</u>	FY 14-15 Actual (A)	FY 15-16 9/30/2015	FY 15-16 Budget (A#1)	FY 16-17 Proposed	<u>Notes</u>
5321 Rentals - Office & Equipment	14,535	1,137	17,000	17,000	32
5330 Equipment Maintenance	2,579	4,066	3,000	3,000	33
5370 Telephone	19,634	4,861	20,000	20,000	34
5305 Printing	22,443	7,276	25,000	25,000	35
5300 Postage	48,112	29,895	52,000	52,000	36
5125 Civil Service Assessment	6,074	6,323	6,400	6,500	37
5230 Office Insurance (ORM)	7,112	8,931	8,400	9,000	38
5190 Dues & Subscriptions	10,613	2,560	20,000	11,000	39
5280 Office Supply Expenses	21,175	4,436	21,000	21,000	40
5381 Financial Service Charges	47,541	2,487	50,000	50,000	41
5180 Depreciation of Fixed Assets	99,091	16,653	64,000	64,000	42
5385 Interest Payments on Building Loan	44,882	4,961	15,000	0	43
5260 Office Meeting Expenses	538	563	500	1,000	44
5390 Utilities	10,614	2,125	11,000	11,000	45
5270 Miscellaneous	0	0	0	0	46
5106 <u>Acquisitions</u>	3,662	0	75,000	25,000	47
5350 <u>Personal Services</u> Salaries	1,477,054	285,696	1,357,400	1,412,000	48
5290 Payroll Taxes (FICA + FUTA)	22,117	4,910	28,000	28,000	49
5340 Retirement Contributions	185,294	102,988	505,000	525,000	50
5220 Health Insurance (SEGBP)	119,813	32,015	135,800	141,000	51
5400 Other Post Employment Benefits (OPEB)	79,132	0	156,000	156,000	52
5152 Board Member Per Diem	29,400	6,225	31,000	30,000	53
5110 <u>Professional Services</u> Accounting	22,519	9,680	25,000	25,000	54
5250 Legal	8,189	56	30,000	25,000	55
5295 Information Systems	93,011	86,820	128,000	120,000	56
5297 Property Management	20,350	5,161	42,000	40,000	57
5296 Temp. Labor	15,507	3,536	20,000	20,000	58
5600 Prescription Monitoring Program	77,300	0	80,000	80,000	59
5361 <u>Staff Expenses</u> ED - Travel	4,264	2,302	10,000	10,000	60
5365 GC - Travel	10,212	2,673	10,000	10,000	61
5373 AED - Travel	1,956	325	10,000	10,000	62
5363 CO - Travel	3,774	1,803	5,000	5,000	63
5371+72 CO - Rental Cars & Fuel	15,886	3,711	17,500	17,500	64
5368 CO - Education	8,514	3,580	10,000	10,000	65
5366 House Staff - Travel	199	0	1,000	1,000	66
5362++ Mileage	15,327	2,482	20,000	20,000	67
<u>Board Expenses</u>					
5153 Meeting Expenses	12,070	4,171	15,000	15,000	68
5155 Committee Expenses	5,315	1,961	8,000	8,000	69
5154 Conventions	22,668	0	15,000	15,000	70
5151 Mileage	12,483	2,420	15,000	15,000	71
5286++ President's Expenses	10,192	1,599	10,000	10,000	72
<b>TOTAL EXPENSES</b>	<b>2,631,151</b>	<b>660,388</b>	<b>3,073,000</b>	<b>3,064,000</b>	<b>73</b>

Louisiana Board of Pharmacy  
FY 2016-2017 ~ Original Budget Worksheet

**Summary**

	FY 14-15 Actual (A)	FY 15-16 9/30/2015	FY 15-16 Budget (A#1)	FY 16-17 Proposed	Notes
<b>Income Statement</b>					
Total Revenue	3,586,686	475,449	3,073,000	3,079,000	
Total Expenses	2,631,151	660,388	3,073,000	3,064,000	
Net Ordinary Income	955,535	(184,939)	0	15,000	
Other Income & Expenses					
6003 Investment	28,347	(22,528)	0	0	
2350 Reserve Accounts	0	0	0	(15,000)	74
Net Income	983,882	(207,467)	0	0	

	FY 14-15 Actual (A)	FY 15-16 9/30/2015	FY 15-16 Budget (A#1)	FY 17-18 Proposed	
<b>Fund Balance</b>					
Beginning Fund Balance	(620,086)	363,796	363,796	363,796	
Total Income	3,615,033	452,921	3,073,000	3,079,000	
Total Expenses	2,631,151	660,388	3,073,000	3,079,000	
Ending Fund Balance	363,796	156,329	363,796	363,796	
Reservations of Fund Balance	1,272,000	1,237,000	1,237,000	1,750,000	75
Unreserved Fund Balance	(908,204)	(1,080,671)	(873,204)	(1,386,204)	

	FY 14-15 Actual (A)	FY 15-16 9/30/2015	FY 15-16 Budget (A#1)	FY 16-17 Proposed
<u>Notes on Reservation of Fund Balance</u>				
Debt Service Payable	450,000	465,000	465,000	0
Net Pension Liability	0	0	0	1,000,000
Other Post Employment Benefits	572,000	572,000	572,000	500,000
Continuing Payroll Obligations	150,000	150,000	150,000	150,000
Land & Bldg Maintenance	<u>100,000</u>	<u>50,000</u>	<u>50,000</u>	<u>100,000</u>
<b>TOTAL</b>	<b>1,272,000</b>	<b>1,237,000</b>	<b>1,237,000</b>	<b>1,750,000</b>

Louisiana Board of Pharmacy  
FY 2016-2017 ~ Original Budget Worksheet

**NOTES**

Revenue

- 1 Estimate 7,800 pharmacists to renew, at \$100 each
- 2 Estimate 350 new graduates + 300 reciprocity applicants, for 650 new applicants, at \$300 each
- 3 Estimate 6,320 technicians to renew, at \$50 each
- 4 Estimate 1,000 applications for pharmacy technician candidate registration, at \$25 each
- 5 Estimate 150 reinstatement applications, at \$200 each, pursuant to modified fee policy
- 6 Estimate 300 applications for pharmacy intern registration, at \$10 each
- 7 Estimate 1,950 pharmacies to renew, at \$125 each + 200 new permits at \$150 each
- 8 Using historical data for CDS license renewals
- 9 Estimate 520 EDK permits at \$25 each
- 10 Estimate 130 AMS registrations at \$150 each
- 11 Estimate 530 DME permits at \$150 each
- 12 Estimate 300 reciprocity applications, at \$150 each
- 13 Estimate 500 applications for pharmacy technician certificate, at \$100 each
- 14 Using historical data for penalty fees applied to renewal of lapsed credentials for people
- 15 Using historical data for penalty fees applied to renewal of lapsed credentials for places
- 16 Using historical data
- 17 Using historical data
- 18 Estimate 4 pharmacists to order silver certificates, at \$100 each
- 19 Estimate 100 pharmacists to order new wall certificates, at \$75 each
- 20 Using historical data
- 21 Using historical data
- 22 Using historical data for law book purchases, including \$40 binders and \$15 supplements
- 23 Estimate sales of 50 lists, at \$150 each
- 24 No contract yet for CPSC inspections
- 25 None planned at this time
- 26 84 cases anticipated: Violations, Reinstatement, and Impairment Committees
- 27 Using historical data prior to FY15
- 28 Using historical data
- 29 Estimate 19,280 clients, at \$25 each
- 30 Using historical data
- 31 Reflects a 0.2% increase from the FY 16 budget and a 14% decrease from FY 15 revenue.

Louisiana Board of Pharmacy  
FY 2016-2017 ~ Original Budget Worksheet

Expenses

- 32 Using historical data for two copiers, postage machine, and folding machine (Data Worksheet)
- 33 Using historical data for all office equipment
- 34 Using historical data for all telephone systems maintenance and call volumes
- 35 Includes office products and NABP e-Newsletter; excludes printed version of newsletter
- 36 Using historical data, with focus on reducing use of snail mail in favor of email
- 37 Using historical data, with premium determined by State Div. of Administration
- 38 Using historical data, with premium determined by State Div. of Administration
- 39 Using historical data, with reduction of certain subscriptions
- 40 Using historical data for purchase of office supplies
- 41 Using historical data for service charges applied to credit cards used for online renewals
- 42 Using historical data from depreciation schedule of fixed assets maintained by accountant
- 43 Final loan payment due December 1, 2015
- 44 Using historical data for office meeting expenses
- 45 Using historical data for utilities
- 46 Using historical data
- 47 Planned reduction of acquisitions (Data Worksheet)
- 48 Includes performance adjustments for staff
- 49 Calculated value: 2% of salaries + temp labor
- 50 Calculated value: 37.2% of salaries
- 51 Calculated value: 10% of salaries
- 52 Actual obligation provided to agency at end of fiscal year; this entry is historical data
- 53 Using historical data for board member per diem payments
- 54 Using historical data, for accountant and legislative auditor
- 55 Using historical data, for prosecuting attorney and advisor to hearing officer, + collections
- 56 Annual maintenance fees for eLicense, network support, and medical assessments
- 57 Routine services for property + anticipated repairs (Data Worksheet)
- 58 Using historical data, for high school COE workers
- 59 Professional services from program vendor, per contract
- 60 Using historical data for travel expenses for executive director
- 61 Using historical data for travel expenses for general counsel
- 62 Using historical data for travel expenses for assistant executive director
- 63 Using historical data for routine travel during inspections and investigations
- 64 Cost of rental cars and fuel for compliance officers
- 65 \$2,000 allowance for each of 5 pharmacist compliance officers
- 66 For educational development of office staff
- 67 Using historical data, for entire staff
- 68 Using historical data for member expenses at board meetings
- 69 Using historical data for member expenses at committee meetings
- 70 Using historical data for member expenses at conferences
- 71 Using historical data for mileage from all members except the president
- 72 Using historical data for the president's expenses
- 73 Reflects a 0.3% decrease from the FY 16 budget and a 16% increase from FY 15 expenses.

Summary

- 74 Planned allocation to reserve accounts to fund long-term liabilities
- 75 General reserve account balance approximately \$1.9 million

Louisiana Board of Pharmacy  
FY 2016-2017 ~ Original Budget Worksheet

<b>Date</b>	<b>Action</b>
11/17/2015	Original Budget - Finance Committee Approval
11/18/2015	Original Budget - Board Approval
	Budget Amendment #1 - Finance Committee Approval
	Budget Amendment #1 - Board Approval
	Acceptance of Final Report

**Louisiana Board of Pharmacy  
FY 2016-2017  
Budget Proposal**

Data Worksheet

<u>Acct</u>			<u>Name</u>	
	<b>Operations</b>			
5321	Equipment Rentals			17,000
	Copier #1	375/month	04,500	
	Copier #2	375/month	04,500	
	Postage + folder	650/month	07,800	
5370	Telephone System			18,400
	Annual Maintenance Fee	1,600/year	01,600	
	AT&T charges	400/month	04,800	
	State OTM charges	675/month	08,100	
	Administrative officers	325/month	03,900	
5305	Printing			17,000
	Office products	historical basis/year	15,000	
	NABP e-Newsletter	4 issues/year	01,000	
	Board member elections	2018 term expirations	01,000	
5125	Civil Service Assessment			06,400
		FY 15-16 actual	06,323	
5230	Office Insurance (ORM)			09,000
		FY 15-16 actual	08,931	
5190	Dues & Subscriptions			11,000
		FY 14-15 actual	10,613	
		FY 15-16 budget	20,000	
		(included ~ \$9,300 for MelissaData)		
5390	Utilities			11,000
		Electric	09,000	
		Water	00,900	
		FY 14-15 actual	10,614	

**Acquisitions**

5105	Acquisitions			25,000
		Planned rotations of computers, printers, software, and furniture		

***Personal Services***

5350	Salaries		1,412,000
		Includes performance adjustments	
5340	Retirement		529,000
		FY 14-15 Rate – 37%	
		FY 15-16 Rate – 37.2%	
		FY 16-17 Rate – ?	

***Professional Services***

5295	Information Systems		120,000
		Iron Data Maintenance	70,000
		Essential Solutions (support)	45,000
		Medical assessments	05,000
5297	Property Management		40,000
	Security	236/month	02,800
	Interior Maintenance	250/month	03,000
	Groundskeeping + Pest	460/month	05,500
	Trash & Recycling	140/month	01,680
	General Maintenance	165/month	02,000
	A/C Unit Replacement	10,000/each	10,000
	General Repairs (roof replacement)		15,000



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## Application Review Committee

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**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.



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## Reciprocity Committee

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## Violations Committee

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## Impairment Committee

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**NOTICE IS HEREBY GIVEN** that a meeting of the Impairment Committee has been ordered and called for 1:00 p.m. on Tuesday, November 17, 2015 at the Board office, for the purpose to wit:

## AGENDA

NOTE: This agenda is tentative until 24 hours in advance of the meeting, at which time the most recent revision becomes official.

**Revised 10-14-2015**

1. Call to Order
2. Quorum Call
3. Call for Additional Agenda Items & Adoption of Agenda
4. Opportunity for Public Comment
5. Review of Docket
  - A. *For Acceptance of Voluntary Surrenders of Credentials*
    - i. Case No. 15-0298 ~ PST.020067 – Charles Paul Guidry
    - ii. Case No. 15-0315 ~ CPT.012498 – Kelly Ann Smith
    - iii. Case No. 15-0336 ~ PST.019587 – Andrea Katherine Bourque
  - B. *Petitions For Reinstatement of Suspended Credentials*
    - i. Case No. 15-0241 ~ PNT.046513 – Hoa Thi Pham
  - C. *Petitions for Modification of Previous Orders*
    - i. Case No. 15-0335 ~ PST.016348 – Benji Joseph Juneau
    - ii. Case No. 15-0308 ~ PST.015687 – Clay Devoe Jones
    - iii. Case No. 15-0330 ~ PST.018936 – Tiffany Cathleen Luse Upshaw
  - D. *Applications for a Credential*
    - i. Case No. 15-0234 ~ PTC-A – Sonya Darlene Coleman
    - ii. Case No. 15-0264 ~ PST-A – Amy Rebecca Douglass
    - iii. Case No. 15-0280 ~ PST-A – Aaron Joe Stutzman (appearance waived)
  - E. *Appearances for Informal Conference*
    - i. Case No. 15-0196 ~ PST.015778 – John Sherwood Bannister
    - ii. Case No. 15-0333 ~ PST.011311 – Stephen Leonard Collins
  - F. *Appearances for Guidance*
6. Adjourn

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**NOTE:** Pursuant to the Open Meetings Law at La. R.S. 42:16, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, (4) discussions regarding personnel matters, or other purposes itemized at La. R.S. 42:17..



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## Reinstatement Committee

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**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.



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**NOTICE IS HEREBY GIVEN** that a meeting of the Reinstatement Committee has been ordered and called for 8:00 a.m. on Tuesday, November 17, 2015 in the Board office, for the purpose to wit:

## AGENDA

NOTE: This agenda is tentative until 24 hours in advance of the meeting, at which time the most recent revision becomes official.

**Revised 11-15-2015**

1. Call to Order
  2. Quorum Call
  3. Call for Additional Agenda Items & Adoption of Agenda
  4. Opportunity for Public Comment
  5. Consideration of Applications
    - A. *Petitions for Reinstatement (suspended + lapsed > 5 years)*
      - i. Case No. 15-0241 ~ PHY.006889 – NMB Generics
      - ii. Case No. 15-0314 ~ PHY.006739 – Physician Choice Pharmacy
      - iii. Case No. 15-0334 ~ CPT.010037 – Shantelle Dionne Payton
      - iv. Case No. 15-0337 ~ CPT.008812 – Jennifer LaCole Farmer
      - v. Case No. 15-0340 ~ CPT.006116 – Crystal Eva Terrebonne
      - vi. Case No. 15-0341 ~ CPT.004717 – Trang Phuong Nguyen
      - vii. Case No. 15-0342 ~ CPT.004491 – Delilah Burgess LaFitte
      - viii. Case No. 15-0343 ~ CDS.045878 – Bruce Leonard Wilson  
(*appearance waived*)
    - B. *Petitions for Modification of Previous Orders*
      - i. Case No. 15-0340 ~ PST.010983 – Aaron Wayne Nash
    - C. *Petitions for Return of Inactive Licenses to Active Status*
- [Note: Appearances are not required for the remaining applicants.]**
- D. *Petitions for Reinstatement (suspended + lapsed > 5 years + chair's discretion)*
    - i. PST.017532 – Curtis Byron Hughes
    - ii. PST.017921 – Robin McCoy Thompson
    - iii. PNT.046190 – Hoai-Nam Phuc Ngo
  - E. *Applications for Reinstatement of CDS Licenses Lapsed > 5 years*
    - i. CDS.033782-MD – Monique McConduit Jones

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- ii. CDS.027194.MD – Joseph Anthony Pistone
- iii. CDS.029589.MD – Peggy Helen Gramates
- iv. CDS.024369.MD – James Alfred Chiverton
- v. CDS.001983.MD – Wallace Harden Smith, II
- vi. CDS.008562.MD - Harold Thomas Shelby
- vii. CDS.035206.MD – Robert S. Fields
- viii. CDS.028158.MD – Neil B. Billeaud
- ix. CDS.029374.MD – Shamita B. Shah
- x. CDS.035224.DVM – Nicholas Argeros Moraites
- xi. CDS.019835.DDS – Chet Alan Smith
- xii. CDS.015147.DDS – William Montie Dalton
- xiii. CPT.006973 – Bonnie Suzanne Hughes DeLaney
- xiv. CPT.015651 – Deborah Cooper Brumley

*F. Applications for Reinstatement of CDS Licenses Previously Suspended Secondary to Action by Another Agency*

*G. Discretionary Approvals by Committee Chair (lapsed > 1 year but < 5 years)*

- i. CDS.034151.OD – Thao Phuong Mai
- ii. CDS.040823.MD – David Richard Wallace
- iii. CDS.036539-MD – Bente Y. Hoegsberg
- iv. CDS.043408.MD – Lydia Elizabeth Andras
- v. CDS.038379.DVM – Jorge Luis Vila
- vi. CPT.001887 – Jennifer Truxillo Lasseigne
- vii. CPT.007201 – Lucretia Marie Naquin
- viii. CPT.005080 – Jennifer Dawn Tucker
- ix. CDS.036266.MD – Adam Irwin Riker
- x. CDS.039850.MD - Mohit Kapoor
- xi. CPT.010883 – Alicia Nicole Rucker
- xii. CDS.021609.MD - Gina Marie Bagneris
- xiii. CDS.041465.MD – Kira Nicole Long
- xiv. CPT.011156 – Rosa Mary Williams
- xv. PST.018590 – B’Nai Tierra DeBruy
- xvi. CDS.027639.DVM – Amy Virginia Grayson
- xvii. CDS.040476.DDS – Lauri Breaud Daigle
- xxviii. CDS.032899.MD – Sergio Alberto Castillo
- xix. CDS.027012.DDS – Laurie Frances Moeller
- xx. CDS.036914.MD – Emily Tan Aventura
- xxi. CDS.038020.MD – Janet Lynn Gregory
- xxii. CDS.012333.DDS – Ronald Joseph Gustafson
- xxiii. CDS.031248.DVM – Morgan Lee Burger
- xxiv. CDS.040219.DVM – Bethamy L. Frank
- xxv. CDS.027387.MD – Louie Keith Scott
- xxvi. CDS.002323.HOS – St. Helena Parish Hospital
- xxvii. CDS.009049.DDS- Oncale Louis David
- xxviii. CDS.041543.MD – Sandra A. Rhoden
- xxix. CDS.029955.MD – Darren Michael Rowan
- xxx. CDS.042232.HOS – Compass Behavioral Center of Houma
- xxxi. CDS.039941.MD – Julia Lynne Schweizer
- xxxii. CDS.024329.DDS – Susanne Ogden Core
- xxxiii. CDS.040342.MD – Alvaro Manrique Garcia

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- xxxiv. CDS.041216.DVM – Michael Ryan Smith
- xxxv. CPT.007456 – Julie Ann Johnson
- xxxvi. CPT.010523 – Raushanah Satimah Smith
- xxxvii. CPT.011524 – Braydon Hoyt Bolton
- xxxviii. CDS.031447.MD – Kenneth J. Wright
- xxxix. CDS.036158.MD – Maurice L. King
  - xl. CDS.038257.MD – John Blair Hamner
  - xli. CDS.042323.MD – Vininder Khunkhun
  - xlII. CPT.008637 – Holly Renee Griffith
  - xlIII. CPT.009262 – Chime Roseizina Dozier
  - xlIV. CPT.002538 – Michele Katherine Vicnair
  - xlV. CPT.010026 – Houda Nour Hameurlaine
  - xlVI. CDS.038207.DDS – Erin Ainsley Fontenot
  - xlVII. CDS.037177.DDS – Brian William Kelley
  - xlVIII. CDS.015919.MD – Carl D. Walker
  - xlIX. CPT.007451 – Shannon Lynn Guillot
    - I. CDS.030542.DDS – Jacob R. Dent
    - II. DME.000162 – DXI Health Solutions, Inc.
    - III. CPT.007197 – Caley Langois Mellor
    - IIII. CPT.011916 – Courtney DeAnn Perry
    - liv. CDS.011399.MD – Theresita Gacusana Jimenez
    - lv. CDS.036093.MD – Gillian Ann Ellis
    - lvi. CPT.011310 – Stephanie Elizabeth Marciante

*H. Staff Approvals by Board Policy (lapsed < 1 year)*

- i. CDS.026179.MD – Teresa Elena Klainer
- ii. CDS.013194.MD – Steven Harry Lesser
- iii. CDS.040519.MD - Elizabeth Anne Clement
- iv. CDS.040453.DVM – Laura Colleen Managan
- v. AMS.010775 – Franklin Healthcare
- vi. EDK.007517 – Lakeview Manor Nursing Home
- vii. CDS.041941.MD - Leslie M. Lindley
- viii. CPT.008597 – Gabrielle Rae Richard
- ix. PST.009282 – Fred Fulton Parker, II
- x. CPT.010545 – Ericca Lanne Halford
- xi. CPT.007279 – Yeita Donelle Slaughter
- xii. CPT.008177 – Rachel Marie Roberson
- xiii. CPT.012038 – Hope Michelle Chadaud
- xiv. CPT.011949 – Terry Lynn Williams
- xv. CPT.010151 – Andrea Renee Hurley
- xvi. CPT.005928 – Crystal Monk Smith
- xvii. CDS.041854.DDS – Rodney J. Isolami
- xviii. CDS.041993.APN – Katherine Eagle LeDoux
- xix. CDS.007257.MD – Lee Roberts Pankey
- xx. CDS.036743.MD – Richard Dinkins
- xxi. CDS.028973.DDS – Marilyn Louise Deville
- xxii. CDS.043095.APN – Kimberly MacGown Bonvillain
- xxiii. CDS.002342.MD – Irwin M. Marcus
- xxiv. CDS.044420.MD – Mohamed Wael Khirfan
- xxv. CDS.010283MD – Stephen R. Meyer
- xxvi. CDS.004102.MD – Winston P. Riehl

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- xxvii. CDS.028852.MD – Tanya R. Reed
- xxviii. EDK.007090 – Many Healthcare
- xxix. CDS.027820.DDS – Melinda Eiserloh Hickey
- xxx. CDS.029690.MD – Sterling Milton
- xxxi. CDS.044705.MD – Steven Dionisio Grijalva
- xxxii. CDS.045093.DVM – Matthew Edward Levy
- xxxiii. CDS.008244.DDS – Galen Frank Meyers, Jr.
- xxxiv. CDS.025443.DDS- Michelle Nicole LeBlanc
- xxxv. CDS.016333.MD – Kevin Ulysse Stephens
- xxxvi. CDS.031648.APN – Melinda Koonce Strickland
- xxxvii. CDS.010695.MD – Otholino Remedios
- xxxviii. CDS.041926.APN – Billie Jo Bailey
- xxxix. CDS.030771.DVM – Laurie Spears LeBlanc
  - xl. CDS.045113.DVM – Amanda Renee Normand
  - xli. CDS.015431.DVM – Thomas C. Armstrong
  - xl.ii. CDS.014860.DDS – James Rooney
  - xl.iii. CDS.026331.DDS – Ryan Garrett Walker
  - xl.iv. CDS.029812.DDS – Bruce A. Schneider
  - xl.v. CDS.44043.MD – Jenny Guerre
  - xl.vi. CDS.018589.DDS – Michael Garner Vienne
  - xl.vii. CDS.015283.DDS – John Chaille Stovall
  - xl.viii. CDS.024586.MD – Christine L. Smith
  - xl.ix. CDS.007553.MD – Darryl Johnson
    - I. CDS.011961.DVM – Eugene T. Segura
    - li. CDS.015135.DDS – J. Skelly Kreller, DDS
    - lii. CDS.004162.MD – Milton Charles Chapman
    - liii. CDS.014389.DDS – Michael R. Tucker
    - liv. CDS.028060.MD – Rosalind Annette Cropper
    - lv. CDS.041992.DDS – Richard Martin Rathke
    - lvi. CDS.045003.APN – Inna Goldarg-Abud
    - lvii. CDS.028993.DDS – Kenneth Shane Fowler
    - lviii. CDS.008931.DDS – Robert Engena Spatafora
    - lix. CDS.019929.MD – George A. Bray
    - lx. CDS.036911.MD – Duncan Franklin Guedon
    - lxi. CDS.016342.MD – Sofia Duque Botero
    - lxii. CDS.003512.MD – Alfredo Botero
    - lxiii. CDS.011019.DVM – Warren Dale Joubert
    - lxiv. CDS.044915.MD – Steven Hedlesky
    - lxv. CDS.016343.DDS – Charles Austin Boudreaux
    - lxvi. CDS.041241.DDS – Gregory W. Greenwood
    - lxvii. CDS.041955.DDS – Jacob Charles McInnis
    - lxviii. CDS.032520.DDS – Michael P. Tuite
    - lxix. CDS.012041.MD – David Scott Morrill
    - lxx. CDS.037744.DVM – Katie Foote Bannerman
    - lxxi. CDS.033615.DDS – Daniel Lester
    - lxxii. CDS.043219.AON – Jeronica J. Hinyard
    - lxxiii. CDS.029592.MD – Nicholas A. Chetta
    - lxxiv. CDS.012319.DDS – Michael David Barry
    - lxxv. CDS.010547.MD – Richard W. Richoux
    - lxxvi. CDS.037953.DDS – Tony Drew Hammack
    - lxxvii. CDS.031522.DDS – Sean Gaffney

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- lxxviii. CDS.017821.MD – Michael Kuang Hsu
- lxxix. CDS.012412.DPM – Gerard G. Guerin
- lxxx. CDS.043309.APN – Letitia S. Dumas
- lxxxi. CDS.044966.MD – Timothy Jeider
- lxxxii. CDS.044702.ETL – Mary Elizabeth Gray
- lxxxiii. CDS.037870.EMS – Red River Emergency Medical Services
- lxxxiv. CDS.030569.DDS – Jennifer L. Banquer
- lxxxv. CDS.040012.MD – John Nelken Bienvonn
- lxxxvi. CDS.021188.MD – Richard Witzig
- lxxxvii. CPT.006720 – Shameka Shandrell Jackson
- lxxxviii. CPT.011582 – Jace Jaret Morein
- lxxxix. CPT.009446 – Devin Elaine Cruse
  - xc. CPT.010143 – Kaleb Paul Carlin
  - xc. CPT.007664 – JoAnn Thomas
  - xcii. CPT.009803 – Roynesha Monique Fox
  - xciii. CPT.006478 – Britnee Anne Heinen
  - xciv. CDS.029712.DDS – Karen Koehler
  - xcv. CDS.013343.MD – Tim Baker
  - xcvi. CDS.010995.DVM – Phillip Duane Griggs
  - xcvii. CDS.014094.DDS – Hal Edward Bailey
  - xcviii. CDS.023758.MD – Barbara M. Stryjewska
  - xcix. CDS.008874.DDS – Neil J. Bernard
    - c. CDS.028100.MD – Darren Duet
    - ci. CDS.010535.MD – Lynn M. Guidry
    - cii. CDS.043552.MD – Daniella Miller
    - ciii. CDS.018041.MD – Elenita Santos Mata
    - civ. CDS.007227.MD – Charles E. Kaufman
    - cv. CDS.019790.MD – Margaret Ann Springer
    - cvi. CDS.015196.DDS – Emmett Lawrence Zimmerman
    - cvii. CDS.032643.DDS – Charles Roberson Morice
    - cviii. CDS.026248.MD – Betty Jean Dowty
    - cix. CDS.042201.MD – Lara Patrice Fox
    - cx. CDS.032548.MD – Jane DiLeo Congeni
    - cx. CDS.037503.DVM – Gregory Lyle Bennett, Jr.
    - cxii. CPT.011629 – Catherine Elizabeth Torres
    - cxiii. CPT.006150 – Linda Hulin Landry
    - cxiv. CPT.001862 – Nicole Angelle Buteau
    - cxv. DME.000409 – Hanger Prosthetics & Orthotics, Inc.
    - cxvi. DME.000111 – Medical Technology of Louisiana, LLC
    - cxvii. DME.000109 - Medical Technology of Louisiana, LLC
    - cxviii. DME.000110 - Medical Technology of Louisiana, LLC
    - cxix. DME.000410 - Hanger Prosthetics & Orthotics, Inc.
    - cxx. DME.000417 - Hanger Prosthetics & Orthotics, Inc.
    - cxxi. DME.000553 – Solara Medical Supplies, Inc.
    - cxxii. CDS.007418.MD – David Gregory Baker
    - cxxiii. CDS.011284.MD – Edward Gregory Helm
    - cxxiv. CDS.041869.DDS – Martha Jennilee Nolan
    - cxxv. CDS.030659.DVM – Susan Yarnall
    - cxxvi. CDS.009515.MD – Russell Wayne Roberts
    - cxxvii. CDS.022695.MD – Lee Marc Schwalben
    - cxxviii. CDS.044442.DVM – Patrick Ryan Cutbirth

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**NOTE:** Pursuant to the Open Meetings Law at La. R.S. 42:16, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, (4) discussions regarding personnel matters, or other purposes itemized at La. R.S. 42:17.

- cxxix. CDS.035167.APN – Deborah Leann Carey
- cxxx. CDS.044521.APN – Pamela Hamilton Johnson
- cxxxi. CDS.041987.MD – M'Liss Ann Hudson
- cxxxii. CDS.032619.MD – Vincent H. Dodge
- cxxxiii. DME.000434 – Analgesic Healthcare
- cxxxiv. DME.000230 – Norma Tec Industries, LP
- cxxxv. CDS.038281.MD – Abdulrahman Abdulbaki
- cxxxvi. DME.000505 – Magnum Medical, LLC
- cxxxvii. CDS.043611.DVM – Robert Blake Hooks
- cxxxviii. DME.000731 – Omnis Health, LLC
- cxxxix. CDS.045240.OD – Jonathan Erik Scogin
- cxl. CDS.031657.MD – Eleanor J. Daveron
- cxli. CDS.032580.PA – Diep Morris
- cxlii. CDS.018600.DVM – William Joseph Townsend
- cxliii. CDS.041669.APN – Scharalda Getz Jeanfreau
- cxliv. CDS.026477.DDS – Mark Morell Winkler
- cxlv. CDS.030723.DDS – Larry Kenneth Robinson
- cxlvi. CDS.017255.DDS – Barton Charles Barre
- cxlvii. CDS.014195.DDS – Joel Jarrett Safer
- cxlviii. DME.000540 – Louisiana Foot and Ankle Specialists, LLC
- cxlix. CDS.036583.DDS – Timothy John St. Romain
- cl. CDS.206421.MD – Scott Franklin Steed
- cli. CDS.031748.DDS – Willie Golden Williams
- clii. CDS.043690.DVM – Erin Elizabeth Kliebert
- cliii. CDS.043349.DVM – Amelie Elaine Lanaux
- cliv. CDS.009161.MD – Ashok Subbarao Rao
- clv. CDS.022186.MD – Alok Kumar Gupta
- clvi. CDS.036978.DVM – Vasiliki Andrew Panos
- clvii. PST.014100 – John Scott Blake
- clviii. CDS.032696.MD – Takeisha Charles Davis
- clix. CDS.033400.DVM – Stephen Bruce Bryan

6. Adjourn



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Tripartite Committee

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**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.



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## Regulation Revision Committee

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**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.

# Louisiana Administrative Code

## Title 46 – Professional and Occupational Standards

### Part LIII: Pharmacists

#### Chapter 25. Prescriptions, Drugs, and Devices

...

#### Subchapter C. Compounding of Drugs

...

#### §2535. General Standards

A. – D. ...

E. Veterinarian Administered Compounds, also referred to as Pharmacy-Generated Drugs

1. Upon receipt of a valid non-patient-specific medical order from a licensed veterinarian, the pharmacy may compound a preparation intended for administration to an animal patient by the veterinarian.
2. These preparations may not be distributed to any other third party by the pharmacy, nor may these preparations be further re-sold or distributed by the veterinarian ordering the preparation from the pharmacy.
3. This authorization is primarily intended to facilitate the preparation of medications needed for emergency use in a veterinary office practice. Given the limited application of this authorization, which allows these products to be prepared using less rigorous standards applicable to compounding as opposed to the more rigorous standards applicable to manufacturing processes, the compounding pharmacy preparing these products shall be limited in the amount of such products they can prepare.
  - a. No Louisiana-licensed pharmacy may distribute any amount of practitioner administered compounds in excess of five percent of the total amount of drug products dispensed and/or distributed from their pharmacy.
  - b. The five percent limitation shall be calculated on a monthly basis and shall reference the number of dosage units.
  - c. For those Louisiana-licensed pharmacies located outside Louisiana, the total amount distributed and/or dispensed shall reference the pharmacy's total business within the state of Louisiana.

~~E. F. Compounding Commercial Products not Available.~~ A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:

1. Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP).
2. Products temporarily unavailable from manufacturers, as documented by invoice or other communication from the distributor or manufacturer.

~~F. G. Labeling of Compounded Preparations.~~

1. For patient-specific compounded preparations, the labeling requirements of R.S. 37:1225, or its successor, as well as §2527 of this Chapter, or its successor shall apply.
2. For veterinarian administered compounds, the label shall contain, at a minimum, the following data elements:
  - a. pharmacy's name, address, and telephone number;
  - b. veterinarian's name;
  - c. name of preparation;
  - d. strength and concentration;
  - e. lot number;
  - f. beyond use date;
  - g. special storage requirements, if applicable;
  - h. identification number assigned by the pharmacy; and
  - i. name or initials of pharmacist responsible for final check of the preparation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015), amended LR

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Baton Rouge, Louisiana 70809-1700  
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[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Summary of Testimony & Public Comments re

### Regulatory Project 2015-4 ~ Compounding for Office Use for Veterinarians at

August 26, 2015 Public Hearing

#### 1. E-mail from Mark Johnston, recently retired Executive Director of the Idaho Board of Pharmacy, now with CVS Caremark

Indicated his opinion that all veterinary compounding was illegal, and referenced the recently issued FDA draft guidance document [*FDA Guidance for Industry – Compounding Animal Drugs from Bulk Drug Substances*, GFI#230 published 05-25-2015]. He expressed concern for the Board's apparent belief that compounding for office use for veterinarians was now legal.

#### 2. Letter from Kirk Ryan, DVM, President, Louisiana Veterinary Medical Association

Dr. Ryan appeared at the hearing and reinforced the association's support for the proposed rule as published.

#### 3. Michael Weber, Roadrunner Pharmacy

Presented verbal comments in support of the proposed rule as published.

The deadline for all comments and testimony on the regulatory proposal was August 26, 2015. The Board is scheduled to review those comments during their November 18, 2015 meeting. In the interim, Roadrunner Pharmacy submitted a copy of the American Veterinary Medicine Association (AVMA)'s August 14, 2015 letter to the FDA with their comments on the proposed draft guidance for industry referenced above. Although the comments reference a draft federal guidance document as opposed to the Board's proposed rule, the draft federal guidance document proposes to prohibit all veterinary compounding for office use, which is in contrast to the Board's proposed rule. Given the relevancy of the matter, the late submission was included in the packet of comments to be considered by the Board.

#### 4. Letter from Robert Eaton, CEO of Roadrunner Pharmacy

Raised several concerns with the draft federal guidance relative to veterinary compounding and a direct conflict with the Board's proposed rule relative to compounding for office use for veterinarians. Included letter from AVMA to the FDA offering comments on the draft federal guidance document.

**From:** [info](#)  
**To:** [Malcolm J. Broussard](#)  
**Subject:** FW: E-mail for Malcolm  
**Date:** Friday, July 31, 2015 8:05:36 AM

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**Felicia Smith**  
**Administrative Coordinator 3**  
**Louisiana Board of Pharmacy**  
**3388 Brentwood Drive**  
**Baton Rouge, LA 70809**  
**Email:** [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)  
**Website:** [www.pharmacy.la.gov](http://www.pharmacy.la.gov)

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**From:** Johnston, Mark D. [mailto:Mark.Johnston@CVSCaremark.com]  
**Sent:** Thursday, July 30, 2015 5:56 PM  
**To:** info  
**Cc:** 'ccatizone@nabp.net'  
**Subject:** E-mail for Malcolm

Malcolm,

Mark Johnston here. As I left the ID BOP, some of my contacts did not transfer well, thus this e-mail to your Board's general e-mail box. I sure did enjoy this year's annual meeting in New Orleans, including getting to know your various Board members better.

I write today, because I read your news letter article concerning the compounding of veterinarian drugs for office use (pasted below). This is contrary to my understanding of federal law. The fact that the DQSA does not pertain to vet drugs is a bad thing, as the DQSA outlines the only legal way to compound. Thus, all vet compounding is illegal. I asked this question at this year's FDA 50 state meeting on compounding, and my reasoning was confirmed. Shortly thereafter, the FDA printed the proposed Guidance For Industry, Compounding Animal Drugs From Bulk Drug Substances. In this Guidance, the FDA explains that they will use enforcement discretion to allow certain vet compounding that adheres to certain conditions. Condition #2 is that the pharmacist compounds pursuant to the receipt of a valid prescription. Thus, office use compounding of vet drugs is clearly illegal and outside of the FDA's proposed enforcement discretion.

Idaho promulgated a similar 5% rule for all non-sterile drugs, even though this is illegal federally. Thus, I understand why LA would do the same, but the way the article reads, the LA Board believes that vet office use compounding is federally legal. Idaho chose to explain to our pharmacists that our Board will not take issue with the allowances within our 5% rule, but that they will have to weigh their options when it comes to the feds.

I hope this is received with the helpful intentions that it was sent with.

See you at the District 6, 7, 8 meeting.

Sincerely,

Mark Johnston

With the recent clarification that the federal prohibition on compounding for office use for practitioners by

pharmacies was applicable only to drugs for human use, the veterinarian community approached the Board for a restoration of the authority for pharmacies to compound medications for office use for veterinarians.... The Board has responded with a proposed change in its compounding rules to allow pharmacies to compound medications for office use for veterinarians...

the Board authorized the adoption of the emergency rule

*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

#230

# Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances

## ***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Eric Nelson (CVM) at 240-402-5642, or by e-mail at [eric.nelson@fda.hhs.gov](mailto:eric.nelson@fda.hhs.gov).

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine (CVM)**

**May 2015**

*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

**TABLE OF CONTENTS**

**I. INTRODUCTION AND SCOPE ..... 1**

**II. BACKGROUND ..... 2**

**A. Regulatory Framework ..... 2**

**B. Compounding Animal Drugs ..... 3**

**III. POLICY ..... 3**

**APPENDIX A ..... 9**

## *Contains Nonbinding Recommendations*

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# **Guidance for Industry<sup>1</sup>** **Compounding Animal Drugs from Bulk Drug Substances**

*This draft guidance, when finalized, represents the Food and Drug Administration's (FDA or Agency) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this draft guidance using the contact information on the title page of this guidance.*

## **I. INTRODUCTION AND SCOPE**

This draft guidance sets forth the Food and Drug Administration's ("FDA") policy regarding compounding animal drugs from bulk drug substances<sup>2</sup> by state-licensed pharmacies, licensed veterinarians, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b). This guidance reflects FDA's current thinking regarding compounding animal drugs from bulk drug substances and describes the conditions under which FDA generally does not intend to take action for violations of the following sections of the FD&C Act: section 512 (21 U.S.C. 360b), section 501(a)(5) (21 U.S.C. 351(a)(5)), section 502(f)(1) (21 U.S.C. 352 (f)(1)), and, where specified, section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), when a state-licensed pharmacy, licensed veterinarian, or an outsourcing facility<sup>3</sup> compounds animal drugs from bulk drug substances.

This draft guidance only addresses the compounding of animal drugs from bulk drug substances. It does not apply to the compounding of animal drugs from approved new animal or new human drugs. Such compounding can be conducted in accordance with the provisions of section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)) and 21 CFR part 530. In addition, this draft guidance does not address the compounding of drugs intended for use in

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<sup>1</sup> This draft guidance has been prepared by the Center for Veterinary Medicine (CVM) in consultation with the Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

<sup>2</sup> FDA regulations define "bulk drug substance" as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances." 21 CFR 207.3(a)(4). "Active ingredient" is defined as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." 21 CFR 210.3(b)(7). Any component other than an active ingredient is an "inactive ingredient." See 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients.

<sup>3</sup> "Outsourcing facility" refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act. See draft guidance for industry *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm434171.pdf>.

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humans, which is addressed in other guidances.<sup>4</sup> Further, the draft guidance does not address new animal drugs for investigational use. See 21 CFR part 511.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

## **II. BACKGROUND**

### **A. Regulatory Framework**

To be legally marketed, new animal drugs must be approved under section 512 of the FD&C Act, conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc), or included on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species under section 572 of the FD&C Act (21 U.S.C. 360ccc-1). The FD&C Act does not generally distinguish between compounding and other methods of animal drug manufacturing. Animal drugs that are not approved or indexed are considered "unsafe" under section 512(a)(1) of the FD&C and adulterated under section 501(a)(5) of the FD&C Act.

Although sections 503A (21 U.S.C. 353a) and 503B of the FD&C Act provide certain statutory exemptions for compounded human drugs, these sections do not provide exemptions for drugs compounded for animal use. The compounding of an animal drug from bulk drug substances results in a new animal drug that must comply with the FD&C Act's approval/indexing requirements.<sup>5</sup> Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (cGMP) requirements (section 501(a)(2)(B)) of the FD&C Act and 21 CFR parts 210 and 211) and have adequate directions for use (section 502(f)(1) of the FD&C Act).

Sections 512(a)(4) and (5) of the FD&C Act provide a limited exemption from certain requirements for compounded animal drugs made from already approved animal or human drugs. Such use is considered an extralabel use and the FD&C Act provides an exemption from the approval requirements and requirements of section 502(f) of the FD&C Act for extralabel uses that meet the conditions set out in the statute and FDA regulations at 21 CFR part 530. Among other things, these regulations specify that nothing in the regulations should be construed as permitting compounding animal drugs from bulk drug substances.

In 1996, FDA announced the availability of a CPG (section 608.400) entitled, "Compounding of Drugs for Use in Animals" (61 FR 34849, July 3, 1996), to provide guidance to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists. An updated CPG was made available on July 14, 2003 (68 FR 41591). This draft guidance supersedes that CPG, which has now been withdrawn.

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<sup>4</sup> <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm>.

<sup>5</sup> See *Medical Center Pharmacy v. Mukasey*, 536 F.3d 383, 394 (5<sup>th</sup> Cir. 2008).

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### **B. Compounding Animal Drugs**

Numerous drugs are approved or indexed for use in animals. However, there are many different species of animals with different diseases and conditions for which there are no approved or indexed animal drugs. In some cases, approved human drugs can be used to treat an animal under the extralabel use provisions of the FD&C Act and FDA regulations (sections 512(a)(4) and (a)(5) of FD&C Act and 21 CFR part 530). For example, various chemotherapeutic drugs approved for humans are used to treat cancer in dogs and cats. FDA recognizes that there are circumstances where there is no drug available to treat a particular animal with a particular condition, because either no drug is approved for a specific animal species or no drug is available under the extralabel drug use provisions. In those limited circumstances, an animal drug compounded from bulk drug substances may be an appropriate treatment option.

However, FDA is concerned about the use of animal drugs compounded from bulk drug substances, especially when approved alternatives exist that can be used as labeled or in an extralabel manner consistent with the requirements of FDA's extralabel provisions. Compounded drugs have not undergone premarket FDA review of safety, effectiveness, or manufacturing quality. The unrestricted compounding of animal drugs from bulk drug substances has the potential to compromise food safety, place animals or humans at undue risk from unsafe or ineffective treatment, and undermine the incentives to develop and submit new animal drug applications to FDA containing data and information to demonstrate that the product is safe, effective, properly manufactured, and accurately labeled.

### **III. POLICY**

As discussed above, animal drugs are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act. Generally, FDA does not intend to take action under sections 512(a), 501(a)(5), 502(f)(1) and 501(a)(2)(B) of the FD&C Act if a state-licensed pharmacy or a licensed veterinarian compounds animal drugs from bulk drug substances in accordance with the conditions described below, and the drug is not otherwise adulterated or misbranded. In addition, FDA generally does not intend to take action under sections 512(a), 501(a)(5), and 502(f)(1) of the FD&C Act if an outsourcing facility compounds animal drugs in accordance with all of the applicable conditions described below, and the drug is not otherwise adulterated or misbranded.

FDA's decision not to take enforcement action depends on its ability to evaluate whether the compounding of animal drugs is in accordance with the conditions below. Therefore, entities compounding animal drugs should keep adequate records to demonstrate that they are compounding such drugs in accordance with all of the applicable conditions described below.

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The conditions referred to above are as follows:

- A. If the animal drug is compounded in a state-licensed pharmacy:
1. The drug is compounded by or under the direct supervision of a licensed pharmacist.
  2. The drug is dispensed after the receipt of a valid prescription from a veterinarian for an individually identified animal patient that comes directly from the prescribing veterinarian or from the patient's owner or caretaker to the compounding pharmacy. A drug may be compounded in advance of receipt of a prescription in a quantity that does not exceed the amount of drug product that the state-licensed pharmacy compounded pursuant to patient-specific prescriptions based on a history of receipt of such patient-specific prescriptions for that drug product over any consecutive 14-day period within the previous 6 months.
  3. The drug is not intended for use in food-producing animals, and the prescription or documentation accompanying the prescription for the drug contains the statement "This patient is not a food-producing animal." For purposes of this draft guidance, all cattle, swine, chicken, turkey, sheep, goats, and non-ornamental fish are always considered to be food-producing animals regardless of whether the specific animal or food from the specific animal is intended to be introduced into the human or animal food chain (e.g., pet pot-bellied pigs and pet chicks are always considered to be food-producing animals). In addition, for purposes of this draft guidance, any other animal designated on the prescription or in documentation accompanying the prescription by the veterinarian as a food-producing animal, regardless of species, is considered to be a food-producing animal (e.g., rabbits, captive elk, captive deer).
  4. If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug:
    - a. there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his/her patient under his/her care, and
    - b. the prescription or documentation accompanying the prescription contains a statement that the change between the compounded drug and the FDA-approved drug would produce a clinical difference for the individually identified animal patient. For example, the veterinarian could state that, "Compounded drug X would produce a clinical difference for the individually identified animal patient because the approved drug is too large a dose for the animal and cannot be divided or diluted into the small dose required."
  5. If there is an FDA-approved animal or human drug with the same active ingredient(s), the pharmacy determines that the compounded drug cannot be made from the FDA-approved drug(s), and documents that determination.

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6. The pharmacy receives from the veterinarian (either directly or through the patient's owner or caretaker), in addition to any other information required by state law, the following information, which can be documented on the prescription or documentation accompanying the prescription:
    - a. Identification of the species of animal for which the drug is prescribed; and,
    - b. The statement "There are no FDA-approved animal or human drugs that can be used as labeled or in an extralabel manner under section 512(a)(4) or (5) and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed."
  7. Any bulk drug substance used to compound the drug is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 510) and is accompanied by a valid certificate of analysis.
  8. The drug is compounded in accordance with Chapters <795> and <797> of the United States Pharmacopeia and National Formulary (USP—NF)<sup>6</sup> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).
  9. The drug is not sold or transferred by an entity other than the entity that compounded such drug. For purposes of this condition, a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care.
  10. Within 15 days of becoming aware of any product defect or serious adverse event associated with animal drugs it compounded from bulk drug substances, the pharmacy reports it to FDA on Form FDA 1932a. Form FDA 1932a can be downloaded at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/animaldrugforms/ucm048817.pdf>.
  11. The label of any compounded drug indicates the species of the intended animal patient, the name of the animal patient and the name of the owner or caretaker of the animal patient.
- B. If the animal drug is compounded by a licensed veterinarian:
1. The drug is compounded and dispensed by the veterinarian to treat an individually identified animal patient under his or her care.

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<sup>6</sup> Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations* can be found in the combined *United States Pharmacopeia and National Formulary (USP-NF)*, available at <http://www.usp.org>.

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2. The drug is not intended for use in food-producing animals as defined in section III.A.3 of this guidance.
  3. If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his/her patient under his/her care.
  4. There are no FDA-approved animal or human drugs that can be used as labeled or in an extralabel manner under sections 512(a)(4) and (5) of the FD&C Act and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which the drug is being prescribed.
  5. The drug is compounded in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).
  6. Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.
  7. The drug is not sold or transferred by the veterinarian compounding the drug. For purposes of this condition, a sale or transfer does not include administration of a compounded drug by the veterinarian to a patient under his or her care, or the dispensing of an animal drug compounded by the veterinarian to the owner or caretaker of an animal under his or her care.
  8. Within 15 days of becoming aware of any product defect or serious adverse event associated with animal drugs the veterinarian compounded from bulk drug substances, he or she reports it to FDA on Form FDA 1932a. Form FDA 1932a can be downloaded at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/animaldrugforms/ucm048817.pdf>.
  9. The label of any compounded drug indicates the species of the intended animal patient, the name of the animal patient and the name of the owner or caretaker of the animal patient.
- C. If the animal drug is compounded by an outsourcing facility:
1. The drugs are compounded only from bulk drug substances appearing on Appendix A of this draft guidance.
  2. The drug is compounded by or under the direct supervision of a licensed pharmacist.

## ***Contains Nonbinding Recommendations***

*Draft — Not for Implementation*

3. The drug is not intended for use in food-producing animals, as defined in Section III.A.3 of this guidance, and the prescription or order, or documentation accompanying the prescription or order, for the drug contains the statement, “This drug will not be dispensed for or administered to food-producing animals.”
4. The drug is compounded in accordance with cGMP requirements.<sup>7</sup>
5. Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.
6. The drug is not sold or transferred by an entity other than the outsourcing facility that compounded such drug. For purposes of this condition, a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care.
7. Within 15 days of becoming aware of any product defect or serious adverse event associated with animal drugs it compounded from bulk drug substances, the outsourcing facility reports it to FDA, on Form FDA1932a. Form FDA 1932a can be downloaded at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/animaldrugforms/ucm048817.pdf>.
8. All drugs compounded for animals by an outsourcing facility are included on the report required by section 503B of the FD&C Act to be submitted to the Food and Drug Administration each June and December identifying the drugs made by the outsourcing facility during the previous 6-month period, and providing the active ingredient(s); source of the active ingredient(s); NDC number of the source ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage form and route of administration; the package description; the number of individual units produced; and the NDC number of the final product, if assigned.<sup>8</sup> The outsourcing facility should identify which reported drugs were intended for animal use.
9. The veterinarian’s prescription or order states that the drug is intended to treat the species and condition(s) for which the substance is listed in Appendix A.

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<sup>7</sup> FDA intends to determine whether this condition is met by evaluating whether the facility complies with FDA regulations applicable to cGMPs for compounding of human drugs by outsourcing facilities. *See, e.g.*, draft guidance for industry, *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* (July 2014), at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf>

<sup>8</sup> FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (November 2014), which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Available at <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM424303.pdf>. Although this guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the animal drug products they compounded.

## ***Contains Nonbinding Recommendations***

*Draft — Not for Implementation*

10. The label of the drug includes the following:

- a. Active ingredient(s).
- b. Dosage form, strength, and flavoring, if any.
- c. Directions for use, as provided by the veterinarian prescribing or ordering the drug.
- d. Quantity or volume, whichever is appropriate.
- e. The statement “Not for resale.”
- f. The statement “For use only in [fill in species and any associated condition or limitation listed in Appendix A].”
- g. The statement “Compounded by [name of outsourcing facility].”
- h. Lot or batch number of drug.
- i. Special storage and handling instructions.
- j. Date the drug was compounded.
- k. Beyond use date (BUD) of the drug.
- l. Name of veterinarian prescribing or ordering the drug.
- m. The address and phone number of the outsourcing facility that compounded the drug.
- n. Inactive ingredients.
- o. The statement “Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a.”
- p. If the drug is compounded pursuant to a patient specific prescription, the species of the animal patient, name of the animal patient, and name of the owner or caretaker of the animal patient.

## *Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

### **APPENDIX A<sup>9</sup>**

#### **LIST OF BULK DRUG SUBSTANCES THAT MAY BE USED BY AN OUTSOURCING FACILITY TO COMPOUND DRUGS FOR USE IN ANIMALS**

This Appendix, when finalized, will contain a list of bulk drug substances that may be used by facilities registered under section 503B as outsourcing facilities to compound animal drugs pursuant to a prescription from a veterinarian for an individually identified animal patient or pursuant to an order from a licensed veterinarian for veterinarian office use, and in accordance with any specified limitations or conditions.

This list will be developed with public input; the process for nominating bulk drug substances for this list is described in the Federal Register notice soliciting nominations for such bulk drug substances. FDA intends to limit the bulk drug substances in this Appendix to address situations where all of the following criteria are met:

- there is no marketed approved, conditionally approved, or index listed animal drug that can be used as labeled to treat the condition;
- there is no marketed approved animal or human drug that could be used under section 512(a)(4) or (a)(5) and 21 CFR Part 530 (addressing extralabel use of approved animal and human drugs) to treat the condition;
- the drug cannot be compounded from an approved animal or human drug;
- immediate treatment with the compounded drug is necessary to avoid animal suffering or death; and
- FDA has not identified a significant safety concern specific to the use of the bulk drug substance to compound animal drugs (under the listed conditions and limitations).

FDA intends to review the nominated bulk drug substances on a rolling basis and to periodically update this Appendix.

LIST:

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<sup>9</sup> To submit nominations for this list, refer to the Federal Register notice entitled, “List of Bulk Drug Substances That May be Used by an Outsourcing Facility to Compound Drugs for Use in Animals,” published May 19, 2015. After the period for nominations closes, you may petition FDA under 21 CFR 10.30 to add or remove specific listings.



8550 United Plaza Boulevard, Suite 1001, Baton Rouge, Louisiana 70809

1 (800) 524-2996 (225) 928-LVMA (225) 922-4611 Fax

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Dr Kirk Ryan  
LSU School of Veterinary  
Medicine  
Veterinary Teaching Hospital  
Skip Bertman Drive  
Baton Rouge, LA 70803  
(225) 578-9600  
(225) 578-9916 Fax

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**DISTRICT 5**

Dr Trisha Marullo  
Broussard Veterinary Clinic  
1723 Roper Road  
Maurice, LA 70555  
(337) 988-5022  
(337) 988-5029 Fax

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**MEMBER-AT-LARGE**

Dr Marion Sewell  
Ruston Animal Clinic  
5605 Highway 167N  
Ruston, LA 71270  
(318) 255-6927  
(318) 255-1501 Fax

**IMMEDIATE PAST PRESIDENT**

**DISTRICT 8**

Dr Sue Olivier  
Acadiana West Animal Clinic  
2600 Baratana Blvd Suite E  
Marrero, LA 70072  
(504) 341-9510  
(504) 328-0820 Fax

**TREASURER**

Dr Dale Peyroux  
46225 North Morrison Blvd  
Hammond, LA 70401  
(985) 345-5157  
(985) 429-8555 Fax

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July 26, 2015

Re: Notice of Intent: Compounding for Office Use for Veterinarians (LAC 46:LIII.2535)

Dear Board Members:

On behalf of Louisiana pet owners and veterinarians, we endorse the rule change published in the above referenced notice of intent in the Louisiana Register.

Compounding is a needed tool and it provides much-needed therapeutic flexibility for veterinarians, especially considering the wide range of species and breeds veterinarians treat.

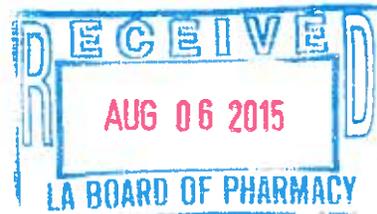
A typical companion animal veterinary clinic cares for pocket pets (guinea pigs, hamsters, rabbits, small reptiles, etc.), birds, cats, and dogs. Compounded medications are integral to treating many of these animals as no approved products are available or because approved product formulations are impossible or impractical to administer to animals.

Many animals do not show clinical signs of illness until they are life-threateningly ill. Biologically speaking, to display signs of illness/weakness is to become prey for predators. Consequently, many animal diseases are diagnosed in advanced stages after the animal can no longer 'hide' its illness. These animals require urgently available medications and often such medications must be compounded to permit administration or because approved products are not available. Without access to compounded medications, animals may die or be euthanized because emergency medications are not available or their treatment is inconvenient.

Permitting compounded medications available for veterinary use, as published in the notice of intent, will avoid a daily impact on the health and safety of companion animals. We appreciate the Board's consideration in meeting the needs of animals, pet owners, and veterinarians.

Sincerely,

Kirk Ryan, DVM  
President, Louisiana Veterinary Medical Association





Dear Pharmacy Board Member,

As you may know, the FDA is proposing "Guidance for Industry-Compounding Animal Drugs from Bulks Drug Substances." This guidance is remarkable in its restrictions and impact to the veterinary community such as:

- documenting clinical need on each prescription for compounded drugs
- no office stock of compounded medicinals, sterile or otherwise
- scripts to be pet-specific--no flocks, fish or groups of shelter animals
- no allowance for dispensing of acute amounts from office stock

Not only do we find these guidelines contrary to the practice of contemporary veterinary medicine, they are also detrimental to pharmacies, many of whom are no longer making sterile products.

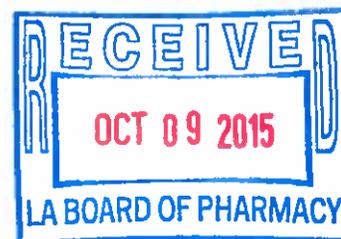
Enclosed is the AVMA response to this proposal which addresses serious deficiencies, intensified record keeping and discusses the need and urgency for compounded sterile items for office use as well as the need to dispense compounds for acute conditions. Additionally, I am enclosing a copy of a letter to the FDA from several congressmen who oppose the FDA's process. They feel the FDA has exceeded its authority and ask that the FDA proposal be withdrawn.

Veterinary medicine is vastly different than human medicine. Vets must deal with numerous species and even more numerous body weights and unusual diseases; human pharmaceuticals rarely meet their needs. Further, industry has abandoned many veterinary products that were unprofitable, notably injectables. Lastly, dispensing small amounts of specialized medication is often essential to a pet's health in the absence of readily available customized strengths and dosage forms.

In spite of recognized shortcomings, some state boards of pharmacy are seriously considering this FDA proposal for incorporation into their own regulations through a Memorandum of Understanding. Roadrunner Pharmacy has been a partner in the veterinary community for more than 16 years; we know how important these issues are to animal health practitioners. As your board addresses veterinary compounding issues, I urge you and your board to oppose these contested FDA guidelines in the presence of an 18 page letter from an organization that represents more than 85,000 veterinarians AND given the serious misgivings from members of Congress. A number of states have granted exclusions, affording unique and often life-saving compounds to veterinarians, both sterile and non-sterile.

Thank you for your time and consideration.

  
ROBERT L. EATON, JR.  
President/CEO  
Roadrunner Pharmacy, Inc





August 14, 2015

Mr. Eric Nelson  
Center for Veterinary Medicine  
Division of Compliance  
FDA Center for Veterinary Medicine  
7519 Standish Pl  
Rockville, MD 20852

**RE: [Docket Nos. FDA-2015-D-1176 and FDA-2003-D-0202] Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Withdrawal of Compliance Policy Guide; Section 608.400 Compounding of Drugs for Use in Animals**

Dear Mr. Nelson:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical organization in the world with over 86,500 members. The AVMA's mission is to lead the profession by advocating for its members and advancing the science and practice of veterinary medicine to improve animal and human health.

The AVMA recognizes that the FDA Draft Guidance for Industry #230 sets forth the Food and Drug Administration's (FDA) policy regarding compounding animal drugs from bulk drug substances by state-licensed pharmacies, licensed veterinarians, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b). We understand this guidance describes the conditions under which FDA generally does not intend to take action for violations of the following sections of the FD&C Act: section 512 (21 U.S.C. 360b), section 501(a)(5) (21 U.S.C. 351(a)(5)), section 502(f)(1) (21 U.S.C. 352 (f)(1)), and, where specified, section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), when a state-licensed pharmacy, licensed veterinarian, or an outsourcing facility compounds animal drugs from bulk drug substances.

Additionally, we recognize that this draft guidance only addresses the compounding of animal drugs from bulk drug substances, and that it does not apply to the compounding of animal drugs from approved new animal or new human drugs. The AVMA was a leader in the development of, and advocacy for, the enactment of the Animal Medicinal Drug Use Clarification Act on behalf of our members and the patients they serve. Extralabel drug use, including the compounding of preparations from FDA-approved drugs, continues to provide access to critical medications and our members continue to rely on this FDA-regulated activity in the practice of veterinary medicine within the confines of the 21 CFR 530.

The AVMA appreciates the FDA's recognition that there is a need for preparations compounded from bulk drug substances. We also share the agency's concern about the use of these preparations when approved alternatives exist that can be used as labeled or in an extralabel manner consistent

with the requirements of FDA's extralabel provisions. The AVMA continues to believe that three circumstances exist wherein compounds prepared from bulk drug substances might be necessary:

- the approved product is not commercially available, or
- the needed compounded preparation cannot be made from the approved product, or
- there is no approved product from which to compound the needed preparation.

While we are formally submitting these comments today, we will continue to assess whether the draft guidance can realistically address the needs of veterinary patients and ask that the FDA continue its dialog with us.

## ***Overarching comments***

### **Drug Availability**

Veterinary medicine is unique in that we treat a multitude of species with an even greater number of unique diseases and conditions. Approval of new animal drugs is critical to veterinary medicine and engaging with the Agency in facilitating that process remains a high priority for our Association. However, compounding from bulk drug substances is still a necessary practice for veterinarians because there are, and always will be, a limited number of FDA-approved drug products for the many species and conditions that we treat. Intermittent drug shortages and commercial unavailability of FDA-approved drug products drive the need for compounded preparations within veterinary practice. While FDA has not identified cost as appropriate reason for compounding from bulk drug substances, the AVMA acknowledges that cost can be a reason veterinarians utilize compounded preparations because that is the only way a client can afford to treat their pet.

Our members have clearly conveyed that they need access to safe and efficacious drug products that can be practicably used in their patients. While recognizing FDA's jurisdiction is limited to issues related to safety and efficacy, not cost or commercial availability of drug products, we underscore the increasingly critical need for effective pathways for drug products to achieve legal marketing status. A robust, competitive animal health industry can benefit animal patients by way of increased numbers of legally marketed products that can be prescribed, dispensed or used in the preparation of compounds.

### **Existing pathways to legal marketing**

- We continue to support the concept of user fees, so long as those fees go toward expedited reviews. Increased numbers of both pioneer and nonproprietary approved drug products can help to minimize the impacts of drug shortages.
- FDA's indexing process can be a valuable way to increase the number of legally marketed drug products for use in minor species or in major species with rare conditions. We recognize that indexing provides a process to obtain legal marketing status for eligible products. The indexing process should be utilized to a fuller extent, or revised accordingly, so that well-vetted drugs that have undergone expert panel scrutiny can be used legally for wildlife, aquaria, zoo, aquacultural, and laboratory animal species, and for major species with rare conditions.

### **Innovative pathways to legal marketing**

- In 2010, the FDA published a Federal Register notice FDA-2010-N-0528 seeking comments related to identification of emerging paths toward legal status of drugs that are medically necessary and manufactured using good manufacturing processes. At the time, FDA conveyed that it is open to using both the agency's existing authority and new approaches to

make more drugs legally available to veterinarians, producers, and pet owners. We commended the FDA on its pursuit at the time and urge the FDA to implement innovative strategies to legal marketing. The AVMA stands ready to discuss possible approaches further with FDA.

### **Non-food minor species**

In species including but not limited to zoo animals, laboratory animals, exotic pets, wildlife, aquaria animals, and non-food aquacultural animals, the use of compounded preparations is unquestionably necessary. We urge FDA to carefully consider the critical need for access to compounded preparations within these species, as FDA further refines its guidance. There are few choices of FDA-approved or indexed products available for use in these species; therefore, availability of properly compounded preparations to be maintained for office use in appropriate strengths and formulations, and the ability to mix and dilute medications are necessary to provide adequate veterinary care. Several provisions within this draft guidance should not apply to non-food minor species in their respective environments, such as limiting preparations to be maintained in office for urgent or emergent needs, patient-specific prescriptions, and detailed labeling requirements for compounded preparations maintained for office use.

### **Federal vs. State Jurisdiction**

The licensure of veterinarians is regulated by state governmental authorities. Given this is a federal guidance, not a regulation, coupled with the existence of a wide range of state compounding rules, we would appreciate clarification on how GFI #230 will be enforced by the FDA. State rules regulating compounding in veterinary practice vary greatly. Some even provide substantial permissiveness for veterinarians to obtain preparations compounded for office use, and administer and dispense from the compounded preparations maintained in their office.

- How will the FDA evaluate whether the compounding of animal drugs is done in accordance with the conditions outlined in the guidance?
- Will the FDA rely on state boards of pharmacy and boards of veterinary medicine to enforce provisions within GFI #230, and how will the FDA reconcile discrepancies between state rules and GFI #230?

### **Enforcement**

For many years the AVMA has advocated for, and applauded, the FDA's enforcement of illegal manufacturing activities. The AVMA asserts that large-scale manufacturing of animal drugs under the guise of compounding does not serve to benefit animal health; rather, circumvention of the drug approval process yields substances with unknown safety, efficacy, and potency, potentially allowing disease to progress. Animal drug manufacturers also contend that these compounded preparations result in a supply/demand disincentive for new FDA-approved drug products.

- As FDA is concerned about the use of animal drugs compounded from bulk drug substances, especially when approved alternatives exist that can be used as labeled or in an extralabel manner consistent with the requirements of FDA's extralabel provisions, how does this guidance change the FDA's ability to take action to address these concerns?
- Does the FDA currently have the needed resources and enforcement capabilities to fully enforce all egregious compounding activities, or are new authorities and appropriations necessary for the agency?
- Will the FDA develop and provide a user's guide on implementing the GFI #230 for state boards of pharmacy, state boards of veterinary medicine, individual veterinarians, and pharmacists to follow? We anticipate that time for a transition to the new paradigm will be

needed across stakeholder groups, especially given the wide array of state rules that exist related to veterinary compounding. Some veterinary state boards might not be prepared to inspect veterinary facilities for compliance with standards delineated within GFI #230.

- How will FDA's enforcement of compounded preparations be reconciled with the Drug Enforcement Administration's expectations that preparations containing controlled substances must only be prepared pursuant to patient-specific prescriptions?
- We also encourage FDA to coordinate with all relevant governmental agencies related to use of bulk drug substances in depopulation efforts, which might be needed during large-scale national emergencies. The AVMA stands ready to serve as a resource to FDA related to this topic.

### **Adverse Event Reporting System**

The AVMA contends that there is a need for the continued development and strengthening of adverse event reporting systems for all adverse events, including lack of efficacy. We believe that there must be a strong, science-based, transparent and systematic surveillance system, especially considering the wide scope of species and disease conditions that veterinarians treat. The AVMA supports development of a user-friendly, easy to access form for all adverse events related to compounding. A user-friendly electronic system would be anticipated to promote both reporting by those compounding, and ease of review by FDA. For example, FDA could maintain a database of recently reported adverse events for veterinarians and pharmacists to use as a resource. Sufficient and meaningful data inputs, or adverse event reports, are imperative for a strong reporting system foundation.

- Does the FDA's current 1932a form, as a means of capturing adverse events, provide the robustness FDA needs to detect and act on trends? The AVMA contends that all adverse events associated with compound preparations should be reported, not just serious adverse events. Adverse events related to lack of efficacy should also be collected and analyzed.

### ***Comments on Specific Provisions within Draft GFI #230***

#### **Scope of AVMA Comments**

The AVMA has chosen to comment on the sections and questions that impact veterinary medicine. We will defer to the pharmacy community for feedback related to the practice of pharmacy and functioning of outsourcing facilities: pharmacist supervision (Section III.A.1. and Section III.C.2); compounding in advance of receipt of a prescription (Section III.A.2); determining and documenting that the compounded drug cannot be made from the FDA-approved drug(s) (Section III.A.5); current Good Manufacturing Practices (cGMP) (Section III.C.4); certain labeling requirements (Section III.C.10); and reporting requirements from 503B of the FD&C Act (Section III.C.8).

#### **Definitions**

We request the FDA provide clarification on the following terms:

- "Outsourcing facility"—Draft GFI #230 defines an "outsourcing facility" as a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act. Section 503B(d)(4) defines an outsourcing facility as a facility at one geographic location or address that (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of that section of the law.

As the use of outsourcing facilities in veterinary medicine is an entirely new concept, we are still assessing how the requirements for registration as an outsourcing facility would impact

the ability to meet veterinary needs. We wish to underscore that there is a substantial need for both non-sterile and sterile compounded preparations to be maintained for office use in veterinary medicine. We appreciate that the use of outsourcing facilities in the preparation of office stock is intended to increase safety of compounded preparations, yet we caution that use of outsourcing facilities might have the unintended consequence that some preparations of critical importance to animal health may no longer be available due to economic or other business considerations.

We ask the FDA to clarify how it will reconcile the clear discrepancies between statutory language and provisions in various agency documents:

- Specifically, it is our understanding that outsourcing facilities in compliance with Section 503B are only exempt from the *human drug approval requirements* in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to be labeled with adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the track and trace requirements in section 582 of the FD&C Act (21 U.S.C. 360eee-1). How does this guidance impact the facility's exemption from animal drug approval requirements?
- Per the FDA's draft guidance for industry *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, referenced in draft GFI #230, outsourcing facilities are required to meet certain conditions to qualify. Of particular concern is the requirement that the outsourcing facilities must not compound drugs that appear on a list published by the FDA of drugs that have been withdrawn or removed from the market because the drugs or components of such drugs have been found to be unsafe or not effective for humans. We are aware of a number of such compounded preparations needed in veterinary medicine, including but not limited to cisapride, asparaginase, and chloramphenicol. In these cases, the FDA-approved product was withdrawn from the market due to human safety concerns, leaving us with no alternative to treat animal patients.
- An additional concern is that a facility, in order to meet the definition of an outsourcing facility, must be engaged in the compounding of sterile human drugs. The draft guidance clearly states that "you should not register a facility as an outsourcing facility if the only activities conducted at the facility are... animal drugs,...because none of the products produced at the facility would qualify for the exemptions provided in section 503B." A number of pharmacies currently exist that serve the needs of veterinarians and would need to register as an outsourcing facility per GFI #230, but they are explicitly prevented from registering per Section 503B because they do not meet certain requirements and were told not to register by the agency in another Guidance for Industry.
- "Compounding" as defined within 503A does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling. Defined within 503B, compounding is the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering a drug or bulk drug substance to create a drug. Is the administration of a bulk drug substance directly to an animal (for example, dissolution of metronidazole powder in aquaria for medical treatment of pet fish) considered compounding, or would administration be considered compounding only if the bulk drug

substance is mixed with another active or inactive ingredient? We ask the FDA to fully clarify its definition of animal drug compounding within this guidance.

- “Bulk drug substance” is defined within 21 CFR 207.3(a)(4) as “any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.” We understand that compressed gases, household items, herbals and homeopathics, and manufactured unapproved drugs such as glucosamine, would be outside the scope of this guidance. We ask the FDA to fully clarify what it considers a bulk drug substance for purposes of this guidance.
  - In its Table 1—Estimated Annual Recordkeeping Burden, please clarify details surrounding FDA’s estimate that 75,000 pharmacies will receive approximately 6,350,000 prescriptions for compounded animal drugs annually. From where were these numbers obtained, and are these numbers specific to preparations compounded from bulk drug substances or prescriptions for all compounded preparations?
- “Patient” is defined by the AVMA (<https://www.avma.org/KB/Policies/Pages/Model-Veterinary-Practice-Act.aspx>) as an animal or group of animals examined or treated by a veterinarian, which would include herds, flocks, groups of shelter animals, laboratory animal colonies or groups, and zoo animal and aquaria collections. We respectfully request the use of this definition for the term “patient.”
- “Non-ornamental fish” needs further clarification. Which definition is the FDA using for this term? The FDA-CVM’s Program Policy and Procedures Manual *Enforcement Priorities For Drug Use In Non-Food Fish* includes a definition of “ornamental fish.” For purposes of GFI #230, are all fish not included in that definition to be considered “non-ornamental fish” and therefore food-producing animals?
- “Clinical difference” is not expressly defined within Section 503B or in the draft GFI #230. How will “clinical difference” be evaluated by the FDA, or does the FDA intend to seek state enforcement of this component?
- The terms “sale” and “transferred” need to be more clearly defined. For example, does this include the sharing of a compounded preparation between one clinic and a co-owned satellite clinic, between multiple zoological institutions or government agencies, or from one university laboratory to another within the same university system?

### Section III.A.

(2) We have serious concerns with the verbiage “The drug is dispensed...for an individually identified animal patient...” AVMA fully supports the requirement that a veterinarian-client-patient relationship must exist for the use of a compounded preparation in an animal patient. However, the requirement that a patient must be ‘individually identified’ would eliminate the ability for veterinarians to obtain a preparation for a collection of animals, such as in a zoo, laboratory animal research facility or aquarium. In some of these situations, the patient cannot be individually identified or the entire group needs to be treated; it would not be feasible or reasonable to write an individual prescription for each animal.

- We request the FDA delete the words “individually identified” and use the AVMA’s definition of “patient”: <https://www.avma.org/KB/Policies/Pages/Model-Veterinary-Practice-Act.aspx>.

(3) “Food-producing animal” defined to include all cattle, swine, chickens, turkeys, sheep, and goats is consistent with our understanding and definition of a “food-producing animal.”

The AVMA contends that compounding from bulk drug substances in food-producing animals is medically necessary for certain poison antidotes, euthanasia, and depopulation medications. There must be some allowance for compounding from bulk ingredients for these explicit situations, when there is no FDA-approved product or the approved product cannot feasibly be used per label or in an extralabel fashion. Veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; for example, methylene blue is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians’ need to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA’s extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

We are not opposed to the requirement that the prescription or documentation accompanying the prescription for a non-food animal must contain the statement “This patient is not a food-producing animal.” The statement also helps to distinguish those patients that could be a food-producing animal in some situations, independent of species (e.g., rabbits, captive elk, captive deer).

We also would appreciate clarification on the wording in the latter half of this provision: “...any other animal designated on the prescription or in documentation accompanying the prescription by the veterinarian as a food-producing animal, regardless of species, is considered to be a food-producing animal.”

- Would this mean that a veterinarian would state “This patient is a food-producing animal” to identify for the pharmacist that a bulk drug substance is not to be used?

(4)(a) The AVMA disagrees with the requirement that a pharmacy may compound a preparation using a bulk drug substance that is a component of any marketed FDA-approved animal or human drug only if the change between the compounded drug and the FDA-approved drug would produce a clinical difference. We assert that compounding should be allowable if the approved product is not commercially available for other reasons (i.e., unavailable) and no therapeutic alternatives exist, or if the needed compounded preparation cannot be made from the approved product (such as preparation of metronidazole benzoate for use in a cat) as allowed per Section III.A.5. We ask the agency to amend the provision accordingly. Given the frequency of FDA-approved drug product shortages and backorders, including all marketed FDA-approved drugs is too restrictive for the needs of veterinary patients.

(4)(b) The AVMA has concerns with, and is opposed to, the requirement for a statement from the veterinarian that the compounded preparation “produces a clinical difference for the individually identified animal patient” with an explanation of that difference. We contend that a medical rationale is necessary for use of compounds, and is a more applicable term than “clinical difference.” However, we believe documentation of why the compounded preparation was chosen is more appropriate for the medical record.

- Should FDA still choose to require inclusion of a statement in documentation, will the statements be evaluated by the FDA, or does the FDA intend to seek state enforcement of this component?

Additionally, we believe that the term “clinical difference” does not capture other medical needs for compounded preparations, such as certain worker and client safety needs, client compliance, and animal stress situations (e.g., fractious cats). These safety/animal handling needs are not related to clinical differences but rather, the ability to adequately medicate patients.

(5) Related to pharmacists documenting that a compounded preparation cannot be made from an FDA-approved drug, what does the FDA consider to be “acceptable documentation,” and to whom will the documentation be provided?

(6)(b) In concept, the AVMA does not oppose the requirement that the statement “There are no FDA-approved animal or human drugs that can be used as labeled or in an extralabel manner under section 512(a)(4) or (5) and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed” be documented on the prescription or documentation accompanying the prescription, because we believe veterinarians need to carefully consider their therapeutic options. However, the statement could inadvertently discourage use of FDA-approved drugs in preparing compounded medications. For example, we understand that sometimes the best starting ingredient for a pharmacist’s preparation of a compounded medication is the FDA-approved drug. If the veterinarian includes the above statement, that essentially would direct the pharmacist to utilize a bulk drug substance. Moreover, the veterinarian writing the prescription would not necessarily know whether the FDA-approved drug or the bulk drug substance is best for the preparation. We wholeheartedly agree with the need for veterinarians to utilize FDA-approved products whenever feasible. We ask that FDA discuss this topic further with the AVMA.

(9) We would like clarification on the statement that “a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care.” It is our understanding that under the guidance, the compounded preparation may only be dispensed by the pharmacy to the patient’s owner or caretaker, a concept with which the AVMA disagrees. Does this provision in some way allow for the veterinarian to receive the compounded preparation from the pharmacy, and then administer and dispense the preparation to the patient’s owner or caretaker? The AVMA asserts that the prescribing veterinarian should be able to dispense these preparations to help ensure that the medications are being used and administered appropriately by the client. Such dispensing also keeps the prescribing veterinarian more closely attuned to the current status of the patient should client questions or concerns (such as adverse events) arise.

We request that the FDA amend the provision to allow dispensing: “...a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care, or the dispensing of a compounded drug by the veterinarian to the owner or caretaker of an animal under his or her care.”

### Section III.B.

(1) Again, the AVMA contends that compounding should be done within the confines of a veterinarian-client-patient relationship. However, veterinarians must be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations, including compounds prepared by veterinarians and pharmacies. In fact, the

maintenance of preparations for office use is lawful for veterinarians under some states' rules. We request that the FDA include an allowance for the preparation of compounds by veterinarians in advance of a specific patient's need.

(2) For food animals, the AVMA, again, asserts that a publically available list of bulk drug substances for veterinarians to prepare poison antidotes, euthanasia, and depopulation preparations should be made available.

As previously stated in Section III (A) 3, veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; for example, methylene blue is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians' need to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA's extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

(3) If the veterinarian is prescribing a medication to be compounded in lieu of an FDA-approved drug, then there is a clinical need that has already been determined by the prescribing veterinarian. Thus the AVMA agrees with the purpose of the provision. We do not support any additional reporting or recordkeeping requirements related to this provision.

We request that the FDA amend the provision to allow for compounding from bulk ingredients if the approved product is not commercially available (either due to a backorder, shortage, or no longer marketed) or if the needed compounded preparation cannot be made from the approved product. As stated with respect to Sec. III.A.4.a., the frequency of FDA-approved drug product shortages and backorders makes inclusion of all marketed FDA-approved drugs too restrictive for the needs of veterinary patients.

(4) The AVMA supports the intentions of this provision as the AVMA believes that an FDA-approved drug product should always be used first and foremost.

(5) The AVMA supports the requirement that veterinarians compounding from bulk drug substances do so in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).

(6) The AVMA agrees with the requirements for use of bulk drug substances that are accompanied by a valid certificate of analysis and that come from FDA-registered manufacturers.

(7) The AVMA agrees with the provision's allowance for veterinarians to administer the preparation to the patient or dispense to the owner or caretaker. The AVMA also agrees that this should all be done within the confines of a veterinarian-client-patient relationship.

The AVMA contends that dispensing practices by veterinarians should be regulated by individual state boards of veterinary medicine. We would like the FDA to clarify what the agency would consider to be the "transfer" of compounded preparations to another veterinarian or a satellite facility.

### Section III.C.

(1) Please see our comments in the section below related to Appendix A. We have reservations about the outline drafted for the creation of such a list and whether patient needs can be met through the use of such a list.

(3) We do not oppose the requirement for a statement on the prescription or supporting documentation that “This drug will not be dispensed for or administered to food-producing animals.” Including such a statement is important to help minimize the risk of the medication being used in a food animal.

As stated previously, the AVMA contends that compounding from bulk drug substances in food-producing animals is medically necessary for certain poison antidotes, euthanasia, and depopulation medications. There must be some allowance for compounding from bulk ingredients for these explicit situations, when there is no FDA-approved product or the approved product cannot feasibly be used per label or in an extralabel fashion. Veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; one example also stated previously is methylene blue, which is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians’ needs to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA’s extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

(6) As the draft guidance is currently written, outsourcing facilities would be the only way by which a veterinarian could obtain office stock of certain compounded preparations. Many of these preparations are not only needed for immediate in-house administration by the veterinarian but also for dispensing to the patient’s owner or caretaker for treatment at home, up to a 14-day timeframe. This allows for dispensing for emerging needs, and to help ensure the drug is going to be effective in a particular patient. It would also help to avoid a client needing two prescriptions for one drug in a short timeframe (which could decrease compliance), and would allow time to detect any immediate adverse events (e.g., intolerance to the drug, such as seen when amlodipine results in inappetence in cats).

We request that the FDA amend the provision to allow dispensing: “...a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care, or the dispensing of a compounded drug by the veterinarian to the owner or caretaker of an animal under his or her care.” This would bring the provision in line with what is allowed for physicians under Sec. 503B of the FD&C Act.

(9) At this time, the AVMA has reservations related to the requirement that a veterinarian’s order state that the product will be used in a manner and in a species that complies with the list of permitted bulk ingredient uses under Appendix A. If any such list is created, it needs to be maintained properly and reflect veterinarians’ needs. These concerns will be further addressed in the feedback below on Appendix A.

(10) The AVMA contends that certain information should be incorporated into labels/packaging and generally agrees with inclusion of:

- a. Active ingredient(s)
- b. Dosage form, strength, and flavoring, if any
- c. Directions for use, as provided by the veterinarian prescribing or ordering the drug

- d. Quantity or volume, whichever is appropriate
- e. The statement "Not for resale."
- f. The statement "For use only in [fill in species and any associated condition or limitation listed in Appendix A]."
- g. The statement "Compounded by [name of outsourcing facility]."
- h. Lot or batch number of drug
- i. Special storage and handling instructions
- j. Date the drug was compounded, and date of dispensing, if dispensed
- k. Beyond use date (BUD) of the drug
- l. Name of veterinarian prescribing or ordering the drug
- m. The address and phone number of the outsourcing facility that compounded the drug
- n. Inactive ingredients
- o. The statement "Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a."
- p. If the drug is compounded pursuant to a patient specific prescription, the species of the animal patient, name of the animal patient, number of refills if applicable, and name of the owner or caretaker of the animal patient. We wish to underscore that "patient" can also mean a herd, collection or group of shelter animals. We assert that the AVMA's definition of "patient" should be used.

We also request that FDA require all compounded preparations be labeled that they are not FDA-approved products. We believe it is important for consumers to recognize that safety, efficacy, potency and sterility, where applicable, of compounded preparations have not been assessed or verified by the FDA.

Labeling requirements for preparations to be maintained for office use can be difficult for minor species, including but not limited to zoo, aquaria, laboratory-animal, and wildlife collections and/or facilities. For example, some compounds maintained for office use will be used to treat lameness in a number of species in a zoo collection. The labeling requirement as posed in (f) would be particularly difficult in these collections.

**Pertaining to Provisions Which Appear in Multiple Sections Related to Labeling by Pharmacies and Veterinarians (Section III.A.11 and Section III.B.9)**

AVMA requests that the labeling requirements for pharmacists and veterinarians include name of client; veterinarian's name and address; identification of animal(s) treated, species and numbers of animals treated, when possible; date of dispensing; name, active ingredient, and quantity of the drug preparation to be dispensed; drug strength (if more than one strength available); dosage and duration; route of administration; number of refills; cautionary statements as needed; beyond use date; and the statement "Compounded by [name, address, and contact number of the pharmacy or veterinarian]." We also assert that compounded preparations should be labeled that they have not been approved by FDA. Patient owners or caretakers should have information available to contact the compounding entity, be it a pharmacy, veterinarian or outsourcing facility.

The AVMA agrees with inclusion of the name of the owner or caretaker and species of animal. AVMA contends that a patient may be an animal or group of animals so the "name" of the animal patient should only be required for prescriptions where applicable and appropriate.

Related to Patient-Specific Prescriptions (Section III.A.2 and Section III.B.1)

Veterinarians must be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations. These cannot be obtained through patient-specific prescriptions. Examples are many, and include: methylene blue to treat nitrate toxicosis; apomorphine to induce emesis in dogs; antibiotics, such as metronidazole, formulated into an appropriate dose for small dogs and cats and a palatable flavor for non-human primates to treat acute diarrhea; and nonsteroidal anti-inflammatory drugs, such as meloxicam, for pain control in small mammals.

This guidance's allowance that preparations that appear in a list will only be available from an outsourcing facility will greatly restrict veterinarians' access to critical medications and hamstring their ability to provide appropriate care in a timely manner. We must ask the FDA to reconsider provisions related to preparations compounded for office use and engage in discussion with the AVMA and the veterinary profession to better ascertain how to best meet the needs of both the FDA and veterinary patients.

Related to Sourcing of, and Information on, Bulk Drug Substances (Section III.A.7, Section III.B.6, and Section III.C.5)

Section III.A.7 states that "Any bulk drug substance used to compound the drug is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 510) and is accompanied by a valid certificate of analysis." How does the intent related to this statement differ from the intents for Section III.B.6 and Section III.C.5, which both state "Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis"?

The AVMA agrees with the requirement that any bulk drug substance used by either a pharmacy, veterinarian, or outsourcing facility be manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.

Related to USP-Related Requirements (Section III.A.8 and Section III.B.5)

The AVMA asserts that compliance with USP guidelines continues to be an element that can be utilized when a veterinarian considers the quality of a compounding pharmacy's preparations. The AVMA supports the requirement that veterinarians, outsourcing facilities, and pharmacists compounding from bulk drug substances do so in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).

Related to the Sale or Transfer of Compounded Preparations (Section III.A.9 and Section III.B.7)

The AVMA advocates that compounded preparations should not be wholesaled. However, we seek clarification from FDA related to the definition of "sale" and "transfer" as indicated previously in our comments.

Related to Adverse Event Reporting Requirements (Section III.A.10, Section III.B.8, and Section III.C.7)

The AVMA advocates for robust, strong adverse event reporting systems. However, we ask whether the FDA's current 1932a form, as a means of capturing adverse events, provides the robustness FDA

needs to detect and act on trends? The AVMA underscores that all adverse events associated with compounded preparations should be reported by those compounding the preparations, rather than just serious adverse events. Adverse events related to lack of efficacy should also be collected and analyzed.

The AVMA contends there is a need for the continued development and strengthening of adverse event reporting systems for all adverse events, including lack of efficacy. We believe there must be a strong, science-based, transparent and systematic surveillance system, especially considering the wide scope of species and disease conditions that veterinarians treat. The AVMA supports development of a user-friendly, easy to access form for all adverse events related to compounding. A user-friendly electronic system would be anticipated to promote both reporting by those compounding and ease of review by the FDA. For example, the FDA could maintain a database of recently reported adverse events for veterinarians and pharmacists to use as a resource. Sufficient and meaningful data inputs, or adverse event reports, are imperative for a strong reporting system.

Related to the proposed requirement for submission of all adverse events within 15 days, the AVMA asserts that this timeframe is acceptable for veterinarians. We hope that such a timeframe is amenable to pharmacies and outsourcing facilities.

#### **Appendix A, List of Bulk Drug Substances That May Be Used By An Outsourcing Facility to Compound Drugs for Use in Animals**

In GFI #230, the FDA conveys its general intent to enforce all adulteration and misbranding provisions of the FD&C Act against entities compounding animal drugs from bulk drug substances if they are not in accordance with provisions delineated within the guidance. The AVMA understands this to mean that while all compounding from bulk drug substances continues to be illegal, those activities not provided for within the confines of GFI #230 are subject to *greater* likelihood of enforcement.

Although we want compounded preparations that veterinarians maintain for office use to be safe, we have concerns that the explicit use of outsourcing facilities might have the unintended consequence of making some preparations unavailable.

The AVMA asserts that use of a compounded preparation should be limited to those individual patients for which no other method or route of drug delivery is practical; those drugs for which safety, efficacy, and stability have been demonstrated in the specific compounded form in the target species; or disease conditions for which a quantifiable response to therapy or drug concentration can be monitored. Needs vary greatly across species treated by veterinarians.

- Zoo animals, laboratory animals, wildlife, exotic pets, camelids, aquaria species, and non-food aquacultural species: These minor species have few FDA-approved animal or human drug products or indexed drugs that can be used as labeled or in an extralabel manner to treat conditions. For example, diminutive dosages and volumes are required for some exotic pets, so office use is critical. Zoo veterinarians have advised they need to have office stock to be able to readily treat lameness or other conditions that can arise at any time among the large collections of animals they treat. For that reason, the importance of having preparations compounded from bulk drug substances in anticipation of the patient's need and available in the hospital or clinic for administration, and dispensing when appropriate, is undeniable.
- Food-producing animals: The AVMA suggests that the FDA draft a separate guidance to address compounding from bulk drug substances for food producing animals. The draft GFI

#230 provides no allowance for the preparation of compounds from bulk drug substances for food-producing animals. The AVMA has advocated for a publically available, current list of bulk drug substances that can be legally compounded within a veterinarian-client-patient relationship specific and limited to euthanasia, depopulation, and poison antidote compounds for food-producing animals. There currently exist no FDA-approved animal or human drug products or indexed drugs that can be used for these specific needs. Therefore, it is imperative that veterinarians have these preparations available and in their clinic when the need arises. Not only is compounding from bulk drug substances necessary for food-producing animals, the FDA must allow for the preparations to be obtained in anticipation of a specific patient's need (i.e. via a nonpatient-specific prescription or prescription order) for treating certain toxicoses and for euthanasia or depopulation.

- Dogs, cats, and horses: While there are a number of FDA-approved drug products for dogs, cats and horses, there remain circumstances where there is no FDA-approved drug product available to treat a particular animal with a particular condition, because either no drug product is approved for a specific animal species or no approved drug product is available or feasible for use under the extralabel drug use provisions. For example, some shelters receive 20,000 to 30,000 animals per year and have immediate needs that require compounded preparations for adequate treatment. Another example is the need for compounded buprenorphine when an owner is unable to adequately medicate their painful cat with the injectable or oral treatment at home. In instances such as these, having access to these compounded preparations for administration and dispensing by the veterinarian is critical to preventing animal suffering and death.

The criteria that all substances must meet to be included on the list are challenging.

- As asked previously, will the identified "significant safety concern specific to the use of the bulk drug substance to compound animal drugs" be related to safety concerns for humans or for animal patients? For example, cisapride was removed from the market due to human safety concerns, but is critical in feline medicine. We contend that safety concerns related to the use of compounded medications in human medicine should have no bearing on their use in animal patients in most circumstances.
- Additionally, evidence clearly indicating the ineffectiveness of a substance to be used should be a criterion by which the substance is not included on the list.

We have concerns related to the feasibility of creating an all-encompassing list of bulk drug substances within the paradigm framed by FDA, with supporting documentation as outlined in the Docket No. FDA-2015-N-1196. In lieu of the list, we contend that compounding from bulk drug substances should be allowed in three general sets of circumstances: the approved product is not commercially available, the needed compounded preparation cannot be made from the approved product, or there is no approved product from which to compound the needed preparation.

AVMA will be providing a separate set of comments pursuant to the Federal Register notice titled, "List of Bulk Drug Substances That May be Used by an Outsourcing Facility to Compound Drugs for Use in Animals."

### ***Specific Topics for Comment***

*Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable (e.g., disruptions in the manufacture or supply chain; business*

*decisions to stop marketing the drug; drug is subject to Agency action based on safety, effectiveness, or manufacturing concerns)?*

The AVMA is committed to the continued availability of medicinal products that are pure, safe, potent and efficacious for animals. While we recognize that many factors can impact a manufacturer's decision or ability to produce and make FDA-approved drug products available, the short and long-term breaks in availability or complete withdrawal of a product from the market make access to compounded preparations even more important. Lack of information regarding why the products have been removed from the market and when they might return causes frustration and uncertainty for veterinarians and pet owners as they plan for treatment of patients.

Accordingly, the AVMA contends that the lack of commercially available FDA-approved drug products is a valid reason for veterinarians to prescribe compounds prepared from bulk drug substances for patients. For example, ticarcillin-clavulanic acid is critical for treatment of certain types of bacterial otitis externa in dogs and must be compounded when commercially unavailable. We ask that the final guidance address the issue of compounding preparations from bulk drug substances when the FDA-approved drug products are unavailable for any reason. As requested earlier in our comments, does the FDA have the needed resources to address and minimize impacts of drug unavailability on patient care? Additionally, what protocols and procedures will FDA follow to assure that timely notification is made regarding emerging drug shortages that impact veterinary medicine and notification when the drug is once again commercially available? And how does FDA know when a shortage of a human FDA-approved drug will impact veterinary medicine?

*How should these situations be addressed in the final guidance?*

The AVMA contends that a robust, nimble, current drug shortage list should be made publically available. While we do not yet have a recommendation on whether this action should be incorporated into the provisions delineated within GFI #230, implemented elsewhere for the agency to manage, or maintained by an external stakeholder(s), appropriate resources must be dedicated toward its continual upkeep. In the interim, any role that the FDA plays with regard to identification of drug shortages needs to be well-informed and more broadly encompassing than the current list housed at

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm267669.htm>.

*How should the final guidance define the terms "shortage" and "unavailable"?*

A "shortage" refers to insufficient quantities of a needed FDA-approved product. "Unavailable" means that the FDA-approved product is entirely inaccessible to practitioners. Shortages and unavailability of products may be due to a back order, temporary discontinuation, or other supply interruption, resulting in limited or no accessibility through regular distribution channels.

*What criteria should FDA use to determine if an approved animal or human drug is in shortage or otherwise unavailable?*

FDA should consider products that are backordered, temporarily discontinued, no longer marketed, or provided intermittently in limited quantities when determining whether a product is in shortage or unavailable.

*Do United States Pharmacopeia and National Formulary (USP-NF) [2] chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?*

The USP chapters 795 and 797 are suitable standards for compounding from bulk drug substances by veterinarians.

*Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a State-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?*

We seek FDA's clarification related to the definitions of "sell," "transfer," and "dispense" before we can provide feedback related to this concept. In general, we assert that the prescribing veterinarian should be able to dispense preparations compounded by pharmacies or outsourcing facilities to his or her clients.

*How should FDA apply the condition to identify an individual patient when it is not possible to identify an individual animal (e.g., koi in a koi pond)?*

The AVMA contends that a "patient" is an animal or group of animals examined or treated by a veterinarian and does not need to always be individually identified. So long as the licensed veterinarian is meeting the requirements of his/her state veterinary practice act with respect to prescribing, then being able to identify an individual patient when it is not possible is unnecessary.

*Should facilities registered as outsourcing facilities under section 503B of the FD&C Act be able to compound animal drugs from bulk drug substances that do not appear on Appendix A for an individually identified animal patient under conditions similar to those applicable to state-licensed pharmacies (i.e., the conditions contained in section III.A. of the draft guidance)?*

Yes, so long as the outsourcing facility is a state-licensed pharmacy.

*Is additional guidance needed to address the repackaging of drugs for animal use?*

- *How widespread is the practice of repackaging drugs for animal use?*
- *What types of drugs are repackaged for animal use, and why are they repackaged?*
- *Have problems been identified with repackaged drugs for animal use?*

We understand repackaging to mean "The act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients." If this is FDA's definition, the AVMA agrees and understands that veterinarians sometimes need to repackage drugs, including compounded preparations, into smaller aliquots for administration by the owner or agent, as long as the repackaging does not affect the stability, efficacy, purity, safety, and potency of the product (e.g., light-sensitive drugs).

*Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under section 512(a)(4) or (a)(5) of the FD&C Act and part 530?*

No. The AVMA was a key leader in the development and advocacy for the Animal Medicinal Drug Use Clarification Act on behalf of our members and the patients they serve. Extralabel drug use, including the preparation of compounds from FDA-approved drugs, continues to be a needed activity in veterinary medicine, and our members continue to utilize this FDA-regulated activity in the practice of veterinary medicine, within the confines of the 21 CFR 530.

*Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?*

Yes. The AVMA suggests that the FDA draft a separate guidance to address compounding from bulk drug substance for food producing animals.

The AVMA continues to recommend that there be a publically available, current list of bulk drug substances that can be legally compounded within a veterinarian-client-patient relationship specific and limited to euthanasia, depopulation, and poison antidote compounds for food animal species. If adequate scientific information is not available to determine a withdrawal time, the AVMA contends that the compounded preparation cannot be used in a food animal or the treated animal cannot enter the food supply.

*As one condition under which FDA does not generally intend to take action for certain violations of the FD&C Act if this and the other conditions are followed, FDA is proposing that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from bulk drug substances to FDA within 15 days of becoming aware of the product defect or serious adverse event. Outsourcing facilities are required to report adverse events associated with the drugs they compound. FDA believes it is important to receive this information from State-licensed pharmacies and veterinarians because there are no other State Departments of Health or Federal Agencies (e.g., the CDC) charged with identifying and tracing animal injuries or disease associated with an animal drug compounded by these entities. FDA has the following specific questions with respect to this proposed condition:*

- *How many State-licensed pharmacies and veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to FDA?*

We are unaware of any data that could assist in answering this question. Anecdotally, we understand that few veterinarians personally compound from bulk drug substances.

- *Are State-licensed pharmacies and veterinarians reporting the same or similar information to any State regulatory agency (e.g., State boards of pharmacy, State boards of veterinary medicine)? If so, how many reports on average does each State-licensed pharmacy and veterinarian submit to these State agencies each year?*

It is our understanding that adverse events are grossly underreported to FDA; however, members have conveyed that when they do report an adverse event, they generally report the adverse event to the respective compounding pharmacy. We do not know the actual number of these reports, nor are we aware of the number of events reported by veterinarians to their state boards.

- *For purposes of the guidance, how should FDA define the terms “product defect” and “serious adverse event”?*

AVMA contends that “serious adverse events” are ones that are fatal, life-threatening, require professional intervention, cause an abortion, stillbirth, infertility, congenital anomaly, prolonged or permanent disability, or disfigurement as referenced in 21 CFR 514.3.

A “product defect” would include any obvious physical abnormalities, such as consistency, color and precipitant materials or contents, or problems with the amount, type or effectiveness of an ingredient triggered by production errors, poor quality bulk drug substances, or problems with transportation and/or storage. Any obvious physical defects of the container, seal or stopper and of the label of the product container would also constitute a product defect.

AVMA believes lack of efficacy is an adverse event and should be included in any reporting system.

- *Can FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from a bulk drug substance through means other than product defect and serious adverse event reporting, and if so, what other means? For example, would reports of product defects alone achieve the same objective?*  
We are unable to provide a clear answer without additional definitions for the terms “product defect” and “serious adverse event,” which would help inform our understanding and opinion.

We appreciate the opportunity to comment on the draft Guidance for Industry and provide needed feedback on behalf of the AVMA’s membership. For questions or concerns regarding the AVMA’s comments, please contact Drs. Ashley Morgan ([amorgan@avma.org](mailto:amorgan@avma.org); 202-289-3210) and Lynne White-Shim ([lwhite@avma.org](mailto:lwhite@avma.org); (800) 248-2862 ext. 6784).

Sincerely,

W. Ron DeHaven, DVM, MBA  
CEO and Executive Vice President



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Executive Committee

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**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.



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**NOTICE IS HEREBY GIVEN** that a meeting of the Executive Committee has been ordered and called for 5:00 p.m. on Tuesday, November 17, 2015 at the Board office, for the purpose to wit:

## AGENDA

NOTE: This agenda is tentative until 24 hours in advance of the meeting, at which time the most recent revision becomes official.

**Revised 11-04-2015**

1. Call to Order
2. Quorum Call
3. Call for Additional Agenda Items & Adoption of Agenda
4. Opportunity for Public Comment
5. Interim Review of Policies & Procedures
  - A. Consideration of Revision to PPM Policy No. II.A.6 ~ Flexible Special Entrance Rates for Salaries
  - B. Consideration of New LPM Policy No. I.P ~ Worker's Compensation Post -Accident Drug Testing
6. Review of Administrative Operations
  - A. Review of Legislative Auditor Report
  - B. Review of Purchase Offer
  - C. Review of Late Expense Reports from Board Members
7. Review of Personnel Issues
8. Adjourn

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**NOTE:** Pursuant to the Open Meetings Law at La. R.S. 42:16, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, (4) discussions regarding personnel matters, or other purposes itemized at La. R.S. 42:17.

- .....
1. The statutory authority for the Board to engage employees is RS 37:1182.B.6.
  2. The regulatory authority for Board employees is LAC 46:LIII.107.F.
  3. The authority of the Louisiana Department of State Civil Service relative to state employees is derived from Article X of the Louisiana State Constitution.
  4. The Civil Service Rules of Pay are found in *Chapter 6 – Pay Plan*.
  5. Civil Service Rule 6.5.b.1 authorizes an appointing authority to institute Flexible Special Entrance Rates (FSER) for current employees, provided that the Civil Service Commission has approved the rate during a regularly scheduled meeting.
  6. The Board reviewed the current salary structure for its administrative and professional personnel. They also reviewed responses to recent job announcements as well as the current job market and general economic conditions. They determined the appointing authority should have flexibility in the maximum hire rate for certain of its classified employees.
    - a. For the following positions in the Administrative Services (AS) classification, the appointing authority may use a FSER in the first quartile of the pay grid for the position.
      - i. Administrative Coordinator 1 (AS 605)
      - ii. Administrative Coordinator 3 (AS 609)
      - iii. Licensing Analyst 2 (AS 611)
      - iv. Administrative Assistant (AS 609)
    - b. For the following positions in the Medical Services (MS) classification, the appointing authority may use a FSER in the third quartile of the pay grid for the position.
      - i. Pharmacist Compliance Officer (MS 525)
      - ii. Pharmacist Chief Compliance Officer (MS 527)
      - iii. Pharmacist Chief Operations Officer (MS 528)
    - c. The following factors, when present, may justify consideration of a FSER for a new hire:
      - i. A qualified applicant with exceptional qualifications; or
      - ii. Prevailing salaries for comparable positions in the private sector;
    - d. In the event the appointing authority intends to offer a flexible special entrance rate to a new hire, he shall first obtain approval from the Board's President.
  7. Civil Service Rule 6.16.2.b authorizes an appointing authority to grant an employee a pay increase of up to 10% of the employee's base pay to reduce compress, realign pay between comparable employees, or alleviate supervisor/subordinate pay inversions caused by job and pay plan changes.

- a. Current employees with annual salaries below the level of a new employee's entrance rate shall be raised to the new employee's rate, provided the increase is no greater than 10% of the current employee's salary.
- b. This policy shall apply to all full-time classified employees with permanent status. The employee must have a current overall Performance Evaluation System (PES) rating of "Exception," "Successful" or equivalent to be eligible for an Optional Pay Adjustment.
- c. Employees who are at range maximum are not eligible to receive a base increase.
- d. This policy shall become effective upon Civil Service Commission approval.

DRAFT

*Title:* Workers' Compensation Post-Accident Drug Testing Policy No. I.P

Approved: 11-18-2015

Revised:

.....

I. AUTHORITY:

Executive Order No. BJ 08-69 provides for the promulgation by executive agencies of written policies mandating drug testing of employees, appointees, prospective employees and prospective appointees in accordance with La. R.S. 49:1001, *et seq.*

La. R.S. 39:1535(B)(12) provides that the Office of Risk Management ("ORM") may promulgate rules and regulations to establish procedures governing risks and injuries sustained where a participating or covered entity of the State may be liable for damages.

La. R.S. 23: 1081 and Louisiana Administrative Code Title 40, Part I, Chapter 15 allows an employer to test an employee for drugs and alcohol when the employee receives a personal injury from an accident arising out of and in the course of his employment.

II. APPLICABILITY:

In addition to any drug testing policy adopted by an executive agency pursuant to Executive Order No. BJ 08-69, this policy shall also apply to all persons having an employment relationship with an executive agency, whether classified, unclassified, student employees, interns, full-time, part-time, or temporary (hereinafter employee(s)), when the employee's agency is provided workers' compensation coverage through ORM.

III. DRUG TESTING:

All employees who are entitled to assert a claim pursuant to the workers' compensation laws of Louisiana shall be subject to, and shall cooperate in, post-accident drug testing. With or without prior notification, any employee in an accident that occurs during the course and scope of employment shall be required to submit to drug and/or alcohol testing as soon as practicable under La. R.S. 23: 1081, whether or not a compensable injury is immediately claimed by the employee, where an accident occurs under any circumstance, regardless of fault, which necessitates, or should reasonably necessitate, medical attention to the employee as determined by the employee, the employee's supervisor(s), or the department head, regardless of whether the employee actually desires, agrees to, seeks, or receives medical attention.

IV. DRUG AND ALCOHOL TESTING PROCEDURES:

Testing shall be performed as provided for in the Louisiana Administrative Code Title 40, Part I, Chapter 15, or its successor.

Testing shall be performed at the most practical hospital, medical facility, or laboratory. ORM, or the agency, reserves the right to require employees to submit to additional testing, if warranted.

A representative of the agency shall transport the employee being tested to and from the testing site. Under no circumstance should any employee who is believed to be impaired or under the influence of any drug or alcohol be permitted to operate a motor vehicle.

V. VIOLATIONS:

Employees found to test positive or failing to promptly submit to testing under this policy may be subject to dismissal or denial of their Workers' Compensation benefits pursuant to La. R.S. 23:1081.

Employees and supervisors may also be subject to discipline, up to and including dismissal, in accordance with their agency's drug-free policy for failing to cooperate with, or to apply, the post-accident drug testing requirements outlined in this policy.

VI. QUESTIONS:

Questions regarding this policy should be directed to the Office of Risk Management.



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## Report of Assistant Executive Director

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# Prescription Monitoring Program

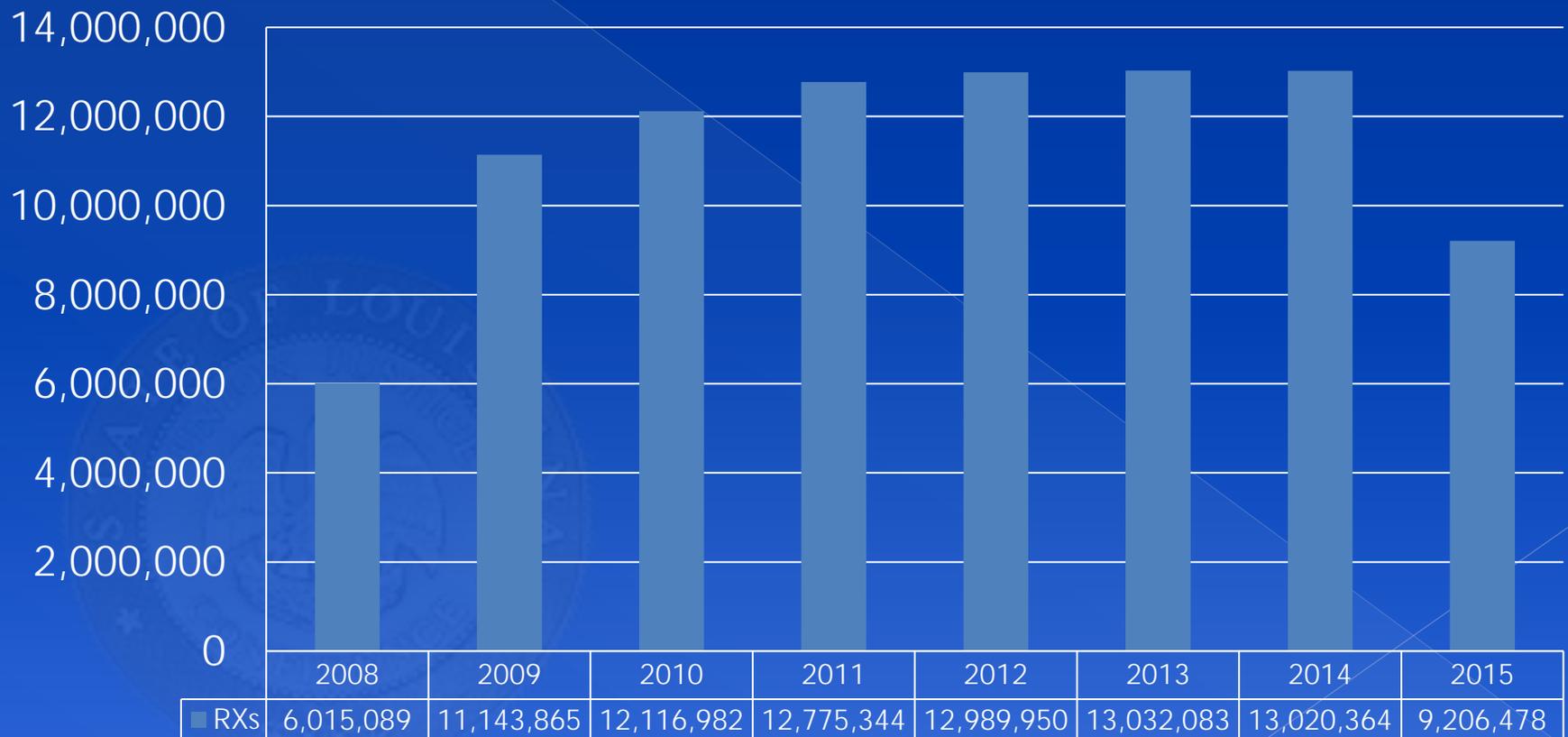
Board Meeting  
November 18, 2015

Joe Fontenot, R.Ph. Assistant Executive Director  
Danielle C. Meadors, Administrative Assistant

# Number of Eligible Transactions Reported to the PMP

Total Reported as of  
September 30, 2015

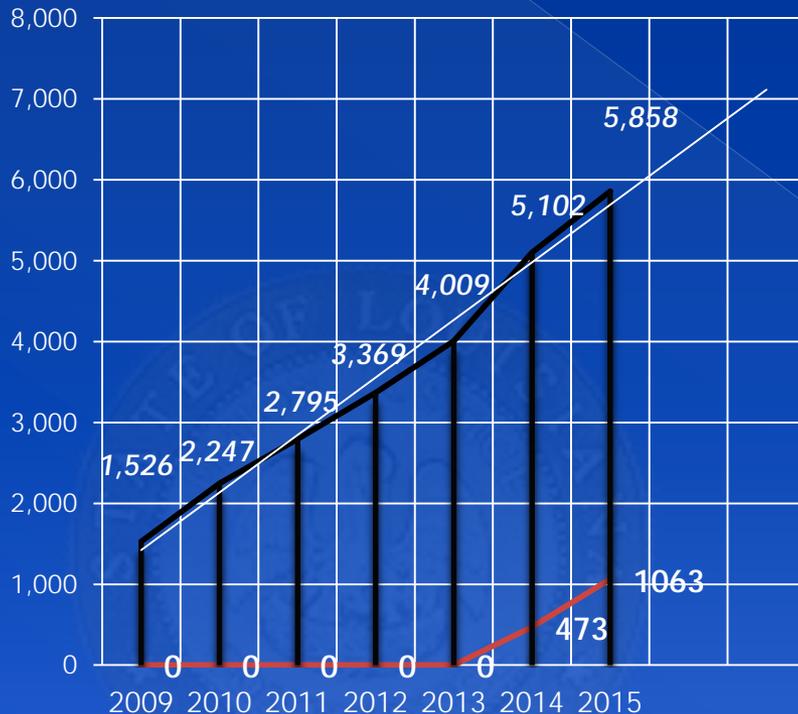
**90,300,155**



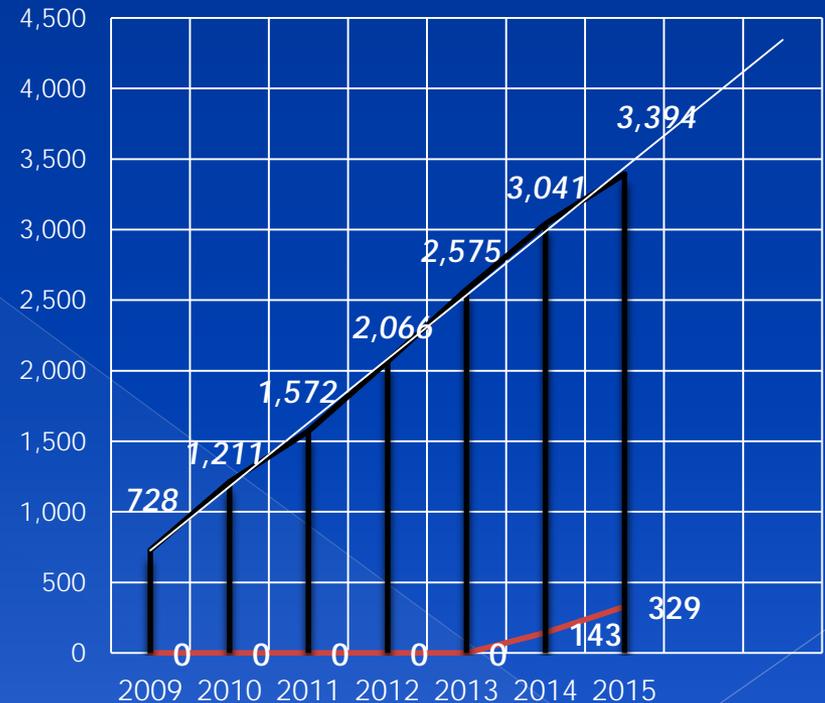
# Prescriber & Pharmacist Access

(as of September 30, 2015)

Prescribers – Total  
Authorized 6,921



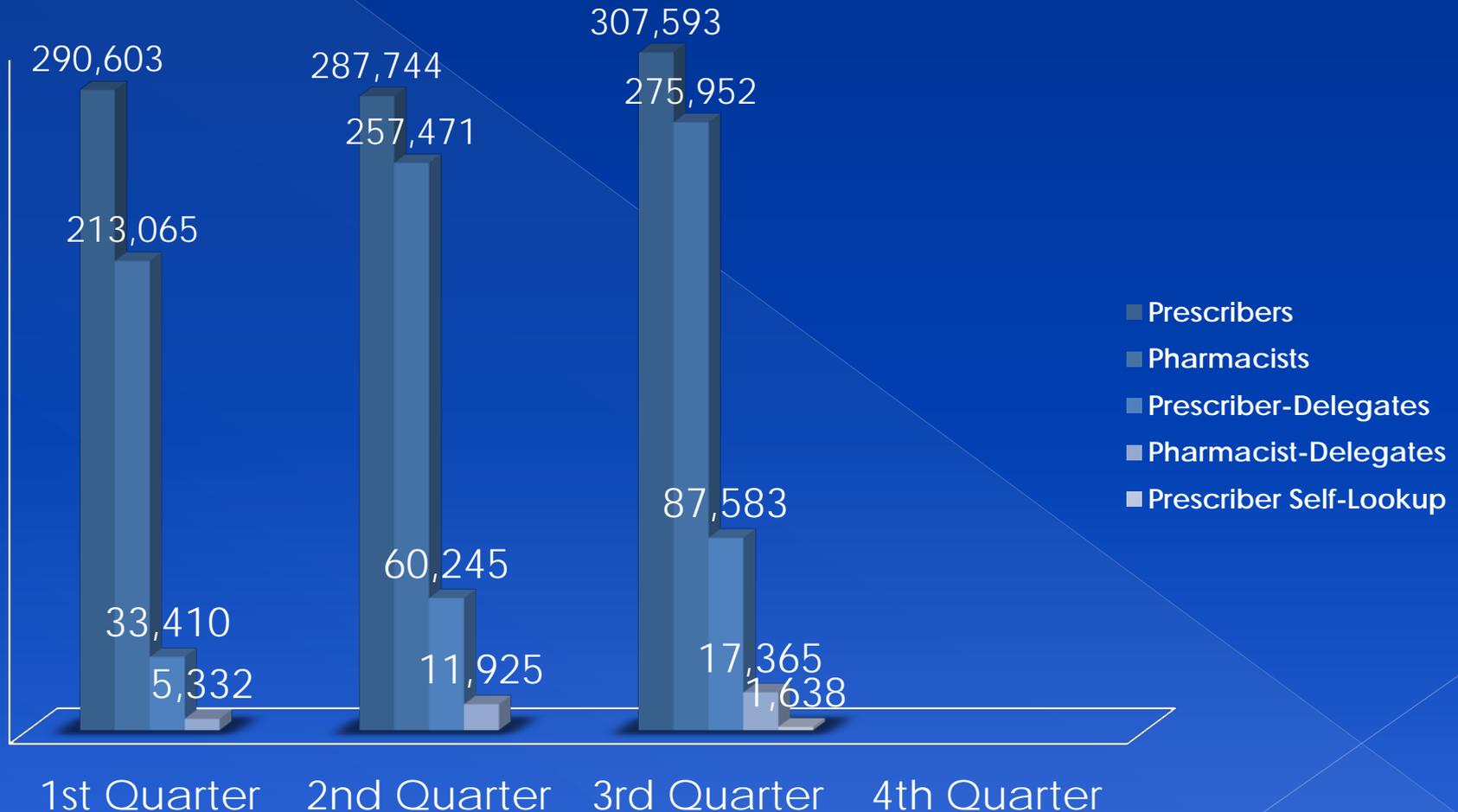
Pharmacists – Total  
Authorized 3,723



Combined totals – 10,644

# Prescriber & Pharmacist Queries – 2015

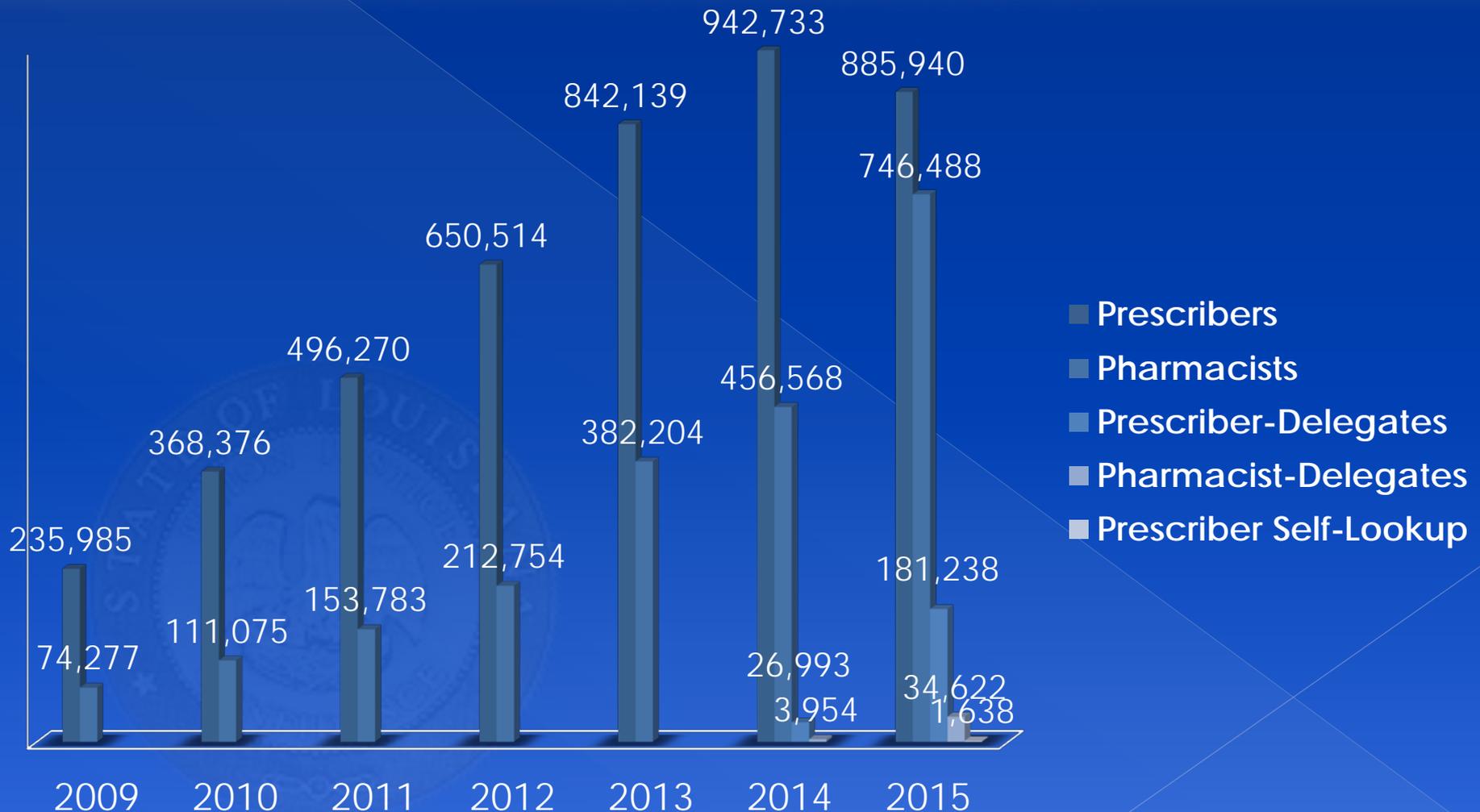
Overall Query total = 1,849,926



# Prescriber & Pharmacist Queries

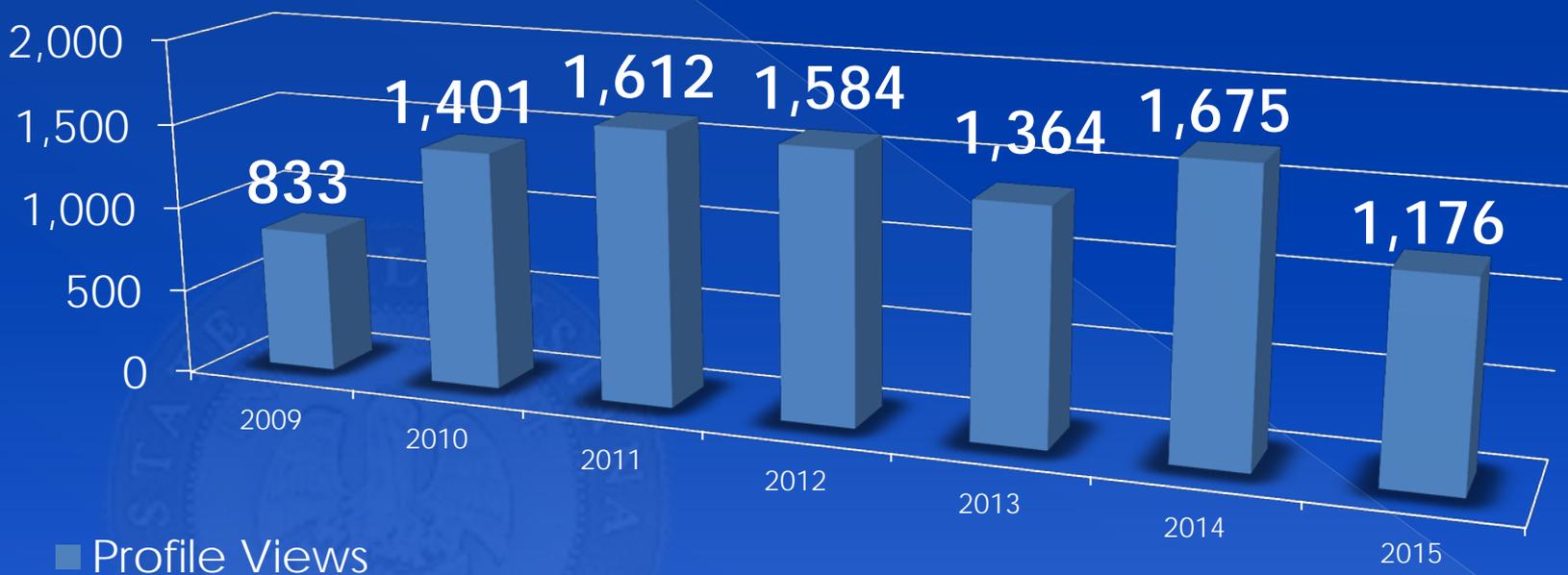
(01/01/2009 through 09/30/2015)

Overall Query total = 6,807,551



# Board and Regulatory Agencies

Profile Views by Boards & Regulatory Agencies Total = **9,645**  
(01/01/2009 through 09/30/2015)



# Law Enforcement Access and Requests

Number of Law Enforcement  
Requests Processed = **6,792**  
(01/01/2009 through 09/30/2015)

2009	2010	2011	2012	2013	2014	2015
<b>680</b>	<b>889</b>	<b>1,230</b>	<b>845</b>	<b>1,150</b>	<b>1,224</b>	<b>774</b>

# PMP Interconnect

## LOUISIANA STATS

Last Updated: 2015-10-12 11:05

<b>Requests</b>	<b>Last 60 Mins</b>	<b>Last 24 Hrs</b>	<b>Last 30 Days</b>
<b>Requests Performed by this PMP</b>	<b>172</b>	<b>730</b>	<b>38613</b>
<b>Processed Successfully</b>	<b>100.0%</b>	<b>100.0%</b>	<b>99.93%</b>
<b>Denied for Interconnect Business Rules</b>	<b>1.16%</b>	<b>0.82%</b>	<b>0.2%</b>
<b>Disclosures</b>	<b>Last 60 Mins</b>	<b>Last 24 Hrs</b>	<b>Last 30 Days</b>
<b>Disclosures Processed by this PMP</b>	<b>379</b>	<b>2162</b>	<b>34284</b>
<b>Asynchronous Deferred from this PMP Processed</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Disclosures Processed Successfully by this PMP</b>	<b>100.0%</b>	<b>100.0%</b>	<b>99.97%</b>
	<b>Total</b>		
<b>Deferred Disclosures owed by this PMP</b>	<b>1</b>		
<b>Deferred Disclosures due to this PMP</b>	<b>0</b>		

# PMP Interconnect

[Back to Dashboard](#)

## PMPi PERFORMANCE REPORT

Date Starting  through Date Ending

	Requests To	# Successful Responses	% Successful Responses	Average Response Time	% Transactions Responded in < 5 seconds
Arizona					
Arkansas	30165	29562	98%	1.21 sec	98%
Colorado					
Connecticut					
Delaware					
Idaho					
Illinois					
Indiana					
Iowa					
Kansas					
Kentucky					
LACIE					
Louisiana	0	0	-	-	-
Maryland Disclosures					
Maryland Requests					
MHIN					
Michigan					
Minnesota					
Mississippi	40067	40041	100%	0.77 sec	99%
Narxcheck					

# Coroner: Baton Rouge on track to see record number of heroin deaths this year

## Officials say heroin-related deaths could reach record

By andrea gallo

[agallo@theadvocate.com](mailto:agallo@theadvocate.com)

Advocate staff photo by ANDREA GALLO -- East Baton Rouge Parish Coroner Dr. Beau Clark said Thursday, Aug. 27 that heroin deaths are expected to reach record highs this year in Baton Rouge. The Coroner's Office and Capital Area Human Services have partnered for a campaign to prevent heroin and synthetic marijuana deaths.

A powerful high, a cheap price and a steady addiction are what pulled recovering addict Michael Rito into the thick of heroin use several years ago.

Rito is a poster child of the "it can happen to anyone" claims about drug use, particularly heroin use, as Baton Rouge health professionals try to spread awareness of the drug's deadly effects. A former collegiate athlete, Rito said he started dealing drugs to make money and then started using them, as well.

He sat in the audience Thursday when East Baton Rouge Parish Coroner Dr. Beau Clark told a group of people at Capital Area Human Services that Baton Rouge is on track to see heroin deaths reach record numbers this year. Rito and several other men in his rehab program listened to Clark and others lay out a new campaign to try to prevent more people in the area from slipping into addiction.

The capital city has already confirmed 24 heroin-related deaths in 2015, and three more are pending from the past 10 days. Shane Evans, the Coroner's Office chief of investigations, said he has seen two young women die from heroin overdoses in the past three days.

The first was in a treatment facility where someone snuck in heroin and gave it to her. The other woman was pregnant.

Heroin deaths in Baton Rouge rose dramatically between 2012 and 2013, going from five deaths the first year to 35 deaths the second. Clark attributed it to an influx of heroin dealers coming to Louisiana because it had weaker penalties for heroin dealing and more people looking for heroin on the streets because it became more difficult to get a prescription for opiate pain medications from a doctor. That difficulty was the result of new a monitoring program that allowed doctors to see what prescriptions a patient was getting from another doctor.

Heroin deaths dipped slightly last year but are already high for 2015. Clark said he is unsure why Baton Rouge experienced the decline in heroin deaths last year. Heroin deaths, he added, tend to be more common during autumn.

Rito, who is from New Orleans but is being treated for the narcotic suboxone in a Baton Rouge rehab center, said he is glad more information is being put out about the drugs. But he said the messages mainly show young adult males as the ones who are overdosing while at home.

He said he has seen people from all walks of life who have used heroin.

Heroin gave Rito a high so powerful that he said he was willing to shell out \$200 to \$300 a day to keep getting it. It was still cheaper than other drugs that gave him a weaker high and lasted for shorter time periods.

“I’ve known doctors that I’ve used with, lawyers, every type (of person),” he said.

The new campaign is meant to address heroin and synthetic marijuana, which is sometimes called mojo or spice and is also deadly. The main messages are “mojo is poison and heroin is deadly,” along with the Coroner’s Office saying “don’t let this be your last ride.”

The videos will be shown at schools, and posters will be distributed to anyone who wants them. Capital Area Human Services is also putting their messaging on billboards.

Rito said he has not used heroin for three years. But he slipped with his use of suboxone, which is actually used to treat opiate addictions, and he entered rehab again earlier this month.

Suboxone is another drug that Rito said is already a problem on the streets. He expects there to be future efforts to curb its use, just like the efforts for heroin and synthetic marijuana.

“It’s been around for seven years. I just don’t understand why it’s not talked about yet,” he said.

While doctors know the deadliness and danger of heroin, synthetic marijuana continues to be uncharted territory. Every time the U.S. Food and Drug Administration bans a version of it, chemists alter the drug’s makeup to make it legal again, Clark said.

Those constant changes mean doctors do not know what side effects synthetic marijuana is capable of causing, he said, nor do they know if synthetic marijuana damage will be permanent. Baton Rouge has had three synthetic marijuana deaths this year, and Clark said there may have been more, but they are difficult to prove because of the drug’s different makeups.

Clark described mojo users — if they did not die — as exhibiting signs of schizophrenia and other mental health issues.

Rito said he experimented with synthetic marijuana before, and he has seen similar side effects on friends and people he knows.

“It’s very schizophrenic, very paranoid, very scattered,” he said.

Rito offered hope for anyone who is struggling with addiction, saying they need more than facts; they also need emotional support. He said he has found that at the Capital Area Recovery Program.

“Everybody can recover,” he said.

## Requests for Full Exemption from PMP Reporting November 18, 2015

In accordance with LA.R.S:40.4.X-A.1006.C. The board may issue an exemption from the reporting requirement to a dispenser whose practice activities are inconsistent with the intent of the program. The board may rescind any previously issued exemption without the need for an informal or formal hearing.

Permit	Permit Type	Name	Scope of Practice	DEA	City	State
2	HOS	Abbeville General Hospital Pharmacy	Inpatient Hospital Pharmacy	Yes	Abbeville	LA
7153	NR	Barnes Precision Specialty Pharmacy	Specialty Pharmacy	Yes	Gainesville	FL
7152	NR	Biocure	Specialty Pharmacy	Yes	Houston	TX
7192	NR	Direct Success Pharmacy Dept.		Yes	Farmingdale	NJ
7173	NR	Liberty Medical Supply	Mail Order Pharmacy	Yes	Port Saint Lucie	FL
6683	HOS	LSU Health Baton Rouge - North Clinic Pharmacy	Infusion Pharmacy	Yes	Baton Rouge	LA
6313	NR	Option Care	Home Infusion Therapy	Yes	Irving	TX
6739	NR	Physician Choice Pharmacy	Specialty Pharmacy	Yes	Sunrise	FL
7150	HOS	Promise Hospital of Miss Lou	Inpatient Hospital Pharmacy	Yes	Vidalia	LA
7083	NR	Rxpress Pharmacy	Mail Order Pharmacy	Yes	Fort Worth	TX
7143	HOS	University Medical Center New Orleans Inpatient Pharmacy	Inpatient Hospital Pharmacy	Yes	New Orleans	LA
6727	IR	University Medical Center New Orleans Outpatient Pharmacy		Yes	New Orleans	LA

### **Staff Recommendation**

Approve the proposed waivers conditioned upon execution of the standard Consent Agreement:

### **EXEMPTION TO PRESCRIPTION MONITORING PROGRAM REPORTING REQUIREMENTS CONSENT AGREEMENT**

WHEREAS, in order to facilitate the pharmacy's request for an exemption to the reporting requirements to the Louisiana Board of Pharmacy's Prescription Monitoring Program (PMP) as required by law, the Pharmacy indicated below agrees to the following terms:

- (1) The Pharmacy shall not be authorized to dispense any controlled dangerous substances (CDS) or *drugs of concern*, with the exception of a hospital pharmacy permit's inpatient dispensing, as identified by the Louisiana Board of Pharmacy (Board) by regulation.
- (2) Upon the first instance of receipt of evidence by the Board indicating the Pharmacy dispensed CDS or drugs of concern, the Pharmacy agrees to the following sanction:  
***The Pharmacy agrees to pay a fine of \$5,000.00 and reimburse the Board \$250.00 in administrative hearing costs, with total payment due the Board of \$5,250.00, due by certified check or money order within 30 days of notice of this prohibited activity.***
- (3) Upon the second instance of receipt of evidence indicating the Pharmacy dispensed CDS or drugs of concern, the Pharmacy agrees to pay the above sanction, the termination of this exemption and the resumption of its reporting to the PMP.
- (4) The Pharmacy shall post a copy of this agreement adjacent or attached to its pharmacy permit.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.



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## Report of General Counsel

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## Report of Executive Director

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November 18, 2015

## Agenda Item 10-L: Report of Executive Director

1. Meeting Activity
2. Reports
3. Examinations
4. Operations
5. State Activities
6. National Activities
7. International Activities

### 1. **Meeting Activity**

In addition to Board and committee meetings, I have also participated in or attended the following meetings since the last Board meeting.

Aug. 18	Pharmacy Law Update CE – New Orleans
Aug. 19	P-1 Orientation – Xavier College of Pharmacy
Aug. 20	Pharmacy Law Update CE – Monroe
Aug. 21	P-1 Orientation – ULM School of Pharmacy
Sep. 10-11	MPJE Item Review Workshop – NABP Office
Sep. 14-18	NABP-AACP Districts 6-7-8 Mtg – Lake Tahoe, NV
Sep. 28 – Oct. 3	FIP World Congress – Dusseldorf, DE
Oct. 6-7	Tri-Regulator Symposium – Washington, DC
Oct. 13-14	Executive Officer Forum – NABP Office
Oct. 25-28	MALTAGON Conference – Louisville, KY

### 2. **Reports** (all in the Boardroom Library)

#### A. Census Reports

1. Compliance Division – Practitioner Recovery Program & Discipline
2. Credentials Division – CDS & Pharmacy Programs

#### B. Credentials Division Production Reports

1. Licensure Activity Report [new credentials in previous quarter]
2. Application Activity Report [pending applications count]
3. Roster of Accredited Pharmacy Technician Training Programs

This is a new item and requires approval by the Board on an annual basis, similar to the roster of schools and colleges of pharmacy.

#### C. Exceptions Report

1. PIC in Multiple Locations
2. Resurrected Credentials / Special Work Permits

### 3. **Examinations**

#### A. MPJE – the results for the second trimester of 2015 are available.

Mr. Fontenot and I participated in the annual review of our law test questions for the MPJE-La. We deleted 24 questions from the item pool based on changes in the

pharmacy laws and rules, and we approved the addition of 180 new items, bringing our total item count to 2,380 questions approved for that test.

NABP has announced some program changes for the MPJE, including new competency statements for the examination blueprint, an increase in the number of questions on the examination, an increase in the amount of time allowed to take the test, as well as a price increase. A copy of the memo from NABP was posted in the Library.

- B. NAPLEX – the results for the second trimester of 2015 are available.
- C. PARE – our last administration of this test was in July 2014.
- D. PTCB – the results for the first three quarters of 2015 are available.

#### 4. **Operations**

##### A. Credentials Division

We opened the renewal cycle for pharmacists and pharmacies on November 1; those currently active credentials will expire on December 31 unless renewed timely. We prepared and mailed renewal reminder notices to 8,400 pharmacists. We prepared renewal reminder notices for 2,003 pharmacies, then held 30 of them before mailing the remainder. Of the 30 pharmacy notices held, 22 of them related to an expired inspection report (more than three years old), and 8 of them related to the absence of a pharmacist-in-charge. We will present updated renewal information at the time of the meeting.

##### B. Compliance Division

Our 5 pharmacist compliance officers are responsible for inspecting all the pharmacies and other facilities holding controlled substances (CDS). The census reports available for this meeting reflect 1,475 pharmacies within the state, as well as approximately 600 various types of facilities for CDS visits, including hospitals, rural health clinics, animal control shelters, researchers, etc.

In addition to their routine site visits, the compliance officers are also responsible for investigating complaints filed with the Board. We began the fiscal year with 214 cases pending from the prior fiscal year. We have entered 155 new cases and closed 122, leaving 247 cases currently open. Of the 122 cases closed this fiscal year, 63% were disposed of through staff activities and the balance through committee and Board action.

##### C. Administrative Division

As we reported during your last meeting, we are working with the medical and optometry boards to facilitate the implementation of Act 453 of the 2015 Legislature. At the beginning of November, we received word from the DEA office in Washington, DC they had updated their schedule of state authorities for mid-level practitioners to include physician assistants and optometrists. The leaders for those statewide membership organizations are aware of that development, and we are beginning to see some requests to update CDS licenses. That means those mid-level practitioners in this state will soon be able to update their DEA registrations, and when they do, they will then have the required credentials to write prescriptions for Schedule II medications within their scope of practice.

The Legislative Auditor completed their work in early October. A large part of the delay was the necessity to audit the original OPEB numbers issued to the Board by the state several years ago and make some corrections in that area. As you can see in their report, they also made two findings relative to our internal operations – one concerning procedures for small purchases (\$5,000 - \$25,000) and the other concerning certificates of deposit in our investment accounts. We have already made the appropriate adjustments and our response was included in their report.

As part of NABP's continuing efforts to assist state boards of pharmacy regulate the compounding of sterile preparations by pharmacies licensed by those boards, NABP has partnered with CriticalPoint, a private firm headed by Eric Kastango, a pharmacist known nationally for his long work in this field, and who has completed at least one term of service on the expert committee assisting USP with its standards in Chapter 795 and

797. As you may recall, that firm operates a 'boot camp' in Denver that educates pharmacists and compliance officers on how to operate and inspect cleanroom facilities for sterile compounding. They also offer extensive continuing education opportunities including webinars for compliance officers. All of our compliance officers have completed that one-week 'boot camp', and further, are scheduled to attend a refresher course this coming January. As a further development in that partnership, CriticalPoint has offered to develop a sterile compounding certification program – first for an individual, and then for that individual to certify a compounding operation. We posted the announcement in the Boardroom Library; please note that NABP is requesting information from the boards as to their interest in, and possible use of, such a program. Given the timelines involved, we would appreciate your input on this topic at this meeting.

Finally, we are aware of the requirements of Act 261 of the 2015 Legislature that calls for a report from the Board of Pharmacy no later than January 1, 2016; that report is to recommend possible fees relevant to the dispensing of marijuana for therapeutic purposes. That report is still under construction, and we will certainly share it with you before its submission to the legislature. Our permit fees are already identified in our statute; we believe that fee may be appropriate given the limited number of permits authorized by the statute, but that perhaps a non-refundable application fee would be in order to offset the costs of preliminary investigations of applicants and proposed sites. We anticipate that some – if not all – of the permits will have competitive applications.

## 5. **State Activities**

### A. 2016 Louisiana Legislature

The new legislature will convene for its Organizational Session on January 11, 2016; it shall not exceed three days. The Regular Session will convene on March 14 and shall adjourn no later than June 6, 2016.

Act 261 of the 2015 Legislature requires the Board to file a report with the legislature no later than January 1, 2016, detailing the fees required in order to manage the special pharmacy permits authorized to dispense marijuana for therapeutic purposes.

## 6. **National Activities**

### A. U.S. Environmental Protection Agency (EPA)

The EPA regulates hazardous waste under the authority of the Resource Conservation & Recovery Act (RCRA) of 1976, its subsequent amendments, as well as the ensuing regulations at 40 CFR 239 to 282. Although there are approximately 30 commercial chemical products residing on the P and U lists described in 40 CFR 261, most healthcare entities have had trouble understanding and complying with the current rules.

The EPA has proposed new management standards for hazardous waste pharmaceuticals, publishing them in the Sept. 25, 2015 edition of the *Federal Register*. They have recently extended the comment period, which will now close on Dec. 24, 2015. A copy of the proposed rule was posted in the Boardroom Library.

### B. United States Pharmacopeia (USP)

USP published their first sterile compounding standards in Chap. 797 in 2004, then revised them in 2008. Their expert committee has been working on another revision since 2010. The proposed revision was posted in the Boardroom Library; the comment period will close on January 31, 2016.

USP published their initial version of Chap. 800 in March 2014, and then posted a revision in March 2015 to address comments offered. The comment period for the revision ended on May 31, 2015, and USP is still evaluating comments offered for that revision. A copy of that revision was posted in the Boardroom Library; it remains to be seen whether that version will become official as is or is further revised.

### C. National Association of Boards of Pharmacy (NABP)

For your planning purposes, the 2016 meeting will be held May 14-17 in San Diego, CA. This conference is one of the three meetings for which your travel expenses

are eligible for reimbursement, subject to the limitations itemized in the Board's travel policy as well as the state's travel policy in PPM-49.

D. NABP-AACP District 6 Annual Meeting

For your planning purposes, the 2016 meeting will be held Sep. 11-14 in Portland, OR. This conference is one of the three meetings for which your travel expenses are eligible for reimbursement, subject to the limitations itemized in the Board's travel policy as well as the state's travel policy in PPM-49.

E. MALTAGON

For your planning purposes, the 2016 meeting will be held in Texas, most likely in October in Austin. When we get more definitive information, we will let you know. This conference is one of the three meetings for which your travel expenses are eligible for reimbursement, subject to the limitations itemized in the Board's travel policy as well as the state's travel policy in PPM-49.

**7. International Activities**

A. International Pharmaceutical Federation (FIP)

The 75<sup>th</sup> World Congress of the International Pharmaceutical Federation was held in Dusseldorf, Germany on Sep 28 – Oct 3. As expected for a location in the heart of the FIP membership base, the attendance was approximately 3,100 pharmacists, students, and technicians from 132 countries around the world

For your planning purposes, the next three hosting sites have been identified: 2016 in Buenos Aires, Argentina; 2017 in Seoul, South Korea; and 2018 in Glasgow, Scotland.

B. World Health Professional Alliance (WHPA)

The alliance will host its 5<sup>th</sup> International Conference on the Regulation of Health Professions in Geneva, CH on May 21-22, 2016, immediately preceding the World Health Organization's (WHO) World Health Assembly. Presentations will explore health professions and trade agreements in terms of protecting the public vs facilitating commerce, balancing regulation of individual health professions and health services, as well as discussing the implications for health regulation from the WHO Global Strategy on Human Resources for Health: Workforce 2030.

Respectfully submitted,  
Malcolm J Broussard  
Executive Director



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Compliance Division Census Report

November 6, 2015

### Practitioner Recovery Program

- Probation Completion Report

08-16-2015	PST.013546	Mitchell John Kimball
09-30-2015	CPT.007882	Lyndria Monette Page

- Active Probation                    47      Pharmacist  
    1      Technician
- Active Suspension                43      Pharmacist  
    3      Pharmacy intern  
    15     Technician  
    4      Technician candidate

### Disciplinary Restrictions

- Probation Completion Report

09-09-2015	PST.016415	Gene Raymond Lachney
09-30-2015	PST.014644	Jimmy Martin Taylor, II
09-30-2015	PST.014603	Michael James Adkins
10-17-2015	PHY.001159	Tewelde's Lafitte Drugs

- Active Probation                    21      Pharmacist  
    6      Technician  
    4      Technician candidate  
    11     Pharmacy permit  
    4      CDS-PHY license  
    1      CDS-DIS license  
    1      CDS license for practitioner  
    1      DME permit
- Active Suspension                41      Pharmacist  
    1      Pharmacy intern  
    64     Technician  
    15     Technician candidate  
    13     Pharmacy permit  
    3      CDS-PHY license  
    66     CDS license for practitioners

Louisiana Board of Pharmacy  
Census Report

<i>Type of Credential</i>	<u>3/17/1995</u>	<u>6/30/1996</u>	<u>3/19/1997</u>	<u>6/30/1998</u>	<u>6/30/1999</u>	<u>6/30/2000</u>	<u>6/30/2001</u>	<u>6/30/2002</u>	<u>6/30/2003</u>	<u>6/30/2004</u>	<u>6/30/2005</u>
Pharmacists											
In-state	3,642	3,660	4,143	4,247	4,269	4,830	3,887	4,386	4,435	4,486	4,532
Out-of-state	377	446	1,339	1,435	1,421	944	1,901	1,453	1,455	1,484	1,686
TOTAL	4,019	4,106	5,482	5,682	5,690	5,774	5,788	5,839	5,890	5,970	6,218
Pharmacy Interns											
In-state											
Out-of-state											
TOTAL							957	976	929	995	1,154
Pharmacy Technicians											
In-state											
Out-of-state											
TOTAL							3,216	3,453	3,505	4,114	4,455
Pharmacy Technician Candidates											
In-state											
Out-of-state											
TOTAL							2,896	2,372	1,336	1,069	1,074
Pharmacy Permits											
IR	651	634	636	609	621	585	584	576	573	633	729
RC	464	473	471	493	505	520	528	535	541	555	473
H	177	174	171	175	172	171	171	174	179	181	181
IN	46	45	38	39	19		17	18	19	27	36
NU	9	10	10	9	10		12	14	13	13	13
CH	4	4	4	7	4		8	9	11	12	12
PEN											
OS	122	152	168	175	216	223	262	313	353	339	200
PE	78	104	102	120	102			95	94	0	
CO	13	12	12	12	12		12	13	13	0	
TOTAL	1,564	1,608	1,612	1,639	1,668	1,663	1,717	1,771	1,818	1,760	1,644
Equipment Permits											
AMS							0	109	136	158	174
EDK							468	461	474	444	471

Louisiana Board of Pharmacy  
Census Report

<i>Type of Credential</i>	<u>6/30/2006</u>	<u>6/30/2007</u>	<u>6/30/2008</u>	<u>6/30/2009</u>	<u>6/30/2010</u>	<u>6/30/2011</u>	<u>6/30/2012</u>	<u>6/30/2013</u>	<u>6/30/2014</u>	<u>6/30/2015</u>	<u>11/3/2015</u>
<b>Pharmacists</b>											
In-state	4,460	4,522	4,612	4,750	4,860	5,000	5,095	5,170	5,329	5,596	5,488
Out-of-state	1,915	1,975	1,964	2,029	2,098	2,179	2,258	2,588	2,542	2,512	2,841
<b>TOTAL</b>	<b>6,375</b>	<b>6,497</b>	<b>6,576</b>	<b>6,779</b>	<b>6,958</b>	<b>7,179</b>	<b>7,353</b>	<b>7,758</b>	<b>7,871</b>	<b>8,108</b>	<b>8,429</b>
<b>Pharmacy Interns</b>											
In-state	980	1,079	1,074	1,035	965	917	938	945	950	953	927
Out-of-state	109	117	67	84	153	137	128	128	131	144	137
<b>TOTAL</b>	<b>1,089</b>	<b>1,196</b>	<b>1,141</b>	<b>1,119</b>	<b>1,118</b>	<b>1,054</b>	<b>1,066</b>	<b>1,073</b>	<b>1,081</b>	<b>1,097</b>	<b>1,064</b>
<b>Pharmacy Technicians</b>											
In-state	4,552	4,587	4,780	4,733	5,363	5,722	5,509	5,752	6,463	6,585	6,458
Out-of-state	163	152	144	109	144	145	120	112	138	141	137
<b>TOTAL</b>	<b>4,715</b>	<b>4,739</b>	<b>4,924</b>	<b>4,842</b>	<b>5,507</b>	<b>5,867</b>	<b>5,629</b>	<b>5,864</b>	<b>6,601</b>	<b>6,726</b>	<b>6,595</b>
<b>Pharmacy Technician Candidates</b>											
In-state	1,081	1,389	1,446	1,510	1,679	1,574	1,665	1,658	1,870	1,929	1,830
Out-of-state	32	32	23	32	35	35	39	31	37	52	43
<b>TOTAL</b>	<b>1,113</b>	<b>1,421</b>	<b>1,469</b>	<b>1,542</b>	<b>1,714</b>	<b>1,609</b>	<b>1,704</b>	<b>1,695</b>	<b>1,907</b>	<b>1,981</b>	<b>1,873</b>
<b>Pharmacy Permits</b>											
IR	681	620	588	592	587	591	587	575	583	598	590
RC	430	491	534	545	562	576	587	597	619	649	663
H	167	164	167	167	165	170	172	172	175	174	173
IN	35	36	37	37	27	25	24	25	23	21	22
NU	17	16	16	16	16	15	15	15	15	14	15
CH	12	12	11	12	14	12	12	12	12	12	12
PEN								1	2	2	2
NR	226	240	250	256	286	318	361	387	432	484	505
<b>TOTAL</b>	<b>1,568</b>	<b>1,579</b>	<b>1,603</b>	<b>1,625</b>	<b>1,657</b>	<b>1,707</b>	<b>1,758</b>	<b>1,784</b>	<b>1,861</b>	<b>1,954</b>	<b>1,982</b>
<b>Equipment Permits</b>											
AMS	173	212	255	306	361	356	366	638	451	812	469
EDK	428	412	439	388	503	430	448	431	474	484	471
DME							223	378	490	603	574
Special Activity								41	41	52	55
								1,617	2,037	2,383	2,550
Special Work Permit						58	78	126	38	54	49

Louisiana Board of Pharmacy  
CDS Program - Census Report

<i>Classification</i>	<u>6/30/2008</u>	<u>6/30/2009</u>	<u>6/30/2010</u>	<u>6/30/2011</u>	<u>6/30/2012</u>	<u>6/30/2013</u>	<u>6/30/2014</u>	<u>06/30/15</u>	<u>11/03/15</u>
ACS Animal Control Shelter	0	0	1	1	1	1	1	1	1
AMS Automated Medication System	0	0	0	0	0	0	28	30	20
APN Advanced Practice Registered Nurse	479	607	758	889	1,015	1,103	1,479	1,954	2,109
ASC Ambulatory Surgical Center	101	106	113	90	88	85	89	87	85
CRX Correctional Center	0	0	0	7	6	5	6	4	3
DDS Dentist	2,177	2,267	2,363	2,027	2,048	1,902	2,123	2,133	2,100
DET Drug Detection Canine	20	20	22	14	12	10	11	12	11
DIS Distributor	322	363	400	279	288	273	324	319	312
DPM Podiatrist	153	161	165	139	136	118	133	142	144
DVM Veterinarian	936	1,000	1,065	922	901	852	1,002	1,045	1,056
DYS Dialysis Center	63	63	63	6	4	3	4	0	0
EMC Emergency Medical Center	17	17	18	14	16	17	22	26	25
EMS Emergency Medical Service	58	63	66	54	50	45	50	49	46
ETC Animal Euthanasia Tech - Cert	39	44	49	28	27	27	29	28	27
HOS Hospital	387	405	438	292	281	268	278	277	288
LAB Analytical Laboratory	14	14	15	12	11	12	13	13	5
MD Physician	13,876	14,599	15,269	12,362	11,727	10,698	11,913	12,124	12,093
MDT Physician on Telemedicine	0	0	0	0	0	0	2	1	0
MED Medical Clinic	78	88	102	80	86	82	89	81	50
MFR Manufacturer	43	52	58	48	50	45	42	42	42
MIS Other	73	58	59	20	14	12	13	11	10
MP Medical Psychologist	44	50	58	65	67	69	78	82	83
OD Optometrist	253	269	278	275	287	279	309	316	326
PA Physician's Assistant	194	232	272	294	326	344	449	487	509
PHY Pharmacy	0	0	0	1357	1,365	1,370	1,387	1,403	1,407
REP Sales Representative	65	66	88	29	20	7	0	0	0
RES Researcher	110	119	156	109	110	98	113	113	110
RHC Rural Health Clinic	20	21	23	17	12	11	12	11	8
ROF Registered Outsourcing Facility	0	0	0	0	0	0	0	8	10
SAC Substance Abuse Clinic	<u>14</u>	<u>14</u>	<u>17</u>	<u>7</u>	<u>9</u>	<u>9</u>	<u>9</u>	<u>10</u>	<u>10</u>
<b>TOTAL</b>	<b>19,502</b>	<b>20,663</b>	<b>21,916</b>	<b>19,437</b>	<b>18,957</b>	<b>17,745</b>	<b>20,009</b>	<b>20,809</b>	<b>20,890</b>

Total Credentials Under Board Management

Pharmacy Program	16,407	16,601	17,818	18,260	18,625	21,405	22,865	24,254	24,111
CDS Program	<u>19,536</u>	<u>20,698</u>	<u>21,916</u>	<u>19,437</u>	<u>18,957</u>	<u>17,745</u>	<u>20,009</u>	<u>20,809</u>	<u>20,898</u>
<b>TOTAL</b>	<b>35,943</b>	<b>37,299</b>	<b>39,734</b>	<b>37,697</b>	<b>37,582</b>	<b>39,150</b>	<b>42,874</b>	<b>45,063</b>	<b>45,009</b>

Louisiana Board of Pharmacy  
 Credentials Division  
 CDS Program

<i>Classification</i>	<u>06/30/09</u>	<u>06/30/10</u>	<u>06/30/11</u>	<u>06/30/12</u>	<u>06/30/13</u>	<u>06/30/14</u>	<u>06/30/15</u>	<u>11/03/15</u>
ACS Animal Control Shelter	0	1	1	1	1	1	1	1
AMS Automated Medication Sys	0	0	0	0	0	26	29	20
AMX Automated Medication Sys - Exempt	0	0	0	0	0	2	1	0
APN APRN	607	758	889	1,015	1,103	1,479	1,954	2,109
ASC Ambulatory Surgical Ctr	106	113	90	88	85	89	87	85
CRX Correctional Ctr - Exempt	0	0	7	6	5	6	4	3
DDS Dentist	2,267	2,363	2,027	2,048	1,902	2,123	2,133	2,100
DET Drug Detection / Canine	20	22	14	12	10	11	11	10
DEX Drug Detection / Canine - Exempt						1	1	1
DIS Distributor	363	400	279	288	273	324	319	312
DPM Podiatrist	161	165	139	136	118	133	142	144
DVM Veterinarian	1,000	1,065	922	901	852	1,002	1,045	1,056
DYS Dialysis Ctr	63	63	6	4	3	4	0	0
EMC Emergency Medical Ctr	17	18	14	16	17	22	26	25
EMS Emergency Medical Service	63	66	54	50	45	50	49	46
ETC Animal Euthanasia Tech - Cert	44	49	16	7	6	6	5	4
ETL Animal Euthanasia Tech - Lead	0	0	12	20	21	23	23	23
HOS Hospital	405	438	280	267	263	272	271	283
HOX Hospital - Exempt	0	0	12	14	5	6	6	5
LAB Laboratory	14	15	8	6	7	8	8	8
LAX Laboratory - Exempt	0	0	4	5	5	5	5	5
MD Physician	14,599	15,269	12,362	11,727	10,698	11,913	12,124	12,093
MDT Physician on Telemedicine	0	0	0	0	0	2	1	0
MED Medical Clinic	88	102	77	81	68	78	71	47
MEX Medical Clinic - Exempt	0	0	3	5	14	11	10	3
MFR Manufacturer	52	58	48	50	45	42	42	42
MIS Miscellaneous	58	59	11	10	9	11	9	8
MIX Miscellaneous - Exempt	0	0	9	4	3	2	2	2
MP Medical Psychologist	50	58	65	67	69	78	82	83
OD Optometrist	269	278	275	287	279	309	316	326
PA Physician Assistant	232	272	294	326	344	449	487	509
PHX Pharmacy - Exempt	0	0	50	47	41	30	24	24
PHY Pharmacy	0	0	1,307	1,318	1,329	1,357	1,379	1,383
REP Sales Representative	66	88	29	20	7	0	0	0
RES Researcher	119	156	109	110	98	113	113	110
RHC Rural Health Clinic	21	23	17	12	11	12	11	8
ROF Registered Outsourcing Facility	0	0	0	0	0	0	8	10
SAC Substance Abuse Clinic	14	17	7	9	9	9	9	9
SAX Subst. Abuse Clinc - Exempt	0	0	0	0	0	0	1	1
<b>Total</b>	<b>20,698</b>	<b>21,916</b>	<b>19,437</b>	<b>18,957</b>	<b>17,745</b>	<b>20,009</b>	<b>20,809</b>	<b>20,898</b>

Total Credentials Under Management

Pharmacy	16,601	17,818	18,260	18,625	21,405	22,865	24,254	24,111
CDS	<u>20,698</u>	<u>21,916</u>	<u>19,437</u>	<u>18,957</u>	<u>17,745</u>	<u>20,009</u>	<u>20,809</u>	<u>20,898</u>
<b>Total</b>	<b>37,299</b>	<b>39,734</b>	<b>37,697</b>	<b>37,582</b>	<b>39,150</b>	<b>42,874</b>	<b>45,063</b>	<b>45,009</b>

Louisiana Board of Pharmacy  
 Credentials Division  
 Pharmacy Program

		06/30/07	06/30/08	06/30/09	06/30/10	06/30/11	06/30/12	06/30/13	06/30/14	06/30/15	11/315
PST-VI	LA	0	0	0	0	12	10	9	9	13	13
	NR	0	0	0	0	9	10	15	14	15	15
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>21</b>	<b>20</b>	<b>24</b>	<b>23</b>	<b>28</b>	<b>28</b>
PST-GVI	LA	0	0	0	0	0	6	13	13	12	14
	NR	0	0	0	0	0	0	3	5	5	5
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>6</b>	<b>16</b>	<b>18</b>	<b>17</b>	<b>19</b>
PST-M	LA	0	0	0	0	3	5	3	1	2	2
	NR	0	0	0	0	11	11	11	13	10	10
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>14</b>	<b>16</b>	<b>14</b>	<b>14</b>	<b>12</b>	<b>12</b>
PST-G	LA	0	0	0	0	158	157	164	166	186	186
	NR	0	0	0	0	30	35	32	31	31	31
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>188</b>	<b>192</b>	<b>196</b>	<b>197</b>	<b>217</b>	<b>217</b>
PST	LA	4,522	4,612	4,750	4,860	4,654	4,933	4,981	5,140	5,408	5,373
	NR	1,975	1,964	2,029	2,098	2,079	2,212	2,527	2,479	2,471	2,780
	<b>Total</b>	<b>6,497</b>	<b>6,576</b>	<b>6,779</b>	<b>6,958</b>	<b>6,733</b>	<b>7,145</b>	<b>7,508</b>	<b>7,619</b>	<b>7,879</b>	<b>8,153</b>
	<b>PST</b>	<b>6,497</b>	<b>6,576</b>	<b>6,779</b>	<b>6,958</b>	<b>6,935</b>	<b>7,353</b>	<b>7,758</b>	<b>7,871</b>	<b>8,108</b>	<b>8,429</b>
PNT	LA	1,079	1,074	1,035	965	907	938	942	948	952	925
	NR	117	67	84	153	137	128	128	127	143	137
	<b>Total</b>	<b>1,196</b>	<b>1,141</b>	<b>1,119</b>	<b>1,118</b>	<b>1,044</b>	<b>1,066</b>	<b>1,070</b>	<b>1,075</b>	<b>1,095</b>	<b>1,062</b>
PNT-FPG	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>3</b>	<b>6</b>	<b>2</b>	<b>2</b>
	<b>PNT</b>	<b>1,196</b>	<b>1,141</b>	<b>1,119</b>	<b>1,118</b>	<b>1,049</b>	<b>1,066</b>	<b>1,073</b>	<b>1,081</b>	<b>1,097</b>	<b>1,064</b>
CPT	LA	4,587	4,780	4,733	5,363	5,720	5,509	5,751	6,463	6,584	6,458
	NR	152	144	109	144	145	120	112	138	141	135
	<b>Total</b>	<b>4,739</b>	<b>4,924</b>	<b>4,842</b>	<b>5,507</b>	<b>5,865</b>	<b>5,629</b>	<b>5,863</b>	<b>6,601</b>	<b>6,725</b>	<b>6,593</b>
CPT-M	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>2</b>
	<b>CPT</b>	<b>4,739</b>	<b>4,924</b>	<b>4,842</b>	<b>5,507</b>	<b>5,866</b>	<b>5,629</b>	<b>5,864</b>	<b>6,603</b>	<b>6,726</b>	<b>6,595</b>
PTC	LA	1,389	1,446	1,510	1,679	1,574	1,665	1,658	1,870	1,929	1,830
	NR	32	23	32	35	35	39	37	37	52	43
	<b>Total</b>	<b>1,421</b>	<b>1,469</b>	<b>1,542</b>	<b>1,714</b>	<b>1,609</b>	<b>1,704</b>	<b>1,695</b>	<b>1,907</b>	<b>1,981</b>	<b>1,873</b>
PHY	CH	12	11	12	14	12	12	12	12	12	12
	HOS	164	167	167	165	151	154	158	164	163	163
	HOX	0	0	0	0	19	18	14	11	8	7
	IN	36	37	37	27	14	10	12	12	11	11
	INX	0	0	0	0	11	14	13	11	10	11
	IR	620	588	592	587	570	568	558	583	588	581
	IRX	0	0	0	0	21	19	17	10	10	9
	NR	240	250	256	286	318	361	387	422	473	494
	NRN	0	0	0	0	0	0	0	9	9	9
	NRP	0	0	0	0	0	0	0	1	2	2
	NU	16	16	16	16	15	15	15	15	14	15
	PEN	0	0	0	0	0	0	0	0	0	0
	PEX	0	0	0	0	0	0	1	2	2	2
	SAT	0	0	0	0	0	0	0	1	3	3
RC	491	534	545	562	576	587	597	619	649	663	
	<b>PHY</b>	<b>1,579</b>	<b>1,603</b>	<b>1,625</b>	<b>1,657</b>	<b>1,707</b>	<b>1,758</b>	<b>1,784</b>	<b>1,872</b>	<b>1,954</b>	<b>1,982</b>
AMS	AMS	212	255	306	361	55	64	349	92	456	107
	AMS-X	0	0	0	0	301	302	289	359	356	362
	<b>AMS</b>	<b>212</b>	<b>255</b>	<b>306</b>	<b>361</b>	<b>356</b>	<b>366</b>	<b>638</b>	<b>451</b>	<b>812</b>	<b>469</b>
EDK	EDK	412	439	388	503	417	435	421	464	474	461
	EDK-X	0	0	0	0	13	13	10	10	10	10
	<b>EDK</b>	<b>412</b>	<b>439</b>	<b>388</b>	<b>503</b>	<b>430</b>	<b>448</b>	<b>431</b>	<b>474</b>	<b>484</b>	<b>471</b>
DME	LA						223	160	209	336	187
	NR							218	281	267	387
	<b>DME</b>							<b>378</b>	<b>490</b>	<b>603</b>	<b>574</b>
CDTM							41	41	52	55	
MAR							1,617	2,037	2,383	2,550	
SWP					58	78	126	38	54	49	
<b>TOTAL</b>							<b>21,405</b>	<b>22,865</b>	<b>24,254</b>	<b>24,111</b>	

**New Credentials Issued  
FY 2016 - 1st Quarter  
July 1, 2015 through September 30, 2015**

Prefix	Subcategory	CredentialType	Total
AMS		Automated Medication System	19
AMS	X	Automated Medication System - Exempt	16
<b>Prefix Totals</b>			<b>35</b>
CDS	AMS	CDS License - Automated Medication System	4
CDS	APN	CDS License - APRN	152
CDS	DDS	CDS License - Dentist	26
CDS	DIS	CDS License - Distributor	3
CDS	DPM	CDS License - Podiatrist	1
CDS	DVM	CDS License - Veterinarian	33
CDS	HOS	CDS License - Hospital	4
CDS	MD	CDS License - Physician	247
CDS	MP	CDS License - Medical Psychologist	1
CDS	OD	CDS License - Optometrist	12
CDS	PA	CDS License - Physician Assistant	19
CDS	PHY	CDS License - Pharmacy	21
CDS	RES	CDS License - Researcher	2
CDS	ROF	CDS License - Registered Outsourcing Facility	3
<b>Prefix Totals</b>			<b>528</b>
CDTM		Collaborative Drug Therapy Management (V)	2
<b>Prefix Totals</b>			<b>2</b>
CPT		Certified Pharmacy Technician	222
<b>Prefix Totals</b>			<b>222</b>
DME		Durable Medical Equipment (DME) Provider	15
<b>Prefix Totals</b>			<b>15</b>
EDK		Emergency Drug Kit	13
<b>Prefix Totals</b>			<b>13</b>
LB		Law Book	1
<b>Prefix Totals</b>			<b>1</b>
MA		Medication Administration (V)	120
<b>Prefix Totals</b>			<b>120</b>
PHY	HOS	Pharmacy - Hospital Inpatient	4
PHY	IR	Pharmacy - Community ~ Independent	13
PHY	NR	Pharmacy - Nonresident	21
PHY	NU	Pharmacy - Nuclear	1
PHY	RC	Pharmacy - Community ~ Chain	8
<b>Prefix Totals</b>			<b>47</b>
PIC		Pharmacist-in-Charge (V)	24
<b>Prefix Totals</b>			<b>24</b>
PMP	CDS	PMP - CDS Credential	301
PMP	PST	PMP - Pharmacist	183
<b>Prefix Totals</b>			<b>484</b>
PNT		Pharmacy Intern	31
<b>Prefix Totals</b>			<b>31</b>
PST		Pharmacist	237
<b>Prefix Totals</b>			<b>237</b>
PTC		Pharmacy Technician Candidate	345
<b>Prefix Totals</b>			<b>345</b>
SWP		Special Work Permit	16
<b>Prefix Totals</b>			<b>16</b>
<b>Grand Totals</b>			<b>2120</b>

## Pending Applications

### PHARMACY CREDENTIALS

Prefix	Subcat.	CredentialType	05/07/14	07/29/14	11/07/14	02/16/15	05/06/15	07/21/15	11/3/2015
AMS		Automated Medication System			1	3	4	2	3
CPT		Certified Pharmacy Technician	40	44	43	47	56	39	50
DME		Durable Medical Equipment	12	13	11	12	14	15	17
EDK		Emergency Drug Kit						1	
PHY	CH	Pharmacy - Charitable							
PHY	HOS	Pharmacy - Hospital Inpatient	7	6	3	6	7	4	5
PHY	IN	Pharmacy - Institutional							
PHY	IR	Pharmacy - Community ~ Independent	15	17	23	18	11	16	13
PHY	NR	Pharmacy - Nonresident	64	66	71	63	72	75	84
PHY	NRN	Pharmacy - Nonresident Nuclear			1				
PHY	NU	Pharmacy - Nuclear	5	1			1	1	
PHY	PEN	Pharmacy - Penal							
PHY	RC	Pharmacy - Community ~ Chain	7	5	22	3	4	11	13
PHY	SAT	Pharmacy - Hospital Off-Site Satellite	1	4	5	4	4	2	1
PIC		Pharmacist-in-Charge	1			1			
PNT	FPG	Pharmacy Intern - Foreign Graduate	2	1	2	3	2	2	
PNT		Pharmacy Intern	28	70	71	42	50	74	90
PST		Pharmacist	251	378	290	276	389	431	281
PTC		Pharmacy Technician Candidate	327	371	348	410	394	377	352
<b>Subtotal</b>			<b>760</b>	<b>976</b>	<b>891</b>	<b>888</b>	<b>1008</b>	<b>1050</b>	<b>909</b>

### CDS CREDENTIALS

Prefix	Subcat.	CredentialType	02/05/14	07/29/14	11/07/14	02/16/15	05/06/15	07/21/15	11/3/2015
CDS	ACS	CDS - Animal Control Shelter			1				2
CDS	AMS	CDS - Automated Medication System	1	1	1	1	1		
CDS	APN	CDS - APRN	19	21	18	17	16	19	11
CDS	DDS	CDS - Dentist	1					3	1
CDS	DET	CDS - Drug Detection / Canine	3	2	2	1	1	1	1
CDS	DIS	CDS - Distributor	2	6	5	7	7	7	5
CDS	DPM	CDS - Podiatrist							1
CDS	DVM	CDS - Veterinarian		2	2	2	2	2	1
CDS	ETC	CDS - Animal Euthanasia Tech, Certified	1						
CDS	ETL	CDS - Animal Euthanasia Tech, Lead							1
CDS	MD	CDS - Physician	14	16	18	13	20	19	7
CDS	MFR	CDS - Manufacturer	1	1	2	1	1	1	
CDS	MP	CDS - Medical Psychologist							
CDS	OD	CDS - Optometrist	1	1					
CDS	PA	CDS - Physician Assistant	2	3	4	8	7	6	8
CDS	PHY	CDS - Pharmacy	19	15	42	24	13	27	27
CDS	PHX	CDS - Pharmacy - Exempt		1					
CDS	REP	CDS - Sales Representative							
CDS	RES	CDS - Researcher	1	2	2	1	1	1	1
CDS	ROF	CDS - Registered Outsourcing Facility					1		
<b>Subtotal</b>			<b>65</b>	<b>71</b>	<b>97</b>	<b>75</b>	<b>70</b>	<b>87</b>	<b>65</b>

### OTHER CREDENTIALS

Prefix	Subcat.	CredentialType	02/05/14	07/29/14	07/29/14	02/16/15	05/06/15	07/21/15	07/21/15
CDTM		Collaborative Drug Therapy Management							
LB		Law Book	0	1	1	3	6	6	6
MA		Medication Administration	15	20	11	7	7	7	2
PMP		PMP - CDS Credential	165	159	133	88	85	85	69
PMP		PMP - MIS Credential							
PMP		PMP - PST Credential	20	19	13	16	13	18	79
SWP		Special Work Permit	65	65	83	103	120	140	164
<b>Subtotal</b>			<b>265</b>	<b>264</b>	<b>241</b>	<b>217</b>	<b>231</b>	<b>256</b>	<b>320</b>

**TOTAL** **1090** **1311** **1229** **1180** **1309** **1393** **1294**

Roster of Pharmacy Technician Training Programs  
Status of Accreditation by ASHP / PTAC

<u>ASHP #</u>	<u>Name</u>	<u>City</u>	<u>State</u>	<u>Status</u>	<u>Application Date</u>
LA-21	Allied Prep Technical Institute	Marrero	LA	Candidate	9/22/2015
LA-07	Ayers Career College	Shreveport	LA	Candidate	7/28/2014
LA-02	Bossier Parish Community College	Bossier City	LA	Accredited	5/16/2000
RI-01	CVS Caremark	Woonsocket	RI	Accredited	4/6/2006
LA-04	Delgado Community College	New Orleans	LA	Accredited	3/5/2002
LA-20	Healthcare Training Institute	Kenner	LA	Candidate	8/6/2015
LA-18	Infinity College	Lafayette	LA	Candidate	7/27/2015
LA-03	Louisiana State University at Alexandria	Alexandria	LA	Accredited	2/6/2001
LA-08	Northshore Technical Community College	Bogalusa	LA	Candidate	10/27/2014
LA-06	Nursing Assistant Network Association	New Orleans	LA	Candidate	4/10/2014
LA-11	Remington College at Baton Rouge	Baton Rouge	LA	Candidate	1/21/2015
LA-10	Remington College at Lafayette	Lafayette	LA	Candidate	1/21/2015
LA-09	Remington College at Shreveport	Shreveport	LA	Candidate	1/21/2015
PA-06	Rite Aid Pharmacies	Camp Hill	PA	Accredited	8/5/2008
LA-14	Unitech Training Academy at Alexandria	Alexandria	LA	Candidate	3/11/2015
LA-15	Unitech Training Academy at Houma	Houma	LA	Candidate	3/11/2015
LA-17	Unitech Training Academy at Lafayette	Lafayette	LA	Candidate	3/11/2015
LA-13	Unitech Training Academy at Lake Charles	Lake Charles	LA	Candidate	3/11/2015
LA-12	Unitech Training Academy at Metairie	Metairie	LA	Candidate	3/11/2015
LA-16	Unitech Training Academy at West Monroe	West Monroe	LA	Candidate	3/11/2015
LA-01	Virginia College at Baton Rouge	Baton Rouge	LA	Accredited	3/19/2012
LA-05	Virginia College at Shreveport/Bossier City	Shreveport	LA	Accredited	9/24/2013
IL-05	Walgreen Co.	Deerfield	IL	Accredited	12/27/2005
AR-04	WalMart Stores	Bentonville	AR	Candidate	7/28/2015

*Counts*

8 Accredited  
16 Candidate  
 24 Total



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



November 18, 2015

## Agenda Item 10-L: Report of Executive Director

### Section 2.C – Exceptions Report

#### 1. **PIC at Multiple Pharmacies**

Board Policy I.A.4 permits the Executive Director to approve requests from pharmacists wishing to serve as the Pharmacist-in-Charge (PIC) of more than one pharmacy at the same time. The policy requires the concurrence of the President, as well as notice to the Board at its next meeting. As authorized by the President, the Executive Director has delegated this authority to the General Counsel and the Assistant Executive Director.

- On September 30, 2015, Mr. Aron and Mr. Fontenot concurred to grant a request from Timothy J. Smith (PST.013938) for dual PIC privileges at H & W Drug Store (PHY.006659-IR) in Marrero and USA Pharmacy & Medical Supplier (PHY.007096-IR) in New Orleans for a limited period of time with the authority set to expire on December 28, 2015 which is 90 days from the date of the request.

#### 2. **Special Work Permits for military-trained applicants and their spouses**

LAC Title 46: LIII §904 authorizes the Board to provide preferential licensing procedures for military-trained applicants and their spouses. As authorized by the President, the Executive Director has delegated this authority to the General Counsel and the Assistant Executive Director.

- On August 17, 2015, Mr. Aron and Mr. Finalet concurred to grant a request of Andria Latasha Phifer-Walker. She has been issued SWP.00562 to practice for up to 120 days while her application to become a PST is in process. The SWP will expire on December 17, 2015.
- On September 8, 2015, Mr. Aron and Mr. Finalet concurred to grant a request of Stacey Jo Walker. She has been issued SWP.00568 to practice for up to 120 days while her application to become a PST is in process. The SWP will expire on January 8, 2016.

#### 3. **Special Work Permits**

Board Policy I.A.7 permits the Executive Director to issue Special Work Permits to document the resurrection of expired non-renewable credentials and for other purposes as authorized by the Board. The policy requires the concurrence of the President, as well as notice to the Board at its next meeting. As authorized by the President, the Executive Director has delegated this authority to the General Counsel and the Assistant Executive Director.

- On August 1, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Snabel Khaled Kasem. She had previously obtained PTC.020769 which expired on June 6, 2015. Should she pass the PTCB examination she is authorized to receive a Special Work Permit for one year to earn her 600 hours of practical experience.
- On August 3, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Trinesha Lynn Pearley. She had previously obtained PTC.019018 which expired on January 3, 2014. Should she pass the PTCB examination she is authorized to receive a Special Work Permit for one year to earn her 600 hours of practical experience.
- On August 7, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Alisa Jo Mitchell. She had previously obtained PTC.019578 which expired on July 4, 2014. Should she pass the PTCB examination by February 1, 2016 she is authorized to receive

- a Special Work Permit for one year to earn her 600 hours of practical experience.
- On August 10, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Bradley Kane Manuel. He had previously obtained PTC.017575 which expired on December 1, 2012. He is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On August 13, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Angela Mechell Dale. She had previously obtained PTC.012273 which expired on March 19, 2008. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On August 13, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Wendy Renia Carter. She had previously obtained PTC.020085 which expired on November 29, 2014. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On August 18, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Kevin Thomas Krul. He had previously obtained PTC.011244 which expired on January 26, 2007. He is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On August 27, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Lanesia Yvonne Critton. She had previously obtained PTC.016645 which expired on February 4, 2012. Should she pass the PTCB examination by February 1, 2016 she is authorized to receive a Special Work Permit for one year to earn her 600 hours of practical experience.
- On August 27, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Marty Nicole Johnson. She had previously obtained PTC.021042 which expired on August 19, 2015. Should she pass the PTCB examination by February 1, 2016 she is authorized to receive a Special Work Permit for one year to earn her 600 hours of practical experience.
- On September 1, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Ashley Kiara White. She had previously obtained PTC.017079 which expired on June 6, 2012. Should she pass the PTCB examination by March 1, 2016 she is authorized to receive a Special Work Permit for one year to earn her 600 hours of practical experience.
- On September 19, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Samantha Renee Miles. She had previously obtained PTC.017212 which expired on July 25, 2012. Should she pass the PTCB examination by March 1, 2016 she is authorized to receive a Special Work Permit for one year to earn her 600 hours of practical experience.
- On September 20, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Eunice Sunhyo Park. She is applying to be a pharmacist in Louisiana but does not have the required 500 practical experience hours required to do so. She was issued a Special Work Permit to earn her 500 hours of practical experience. The SWP expires on September 20, 2016.
- On September 21, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Akeem Rashad Davis. She had previously obtained PTC.020860 which expired on July 2, 2015. Should he pass the PTCB examination by March 1, 2016 he is authorized to receive a Special Work Permit for one year to earn his 600 hours of practical experience.
- On September 23, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Tieaira Lenee John. She had previously obtained PTC.019647 which expired on July 30, 2014. Should she pass the PTCB examination by March 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
- On September 29, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Tlffany Miki Gatén. She had previously obtained PTC.018799 which expired on November 1, 2013. Should she pass the PTCB examination by March 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
- On September 30, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Victoria Brook Ashley. She had previously obtained PTC.021009 which expired on August 12, 2013. She is PTCB-certified and was issued a Special Work Permit for one year to earn her remaining hours of practical experience.
- On September 30, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Mayme Lucille Hynel. She had previously obtained PTC.014583 which expired on May 13, 2010. She is PTCB-certified and was issued a Special Work Permit for one year to

- earn 600 hours of practical experience.
- On October 6, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Chelsea Chartravia Mamou. She had previously obtained PTC.018643 which expired on September 27, 2013. Should she pass the PTCB examination by April 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On October 6, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Katrice Anjelicia Andrews. She had previously obtained PTC.020796 which expired on June 17, 2015. Should she pass the PTCB examination by April 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On October 7, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Robyn Williams. She had previously obtained PTC.012525 which expired on July 4, 2008. She is PTCB-certified and was issued a Special Work Permit for one year to earn her 600 hours of practical experience.
  - On October 14, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Tiffany Sheleese Harris. She had previously obtained PTC.015130 which expired on November 26, 2010. She is PTCB-certified and was issued a Special Work Permit for one year to earn her 600 hours of practical experience.
  - On October 19, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Shelley LeAnne Cahoon. She had previously obtained PTC.020360 which expired on February 13, 2015. Should she pass the PTCB examination by April 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On October 20, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Norseen Clarise Wells. She had previously obtained PTC.019389 which expired on October 24, 2014. Should she pass the PTCB examination by April 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On October 20, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Rachel DeJean Mitchell. She had previously obtained PTC.019632 which expired on July 24, 2014. Should she pass the PTCB examination by April 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On October 20, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Terryell Anthisha Jones. She had previously obtained PTC.016105 which expired on September 8, 2011. Should she pass the PTCB examination by April 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On October 29, 2015, Mr. Aron and Mr. Finalet concurred to grant one final request from La'Sondra Sharnae Jackson. She had previously obtained PTC.018521 which expired on August 28, 2013. Should she pass the PTCB examination by December 31, 2015 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On October 29, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Kristian Danielle Goins. She had previously obtained PTC.015511 which expired on March 2, 2011. Should she pass the PTCB examination by April 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On October 30, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Anna Claire Aloisio. She had previously obtained PTC.019775 which expired on August 28, 2014. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
  - On November 3, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Constance Denise Lewis. She had previously obtained PTC.020765 which expired on June 5, 2015. Should she pass the PTCB examination by May 1, 2016 she is authorized to receive a Special Work Permit for one year to earn 600 hours of practical experience.
  - On November 6, 2015, Mr. Aron and Mr. Finalet concurred to grant a request from Justin Jeriod Self. He had previously obtained PTC.018840 which expired on November 8, 2013. He is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.



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3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Multistate Pharmacy Jurisprudence Examination (MPJE™)

May 1 – August 31, 2015

School Reports  
Interpretation of Scores  
Frequency Distribution of Scaled Scores  
Cumulative Record (since January 2000)

November 18, 2015

## **Multistate Pharmacy Jurisprudence Examination (MPJE™)**

This computer adaptive competency assessment is administered by the National Association of Boards of Pharmacy (NABP). The examination blueprint is designed to assess the applicant's competency in federal and state laws relative to pharmacy practice and is therefore specific for a given state. The examination is administered via an open window process; applicants may schedule the examination at a local testing center at any time following approval by the state board and receipt of an Authorization to Test (ATT) document from NABP. Individual scores are available to applicants via secure web posting approximately 7-10 days following the examination. Summary reports are provided to the state boards on a calendar trimester basis.

### *Table of Contents*

Current Trimester Report for ULM School of Pharmacy	03
Cumulative Report (since January 2000) for ULM School of Pharmacy	11
Current Trimester Report for Xavier College of Pharmacy	15
Cumulative Report (since January 2000) for Xavier College of Pharmacy	25



**Multistate Pharmacy Jurisprudence Examination® (MPJE®)  
School Summary Report**

**Test Window:** May 1, 2015 - August 31, 2015

**School Name:** University Louisiana Monroe

This MPJE score report consists of two levels of scores: school-aggregated scores and individual candidate scores. Summary information is provided separately for first-time examinees from ACPE schools/colleges and for all examinees, regardless of repeater status and/or the educational institution. Tables 1 and 2 contain school-specific as well as national pass rate information.

School 1: Examinees testing in same state as respective college

School 2: Examinees testing in different states than respective college

**Table 1 First Time Candidates**

	<b>Candidates</b>	<b>Pass Rate %</b>	<b>Total Scaled Score Mean</b>	<b>Standard Deviation</b>
<b>School 1</b>	68	94.12	81.44	3.88
<b>School 2</b>	52	98.08	84.40	4.96
<b>State</b>	285	88.77	80.62	4.70
<b>National</b>	16114	93.97	82.66	5.36

Candidates who did not answer enough questions to receive a score are reflected in pass rate data as a fail but are not included in mean scaled score data.

**Table 2 All Candidates**

	<b>Candidates</b>	<b>Pass Rate %</b>	<b>Total Scaled Score Mean</b>	<b>Standard Deviation</b>
<b>School 1</b>	68	94.12	81.44	3.88
<b>School 2</b>	54	98.15	84.13	5.08
<b>State</b>	312	88.14	80.56	4.73
<b>National</b>	17162	93.04	82.40	5.45

Candidates who did not answer enough questions to receive a score are reflected in pass rate data as a fail but are not included in mean scaled score data.

### Table 3 Candidate Summary Report

**Test Window:** May 1, 2015 - August 31, 2015

	Pass/Fail	Total Scaled Score	Test Date	Graduation Date	First Attempt	State
1	Fail	73	08/27/2015	05/09/2015	Y	LA
2	Pass	81	08/25/2015	05/09/2015	Y	LA
3	Pass	82	08/25/2015	05/09/2015	Y	TX
4	Pass	80	08/24/2015	05/09/2015	Y	LA
5	Pass	79	08/19/2015	05/09/2015	Y	LA
6	Pass	80	08/19/2015	05/09/2015	Y	LA
7	Pass	75	08/17/2015	05/09/2015	Y	LA
8	Pass	81	08/17/2015	05/09/2015	Y	LA
9	Pass	90	08/13/2015	05/09/2015	Y	TX
10	Pass	82	08/10/2015	05/09/2015	Y	LA
11	Fail	69	08/10/2015	05/09/2015	Y	TX
12	Pass	78	08/10/2015	05/09/2015	Y	LA
13	Pass	81	08/10/2015	05/09/2015	Y	LA
14	Pass	84	08/10/2015	05/09/2015	Y	LA
15	Pass	80	08/08/2015	05/09/2015	Y	LA
16	Pass	89	08/08/2015	05/09/2015	Y	LA
17	Pass	81	08/06/2015	05/09/2015	Y	LA
18	Pass	78	08/03/2015	05/09/2015	Y	MS
19	Pass	80	08/03/2015	05/09/2015	Y	LA
20	Pass	85	07/30/2015	05/09/2015	Y	TX
21	Pass	93	07/30/2015	05/09/2015	Y	TX
22	Fail	74	07/29/2015	05/09/2015	Y	LA
23	Pass	80	07/29/2015	05/09/2015	Y	LA
24	Pass	84	07/28/2015	05/09/2015	Y	LA
25	Fail	72	07/28/2015	05/09/2015	Y	LA
26	Pass	86	07/28/2015	05/09/2015	Y	NJ
27	Pass	83	07/27/2015	05/09/2015	Y	LA
28	Fail	74	07/27/2015	05/09/2015	Y	LA
29	Pass	82	07/27/2015	05/09/2015	Y	LA
30	Pass	78	07/27/2015	05/09/2015	Y	LA
31	Pass	92	07/23/2015	05/09/2015	Y	TX
32	Pass	82	07/18/2015	05/09/2015	Y	LA
33	Pass	78	07/17/2015	05/09/2015	Y	LA
34	Pass	86	07/17/2015	05/09/2015	Y	LA
35	Pass	87	07/17/2015	05/09/2015	Y	LA
36	Pass	83	07/17/2015	05/09/2015	Y	LA
37	Pass	88	07/17/2015	05/09/2015	Y	LA
38	Pass	77	07/17/2015	05/09/2015	Y	LA
39	Pass	85	07/17/2015	05/09/2015	Y	LA
40	Pass	80	07/16/2015	05/09/2015	Y	LA
41	Pass	88	07/16/2015	05/09/2015	Y	TX
42	Pass	81	07/16/2015	05/09/2015	Y	MS
43	Pass	86	07/16/2015	05/09/2015	Y	LA
44	Pass	83	07/16/2015	05/09/2015	Y	LA

**Table 3 Candidate Summary Report**

	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>	<b>State</b>
45	Pass	80	07/16/2015	05/09/2015	Y	LA
46	Pass	88	07/14/2015	05/09/2015	Y	MO
47	Pass	87	07/11/2015	05/09/2015	Y	OH
48	Pass	75	07/10/2015	05/09/2015	Y	LA
49	Pass	85	07/10/2015	05/09/2015	Y	LA
50	Pass	80	07/10/2015	05/09/2015	Y	LA
51	Pass	81	07/09/2015	05/09/2015	Y	LA
52	Pass	80	07/09/2015	05/09/2015	Y	LA
53	Pass	80	07/09/2015	05/09/2015	Y	LA
54	Pass	87	07/08/2015	05/09/2015	Y	LA
55	Pass	75	07/06/2015	05/09/2015	Y	LA
56	Pass	88	06/30/2015	05/09/2015	Y	MS
57	Pass	84	06/29/2015	05/09/2015	Y	LA
58	Pass	86	06/29/2015	05/09/2015	Y	LA
59	Pass	79	06/29/2015	05/09/2015	Y	LA
60	Pass	85	06/29/2015	05/09/2015	Y	LA
61	Pass	80	06/27/2015	05/09/2015	Y	MS
62	Pass	83	06/27/2015	05/09/2015	Y	MS
63	Pass	83	06/27/2015	05/09/2015	Y	LA
64	Pass	83	06/27/2015	05/09/2015	Y	MS
65	Pass	83	06/26/2015	05/09/2015	Y	LA
66	Pass	81	06/24/2015	05/09/2015	Y	LA
67	Pass	76	06/24/2015	05/09/2015	Y	LA
68	Pass	81	06/22/2015	05/09/2015	Y	LA
69	Pass	80	06/22/2015	05/09/2015	Y	LA
70	Pass	86	06/19/2015	05/09/2015	Y	LA
71	Pass	81	06/19/2015	05/09/2015	Y	LA
72	Pass	85	06/19/2015	05/09/2015	Y	LA
73	Pass	90	06/19/2015	05/09/2015	Y	LA
74	Pass	79	06/18/2015	05/09/2015	Y	LA
75	Pass	83	06/15/2015	05/09/2015	Y	LA
76	Pass	79	06/11/2015	05/09/2015	Y	LA
77	Pass	82	06/08/2015	05/09/2015	Y	LA
78	Pass	83	06/04/2015	05/09/2015	Y	LA
79	Pass	80	06/04/2015	05/09/2015	Y	LA
80	Pass	88	06/02/2015	05/09/2015	Y	LA
81	Pass	84	06/02/2015	05/09/2015	Y	LA
82	Pass	82	06/01/2015	05/09/2015	Y	LA
83	Pass	83	07/25/2015	05/10/2014	Y	TX
84	Pass	83	06/20/2015	05/10/2014	Y	MS
85	Pass	86	07/17/2015	05/11/2013	Y	TX
86	Pass	84	06/13/2015	05/11/2013	Y	AL
87	Pass	83	05/14/2015	05/11/2013	Y	OR
88	Pass	81	07/17/2015	05/19/2012	Y	NY

**Table 3 Candidate Summary Report**

	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>	<b>State</b>
89	Pass	83	07/28/2015	05/21/2011	Y	MD
90	Pass	78	06/05/2015	05/21/2011	Y	TX
91	Pass	78	08/19/2015	05/17/2008	Y	NH
92	Pass	90	08/10/2015	05/17/2008	Y	OR
93	Pass	91	07/17/2015	05/17/2008	Y	MD
94	Pass	86	05/23/2015	05/19/2007	Y	LA
95	Pass	85	05/19/2015	05/19/2007	Y	TN
96	Pass	83	07/16/2015	05/20/2006	Y	NE
97	Pass	88	08/14/2015	05/01/2004	Y	HI
98	Pass	83	05/13/2015	12/01/2000	Y	OK
99	Pass	83	06/26/2015	12/01/1998	Y	TN
100	Pass	90	05/04/2015	12/01/1998	Y	MS
101	Pass	79	08/14/2015	05/01/1998	Y	IL
102	Pass	86	06/19/2015	12/01/1997	Y	AL
103	Pass	90	05/05/2015	12/01/1997	Y	MS
104	Pass	83	06/24/2015	12/01/1995	Y	LA
105	Pass	87	06/04/2015	08/12/1995	Y	MS
106	Pass	75	07/09/2015	08/14/1994	N	TN
107	Pass	86	06/04/2015	08/13/1994	Y	AZ
108	Pass	79	05/04/2015	06/10/1994	Y	MS
109	Pass	79	06/13/2015	05/01/1993	N	TN
110	Pass	83	06/01/2015	08/01/1992	Y	AK
111	Pass	75	05/19/2015	08/01/1992	Y	WA
112	Pass	85	06/24/2015	05/17/1991	Y	MS
113	Pass	81	08/27/2015	05/19/1985	Y	TX
114	Pass	88	06/11/2015	08/17/1984	Y	TN
115	Pass	86	08/25/2015	05/09/1981	Y	OR
116	Pass	91	07/08/2015	05/09/1981	Y	MS
117	Pass	90	06/29/2015	05/09/1981	Y	OR
118	Pass	84	06/19/2015	12/10/1980	Y	AL
119	Pass	82	06/03/2015	12/10/1980	Y	WV
120	Pass	95	08/04/2015	12/17/1977	Y	OK
121	Pass	81	06/18/2015	12/01/1974	Y	OR
122	Pass	76	05/27/2015	12/01/1974	Y	CO

**National Statistics for All Candidates**

**Mean Scaled Score: 82.40**  
**Standard Deviation: 5.45**  
**Range: 50 - 100**  
**Passing Rate (%): 93.04**

**National Statistics for First-Time Candidates**

**Mean Scaled Score: 82.66**  
**Standard Deviation: 5.36**  
**Range: 50 - 100**  
**Passing Rate (%): 93.97**

The following tables are scaled score frequency distributions for MPJE® candidates.  
 Candidates who did not answer enough questions to receive a score are not reflected in the frequency distributions.

**Table 4 National Frequency Distribution of Scaled Scores**

Based on Total Tests Administered (N = 17162 )

Test Window: May 1, 2015 - August 31, 2015

Scaled Score	Frequency	Cumulative Percent of the Upper Limit of the Interval
0 - 4	0	0.0%
5 - 9	0	0.0%
10 - 14	0	0.0%
15 - 19	0	0.0%
20 - 24	0	0.0%
25 - 29	0	0.0%
30 - 34	0	0.0%
35 - 39	0	0.0%
40 - 44	0	0.0%
45 - 49	0	0.0%
50 - 54	2	0.0%
55 - 59	3	0.0%
60 - 64	20	0.1%
65 - 69	165	1.1%
70 - 74	1003	7.0%
75 - 79	3830	29.3%
80 - 84	6264	65.8%
85 - 89	4266	90.6%
90 - 94	1343	98.5%
95 - 100	265	100.0%

**Table 5 National Frequency Distribution of Scaled Scores**

Based on First-Time Candidates from ACPE-Accredited Programs (N = 16114 )

Test Window: May 1, 2015 - August 31, 2015

<b>Scaled Score</b>	<b>Frequency</b>	<b>Cumulative Percent of the Upper Limit of the Interval</b>
0 - 4	0	0.0%
5 - 9	0	0.0%
10 - 14	0	0.0%
15 - 19	0	0.0%
20 - 24	0	0.0%
25 - 29	0	0.0%
30 - 34	0	0.0%
35 - 39	0	0.0%
40 - 44	0	0.0%
45 - 49	0	0.0%
50 - 54	2	0.0%
55 - 59	1	0.0%
60 - 64	12	0.1%
65 - 69	118	0.8%
70 - 74	838	6.0%
75 - 79	3440	27.4%
80 - 84	5942	64.2%
85 - 89	4169	90.1%
90 - 94	1331	98.4%
95 - 100	261	100.0%

**Multistate Pharmacy Jurisprudence Examination (MPJE)**

**University of Louisiana at Monroe**

	<b>2000</b>		<b>2001</b>		<b>2002</b>		<b>2003</b>	
	<u>Jan - Jun</u>	<u>Jul - Dec</u>						
<b>TOTAL CANDIDATE GROUP</b>								
No. of Candidates	125	82	100	57	59	123	77	119
School Average Score:	83.27	82.76	80.84	81.37	80.17	80.41	78.57	80.04
State Average Score:	81.64	80.49	80.64	80.32	80.34	79.41	77.32	78.87
National Average Score:	82.24	81.75	82.25	81.51	90.78	79.85	79.92	79.33
School Pass Rate:	94.40	91.46	90.00	91.23	88.14	88.62	77.92	88.24
State Pass Rate:	89.89	86.25	87.84	90.00	92.00	85.98	72.88	84.67
National Pass Rate:	91.37	90.50	91.22	90.54	90.78	84.93	84.52	82.61
<b>FIRST-TIME CANDIDATE GROUP</b>								
No. of Candidates	117	78	92	51	55	111	59	110
School Average Score:	83.67	83.14	80.89	81.78	80.22	80.58	79.31	80.22
State Average Score:	82.14	80.97	80.67	80.51	80.30	79.41	77.69	79.23
National Average Score:	82.55	82.05	82.59	81.86	82.08	80.19	80.34	79.76
School Pass Rate:	96.58	93.59	90.22	90.20	89.09	88.29	81.36	88.18
State Pass Rate:	92.59	87.32	88.06	89.77	91.49	86.32	75.00	86.55
National Pass Rate:	92.57	91.37	92.45	91.75	92.15	86.45	86.58	84.67

**Multistate Pharmacy Jurisprudence Examination (MPJE)**

**University of Louisiana at Monroe**

	<b>2004</b>		<b>2005</b>		<b>2006</b>		<b>2007</b>	
	<u>Jan - Jun</u>	<u>Jul - Dec</u>						
<b>TOTAL CANDIDATE GROUP</b>								
No. of Candidates	62	110	59	146	68	111	50	151
School Average Score:	79.39	80.79	79.25	80.50	80.43	81.92	80.20	81.62
State Average Score:	78.58	80.03	80.50	80.03	80.01	81.34	80.15	81.47
National Average Score:	80.10	79.83	80.39	80.04	80.68	80.42	81.26	81.14
School Pass Rate:	91.94	91.82	89.83	87.67	88.24	92.79	90.00	92.05
State Pass Rate:	86.90	92.55	90.55	87.03	91.09	92.39	87.18	90.39
National Pass Rate:	85.63	84.75	86.57	85.69	87.25	87.82	89.38	89.78
<b>FIRST-TIME CANDIDATE GROUP</b>								
No. of Candidates	52	104	55	132	60	102	43	140
School Average Score:	79.73	80.96	79.33	80.66	80.80	82.14	81.05	81.83
State Average Score:	79.04	80.11	80.71	80.29	80.24	81.52	80.59	81.84
National Average Score:	80.58	80.25	80.80	80.44	81.09	80.80	81.72	81.51
School Pass Rate:	92.31	92.31	89.09	87.12	91.67	94.12	95.35	93.57
State Pass Rate:	90.14	92.53	91.38	88.69	92.31	93.53	91.18	92.49
National Pass Rate:	88.16	86.87	88.51	87.51	89.41	89.34	91.43	91.24

**Multistate Pharmacy Jurisprudence Examination (MPJE)**

**University of Louisiana at Monroe**

	<b>2008</b>		<b>2009</b>			<b>2010</b>			<b>2011</b>		
	<u>Jan - Jun</u>	<u>Jul - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>											
No. of Candidates	61	137	42	120	36	38	104	35	5	71	12
Mean Scaled Score - School	81.26	81.99	80.95	82.58	80.75	81.47	82.14	81.89	82.60	82.73	83.83
Mean Scaled Score - State	81.33	81.34	79.57	81.69	80.35	81.37	80.88	81.64		81.01	80.41
Mean Scaled Score - National	81.59	81.27	80.29	82.39	80.25	80.45	82.51	80.57	80.27	82.23	80.46
School Pass Rate:	96.72	91.97	88.10	95.00	86.11	94.74	90.38	91.43	100.00	97.18	100.00
State Pass Rate:	91.75	91.05	81.03	94.52	85.92	90.00	92.64	95.79		89.91	90.99
National Pass Rate:	90.31	89.92	86.23	93.74	87.04	89.09	94.83	89.35	86.43	92.17	86.24
<b>FIRST-TIME CANDIDATE GROUP</b>											
No. of Candidates	58	127	37	117	34	34	96	30	5	66	11
Mean Scaled Score - School	81.52	82.13	81.30	82.56	81.09	82.12	82.67	82.33	82.60	83.08	84.18
Mean Scaled Score - State	81.53	81.62	79.69	81.76	80.98	82.07	80.93	82.07		81.52	81.14
Mean Scaled Score - National	81.97	81.57	80.75	82.58	80.63	80.82	82.67	80.94	81.17	82.86	81.76
School Pass Rate:	96.55	91.34	89.19	94.87	88.24	97.06	93.75	93.33	100.00	100.00	100.00
State Pass Rate:	92.31	91.95	80.77	94.34	89.66	93.44	92.92	97.56		94.06	94.32
National Pass Rate:	91.82	91.16	88.45	94.30	88.68	90.64	95.50	90.79	92.24	96.05	94.00

**Multistate Pharmacy Jurisprudence Examination (MPJE)**

**University of Louisiana at Monroe**

	<b>2012</b>			<b>2013</b>			<b>2014</b>			<b>2015</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	4	126	87	47	94	30	32	122	39	42	122	
<i>* testing in same/different state</i>		72 / 54	11 / 34	11 / 36	40 / 54	2 / 28	5 / 27	62 / 60	6 / 33	13 / 29	68 / 54	
Mean Scale Score - School *	82.25	82.44/82.70	80.09/79.85	81.45/84.03	82.50/82.59	80.50/82.79	79.40/81.41	81.44/83.32	78.50/81.42	76.85/81.90	81.44/84.13	
<i>* testing in same/different state</i>												
Mean Scaled Score - State	81.18	80.91	79.62	81.33	80.82	80.43	80.36	80.18	80.13	79.81	80.56	
Mean Scaled Score - National	80.41	82.43	80.55	80.92	82.50	80.52	81.04	82.52	81.08	81.32	82.40	
School Pass Rate: *	100.00	97.22/90.74	90.91/85.29	100/97.22	95.00/98.15	100 / 92.86	100 / 85.19	95.16/96.67	83.33/87.88	76.92/93.10	94.12/98.15	
<i>* testing in same/different state</i>												
State Pass Rate:	90.41	90.69	81.61	93.98	90.51	85.21	82.52	86.08	82.69	80.69	88.14	
National Pass Rate:	84.54	92.76	86.85	87.18	92.98	87.01	87.62	93.28	88.50	88.20	93.04	
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	4	124	70	44	93	28	29	119	33	38	120	
<i>* testing in same/different state</i>		72 / 52	10 / 29	10 / 34	39 / 54	1 / 27	5 / 24	62 / 57	3 / 30	11 / 27	68 / 52	
Mean Scaled Score - School *	82.25	82.44/83.02	80.62/79.90	81.80/84.26	82.77/82.59	82.00/83.19	79.40/82.29	81.44/83.58	78.00/81.97	76.91/82.04	81.44/84.40	
<i>* testing in same/different state</i>												
Mean Scaled Score - State	81.75	81.03	80.21	81.90	81.03	81.08	81.05	80.62	81.13	80.63	80.62	
Mean Scaled Score - National	81.44	82.75	81.26	81.78	82.76	81.22	81.82	82.80	81.79	82.14	82.66	
School Pass Rate: *	100.00	97.22/92.31	89.66/90.00	100.00/97.06	97.44/98.15	100 / 96.30	100 / 91.67	95.16/98.25	66.67/90.00	72.73/92.59	94.12/98.08	
<i>* testing in same/different state</i>												
State Pass Rate:	93.22	91.03	85.71	97.22	91.88	87.29	85.88	89.29	84.96	83.61	88.77	
National Pass Rate:	89.13	93.94	89.60	91.08	93.95	90.04	90.85	94.34	90.87	91.72	93.97	



**Multistate Pharmacy Jurisprudence Examination® (MPJE®)  
School Summary Report**

**Test Window:** May 1, 2015 - August 31, 2015

**School Name:** Xavier University of Louisiana

This MPJE score report consists of two levels of scores: school-aggregated scores and individual candidate scores. Summary information is provided separately for first-time examinees from ACPE schools/colleges and for all examinees, regardless of repeater status and/or the educational institution. Tables 1 and 2 contain school-specific as well as national pass rate information.

School 1: Examinees testing in same state as respective college

School 2: Examinees testing in different states than respective college

**Table 1 First Time Candidates**

	<b>Candidates</b>	<b>Pass Rate %</b>	<b>Total Scaled Score Mean</b>	<b>Standard Deviation</b>
<b>School 1</b>	94	80.85	79.24	4.90
<b>School 2</b>	99	91.92	81.07	5.60
<b>State</b>	285	88.77	80.62	4.70
<b>National</b>	16114	93.97	82.66	5.36

Candidates who did not answer enough questions to receive a score are reflected in pass rate data as a fail but are not included in mean scaled score data.

**Table 2 All Candidates**

	<b>Candidates</b>	<b>Pass Rate %</b>	<b>Total Scaled Score Mean</b>	<b>Standard Deviation</b>
<b>School 1</b>	105	81.90	79.39	4.87
<b>School 2</b>	110	89.09	80.75	5.59
<b>State</b>	312	88.14	80.56	4.73
<b>National</b>	17162	93.04	82.40	5.45

Candidates who did not answer enough questions to receive a score are reflected in pass rate data as a fail but are not included in mean scaled score data.

### Table 3 Candidate Summary Report

**Test Window:** May 1, 2015 - August 31, 2015

	Pass/Fail	Total Scaled Score	Test Date	Graduation Date	First Attempt	State
1	Pass	90	08/29/2015	05/09/2015	Y	GA
2	Pass	89	08/26/2015	05/09/2015	Y	TX
3	Pass	87	08/26/2015	05/09/2015	Y	MS
4	Pass	80	08/26/2015	05/09/2015	Y	LA
5	Pass	96	08/26/2015	05/09/2015	Y	TX
6	Fail	74	08/26/2015	05/09/2015	Y	LA
7	Pass	79	08/25/2015	05/09/2015	Y	MS
8	Fail	74	08/25/2015	05/09/2015	Y	IL
9	Pass	87	08/25/2015	05/09/2015	Y	TX
10	Pass	82	08/24/2015	05/09/2015	Y	TX
11	Pass	80	08/24/2015	05/09/2015	Y	LA
12	Pass	79	08/24/2015	05/09/2015	Y	MS
13	Pass	84	08/24/2015	05/09/2015	Y	LA
14	Pass	86	08/24/2015	05/09/2015	Y	MS
15	Fail	69	08/24/2015	05/09/2015	Y	AL
16	Pass	92	08/24/2015	05/09/2015	Y	TX
17	Pass	80	08/24/2015	05/09/2015	Y	MS
18	Pass	82	08/24/2015	05/09/2015	Y	TX
19	Pass	83	08/24/2015	05/09/2015	Y	TX
20	Pass	90	08/24/2015	05/09/2015	Y	TX
21	Pass	81	08/20/2015	05/09/2015	Y	LA
22	Pass	82	08/20/2015	05/09/2015	Y	LA
23	Pass	76	08/20/2015	05/09/2015	Y	LA
24	Fail	69	08/20/2015	05/09/2015	Y	FL
25	Pass	81	08/20/2015	05/09/2015	Y	LA
26	Pass	77	08/20/2015	05/09/2015	Y	MS
27	Pass	78	08/19/2015	05/09/2015	Y	LA
28	Pass	88	08/19/2015	05/09/2015	Y	MA
29	Pass	77	08/19/2015	05/09/2015	Y	LA
30	Fail	69	08/17/2015	05/09/2015	Y	LA
31	Fail	74	08/17/2015	05/09/2015	Y	LA
32	Pass	79	08/17/2015	05/09/2015	N	LA
33	Pass	80	08/17/2015	05/09/2015	Y	LA
34	Pass	87	08/17/2015	05/09/2015	Y	TX
35	Pass	79	08/17/2015	05/09/2015	Y	LA
36	Fail	70	08/17/2015	05/09/2015	Y	LA
37	Pass	80	08/15/2015	05/09/2015	Y	LA
38	Pass	88	08/15/2015	05/09/2015	Y	LA
39	Pass	87	08/15/2015	05/09/2015	Y	LA
40	Fail	68	08/15/2015	05/09/2015	Y	LA
41	Pass	83	08/14/2015	05/09/2015	N	LA
42	Pass	75	08/13/2015	05/09/2015	Y	LA
43	Pass	77	08/13/2015	05/09/2015	Y	TN
44	Pass	82	08/13/2015	05/09/2015	Y	LA

**Table 3 Candidate Summary Report**

	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>	<b>State</b>
45	Pass	76	08/13/2015	05/09/2015	Y	GA
46	Fail	68	08/11/2015	05/09/2015	Y	LA
47	Pass	76	08/11/2015	05/09/2015	Y	TX
48	Pass	90	08/11/2015	05/09/2015	Y	TX
49	Pass	81	08/10/2015	05/09/2015	Y	LA
50	Pass	78	08/10/2015	05/09/2015	Y	LA
51	Pass	85	08/10/2015	05/09/2015	Y	LA
52	Fail	72	08/10/2015	05/09/2015	Y	LA
53	Pass	75	08/10/2015	05/09/2015	N	LA
54	Pass	86	08/08/2015	05/09/2015	Y	LA
55	Pass	78	08/08/2015	05/09/2015	Y	LA
56	Pass	82	08/08/2015	05/09/2015	N	LA
57	Pass	85	08/08/2015	05/09/2015	Y	MS
58	Fail	73	08/07/2015	05/09/2015	Y	LA
59	Pass	91	08/07/2015	05/09/2015	Y	TX
60	Pass	81	08/07/2015	05/09/2015	Y	LA
61	Pass	83	08/07/2015	05/09/2015	Y	LA
62	Pass	80	08/06/2015	05/09/2015	Y	TX
63	Pass	77	08/06/2015	05/09/2015	Y	LA
64	Pass	78	08/06/2015	05/09/2015	Y	LA
65	Pass	83	08/06/2015	05/09/2015	Y	LA
66	Pass	78	08/06/2015	05/09/2015	Y	LA
67	Pass	80	08/06/2015	05/09/2015	Y	LA
68	Pass	77	08/05/2015	05/09/2015	Y	MS
69	Pass	89	08/05/2015	05/09/2015	Y	MS
70	Pass	81	08/05/2015	05/09/2015	Y	MS
71	Pass	85	08/05/2015	05/09/2015	N	LA
72	Pass	77	08/05/2015	05/09/2015	Y	TX
73	Pass	79	08/03/2015	05/09/2015	Y	TX
74	Pass	77	07/30/2015	05/09/2015	Y	TX
75	Pass	85	07/29/2015	05/09/2015	Y	LA
76	Pass	82	07/29/2015	05/09/2015	Y	MS
77	Pass	77	07/29/2015	05/09/2015	Y	LA
78	Fail	72	07/29/2015	05/09/2015	Y	LA
79	Pass	88	07/29/2015	05/09/2015	Y	LA
80	Pass	84	07/29/2015	05/09/2015	Y	LA
81	Pass	80	07/29/2015	05/09/2015	Y	LA
82	Pass	85	07/28/2015	05/09/2015	Y	LA
83	Pass	78	07/28/2015	05/09/2015	Y	LA
84	Pass	79	07/28/2015	05/09/2015	Y	LA
85	Pass	79	07/28/2015	05/09/2015	Y	TX
86	Pass	80	07/28/2015	05/09/2015	Y	LA
87	Fail	74	07/28/2015	05/09/2015	Y	LA
88	Pass	85	07/28/2015	05/09/2015	Y	LA

**Table 3 Candidate Summary Report**

	Pass/Fail	Total Scaled Score	Test Date	Graduation Date	First Attempt	State
89	Fail	73	07/28/2015	05/09/2015	Y	LA
90	Pass	75	07/28/2015	05/09/2015	Y	LA
91	Pass	81	07/28/2015	05/09/2015	Y	LA
92	Fail	74	07/27/2015	05/09/2015	Y	LA
93	Pass	78	07/27/2015	05/09/2015	Y	AL
94	Pass	81	07/27/2015	05/09/2015	Y	LA
95	Pass	79	07/27/2015	05/09/2015	Y	LA
96	Fail	73	07/27/2015	05/09/2015	Y	FL
97	Pass	80	07/27/2015	05/09/2015	Y	LA
98	Pass	81	07/27/2015	05/09/2015	Y	LA
99	Pass	80	07/25/2015	05/09/2015	Y	AL
100	Pass	78	07/25/2015	05/09/2015	Y	LA
101	Pass	84	07/25/2015	05/09/2015	Y	LA
102	Pass	89	07/25/2015	05/09/2015	Y	LA
103	Pass	81	07/23/2015	05/09/2015	Y	MS
104	Pass	82	07/22/2015	05/09/2015	Y	MS
105	Pass	83	07/20/2015	05/09/2015	Y	LA
106	Pass	79	07/20/2015	05/09/2015	Y	LA
107	Pass	88	07/20/2015	05/09/2015	Y	MS
108	Fail	73	07/18/2015	05/09/2015	Y	LA
109	Pass	88	07/18/2015	05/09/2015	Y	LA
110	Pass	79	07/18/2015	05/09/2015	Y	MS
111	Pass	75	07/17/2015	05/09/2015	Y	MS
112	Pass	80	07/17/2015	05/09/2015	Y	OH
113	Pass	85	07/16/2015	05/09/2015	Y	TX
114	Pass	88	07/16/2015	05/09/2015	Y	TX
115	Pass	87	07/15/2015	05/09/2015	Y	LA
116	Pass	77	07/15/2015	05/09/2015	Y	LA
117	Fail	74	07/15/2015	05/09/2015	Y	LA
118	Pass	86	07/14/2015	05/09/2015	Y	TX
119	Pass	78	07/13/2015	05/09/2015	Y	LA
120	Fail	73	07/10/2015	05/09/2015	Y	LA
121	Pass	77	07/10/2015	05/09/2015	Y	LA
122	Pass	81	07/10/2015	05/09/2015	Y	LA
123	Pass	82	07/10/2015	05/09/2015	Y	LA
124	Pass	77	07/09/2015	05/09/2015	Y	LA
125	Pass	81	07/09/2015	05/09/2015	Y	LA
126	Pass	87	07/09/2015	05/09/2015	Y	LA
127	Pass	85	07/09/2015	05/09/2015	Y	LA
128	Pass	88	07/09/2015	05/09/2015	Y	TX
129	Pass	79	07/09/2015	05/09/2015	Y	LA
130	Fail	72	07/09/2015	05/09/2015	Y	LA
131	Pass	87	07/02/2015	05/09/2015	Y	LA
132	Pass	80	07/01/2015	05/09/2015	Y	LA

**Table 3 Candidate Summary Report**

	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>	<b>State</b>
133	Pass	82	06/30/2015	05/09/2015	Y	LA
134	Fail	73	06/30/2015	05/09/2015	Y	LA
135	Pass	82	06/29/2015	05/09/2015	Y	LA
136	Pass	76	06/24/2015	05/09/2015	Y	LA
137	Fail	71	06/24/2015	05/09/2015	Y	LA
138	Pass	88	06/19/2015	05/09/2015	Y	LA
139	Pass	82	06/12/2015	05/09/2015	Y	LA
140	Pass	86	06/05/2015	05/09/2015	Y	TX
141	Pass	79	07/15/2015	05/05/2015	Y	LA
142	Pass	88	07/16/2015	12/12/2014	N	LA
143	Fail	72	05/27/2015	12/12/2014	N	LA
144	Pass	83	06/09/2015	06/28/2014	N	LA
145	Pass	76	06/02/2015	06/13/2014	Y	LA
146	Pass	83	08/27/2015	05/10/2014	N	TX
147	Pass	80	08/22/2015	05/10/2014	Y	MS
148	Pass	75	08/14/2015	05/10/2014	Y	MS
149	Pass	95	08/11/2015	05/10/2014	Y	ID
150	Pass	77	08/08/2015	05/10/2014	Y	WY
151	Pass	76	07/28/2015	05/10/2014	Y	GA
152	Pass	75	07/25/2015	05/10/2014	Y	NV
153	Fail	74	07/24/2015	05/10/2014	Y	GA
154	Pass	80	07/17/2015	05/10/2014	N	LA
155	Pass	84	07/15/2015	05/10/2014	Y	MS
156	Fail	71	07/13/2015	05/10/2014	Y	TX
157	Pass	81	07/09/2015	05/10/2014	Y	NE
158	Pass	83	06/19/2015	05/10/2014	Y	TX
159	Pass	81	06/13/2015	05/10/2014	Y	FL
160	Pass	79	06/05/2015	05/10/2014	Y	GA
161	Fail	73	05/22/2015	05/10/2014	N	AL
162	Pass	76	05/13/2015	05/10/2014	N	MS
163	Pass	83	05/07/2015	05/10/2014	N	LA
164	Pass	79	05/07/2015	05/10/2014	Y	TN
165	Pass	78	05/05/2015	05/10/2014	Y	LA
166	Pass	80	05/04/2015	05/10/2014	Y	LA
167	Fail	70	07/17/2015	06/29/2013	Y	TX
168	Pass	78	07/17/2015	05/11/2013	Y	TX
169	Pass	75	07/08/2015	05/11/2013	Y	MS
170	Fail	74	05/19/2015	05/11/2013	Y	IN
171	Pass	78	05/13/2015	05/11/2013	Y	TX
172	Pass	78	05/07/2015	05/11/2013	Y	TX
173	Pass	79	05/05/2015	05/11/2013	Y	TX
174	Pass	81	08/19/2015	05/12/2012	Y	OR
175	Pass	81	06/27/2015	05/12/2012	Y	TX
176	Pass	86	06/24/2015	05/12/2012	Y	LA

**Table 3 Candidate Summary Report**

	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>	<b>State</b>
177	Pass	83	05/12/2015	05/12/2012	Y	TX
178	Pass	77	08/26/2015	05/08/2010	Y	FL
179	Pass	76	07/01/2015	05/08/2010	Y	TX
180	Pass	81	06/19/2015	05/08/2010	Y	TX
181	Pass	78	05/04/2015	05/08/2010	Y	TN
182	Pass	82	06/13/2015	03/08/2010	Y	TX
183	Pass	88	07/28/2015	05/09/2009	Y	TX
184	Pass	76	05/01/2015	05/09/2009	Y	MS
185	Pass	92	08/22/2015	05/10/2008	Y	AL
186	Pass	82	08/19/2015	05/10/2008	Y	AZ
187	Pass	75	08/15/2015	05/10/2008	Y	LA
188	Pass	80	06/18/2015	05/10/2008	N	MS
189	Pass	78	08/24/2015	05/20/2006	Y	OK
190	Pass	80	05/06/2015	05/20/2006	N	FL
191	Pass	75	07/27/2015	05/01/2005	Y	TN
192	Pass	79	06/20/2015	05/31/2004	N	NJ
193	Pass	84	08/26/2015	05/08/2004	Y	OK
194	Pass	86	08/07/2015	05/08/2004	Y	MI
195	Pass	75	07/18/2015	05/01/2003	Y	FL
196	Pass	82	05/27/2015	05/01/2003	Y	OK
197	Pass	77	05/04/2015	05/01/2003	N	LA
198	Fail	73	06/26/2015	05/01/2001	N	NY
199	Pass	87	06/11/2015	05/01/2001	N	TN
200	Pass	84	08/28/2015	05/01/2000	Y	TX
201	Pass	77	08/17/2015	05/01/2000	Y	MO
202	Pass	79	05/04/2015	05/01/1999	N	TN
203	Pass	89	08/20/2015	05/10/1997	Y	PA
204	Fail	73	06/06/2015	05/10/1997	N	FL
205	Fail	73	07/14/2015	05/01/1997	N	AL
206	Pass	83	05/23/2015	05/11/1996	Y	MI
207	Pass	78	08/27/2015	05/01/1996	Y	AL
208	Pass	76	07/31/2015	05/01/1995	Y	LA
209	Pass	79	06/19/2015	05/01/1993	Y	OK
210	Pass	79	07/01/2015	12/14/1992	Y	OR
211	Pass	80	06/25/2015	12/14/1992	Y	NE
212	Pass	77	06/17/2015	12/14/1992	Y	LA
213	Pass	85	06/06/2015	12/14/1992	Y	AL
214	Pass	77	08/07/2015	05/18/1986	Y	KY
215	Pass	85	08/10/2015	05/01/1986	Y	FL

**National Statistics for All Candidates**

**Mean Scaled Score: 82.40**  
**Standard Deviation: 5.45**  
**Range: 50 - 100**  
**Passing Rate (%): 93.04**

**National Statistics for First-Time Candidates**

**Mean Scaled Score: 82.66**  
**Standard Deviation: 5.36**  
**Range: 50 - 100**  
**Passing Rate (%): 93.97**

The following tables are scaled score frequency distributions for MPJE® candidates.  
 Candidates who did not answer enough questions to receive a score are not reflected in the frequency distributions.

**Table 4 National Frequency Distribution of Scaled Scores**

Based on Total Tests Administered (N = 17162 )

Test Window: May 1, 2015 - August 31, 2015

Scaled Score	Frequency	Cumulative Percent of the Upper Limit of the Interval
0 - 4	0	0.0%
5 - 9	0	0.0%
10 - 14	0	0.0%
15 - 19	0	0.0%
20 - 24	0	0.0%
25 - 29	0	0.0%
30 - 34	0	0.0%
35 - 39	0	0.0%
40 - 44	0	0.0%
45 - 49	0	0.0%
50 - 54	2	0.0%
55 - 59	3	0.0%
60 - 64	20	0.1%
65 - 69	165	1.1%
70 - 74	1003	7.0%
75 - 79	3830	29.3%
80 - 84	6264	65.8%
85 - 89	4266	90.6%
90 - 94	1343	98.5%
95 - 100	265	100.0%

**Table 5 National Frequency Distribution of Scaled Scores**

Based on First-Time Candidates from ACPE-Accredited Programs (N = 16114 )

Test Window: May 1, 2015 - August 31, 2015

<b>Scaled Score</b>	<b>Frequency</b>	<b>Cumulative Percent of the Upper Limit of the Interval</b>
0 - 4	0	0.0%
5 - 9	0	0.0%
10 - 14	0	0.0%
15 - 19	0	0.0%
20 - 24	0	0.0%
25 - 29	0	0.0%
30 - 34	0	0.0%
35 - 39	0	0.0%
40 - 44	0	0.0%
45 - 49	0	0.0%
50 - 54	2	0.0%
55 - 59	1	0.0%
60 - 64	12	0.1%
65 - 69	118	0.8%
70 - 74	838	6.0%
75 - 79	3440	27.4%
80 - 84	5942	64.2%
85 - 89	4169	90.1%
90 - 94	1331	98.4%
95 - 100	261	100.0%

**Multistate Pharmacy Jurisprudence Examination (MPJE)**

**Xavier College of Pharmacy**

	<b>2000</b>		<b>2001</b>		<b>2002</b>		<b>2003</b>	
	<u>Jan - Jun</u>	<u>Jul - Dec</u>						
<b>TOTAL CANDIDATE GROUP</b>								
No. of Candidates	25	94	53	126	43	122	71	158
School Average Score:	78.92	78.90	77.43	79.86	79.12	78.18	76.75	77.99
State Average Score:	81.64	80.49	80.64	80.32	80.34	79.41	77.32	78.87
National Average Score:	82.24	81.75	82.25	81.51	81.72	79.85	79.92	79.33
School Pass Rate:	80.00	80.85	69.81	88.10	81.40	77.05	67.61	75.95
State Pass Rate:	89.89	86.25	87.84	90.00	92.00	85.98	72.88	84.67
National Pass Rate:	91.37	90.50	91.22	90.54	90.78	84.93	84.52	82.61
<b>FIRST-TIME CANDIDATE GROUP</b>								
No. of Candidates	23	86	38	107	38	102	53	122
School Average Score:	79.04	79.01	77.58	79.92	79.58	78.18	77.04	78.48
State Average Score:	82.14	80.97	80.67	80.51	80.30	79.41	77.69	79.23
National Average Score:	82.55	82.05	82.59	81.86	82.08	80.19	80.34	79.76
School Pass Rate:	78.26	80.23	71.05	86.92	86.84	78.43	71.70	78.69
State Pass Rate:	92.59	87.32	88.06	89.77	91.49	86.32	75.00	86.55
National Pass Rate:	92.57	91.37	92.45	91.75	92.15	86.45	86.58	84.67

**Multistate Pharmacy Jurisprudence Examination (MPJE)**

**Xavier College of Pharmacy**

	<b>2004</b>		<b>2005</b>		<b>2006</b>		<b>2007</b>	
	<u>Jan - Jun</u>	<u>Jul - Dec</u>						
<b>TOTAL CANDIDATE GROUP</b>								
No. of Candidates	66	123	82	135	139	181	77	169
School Average Score:	77.36	78.64	78.06	78.96	79.04	79.82	78.47	79.76
State Average Score:	78.58	80.03	80.50	80.03	80.01	81.34	80.15	81.47
National Average Score:	80.10	79.83	80.39	80.04	80.68	80.42	81.26	81.14
School Pass Rate:	78.79	80.49	76.83	82.22	87.77	86.19	77.92	87.57
State Pass Rate:	86.90	92.55	90.55	87.03	91.09	92.39	87.18	90.39
National Pass Rate:	85.63	84.75	86.57	85.69	87.25	87.82	89.38	89.78
<b>FIRST-TIME CANDIDATE GROUP</b>								
No. of Candidates	56	101	63	121	121	156	62	154
School Average Score:	77.73	79.19	78.57	79.36	79.14	80.27	79.47	80.03
State Average Score:	79.04	80.11	80.71	80.29	80.24	81.52	80.59	81.84
National Average Score:	80.58	80.25	80.80	80.44	81.09	80.80	81.72	81.51
School Pass Rate:	80.36	84.16	79.37	85.12	87.60	89.10	85.48	88.96
State Pass Rate:	90.14	92.53	91.38	88.69	92.31	93.53	91.18	92.49
National Pass Rate:	88.16	86.87	88.51	87.51	89.41	89.34	91.43	91.24

**Multistate Pharmacy Jurisprudence Examination (MPJE)**

**Xavier College of Pharmacy**

	<b>2008</b>		<b>2009</b>			<b>2010</b>			<b>2011</b>		
	<u>Jan - Jun</u>	<u>Jul - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>											
No. of Candidates	55	208	63	162	68	42	160	83	10	77	44
Mean Scaled Score - School	78.25	79.49	78.03	80.20	78.10	78.93	79.89	78.17	76.50	79.32	78.93
Mean Scaled Score - State	81.33	81.34	79.57	81.69	80.35	81.37	80.88	81.64		81.01	80.41
Mean Scaled Score - National	81.59	81.27	80.29	82.39	80.25	80.45	82.51	80.57	80.27	82.23	80.46
School Pass Rate:	80	83.17	74.60	88.27	77.94	80.95	88.75	78.31	70.00	81.82	81.82
State Pass Rate:	91.75	91.05	81.03	94.52	85.92	90.00	92.64	95.79		89.91	90.99
National Pass Rate:	90.31	89.92	86.23	93.74	87.04	89.08	94.83	89.35	86.43	92.17	86.24
<b>FIRST-TIME CANDIDATE GROUP</b>											
No. of Candidates	45	181	44	150	47	32	157	61	7	67	29
Mean Scaled Score - School	79.02	79.71	78.55	80.35	78.79	79.66	79.95	78.48	78.14	79.84	80.14
Mean Scaled Score - State	81.53	81.62	79.69	81.76	80.98	82.07	80.93	82.07		81.52	81.14
Mean Scaled Score - National	81.97	81.57	80.75	82.58	80.63	80.82	82.67	80.94	81.17	82.86	81.76
School Pass Rate:	88.89	85.64	79.55	88.67	82.98	84.38	89.17	78.69	85.71	86.57	89.66
State Pass Rate:	92.31	91.95	80.77	94.34	89.66	93.44	92.92	97.56		94.06	94.32
National Pass Rate:	91.82	91.16	88.45	94.30	88.68	90.64	95.50	90.89	92.24	96.05	94.00

**Multistate Pharmacy Jurisprudence Examination (MPJE)**

**Xavier College of Pharmacy**

	<b>2012</b>			<b>2013</b>			<b>2014</b>			<b>2015</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sep - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	13	181	87	53	188	115	52	193	128	81	215	
<i>* testing in same/different state</i>		94 / 87	23 / 65	6 / 47	95 / 93	46 / 69	12 / 40	82 / 111	43 / 85	26 / 55	105 / 110	
Mean Scaled Score - School *	79.69	79.27/78.48	76.96/79.95	78.17/79.09	79.46/79.55	77.33/78.72	76 / 79.28	78.35/79.98	77.05/80.62	75.27/79.70	79.39/80.75	
<i>* testing in same/different state</i>												
Mean Scaled Score - State	81.18	80.91	79.62	81.33	80.82	80.43	80.36	80.18	80.13	79.81	80.56	
Mean Scaled Score - National	80.41	82.43	80.55	80.92	82.50	80.52	81.04	82.52	81.08	81.32	82.40	
School Pass Rate: *	84.62	84.04/81.61	60.87/86.15	83.33/76.60	85.26/81.72	71.74/76.81	50 / 82.50	76.83/90.09	65.12/90.59	50.00/72.73	81.90/89.09	
<i>* testing in same/different state</i>												
State Pass Rate:	90.41	90.69	81.61	93.98	90.51	85.21	82.52	86.08	82.69	80.69	88.14	
National Pass Rate:	84.54	92.76	86.85	87.18	92.98	87.01	87.62	93.28	88.50	88.20	93.04	
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	9	163	70	43	171	86	43	176	98	65	193	
<i>* testing in same/different state</i>		87 / 76	11 / 54	3 / 40	89 / 82	31 / 55	8 / 35	76 / 100	24 / 74	14 / 51	94 / 99	
Mean Scaled Score - School *	79.78	79.34/78.70	77.55/80.57	81.33/79.38	79.66/79.94	77.03/78.85	76.63/79.31	78.83/80.23	77.33/80.86	76.29/80.28	79.24/81.07	
<i>* testing in same/different state</i>												
Mean Scaled Score - State	81.75	81.03	80.21	81.90	81.03	81.08	81.05	80.62	81.13	80.63	80.62	
Mean Scaled Score - National	81.44	82.75	81.26	81.78	82.76	81.22	81.82	82.80	81.79	82.14	82.66	
School Pass Rate: *	88.89	83.91/84.24	63.64/87.04	100 / 77.50	87.64/82.93	67.74/74.55	50 / 80	80.26/90.00	62.5 / 91.89	57.14/78.43	80.85/91.92	
<i>* testing in same/different state</i>												
State Pass Rate:	93.22	91.03	85.71	97.22	91.88	87.29	85.88	89.29	84.96	83.61	88.77	
National Pass Rate:	89.13	93.94	89.60	91.08	93.95	90.04	90.85	94.34	90.87	91.72	93.97	



## National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014  
Tel: 847/391-4406 • Fax: 847/391-4502  
Web Site: [www.nabp.net](http://www.nabp.net)

nabp

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY,  
DEANS – SCHOOLS AND COLLEGES OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: October 8, 2015

RE: MPJE Program Notification

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In 2014, the National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) facilitated a review of the Multistate Pharmacy Jurisprudence Examination<sup>®</sup> (MPJE<sup>®</sup>) competency statements to ensure that the content areas represented are current and relevant to the application of pharmacy law in practice. The review resulted in modifications and additions to the content areas and these outcomes were included in a national survey of pharmacy regulators earlier this year. The survey yielded information regarding the importance of each of the content areas in practice which in turn produced weights for the MPJE blueprint.

Following the survey, NABP conducted an evaluation of the passing standard for the MPJE. The purpose of the MPJE passing standard meeting is to make a recommendation regarding the level of demonstrable performance that is necessary to pass the examination. To support the validation of a passing (cut) score recommendation and decision, standard setting meetings are held with subject matter experts who understand the purpose of the examination, the content being tested, and characteristics of the examinees. The panel that participated in the MPJE standard setting process was composed of pharmacists from a variety of backgrounds and experiences – board of pharmacy affiliates (executives, members), active practitioners, inspectors/compliance officers, board counsel, and academicians. Collectively, the panel has the requisite expertise encompassing the scope of pharmacy practice and the capacity to recommend a minimum standard for the knowledge and skills necessary for licensure.

NABP is providing the following summary of updates to the MPJE program to provide timely information to the boards of pharmacy participating in the MPJE program and to the schools and colleges of pharmacy. The implementation of the MPJE program changes will be effective April 2016.

- The MPJE will be assembled under the new (updated) competency statements and content area domain allocations (see accompanying attachment).
- The number of examination items will increase from 90 to 120. Of the 120 items, 100 will be used to produce a score for the MPJE and 20 will non-scored or pretest items. The increase in the number of questions will ensure testing across all of the content areas.

October 8, 2015

Page 2

- Maximum testing time for the examination will increase from two hours to two and a half hours. The appointment time with the vendor, Pearson VUE, will be three hours to allow for time to read and agree to the confidentially/non-disclosure agreement, tutorial, and post-exam survey. To account for the additional seat time and exam development, the MPJE registration fee will increase from \$210 to \$250.
- A new passing standard for the MPJE will be implemented on April, 2016; however, the scaled score required to pass will remain at 75. It is typical to see variations in the pass rates after a new standard is in place.

If you have any questions regarding the updates to the MPJE program, please contact Maria Incrocci, competency assessment senior manager at [mincrocci@nabp.net](mailto:mincrocci@nabp.net) or 847/391-4426.

cc: Lucinda Maine, American Association of Colleges of Pharmacy  
Peter Vlasses, Accreditation Council for Pharmacy Education  
NABP Executive Committee  
NABP Advisory Committee on Examinations  
NABP MPJE Review Committee  
Carmen A. Catizone, Executive Director/Secretary

# Multistate Pharmacy Jurisprudence Examination

## Competency Statements (to be implemented April 2016)

### Area 1 Pharmacy Practice (83%)

#### 1.1 Legal responsibilities of the pharmacist and other pharmacy personnel

- 1.1.1 Unique legal responsibilities of the pharmacist-in-charge (or equivalent), pharmacists, interns, and pharmacy owners

Responsibilities for inventory, loss and/or theft of prescription drugs, the destruction/disposal of prescription drugs and the precedence of Local, State, or Federal requirements

- 1.1.2 Qualifications, scope of duties, and conditions for practice relating to pharmacy technicians and all other non-pharmacist personnel

Personnel ratios, duties, tasks, roles, and functions of non-pharmacist personnel

#### 1.2 Requirements for the acquisition and distribution of pharmaceutical products, including samples

- 1.2.1 Requirements and record keeping in relation to the ordering, acquiring, and maintenance of all pharmaceutical products and bulk drug substances/excipients

Legitimate suppliers, pedigrees and the maintenance of acquisition records

- 1.2.2 Requirements for distributing pharmaceutical products and preparations, including the content and maintenance of distribution records

Legal possession of pharmaceutical products (including drug samples), labeling, packaging, repackaging, compounding, and sales to practitioners

#### 1.3 Legal requirements that must be observed in the issuance of a prescription/drug order

- 1.3.1 Prescription/order requirements for pharmaceutical products and the limitations on their respective therapeutic uses

Products, preparations, their uses and limitations applicable to all prescribed orders for both human and veterinary uses

- 1.3.2 Scope of authority, scope of practice, and valid registration of all practitioners who are authorized under law to prescribe, dispense, or administer pharmaceutical products, including controlled substances

Federal and State registrations, methadone programs, office-based opioid treatment programs, regulations related to retired or deceased prescribers, Internet prescribing, limits on jurisdictional prescribing

- 1.3.3 Conditions under which the pharmacist participates in the administration of pharmaceutical products, or in the management of patients' drug therapy

Prescriptive authority, collaborative practice, consulting, counseling, medication administration (including immunization, vaccines), ordering labs, medication therapy management, and disease state management

- 1.3.4 Requirements for issuing a prescription/order

Content and format for written, telephonic voice transmission, electronic facsimile, computer and Internet, during emergency conditions, and tamper-resistant prescription forms.

- 1.3.5 Requirements for the issuance of controlled substance prescriptions/orders

Content and format for written, telephonic voice transmission, electronic facsimile, computerized and Internet, during emergency conditions, conditions for changing a prescription, time limits for dispensing initial prescriptions/drug orders, and requirements for multiple Schedule II orders

- 1.3.6 Limits of a practitioner's authority to authorize refills of a pharmaceutical product, including controlled substances

**1.4 Procedures necessary to properly dispense a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order**

- 1.4.1 Responsibilities for determining whether prescriptions/orders were issued for a legitimate medical purpose and within all applicable legal restrictions

Corresponding responsibility, maximum quantities, restricted distribution systems, red flags/automated alerts, controlled substances, valid patient / prescriber relationship, and due diligence to ensure validity of the order

- 1.4.2 Requirements for the transfer of existing prescription/order information from one pharmacist to another

- 1.4.3 Conditions under which a prescription/order may be filled or refilled

Emergency fills or refills, partial dispensing of a controlled substance, disaster or emergency protocol, patient identification, requirement for death with dignity, medical marijuana, and conscience /moral circumstances

- 1.4.4 Conditions under which prospective drug use review is conducted prior to dispensing

Patient specific therapy and requirements for patient specific documentation

- 1.4.5 Conditions under which product selection is permitted or mandated

Consent of the patient and/or prescriber, passing-on of cost savings, and appropriate documentation

- 1.4.6 Requirements for the labeling of pharmaceutical products and preparations dispensed pursuant to a prescription/order

Generic and therapeutic equivalency, formulary use, auxiliary labels, patient package inserts, FDA medication guides, and written drug information

- 1.4.7 Packaging requirements of pharmaceutical products, preparations, and devices to be dispensed pursuant to a prescription/order

Child-resistant and customized patient medication packaging

- 1.4.8 Conditions under which a pharmaceutical product, preparation, or device may not be dispensed  
Adulteration, misbranding, and dating

- 1.4.9 Requirements for compounding pharmaceutical products

Environmental controls, release checks and testing, beyond use date (BUD), initial and ongoing training

- 1.4.10 Requirements for emergency kits

Supplying, maintenance, access, security, and inventory

- 1.4.11 Conditions regarding the return and/or reuse of pharmaceutical products, preparations, bulk drug substances/excipients, and devices

Charitable programs, cancer or other repository programs, previously dispensed, and from "will call" areas of pharmacies

- 1.4.12 Procedures and requirements for systems or processes whereby a non-pharmacist may obtain pharmaceutical products, preparations, bulk drug substances/excipients, and devices

Pyxis (vending), after hour's access, telepharmacies, and secure automated patient drug retrieval centers

- 1.4.13 Procedures and requirements for establishing and operating central processing and central fill pharmacies

Remote order verification

- 1.4.14 Requirements for reporting to PMP, accessing information in a PMP and the maintenance of security and confidentiality of information accessed in PMPs

- 1.4.15 Requirements when informed consent must be obtained from the patient and/or a duty to warn must be executed

Collaborative practice and investigational drug therapy

**1.5 Conditions for making an offer to counsel or counseling appropriate patients, including the requirements for documentation**

1.5.1 Requirements to counsel or to make an offer to counsel

1.5.2 Required documentation necessary for counseling

**1.6 Requirements for the distribution and/or dispensing of non-prescription pharmaceutical products, including controlled substances**

1.6.1 Requirements for the labeling of non-prescription pharmaceutical products and devices

1.6.2 Requirements for the packaging and repackaging of non-prescription pharmaceutical products and devices

1.6.3 Requirements for the distribution and/or dispensing of poisons, restricted, non-prescription pharmaceutical products, and other restricted materials or devices

Pseudoephedrine, dextromethorphan, emergency contraception, and behind the counter products as appropriate

**1.7 Procedures for keeping records of information related to pharmacy practice, pharmaceutical products and patients, including requirements for protecting patient confidentiality**

1.7.1 Requirements pertaining to controlled substance inventories

1.7.2 Content, maintenance, storage, and reporting requirements for records required in the operation of a pharmacy

Prescription filing systems, computer systems and backups, and prescription monitoring programs

1.7.3 Requirements for protecting patient confidentiality and confidential health records

HIPAA requirements and conditions for access and use of information

**1.8 Requirements for handling hazardous materials such as described in USP <800>**

1.8.1 Requirements for appropriate disposal of hazardous materials

1.8.2 Requirements for training regarding hazardous materials

Reverse distributors, quarantine procedures, comprehensive safety programs, Material Safety Data Sheets

1.8.3 Environmental controls addressing the proper storage, handling, and disposal of hazardous materials

Ventilation controls, personal protective equipment, work practices, and reporting

1.8.4 Methods for the compounding, dispensing and administration of hazardous materials

All hazardous materials including sterile and non-sterile compounding

## **Area 2 Licensure, Registration, Certification, and Operational Requirements (15%)**

### **2.1 Qualifications, application procedure, necessary examinations, and internship for licensure, registration, or certification of individuals engaged in the storage, distribution, and/or dispensing of pharmaceutical products (prescription and non-prescription)**

#### 2.1.1 Requirements for special or restricted licenses, registration, authorization, or certificates

Pharmacists, pharmacist preceptors, pharmacy interns, pharmacy technicians, controlled substance registrants, and under specialty pharmacist licenses (Nuclear, Consultant etc.)

#### 2.1.2 Standards of practice related to the practice of pharmacy

Quality assurance programs (including peer review), changing dosage forms, therapeutic substitution, error reporting, public health reporting requirements (such as notification of potential terrorist event, physical abuse, and treatment for tuberculosis), and issues of conscience and maintaining competency

#### 2.1.3 Requirements for classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted individual

#### 2.1.4 Requirements for reporting to, and participating in, programs addressing the inability of an individual licensed, registered, or certified by the Board to engage in the practice of pharmacy with reasonable skill and safety

Impairment caused by the use of alcohol, drugs, chemicals, or other materials, or mental, physical, or psychological conditions

### **2.2 Requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity**

#### 2.2.1 Requirements for registration, license, certification, or permitting of a practice setting

In-state pharmacies, out-of-state pharmacies, specialty pharmacies, controlled substance registrants, wholesalers, distributors, manufacturers/repackagers, computer services providers, and internet pharmacies

#### 2.2.2 Requirements for an inspection of a licensed, registered, certified, or permitted practice setting

#### 2.2.3 Requirements for the renewal or reinstatement of a license, registration, certificate, or permit of a practice setting

#### 2.2.4 Classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted practice setting

### **2.3 Operational requirements for a registered, licensed, certified, or permitted practice setting**

#### 2.3.1 Requirements for the operation of a pharmacy or practice setting that is not directly related to the dispensing of pharmaceutical products

Issues related to space, equipment, advertising and signage, security (including temporary absences of the pharmacist), policies and procedures, libraries and references (including veterinary), and the display of licenses

- 2.3.2 Requirements for the possession, storage, and handling of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances

Investigational new drugs, repackaged or resold drugs, sample pharmaceuticals, recalls, and outdated pharmaceutical products

- 2.3.3 Requirements for delivery of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances

Issues related to identification of the person accepting delivery of a drug, use of the mail, contract delivery, use of couriers, use of pharmacy employees, use of kiosks, secure mail boxes, script centers, use of vacuum tubes, and use of drive-up windows

### **Area 3 General Regulatory Processes (2%)**

#### **3.1 Application of regulations**

- 3.1.1 Laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, (prescription and non-prescription), including controlled substances

Food, Drug, and Cosmetic Act(s) and Regulations, the Controlled Substances Act(s) and Regulations, OBRA 90's Title IV Requirements, Practice Acts and Rules, other statutes and regulations, including but not limited to, dispensing of methadone, child-resistant packaging, tamper resistant packaging, drug paraphernalia, drug samples, pharmacist responsibilities in Medicare-certified skilled-nursing facilities, NDC numbers, and schedules of controlled substances



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## North American Pharmacist Licensure Examination (NAPLEX™)

May 1 – August 31, 2015

School Reports  
Interpretation of Scores  
Frequency Distribution of Scaled Scores  
Cumulative Record (since January 2000)

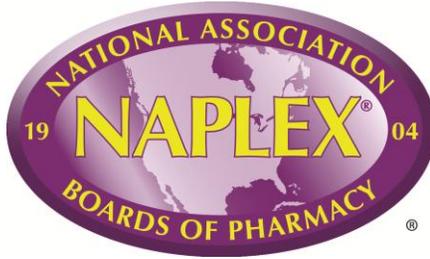
November 18, 2015

## **North American Pharmacist Licensure Examination (NAPLEX™)**

This computer adaptive competency assessment is administered by the National Association of Boards of Pharmacy (NABP). The examination blueprint is designed to assess the applicant's competency in basic pharmacy practice and is recognized by pharmacy regulatory authorities in all of the states and territories within the USA. The examination is administered via an open window process; applicants may schedule the examination at a local testing center at any time following approval by the state board and receipt of an Authorization to Test (ATT) document from NABP. Individual scores are available to applicants via secure web posting approximately 7-10 days following the examination. Summary reports are provided to the state boards on a calendar trimester basis.

### *Table of Contents*

Current Trimester Report for ULM College of Pharmacy	03
Cumulative Report (since January 2000) for ULM College of Pharmacy	11
Current Trimester Report for Xavier College of Pharmacy	15
Cumulative Report (since January 2000) for Xavier College of Pharmacy	25



**North American Pharmacist Licensure Examination® (NAPLEX) ®  
School Summary Report**

**Test Window:** May 1, 2015 - August 31, 2015

**School Name:** University Louisiana Monroe

This NAPLEX score report consists of two levels of scores: school-aggregated scores and individual candidate scores. Summary information is provided separately for first-time examinees from ACPE schools/colleges and for all examinees, regardless of repeater status and/or the educational institution.

Tables 1 and 2 contain school-specific as well as national pass rate information and mean area scores for each of the three main NAPLEX competency areas:

- Area 1 - Assess Pharmacotherapy to Assure Safe and Effective Therapeutic Outcomes (56%),
- Area 2 - Assess Safe and Accurate Preparation and Dispensing of Medications (33%), and
- Area 3 - Assess, Recommend and Provide Health Care Information that Promotes Public Health (11%).

**Table 1 First-Time Candidates, ACPE-Accredited Programs Only**

	Candidates	Pass Rate %	Total Scaled Score Mean	Standard Deviation	Area 1 Scaled Score Mean	Standard Deviation	Area 2 Scaled Score Mean	Standard Deviation	Area 3 Scaled Score Mean	Standard Deviation
<b>School</b>	78	89.74	94.62	15.99	11.85	1.11	12.08	1.37	11.97	1.82
<b>State</b>	197	89.34	96.08	17.23	12.11	1.17	12.04	1.36	12.09	1.74
<b>National</b>	12507	93.86	101.53	15.89	12.47	1.20	12.47	1.37	12.54	1.78

**Candidates who did not answer enough questions to receive a score are reflected in pass rate data as a fail but are not included in mean scaled score data.**

**Table 2 All Candidates**

	Candidates	Pass Rate %	Total Scaled Score Mean	Standard Deviation	Area 1 Scaled Score Mean	Standard Deviation	Area 2 Scaled Score Mean	Standard Deviation	Area 3 Scaled Score Mean	Standard Deviation
<b>School</b>	79	89.87	94.43	15.97	11.84	1.10	12.06	1.36	11.99	1.81
<b>State</b>	204	88.24	95.51	17.57	12.08	1.17	12.01	1.36	12.04	1.76
<b>National</b>	13086	92.29	100.46	17.08	12.40	1.25	12.41	1.41	12.48	1.81

**Candidates who did not answer enough questions to receive a score are reflected in pass rate data as a fail but are not included in mean scaled score data.**

### Interpretation and Uses of Candidate Scores

At the candidate level, two sets of scores are produced: an overall, composite scaled score and individual area scores. Only overall scores are used to make pass/fail decisions. Area scores are intended to provide insight into areas of strength and weakness and can be used as a tool for self-assessment and subsequent remediation.

Area scores are numerical performance indicators for each of the three main competency areas of the NAPLEX. There are a total of three area scores, one per main competency area. Area scores are always reported on a scale of [6, 18], where a score of 6 is the lowest possible score and a score of 18 is the highest possible score. This reporting scale does not have a number-correct interpretation. In other words, a score of 6 does not mean that the candidate answered 6 questions correctly. Instead, area scores are computed from ability estimates that are created for sets of items that map to each of the three content areas.

Reference Tables 3 and 4 contain summative data for all first-time test takers from ACPE-accredited programs (2014). In table 3, scaled scores were ordered and divided into four equi-sized bins for the computation of quartile values. The column labeled "Top (1st) Quartile" applies to the highest scoring group of examinees. The column labeled "Bottom (4th) Quartile" applies to the lowest scoring group. Table 4 contains similar information but is based on pass/fail status of examinees.

**Reference Table 3 NAPLEX  
Mean Area Score Summary (2014) by Quartiles**

	Top (1st) Quartile	2nd Quartile	3rd Quartile	Bottom (4th) Quartile
Mean Area 1 Scaled Score	13.75	12.67	11.89	10.76
Mean Area 2 Scaled Score	13.80	12.74	11.97	10.80
Mean Area 3 Scaled Score	13.89	12.92	12.20	11.12
Mean Overall Scaled Score	118.80	106.64	95.26	74.28
Scaled Score Range	[112, 138]	[101, 112]	[88, 101]	[5, 88]
# Examinees per bin	3,968	3,968	3,968	3,968

**Reference Table 4 NAPLEX  
Mean Area Score Summary (2014) by Pass/Fail Status**

	Pass	Fail
Mean Area 1 Scaled Score	12.49	10.13
Mean Area 2 Scaled Score	12.55	10.19
Mean Area 3 Scaled Score	12.75	10.48
Mean Overall Scaled Score	102.71	61.55
Scaled Score Range	[75, 138]	[5, 74]
# Examinees per bin	14,343	1,529

## Table 5 Candidate Summary Report

**Test Window:** May 1, 2015 - August 31, 2015

Candidate	Pass/Fail	Total Scaled Score	Area 1 Scaled Score	Area 2 Scaled Score	Area 3 Scaled Score	Test Date	Graduation Date	First Attempt
1	Pass	93	12	11	10	08/31/2015	05/09/2015	Y
2	Pass	82	11	12	11	08/10/2015	05/09/2015	Y
3	Pass	89	11	12	10	08/06/2015	05/09/2015	Y
4	Pass	103	12	12	12	08/05/2015	05/09/2015	Y
5	Pass	84	11	11	10	08/03/2015	05/09/2015	Y
6	Pass	95	12	12	12	08/03/2015	05/09/2015	Y
7	Pass	109	13	13	12	08/01/2015	05/09/2015	Y
8	Fail	71	10	11	13	07/29/2015	05/09/2015	Y
9	Pass	123	14	16	15	07/28/2015	05/09/2015	Y
10	Pass	91	12	12	9	07/28/2015	05/09/2015	Y
11	Pass	76	11	10	10	07/28/2015	05/09/2015	Y
12	Pass	107	13	11	14	07/28/2015	05/09/2015	Y
13	Pass	112	13	14	11	07/28/2015	05/09/2015	Y
14	Pass	105	12	13	13	07/28/2015	05/09/2015	Y
15	Pass	97	11	14	12	07/27/2015	05/09/2015	Y
16	Pass	90	12	11	13	07/27/2015	05/09/2015	Y
17	Pass	76	11	10	11	07/27/2015	05/09/2015	Y
18	Pass	104	12	13	11	07/25/2015	05/09/2015	Y
19	Pass	92	12	12	9	07/25/2015	05/09/2015	Y
20	Pass	97	12	12	11	07/25/2015	05/09/2015	Y
21	Pass	88	11	11	15	07/24/2015	05/09/2015	Y
22	Fail	70	10	11	10	07/23/2015	05/09/2015	Y
23	Pass	107	13	13	14	07/22/2015	05/09/2015	Y
24	Pass	80	11	10	11	07/22/2015	05/09/2015	Y
25	Pass	116	13	15	12	07/22/2015	05/09/2015	Y
26	Pass	100	12	11	14	07/22/2015	05/09/2015	Y
27	Pass	87	11	12	12	07/20/2015	05/09/2015	Y
28	Pass	112	13	14	15	07/17/2015	05/09/2015	Y
29	Fail	63	10	10	12	07/17/2015	05/09/2015	Y
30	Pass	101	12	12	11	07/16/2015	05/09/2015	Y
31	Pass	101	12	12	13	07/16/2015	05/09/2015	Y
32	Pass	117	14	12	11	07/16/2015	05/09/2015	Y
33	Pass	106	13	12	13	07/16/2015	05/09/2015	Y
34	Pass	102	12	13	14	07/16/2015	05/09/2015	Y
35	Pass	105	12	14	12	07/16/2015	05/09/2015	Y
36	Fail	50	10	10	9	07/16/2015	05/09/2015	Y
37	Pass	94	11	13	11	07/15/2015	05/09/2015	Y
38	Pass	81	11	11	10	07/15/2015	05/09/2015	Y
39	Fail	62	10	10	11	07/10/2015	05/09/2015	Y
40	Pass	80	11	11	10	07/10/2015	05/09/2015	Y
41	Pass	93	11	12	12	07/09/2015	05/09/2015	Y
42	Pass	102	11	15	14	07/09/2015	05/09/2015	Y
43	Pass	106	12	12	14	07/09/2015	05/09/2015	Y
44	Pass	104	12	14	12	07/09/2015	05/09/2015	Y

**Table 5 Candidate Summary Report**

<b>Candidate</b>	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Area 1 Scaled Score</b>	<b>Area 2 Scaled Score</b>	<b>Area 3 Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>
45	Pass	102	12	12	12	07/08/2015	05/09/2015	Y
46	Pass	102	12	13	11	07/08/2015	05/09/2015	Y
47	Pass	116	14	13	14	07/08/2015	05/09/2015	Y
48	Pass	100	12	12	13	07/01/2015	05/09/2015	Y
49	Pass	104	13	12	13	06/29/2015	05/09/2015	Y
50	Fail	72	10	11	11	06/29/2015	05/09/2015	Y
51	Pass	93	14	11	18	06/29/2015	05/09/2015	Y
52	Pass	108	13	13	10	06/29/2015	05/09/2015	Y
53	Pass	112	13	14	13	06/27/2015	05/09/2015	Y
54	Pass	86	11	12	7	06/27/2015	05/09/2015	Y
55	Pass	84	11	11	12	06/27/2015	05/09/2015	Y
56	Pass	80	11	12	9	06/26/2015	05/09/2015	Y
57	Pass	76	10	12	12	06/26/2015	05/09/2015	Y
58	Pass	109	13	13	13	06/25/2015	05/09/2015	Y
59	Pass	92	11	12	13	06/25/2015	05/09/2015	Y
60	Fail	59	10	10	10	06/24/2015	05/09/2015	Y
61	Pass	81	11	11	12	06/24/2015	05/09/2015	Y
62	Pass	83	11	11	13	06/20/2015	05/09/2015	Y
63	Fail	46	9	9	10	06/20/2015	05/09/2015	Y
64	Pass	98	12	13	12	06/20/2015	05/09/2015	Y
65	Pass	92	12	10	14	06/20/2015	05/09/2015	Y
66	Pass	101	12	12	13	06/20/2015	05/09/2015	Y
67	Pass	95	12	12	10	06/20/2015	05/09/2015	Y
68	Pass	108	13	13	12	06/19/2015	05/09/2015	Y
69	Pass	89	12	11	12	06/19/2015	05/09/2015	Y
70	Pass	103	13	12	10	06/15/2015	05/09/2015	Y
71	Pass	110	13	14	11	06/12/2015	05/09/2015	Y
72	Pass	108	13	13	14	06/11/2015	05/09/2015	Y
73	Pass	94	12	11	14	06/05/2015	05/09/2015	Y
74	Pass	112	13	13	12	06/04/2015	05/09/2015	Y
75	Pass	111	13	12	12	06/02/2015	05/09/2015	Y
76	Pass	112	13	13	13	06/02/2015	05/09/2015	Y
77	Pass	120	13	15	16	06/02/2015	05/09/2015	Y
78	Pass	99	12	12	12	06/02/2015	05/09/2015	Y
79	Pass	80	11	11	13	06/02/2015	12/06/2014	N

**National Statistics for All NAPLEX Candidates**

**Mean Scaled Score: 100.46**  
**Standard Deviation: 17.08**  
**Range: 3 - 138**  
**Passing Rate (%): 92.29**

**National Statistics for First-Time NAPLEX Candidates**

**Mean Scaled Score: 101.53**  
**Standard Deviation: 15.89**  
**Range: 3 - 138**  
**Passing Rate (%): 93.86**

The following tables are scaled score frequency distributions for NAPLEX candidates.  
 Candidates who did not answer enough questions to receive a score are not reflected in the frequency distributions.

**Table 6 National Frequency Distribution of Scaled Scores**

Based on Total Tests Administered (N = 13086 )

Test Window: May 1, 2015 - August 31, 2015

Scaled Score	Frequency	Cumulative Percent of the Upper Limit of the Interval
0 - 4	3	0.0%
5 - 9	4	0.1%
10 - 14	6	0.1%
15 - 19	2	0.1%
20 - 24	5	0.2%
25 - 29	7	0.2%
30 - 34	13	0.3%
35 - 39	22	0.5%
40 - 44	33	0.7%
45 - 49	37	1.0%
50 - 54	63	1.5%
55 - 59	95	2.2%
60 - 64	160	3.4%
65 - 69	222	5.1%
70 - 74	308	7.5%
75 - 79	492	11.3%
80 - 84	658	16.3%
85 - 89	909	23.3%
90 - 94	1093	31.6%
95 - 99	1342	41.9%
100 - 104	1515	53.5%
105 - 109	1639	66.1%
110 - 114	1745	79.4%
115 - 119	1290	89.3%
120 - 124	890	96.1%
125 - 129	395	99.2%
130 - 134	100	99.9%
135 - 139	9	100.0%
140 - 144	0	100.0%
145 - 150	0	100.0%

**Table 7 National Frequency Distribution of Scaled Scores**

Based on First-Time Candidates from ACPE-Accredited Programs (N = 12507 )

Test Window: May 1, 2015 - August 31, 2015

<b>Scaled Score</b>	<b>Frequency</b>	<b>Cumulative Percent of the Upper Limit of the Interval</b>
0 - 4	1	0.0%
5 - 9	1	0.0%
10 - 14	0	0.0%
15 - 19	0	0.0%
20 - 24	1	0.0%
25 - 29	2	0.0%
30 - 34	4	0.1%
35 - 39	12	0.2%
40 - 44	18	0.3%
45 - 49	18	0.5%
50 - 54	44	0.8%
55 - 59	65	1.3%
60 - 64	131	2.4%
65 - 69	182	3.8%
70 - 74	266	6.0%
75 - 79	433	9.4%
80 - 84	613	14.3%
85 - 89	854	21.2%
90 - 94	1052	29.6%
95 - 99	1301	40.0%
100 - 104	1489	52.0%
105 - 109	1611	64.9%
110 - 114	1728	78.7%
115 - 119	1279	89.0%
120 - 124	876	96.0%
125 - 129	394	99.1%
130 - 134	100	99.9%
135 - 139	9	100.0%
140 - 144	0	100.0%
145 - 150	0	100.0%

**North American Pharmacist Licensure Examination (NAPLEX)**

**University of Louisiana at Monroe**

	<b>2000</b>			<b>2001</b>			<b>2002</b>			<b>2003</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	76	47	18	40	30	10	13	62	27	10	70	24
School Average Score:	96.51	91.62	88.61	88.93	87.30	87.00	82.85	100.24	89.56	78.40	101.44	92.50
State Average Score:	96.75	88.52	86.05	84.66	93.82	82.05	75.50	101.46	87.48	77.50	99.40	87.33
National Average Score:	91.78	99.86	91.21	90.25	101.70	90.50	90.81	101.21	90.02	91.50	101.40	89.40
School Pass Rate:	96.05	82.98	88.89	85.00	90.00	90.00	84.62	85.48	77.78	60.00	95.71	87.50
State Pass Rate:	92.50	78.57	77.27	75.86	89.29	70.00	50.00	85.90	70.37	62.50	94.90	80.00
National Pass Rate:	82.95	92.05	83.04	81.07	94.38	83.69	81.52	93.76	81.73	82.77	93.84	79.55
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	71	33	9	37	20	6	13	61	20	2	64	16
School Average Score:	97.13	96.00	94.00	88.32	86.90	90.67	82.85	100.44	92.80	73.50	102.69	98.56
State Average Score:	97.49	93.61	87.77	88.78	95.92	85.93	81.89	103.71	91.15	74.00	100.41	92.38
National Average Score:	96.51	101.85	96.48	94.54	103.35	94.22	95.13	103.00	94.62	97.39	103.38	95.88
School Pass Rate:	95.77	96.97	100.00	83.78	85.00	100.00	84.62	85.25	75.00	50.00	96.88	100.00
State Pass Rate:	94.59	93.18	84.62	83.33	91.84	73.33	77.78	90.28	70.00	66.67	95.65	90.48
National Pass Rate:	91.44	95.44	91.39	87.91	96.75	90.10	89.27	96.74	88.52	91.47	96.54	89.64

**North American Pharmacist Licensure Examination (NAPLEX)**

**University of Louisiana at Monroe**

	<b>2004</b>			<b>2005</b>			<b>2006</b>			<b>2007</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	3	64	18	9	72	17	2	60	10	3	90	23
School Average Score:	85.67	105.30	94.83	82.67	104.17	101.65	98.00	113.17	95.80	107.67	117.27	101.57
State Average Score:	81.33	103.47	96.71	95.00	101.77	92.50	86.67	111.87	96.07	88.00	117.29	94.73
National Average Score:	92.13	102.16	91.70	91.32	104.85	87.72	86.89	107.02	93.18	89.95	113.33	94.18
School Pass Rate:	100.00	96.88	94.44	88.89	90.28	94.12	100.00	93.33	80.00	100.00	95.56	78.26
State Pass Rate:	83.33	96.12	100.00	100.00	87.83	78.57	77.78	89.17	79.31	63.64	95.52	74.51
National Pass Rate:	83.22	95.11	84.79	82.88	89.15	71.73	68.82	90.52	77.07	71.38	94.47	78.76
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	2	58	17	5	70	11	2	58	4	3	89	19
School Average Score:	87.00	107.34	93.47	81.40	105.09	110.09	98.00	114.59	125.00	107.67	117.66	103.05
State Average Score:	84.00	105.61	99.73	101.50	103.64	98.94	93.33	112.95	95.41	103.40	118.18	95.00
National Average Score:	100.14	104.14	96.60	98.84	107.67	95.89	97.18	110.34	99.96	102.16	116.00	102.19
School Pass Rate:	100.00	100.00	94.12	80.00	91.43	100.00	100.00	94.83	100.00	100.00	95.51	78.95
State Pass Rate:	100.00	100.00	100.00	100.00	90.09	88.89	100.00	90.38	70.59	100.00	96.69	76.74
National Pass Rate:	95.07	97.38	92.22	91.31	92.86	82.12	81.12	94.49	84.74	84.09	97.23	88.12

**North American Pharmacist Licensure Examination (NAPLEX)**

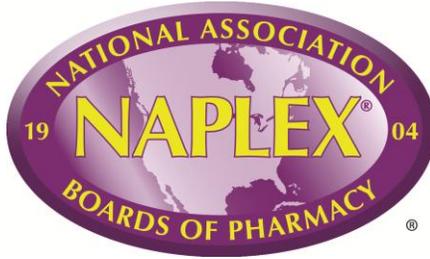
**University of Louisiana at Monroe**

	<b>2008</b>			<b>2009</b>			<b>2010</b>			<b>2011</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	11	98	12	6	91	8	3	67	6	2	91	9
Mean Scaled Score - School	94.73	106.39	93.83	97.83	113.84	77.25	98.00	99.97	93.17	67.50	97.40	87.22
Mean Scaled Score - State	93.70	103.31	95.41	94.80	108.26	84.32	83.15	94.22	80.13		99.66	85.27
Mean Scaled Score - National	96.76	112.08	96.61	93.72	112.51	93.62	84.75	101.11	84.90	83.97	103.27	88.08
School Pass Rate:	90.91	92.86	83.33	83.33	95.60	50.00	100.00	95.52	100.00	0.00	89.01	77.78
State Pass Rate:	90.00	90.34	82.76	80.00	92.64	63.16	61.54	83.24	65.00		90.81	73.17
National Pass Rate:	83.11	95.48	81.96	76.40	95.03	78.20	65.07	92.39	72.20	67.85	94.16	76.57
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	3	97	5	3	88	3	0	67	2	1	87	3
Mean Scaled Score - School	110.33	106.76	95.80	93.00	115.34	78.33	0.00	99.97	97.00	62.00	99.39	84.67
Mean Scaled Score - State	96.00	104.42	95.82	86.00	108.80	84.10	92.00	94.46	90.75		100.88	83.70
Mean Scaled Score - National	106.63	114.11	103.62	106.27	114.65	102.87	100.12	103.06	94.26	96.99	105.03	96.71
School Pass Rate:	100.00	93.81	80.00	66.67	96.59	33.33	0.00	95.52	100.00	0.00	93.10	66.67
State Pass Rate:	83.33	92.35	82.35	57.14	93.04	60.00	66.67	84.15	83.33		93.18	74.07
National Pass Rate:	92.24	97.44	90.66	90.76	97.50	89.51	88.38	95.31	86.71	87.50	96.57	89.24

**North American Pharmacist Licensure Examination (NAPLEX)**

**University of Louisiana at Monroe**

	<b>2012</b>			<b>2013</b>			<b>2014</b>			<b>2015</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	6	80	17	3	40	7	1	68	11	4	79	
Mean Scaled Score - School	75.33	97.14	85.41	92.00	100.45	88.43	101.00	95.10	82.27	82.00	94.93	
Mean Scaled Score - State	81.25	98.42	86.95	77.25	98.66	86.88	73.85	96.45	80.88	82.15	95.51	
Mean Scaled Score - National	83.15	102.81	88.15	80.17	102.78	87.03	80.22	101.71	89.22	83.84	100.46	
School Pass Rate:	83.33	92.50	82.35	100.00	90.00	100.00	100.00	89.71	63.64	50.00	89.87	
State Pass Rate:	68.75	93.82	76.19	55.56	92.95	81.82	53.85	90.75	70.59	69.23	88.24	
National Pass Rate:	68.33	95.21	77.86	61.07	94.65	75.91	63.24	93.86	79.77	67.06	92.29	
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	2	80	9	3	38	4	1	68	3	1	78	
Mean Scaled Score - School	49.50	97.14	87.11	92.00	101.68	92.00	101.00	95.10	92.00	74.00	94.62	
Mean Scaled Score - State	84.00	99.47	91.00	80.75	99.30	88.33	85.00	96.96	83.34	77.00	96.08	
Mean Scaled Score - National	94.87	104.13	95.75	92.48	104.02	92.69	90.89	102.80	93.94	94.01	101.53	
School Pass Rate:	50.00	92.50	77.78	100.00	92.11	100.00	100.00	89.71	66.67	0.00	89.74	
State Pass Rate:	75.00	95.35	72.73	75.00	94.08	83.33	100.00	92.12	73.68	33.33	89.34	
National Pass Rate:	87.69	97.19	90.14	85.14	96.57	84.46	83.15	95.61	85.36	84.96	93.86	



**North American Pharmacist Licensure Examination® (NAPLEX) ®  
School Summary Report**

**Test Window:** May 1, 2015 - August 31, 2015

**School Name:** Xavier University of Louisiana

This NAPLEX score report consists of two levels of scores: school-aggregated scores and individual candidate scores. Summary information is provided separately for first-time examinees from ACPE schools/colleges and for all examinees, regardless of repeater status and/or the educational institution.

Tables 1 and 2 contain school-specific as well as national pass rate information and mean area scores for each of the three main NAPLEX competency areas:

- Area 1 - Assess Pharmacotherapy to Assure Safe and Effective Therapeutic Outcomes (56%),
- Area 2 - Assess Safe and Accurate Preparation and Dispensing of Medications (33%), and
- Area 3 - Assess, Recommend and Provide Health Care Information that Promotes Public Health (11%).

**Table 1 First-Time Candidates, ACPE-Accredited Programs Only**

	Candidates	Pass Rate %	Total Scaled Score Mean	Standard Deviation	Area 1 Scaled Score Mean	Standard Deviation	Area 2 Scaled Score Mean	Standard Deviation	Area 3 Scaled Score Mean	Standard Deviation
<b>School</b>	137	87.59	97.31	18.34	12.34	1.26	12.01	1.38	12.04	1.77
<b>State</b>	197	89.34	96.08	17.23	12.11	1.17	12.04	1.36	12.09	1.74
<b>National</b>	12507	93.86	101.53	15.89	12.47	1.20	12.47	1.37	12.54	1.78

**Candidates who did not answer enough questions to receive a score are reflected in pass rate data as a fail but are not included in mean scaled score data.**

**Table 2 All Candidates**

	Candidates	Pass Rate %	Total Scaled Score Mean	Standard Deviation	Area 1 Scaled Score Mean	Standard Deviation	Area 2 Scaled Score Mean	Standard Deviation	Area 3 Scaled Score Mean	Standard Deviation
<b>School</b>	141	85.11	96.03	19.77	12.26	1.34	11.95	1.42	11.97	1.80
<b>State</b>	204	88.24	95.51	17.57	12.08	1.17	12.01	1.36	12.04	1.76
<b>National</b>	13086	92.29	100.46	17.08	12.40	1.25	12.41	1.41	12.48	1.81

**Candidates who did not answer enough questions to receive a score are reflected in pass rate data as a fail but are not included in mean scaled score data.**

### Interpretation and Uses of Candidate Scores

At the candidate level, two sets of scores are produced: an overall, composite scaled score and individual area scores. Only overall scores are used to make pass/fail decisions. Area scores are intended to provide insight into areas of strength and weakness and can be used as a tool for self-assessment and subsequent remediation.

Area scores are numerical performance indicators for each of the three main competency areas of the NAPLEX. There are a total of three area scores, one per main competency area. Area scores are always reported on a scale of [6, 18], where a score of 6 is the lowest possible score and a score of 18 is the highest possible score. This reporting scale does not have a number-correct interpretation. In other words, a score of 6 does not mean that the candidate answered 6 questions correctly. Instead, area scores are computed from ability estimates that are created for sets of items that map to each of the three content areas.

Reference Tables 3 and 4 contain summative data for all first-time test takers from ACPE-accredited programs (2014). In table 3, scaled scores were ordered and divided into four equi-sized bins for the computation of quartile values. The column labeled "Top (1st) Quartile" applies to the highest scoring group of examinees. The column labeled "Bottom (4th) Quartile" applies to the lowest scoring group. Table 4 contains similar information but is based on pass/fail status of examinees.

**Reference Table 3 NAPLEX  
Mean Area Score Summary (2014) by Quartiles**

	Top (1st) Quartile	2nd Quartile	3rd Quartile	Bottom (4th) Quartile
Mean Area 1 Scaled Score	13.75	12.67	11.89	10.76
Mean Area 2 Scaled Score	13.80	12.74	11.97	10.80
Mean Area 3 Scaled Score	13.89	12.92	12.20	11.12
Mean Overall Scaled Score	118.80	106.64	95.26	74.28
Scaled Score Range	[112, 138]	[101, 112]	[88, 101]	[5, 88]
# Examinees per bin	3,968	3,968	3,968	3,968

**Reference Table 4 NAPLEX  
Mean Area Score Summary (2014) by Pass/Fail Status**

	Pass	Fail
Mean Area 1 Scaled Score	12.49	10.13
Mean Area 2 Scaled Score	12.55	10.19
Mean Area 3 Scaled Score	12.75	10.48
Mean Overall Scaled Score	102.71	61.55
Scaled Score Range	[75, 138]	[5, 74]
# Examinees per bin	14,343	1,529

## Table 5 Candidate Summary Report

**Test Window:** May 1, 2015 - August 31, 2015

Candidate	Pass/Fail	Total Scaled Score	Area 1 Scaled Score	Area 2 Scaled Score	Area 3 Scaled Score	Test Date	Graduation Date	First Attempt
1	Pass	78	11	11	10	08/27/2015	05/09/2015	Y
2	Fail	74	11	11	10	08/27/2015	05/09/2015	Y
3	Pass	96	12	12	16	08/27/2015	05/09/2015	Y
4	Fail	63	11	10	9	08/26/2015	05/09/2015	Y
5	Pass	98	12	12	11	08/25/2015	05/09/2015	Y
6	Pass	114	14	13	12	08/24/2015	05/09/2015	Y
7	Pass	83	11	12	11	08/20/2015	05/09/2015	Y
8	Pass	99	12	12	11	08/19/2015	05/09/2015	Y
9	Fail	60	10	10	9	08/17/2015	05/09/2015	Y
10	Pass	88	12	10	12	08/14/2015	05/09/2015	Y
11	Pass	88	12	11	12	08/14/2015	05/09/2015	Y
12	Pass	105	12	13	11	08/14/2015	05/09/2015	Y
13	Pass	87	11	12	12	08/14/2015	05/09/2015	Y
14	Fail	73	11	10	10	08/13/2015	05/09/2015	Y
15	Pass	86	12	11	11	08/12/2015	05/09/2015	Y
16	Pass	125	15	14	13	08/11/2015	05/09/2015	Y
17	Pass	101	12	12	11	08/11/2015	05/09/2015	Y
18	Pass	110	13	13	10	08/10/2015	05/09/2015	Y
19	Pass	114	13	13	15	08/07/2015	05/09/2015	Y
20	Pass	119	14	14	12	08/07/2015	05/09/2015	Y
21	Pass	98	11	13	14	08/06/2015	05/09/2015	Y
22	Pass	82	11	12	9	08/06/2015	05/09/2015	Y
23	Pass	118	14	15	9	08/06/2015	05/09/2015	Y
24	Pass	94	12	11	11	08/06/2015	05/09/2015	Y
25	Pass	120	14	13	14	08/06/2015	05/09/2015	Y
26	Pass	93	13	11	10	08/05/2015	05/09/2015	Y
27	Pass	117	14	14	12	08/05/2015	05/09/2015	Y
28	Fail	51	10	9	11	08/05/2015	05/09/2015	Y
29	Pass	115	14	12	15	08/05/2015	05/09/2015	Y
30	Pass	91	12	10	10	08/05/2015	05/09/2015	Y
31	Pass	115	13	13	14	08/03/2015	05/09/2015	Y
32	Pass	102	12	13	12	08/01/2015	05/09/2015	Y
33	Pass	106	13	13	12	07/30/2015	05/09/2015	Y
34	Pass	110	12	14	14	07/30/2015	05/09/2015	Y
35	Pass	98	12	12	13	07/30/2015	05/09/2015	Y
36	Pass	83	12	11	10	07/29/2015	05/09/2015	Y
37	Pass	94	12	11	11	07/29/2015	05/09/2015	Y
38	Fail	62	12	10	10	07/29/2015	05/09/2015	Y
39	Pass	91	12	11	11	07/29/2015	05/09/2015	Y
40	Pass	97	13	10	13	07/29/2015	05/09/2015	Y
41	Pass	104	13	12	12	07/29/2015	05/09/2015	Y
42	Pass	98	13	12	10	07/29/2015	05/09/2015	Y
43	Pass	81	11	10	11	07/29/2015	05/09/2015	Y
44	Pass	94	12	12	10	07/29/2015	05/09/2015	Y

**Table 5 Candidate Summary Report**

<b>Candidate</b>	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Area 1 Scaled Score</b>	<b>Area 2 Scaled Score</b>	<b>Area 3 Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>
45	Pass	113	13	14	10	07/28/2015	05/09/2015	Y
46	Pass	117	14	13	12	07/28/2015	05/09/2015	Y
47	Pass	84	12	10	11	07/28/2015	05/09/2015	Y
48	Pass	121	14	14	14	07/28/2015	05/09/2015	Y
49	Pass	126	15	14	16	07/28/2015	05/09/2015	Y
50	Pass	92	11	13	12	07/28/2015	05/09/2015	Y
51	Pass	106	13	12	11	07/28/2015	05/09/2015	Y
52	Pass	104	12	13	12	07/28/2015	05/09/2015	Y
53	Pass	99	13	11	13	07/28/2015	05/09/2015	Y
54	Pass	100	12	13	12	07/28/2015	05/09/2015	Y
55	Pass	124	14	14	14	07/28/2015	05/09/2015	Y
56	Pass	113	13	14	11	07/28/2015	05/09/2015	Y
57	Pass	98	12	12	12	07/25/2015	05/09/2015	Y
58	Pass	87	12	11	10	07/25/2015	05/09/2015	Y
59	Pass	91	12	12	9	07/25/2015	05/09/2015	Y
60	Pass	76	11	11	15	07/25/2015	05/09/2015	Y
61	Pass	78	12	10	12	07/22/2015	05/09/2015	Y
62	Pass	108	12	15	11	07/21/2015	05/09/2015	Y
63	Pass	92	11	12	15	07/21/2015	05/09/2015	Y
64	Pass	111	13	12	14	07/21/2015	05/09/2015	Y
65	Pass	87	11	12	12	07/21/2015	05/09/2015	Y
66	Fail	33	9	8	10	07/21/2015	05/09/2015	Y
67	Pass	112	14	12	13	07/20/2015	05/09/2015	Y
68	Pass	99	12	12	12	07/20/2015	05/09/2015	Y
69	Fail	44	10	9	9	07/20/2015	05/09/2015	Y
70	Pass	121	14	14	14	07/20/2015	05/09/2015	Y
71	Pass	118	14	13	15	07/20/2015	05/09/2015	Y
72	Pass	99	12	12	13	07/20/2015	05/09/2015	Y
73	Pass	109	13	13	13	07/20/2015	05/09/2015	Y
74	Pass	104	12	13	13	07/20/2015	05/09/2015	Y
75	Pass	98	12	12	16	07/20/2015	05/09/2015	Y
76	Pass	83	11	12	11	07/20/2015	05/09/2015	Y
77	Pass	94	12	12	12	07/18/2015	05/09/2015	Y
78	Pass	112	13	14	14	07/18/2015	05/09/2015	Y
79	Pass	117	14	13	16	07/18/2015	05/09/2015	Y
80	Pass	86	11	13	11	07/18/2015	05/09/2015	Y
81	Pass	111	13	13	14	07/18/2015	05/09/2015	Y
82	Fail	72	11	10	11	07/18/2015	05/09/2015	Y
83	Pass	96	12	11	13	07/17/2015	05/09/2015	Y
84	Pass	106	13	13	12	07/17/2015	05/09/2015	Y
85	Fail	68	9	12	11	07/17/2015	05/09/2015	Y
86	Pass	114	14	13	10	07/17/2015	05/09/2015	Y
87	Pass	102	12	13	13	07/17/2015	05/09/2015	Y
88	Pass	122	14	14	14	07/17/2015	05/09/2015	Y

**Table 5 Candidate Summary Report**

<b>Candidate</b>	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Area 1 Scaled Score</b>	<b>Area 2 Scaled Score</b>	<b>Area 3 Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>
89	Pass	101	12	12	14	07/17/2015	05/09/2015	Y
90	Pass	84	11	11	12	07/17/2015	05/09/2015	Y
91	Fail	69	11	11	9	07/17/2015	05/09/2015	Y
92	Pass	89	12	11	11	07/17/2015	05/09/2015	Y
93	Fail	73	12	12	9	07/16/2015	05/09/2015	Y
94	Pass	85	11	11	14	07/16/2015	05/09/2015	Y
95	Pass	113	13	13	14	07/16/2015	05/09/2015	Y
96	Pass	104	13	12	12	07/16/2015	05/09/2015	Y
97	Pass	97	13	11	11	07/16/2015	05/09/2015	Y
98	Pass	95	12	11	12	07/16/2015	05/09/2015	Y
99	Pass	119	14	14	13	07/16/2015	05/09/2015	Y
100	Pass	87	11	11	12	07/14/2015	05/09/2015	Y
101	Pass	99	12	11	12	07/13/2015	05/09/2015	Y
102	Pass	94	12	12	10	07/13/2015	05/09/2015	Y
103	Pass	103	13	11	13	07/09/2015	05/09/2015	Y
104	Pass	112	13	13	14	07/09/2015	05/09/2015	Y
105	Pass	119	14	13	14	07/09/2015	05/09/2015	Y
106	Pass	106	14	11	11	07/08/2015	05/09/2015	Y
107	Pass	88	12	11	11	07/08/2015	05/09/2015	Y
108	Pass	123	14	15	15	07/08/2015	05/09/2015	Y
109	Pass	94	12	11	13	07/08/2015	05/09/2015	Y
110	Pass	111	13	13	11	07/08/2015	05/09/2015	Y
111	Pass	103	13	12	12	07/01/2015	05/09/2015	Y
112	Pass	100	12	12	11	06/29/2015	05/09/2015	Y
113	Pass	105	12	13	12	06/29/2015	05/09/2015	Y
114	Pass	92	13	10	10	06/29/2015	05/09/2015	Y
115	Pass	99	12	12	13	06/27/2015	05/09/2015	Y
116	Pass	120	15	11	15	06/27/2015	05/09/2015	Y
117	Pass	112	13	13	13	06/27/2015	05/09/2015	Y
118	Pass	107	12	13	13	06/27/2015	05/09/2015	Y
119	Pass	112	13	14	11	06/26/2015	05/09/2015	Y
120	Fail	55	10	9	11	06/26/2015	05/09/2015	Y
121	Pass	87	11	13	11	06/26/2015	05/09/2015	Y
122	Pass	110	13	13	13	06/25/2015	05/09/2015	Y
123	Pass	112	13	12	14	06/25/2015	05/09/2015	Y
124	Pass	118	14	13	14	06/24/2015	05/09/2015	Y
125	Fail	72	10	10	12	06/24/2015	05/09/2015	Y
126	Pass	85	11	12	10	06/22/2015	05/09/2015	Y
127	Pass	118	14	13	14	06/20/2015	05/09/2015	Y
128	Pass	119	14	14	13	06/19/2015	05/09/2015	Y
129	Pass	115	14	13	14	06/19/2015	05/09/2015	Y
130	Pass	121	14	14	13	06/18/2015	05/09/2015	Y
131	Pass	102	13	12	14	06/18/2015	05/09/2015	Y
132	Pass	115	14	12	14	06/18/2015	05/09/2015	Y

**Table 5 Candidate Summary Report**

<b>Candidate</b>	<b>Pass/Fail</b>	<b>Total Scaled Score</b>	<b>Area 1 Scaled Score</b>	<b>Area 2 Scaled Score</b>	<b>Area 3 Scaled Score</b>	<b>Test Date</b>	<b>Graduation Date</b>	<b>First Attempt</b>
133	Pass	104	13	11	12	06/15/2015	05/09/2015	Y
134	Pass	80	12	10	10	06/27/2015	05/05/2015	Y
135	Fail	71	10	11	11	07/22/2015	03/09/2015	Y
136	Fail	56	10	10	10	06/05/2015	06/28/2014	N
137	Fail	53	10	10	9	05/30/2015	06/28/2014	Y
138	Fail	51	11	10	8	06/23/2015	05/10/2014	N
139	Fail	74	11	10	12	05/07/2015	05/10/2014	N
140	Fail	28	7	9	9	06/05/2015	05/12/2012	N
141	Fail	57	10	10	9	07/24/2015	05/18/1986	Y

**National Statistics for All NAPLEX Candidates**

**Mean Scaled Score: 100.46**  
**Standard Deviation: 17.08**  
**Range: 3 - 138**  
**Passing Rate (%): 92.29**

**National Statistics for First-Time NAPLEX Candidates**

**Mean Scaled Score: 101.53**  
**Standard Deviation: 15.89**  
**Range: 3 - 138**  
**Passing Rate (%): 93.86**

The following tables are scaled score frequency distributions for NAPLEX candidates. Candidates who did not answer enough questions to receive a score are not reflected in the frequency distributions.

**Table 6 National Frequency Distribution of Scaled Scores**

Based on Total Tests Administered (N = 13086 )

Test Window: May 1, 2015 - August 31, 2015

Scaled Score	Frequency	Cumulative Percent of the Upper Limit of the Interval
0 - 4	3	0.0%
5 - 9	4	0.1%
10 - 14	6	0.1%
15 - 19	2	0.1%
20 - 24	5	0.2%
25 - 29	7	0.2%
30 - 34	13	0.3%
35 - 39	22	0.5%
40 - 44	33	0.7%
45 - 49	37	1.0%
50 - 54	63	1.5%
55 - 59	95	2.2%
60 - 64	160	3.4%
65 - 69	222	5.1%
70 - 74	308	7.5%
75 - 79	492	11.3%
80 - 84	658	16.3%
85 - 89	909	23.3%
90 - 94	1093	31.6%
95 - 99	1342	41.9%
100 - 104	1515	53.5%
105 - 109	1639	66.1%
110 - 114	1745	79.4%
115 - 119	1290	89.3%
120 - 124	890	96.1%
125 - 129	395	99.2%
130 - 134	100	99.9%
135 - 139	9	100.0%
140 - 144	0	100.0%
145 - 150	0	100.0%

**Table 7 National Frequency Distribution of Scaled Scores**

Based on First-Time Candidates from ACPE-Accredited Programs (N = 12507 )

Test Window: May 1, 2015 - August 31, 2015

Scaled Score	Frequency	Cumulative Percent of the Upper Limit of the Interval
0 - 4	1	0.0%
5 - 9	1	0.0%
10 - 14	0	0.0%
15 - 19	0	0.0%
20 - 24	1	0.0%
25 - 29	2	0.0%
30 - 34	4	0.1%
35 - 39	12	0.2%
40 - 44	18	0.3%
45 - 49	18	0.5%
50 - 54	44	0.8%
55 - 59	65	1.3%
60 - 64	131	2.4%
65 - 69	182	3.8%
70 - 74	266	6.0%
75 - 79	433	9.4%
80 - 84	613	14.3%
85 - 89	854	21.2%
90 - 94	1052	29.6%
95 - 99	1301	40.0%
100 - 104	1489	52.0%
105 - 109	1611	64.9%
110 - 114	1728	78.7%
115 - 119	1279	89.0%
120 - 124	876	96.0%
125 - 129	394	99.1%
130 - 134	100	99.9%
135 - 139	9	100.0%
140 - 144	0	100.0%
145 - 150	0	100.0%

**North American Pharmacist Licensure Examination (NAPLEX)**

**Xavier College of Pharmacy**

	<b>2000</b>			<b>2001</b>			<b>2002</b>			<b>2003</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	10	80	43	28	85	40	22	69	48	19	90	40
School Average Score:	77.60	87.99	81.67	76.50	93.14	85.15	76.00	93.23	86.98	79.42	94.46	84.33
State Average Score:	96.75	88.52	86.05	84.66	93.82	82.05	75.50	101.46	87.48	77.50	99.40	87.33
National Average Score:	91.78	99.86	91.21	90.25	101.70	83.69	90.81	101.21	90.02	91.50	101.40	89.40
School Pass Rate:	60.00	77.50	62.79	57.14	85.88	82.50	54.55	79.71	85.42	68.42	90.00	75.00
State Pass Rate:	92.50	78.57	77.27	75.86	89.29	70.00	50.00	85.90	70.37	62.50	94.90	80.00
National Pass Rate:	82.95	92.05	83.04	81.07	94.38	83.69	81.52	93.76	81.73	82.77	93.84	79.55
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	1	77	23	10	74	29	8	63	40	8	83	26
School Average Score:	95.00	88.19	82.13	74.80	95.92	86.48	80.63	95.00	88.60	87.75	95.34	88.04
State Average Score:	97.49	93.61	87.77	88.78	95.92	85.93	81.89	103.71	91.15	74.00	100.41	92.38
National Average Score:	96.51	101.85	96.48	94.54	103.35	94.22	95.13	103.00	94.62	97.39	103.38	95.88
School Pass Rate:	100.00	77.92	65.22	50.00	90.54	82.76	75.00	84.13	90.00	87.50	90.36	80.77
State Pass Rate:	94.59	93.18	84.62	83.33	91.84	73.33	77.78	90.28	70.00	66.67	95.65	90.48
National Pass Rate:	91.44	95.44	91.39	87.91	96.75	90.10	89.27	96.74	88.52	91.47	96.54	89.64

**North American Pharmacist Licensure Examination (NAPLEX)**

**Xavier College of Pharmacy**

	<b>2004</b>			<b>2005</b>			<b>2006</b>			<b>2007</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	10	82	19	6	95	30	20	94	48	17	81	56
School Average Score:	76.40	98.99	91.68	83.00	98.92	73.07	72.15	106.20	92.81	74.18	109.07	86.77
State Average Score:	81.33	103.47	96.71	95.00	101.77	92.50	86.67	111.87	96.07	88.00	117.29	94.73
National Average Score:	92.13	102.16	91.70	91.32	104.85	87.72	86.89	107.02	93.18	89.95	113.33	94.18
School Pass Rate:	70.00	96.34	84.21	83.33	86.32	56.67	50.00	82.98	77.08	52.94	83.95	64.29
State Pass Rate:	83.33	96.12	100.00	100.00	87.83	78.57	77.78	89.17	79.31	63.64	95.52	74.51
National Pass Rate:	83.22	95.11	84.79	82.88	89.15	71.73	68.82	90.52	77.07	71.38	94.47	78.76
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	2	79	10	3	90	19	5	87	31	3	68	46
School Average Score:	72.50	100.06	98.80	85.00	101.34	79.79	69.40	109.32	93.10	94.67	114.60	90.50
State Average Score:	84.00	105.61	99.73	101.50	103.64	98.94	93.33	112.95	95.41	103.40	118.18	95.00
National Average Score:	100.14	104.14	96.60	98.84	107.67	95.89	97.18	110.34	99.96	102.16	116.00	102.19
School Pass Rate:	50.00	98.73	100.00	66.67	88.89	68.42	40.00	86.21	77.42	100.00	92.65	71.74
State Pass Rate:	100.00	100.00	100.00	100.00	90.09	88.89	100.00	90.38	70.59	100.00	96.69	76.74
National Pass Rate:	95.07	97.38	92.22	91.31	92.86	82.12	81.12	94.49	84.74	84.09	97.23	88.12

**North American Pharmacist Licensure Examination (NAPLEX)**

**Xavier College of Pharmacy**

	<b>2008</b>			<b>2009</b>			<b>2010</b>			<b>2011</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	22	138	55	18	138	28	19	148	52	25	124	45
Mean Scaled Score - School	81.36	96.77	89.82	80.33	97.59	86.96	73.63	89.73	77.15	76.00	99.13	85.04
Mean Scaled Score - State	93.70	103.31	95.41	94.80	108.26	84.32	83.15	94.22	80.13		99.66	85.27
Mean Scaled Score - National	96.76	112.08	96.61	93.72	112.51	93.62	84.75	101.11	84.90	83.97	103.27	88.08
School Pass Rate:	68.18	81.88	76.36	61.11	83.33	71.43	42.11	75.00	59.62	64.00	87.10	75.56
State Pass Rate:	90.00	90.34	82.76	80.00	92.64	63.16	61.54	83.24	65.00		90.81	73.17
National Pass Rate:	83.11	95.48	81.96	76.40	95.03	78.20	65.07	92.39	72.20	67.85	94.16	76.57
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	5	124	36	6	127	12	6	143	16	6	115	33
Mean Scaled Score - School	85.40	98.77	92.47	81.00	99.77	83.33	79.83	90.78	84.00	61.00	101.95	85.45
Mean Scaled Score - State	96.00	104.42	95.82	86.00	108.80	84.10	92.00	94.46	90.75		100.88	83.70
Mean Scaled Score - National	106.63	114.11	103.62	106.27	114.65	102.87	100.12	103.06	94.26	96.99	105.03	96.71
School Pass Rate:	80.00	84.68	80.56	50.00	86.61	66.67	50.00	76.92	75.00	16.67	92.17	81.82
State Pass Rate:	83.33	92.35	82.35	57.14	93.04	60.00	66.67	84.15	83.33		93.18	74.07
National Pass Rate:	92.24	97.44	90.66	90.76	97.50	89.51	88.38	95.31	86.71	87.50	96.57	89.24

**North American Pharmacist Licensure Examination (NAPLEX)**

**Xavier College of Pharmacy**

	<b>2012</b>			<b>2013</b>			<b>2014</b>			<b>2015</b>		
	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>	<u>Jan - Apr</u>	<u>May - Aug</u>	<u>Sept - Dec</u>
<b>TOTAL CANDIDATE GROUP</b>												
No. of Candidates	13	120	21	10	136	43	18	138	27	15	141	
Mean Scaled Score - School	76.69	95.13	83.24	68.67	95.13	81.47	70.72	96.29	80.41	72.13	96.03	
Mean Scaled Score - State	81.25	98.42	86.95	77.25	98.66	86.88	73.85	96.45	80.88	82.15	95.51	
Mean Scaled Score - National	83.15	102.81	88.15	80.17	102.78	87.03	80.22	101.71	89.22	83.84	100.46	
School Pass Rate:	46.15	90.00	61.90	40.00	86.03	65.12	50.00	92.75	70.37	53.33	85.11	
State Pass Rate:	68.75	93.82	76.19	55.56	92.95	81.82	53.85	90.75	70.59	69.23	88.24	
National Pass Rate:	68.33	95.21	77.86	61.07	94.65	75.91	63.24	93.86	79.77	67.06	92.29	
<b>FIRST-TIME CANDIDATE GROUP</b>												
No. of Candidates	3	111	12	1	131	29	3	131	18	4	137	
Mean Scaled Score - School	84.67	97.71	95.58	47.00	96.65	82.76	61.00	97.15	82.33	84.75	97.31	
Mean Scaled Score - State	84.00	99.47	91.00	80.75	99.30	88.33	85.00	96.96	83.84	77.00	96.08	
Mean Scaled Score - National	94.87	104.13	95.75	92.48	104.02	92.69	90.89	102.80	93.94	94.01	101.53	
School Pass Rate:	66.67	93.69	91.67	0.00	89.31	68.97	66.67	93.89	72.22	75.00	87.59	
State Pass Rate:	75.00	95.35	72.73	75.00	94.08	83.33	100.00	92.12	73.68	33.33	89.34	
National Pass Rate:	87.69	97.19	90.14	85.14	96.57	84.46	83.15	95.61	85.36	84.96	93.86	



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Pharmacy Technician Certification Examination (PTCE™)

January 1 – September 30, 2015

Cumulative Record (since January 2000)

November 18, 2015

## **Pharmacy Technician Certification Examination (PTCE™)**

This computer adaptive competency assessment is administered by the Pharmacy Technician Certification Board (PTCB). The examination blueprint is designed to assess the applicant's competency in basic pharmacy practice and is recognized by pharmacy regulatory authorities in most of the states and territories within the USA. The examination is administered via an open window process; applicants may schedule the examination at a designated testing center at any time following approval by PTCB and receipt of an Authorization to Test (ATT) document from PTCB. Individual scores are available to applicants immediately after the test; certificates are mailed to the applicant within 30 days following the examination. Summary reports are provided to the state boards on a semi-annual basis.

### *Table of Contents*

Cumulative Report (since January 2000)

03

Louisiana Board of Pharmacy

Pharmacy Technician Certification Board (PTCB) Examination

	1995-1999									
<b><u>National Data</u></b>	<u>Data</u>	<u>3/25/2000</u>	<u>7/22/2000</u>	<u>11/18/2000</u>	<u>3/10/2001</u>	<u>7/14/2001</u>	<u>11/10/2001</u>	<u>3/16/2002</u>	<u>7/27/2002</u>	<u>11/16/2002</u>
No. of Candidates Attempting	58,382	8,101	12,317	12,941	8,442	12,057	10,608	8,874	13,399	11,521
No. of Candidates Passing	47,973	6,206	10,006	9,520	6,116	9,799	8,354	7,072	10,681	9,164
Passing Score										
Average Score										
Pass Rate	82%	77%	81%	74%	72%	81%	79%	80%	80%	80%
<b>Louisiana Data</b>										
No. of Candidates Attempting	514	141	346	327	187	310	324	269	383	308
No. of Candidates Passing	390	92	271	221	125	227	228	184	269	213
Average Score										
Pass Rate	76%	65%	78%	68%	67%	73%	70%	68%	70%	69%
<hr/>										
	2000-2002									
<b><u>National Data</u></b>	<u>Data</u>	<u>3/29/2003</u>	<u>7/26/2003</u>	<u>11/15/2003</u>	<u>3/20/2004</u>	<u>7/17/2004</u>	<u>11/13/2004</u>	<u>3/19/2005</u>	<u>7/23/2005</u>	<u>11/19/2005</u>
No. of Candidates Attempting	98,260	12,147	14,162	13,401	11,508	15,942	13,795	13,673	18,250	14,068
No. of Candidates Passing	76,918	9,506	11,720	11,006	9,100	12,196	10,818	11,009	14,246	10,583
Passing Score										650
Average Score										702
Pass Rate	78%	78%	83%	82%	79%	77%	78%	81%	78%	75%
<b>Louisiana Data</b>										
No. of Candidates Attempting	2,595	385	384	351	285	382	290	337	488	216
No. of Candidates Passing	1,830	294	286	271	211	281	214	274	351	167
Average Score										688
Pass Rate	71%	76%	74%	77%	74%	74%	74%	81%	72%	77%

Louisiana Board of Pharmacy

Pharmacy Technician Certification Board (PTCB) Examination

	2000-2005 Data	3/11/2006	7/22/2006	9/9/2006	11/18/2006	2000-2006 Data	2/5/2007 3/9/2007	4/24/2007 5/25/2007	8/27/2007 9/28/2007	11/26/2007 12/31/2007
<b>National Data</b>										
No. of Candidates Attempting	225,206	12,383	18,992	3,029	15,285	274,895	8,768	10,730	14,666	10,881
No. of Candidates Passing	177,102	8,559	12,609	2,006	9,145	209,421	6,034	7,487	10,497	7,472
Passing Score		650	650	650	650	650	650	650	650	650
Average Score		688	683	683	668					
Pass Rate	79%	69%	66%	66%	60%	76%	69%	70%	72%	69%
<b>Louisiana Data</b>										
No. of Candidates Attempting	5,713	288	420	59	312	6,792	216	306	266	207
No. of Candidates Passing	4,179	181	239	37	137	4,773	133	196	177	121
Average Score		673	664	685	641					
Pass Rate	73%	63%	57%	63%	44%	70%	62%	64%	67%	58%
<hr/>										
	2000-2007 Data	2/4/2008 3/14/2008	4/28/2008 6/20/2008	8/18/2008 10/10/2008	11/10/2008 12/19/2008	2000-2008 Data	1/1/2009 3/31/2009	4/1/2009 6/30/2009	7/1/2009 9/30/2009	10/1/2009 12/31/2009
<b>National Data</b>										
No. of Candidates Attempting	319,940	7,547	14,291	16,385	11,792	369,955	13,087	8,424	13,735	10,674
No. of Candidates Passing	240,911	5,165	10,155	11,781	7,770	275,782	9,141	6,363	10,067	7,682
Passing Score	650	650	650	650	650	650	650	650	650	650
Average Score										
Pass Rate	75%	68%	72%	72%	66%	75%	70%	76%	73%	72%
<b>Louisiana Data</b>										
No. of Candidates Attempting	7,787	128	392	304	215	8,826	301	260	238	218
No. of Candidates Passing	5,400	72	233	182	118	6,005	184	196	166	137
Average Score										
Pass Rate	69%	56%	59%	60%	55%	68%	61%	75%	70%	63%

Louisiana Board of Pharmacy

Pharmacy Technician Certification Board (PTCB) Examination

	2000-2009 Data	1/1/2010 3/31/2010	4/1/2010 6/30/2010	7/1/2010 9/30/2010	10/1/2010 12/31/2010	2000-2010 Data	1/1/2011 3/31/2011	4/1/2011 6/30/2011	7/1/2011 9/30/2011	10/1/2011 12/31/2011
<b>National Data</b>										
No. of Candidates Attempting	415,875	11,611	15,033	16,025	12,774	471,318	11,219	14,026	12,356	14,031
No. of Candidates Passing	309,035	8,521	11,216	12,349	9,275	350,396	8,366	10,472	9,565	10,826
Passing Score	650	650	650	650	650	650	650	650	650	650
Average Score										
Pass Rate	74%	73%	75%	77%	73%	74%	75%	75%	77%	77%
<b>Louisiana Data</b>										
No. of Candidates Attempting	9,843	217	421	320	268	11,069	247	437	268	257
No. of Candidates Passing	6,688	121	287	219	166	7,481	161	306	182	168
Average Score										
Pass Rate	68%	56%	68%	68%	62%	68%	65%	70%	68%	65%
<hr/>										
	2000-2011 Data	1/1/2012 3/31/2012	4/1/2012 6/30/2012	7/1/2012 9/30/2012	10/1/2012 12/31/2012	2000-2012 Data	Changed to semi-annual reports			
<b>National Data</b>							1/1/2013 to 6/30/2013		7/1/2013 to 12/31/2013	
No. of Candidates Attempting	522,950	11,851	14,356	14,375	11,180	574,712	25,448		28,797	
No. of Candidates Passing	389,625	9,232	11,044	10,982	8,471	429,354	19,581		21,745	
Passing Score	650	650	650	650	650	650	650		650	
Average Score										
Pass Rate	75%	78%	77%	76%	76%	75%	77%		76%	
<b>Louisiana Data</b>										
No. of Candidates Attempting	12,278	246	368	329	239	13,460	622		537	
No. of Candidates Passing	8,298	158	269	226	168	9,119	412		351	
Average Score										
Pass Rate	68%	64%	73%	69%	70%	68%	66%		65%	

Louisiana Board of Pharmacy

Pharmacy Technician Certification Board (PTCB) Examination

	2000-2013 Data	<u>1/1/2014 to 6/30/2014</u>	<u>7/1/2014 to 12/31/2014</u>	2000-2014 Data	<u>1/1/2015 to 9/30/2015</u>	
<b>National Data</b>						
No. of Candidates Attempting	628,957	26,423	27,085	682,465	43,883	
No. of Candidates Passing	470,680	15,233	15,125	501,038	24,763	
Passing Score	650	650	650	650	650	
Average Score						
Pass Rate	75%	58%	56%	73%	56%	
<b>Louisiana Data</b>						
No. of Candidates Attempting	11,002	630	568	12,200	1,252	
No. of Candidates Passing	7,451	287	265	8,003	567	
Average Score						
Pass Rate	68%	46%	47%	66%	45%	
<hr/>						
	2000-2015 Data	<u>1/1/2016 to 6/30/2016</u>	<u>7/1/2016 to 12/31/2016</u>	2000-2016 Data	<u>1/1/2017 to 6/30/2017</u>	<u>7/1/2017 to 12/31/2017</u>
<b>National Data</b>						
No. of Candidates Attempting						
No. of Candidates Passing						
Passing Score						
Average Score						
Pass Rate						
<b>Louisiana Data</b>						
No. of Candidates Attempting						
No. of Candidates Passing						
Average Score						
Pass Rate						

LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS

A COMPONENT UNIT OF THE  
STATE OF LOUISIANA



FINANCIAL STATEMENT AUDIT  
FOR THE YEAR ENDED JUNE 30, 2015  
ISSUED OCTOBER 14, 2015

**LOUISIANA LEGISLATIVE AUDITOR  
1600 NORTH THIRD STREET  
POST OFFICE BOX 94397  
BATON ROUGE, LOUISIANA 70804-9397**

**LEGISLATIVE AUDITOR**  
DARYL G. PURPERA, CPA, CFE

**FIRST ASSISTANT LEGISLATIVE AUDITOR  
AND STATE AUDIT SERVICES**  
NICOLE B. EDMONSON, CIA, CGAP, MPA

**DIRECTOR OF FINANCIAL AUDIT**  
ERNEST F. SUMMERVILLE, JR., CPA

Under the provisions of state law, this report is a public document. A copy of this report has been submitted to the Governor, to the Attorney General, and to other public officials as required by state law. A copy of this report has been made available for public inspection at the Baton Rouge office of the Louisiana Legislative Auditor.

This document is produced by the Louisiana Legislative Auditor, State of Louisiana, Post Office Box 94397, Baton Rouge, Louisiana 70804-9397 in accordance with Louisiana Revised Statute 24:513. One copy of this public document was produced at an approximate cost of \$1.70. This material was produced in accordance with the standards for state agencies established pursuant to R.S. 43:31. This report is available on the Legislative Auditor's Web site at [www.la.la.gov](http://www.la.la.gov). When contacting the office, you may refer to Agency ID No. 3467 or Report ID No. 80150160 for additional information.

In compliance with the Americans With Disabilities Act, if you need special assistance relative to this document, or any documents of the Legislative Auditor, please contact Elizabeth Coxe, Chief Administrative Officer, at 225-339-3800.

# TABLE OF CONTENTS

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	Page
Independent Auditor’s Report.....	2
Management’s Discussion and Analysis .....	5
	<b>Statement</b>
Basic Financial Statements:	
Statement of Net Position.....	A .....10
Statement of Revenues, Expenses, and Changes in Net Position.....	B .....12
Statement of Cash Flows .....	C .....13
Notes to the Financial Statements .....	15
	<b>Schedule</b>
Required Supplementary Information:	
Schedule of the Board’s Proportionate Share of Net Pension Liability .....	1.....30
Schedule of Board Contributions .....	2.....30
Schedule of Funding Progress for the Other Postemployment Benefits Plan .....	3.....31
Supplementary Information Schedules:	
Schedule of Per Diem Paid Board Members .....	4.....33
	<b>Exhibit</b>
Report on Internal Control over Financial Reporting and on Compliance and Other Matters Based on an Audit of Financial Statements Performed in Accordance with <i>Government Auditing Standards</i> .....	A
	<b>Appendix</b>
Management’s Corrective Action Plan and Response to the Findings and Recommendations .....	A





LOUISIANA LEGISLATIVE AUDITOR  
DARYL G. PURPERA, CPA, CFE

September 21, 2015

## Independent Auditor's Report

**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA  
Baton Rouge, Louisiana**

### **Report on the Financial Statements**

We have audited the accompanying financial statements of the business-type activities of the Louisiana Board of Pharmacy (Board), a component unit of the state of Louisiana, as of and for the year ended June 30, 2015, and the related notes to the financial statements, which collectively comprise the Board's basic financial statements as listed in the Table of Contents.

### **Management's Responsibility for the Financial Statements**

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

### **Auditor's Responsibility**

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not

for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### **Opinion**

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the business-type activities of the Board as of June 30, 2015, and the respective changes in financial position and cash flows thereof for the year then ended in accordance with accounting principles generally accepted in the United States of America.

### **Emphasis of Matters**

As disclosed in Note 7 to the financial statements, the net pension liability for the Board was \$4,117,091 at June 30, 2015 as determined by the Louisiana State Employees' Retirement System (LASERS). The related actuarial valuation was performed by LASERS's actuary using various assumptions. Because actual experience may differ from the assumptions used, there is a risk that this amount at June 30, 2015 could be under or overstated.

As discussed in notes 1-I and 10 to the financial statements, the Board implemented Governmental Accounting Standards Board (GASB) Statement 68, *Accounting and Financial Reporting for Pensions - an amendment of GASB Statement No. 27*, and GASB Statement No. 71, *Pension Transition for Contributions Made Subsequent to the Measurement Date - an amendment of GASB Statement No. 68*, for the year ended June 30, 2015. The adoption of these standards required the Board to record its proportionate share of pension amounts related to its participation in a cost-sharing, multiple-employer defined benefit pension plan, restating the previous year. As a result of the implementation, the Board's net position decreased by \$4,140,810, net pension liability was recorded in the amount of \$4,526,010, and deferred outflow of resources was recorded in the amount of \$385,200 as of July 1, 2014.

Our opinion is not modified with respect to the matters emphasized above.

### **Other Matters**

#### *Required Supplementary Information*

Accounting principles generally accepted in the United States of America require that the Management's Discussion and Analysis on pages 5 through 9 and the Schedule of the Board's Proportionate Share of Net Pension Liability, the Schedule of Board Contributions, and the Schedule of Funding Progress for the Other Postemployment Benefits Plan on pages 30 through 31, be presented to supplement the basic financial statements. Such information, although not a part of the basic financial statements, is required by GASB, who considers it to be an essential

part of financial reporting for placing the basic financial statements in an appropriate operational, economic, or historical context. We have applied certain limited procedures to the required supplementary information in accordance with auditing standards generally accepted in the United States of America, which consisted of inquiries of management about the methods of preparing the information and comparing the information for consistency with management's responses to our inquiries, the basic financial statements, and other knowledge we obtained during our audit of the basic financial statements. We do not express an opinion or provide any assurance on the information because the limited procedures do not provide us with sufficient evidence to express an opinion or provide any assurance.

### *Supplementary Information*

Our audit was conducted for the purpose of forming an opinion on the financial statements that collectively comprise the Board's basic financial statements. The Schedule of Per Diem Paid Board Members is presented for purposes of additional analysis and is not a required part of the basic financial statements.

The Schedule of Per Diem Paid Board Members is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the basic financial statements. Such information has been subjected to the auditing procedures applied in the audit of the basic financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the basic financial statements or to the basic financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the Schedule of Per Diem Paid Board Members is fairly stated, in all material respects, in relation to the basic financial statements taken as a whole.

### **Other Reporting Required by *Government Auditing Standards***

In accordance with *Government Auditing Standards*, we have also issued our report dated September 21, 2015, on our consideration of the Board's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, regulations, contracts, and other matters. The purpose of that report is to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the internal control over financial reporting or on compliance. That report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the Board's internal control over financial reporting and compliance.

Respectfully submitted,



Daryl G. Purpera, CPA, CFE  
Legislative Auditor



# MANAGEMENT'S DISCUSSION AND ANALYSIS

---

This Management's Discussion and Analysis of the Louisiana Board of Pharmacy's (Board) financial performance presents a narrative overview and analysis of the Board's financial activities for the year ended June 30, 2015. This document focuses on the current-year's activities, resulting changes, and currently-known facts in comparison with the prior-year's information. Please read this document in conjunction with the additional information contained in the Board's financial statements which begin on page 10.

## FINANCIAL HIGHLIGHTS

- The Board's assets exceeded its liabilities at the close of fiscal year 2015 by \$363,796. The significant reduction from \$3,520,725 of the previous fiscal year is a function of the Governmental Accounting Standards Board (GASB) 68 Restatement, described elsewhere in this report.
- From the prior fiscal year, the Board's operating revenues increased \$550,226 (18.1%), operating expenses decreased \$114,752 (4.2%), and the net results from activities increased \$664,978.

## OVERVIEW OF THE FINANCIAL STATEMENTS

These financial statements consist of three sections – Management's Discussion and Analysis (this section), the basic financial statements (including the notes to the financial statements), and Required Supplementary Information.

### Basic Financial Statements

The basic financial statements present information for the Board, as a whole, in a format designed to make the statements easier for the reader to understand. The statements in this section include the Statement of Net Position; the Statement of Revenues, Expenses, and Changes in Net Position; and the Statement of Cash Flows.

The **Statement of Net Position** (pages 10-11) presents the current and long-term portions of assets and liabilities separately. The difference between total assets and deferred outflows of resources and total liabilities and deferred inflows of resources is net position and may provide a useful indicator of whether the Board's financial position is improving or deteriorating.

The **Statement of Revenues, Expenses, and Changes in Net Position** (page 12) presents information showing how the Board's net position changed as a result of current-year operations. Regardless of when cash is collected, all changes in net position are reported when the underlying transactions occur. As a result, there are transactions included that will not affect cash until future fiscal periods.

The **Statement of Cash Flows** (pages 13-14) presents information showing how the Board's cash changed as a result of current-year operations. The cash flows statement is prepared using the direct method and includes the reconciliation of operating income (loss) to net cash provided (used) by operating activities (indirect method) as required by GASB Statement No. 34.

## FINANCIAL ANALYSIS OF THE BOARD

### Statement of Net Position As of June 30, 2015 and June 30, 2014

	2015	2014*
Current and other assets	\$4,143,069	\$3,562,797
Capital assets	2,079,320	2,139,037
Deferred outflows of resources	644,896	112,878*
Total assets and deferred outflows	<u>6,867,285</u>	<u>5,814,713</u>
Current liabilities	628,995	215,904
Long-term liabilities	5,267,053	6,218,894*
Deferred inflows of resources	607,441	
Total liabilities and deferred inflows	<u>6,503,489</u>	<u>6,434,798</u>
Net position:		
Net investment in capital assets	1,605,186	2,063,242
Unrestricted	<u>(1,241,390)</u>	<u>(2,683,327)</u>
Total net position	<u>\$363,796</u>	<u>(\$620,085*)</u>

\*Net position amounts for 2014 were restated for GASB 68.

Unrestricted net position represents net earnings that do not have any limitations on how the amounts may be spent. The Board has established a separate reserve fund intended to match its ongoing OPEB liability.

Net position of the Board increased \$983,881 from June 30, 2014, to June 30, 2015.

**Statement of Revenues, Expenses, and  
Changes in Net Position  
For the Years Ended June 30, 2015 and June 30, 2014**

	<u>2015</u>	<u>2014</u>
Operating revenues	\$3,586,685	\$3,036,459
Operating expenses	<u>(2,586,269)</u>	<u>(2,701,021)</u>
Operating income (loss)	<u>1,000,416</u>	<u>335,438</u>
Nonoperating revenues	28,347	22,938
Nonoperating expenses	<u>(44,882)</u>	<u>(63,000)</u>
Net increase (decrease) in net assets	983,881	295,376
Total net position, beginning of year	(620,085)	3,225,349
Restatement of beginning net position		<u>(4,140,810)</u>
Total net position, restated beginning of year		
Total net position, end of year	<u><u>\$363,796</u></u>	<u><u>(\$620,085)</u></u>

Because the impact of the implementation of GASB Statement 68 on the fiscal year 2014 beginning net position is unknown, it was adjusted by the same amount as the fiscal year 2015 beginning net position for the purposes of this comparison only.

The Board's operating revenues increased by \$550,226 (or 18.1%). The total costs of all programs and services decreased from the prior fiscal year by \$114,752 (or 4.2%).

### **CAPITAL ASSETS**

At the conclusion of the fiscal year ended June 30, 2015, the Board had \$2,079,320 invested in a broad range of capital assets including property, furniture, office equipment, and information systems (see the table following). This amount represents a net decrease of \$59,716 from last year.

#### **Capital Assets at Year-End**

	<u>2015</u>	<u>2014</u>
Land	\$1,004,940	\$1,004,940
Buildings and improvements	1,057,861	1,052,255
Furniture and equipment	370,317	348,347
Software, licensure, and website	408,560	408,560
Accumulated depreciation	<u>(762,358)</u>	<u>(675,066)</u>
Total	<u><u>\$2,079,320</u></u>	<u><u>\$2,139,036</u></u>

## **DEBT ADMINISTRATION**

To purchase the office building in 2010, the Board pledged its future receivables from the sale of a parcel of land to secure a note for \$1.3 million, with a term of five years. The separate property acquired in 2007, originally intended to host a new office building, has been listed for sale. The proceeds from the sale of that property will be used to settle or offset the remaining balance on the note for the office building.

The Board has set aside funds for the Other Post Employment Benefit (OPEB) obligation first identified in 2008. Although the entire obligation has not yet been recorded, the Board has sufficient designated reserve funds to cover 89% of the liability recorded to date.

At the close of the fiscal year, the Board was notified of its new long-term liability relative to pensions for its retirees. The entire liability has been recorded, with the net liability of \$4,117,091. The Board plans to initiate a second designated reserve fund to begin funding this new long-term liability.

There were no claims or judgments at the end of the fiscal year, and the only remaining significant liability was in the form of compensated absences.

## **VARIATIONS BETWEEN ORIGINAL AND FINAL BUDGETS**

Revenues were approximately \$526,386 (or 17.2%) over budget, and expenses were \$551,201 (or 18.4%) less than budget. Most of the excess revenue was derived from unanticipated disciplinary cases resulting in a significant amount of fines. In addition, the total number of credentials under management increased by 5% from the previous year. The expense reduction came primarily from a deferral of planned equipment acquisitions as well as a restatement of retirement premium expenses paid during the year as a result of GASB 68.

## **ECONOMIC FACTORS AND NEXT YEAR'S BUDGETS AND RATES**

The Board's elected and appointed officials considered the following factors and indicators when setting next year's budget:

- Anticipated licensure activity (acquisition, renewal, and attrition)
- Demand for goods and services
- Enforcement actions
- Historical pattern of operational costs

The Board expects that next year's results may or may not improve based on the following:

- Continued growth in total number of credentials under management
- Additional investments in technology infrastructure

**CONTACTING THE LOUISIANA BOARD  
OF PHARMACY'S FINANCIAL MANAGEMENT**

This financial report is designed to provide our citizens, taxpayers, customers, investors, and creditors with a general overview of the Board's finances and show the Board's accountability for the money it receives. If you have questions about this report or need additional financial information, contact Malcolm Broussard, Executive Director, at [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov) or (225) 925-6496.



**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA**

**Statement of Net Position  
June 30, 2015**

**ASSETS**

Current assets:

Cash and cash equivalents (note 2)	\$1,174,218
Investments (note 2)	1,198,244
Prepaid expenses	3,000
Total current assets	<u>2,375,462</u>

Non-current assets:

Investments (note 2)	1,767,606
Capital assets, net (note 3)	2,079,320
Total non-current assets	<u>3,846,926</u>

Total assets	<u>6,222,388</u>
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**DEFERRED OUTFLOWS OF RESOURCES**

Deferred outflows related to pensions (note 7)	644,896
Total deferred outflows of resources	<u>644,896</u>

**LIABILITIES**

Current liabilities:

Accounts payable	2,225
Salaries payable	82,372
Payroll taxes payable	3,422
Interest payable	2,469
Note payable - current portion (note 5)	474,134
Compensated absences - current portion (note 5)	64,373
Total current liabilities	<u>628,995</u>

Noncurrent liabilities:

Compensated absences (note 5)	53,962
OPEB payable (note 8)	1,096,000
Pension liability (note 7)	4,117,091
Total noncurrent liabilities	<u>5,267,053</u>

Total liabilities	<u>5,896,048</u>
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(Continued)

The accompanying notes are an integral part of this statement.

**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA  
Statement of Net Position, June 30, 2015**

**DEFERRED INFLOWS OF RESOURCES**

Deferred inflows related to pensions (note 7)	\$607,441
Total deferred inflows of resources	<u>607,441</u>

**NET POSITION**

Net investment in capital assets	1,605,186
Unrestricted	<u>(1,241,390)</u>

<b>TOTAL NET POSITION</b>	<b><u><u>\$363,796</u></u></b>
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(Concluded)

The accompanying notes are an integral part of this statement.

**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA**

**Statement of Revenues, Expenses, and  
Changes in Net Position  
For the Fiscal Year Ended June 30, 2015**

**OPERATING REVENUES**

Licenses, permits, and fees	\$3,586,685
<b>Total operating revenues</b>	<u>3,586,685</u>

**OPERATING EXPENSES**

Personnel services and related benefits	1,921,523
Operating services	228,082
Materials and supplies	72,949
Professional fees	149,939
Travel	114,685
Depreciation	99,091
<b>Total operating expenses</b>	<u>2,586,269</u>

**OPERATING INCOME**

1,000,416

**NONOPERATING REVENUES (Expenses)**

Net investment income	28,347
Interest expense	(44,882)
<b>Total nonoperating expenses</b>	<u>(16,535)</u>

**CHANGE IN NET POSITION**

983,881

**NET POSITION - BEGINNING OF YEAR (restated) (note 10)**

(620,085)

**TOTAL NET POSITION AT END OF YEAR**

\$363,796

The accompanying notes are an integral part of this statement.



**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA**

**Statement of Cash Flows  
For the Year Ended June 30, 2015**

<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>	
Cash received from licenses	\$3,586,685
Cash payments to suppliers for goods and services	(570,925)
Cash payments to employees for services	(1,892,940)
<b>Net cash provided by operating activities</b>	<u>1,122,820</u>
<b>CASH FLOWS FROM CAPITAL AND RELATED FINANCING ACTIVITIES</b>	
Principal paid on note	(486,770)
Interest paid on note	(47,751)
Purchase of capital assets	(39,374)
<b>Net cash used by capital and related financing activities</b>	<u>(573,895)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>	
Purchase of securities	(1,006,239)
Interest income	28,347
<b>Net cash used by investing activities</b>	<u>(977,892)</u>
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	(428,967)
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR</b>	<u>1,603,185</u>
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<u>\$1,174,218</u>

(Continued)

The accompanying notes are an integral part of this statement.

**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA  
Statement of Cash Flows, June 30, 2015**

**RECONCILIATION OF OPERATING INCOME TO NET CASH  
PROVIDED BY OPERATING ACTIVITIES:**

Operating income	\$1,000,416
Adjustments to reconcile operating income to net cash provided (used) by operating activities:	
Depreciation	99,091
Pension expense	403,452
Current-year pension contributions made subsequent to the measurement date	(464,626)
Changes in assets and liabilities:	
Increase in prepaid expenses	(3,000)
Decrease in accounts payable	(1,311)
Increase in salaries and benefits payable	10,325
Increase in payroll tax liability	299
Decrease in compensated absences	(958)
Increase in OPEB payable	79,132
<b>Net cash provided by operating activities</b>	<u><u>\$1,122,820</u></u>

(Concluded)

The accompanying notes are an integral part of this statement.

# NOTES TO THE FINANCIAL STATEMENTS

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## INTRODUCTION

The Louisiana Board of Pharmacy (Board) is a component unit of the state of Louisiana created within the Louisiana Department of Health and Hospitals, as provided by Louisiana Revised Statute (R.S.) 37:1171. The Board is charged with the authority and responsibility of regulating the profession and practice of pharmacy in the interest of the health, safety, and welfare of the citizens of the state of Louisiana.

The Board is composed of 17 members, appointed by the governor, including two licensed pharmacists from each of the eight pharmacy districts and one representative of the consumers from the state at large. Operations of the Board are funded through self-generated revenues primarily derived from fees for the issuance of licenses, permits, and examinations. The Board has 16 employees. During the year, the Board issued 45,063 permits and 7,171 new credentials.

## 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### A. BASIS OF PRESENTATION

The Governmental Accounting Standards Board (GASB) promulgates accounting principles generally accepted in the United States of America and reporting standards for state and local governments. These principles are found in the *Codification of Governmental Accounting and Financial Reporting Standards*, published by GASB. The accompanying financial statements have been prepared in accordance with such principles.

### B. REPORTING ENTITY

GASB Codification Section 2100 has defined the governmental reporting entity to be the state of Louisiana. The Board is considered a component unit of the state of Louisiana because the state exercises oversight responsibility in that the governor appoints the Board members and public service is rendered within the state's boundaries. The accompanying financial statements present information only as to the transactions of the Board as authorized by Louisiana statutes and administrative regulations.

Annually, the state of Louisiana issues basic financial statements, which include the activity contained in the accompanying financial statements. The financial statements are audited by the Louisiana Legislative Auditor.

### C. BASIS OF ACCOUNTING

For financial reporting purposes, the Board is considered a special-purpose government engaged only in business-type activities. All activities of the Board are accounted for within a single proprietary (enterprise) fund.

Basis of accounting refers to when revenues and expenses are recognized in the accounts and reported in the financial statements. Basis of accounting relates to the timing of the measurements made, regardless of the measurement focus applied. The transactions of the Board are accounted for using the economic resources measurement focus. With this measurement focus, all assets and all liabilities associated with the operations are included on the Statement of Net Position.

Under the accrual basis, revenues are recognized in the accounting period when they are earned and expenses are recognized when the related liability is incurred.

Proprietary funds distinguish operating revenues and expenses from nonoperating items. Operating revenues and expenses generally result from providing services and/or producing and delivering goods in connection with a proprietary fund's principal ongoing operations. All revenues and expenses not meeting this definition are reported as nonoperating revenues and expenses.

#### **D. CASH AND INVESTMENTS**

Cash includes amounts on deposit with the fiscal agent bank. Investments include amounts invested in certificates of deposit and United States Treasury notes. The Board considers all highly-liquid investments and deposits with a maturity of three months or less when purchased to be cash equivalents. Under state law, the Board may deposit funds within a fiscal agent bank organized under the laws of the state of Louisiana, the laws of any other state in the Union, or the laws of the United States.

#### **E. CAPITAL ASSETS**

Capital assets purchased with an original cost of \$1,000 or more are recorded at historical cost and depreciated over their estimated useful lives (excluding salvage value). Estimated useful life is management's estimate of how long the asset is estimated to meet service demands. Straight-line depreciation is used based on the following estimated useful lives:

	<u>Years</u>
Building	40
Building Improvements	10-20
Equipment	5-10
Software	5

#### **F. EMPLOYEE COMPENSATED ABSENCES**

Employees earn and accumulate vacation and sick leave at varying rates, depending on their years of service. The amount of vacation and sick leave that may be accumulated by each employee is unlimited. Upon termination, employees are compensated for up to 300 hours of unused vacation leave at the employee's hourly rate of pay at the time of termination. Upon retirement, unused vacation leave in excess of 300 hours plus unused

sick leave are used to compute retirement benefits. The cost of current leave privileges are recognized as a current-year expense. The cost of leave not requiring current resources is recorded as a long-term obligation.

#### **G. NONCURRENT LIABILITIES - PENSIONS**

For purposes of measuring the net pension liability, deferred outflows of resources and deferred inflows of resources related to pensions and pension expense, information about the fiduciary net position of the Louisiana State Employees' Retirement System (system), and additions to/deductions from the system's fiduciary net position have been determined on the same basis as they are reported by the system. For this purpose, benefit payments (including refunds of employee contributions) are recognized when due and payable in accordance with the benefit terms. Investments are reported at fair value.

#### **H. NET POSITION**

Net position comprises the various net earnings from operations, nonoperating revenues, and expenses. Net position is classified in the following components:

Net investment in capital assets consists of all capital assets, net of accumulated depreciation and reduced by the outstanding balances of any borrowings that are attributable to the acquisition, construction, or improvement of those assets.

Unrestricted net position consists of all other resources that are not included in the other category previously mentioned.

#### **I. ADOPTION OF NEW ACCOUNTING PRINCIPLES**

For the year ended June 30, 2015, the following statements were implemented: GASB Statement No. 68, *Accounting and Financial Reporting for Pensions - an amendment of GASB Statement No. 27*, and GASB Statement No. 71, *Pension Transition for Contributions Made Subsequent to the Measurement Date - an amendment of GASB Statement No. 68*. These statements changed the accounting and financial reporting for pensions that are provided to the employees of state and local governmental employers through pension plans that are administered through trusts.

#### **J. USE OF ESTIMATES**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

## 2. CASH AND CASH EQUIVALENTS AND INVESTMENTS

For reporting purposes, deposits with financial institutions include savings, demand deposits, time deposits, and certificates of deposit. Under state law, the Board may deposit funds within a fiscal agent bank selected and designated by the Interim Emergency Board. Further, the Board may invest in time certificates of deposit in any bank domiciled or having a branch office in the state of Louisiana; in savings accounts or shares of savings and loan associations and savings banks, and in share accounts and share certificate accounts of federally- or state-chartered credit unions.

Deposits in bank accounts are stated at cost, which approximates market. Under state law these deposits must be secured by federal deposit insurance or the pledge of securities owned by the fiscal agent bank. The market value of the pledged securities plus the federal deposit insurance must at all times equal the amount on deposit with the fiscal agent. These pledged securities are held in the name of the pledging fiscal agent bank in a holding custodial bank in the form of safekeeping receipts.

The deposits at June 30, 2015, consisted of the following:

	Cash and Cash Equivalents	Nonnegotiable Certificates of Deposit	Total
Deposits per Statement of Net Position	\$1,174,218	\$2,936,832	\$4,111,050
Bank deposits in bank accounts per bank	\$1,177,052	\$2,935,418	\$4,112,470

All deposits are covered by FDIC and pledged securities held in the Board's name.

Investments of the Board consist of U.S. Treasury securities. These securities are stated at their fair value as required by GASB Statement No. 31, *Accounting and Financial Reporting for Certain Investments and External investment Pools*. The Board used quoted market values to determine the fair value of their investments.

<u>Descriptions</u>	<u>Cost</u>	<u>Fair Value</u>	<u>Interest Rates</u>	<u>Moody's Investors Service Credit Quality</u>	<u>Maturity Date</u>
U.S. Treasury Security	\$25,000	\$29,019	1.25%	Aaa	7/15/20

***Interest Rate Risk.*** The Board has a formal investment policy that limits investment maturities to five years as a means of managing its exposure to fair value losses arising from increasing interest rates.

Credit Risk. The Board has adopted the state investment policy at R.S. 49:327. The Board does not have any other policy that would further limit the investment choices. The investments are government-backed securities.

Concentration of Credit Risk. The Board places no limits on the amount the Board may invest in any one issuer.

### 3. CAPITAL ASSETS

A summary of changes in capital assets and related depreciation for the fiscal year ended June 30, 2015, is as follows:

	Balance June 30, 2014	Additions	Retirement	Balance June 30, 2015
Capital assets, not being depreciated				
Land	\$1,004,940	NONE	NONE	\$1,004,940
Total capital assets, not being depreciated	<u>1,004,940</u>	<u>NONE</u>	<u>NONE</u>	<u>1,004,940</u>
Capital assets, being depreciated				
Buildings and building improvements	1,052,255	\$5,606	NONE	1,057,861
Less accumulated depreciation	(83,314)	(26,708)	NONE	(110,022)
Total buildings and buildings improvements	<u>968,941</u>	<u>(21,102)</u>	<u>NONE</u>	<u>947,839</u>
Office equipment	348,347	33,768	(\$11,798)	370,317
Less accumulated depreciation	(249,801)	(30,309)	11,798	(268,312)
Total office equipment	<u>98,546</u>	<u>3,459</u>	<u>NONE</u>	<u>102,005</u>
Software	408,560	NONE	NONE	408,560
Less accumulated depreciation	(341,950)	(42,074)	NONE	(384,024)
Total software	<u>66,610</u>	<u>(42,074)</u>	<u>NONE</u>	<u>24,536</u>
Total capital assets, being depreciated	<u>1,134,097</u>	<u>(59,717)</u>	<u>NONE</u>	<u>1,074,380</u>
Total capital assets, net	<u>\$2,139,037</u>	<u>(\$59,717)</u>	<u>NONE</u>	<u>\$2,079,320</u>

#### 4. OPERATING LEASES

The total payments for operating leases for office equipment during the fiscal year amounted to \$14,535. The following is a schedule, by year, of future minimum annual rental payments required under the leases:

<u>Fiscal Year</u>	<u>Total</u>
2016	\$15,348
2017	4,452
2018	4,452
2019	<u>371</u>
	<u><u>\$24,623</u></u>

#### 5. LONG-TERM LIABILITIES

The following is a summary of changes in long-term liabilities of the Board for the year ended June 30, 2015:

	<u>Balance June 30, 2014</u>	<u>Additions</u>	<u>Reductions</u>	<u>Balance June 30, 2015</u>	<u>Amounts Due Within One Year</u>
Notes payable	\$960,904	NONE	(\$486,770)	\$474,134	\$474,134
Compensated absences	119,293	\$8,308	(9,266)	118,335	64,373
Net OPEB obligation	1,016,868	122,841	(43,709)	1,096,000	
Net pension obligation*	<u>4,526,010</u>	<u>590,336</u>	<u>(999,255)</u>	<u>4,117,091</u>	
Total	<u><u>\$6,623,075</u></u>	<u><u>\$721,485</u></u>	<u><u>(\$1,539,000)</u></u>	<u><u>\$5,805,560</u></u>	<u><u>\$538,507</u></u>

\*Denotes beginning balance was restated

#### 6. NOTES PAYABLE

In January 2011, the Board purchased an office building and acquired a loan in the amount of \$1,300,000, with an interest rate at 6.25% and a maturity date of January 16, 2016. Iberia Bank currently holds the lien to the building title, and the vacant lot valued at \$709,080 is pledged as collateral against the loan.

#### 7. PENSIONS

The Board is a participating employer in a statewide, public employee retirement system, the Louisiana State Employees' Retirement System (LASERS). LASERS has a separate board of

trustees and administers a cost-sharing, multiple-employer defined benefit pension plan, including classes of employees with different benefits and contribution rates (subplans). Article X, Section 29(F) of the Louisiana Constitution of 1974 assigns the authority to establish and amend benefit provisions of all plans administered by LASERS to the state legislature. LASERS issues a public report that includes financial statements and required supplementary information, and a copy of the report may be obtained at [www.lasersonline.org](http://www.lasersonline.org).

### **General Information about the Pension Plan**

*Plan Descriptions/Benefits Provided.* LASERS administers a plan to provide retirement, disability, and survivor's benefits to eligible state employees and their beneficiaries as defined in R.S. 11:411-414. The age and years of creditable service (service) required in order for a member to receive retirement benefits are established by R.S. 11:441 and vary depending on the member's hire date, employer, and job classification. Act 992 of the 2010 Regular Legislative Session closed existing subplans for members hired before January 1, 2011, and created new subplans for regular members, hazardous duty members, and judges.

The substantial majority of members may retire with full benefits at any age upon completing 30 years of service and at age 60 upon completing 5-10 years of service. Additionally, members may choose to retire with 20 years of service at any age, with an actuarially-reduced benefit. Eligibility for retirement benefits and the computation of retirement benefits are provided for in R.S. 11:444. The basic annual retirement benefit for members is equal to a percentage (between 2.5% and 3.5%) of average compensation multiplied by the number of years of service, generally not to exceed 100% of average compensation. Average compensation is defined as the member's average annual earned compensation for the highest 36 consecutive months of employment for members employed prior to July 1, 2006, or highest 60 consecutive months of employment for members employed after that date. A member leaving service before attaining minimum retirement but after completing certain minimum service requirements, generally 10 years, becomes eligible for a benefit provided the member lives to the minimum service retirement age and does not withdraw the accumulated contributions.

Eligibility requirements and benefit computations for disability benefits are provided for in R.S. 11:461. All members with 10 or more years of service or members aged 60 or older regardless of date of hire who become disabled may receive a maximum disability benefit equivalent to the regular retirement formula without reduction by reason of age. Hazardous duty personnel who become disabled in the line of duty will receive a disability benefit equal to 75% of final average compensation.

Provisions for survivor's benefits are provided for in R.S. 11:471-478. Under these statutes, the deceased member who was in state service at the time of death must have a minimum of five years of service, at least two of which were earned immediately prior to death, or who has a minimum of twenty years of service regardless of when earned in order for a benefit to be paid to a minor or handicapped child. Benefits are payable to an unmarried child until age 18, or age 23, if the child remains a full-time student. The minimum service requirement is ten years for a surviving spouse with no minor children, and benefits are to be paid for life to the spouse or qualified handicapped child.

LASERS has established a Deferred Retirement Option Plan (DROP). When members enter DROP, their status changes from active member to retiree even though they continue to work and draw their salary for a period up to three years. The election is irrevocable once participation begins. During participation, benefits otherwise payable are fixed and deposited in an individual DROP account. Upon leaving DROP, members must choose among available alternatives for the distribution of benefits that have accumulated in their DROP accounts.

*Cost of Living Adjustments.* As fully described in Title 11 of the Louisiana Revised Statutes, LASERS allows for the payment of cost of living adjustments, or COLAs, that are funded through investment earnings when recommended by the board of trustees and approved by the Legislature. These ad hoc COLAs are not considered to be substantively automatic.

*Contributions.* Article X, Section 29(E)(2)(a) of the Louisiana Constitution of 1974 assigns the Legislature the authority to determine employee contributions. Employer contributions are actuarially determined using statutorily-established methods on an annual basis and are constitutionally required to cover the employer's portion of the normal cost and provide for the amortization of the unfunded accrued liability. Employer contributions are adopted by the Legislature annually upon recommendation of the Public Retirement Systems' Actuarial Committee.

The Board's contributions to LASERS for fiscal year 2015 were \$464,626, with active member contributions ranging from 7.5% to 8%, and employer contributions of 37%.

#### **Pension Liabilities, Pension Expense, and Deferred Outflows of Resources and Deferred Inflows of Resources Related to Pensions**

At June 30, 2015, the Board reported a liability of \$4,117,091 for its proportionate share of the LASERS Net Pension Liability (NPL). The NPL for LASERS was measured as of June 30, 2014, and the total pension liability used to calculate the NPL was determined by an actuarial valuation as of that date. The Board's proportion of the NPL was based on projections of the Board's long-term share of contributions to the pension plan relative to the projected contributions of all participating employers, actuarially determined. As of June 30, 2014, the most recent measurement date, the Board's proportion and the change in proportion from the prior measurement date was 0.06584%, or an increase of 0.00371%.

For the year ended June 30, 2015, the Board recognized a total pension expense of \$403,452. The Board reported deferred outflows of resources and deferred inflows of resources related to pensions from the following sources:

	<u>Deferred Outflows of Resources</u>	<u>Deferred Inflows of Resources</u>
Differences between expected and actual experience		(\$73,362)
Net difference between projected and actual earnings on pension plan investments		(520,851)
Changes in proportion and differences between Employer contributions and proportionate share of contributions	\$180,270	(13,228)
Employer contributions subsequent to the measurement date	464,626	
Total	<u>\$644,896</u>	<u>(\$607,441)</u>

Deferred outflows of resources related to pensions resulting from the Board's contributions subsequent to the measurement date will be recognized as a reduction of the LASERS NPL in the year ended June 30, 2016. Other amounts reported as deferred outflows of resources and deferred inflows of resources related to pensions will be recognized in pension expense as follows:

<u>Year ended June 30</u>	
2016	(\$83,373)
2017	(\$83,373)
2018	(\$130,213)
2019	(\$130,213)

*Actuarial Assumptions.* The total pension liability for LASERS in the June 30, 2014, actuarial valuation was determined using the following actuarial assumptions, applied to all periods included in the measurements:

Valuation Date	June 30, 2014
Actuarial Cost Method	Entry Age Normal
Expected Remaining Service Lives	3 years
Investment Rate of Return	7.75% per annum
Inflation Rate	3% per annum
Mortality - Non-disabled	RP-2000, improvement to 2015
Mortality - Disabled	RP-2000
Termination, Disability, Retirement	2009-2013 experience study
Salary Increases	2009-2013 experience study, ranging from 3.0% to 14.5%
Cost of Living Adjustments	Not substantively automatic

The long-term expected rate of return was determined using a building-block method in which best-estimate ranges of expected future real rates of return (expected returns, net of pension plan investment expenses and inflation) are developed for each major asset class. These ranges are combined to produce the long-term expected rate of return by weighting the expected future real rates of return by the target asset allocation percentage and by adding expected inflation and an adjustment for the effect of rebalancing/diversification. The target allocation and best estimates of arithmetic/geometric real rates of return for each major asset class are summarized in the following table:

	<u>Target Allocation</u>	<u>Long-Term Expected Real Rate of Return</u>
LASERS (geometric)		
Cash	0.00%	0.50%
Domestic equity	27.00%	4.69%
International equity	30.00%	5.83%
Domestic fixed income	11.00%	2.34%
International fixed income	2.00%	4.00%
Alternative investments	23.00%	8.09%
Global tactical asset allocation	7.00%	3.42%
Total	<u>100.00%</u>	<u>5.78%</u>

*Discount Rate.* The discount rate used to measure the total pension liability was 7.75%. The projection of cash flows used to determine the discount rate assumed that employee contributions will be made at the current contribution rate and that employer contributions from participating employers will be made at contractually-required rates, actuarially determined. Based on those assumptions, the pension plan's fiduciary net position was projected to be available to make all projected future benefit payments of current active and inactive plan members. Therefore, the long-term expected rate of return on pension plan investments was applied to all periods of projected benefit payments to determine the total pension liability.

*Sensitivity of the proportionate share of the NPL to changes in the discount rate.* The following presents the Board's proportionate share of the NPL using the current discount rate as well as what the Board's proportionate share of the NPL would be if it were calculated using a discount rate that is one percentage-point lower or one percentage-point higher than the current rate:

	<u>1.0% Decrease</u>	<u>Current Discount Rate</u>	<u>1.0% Increase</u>
LASERS	\$5,280,503	\$4,117,091	\$3,130,934

*Pension plan fiduciary net position.* Detailed information about LASERS fiduciary net position is available in the separately-issued financial reports referenced previously.

*Payables to the Pension Plan.* At June 30, 2015, the Board had \$26,416 in payables to LASERS for the June 2015 employee and employer legally-required contributions.

## 8. OTHER POSTEMPLOYMENT BENEFITS PLAN

*Plan Description.* The Board's employees may participate in the state of Louisiana's Other Postemployment Benefit Plan (OPEB Plan), an agent, multiple-employer defined benefit OPEB Plan that provides medical, prescription drug, and life insurance benefits to eligible active employees, retirees, and their beneficiaries.

The state administers the OPEB Plan through the Office of Group Benefits (OGB). R.S. 42:801-883 assigns the authority to establish and amend benefit provisions of the OPEB Plan. OGB offers several standard healthcare plans for both active and retired employees. OGB does not issue a publicly-available financial report of the OPEB Plan; however, it is included in the state of Louisiana's Comprehensive Annual Financial Report (CAFR). The CAFR may be obtained from the Office of Statewide Reporting and Accounting Policy's website at [www.doa.la.gov/osrap](http://www.doa.la.gov/osrap).

*Funding Policy.* The contribution requirements of OPEB Plan members and the Board are established and may be amended by R.S. 42:801-883. The OPEB Plan is currently funded on a pay-as-you-go basis through a combination of retiree and Board contributions. Employees do not contribute to their postemployment benefits costs until they become retirees and begin receiving those benefits. The retirees contribute to the cost of retiree healthcare based on a service schedule. Contribution amounts vary depending on what healthcare provider is selected from the OPEB Plan, and if the member has Medicare coverage.

Employer contributions are based on plan premiums and the employer contribution percentage. This percentage is based on the date of participation in an OGB plan (before or after January 1, 2002) and employee years of service at retirement. Employees who begin participation or rejoin the plan before January 1, 2002, pay approximately 25% of the cost of coverage (except single retirees under age 65, who pay approximately 25% of the active employee cost). For those beginning participation or rejoining on or after January 1, 2002, the percentage of premiums contributed by the employer and employee is based on the following schedule:

Service	Employer Percentage	Employee Percentage
Under 10 years	19%	81%
10-14 years	38%	62%
15-19 years	56%	44%
20+ years	75%	25%

In addition to healthcare benefits, retirees may elect to receive life insurance benefits. Basic and supplemental life insurance is available for the individual retiree and spouses of retirees subject to maximum values. Employers pay approximately 50% of monthly premiums. Participating

retirees paid \$0.54 each month for each \$1,000 of life insurance and \$0.98 each month for each \$1,000 of spouse life insurance.

*Annual OPEB Cost and Net OPEB Obligation.* The Board's Annual Required Contribution (ARC) represents a level of funding that, if paid on an ongoing basis, is projected to cover normal cost each year and to amortize any unfunded actuarial liabilities over a period not to exceed thirty years. The annual OPEB cost, the percentage of annual OPEB cost contributed to the plan, and the net OPEB obligation at the end of the year for the Board were as follows:

Net OPEB Obligation at June 30, 2014	<u>\$1,016,868</u>
Annual Required Contribution	121,000
Interest on Net OPEB Obligation	40,700
ARC Adjustment	<u>(38,859)</u>
Annual OPEB Cost	122,841
Contributions made	<u>(43,709)</u>
Net OPEB Obligation at June 30, 2015	<u><u>\$1,096,000</u></u>
Percentage of Annual OPEB Cost Contributed	35.58%

The following table provides the Board's annual OPEB cost, the percentage of annual OPEB cost contributed to the plan, and the net OPEB obligation for the last three fiscal years:

Fiscal Year Ended	Annual OPEB Cost	Percentage of Annual OPEB Cost Contributed	Net OPEB Obligation
6/30/2013	\$129,800	37.98%	\$925,404
6/30/2014	\$138,800	34.10%	\$1,016,868
6/30/2015	\$122,841	35.58%	\$1,096,000

*Funding Status and Funding Progress.* As of July 1, 2014, the most recent actuarial valuation date, the funded status of the plan was as follows:

Actuarial accrued liability (AAL)	\$1,742,900
Actuarial value of plan assets	
Unfunded actuarial accrued liability (UAAL)	<u><u>\$1,742,900</u></u>
Funded ratio (actuarial value of plan assets/AAL)	0%
Covered payroll (annual payroll of active employees)	1,186,200
UAAL as a percentage of covered payroll	147%

*Actuarial Methods and Assumptions.* Actuarial valuations of an ongoing plan involve estimates of the value of reported amounts and assumptions about the probability of occurrence of events

far into the future. Examples include assumptions about future employment, mortality, and healthcare cost trend. Amounts determined regarding the funded status of the plan and the annual required contributions are subject to continual revision as actual results are compared with past expectations and new estimates are made about the future.

The Schedule of Funding Progress presented as required supplementary information following the notes to the financial statements presents multiyear trend information that shows whether the actuarial value of plan assets is increasing or decreasing over time relative to the actuarial accrued liabilities for benefits.

Projections of benefits for financial reporting purposes are based on the substantive plan (the plan as understood by the employer and plan members) and include the types of benefits provided at the time of each valuation and the historical pattern of sharing of benefit costs between the employer and the plan members to that point. The actuarial methods and assumptions used include techniques that are designed to reduce short-term volatility in actuarial accrued liabilities consistent with the long-term perspective of the calculations.

In the July 1, 2014, actuarial valuation, the projected unit credit actuarial cost method was used. The actuarial assumptions included a 4.0 percent investment rate of return (net of administrative expenses). The UAAL is amortized over the maximum acceptable period of 30 years on an open basis. It is calculated assuming a level percentage of projected payroll. Other critical assumptions used in the actuarial valuation are the health care cost trend rate and participation assumptions. The health care cost trend assumption is used to project the cost of health care to future years. The valuation uses a health care cost trend rate assumption of 8.0% (7.0% post-Medicare) in the year July 1, 2014, to June 30, 2015, grading down by 0.5% each year until an ultimate health care cost trend rate of 4.5% is reached. The participation assumption is the assumed percentage of future retirees that participate and enroll in the health plan. The participation breakouts are provided in the following table.

<u>Years of Service</u>	<u>Participation Percentage</u>
< 10	57%
10-14	72%
15-19	82%
20+	100%

## **9. RISK MANAGEMENT**

Losses arising from judgments, claims, and similar contingencies are paid through the state's self-insurance fund operated by the Office of Risk Management, the agency responsible for the state's risk management program, or by General Fund appropriation.

There is no pending litigation or claims against the Board at June 30, 2015, which if asserted, in the opinion of the Board's legal advisors, would have at least a reasonable probability of an unfavorable outcome or for which resolution would materially affect the financial statements.

**10. RESTATEMENT OF NET POSITION**

Beginning net position as reflected on Statement B has been restated to reflect the following adjustments:

Net Position at July 1, 2014	\$3,520,725
GASB 68 Net Pension Liability	(4,526,010)
GASB 68 Beginning Deferred Outflows	<u>385,200</u>
Net Position at July 1, 2014, as restated	<u><u>(\$620,085)</u></u>

## REQUIRED SUPPLEMENTARY INFORMATION

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### **SCHEDULE OF THE BOARD'S PROPORTIONATE SHARE OF THE NET PENSION LIABILITY**

Schedule 1 presents the Board's Net Pension Liability

### **SCHEDULE OF BOARD PENSION CONTRIBUTIONS**

Schedule 2 presents the amount of contributions the Board made to the pension system.

### **SCHEDULE OF FUNDING PROGRESS FOR THE OTHER POST EMPLOYMENT BENEFITS PLAN**

Schedule 3 presents certain specific data regarding the funding progress for the Other Postemployment Benefits Plan, including the unfunded actuarial accrued liability.

**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA**

**Schedules of Required Supplementary Information  
Fiscal Year Ended June 30, 2015**

**Schedule of the Board's Proportionate Share  
of the Net Pension Liability** **Schedule 1**

Fiscal Year*	Board's proportion of the net pension liability (asset)	Board's proportionate share of the net pension liability (asset)	Board's covered-employee payroll	Board's proportionate share of the net pension liability (asset) as a percentage of its covered-employee payroll	Plan fiduciary net position as a percentage of the total pension liability
Louisiana State Employees' Retirement System					
2015	0.06584%	\$4,117,091	\$1,193,177	345%	65.0%

\*Amounts presented were determined as of the measurement date (previous fiscal year end).

*This schedule is intended to show information for 10 years. Additional years will be displayed as they become available.*

**Schedule of Board Contributions** **Schedule 2**

Fiscal Year*	(a) Statutorily- Required Contribution	(b) Contributions in relation to the statutorily- required contribution	(a-b) Contribution Deficiency (Excess)	Board's covered-employee payroll	Contributions as a percentage of covered-employee payroll
Louisiana State Employees' Retirement System					
2015	\$464,626	\$464,626	-	\$1,258,895	36.9%

\*Amounts presented were determined as of the end of the fiscal year.

*This schedule is intended to show information for 10 years. Additional years will be displayed as they become available.*

**Notes to Required Supplementary Information**

Changes of Benefit Terms include:

A 1.5% COLA, effective July 1, 2014, provided by Act 102 of the 2014 Louisiana Regular Legislative Session, and, Improved benefits for certain members employed by the Office of Adult Probation and Parole within the Department of Public Safety and Corrections, as established by Act 852 of 2014.

**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA**

**Schedule of Funding Progress for the  
Other Postemployment Benefits Plan  
Three Fiscal Years Ended June 30, 2015**

Actuarial Valuation Date	Actuarial Value of Assets (a)	Actuarial Accrued Liability (AAL) - Projected Unit Cost (b)	Unfunded AAL (UAAL) (b-a)	Fund Ratio (a/b)	Covered Payroll (c)	UAAL as a Percentage of Covered Payroll [(b-a)/c]
July 1, 2012	NONE	\$1,471,800	\$1,471,800	0.0%	\$973,000	151%
July 1, 2013	NONE	\$1,619,300	\$1,619,300	0.0%	\$960,400	169%
July 1, 2014	NONE	\$1,742,900	\$1,742,900	0.0%	\$1,186,200	147%

## SUPPLEMENTARY INFORMATION

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### **SCHEDULE OF PER DIEM PAID TO BOARD MEMBERS**

This schedule presents the amounts paid to Board members.

**LOUISIANA BOARD OF PHARMACY  
DEPARTMENT OF HEALTH AND HOSPITALS  
STATE OF LOUISIANA**

**Schedule of Per Diem Paid to Board Members  
for the Year Ended June 30, 2015**

<u>Board Member</u>	<u>Amount</u>
Carl W. Aron	\$3,375
Brian A. Bond	2,700
Clovis Burch	1,650
Ryan Dartez	675
Jacqueline Hall	1,050
Richard M. Indovina Jr.	1,650
Marty R. McKay	1,950
Chris B. Melancon	1,725
Diane G. Milano	825
Ronald E. Moore	750
Blake P. Pitre	1,875
T. Morris Rabb	2,475
Pamela G. Reed	1,800
Don L. Resweber	1,275
Deborah H. Simonson	1,800
Richard A. "Andy" Soileau	2,400
Rhonny K. Valentine	1,425
Total	<u><u>\$29,400</u></u>

The Schedule of Per Diem paid to Board members is presented in compliance with House Concurrent Resolution No. 54 of the 1979 Session of the Louisiana Legislature.

OTHER REPORT REQUIRED BY  
*GOVERNMENT AUDITING STANDARDS*

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Exhibit A

The following pages contain a report on internal control over financial reporting and on compliance with laws, regulations, and other matters required by *Government Auditing Standards* issued by the Comptroller General of the United States. The report is based solely on the audit of the financial statements and includes, where appropriate, any significant deficiencies and/or material weaknesses in internal control or compliance and other matters that would be material to the presented financial statements.



LOUISIANA LEGISLATIVE AUDITOR  
DARYL G. PURPERA, CPA, CFE

September 21, 2015

Report on Internal Control over Financial Reporting  
and on Compliance and Other Matters Based on an Audit of Financial Statements  
Performed in Accordance with *Government Auditing Standards*

Independent Auditor's Report

**LOUISIANA BOARD OF PHARMACY**  
**DEPARTMENT OF HEALTH AND HOSPITALS**  
**STATE OF LOUISIANA**  
Baton Rouge, Louisiana

We have audited, in accordance with the auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States, the financial statements of the business-type activities of the Louisiana Board of Pharmacy (Board), a component unit of the state of Louisiana, as of and for the year ended June 30, 2015, and the related notes to the financial statements, which collectively comprise the Board's basic financial statements, and have issued our report thereon dated September 21, 2015. Our report was modified to include emphasis of a matter paragraphs regarding actuarial assumptions and financial statement comparability.

**Internal Control over Financial Reporting**

In planning and performing our audit of the financial statements, we considered the Board's internal control over financial reporting (internal control) to determine the audit procedures that are appropriate in the circumstances for the purpose of expressing our opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of the Board's internal control. Accordingly, we do not express an opinion on the effectiveness of the Board's internal control.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. A material weakness is a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected, on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies and therefore, material weaknesses or significant deficiencies may exist that were not identified. Given these limitations, during our audit we did not identify deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

## **Compliance and Other Matters**

As part of obtaining reasonable assurance about whether the Board's financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, and contracts, noncompliance with which could have a direct and material effect on the determination of financial statement amounts. However, providing an opinion on compliance with those provisions was not an objective of our audit, and, accordingly, we do not express such an opinion. As described below, the results of our tests disclosed instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards*.

### **Improper Investment of Certificates of Deposit**

The Board failed to invest certificates of deposit in banks domiciled or having a branch office in the state of Louisiana. Louisiana Revised Statute 49:327(C) states that "agencies are authorized and directed to invest ... in time certificates of deposit of any bank domiciled or having a branch office in the state of Louisiana." The Board invested 17 certificates of deposit in the amount of \$2,510,235 in banking locations outside of the state of Louisiana. Failure to invest in banks domiciled or having a branch office in the state of Louisiana results in noncompliance with the state law.

Board management should ensure that investments are properly made in accordance with state law and board policies and procedures. Management concurred with the finding and provided a corrective action plan (see Appendix A).

### **Improper Purchasing Procedures**

The Board purchased four servers totaling \$18,496, without following the state small purchasing guidelines. Executive Order No. BJ 2010-16, *Small Purchases Procedures*, was authorized by Louisiana Revised Statute 39:1596, and states that "price quotations shall be solicited from five (5) or more bona fide, qualified vendors for purchases exceeding fifteen thousand (\$15,000) but not exceeding twenty-five thousand dollars (\$25,000)." The Board did not solicit quotes from any vendors for the purchase of the items. The Board was not aware of the executive order, and failed to implement procedures to follow the applicable purchasing guidelines. Failure to follow the purchasing guidelines results in noncompliance with state law.

The Board should strengthen its controls related to purchasing to ensure it follows all applicable state purchasing guidelines. Management concurred with the finding and provided a corrective action plan (see Appendix A).

### **Board's Response to Findings**

The Board's response to the findings identified in this report is attached in Appendix A. The Board's response was not subjected to the auditing procedures applied in the audit of the financial statements and, accordingly, we express no opinion on it.

### **Purpose of This Report**

The purpose of this report is solely to describe the scope of our testing of internal control and compliance, and the results of that testing, and not to provide an opinion on the effectiveness of the entity's internal control or on compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the entity's internal control and compliance. Accordingly, this communication is not suitable for any other purpose. Under Louisiana Revised Statute 24:513, this communication is distributed by the Legislative Auditor as a public document.

Respectfully submitted,



Daryl G. Purpera, CPA  
Legislative Auditor

KDD:CR:WDG:EFS:aa

LBP 2015

## APPENDIX A

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# Management's Corrective Action Plan and Response to the Findings and Recommendations



## Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



September 8, 2015

Daryl G. Purpera, CPA, CFE  
Louisiana Legislative Auditor  
PO Box 94397  
Baton Rouge, LA 70804-9397

Dear Mr. Purpera:

This will confirm receipt of your September 4 letter, wherein you identified two findings in connection with your audit of the Board's financial operations and internal controls and requested a reply from the Board's management.

With respect to the investment of certificates of deposit, we had operated under the belief that holding all of the Board's funds in a bank located within Louisiana and allowing that bank to find the best investments for the Board relying on the parameters of the investment policy was in compliance with the law. We had not provided specific instructions that certificates of deposit must be limited to banks located within the state. We have today notified the Board's account manager of this requirement. On analysis of our holdings, I have classified them by their maturities as well as current trading values:

- We have 4 items with an approximate value of \$333,000 maturing in different years, but currently trading at a premium to their original investment value. We will ask for those items to be redeemed as soon as possible and replacement items purchased at in-state banks no later than September 15.
- We have 4 items with an approximate value of \$659,000 maturing in November 2015. Since they are currently trading at a deficit to their original value, we will hold them to maturity and purchase replacement items at in-state banks.
- We have 4 items with an approximate value of \$556,000 maturing during Calendar Year 2016. Since they are currently trading at a deficit to their original value, we will hold them to maturity, unless their value should improve in the interim. Replacement items will be placed at in-state banks.
- We have 7 items with an approximately value of \$1,097,000 maturing between May 2017 and March 2020. Since they are currently trading at a deficit to their original value, we will monitor those items for the opportunity to redeem them at either a premium or at a negligible loss. Replacement items will be placed at in-state banks.

Mr. Daryl G. Purpera  
September 8, 2015  
Page 2 of 2

With respect to the Board's purchasing procedures, we routinely use professional service contracts implemented in accordance with the state's procurement code; however, we rarely have a need to make a purchase in the range of an amount not requiring the public bid process. Viewed in the retrospective of the previous twenty years, we have averaged less than one such purchase per fiscal year. We failed to recall the provisions of the 2010 executive order relative to small purchases. Going forward, we have identified some guidance resources at the Office of State Procurement, and will require consultation with that office for any anticipated purchase in excess of \$5,000.

We trust this information is responsive to your request.

For the Board:



Malcolm J. Broussard  
Executive Director



nabp  
**National Association of Boards of Pharmacy**  
1600 Feehanville Drive • Mount Prospect, IL 60056-6014  
Tel: 847/391-4406 • Fax: 847/391-4502  
Web Site: [www.nabp.net](http://www.nabp.net)

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
FROM: Carmen A. Catizone, Executive Director/Secretary  
DATE: November 12, 2015  
RE: CriticalPoint, LLC’s Proposed Development of a Comprehensive Pharmacy Sterile Compounding Certification Program (QP503A)

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The National Association of Boards of Pharmacy (NABP) is pleased to announce that Critical Point, LLC, has informed the Association of a proposed comprehensive pharmacy sterile compounding certification program. CriticalPoint, wishes to obtain feedback from the state boards of pharmacy about state interest and possible support through future regulation and recommendation by the state boards of pharmacy for their licensees to obtain such certification.

As outlined in the attached CriticalPoint memo, the proposed program (QP503A) would be comprised of two separate credentialing steps. The first step (QP503A.1) would involve home study and live didactic and practicum activities accompanied by personnel testing. The goal of the first part (QP503A.1) would be to train and certify at least one individual in common aspects of pharmacy sterile compounding. The second step (QP503A.2) would then certify individuals in the completion of a “Sterile Compounding Change Project” whereby the credentialed individual would use information obtained in the common aspects training to identify specific areas of their compounding operation that need improvement to bring about measurable change.

CriticalPoint, is requesting feedback directly from the state boards of pharmacy about interest for collaboration in the above proposed program. Please visit [www.surveymonkey.com/r/QP503A](http://www.surveymonkey.com/r/QP503A) by **November 20, 2015**, to provide your feedback.

Attachments: CriticalPoint’s Proposed Roadmap for Certification Program Development

cc: NABP Executive Committee

**CriticalPoint's Proposed Roadmap for the Development of a  
Comprehensive Pharmacy Sterile Compounding Certification Program (QP503A)**

CriticalPoint wishes to work with regulators and key opinion leaders to develop **QP503A**, a comprehensive pharmacy sterile compounding certification program. As we conceive it now, this program would have 2 components.

**1. QP503A Training and Competency Verification Program (projected timeline: as soon as possible if desired by State Boards of Pharmacy and developed and offered by CriticalPoint)**

**a. QP503A.1 (Part 1 of 2)**

- i. The participant would successfully complete a program of home study, live didactic and practicum activities accompanied by required objective personnel testing.
- ii. The goal of this program is to provide an immediate opportunity for all sterile compounding pharmacies to train **at least** one individual in the common aspects of pharmacy sterile compounding.
- iii. **QP503A.1** is described on the following page. It is intended to provide the underpinning necessary for individuals to successfully complete **QP503A.2**, the next element of the credentialing, requiring the participant to demonstrate their ability to use what they have learned to facilitate pharmacy sterile compounding operations that are compliant with USP <797>.

**b. QP503A.2 (Part 2 of 2)**

- i. Persons who have already earned the **QP503A.1** credential must complete a "**Sterile Compounding Change Project**" to earn the **QP503A.2** credential.
- ii. The project would demonstrate the ability of the individual to use the information and behaviors learned in **QP503A.1** to produce a measurable change in performance in the work setting. The individual would identify a specific area of their compounding operation where improvement is required in order to achieve consistent quality and reduce the risk to patients.
- iii. The candidate designs a plan for remediation, implements the plan, measures the outcome of the plan as well as any alterations to the plan and submits documentation of these elements and the outcomes in measurable terms.
- iv. Specific project requirements and elements of performance will be clearly communicated to participants.
- v. This project must be identified, implemented and submitted to CriticalPoint no longer than 12 months from earning the **QP503A.1** credential.

**2. Future Certification Test (CriticalPoint and established certification and testing entities; projected timeline 2 years)**

CriticalPoint and its subject matter experts wish to work in concert with an appropriate credentialing body to design and validate an exam that will serve as an additional piece of a sterile compounding certification for pharmacists and technicians.

CriticalPoint is sharing this vision with State Boards of Pharmacy now so that we can understand if this type of strategy will be supported by regulators either through mandates to licensed provider pharmacies or encouragement of licensees to pursue this type of credentialing program. CriticalPoint does not expect to remain the sole provider of such educational programs and it is likely that competitive programs may be offered in the future. This program may also be utilized by State Boards of Pharmacy as one of the elements of a state mandated "Directed Plan of Correction" for Licensees requiring significant remediation in their sterile compounding practices.

**QP503A.1: Initial training and competency program**

CriticalPoint is a training company and through our subject matter experts, we provide guidance and training to regulators and practitioners in the practice of non-sterile and sterile compounding. It is our intent to develop an initial program that will result in the development of specific essential knowledge and behaviors that will facilitate an individuals' ability to successfully plan, develop and operate 503A pharmacy sterile compounding operations.

This offering consist of the following elements:

- Step 1: Submission of Application for **QP503A** with the following prerequisites:
- Licensed pharmacist or technician
  - At least 3120 hours (2 years averaging 30 hours per week) recent experience in sterile compounding
- Step 2: Successful completion of CriticalPoint's Pharmacy Math Calculations and Sterile Compounding eLearning lessons and posttests prior to the live training component (worth 39 hours of ACPE-approved CE)
- Step 3: 4 days of classroom and practicum activities (approximately 26 hours of ACPE-approved CE) at the CriticalPoint Center for Training and Research (CCTR) which consists of:
- Completion of a 1-day program on Hand Hygiene and Garbing and Aseptic Technique which consists of lectures as well as completion of practice exercises with instructor feedback; first two of three instances of initial gloved fingertip samples
  - Completion of our 2.5-day Sterile Compounding Boot Camp Curriculum
  - Completion of half day covering:
    - Evaluation of Hand Hygiene and Garbing Proficiency
    - Additional instance of initial GFS (for a total of 3)\*
    - Evaluation of Aseptic Technique Proficiency
    - Preparation of Media Fill Units (MFUs)\*
    - Ongoing GFS (taken immediately after compounding MFUs)\*
    - Surface Sampling (taken immediately after compounding MFUs)\*
- \*CriticalPoint will incubate and read all samples and MFUs as well as complete documentation of competencies and outcome of sampling. Candidates must pass all behavioral and objective sampling components.
- Step 4: Successfully complete and submit the following:
- 10 hours of sterile compounding specific education (ACPE-approved) annually
  - Complete and submit an approved QP503A.2 Sterile Compounding Change Project within 12 months of earning of the QP503A.1 credential.

Please visit (<https://www.surveymonkey.com/r/QP503A>) by November 20<sup>th</sup>, 2015 to provide feedback directly to CriticalPoint on your state's interest in this program.



# FEDERAL REGISTER

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Part III

## Environmental Protection Agency

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40 CFR Parts 261, 262, 266, *et al.*

Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 261, 262, 266, 268, and 273**

[EPA-HQ-RCRA-2007-0932; FRL-9924-08-OSWER]

RIN 2050-AG39

**Management Standards for Hazardous Waste Pharmaceuticals**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. Healthcare facilities that generate hazardous waste pharmaceuticals as well as associated facilities have reported difficulties complying with the Subtitle C hazardous waste regulations for a number of reasons. First, healthcare workers, whose primary focus is to provide care for patients, are not knowledgeable about the RCRA hazardous waste regulations, but are often involved in the implementation of the regulations. Second, a healthcare facility can have thousands of items in its formulary, making it difficult to ascertain which ones are hazardous wastes when disposed. Third, some active pharmaceutical ingredients are listed as acute hazardous wastes, which are regulated in small amounts. To facilitate compliance and to respond to

these concerns, the U.S. Environmental Protection Agency (EPA or the Agency) is proposing to revise the regulations to improve the management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific issues that hospitals, pharmacies and other healthcare-related facilities face. The revisions are also intended to clarify the regulation of the reverse distribution mechanism used by healthcare facilities for the management of unused and/or expired pharmaceuticals.

**DATES:** Comments must be received on or before November 24, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-RCRA-2007-0932, to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full

EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Kristin Fitzgerald, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: 703-308-8286; email address: [fitzgerald.kristin@epa.gov](mailto:fitzgerald.kristin@epa.gov) or Josh Smeraldi, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: 703-308-0441; email address: [smeraldi.josh@epa.gov](mailto:smeraldi.josh@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*Does this action apply to me?*

This is a proposed rule. If finalized, this rule would apply to healthcare facilities, pharmaceutical reverse distributors, and owners or operators of treatment, storage, and disposal facilities engaged in the management of hazardous waste pharmaceuticals. The list of NAICS codes for the potentially affected entities, other than RCRA treatment, storage and disposal facilities (TSDFs), are presented in Table 1. More detailed information on the potentially affected entities is presented in Section V.A and Section V.B.1 of this preamble.

**TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE—HEALTHCARE FACILITIES AND PHARMACEUTICAL REVERSE DISTRIBUTORS**

NAICS codes	Description of NAICS code
44611 .....	Pharmacies.
54194 .....	Veterinary Clinics.
6211 .....	Physicians' Offices.
6212 .....	Dentists' Offices.
6213 .....	Other Health Practitioners ( <i>e.g.</i> , chiropractors).
6214 .....	Outpatient Care Centers.
6219 .....	Other Ambulatory Health Care Services.
622 .....	Hospitals.
6231 .....	Nursing Care Facilities ( <i>e.g.</i> , assisted living facilities, nursing homes, U.S. veterans domiciliary centers).
623311 .....	Continuing Care Retirement Communities ( <i>e.g.</i> , assisted living facilities with on-site nursing facilities).
Subset of 92219 .....	Medical Examiners and Coroners' Offices.
Various NAICS .....	Pharmaceutical Reverse Distributors.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially impacted by this action. This table lists examples of the types of entities of which EPA is aware that could potentially be affected by this action. Other types of entities not listed could also be affected. To determine whether

your entity, company, business, organization, etc. is affected by this action, you should examine the applicability criteria in this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER**

**INFORMATION CONTACT** section of this document.

**Preamble Outline**

- I. Statutory Authority
- II. List of Abbreviations and Acronyms
- III. Summary of the Proposed Rule
- IV. Background

- A. What is the history of hazardous waste pharmaceutical management under RCRA?
- B. What are the rationale and goals for this proposed rule?
- C. What was the 2008 pharmaceutical universal waste proposal?
- D. EPA's Office of Inspector General Report
- V. Detailed Discussion of the Proposed Rule
  - A. What terms are defined in this proposed rule?
  - B. What is the scope of this proposed rule?
  - C. What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals?
  - D. How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors?
  - E. What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?
  - F. What are the proposed standards for shipping hazardous waste pharmaceuticals?
  - G. What are the proposed standards for pharmaceutical reverse distributors?
- VI. Implementation and Enforcement
  - A. Healthcare Facilities
  - B. Pharmaceutical Reverse Distributors
  - C. Healthcare Facilities and Pharmaceutical Reverse Distributors Managing Non-Pharmaceutical Hazardous Waste in Accordance With 40 CFR Part 262 or Part 273
  - D. State Enforcement Activities and Interpretations
- VII. Request for Comment on EPA's Efforts To Identify Additional Pharmaceuticals as Hazardous Wastes
- VIII. Request for Comment on EPA's Efforts To Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)
  - A. Background
  - B. Basis for Original Listing
  - C. Rationale for EPA's Efforts To Amend the P075 Listing
  - D. Two Possible Approaches for Amending the P075 Listing
  - E. Request for Comments
- IX. State Authorization
  - A. Applicability of Rules in Authorized States
  - B. Effect on State Authorization
  - C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program
- X. Adding and Reserving Part 266, Subpart O
- XI. Summary of the Regulatory Impact Analysis
- XII. Statutory and Executive Order Reviews
  - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  - B. Paperwork Reduction Act (PRA)
  - C. Regulatory Flexibility Small Business Analysis
  - D. Unfunded Mandates Reform Act (UMRA)
  - E. Executive Order 13132: Federalism

- F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
- G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
- H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act (NTTAA)
- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

### I. Statutory Authority

These regulations are proposed under the authority of §§ 2002, 3001, 3002, and 3004 of the Solid Waste Disposal Act (SWDA) of 1970, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6921, 6922, 6923, and 6924.

### II. List of Abbreviations and Acronyms

- AARP American Association of Retired Persons
- AEA Atomic Energy Act
- API Active Pharmaceutical Ingredient
- BDAT Best Demonstrated Available Technology
- CERCLA Comprehensive Environmental Response, Compensation and Liability Act
- CESSQG Conditionally Exempt Small Quantity Generator
- CFR Code of Federal Regulations
- CSA Controlled Substances Act
- CWA Clean Water Act
- DEA Drug Enforcement Administration
- DHHS Department of Health and Human Services
- DOE Department of Energy
- DOT Department of Transportation
- EPA Environmental Protection Agency
- EO Executive Order
- FDA U.S. Food and Drug Administration
- FR Federal Register
- HIPAA Health Insurance Portability and Accountability Act
- HSWA Hazardous and Solid Waste Amendments
- LQG Large Quantity Generator
- LQUWH Large Quantity Universal Waste Handler
- LTCF Long-term Care Facility
- LTCP Long-term Care Pharmacy
- MSWLF Municipal Solid Waste Landfill
- NIOSH National Institute for Occupational Safety and Health
- NPRM Notice of Proposed Rulemaking
- NRC Nuclear Regulatory Commission
- OIG Office of Inspector General
- OMB Office of Management and Budget
- ONDCP Office of National Drug Control Policy
- OSHA U.S. Department of Labor's Occupational Safety and Health Administration
- OSWER Office of Solid Waste and Emergency Response
- OSWI Other Solid Waste Incinerators

- OTC Over-the-counter
- POTW Publicly Owned Treatment Works
- RCRA Resource Conservation and Recovery Act
- RQ Reportable Quantity
- SQG Small Quantity Generator
- SQUWH Small Quantity Universal Waste Handler
- SWDA Solid Waste Disposal Act
- TC Toxicity Characteristic
- TCLP Toxicity Characteristic Leaching Procedure
- TSDF Treatment, Storage and Disposal Facility

### III. Summary of the Proposed Rule

EPA is proposing to add a subpart P under 40 CFR part 266. Part 266 is entitled, "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities." This new subpart P is a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. If finalized, healthcare facilities that are currently small quantity generators (SQGs) or large quantity generators (LQGs) and all pharmaceutical reverse distributors, regardless of their RCRA generator category, will be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of 40 CFR part 262. That is, the proposed standards are not an optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they are mandatory standards.

Briefly, healthcare facilities will have different management standards for their non-creditable and creditable hazardous waste pharmaceuticals. Non-creditable hazardous waste pharmaceuticals (*i.e.*, those that are not expected to be eligible to receive manufacturer's credit) will be managed on-site similar to how they would have been under a previous proposal for managing these wastes: The 2008 Universal Waste proposal for pharmaceutical waste (73 FR 73520; December 2, 2008). When shipped off-site, they must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA interim status or permitted facility. On the other hand, healthcare facilities will continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors for processing manufacturers' credit. In response to comments received on the Universal Waste proposal, EPA is proposing standards to ensure the safe and secure delivery of the creditable

hazardous waste pharmaceuticals to pharmaceutical reverse distributors.

EPA is also proposing standards for the accumulation of the creditable hazardous waste pharmaceuticals at pharmaceutical reverse distributors. Like healthcare facilities, pharmaceutical reverse distributors will not be regulated under 40 CFR part 262 as hazardous waste generators, nor will they be regulated under 40 CFR parts 264, 265 and 270 as treatment, storage, and disposal facilities (TSDFs). Rather, the proposal establishes a new category of hazardous waste entity, called pharmaceutical reverse distributors. The proposed standards for pharmaceutical reverse distributors are, in many respects, similar to the LQGs standards, with supplementary standards added to respond to commenters' concerns.

For both healthcare facilities and reverse distributors, EPA is proposing to prohibit facilities from disposing of hazardous waste pharmaceuticals down the toilet or drain (*i.e.*, flushed or sewered). Further, EPA proposes that hazardous waste pharmaceuticals managed under subpart P will not be counted toward calculating the site's generator category. Additionally, EPA is proposing a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances. Finally, EPA is proposing management standards for hazardous waste pharmaceutical residues remaining in containers.

#### IV. Background

##### A. What is the history of hazardous waste pharmaceutical management under RCRA?

##### 1. What Is the Resource Conservation and Recovery Act?

The Resource Conservation and Recovery Act governs the management and disposal of hazardous wastes.<sup>1</sup> Under Subtitle C of RCRA, EPA has established a comprehensive set of regulations for hazardous waste management, generation, transportation, treatment, storage, and disposal. EPA can authorize an individual state hazardous waste program to operate in lieu of the federal program provided the authorized state's program is at least as stringent as, and consistent with, the federal program.<sup>2</sup> However, EPA maintains oversight of the authorized

<sup>1</sup> RCRA also governs the disposal of non-hazardous solid wastes; however, state and/or local environmental regulatory agencies predominantly administer the regulations pertaining to the management of non-hazardous wastes.

<sup>2</sup> For more information on RCRA State Authorization, see: <http://www.epa.gov/osw/laws-regs/state/index.htm>.

state's hazardous waste program and the authority to take independent enforcement actions. RCRA regulates pharmaceutical wastes that meet a listing of hazardous waste or exhibit one or more characteristics of hazardous waste. Accordingly, hospitals, pharmacies, reverse distributors and other healthcare-related establishments that generate hazardous wastes, including hazardous waste pharmaceuticals, are required to manage and dispose of their hazardous wastes in accordance with applicable federal, state, and/or local environmental regulations.

##### 2. What are the current standards for generators of hazardous waste?

Currently, there are no RCRA Subtitle C regulations that focus specifically on the management of hazardous wastes from hospitals, pharmacies, reverse distributors and other healthcare-related facilities. Rather, healthcare facilities are currently required to comply with the same RCRA hazardous waste regulations as many other industries that generate hazardous waste. While the RCRA Subtitle C program has requirements for all aspects of hazardous waste management, including those generating (referred to as "generators" by RCRA), transporting, storing, treating, and disposing of hazardous wastes, it is the generator requirements found under 40 CFR part 262 that will typically be most pertinent to healthcare-related facilities.

Under the federal RCRA regulations, the standards for hazardous waste generators are divided into three categories—LQGs, SQGs, and Conditionally Exempt Small Quantity Generators (CESQGs) depending upon the total amount of hazardous waste a facility generates per calendar month. It is the facility's generator category that determines the applicable RCRA hazardous waste management requirements with which the generator must comply.<sup>3</sup>

A generator that generates a solid waste<sup>4</sup> is required by § 262.11 to determine whether such waste meets the definition of RCRA hazardous waste.<sup>5</sup> If the waste meets the RCRA

<sup>3</sup> For more information on hazardous waste generators, please see: <http://www.epa.gov/waste/hazard/generation/index.htm>.

<sup>4</sup> See 40 CFR 261.2 for the definition of solid waste.

<sup>5</sup> The waste determination process includes determining if the waste is specifically excluded or exempted from the RCRA hazardous waste regulations. If not, then the entity must determine if the waste is listed by EPA under the F-, K-, P- or U-lists of hazardous wastes (§§ 261.31–33). If the waste is not listed, then it must be determined if the waste exhibits a characteristic of a hazardous

definition of a hazardous waste, then the generator must manage the waste in accordance with the regulations that apply to its hazardous waste generator category (see § 261.5 and 40 CFR part 262 for the generator regulations). In particular:

- Facilities qualify as LQGs if in a calendar month they generate 1,000 kg or more of hazardous waste or more than 1 kg of acute hazardous waste (*i.e.*, P-listed waste), or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31 or 261.33(e). Federal regulations for LQGs include, but are not limited to the following: Obtaining an EPA Identification number; a 90-day limit for accumulating hazardous waste on-site (with relevant standards for the accumulation of hazardous waste) without having to obtain a RCRA permit or comply with the interim status standards, provided that they comply with the conditions for exemption set forth in § 262.34(a) such as management and labeling standards specific to the type of accumulation unit (*e.g.*, container, tank); RCRA training of personnel; contingency planning; manifesting and recordkeeping and reporting (biennial report).

- Facilities qualify as SQGs if in a calendar month they generate more than 100 kg but less than 1,000 kg of hazardous waste. SQGs are subject to fewer requirements than LQGs and are given additional flexibility. For example, SQGs have a longer on-site accumulation time limit (180 or 270 days vs. 90 days for LQGs), with fewer standards for the accumulation of hazardous waste, without having to obtain a RCRA permit or comply with the interim status standards, provided that they comply with the conditions set forth in § 262.34(d) (which have fewer personnel training and contingency planning obligations than in the conditions for exemption for LQGs); and do not need to complete a biennial report (BR).

- Facilities qualify as CESQGs if in a calendar month they generate less than or equal to 100 kg of hazardous waste, and less than or equal to 1 kg of acutely hazardous waste (*i.e.*, P-listed), and less than or equal to 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in

waste: Ignitability, corrosivity, reactivity, or toxicity (§§ 261.21–24).

§§ 261.31, or 261.33(e).<sup>6</sup> CESQGs are subject to very few of the RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 261.5(f)(3) and (g)(3).

Finally, under the household hazardous waste exemption in § 261.4(b)(1), hazardous wastes generated by households are not subject to the RCRA hazardous waste regulations. This exemption from the Subtitle C requirements extends to any household wastes collected during community-oriented take-back programs or events, as long as these collected household hazardous wastes are managed separately from regulated hazardous wastes.<sup>7</sup> However, while collected household hazardous wastes are not regulated under the federal standards, more stringent state standards may apply.

### 3. Are pharmaceuticals considered hazardous wastes under RCRA?

A portion of the pharmaceuticals currently on the market meets RCRA's definition of hazardous waste when discarded. As previously explained, it is the responsibility of the generator of a solid waste to determine if the waste is hazardous; this includes solid wastes that are pharmaceuticals. If the pharmaceutical waste meets RCRA's definition of hazardous waste, then the generator must manage it in accordance with all applicable federal, state, and/or local environmental regulations. A pharmaceutical is considered a hazardous waste under RCRA in one of two ways. First, a discarded pharmaceutical can be a listed hazardous waste if it is a commercial chemical product<sup>8</sup> that is listed under RCRA's P- or U-list, and the pharmaceutical has not been used for its intended purpose (§ 261.33 (e) and (f),

respectively).<sup>9</sup> A few examples of pharmaceuticals that are considered P-listed wastes when discarded are arsenic trioxide (P012), smoking cessation products with nicotine as the sole active ingredient (P075), and pharmaceuticals with greater than 0.3% warfarin (and salts) as the sole active ingredient, such as Coumadin (P001). Some examples of pharmaceuticals that are considered U-listed wastes are: Cyclophosphamide (U058), mitomycin C (U010), streptozotocin (U206) and warfarin and salts ( $\leq 0.3\%$ ) as the sole active ingredient (U248).

Second, if the discarded pharmaceutical is not on the P- or U-list, then the pharmaceutical may be a hazardous waste if it exhibits one or more of the hazardous waste characteristics. Under the federal requirements (§ 261.21–24), a waste is a characteristic hazardous waste if it is ignitable (D001), corrosive (D002), reactive (D003) or toxic (D004–D043).<sup>10</sup> A number of pharmaceuticals are prepared in alcohol, which may cause the waste to be hazardous due to ignitability (D001), even if the active pharmaceutical ingredient itself is not considered hazardous waste. The Regulatory Impact Analysis for this proposed rule includes a list of pharmaceuticals that, to our knowledge, are hazardous waste when disposed, although this list should not be considered exhaustive (see the docket for this proposed rule EPA–HQ–RCRA–2007–0932).

Since the hazardous waste rules were initially promulgated, EPA has issued several clarifications regarding the regulatory status of certain commercial chemical products on the P- and U-lists, and these clarifications have affected the regulatory status of some active pharmaceutical ingredients.<sup>11</sup> For

example, EPA recently clarified that phentermine hydrochloride and other phentermine salts are not included within the scope of the P046 (phentermine) listing.<sup>12</sup> Similarly, EPA has also clarified that epinephrine salts are not included in the epinephrine listing (P042).<sup>13</sup> In addition, medicinal nitroglycerin typically is not considered P081 since the medicinal form of this compound generally does not exhibit the characteristic of reactivity for which nitroglycerin was originally listed.<sup>14</sup> Furthermore, in a 1998 memo, EPA clarified that the U034 listing includes both anhydrous chloral and chloral hydrate.<sup>15</sup> And in a 2010 memo, EPA stated that unused nicotine patches, gums and lozenges are finished dosage forms of nicotine and therefore are regulated as P075 when discarded.<sup>16</sup>

Finally, EPA has developed a “Hazardous Waste Pharmaceuticals Wiki” as a platform to facilitate the sharing of expertise among the healthcare industry and other stakeholders in order to help make accurate hazardous waste determinations for waste pharmaceuticals and increase compliance with the hazardous waste regulations. The Hazardous Waste Pharmaceuticals Wiki will also help users find guidance documents, state-specific information, and manufacturers' information. The Hazardous Waste Pharmaceuticals Wiki can be viewed at: <http://hwpharms.wikispaces.com>. EPA encourages healthcare stakeholders to use the Wiki to share information regarding federal hazardous waste

<sup>6</sup> EPA recommends that facilities that qualify as CESQGs under the federal regulations contact their state and/or local environmental regulatory agencies, as authorized states can be more stringent than the federal regulations. As a result, not all authorized states recognize the CESQG category or they may have more stringent regulatory requirements for CESQGs.

<sup>7</sup> For clarification on household hazardous waste collection issues, please see the November 1, 1988 memo from Win Porter to the Regional Waste Management Division Directors (RCRA Online # 11377) at: [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/\\$file/11377.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/$file/11377.pdf).

<sup>8</sup> Commercial chemical product refers to a chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed and all formulations in which the chemical is the sole active ingredient (§ 261.33(d)).

<sup>9</sup> The P- and U-lists deem as hazardous certain commercial chemical products when they are discarded or intended to be discarded. These listings consist of commercial chemical products having the generic names listed, off-specification species, container residues, and spill residues. Chemicals on the P-list are identified as acute hazardous wastes and are regulated at lower amounts than those on the U-list.

<sup>10</sup> The toxicity characteristic (TC) indicates that the waste is likely to leach concentrations of contaminants that may be harmful, and TC waste is identified using the Toxicity Characteristic Leaching Procedure (see § 261.24). Examples of TC constituents that may be present in pharmaceuticals include, but are not limited to: Arsenic, barium, cadmium, selenium, silver, chloroform, lindane and m-cresol.

<sup>11</sup> In addition, in December 2008, the Agency proposed to regulate hazardous waste pharmaceuticals under the Universal Waste rule. However, based on the comments received, the Agency decided not to finalize that proposal and to proceed with a sector-based approach. (See section IV.C. of the preamble for further discussion of the Universal Waste proposal.)

<sup>12</sup> Memo from Devlin to RCRA Division Directors, February 17, 2012 (RCRA Online #14831) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A5C07D01188ECA59852579EA0067CDB1/\\$file/14831.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A5C07D01188ECA59852579EA0067CDB1/$file/14831.pdf).

<sup>13</sup> Memo December 1, 1994 (RCRA Online #13718) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/\\$file/13718.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/$file/13718.pdf).

<sup>14</sup> Memo from Dellinger to Smith, March 18, 2003 (RCRA Online #14654) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7ACFEC572DE8897F85256D1600748BCB/\\$file/14654.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7ACFEC572DE8897F85256D1600748BCB/$file/14654.pdf).

<sup>15</sup> Memo from Brandes to Knauss, April 6, 1998 (RCRA Online #14175) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7417D2556AD322FA852568E300468198/\\$file/14175.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7417D2556AD322FA852568E300468198/$file/14175.pdf).

<sup>16</sup> Memo from Dellinger to Smith, August 23, 2010 (RCRA Online #14817) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD4ECDC852577ED00624E8F/\\$file/14817.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD4ECDC852577ED00624E8F/$file/14817.pdf).

pharmaceuticals, as well as state-only hazardous waste pharmaceuticals.<sup>17</sup>

*B. What are the rationale and goals for this proposed rule?*

1. Sector-Based Approach

The impetus behind this proposal is to address the various concerns raised by stakeholders regarding the difficulty in implementing the Subtitle C hazardous waste regulations for the management of hazardous waste pharmaceuticals generated at healthcare facilities. EPA has met with various stakeholders to learn about compliance challenges, and it has received input from stakeholders through more formal mechanisms. For instance, when EPA solicited stakeholder input in response to Executive Order 13563 (Improving Regulation and Regulatory Review), retailers submitted comments detailing compliance challenges with hazardous waste pharmaceuticals in their stores.<sup>18</sup> Further, EPA's Office of Inspector General (OIG) published a report citing the need to clarify how hazardous waste pharmaceuticals are regulated (for more information on both of these reports, see the next section). These two reports and input from healthcare (and associated) facilities identified a number of ways in which a healthcare facility differs from a manufacturing facility when it comes to applying the RCRA Subtitle C program for generating and managing hazardous waste.

First, in the healthcare setting, many hazardous waste pharmaceuticals are generated unpredictably and in relatively small quantities by a number of different employees across the facility. This situation differs from a manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes.

Second, under the current hazardous waste regulatory scheme, healthcare workers, whose primary focus is to provide care for patients, are typically responsible for making hazardous waste determinations since they are at the point of generation (e.g., a patient's bedside). Yet, healthcare workers, such as nurses and doctors, do not typically

have the expertise to make hazardous waste determinations.

Third, a healthcare facility can have thousands of items in its formulary at any one time and these may vary over time. In addition, pharmaceutical wastes come in many different forms, such as pills, patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc. The combination of having thousands of different pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare workers to make appropriate hazardous waste determinations when pharmaceuticals are disposed. This situation differs from manufacturing, where fewer, more predictable waste streams are generated.

Fourth, several of the hazardous waste pharmaceuticals that are generated by healthcare facilities are P-listed acute hazardous wastes (see § 261.33(e)), which are regulated at much smaller amounts. If a facility generates more than 1 kg of acute hazardous waste per calendar month or accumulates that amount at any time, it is regulated as an LQG. In addition to the pharmaceuticals, residues within pharmaceutical containers that contained P-listed commercial chemical products must be managed as acute hazardous waste even if the pharmaceutical was fully dispensed,<sup>19</sup> unless the container is RCRA-empty (e.g., by triple-rinsing the container). Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often end up managing these containers as hazardous waste, which can result in the facilities being subject to the most stringently regulated generator category (i.e., LQG).<sup>20</sup>

To facilitate compliance among healthcare facilities and to respond to these concerns, EPA is proposing a new set of sector-specific regulations to

improve the management and disposal of hazardous waste pharmaceuticals at healthcare facilities. This proposed rule also intends to clarify the regulatory status of a major practice used by healthcare facilities for management of unused and/or expired pharmaceuticals, known as reverse distribution (see Sections V.D.1 and V.G).

In addition to improving compliance and responding to stakeholder concerns, the Agency has two additional goals for this proposal. The first is to reduce the amount of pharmaceuticals that are disposed of "down the drain." This is presently an allowable and common disposal practice among healthcare facilities (as long as the pharmaceutical waste is not ignitable (see the Clean Water Act regulations of 40 CFR 403.5(b)(1)) and provided certain conditions are met (see the Clean Water Act regulations of 40 CFR 403.12(p)). Studies have found that many healthcare facilities, particularly long term-care facilities, are using drain disposal as a routine disposal method for pharmaceutical wastes. Although pharmaceuticals are also entering the environment through excretion, reducing sewer disposal is one mechanism to help reduce the environmental loading of pharmaceuticals into our Nation's waters. For more information about sewer disposal and pharmaceuticals in water, see Section V.E.1.

The second goal is to address the overlap between EPA's RCRA hazardous waste regulations and the controlled substances regulations of the Drug Enforcement Administration (DEA). Stakeholders have indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and expensive to dispose of in accordance with both sets of requirements when sent for incineration. In addition, stakeholders have indicated that those regulated hazardous waste pharmaceuticals that are also controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. EPA plans to address this overlap in this proposed rule, as this is an unnecessary burden for healthcare facilities and revised requirements will help to reduce sewer disposal.

2. Executive Order 13563 for the Retrospective Review of Existing Regulations

On January 18, 2011, President Obama issued Executive Order 13563, which directed all federal agencies to perform periodic retrospective reviews of existing regulations to determine whether any should be modified,

<sup>17</sup> Anyone may view the Wiki. Those in the healthcare community who wish to contribute content or edit the Wiki can register by sending an email request to [HWPharmsWiki@epa.gov](mailto:HWPharmsWiki@epa.gov).

<sup>18</sup> Executive Order 13563 was signed by President Obama on January 18, 2011 and published in the **Federal Register** on January 21, 2011 (76 FR 3821). In response to the Executive Order, EPA solicited comments on "Improving EPA Regulations," in a **Federal Register** notice published on February 23, 2011 (76 FR 9988). See docket number EPA-HQ-OA-2011-0160 for public comments related to waste.

<sup>19</sup> P-listed hazardous waste residues in containers are themselves considered P-listed hazardous wastes (see § 261.33(c)), unless the container is considered "RCRA empty" either by undergoing triple-rinsing with an appropriate solvent; or cleaning with a method that has been proven in scientific literature or tests conducted by the generator to achieve equivalent removal (see § 261.7(b)(3)).

<sup>20</sup> On November 4, 2011, ORCR issued a memo to the Regional RCRA Division Directors highlighting three acceptable approaches, beyond triple-rinsing containers, that healthcare facilities can employ when managing P-listed container residues. Please see: Memo from Suzanne Rudzinski to RCRA Division Directors (RCRA Online #14827) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/57B21F2FE33735128525795F00610F0F/\\$file/14827.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/57B21F2FE33735128525795F00610F0F/$file/14827.pdf).

streamlined, expanded, or repealed.<sup>21</sup> EPA made its preliminary plan available for public review and comment during the spring of 2011 and released the final version of the plan in August 2011.<sup>22</sup> During the public comment process, EPA received requests to clarify and make more effective the hazardous waste regulations as they pertain to discarded retail products, including pharmaceutical wastes. In response to this specific issue, EPA agreed to review data and information currently in its possession as part of the development for a rulemaking to address pharmaceutical waste management issues.<sup>23</sup> This Notice of Proposed Rulemaking provides notice that EPA has completed its review and has satisfied this part of its obligation for retail hazardous waste pharmaceutical management issues.

### 3. Retail Notice of Data Availability

EPA published a Notice of Data Availability (NODA) for the Retail Sector on February 14, 2014 (79 FR 8926), in which the Agency requested, among other things, comment on a series of topics related to retail operations in order to better understand the issues retail stores/establishments face in complying with RCRA regulations. Many retail commenters mentioned that because nicotine is an acute hazardous waste (P075), they are considered LQGs when they discard more than 1 kg per month of unused nicotine-containing products (e.g., e-cigarettes and smoking cessation products such as gums, patches and lozenges). Retailers discard these products mainly because they are either expired or they are returned by customers and the retailer does not restock them due to safety concerns. In comments to the NODA, retailers urged the EPA to provide them some regulatory relief with regard to nicotine-containing products. See Section VIII of this preamble for a discussion of EPA's potential future efforts to amend the acute hazardous waste listing for nicotine and salts (P075).

<sup>21</sup> For a copy of Executive Order 13563, please see: <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

<sup>22</sup> US EPA. Improving Our Regulations: Final Plan for Periodic Retrospective Reviews of Existing Regulations. <http://www.epa.gov/regdart/retrospective/documents/eparetroreviewplan-aug2011.pdf>.

<sup>23</sup> See page 45, item 2.2.17 of EPA's "Improving Our Regulations: Final Plan for Periodic Retrospective Reviews of Existing Regulations" at <http://www.epa.gov/regdart/retrospective/documents/eparetroreviewplan-aug2011.pdf>.

### C. What was the 2008 Pharmaceutical Universal Waste proposal?

#### 1. The 2008 Proposal To Add Hazardous Waste Pharmaceuticals to the Federal Universal Waste Program

On December 2, 2008, EPA proposed to add hazardous waste pharmaceuticals to the existing federal universal waste program, which would have provided a streamlined approach to facilitate the proper management and disposal of hazardous waste pharmaceuticals generated at pharmacies, hospitals, reverse distributors, and other healthcare-related facilities. Specifically, under the universal waste program, handlers and transporters who generate or manage items designated as a universal waste<sup>24</sup> are subject to the management standards under part 273, rather than the full RCRA subtitle C hazardous waste regulations. Universal waste handlers include universal waste generators and collection facilities. The regulations distinguish between "large quantity handlers of universal waste" (or those who handle more than 5,000 kilograms of total universal waste at any one time) and "small quantity handlers of universal waste" (or those who handle 5,000 kilograms or less of universal waste at any one time).<sup>25</sup> The streamlined requirements for all types of universal waste include modified requirements for storage, labeling and marking, preparing the waste for shipment off-site, employee training, response to releases and notification.

Transporters of universal waste are also subject to less stringent requirements than the full RCRA subtitle C hazardous waste transportation regulations. However, the primary difference between the universal waste transportation requirements and full RCRA subtitle C requirements is that no hazardous waste manifest is required for the transport of universal waste.

Destination facilities under the universal waste program are those facilities that treat, store, dispose of, or recycle universal wastes. Universal waste destination facilities are subject to all currently applicable requirements for hazardous waste treatment, storage, and disposal facilities (TSDFs), including the requirement to obtain a RCRA permit for such activities. (See 73 FR 73520, December 2, 2008, for a more detailed discussion of the proposed

<sup>24</sup> The current federal universal wastes include hazardous waste batteries, certain hazardous waste pesticides, mercury-containing equipment, and hazardous waste lamps.

<sup>25</sup> The 5,000 kilogram accumulation criterion applies to the quantity of all universal wastes accumulated.

universal waste program for pharmaceutical wastes.)

#### 2. What were the public comments to the 2008 Pharmaceutical Universal Waste proposal?

EPA received approximately 100 public comments on the 2008 proposal to add hazardous waste pharmaceuticals to the universal waste program.<sup>26</sup> Generally, public commenters supported the Agency's desire to address the issue of hazardous waste pharmaceutical management. However, although there were several aspects of the proposal that were well supported (e.g., training requirements, accumulation times, and hazardous waste pharmaceuticals not being counted towards the generator category), public commenters expressed concern over the lack of notification and tracking requirements for small quantity handlers of universal waste and the reduced notification and tracking requirements for large quantity handlers. As a result, commenters, including state environmental regulatory agencies, expressed concern that they would not be informed of hazardous waste pharmaceutical generation, management, and transportation in their regulatory jurisdictions. Furthermore, public commenters expressed concern that because the universal waste program does not require a hazardous waste manifest or another tracking mechanism, the hazardous waste pharmaceuticals could be vulnerable to diversion. Public commenters argued that hazardous waste pharmaceuticals are different from the other federal universal wastes (batteries, mercury-containing equipment, lamps, and pesticides) in that the pharmaceuticals, as well as their containers, still retain considerable value upon disposal and can be easily diverted for illicit purposes. Therefore, tracking requirements beyond the requirements included in the current universal waste program were considered necessary by the majority of the public commenters.

In addition to the public comments about the strengths and weaknesses of using the universal waste program to address the disposal of hazardous waste pharmaceuticals, EPA received other comments expressing concern with the proposal, including the following: The point of generation of hazardous waste pharmaceuticals as it pertains to reverse distribution; the management of

<sup>26</sup> See docket EPA-HQ-RCRA-2007-0932 at [www.regulations.gov](http://www.regulations.gov) for public comments: <http://www.regulations.gov/#1docketDetail;D=EPA-HQ-RCRA-2007-0932;ct=FR%252BPR%252BN%252BO%252BSR>.

containers that contain hazardous waste pharmaceutical residues; the variability in the land disposal restriction (LDR) treatment standards for hazardous waste pharmaceuticals; the overlap of EPA and DEA regulations for the management of hazardous waste pharmaceuticals that are also controlled substances; and the lack of activity to add pharmaceutical wastes to the hazardous waste listings. The Agency provides additional discussion on these specific comments within this preamble.

### 3. Why is EPA not finalizing the 2008 Pharmaceutical Universal Waste proposal?

Based on the adverse comments received on the 2008 Pharmaceutical Universal Waste proposal regarding the lack of notification and tracking requirements for small quantity universal waste handlers, the reduced notification and tracking requirements for large quantity universal waste handlers, as well as the other issues raised in public comments, the Agency has decided to not finalize the proposal to add hazardous waste pharmaceuticals to the Universal Waste program. In fact, EPA has concluded that the universal waste program is not appropriate for managing hazardous waste pharmaceuticals because, among other things, we are unable to adequately address the notification and tracking concerns raised by the public comments within the Universal Waste program.

Under the Universal Waste regulations, there are eight factors to consider when determining whether it is appropriate to add a new hazardous waste or category of hazardous waste to the Universal Waste program (§ 273.81). A hazardous waste does not need to meet every factor in order to be added to the Universal Waste program. Rather, the Agency's decision is "based on the weight of evidence showing that regulation under part 273 is appropriate for the waste or category of waste, will improve management practices for the waste or category of waste, and will improve implementation of the hazardous waste program" (§ 273.80(c)).

The Agency has concluded based on the comments received that the weight of evidence does not show that regulation under the Universal Waste program is appropriate for hazardous waste pharmaceuticals. Specifically, we find the Universal Waste program to be lacking with regard to the factor in § 273.81(e), which states that the risk posed by the waste being considered for universal waste be relatively low compared to other hazardous wastes and that the management standards

would be protective of human health and the environment during accumulation and transport. Although we continue to believe that potentially creditable pharmaceuticals en route to reverse distributors pose a low risk for leaks and other releases to the environment, commenters urged us to consider the unique risk posed by the accumulation and transport of hazardous waste pharmaceuticals: the risk of diversion. Although it is rare that a hazardous waste is so valuable that it is sought for abuse or sale on the black market, EPA believes that the diversion of hazardous waste pharmaceuticals for illicit use is a risk to human health.

The Universal Waste program does not include sufficient tracking requirements to address the potential for diversion. Under part 273, tracking is not required for shipments by small quantity handlers of universal waste; certain tracking of shipments is required only for large quantity handlers of universal waste and destination facilities. More importantly, these basic tracking requirements consist only of recordkeeping of shipments sent and received and no tracking is required to ensure delivery. Commenters noted that these tracking requirements are not sufficient given the high value of many of the unused pharmaceuticals en route to reverse distribution and the potential for diversion.

Accordingly, the Agency is proposing to amend § 273.80 to state that hazardous waste pharmaceuticals may not be added as a category of hazardous waste for management under the Universal Waste program. See Section IX State Authorization of the preamble for a discussion on the effect on the two states that have adopted pharmaceuticals under the Universal Waste program (Michigan and Florida).

By proposing a new set of management standards outside the confines of the Universal Waste program, it allows us greater flexibility in addressing the tracking of such shipments, as well as additional pharmaceutical waste management issues raised by stakeholders, such as drain disposal, container residues, pharmaceutical reverse distribution, and the overlap with DEA regulation. This new action will address the original stakeholder concerns that resulted in the 2008 Pharmaceutical Universal Waste proposal, as well as the comments received on that proposal.

To reiterate, EPA is not adding hazardous waste pharmaceuticals to the federal Universal Waste program. Rather, we are proposing sector-specific regulations for the management of hazardous waste pharmaceuticals by

healthcare facilities and pharmaceutical reverse distributors. If finalized, these regulations will be codified in 40 CFR part 266, separate from both the generator regulations (40 CFR part 262) and the Universal Waste program (40 CFR part 273). This new proposed rulemaking will pertain to those waste pharmaceuticals that meet the current definition of a RCRA hazardous waste *and* are generated by healthcare-related facilities and managed by pharmaceutical reverse distributors, as defined by this proposal. Finally, as this current proposal is a direct result of the comments received on the December 2, 2008, Pharmaceutical Universal Waste proposal, the Agency considers the 2008 Pharmaceutical Universal Waste proposal obsolete. Therefore, EPA is withdrawing the Universal Waste proposal for pharmaceutical waste, and does not seek comment on any provisions of the 2008 Pharmaceutical Universal Waste proposal or the current Universal Waste program. The Agency will only be accepting comments from the public on the provisions of this new proposed rulemaking.

### D. EPA's Office of Inspector General Report

On May 25, 2012, the EPA's Office of Inspector General (OIG) issued the report, "EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal" (Report No. 12-P-0508).<sup>27</sup> The OIG reviewed EPA's process for identifying and listing pharmaceuticals as hazardous wastes. Because of this review, the OIG provided the following recommendations to the Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER):

(1) Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(2) Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(3) Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that healthcare facilities, and others as needed, have in complying with RCRA regulations for managing HWP's [hazardous waste pharmaceuticals] (Report No. 12-P-0508).

As detailed in OSWER's response to OIG, this proposal fulfills our obligation

<sup>27</sup> For a copy of the report, please see: <http://www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf> or see the docket for this proposed rule: EPA-HQ-RCRA-2007-0932.

for addressing the third recommendation.<sup>28</sup> EPA does not address the OIG's first two recommendations as part of this proposed rulemaking; however, in Section VII of this preamble, we solicit comment on our ongoing efforts to identify additional pharmaceuticals as hazardous wastes.

## V. Detailed Discussion of the Proposed Rule

EPA is proposing an entirely new set of regulations (40 CFR part 266, subpart P) for managing hazardous waste pharmaceuticals at both healthcare facilities and pharmaceutical reverse distributors. This section discusses in detail the major features of the proposal. The Agency also presents other options that it is considering or were considered in developing the proposed rule. EPA welcomes comments on all aspects of this proposed rule, and on options under consideration. Throughout this section, EPA requests comments on specific options and on specific issues, but comments are welcome on all provisions of this proposal.

### A. What terms are defined in this proposed rule?

All the definitions that appear in this proposal are for the purposes of 40 CFR part 266, subpart P only. Therefore, the definitions are relevant only to healthcare facilities and pharmaceutical reverse distributors that are subject to these proposed standards. For the purposes of this regulation, the Agency is proposing and soliciting public comment on the following terms and their definitions presented below: "evaluated hazardous waste pharmaceutical," "hazardous waste pharmaceutical," "healthcare facility," "household waste pharmaceutical," "long-term care facility," "non-creditable hazardous waste pharmaceutical," "non-hazardous waste pharmaceutical," "non-pharmaceutical hazardous waste," "pharmaceutical," "pharmaceutical reverse distributor," and "potentially creditable hazardous waste pharmaceutical." Although the proposed definitions appear in alphabetical order in the regulations, we have chosen to discuss the proposed definitions in a different order in the preamble.

#### 1. What is the proposed definition of "pharmaceutical"?

This proposed rule defines "pharmaceutical" as any chemical or

biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act (FD&C Act), prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals.

This proposed definition of "pharmaceutical" is intended to include all dose forms, including, but not limited to tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy pharmaceuticals, vaccines, allergenics, medicinal shampoos, antiseptics, and any delivery device, including medicinal dermal patches, with the primary purpose to deliver or dispense the pharmaceutical. As a rule of thumb, if an over-the-counter product is required by the FDA to include "Drug Facts" on the label, it would be considered a pharmaceutical for the purposes of this rule. EPA asks for comment to identify additional types or forms of pharmaceuticals that are not adequately captured by the definition.

EPA previously proposed to define the term "pharmaceutical" in the December 2008 Pharmaceutical Universal Waste proposal to mean "any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or injury in man or other animals; or any chemical product, vaccine, or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine, or allergenic), not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals. This definition includes products such as transdermal patches, and oral delivery devices such as gums or lozenges. This definition does not include sharps or other infectious or biohazard waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated

cleaning materials." This definition was adapted from FD&C Act's definition for "drug" 21 U.S.C. 321(g).

Based on the comments received in response to the Pharmaceutical Universal Waste proposal, the Agency is continuing to rely primarily on the FD&C Act's definition for "drug" for the definition of pharmaceutical in this proposal and has preserved most of the definition proposed in the previous proposal. However, EPA is proposing to expand on its previous proposed definition of pharmaceutical based on stakeholder input. In particular, stakeholders requested that the Agency take a broad view in delineating what items are included in the definition of pharmaceutical so that the proposed standards apply broadly. Stakeholders indicated a preference for managing more items under the new standards than trying to determine how to apply the existing RCRA framework to pharmaceutical related items. Thus, the proposed definition of pharmaceutical no longer excludes pharmaceuticals with a radioactive component and includes items not specifically recognized by the U.S. Food and Drug Administration (FDA) as drugs, such as dietary supplements and pharmaceutical residues in containers (including delivery devices), personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from spills of pharmaceuticals.

EPA's decision to include dietary supplements under this rulemaking's proposed definition of hazardous waste pharmaceutical reflects our interest in promoting a management scheme for all types of pharmaceuticals, and is based upon our understanding that dietary supplements are commonly found in various healthcare settings because they are recommended or prescribed by healthcare providers to patients.<sup>29</sup> Further, retail pharmacies routinely sell vitamins and other medicinal minerals and supplements.

When EPA uses the term "dietary supplements" in our proposed definition of "pharmaceutical," EPA is referencing the definition for dietary supplement used by the FD&C Act, as amended by the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. 321(ff)).<sup>30</sup> EPA understands that

<sup>29</sup> Including dietary supplements under the definition of pharmaceutical for this regulation does not supersede the requirements of the Dietary Supplement Health and Education Act of 1994, the Federal Food, Drug and Cosmetic Act, or FDA regulations.

<sup>30</sup> The substance of the definition is: a product (other than tobacco) intended to supplement the

<sup>28</sup> For a copy of OSWER's full response to OIG, please see: [http://www.epa.gov/oig/reports/2012/12-P-0508\\_Agency%20Response.pdf](http://www.epa.gov/oig/reports/2012/12-P-0508_Agency%20Response.pdf).

the FDA does not recognize dietary ingredients or dietary supplements under its definition of “drug,” but rather categorizes such items under the general umbrella of foods and therefore, does not review them before being marketed.<sup>31 32</sup> For the purposes of this proposed rule, however, EPA recognizes that healthcare facilities may benefit from managing dietary supplements along with other drugs under the regulatory scheme being proposed, and thus, is including it in the proposed definition of pharmaceutical. Although dietary supplements would be considered pharmaceuticals under this proposed definition, only the dietary supplements that meet the definition of hazardous waste (e.g., exhibits the toxicity characteristic for metal content) would be regulated under part 266, subpart P as hazardous waste pharmaceuticals (see the definition of “hazardous waste pharmaceutical”). We seek public comment on the Agency’s decision to recognize dietary supplements as pharmaceuticals under this regulation.

The Agency also is clarifying that its proposed definition includes any items containing pharmaceutical residuals, such as dispensing bottles, IV bags and tubing, vials, unit dose packages, and delivery devices, such as syringes and patches. In addition, EPA is proposing that items contaminated with or containing residual pharmaceuticals, such as personal protective equipment containing trace amounts of pharmaceuticals or related spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings) also meet this proposed definition of pharmaceutical. However, this proposed definitions does *not* include sharps (e.g., needles from IV bags or syringes). Used sharps, such as needles or syringes with needles, are not included under the proposed rule because sharps are considered medical

diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); For the complete definition for dietary supplement, please see: <http://www.gpo.gov/fdsys/pkg/USCODE-2013-title21/pdf/USCODE-2013-title21-chap9-subchap11-sec321.pdf>.

<sup>31</sup> For more information regarding dietary supplements, please see: <http://www.fda.gov/Food/DietarySupplements/default.htm>.

<sup>32</sup> It is the responsibility of the manufacturers to ensure their dietary supplements are safe and that all claims on labels are true and accurate. Nevertheless, FDA has the authority to take action against any unsafe dietary supplements, as well as to take action against any products with false and misleading claims.

wastes, presently regulated at the state and local level. In addition, sharps pose both an unreasonable physical danger and biohazard danger so have not been included in the definition of pharmaceutical under this proposed rule. OSHA’s Technical Manual incorporates a recommendation from the American Society of Hospital Pharmacists that “all syringes and needles used in the course of preparation be placed in “sharps” containers for disposal without being crushed, clipped or capped.”<sup>33</sup> Further, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation. However, EPA is concerned about the possibility that some syringes may be disposed of in sharps containers that may contain significant amounts of undispensed pharmaceutical. EPA seeks comment on the prevalence of this situation.

The Agency solicits public comment on the proposed definition of “pharmaceutical” in its entirety, and particularly on EPA’s decision to incorporate dietary supplements and items containing pharmaceutical residuals as part of the definition of pharmaceutical.

## 2. What is the proposed definition of a “hazardous waste pharmaceutical”?

This proposed rule defines “hazardous waste pharmaceutical” as a pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C. See Section IV.A.3. of this preamble for a discussion of pharmaceuticals that may be listed or characteristic hazardous wastes.<sup>34</sup>

The Agency is proposing to define the term “hazardous waste pharmaceutical” in order to clarify its intent that only pharmaceuticals (as defined in this proposal) that meet the definition of hazardous waste when disposed or discarded need to be managed under these proposed management standards. This means that any pharmaceutical waste that meets the definition of hazardous waste is a hazardous waste pharmaceutical for the purposes of this rule. For example, the prescription pharmaceutical warfarin (brand name Coumadin) is a listed hazardous waste

<sup>33</sup> See Section VI, Chapter 2 of OSHA’s Technical Manual (paragraph V.C.1.b.) [https://www.osha.gov/dts/osta/otm/otm\\_vi/otm\\_vi\\_2.html](https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html).

<sup>34</sup> For additional information about RCRA hazardous waste listings and characteristics, see: <http://www.epa.gov/osw/hazard/wastetypes/index.htm>.

and when discarded meets the definition of a hazardous waste pharmaceutical. EPA requests public comment on the proposed definition for “hazardous waste pharmaceutical.” The Agency also solicits information on whether any dietary supplements currently on the market meet or potentially could meet RCRA’s definition of a hazardous waste.

## 3. What is the proposed definition of a “potentially creditable hazardous waste pharmaceutical”?

In order to distinguish hazardous waste pharmaceuticals that are transported to RCRA treatment, storage and disposal facilities (TSDFs) from those hazardous waste pharmaceuticals being returned by a healthcare facility to a pharmaceutical reverse distributor for a determination or verification of manufacturer’s credit, the Agency is proposing a definition for “potentially creditable hazardous waste pharmaceutical.”

The proposed rule defines “potentially creditable hazardous waste pharmaceutical” to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer’s credit and is

- (1) unused or un-administered; and
- (2) unexpired or less than one year past expiration date.

The term does not include “evaluated hazardous waste pharmaceuticals,” residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals.

Whether a pharmaceutical is eligible for manufacturer’s credit is determined solely by the manufacturer’s return policy. Based on comments received for the 2008 Universal Waste proposed rule and through discussions with various stakeholders, the Agency understands that the return policies of manufacturers change regularly. As a result, pharmacies are not always aware if a particular pharmaceutical will be creditable at the time that it is pulled from the shelves. However, the Agency also understands that there are instances where it is well known that a pharmaceutical will not be creditable. Examples of these instances include the following: if the pharmaceutical has been removed from the original container and re-packaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which

they had already received compensation by a third-party payer; or if the pharmaceutical is more than one year past its expiration date. In these instances, as well as others, the healthcare facility knows that it will not receive manufacturer's credit. It is the Agency's intent for the proposed definition of potentially creditable hazardous waste pharmaceuticals to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for those hazardous waste pharmaceuticals.

Also, based on communication with stakeholders and the public comments received on the 2008 Universal Pharmaceutical Waste proposal, EPA understands that pharmaceutical manufacturers' policies often allow for credit to be received on the return of 'partials.' Partials is a term used in the industry to refer to opened containers that have had some contents removed. Under the proposed definition, the Agency would consider partials to be potentially creditable hazardous waste pharmaceuticals.

The Agency is soliciting comment on the proposed definition of "potentially creditable hazardous waste pharmaceutical" and whether the definition is broad enough to encompass the various types of hazardous waste pharmaceuticals that are shipped to reverse distributors for manufacturer's credit, while also ensuring that non-creditable hazardous waste pharmaceuticals are not inappropriately shipped to reverse distributors solely for waste management purposes. Finally, the Agency is seeking comment on additional situations where it is well known that a returned pharmaceutical will or will not receive manufacturer's credit.

4. What is the proposed definition of "non-creditable hazardous waste pharmaceutical"?

As discussed previously, there are instances when it is well known that credit will not be received for certain hazardous waste pharmaceuticals. In order to distinguish hazardous waste pharmaceuticals that have the potential for credit from those that have no expectation of receiving credit, the Agency is proposing to define the term "non-creditable hazardous waste pharmaceutical." The proposed definition of a "non-creditable hazardous waste pharmaceutical" is a hazardous waste pharmaceutical that is

not expected to be eligible for manufacturer's credit. Examples include, but are not limited to: if the pharmaceutical has been removed from the original container and re-packaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which they had already received compensation by a third-party payer (e.g. health insurance company); or if the pharmaceutical is more than one year past its expiration date. EPA requests comment on the proposed definition and seeks additional examples of hazardous waste pharmaceuticals that have no expectation of receiving manufacturer's credit.

5. What is the proposed definition of "evaluated hazardous waste pharmaceutical"?

After potentially creditable hazardous waste pharmaceuticals arrive at a pharmaceutical reverse distributor, they are evaluated to determine whether they are eligible for manufacturer's credit, or whether they need to be transferred to another pharmaceutical reverse distributor for additional verification of manufacturer's credit. Hazardous waste pharmaceuticals that need to be transferred to another pharmaceutical reverse distributor for additional verification of manufacturer's credit will continue to be considered potentially creditable hazardous waste pharmaceuticals. EPA is proposing that hazardous waste pharmaceuticals for which manufacturer's credit has been issued (and no further verification of credit is required), as well as those that have been deemed non-creditable, be referred to as "evaluated hazardous waste pharmaceuticals." EPA is proposing to define "evaluated hazardous waste pharmaceutical" as a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification. It is important to define this term since the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals differ from the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals. For a discussion of the proposed management

and shipping standards for potentially creditable hazardous waste pharmaceuticals, see Section V.F.2. For a discussion of the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals, see Section V.F.1.b.

6. What is the proposed definition of "household waste pharmaceutical"?

We are proposing to define the term "household waste pharmaceutical" as a solid waste, as defined in § 261.2, that also meets the definition of pharmaceutical, as defined in this proposed rule, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in § 261.4(b)(1). We are proposing this term to distinguish this type of waste pharmaceutical from the hazardous waste pharmaceuticals that are proposed to be regulated under this new subpart. This proposed rule does not apply to pharmaceutical waste that is exempt due to the household waste exclusion.

7. What is the proposed definition of "non-hazardous waste pharmaceutical"?

We are proposing to define the term "non-hazardous waste pharmaceutical." While hazardous waste pharmaceuticals are proposed to be regulated under this new subpart, non-hazardous waste pharmaceuticals will not be regulated under this new subpart, nor the RCRA subtitle C hazardous waste regulations. The Agency is proposing to include this definition since we believe it important to delineate what is and is not regulated under this new subpart. We propose to define the term "non-hazardous waste pharmaceutical" to mean a pharmaceutical that is a solid waste, as defined in § 261.2, but that is not a listed hazardous waste and does not exhibit any characteristics of hazardous waste (i.e., ignitable, corrosive, reactive, toxic).

8. What is the proposed definition of "non-pharmaceutical hazardous waste"?

Like the previous definition, we are proposing a definition for non-pharmaceutical hazardous waste to help us delineate what is and what is not regulated under this new subpart. We are proposing to define the term "non-pharmaceutical hazardous waste" as a solid waste, as defined in § 261.2, that is either a listed hazardous waste or exhibits one or more characteristics of hazardous waste, but does not meet the definition of a pharmaceutical, as proposed under this new subpart. The management of non-pharmaceutical hazardous wastes is not regulated under this subpart; rather generators of non-

pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to the existing Subtitle C hazardous waste regulations for the management of those hazardous wastes. Examples of non-pharmaceutical hazardous wastes that healthcare facilities may generate include cleaning solutions, solvents, and laboratory wastes. Some hazardous wastes exist in pharmaceutical form and non-pharmaceutical form. For example, warfarin, nicotine, and lindane were all originally listed as hazardous waste because they were pesticides, not medicines. If these products are not intended for human or animal use, they would be considered non-pharmaceutical hazardous wastes and remain subject to the existing RCRA hazardous waste regulations, not part 266, subpart P.

9. What is the proposed definition of a “healthcare facility”?

These proposed regulations differ from those in the Pharmaceutical Universal Waste proposal in that they apply based not only on the type of hazardous waste generated, but also on the sector generating the waste. Accordingly, EPA is proposing a definition for “healthcare facility” so that it is clear to whom these proposed regulations apply. This proposed definition is adapted from the definition of “health care” that the Department of Health and Human Services (DHHS) promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103).<sup>35</sup> Thus, for the purposes of these proposed regulations, EPA is proposing that “healthcare facility” means any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians’ offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and

hospitals. Thus, these proposed regulations will be applicable to any healthcare facility for human or animal which generates hazardous waste pharmaceuticals on its premises.

EPA proposes to include coroners in the definition of a healthcare facility despite the fact that the services coroners provide occur after life. Coroners will often inventory, and then dispose of, any pharmaceuticals that may be found at the scene of a death. A common method of disposal is sewerage. In order to reduce the sewer disposal practices of coroners, and to provide the same management options that are available to other healthcare facilities, EPA has decided to include “coroners” within the definition of healthcare facility, although the Agency solicits comment on including coroners within the definition of healthcare facility.<sup>36</sup>

Under the proposed definition, healthcare facilities include locations that sell pharmaceuticals over the internet, through the mail, or through other distribution mechanisms. A pharmacy does not necessarily have to have a “brick and mortar” or “store front” presence to be considered a healthcare facility for the purposes of this proposed rule. The proposed definition of a “healthcare facility” also applies to entities that engage in drug compounding. In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The proposed definition of “healthcare facility” applies to state-licensed pharmacies, Federal facilities, and licensed physicians that compound drugs in accordance with section 503A of the FD&C Act, and to outsourcing facilities that compound drugs in accordance with section 503B of the FD&C Act. The Agency is soliciting comment on the proposed definition of “healthcare facility,” including whether it is appropriate to consider these compounders as healthcare facilities within the scope of this proposed rule.

The proposed definition of “healthcare facility” does not apply to pharmaceutical manufacturers and their representatives, wholesalers, or any

other entity that is involved in the manufacturing, processing or wholesale distribution of over-the-counter or prescription pharmaceuticals, unless they meet the definition of a “reverse distributor” as discussed in this section and in Section V.G. The purpose for these sector-based regulations is to address the various issues that healthcare facilities and reverse distributors face when managing hazardous waste pharmaceuticals. As noted previously, the Agency does not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities.

10. What is the proposed definition of a “long-term care facility”?

The term “long-term care facility” does not have a standardized, industry definition. EPA is, therefore, proposing the following definition for “long-term care facility” (LTCF): a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

The included facilities are licensed care facilities that are more similar to hospitals than to standard residences. Although group homes may be licensed care facilities, they are typically very small (under 10 beds). Independent living communities are not licensed care facilities, but rather are residences made up of individual units such as townhomes or apartments. Finally, private residences with visiting nurses are not considered long-term care facilities. EPA requests public comment on the proposed definition of long-term care facility, and the inclusion of assisted living facilities, skilled nursing facilities and other LTCFs that administer their residents’ pharmaceuticals as an integral part of their services within the definition of “healthcare facility.”

The DEA’s definition of “long term care facility” is “a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients” (21 CFR 1300.01). EPA’s definition is more descriptive, and includes a list—which is not

<sup>36</sup> For more information on the disposal process, please see: Ruhoy, I.S. and Daughton, C.G. “Types and Quantities of Leftover Drugs Entering the Environment via Disposal to Sewage—Revealed by Coroner Records,” *Sci. Total Environ.*, 2007, 388(1–3):137–148. <http://www.epa.gov/nrelsd1/bios/daughton/SOTE2007.pdf>.

<sup>35</sup> 45 CFR part 160 <http://aspe.hhs.gov/admsimp/final/pvctxt01.htm>.

exhaustive—of examples of long-term care facilities. We feel this a more flexible way to define the universe. Although the definitions differ, they are not necessarily incompatible.

11. What is the proposed definition of a “pharmaceutical reverse distributor”?

As more fully discussed in Section V.G.1 of this preamble, pharmaceutical manufacturers often offer credit to healthcare facilities on the return of unused and/or expired pharmaceuticals.<sup>37</sup> Stakeholders have informed the Agency that manufacturers issue credit for a variety of reasons. For example, it is a marketing incentive tool that helps ensure against illicit diversion<sup>38</sup> or improper disposal, and it allows manufacturers to collect data on the returned items, which then can be used to help plan for future pharmaceutical production. Reverse distributors are contracted by both pharmaceutical manufacturers and healthcare facilities to facilitate the crediting process.

Some of the pharmaceuticals returned for credit will meet RCRA’s definition of a hazardous waste. Due to the fact that the vast majority of pharmaceuticals that are returned for manufacturer’s credit are disposed of once credit eligibility is determined, EPA is proposing new standards for shipment of potentially creditable hazardous waste pharmaceuticals (see Section V.F.2.) and the management of potentially creditable hazardous waste pharmaceuticals by reverse distributors (see Section V.G.). Thus, EPA is proposing to define pharmaceutical reverse distributor to clearly delineate which types of facilities are subject to this proposed rule. In keeping with how the term is commonly used in the healthcare sector, EPA is proposing to define a “pharmaceutical reverse distributor” as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer’s credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer’s credit is considered a pharmaceutical reverse distributor.

<sup>37</sup> As noted in the definition of “potentially creditable hazardous waste pharmaceutical,” credit is provided for those pharmaceuticals that are less than one year past the expiration date.

<sup>38</sup> Through the return of pharmaceuticals by a pharmacy for manufacturer’s credit, manufacturers are able to maintain control of the pharmaceutical up to the point of its disposal, thereby, decreasing the risk of diversion of the pharmaceutical.

The Agency also needs to clarify the difference between what is defined as a pharmaceutical reverse distributor for the purpose of these proposed regulations and how DEA regulations define “reverse distribute.” The recently amended DEA regulatory definition of “reverse distribute” is to “acquire controlled substances from another registrant or law enforcement for the purposes of: (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer’s behalf; or (2) Destruction (21 CFR 1300.01).<sup>39</sup>

Under DEA’s definition, a reverse distributor does not necessarily process pharmaceuticals for the purpose of determining manufacturer’s credit; rather, their main function under DEA’s definition is to destroy the controlled substances. Under EPA’s proposed definition, however, a pharmaceutical reverse distributor is defined more broadly as a facility that can accept potentially creditable pharmaceuticals for the purposes of determining manufacturer’s credit. These potentially creditable pharmaceuticals may or may not be identified as controlled substances by DEA.<sup>40</sup> Therefore, a DEA-registered reverse distributor may or may not meet EPA’s definition of a pharmaceutical reverse distributor and vice versa. For example, a pharmaceutical reverse distributor that accepts controlled substances (that are also hazardous wastes) for the sole purpose of destruction (*e.g.*, incineration) would be regulated as a DEA-registered reverse distributor and as a RCRA TSDF, and not as a pharmaceutical reverse distributor under the RCRA hazardous waste regulations. Conversely, a pharmaceutical reverse distributor that processes pharmaceuticals for manufacturer’s credit, but is not a DEA registrant and therefore, cannot accept controlled substances, would meet the RCRA pharmaceutical reverse distributor definition, but not DEA’s reverse distributor definition. However, EPA has heard from stakeholders that many, if not all, entities that facilitate manufacturer’s credit are also DEA-registered reverse distributors. Therefore, such pharmaceutical reverse

<sup>39</sup> On September 9, 2014, DEA finalized new definitions for “reverse distribute” and “reverse distributor.” Please see 79 FR 53520. The term “reverse distributor” is defined as “a person registered with the Administration [DEA] as a reverse distributor.”

<sup>40</sup> In order for a reverse distributor to be able to accept controlled substances, the reverse distributor must be a DEA registrant. See 21 CFR part 1308 for a complete list of controlled substances.

distributors would meet both EPA’s proposed definition of pharmaceutical reverse distributor, as well as the DEA’s definition of reverse distributor. Lastly, we would note that EPA’s definition for reverse distribution does not alter or supersede the requirements of the Controlled Substances Act and DEA regulations.

In addition, the Department of Transportation’s Pipeline and Hazardous Materials Safety Administration (PHMSA) has defined the closely related term, “reverse logistics,” in a recent proposed rulemaking.<sup>41</sup> The EPA has been coordinating with the PHMSA to ensure that our rules are compatible, even if the definitions differ. It is important to note that, when finalized, the PHMSA rule will not supersede EPA’s RCRA Subtitle C regulations for when something is considered a solid or hazardous waste or how a hazardous waste must be managed.

The Agency solicits public comment on its proposed definition of a “pharmaceutical reverse distributor.” Specifically, EPA asks for comment on whether the definition of “pharmaceutical reverse distributor” captures the universe of facilities acting as reverse distributors for pharmaceuticals. In addition, the Agency asks for comment regarding the intersection of DEA and EPA’s definitions.

*B. What is the scope of this proposed rule?*

1. What facilities are subject to this rulemaking?

*a. Healthcare facilities.* The Agency is proposing that healthcare facilities that are currently considered either SQGs or LQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in accordance with the standards proposed in this document. In other words, these management standards will apply to any healthcare facility that generates (or accumulates) more than 100 kg of hazardous waste per calendar month *or* more than 1 kg of acute hazardous waste per calendar month (*e.g.*, P-listed hazardous waste) *or* more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e) per calendar month. All healthcare facilities

<sup>41</sup> 79 FR 46748; August 11, 2014. The PHMSA’s proposed definition of reverse logistics “is the process of moving goods from their final destination for the purpose of capturing value, recall, replacement, proper disposal, or similar reason.”

that meet these applicability criteria will be subject to the same set of standards for the management of their hazardous waste pharmaceuticals. That is, subpart P is not optional for healthcare facilities that generate above the CESQG monthly quantity limits (see Section V.B.1.c. of the preamble for a discussion of what regulations apply to CESQGs). EPA is proposing to make subpart P mandatory to promote national consistency, a goal championed by stakeholder comments as well as EPA. In addition, having one set of standards applicable to pharmaceutical waste will be less confusing to the regulated community, which should lead to better compliance. The stringency of the subpart P management standards for hazardous waste pharmaceuticals do not change if a healthcare facility generates more hazardous waste pharmaceuticals from one month to another. The generator categories—that is, LQG, SQG, and CESQG—under the part 262 RCRA requirements will only be relevant for the healthcare facilities' non-pharmaceutical hazardous waste because non-pharmaceutical hazardous waste remain subject to the 40 CFR part 262 generator regulations (see Section VI. *Implementation and Enforcement* for further discussion).

*b. Long-term care facilities subject to this rule.* Long-term care facilities are included within the proposed definition of healthcare facility. Further, EPA is proposing to change its policy regarding the management of hazardous waste and hazardous waste pharmaceuticals generated on the premises of long-term care facilities. Under current federal RCRA interpretation (see 73 FR 73525, December 2, 2008), hazardous wastes (including pharmaceuticals) generated on the premises of a long-term care facility can fall under two categories: (1) RCRA Subtitle C hazardous waste or (2) household hazardous waste that is exempt from RCRA Subtitle C regulation. As explained in the preamble to the proposal to add pharmaceuticals to the Universal Waste program, “the [long-term care] facility itself may generate hazardous wastes as a result of its central management of pharmaceuticals in its pharmacy or pharmacy-like area. These hazardous pharmaceutical wastes would be subject to the RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, the resulting wastes are generated by that facility. However, patients and residents in long-term care facilities may generate hazardous wastes. Those pharmaceuticals that are under the

control of the patient or resident of the long-term care facility, when discarded, would be subject to RCRA's household hazardous waste exclusion (§ 261.4(b)(1)). Hazardous pharmaceutical wastes generated by the resident are excluded from regulation because they are considered to be derived from a household” (see December 2, 2008; 73 FR 73525).

The Agency is now providing notice that it intends to revise this interpretation. Specifically, hazardous waste (including pharmaceuticals) generated at long-term care facilities will no longer be considered exempt as household hazardous waste. It will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the standards being proposed. The Agency is revising its interpretation with regard to hazardous wastes generated at long-term care facilities based on a reevaluation of how such facilities operate. Specifically, in order for hazardous waste to qualify for the household hazardous waste exemption of § 261.4(b)(1), it must meet two criteria: (1) The hazardous waste must be generated by individuals on the premises of a household, and (2) the hazardous waste must be composed primarily of materials found in the wastes generated by consumers in their homes.<sup>42</sup> EPA now believes that hazardous waste generated at long-term care facilities, even when those pharmaceuticals are under the control of the patient or resident, does not meet either criterion for the household hazardous waste exemption.

First, a long-term care facility is more akin to a hospital than it is a typical residence and EPA does not consider hospitals to be households. Long-term care facilities are licensed, residential care settings that offer their residents a wide range of services, many of which are centered on administering medications and providing healthcare by various professional healthcare providers, such as medical technicians, nurse's aides, nurses, and doctors. Other services provided involve assistance in performing activities of daily living, such as bathing, and eating. A 2012 American Association of Retired Person (AARP) Public Policy Institute report indicates that there is an average of 24 beds per licensed residential care facilities (excluding nursing homes).<sup>43</sup>

<sup>42</sup> See November 13, 1984; 49 FR 44978.

<sup>43</sup> AARP Public Policy Institute, INSIGHT on the Issues 58, Assisted Living and Residential Care in the States in 2010, April 2012. [http://www.aarp.org/content/dam/aarp/research/public\\_policy\\_institute/lc/2012/residential-care-insight-on-the-issues-july-](http://www.aarp.org/content/dam/aarp/research/public_policy_institute/lc/2012/residential-care-insight-on-the-issues-july-)

Based on another report prepared as a collaborative project of the American Association of Homes and Services for the Aging (AAHSA), American Seniors Housing Association (ASHA), Assisted Living Federation of America (ALFA), National Center for Assisted Living (NCAL) and National Investment Center for the Seniors Housing and Care Industry (NIC), there is an average of 54 units (e.g., rooms) for all types of assisted living/dementia care properties.<sup>44</sup> Unlike other multiple dwellings, approximately 81 percent of these facilities store medications in a central location and 89 percent administer medications to their residents.<sup>45</sup> Given that long-term care facilities are licensed settings for the care of their residents and routinely provide healthcare services, we believe that long-term care facilities more closely resemble hospitals than typical residences.

Second, the hazardous wastes generated by long-term care facilities do not meet the second criteria for the waste to be considered household hazardous waste. This is primarily due to the quantity of pharmaceutical wastes that are often generated on the premises of long-term care facilities when compared to a typical residence. For example, the Colorado Department of Public Health and Environment estimates that a 100-bed nursing home might expect to generate approximately 120 to 336 pounds of pharmaceutical waste per year.<sup>46</sup> In addition, long-term care facilities, such as assisted living facilities and nursing homes, generate a greater variety of hazardous waste pharmaceuticals and a greater quantity of hazardous waste than a typical household generates. The AARP Public Policy Institute report indicates that “residents take an average of seven or eight different prescriptions and two OTC [over-the-counter] medications daily.” This number is larger than what we would expect a typical household to generate. This distinction about volume of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from

*2012-AARP-ppi-ltc.pdf* or see the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

<sup>44</sup> 2009 Overview of Assisted Living; a collaborative research project of AAHSA, ASHA, ALFA, NCAL & NIC.

<sup>45</sup> *Ibid.*

<sup>46</sup> Net weight (without packaging) of types of pharmaceuticals wastes, including those that are RCRA hazardous, non-RCRA hazardous, DEA controlled, prescription and over-the-counter. Memo from Lillian Gonzalez, Colorado Department of Public Health and Environment to Kristin Fitzgerald, EPA; January 9, 2013, see the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

households: waste from “routine residential maintenance” is exempt as household hazardous waste, while waste from “building construction, renovation, demolition” is not exempt.<sup>47</sup> Therefore, EPA is providing notice that if this rule is finalized, long-term care facilities may no longer use the household hazardous waste exemption. If this rule is finalized, long-term care facilities would need to manage their hazardous waste pharmaceuticals in accordance with the healthcare facility specific management standards in this proposal and their non-pharmaceutical hazardous wastes in accordance with the applicable RCRA hazardous waste generator requirements in § 261.5 (for CESQGs) or part 262 (for SQGS and LQGs). However, even though long-term care facilities will no longer be considered eligible to use the household hazardous waste exemption, our data show that only 28% of long-term care facilities generate hazardous waste pharmaceuticals, and of those, 85% are small enough to be considered CESQGs of hazardous waste (regulated under § 261.5) and therefore not subject to part 266, subpart P (except the sewer ban).<sup>48</sup> The Agency seeks comment on whether this proposed change to consider long-term care facilities to be healthcare facilities instead of households is appropriate. We also seeking comment on the extent to which long-term care facilities will pass the cost of compliance onto its customers. Until this rule is finalized, the current interpretation from the Universal Waste preamble will stand regarding hazardous waste from long-term care facilities.

*c. Conditionally exempt small quantity generators (CESQGs).* As discussed in the Background Section (Section IV.A.2), CESQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 261.5.<sup>49</sup> This proposed rulemaking will preserve this current regulatory structure for the most part; therefore, healthcare facilities that

generate hazardous waste pharmaceuticals and qualify as CESQGs, will maintain their conditional exemption under § 261.5 and will not be subject to *most* aspects of this proposal. However, as part of this rulemaking, EPA is proposing a ban on sewer disposal of hazardous waste pharmaceuticals by all healthcare facilities and reverse distributors. EPA is proposing that the sewer ban would apply to all healthcare facilities, including CESQG healthcare facilities. Please see Section V.E.1 of this preamble for a more detailed discussion on this proposed sewer prohibition. EPA asks for comment on whether the proposed healthcare facility standards, in addition to the sewer ban, should apply to CESQG healthcare facilities.

EPA is proposing one additional change for CESQGs in order to allow them to continue to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor. Currently, under § 261.5, CESQGs are limited in where they may send their hazardous waste for treatment and disposal (see § 261.5(f)(3)(i)-(vii) for acute hazardous waste and § 261.5(g)(3)(i)-(vii) for hazardous waste). However, in § 266.504(a) we are proposing to allow CESQGs to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor. Without this change, CESQGs would be required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in § 261.5, which does not include a pharmaceutical reverse distributor. Although we are proposing to make this change within part 266, subpart P, we request comment on whether stakeholders would prefer this change to be made within § 261.5 instead. CESQGs will still be required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in § 261.5.

In addition, it has been suggested that EPA seek comment on providing a rebuttable presumption that LTCFs with fewer than 10-beds are assumed to be CESQGs and thus would not be required to count the amount of hazardous waste generated each month. Under this presumption, they would be subject to all the requirements for CESQGs as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals. Therefore, EPA asks for comment on this rebuttable presumption and specifically whether the 10-bed cut off

is appropriate or whether there are other criteria EPA should take into account. Further, EPA asks for commenters to submit data to support a 10-bed cut off to show that LTCFs with fewer than 10-beds are generally CESQGs. Alternatively, if comments wish to support a different cut-off for the rebuttable assumption, EPA also asks that the commenters submit information/data to support their suggested cut-off.

*d. Pharmaceutical reverse distributors.* EPA is proposing that pharmaceutical reverse distributors, including pharmaceutical manufacturers, which accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to this rule. Pharmaceutical reverse distributors are only subject to this proposed rule for the *accumulation* of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals; if a reverse distributor also treats and/or disposes of hazardous waste pharmaceuticals, it is subject to the applicable RCRA Subtitle C TSDF regulations, including the requirement to have a permit or interim status. Stakeholders have indicated a strong preference for EPA to clarify how pharmaceutical reverse distributors are regulated under RCRA, as states have applied varied hazardous waste regulatory approaches to pharmaceutical reverse distributors. EPA is proposing specific standards in 40 CFR part 266, subpart P for pharmaceutical reverse distributors (as defined in this proposed rule) that incorporate various generator standards, as well as some TSDF standards. See Section V.G for more information.

2. To what facilities does this rule not apply?

*a. Pharmaceutical manufacturers.* EPA does not intend for these proposed regulations to apply to hazardous waste pharmaceuticals that are generated by pharmaceutical manufacturers or wholesalers. Pharmaceutical manufacturers and wholesalers do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals in accordance with the federal RCRA subtitle C requirements (for an explanation of the challenges healthcare facilities face, see discussion in section IV.B.1 of the preamble). These entities (*i.e.*, manufacturers and wholesalers) generate hazardous waste pharmaceuticals that are more predictable and the staff have the

<sup>47</sup> Memo from Petruska to McNally, February 28, 1995; RCRA Online #11897 that discusses the distinction about what renovation waste is household hazardous waste and what is not.

<sup>48</sup> See the docket for this rulemaking for data about long-term care facilities which was developed using data in the economic analysis: EPA-HQ-RCRA-2007-0932.

<sup>49</sup> Not all authorized states recognize the CESQG category and may have more stringent regulatory requirements for CESQGs. Therefore, as noted previously, EPA recommends that facilities that qualify as CESQGs under the federal regulations contact their state and/or local environmental regulatory agencies to determine whether more stringent regulatory requirements apply to CESQGs in their state.

necessary expertise to determine which pharmaceutical waste is hazardous waste. However, as mentioned previously, when any facility, including a pharmaceutical manufacturer, meets the definition found in this proposal for a “pharmaceutical reverse distributor,” it would be subject to the proposed regulations for pharmaceutical reverse distributors with respect to those operations.

*b. Households.* The Agency would like to emphasize that the regulatory requirements in this proposed rule do not apply to households or to household pharmaceutical collection and take-back events and programs. (For information regarding collection programs, see Section V.E.2.) Pharmaceuticals that are unwanted by consumers (households) are not regulated as hazardous waste and are generally considered municipal solid wastes. While a small percentage of these household waste pharmaceuticals meet the definition of hazardous waste under RCRA, the federal RCRA hazardous waste regulations include an exclusion for all hazardous wastes generated by households (see the “household hazardous waste” exclusion at § 261.4(b)(1)). Thus household waste pharmaceuticals—like other household hazardous wastes—are not subject to the federal RCRA hazardous waste regulations.

“EPA excluded household wastes because the legislative history of RCRA indicated an intent to exclude such wastes, though *not* because they necessarily pose no hazard.”<sup>50</sup> Some household products, including pharmaceuticals, contain ignitable, corrosive, reactive, or toxic ingredients. As a result, for household hazardous waste collected at a take-back event or program, the Agency has historically recommended that communities operating the collection programs manage the collected household hazardous wastes as hazardous waste, even though it is not required by RCRA.<sup>51</sup> Furthermore, the Agency has recently recommended that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.<sup>52</sup> The

Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Nevertheless, the Agency is proposing to make this recommendation a requirement for collected household waste pharmaceuticals in § 266.506.<sup>53</sup> The Agency seeks comment on changing this recommendation to a requirement for pharmaceutical collection programs.

The Agency recommends that, whenever possible, households utilize pharmaceutical collection and take-back events as the disposal option for their unwanted pharmaceuticals. For consumers without access to a pharmaceutical take-back event, FDA provides information on the disposal of unused pharmaceuticals and step-by-step guidance for disposing of pharmaceuticals in the household trash. For more information on the safe disposal of household pharmaceuticals, please see: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>.

### 3. Which hazardous wastes are addressed by this proposed rule?

*a. Hazardous waste pharmaceuticals.* If finalized, these regulations will only pertain to those pharmaceutical wastes that are RCRA hazardous wastes generated by healthcare facilities or managed by pharmaceutical reverse distributors. Under this rulemaking, EPA is not proposing to add additional pharmaceuticals to the hazardous waste listings or to expand the hazardous waste characteristics to include additional pharmaceuticals. See Section VII of the preamble, *Request for Comment on EPA’s Efforts to Identify Additional Pharmaceuticals as Hazardous Waste*, for a discussion of possible future actions by EPA to regulate additional pharmaceuticals as hazardous waste.

*b. How does this proposal affect hazardous waste pharmaceuticals that are also regulated by other federal or state regulations?* The management, transportation, treatment, storage and disposal of hazardous waste pharmaceuticals are regulated under RCRA Subtitle C. However, hazardous

waste pharmaceuticals may also be subject to a number of other statutes and implementing regulations administered by state or other federal agencies. Examples include pharmaceuticals that are subject to the Controlled Substances Act and DEA regulations; infectious pharmaceutical wastes that are subject to state and local medical waste regulations; and pharmaceuticals with a radioactive component that are subject to the Atomic Energy Act (AEA). These potentially overlapping requirements make the appropriate management of pharmaceutical wastes a complex matter. The following discusses the impact of this proposed rule on various dually regulated hazardous waste pharmaceuticals.

*i. Hazardous waste pharmaceuticals that are also controlled substances.* Under current regulations, any healthcare facility generating or managing a RCRA hazardous waste pharmaceutical that is also a controlled substance listed in Schedule II–V<sup>54</sup> must comply with the RCRA hazardous waste requirements, as well as the requirements of the Controlled Substances Act and DEA regulations. Recently revised DEA regulations to implement the Secure and Responsible Drug Disposal Act of 2010 require that controlled substances be destroyed so that they are “non-retrievable.”<sup>55</sup> In the preamble to both the proposed and final rules, DEA has stated that flushing alone will not meet DEA’s new non-retrievable standard.<sup>56</sup> Stakeholders have told EPA that it is expensive and difficult to incinerate controlled substances that are also hazardous wastes under both DEA and EPA regulatory schemes. As a result, healthcare facilities with hazardous waste pharmaceuticals that are also controlled substances have often sewered on-site in order to avoid the expense of complying with dual regulation that would apply if they were incinerated. Due to difficulties associated with managing these hazardous waste pharmaceuticals that are also controlled substances, the Agency is proposing to conditionally exempt from RCRA regulatory requirements those pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance, provided the hazardous waste pharmaceuticals that are also DEA controlled substances are combusted at a permitted or interim

<sup>50</sup> See 49 FR 44978; November 13, 1984.

<sup>51</sup> See memo November 1, 1988, from Porter to Regions (RCRA Online #11377). [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/\\$file/11377.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/$file/11377.pdf).

<sup>52</sup> See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14833). <http://yosemite.epa.gov/osw/>

[rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/\\$file/14833.pdf](http://rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/$file/14833.pdf).

<sup>53</sup> Since pharmaceutical collection programs typically co-mingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

<sup>54</sup> See 21 CFR 1308 for a complete list of controlled substances.

<sup>55</sup> Final rule: September 9, 2014; 79 FR 53520.

<sup>56</sup> Proposed rule: December 21, 2012; 77 FR 75784, see page 75803; and final rule: September 9, 2014; 79 FR 53520, see page 53548.

status hazardous waste incinerator, or a permitted municipal solid waste incinerator. A more detailed discussion of this exemption is found in Section V.E.2 of this proposal, *Conditional Exemption for Hazardous Waste Pharmaceuticals that are also Controlled Substances*.

ii. *Hazardous waste pharmaceuticals that are also medical wastes*. There are instances when a hazardous waste pharmaceutical will also exhibit a biological hazard. The healthcare industry often refers to pharmaceutical wastes that are both RCRA hazardous and a biological hazard as “dual wastes,” and such wastes must be managed in accordance with RCRA and state and/or local medical waste regulations. As a result, the healthcare facility must send these dual wastes to a hazardous waste treatment, storage and disposal facility that is also permitted to accept medical wastes. Some examples of dual wastes include un-administered syringes containing hazardous waste pharmaceuticals (e.g., physostigmine) or IV bags containing residues of a hazardous waste pharmaceutical that are attached to the tubing and needles used to administer the pharmaceutical. The RCRA hazardous waste pharmaceutical portion of these “dual” wastes are included within these proposed management standards so that healthcare facilities can obtain the benefits of this proposal, while ensuring the hazardous waste portion of the waste is managed appropriately and ultimately delivered to RCRA-permitted TSDFs. In addition, healthcare facilities must still manage the biological hazard in accordance with state and/or local medical waste requirements. EPA notes that autoclaving is not an acceptable method of treating hazardous wastes that are also medical waste. In addition, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation.

iii. *Hazardous waste pharmaceuticals that contain a radioactive component*. Hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (AEA) (i.e., “mixed waste”) are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste

under the AEA.<sup>57</sup> Healthcare facilities would be able to use this rule (if finalized) to comply with the hazardous waste component for hazardous waste pharmaceuticals. Although we do not believe that anything in this proposal is inconsistent with the AEA, § 1006(a) of RCRA states that if the RCRA requirements are inconsistent with the AEA requirements, then the RCRA requirements do not apply. Therefore, if a healthcare facility that manages hazardous waste pharmaceuticals encounters specific RCRA requirements that are inconsistent with specific AEA requirements, only the AEA requirements would apply.

As is discussed in the Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste (62 FR 62079, 62085; November 20, 1997), an inconsistency occurs when compliance with one statute or set of regulations would necessarily cause non-compliance with the other statute or set of regulations. Relief from the regulatory inconsistency would be provided by the AEA requirement overriding the specific RCRA requirement. It is important to note, however, that the determination of an inconsistency would relieve the healthcare facility only from compliance with the specific RCRA requirement(s) that is deemed inconsistent with the AEA requirement(s); it would still be required to comply with all of the other hazardous waste pharmaceutical management standards.

#### 4. Management of Wastes Generated at Healthcare Facilities That Are Not Included in the Scope of this Proposed Rule

Wastes that are not included in the scope of this proposed rule include non-hazardous wastes or non-pharmaceutical hazardous wastes. Pharmaceutical wastes that are not listed or characteristic hazardous wastes under RCRA Subtitle C may nonetheless pose some risks to public health and the environment. These wastes are discussed further below.

a. *How should non-hazardous waste pharmaceutical be disposed?* A large portion of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of a RCRA hazardous waste under RCRA Subtitle C. This proposal, therefore, does not require that healthcare facilities manage these waste pharmaceuticals under the RCRA subtitle C hazardous waste

<sup>57</sup> The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

regulations, including this proposed rule. However, a healthcare facility may choose to manage its solid and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under these new proposed regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of pharmaceutical hazardous waste generated, managing non-hazardous waste pharmaceuticals as hazardous waste under this subpart would not affect the facility’s hazardous waste generator category. While not regulated by the federal RCRA hazardous waste requirements, non-hazardous waste pharmaceuticals are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state and/or local regulatory requirements.

If a healthcare facility decides to segregate its hazardous and non-hazardous pharmaceuticals, EPA recommends that healthcare facilities follow the best management practices (BMPs) outlined in the “Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States” (Practice Greenhealth, Revised August 2008)<sup>58</sup> for the management, treatment, storage and disposal of non-hazardous waste pharmaceuticals. The following summarizes the recommended BMPs found in the Blueprint for various categories of pharmaceutical wastes, including those wastes that possess hazardous waste-like qualities yet are not regulated as hazardous waste under RCRA Subtitle C.

i. *Recommended BMPs for healthcare facilities managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities*. Currently, most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These “non-RCRA-hazardous” pharmaceuticals can be divided into two categories: those that possess hazardous waste-like qualities and those that do not. As outlined in the Blueprint, there are pharmaceuticals that possess hazardous waste-like qualities, but for various reasons, are not regulated by the RCRA Subtitle C hazardous waste regulations. The Agency supports the Blueprint’s

<sup>58</sup> Published in 2006, the development of the original *Blueprint* was funded by the Office of Solid Waste and Emergency Response and managed by EPA Region 1. The 2008 revision of the *Blueprint* was funded by the Healthcare Environmental Resource Center. <http://practicegreenhealth.org/sites/default/files/upload-files/pharmwasteb Blueprint.pdf>

recommendation of hazardous waste incineration as the BMP for healthcare facilities and pharmaceutical reverse distributors discarding pharmaceuticals that may possess hazardous waste-like qualities, but are not regulated as RCRA hazardous waste. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists,<sup>59</sup> chemotherapeutic agents characterized as bulk wastes,<sup>60</sup> pharmaceuticals which meet the NIOSH Hazardous Drug Criteria,<sup>61</sup> pharmaceuticals listed in Appendix VI of the OSHA Technical Manual,<sup>62</sup> pharmaceuticals with LD50s  $\leq$  50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

ii. *Recommended best management practices for other non-hazardous pharmaceutical wastes (i.e., those not possessing hazardous waste like-qualities).* As far as other non-hazardous waste pharmaceuticals (i.e., those not possessing hazardous waste-like qualities), disposing of non-hazardous waste pharmaceuticals at healthcare facilities via drain disposal is strongly discouraged and not recommended by EPA. Therefore, EPA endorses the Blueprint's recommendation of municipal solid waste or medical waste incineration for any non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste-like qualities. The potential risk remains for active pharmaceutical ingredients (APIs) to be released into the environment if municipal solid waste landfills or medical waste autoclaves are used for the purposes of pharmaceutical waste treatment and disposal. For example, autoclaves are designed to kill pathogens and do not achieve the temperatures required to destroy most APIs during the autoclaving process. As a result, there is the potential for wastewater containing APIs to be generated and discharged into the sewer. In addition, some limited studies have shown APIs present in landfill

leachate collected in municipal solid waste landfill leachate systems.<sup>63 64</sup> Typically, the collected landfill leachate is subsequently sent to wastewater treatment plants for treatment, but their treatment technologies are not designed to remove all APIs from the wastewater (See Section V.E.1 for more information regarding sewerage and APIs).

b. *Non-pharmaceutical hazardous wastes.* These proposed regulations will only pertain to hazardous waste pharmaceuticals. Therefore, other types of hazardous wastes generated at healthcare facilities that do not meet the definition of a hazardous waste pharmaceutical cannot be managed in accordance with these proposed regulations. For example, hazardous wastes generated in hospital laboratories or during cleaning and maintenance of the facility are not considered hazardous waste pharmaceuticals and are not included within the scope of this proposal. The generation of non-pharmaceutical hazardous wastes is often more routine and does not trigger the same concerns that healthcare facilities experience when managing hazardous waste pharmaceuticals.

After a healthcare facility determines it is subject to this proposed rule and manages its hazardous waste pharmaceuticals under part 266, subpart P, it is no longer required to count the hazardous waste pharmaceuticals that it generates towards its generator category. As a result, the healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste. For example, a healthcare facility may shift from being an LQG to a SQG or even CESQG by not counting its hazardous waste pharmaceuticals toward its generator category, especially when acute hazardous waste pharmaceuticals such as warfarin (brand name: Coumadin) no longer need to be counted. A shift in generator category, should it occur, would allow a healthcare facility to manage its non-pharmaceutical hazardous waste, such as hazardous waste from laboratories, according to the reduced generator requirements. It is important to note that only when a

healthcare facility is managing its hazardous waste pharmaceuticals under the new proposed subpart does it have the benefit of not counting them towards its generator category (see Section VI. *Implementation and Enforcement* for further discussion).

C. *What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals?*

This section discusses the proposed management standards for healthcare facilities (except CESQGs) that manage non-creditable hazardous waste pharmaceuticals, which include the following:

- (1) Notification requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (2) personnel training requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (3) making a hazardous waste determination for non-creditable hazardous waste pharmaceuticals;
- (4) elimination of central accumulation area and satellite accumulation area requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (5) container standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (6) labeling standards on containers for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (7) accumulation time limits for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (8) land disposal restrictions for non-creditable hazardous waste pharmaceuticals;
- (9) procedures for shipping non-creditable hazardous waste pharmaceuticals off-site from healthcare facilities;
- (10) procedures for managing rejected shipments of non-creditable hazardous waste pharmaceuticals from healthcare facilities;
- (11) reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (12) recordkeeping requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (13) procedures for responses to releases by healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

<sup>59</sup> As noted in the comment after § 261.33(d), the phrase "commercial chemical product" includes formulations in which the P- or U-listed chemical is the sole active ingredient. Therefore, formulations with more than one active ingredient do not meet the specifications of the P- and U-listings even if one, two or all of the active ingredients are listed on the P- and/or U-lists.

<sup>60</sup> The descriptions "bulk" and "trace" when applied to chemotherapeutic wastes are industry terms and are not defined by the federal RCRA regulations.

<sup>61</sup> *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012.* <http://www.cdc.gov/niosh/docs/2012-150/>.

<sup>62</sup> *OSHA Technical Manual, Section VI: Chapter 2, Appendix VI: 2-1.* [http://www.osha.gov/dts/osta/otm/otm\\_vi/otm\\_vi\\_2.html](http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html).

<sup>63</sup> Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), *Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill.* *Groundwater Monitoring & Remediation*, 24: 119–126.

<sup>64</sup> Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (June 2009), *Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002.* *Bulletin of Environmental Contamination and Toxicology*, V82.6:635–659.

(14) special requirements for long-term care facilities managing non-creditable hazardous waste pharmaceuticals;

(15) conditions for healthcare facilities that accept hazardous waste pharmaceuticals from off-site CESQGs; and

(16) a prohibition of sewerage hazardous waste pharmaceuticals for all healthcare facilities; (see section V.E.1. of the preamble, *Sewer Disposal Prohibition*).

The proposed management standards discussed in this section only apply to hazardous waste pharmaceuticals that are non-creditable hazardous waste pharmaceuticals (*i.e.*, they are destined for a RCRA permitted or interim status TSD). They do not apply to those hazardous waste pharmaceuticals that meet the definition of a “potentially creditable hazardous waste pharmaceutical.” Please refer to Section V.D for the proposed healthcare facility management standards for potentially creditable hazardous waste pharmaceuticals that are transported to reverse distributors for the processing of manufacturer’s credit.

#### 1. Notification Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

In order to address commenters’ concerns from the 2008 Pharmaceutical Universal Waste proposal that regulatory agencies are unaware of hazardous waste pharmaceutical management activities, EPA is proposing to require that a healthcare facility that does not qualify as a CESQG to submit a one-time notification as a “healthcare facility” to the appropriate EPA Regional Administrator. Healthcare facilities subject to 40 CFR part 266, subpart P will have to submit notification even if the healthcare facility has previously obtained an EPA identification number. The required notification will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals subject to the 40 CFR part 266, subpart P requirements. In addition, having this information allows EPA and state environmental regulatory agencies to track healthcare facilities for enforcement and inspection purposes, ensuring the hazardous waste pharmaceuticals are managed in accordance with the regulations.

At any point a healthcare facility’s hazardous waste pharmaceutical generation may change due to waste minimization efforts or other reasons, causing the facility to legitimately

decrease its total monthly hazardous waste generation enough to qualify as a CESQG. In this case, if the healthcare facility plans to withdraw from the 40 CFR part 266, subpart P requirements due to qualifying as a CESQG, it will be required to re-notify EPA of its choice to withdraw.

Alternatively, if a healthcare facility determines that it is a CESQG,<sup>65</sup> but does not want to keep track of the amount of hazardous waste generated and whether it is above or below the CESQG threshold limit, it can choose to operate under this proposed rule. By choosing to operate under this proposed rule, the CESQG healthcare facility must comply with *all* of the requirements and must submit the one-time notification that it is operating under 40 CFR part 266, subpart P. Healthcare facilities that are not CESQGs, however, are required to operate under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals.

The Agency is proposing that this notification occur via the RCRA Subtitle C Site Identification Form (EPA Form 8700–12; or Site Identification Form).<sup>66</sup> EPA believes that notification via the Site Identification Form is the preferred approach for notification purposes for several reasons. First, both state environmental regulatory agencies and hazardous waste generators are familiar with the form, as it is the form currently used by hazardous waste generators to notify regulators of their RCRA Subtitle C activities. Second, as stated previously, the use of the Site Identification Form will allow for EPA and state regulatory agencies to monitor the healthcare facilities utilizing the new regulatory requirements. Lastly, public comments received on previous EPA actions (*e.g.*, Academic Laboratories Rulemaking (73 FR 72912; December 1, 2008)) have indicated that notification via the Site Identification Form is the notification approach typically preferred by the regulated community. We are proposing that healthcare facilities can submit their notification as part of the Biennial Report, if the healthcare facility will be

<sup>65</sup> A generator is a CESQG if it generates less than or equal to 100 kg of hazardous waste per calendar month, and less than or equal to 1 kg of acute hazardous waste per calendar month and <100 kg of any residue or contaminated soil, waste or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) per calendar month, provided it does not accumulate on-site at any time >1 kg of acute hazardous waste or >1000 kg of hazardous waste.

<sup>66</sup> For information on the current Site Identification Form, please see: <http://www.epa.gov/wastes/inforesources/data/form8700/8700-12.pdf>.

required to submit a Biennial Report due to its non-pharmaceutical hazardous waste. Otherwise, healthcare facilities are required to notify within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart.

If this notification requirement is finalized, the Site Identification Form will be modified by EPA in a separate action.<sup>67</sup> Specifically, the Agency intends to amend the Site Identification Form by adding a section to the form for a healthcare facility to indicate the type of entity it is (*e.g.*, a hospital, a doctor’s office, a veterinary clinic, a pharmacy, an assisted living facility, etc.) and to indicate that it generates hazardous waste pharmaceuticals. The healthcare facility will no longer be required to identify on the Site Identification Form the specific types of hazardous waste pharmaceuticals it generates. The Agency also intends to add a checkbox to the section in order to allow a healthcare facility to indicate that its generator category is changing to a CESQG and it is no longer managing its hazardous waste pharmaceuticals according to 40 CFR part 266, subpart P.

The Agency does not anticipate that this proposed notification requirement will place any undue economic burden upon healthcare facilities or the environmental regulatory agencies that process these notifications (see the Regulatory Impact Analysis for the proposed rule in the rulemaking docket EPA–HQ–RCRA–2007–0932). In fact, under these proposed regulations, healthcare facilities would no longer need to count the hazardous waste pharmaceuticals managed under 40 CFR part 266, subpart P towards a healthcare facility’s generator category. As a result, EPA anticipates that many healthcare facilities will change their generator category to either a SQG or CESQG for their other, non-pharmaceutical hazardous wastes. So while the notification requirement ensures that the environmental regulatory agencies are informed of all hazardous waste pharmaceutical management activities subject to the 40 CFR part 266, subpart P requirements in their jurisdictions, the fact that some healthcare facilities will no longer qualify as LQGs will reduce the number of healthcare facilities in the LQG universe. Because LQGs are inspected more frequently than SQGs or CESQGs, EPA expects this could result in an overall decrease in burden for both

<sup>67</sup> The Information Collection Request (ICR) for the Site Identification Form (87000–12) is updated every three years and must be approved by the Office of Management and Budget (OMB). These updates and OMB approvals are published in the **Federal Register** and are subject to public comment.

the healthcare facilities and the environmental regulatory agencies.

The Agency is soliciting comment on the notification requirement for healthcare facilities, the method of notification via the Site Identification Form, and whether this notification requirement will result in any undue burden to either healthcare facilities or state environmental regulatory agencies.

## 2. Personnel Training Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Under the current RCRA Subtitle C regulations, an LQG healthcare facility must provide RCRA training to its healthcare workers involved in the generation and/or management of hazardous waste. Under § 262.34(a)(4), LQGs are required to comply with the personnel training requirements for interim status TSDFs (which are found in § 265.16). These personnel training requirements include either classroom instruction or on-the-job training in RCRA and state that the facility must maintain training documents and records for each trained staff person. On the other hand, under current regulation, healthcare facilities that are SQGs must meet a performance-based standard when training their healthcare workers. This entails ensuring “that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies” (§ 262.34(d)(5)(iii)). For comparative purposes, healthcare facilities that are considered CESQGs do not have any personnel training requirements under the current federal regulations. Similarly, generators, including healthcare facilities, are not required to provide RCRA training to personnel that only work in satellite accumulation areas regulated under § 262.34(c). However, healthcare personnel that are involved in the generation of pharmaceutical waste must be familiar enough with the pharmaceuticals with which they are working to know when they have generated a hazardous waste so that it will be managed in accordance with the RCRA regulations.

EPA believes that the LQG RCRA training requirement is excessive for healthcare workers who sporadically generate hazardous waste pharmaceuticals at healthcare facilities, but believe it is necessary to have some familiarity with the dangers that hazardous waste pharmaceuticals can pose. Therefore, the Agency is proposing healthcare facility-specific personnel training requirements that are

akin to the training requirements for SQGs and small quantity universal waste handlers. Specifically, healthcare facilities managing their hazardous waste pharmaceuticals in accordance with the proposed healthcare facility standards must inform all employees that handle or have responsibility for generating and/or managing hazardous waste pharmaceuticals of the proper handling and emergency procedures appropriate to their responsibilities during normal facility operations and emergencies. This training information can be disseminated through verbal communication or through distribution of pamphlets or other documentation. However, a healthcare facility that is an LQG due to its non-pharmaceutical hazardous wastes may choose to continue to use its existing training program as an LQG so as not to have different training programs and that would be acceptable, as well.

The Agency solicits comments on the personnel training requirements proposed in this document for healthcare facilities managing hazardous waste pharmaceuticals. Specifically, the Agency is seeking comment regarding the appropriateness of these personnel training requirements and if these requirements will be sufficient for communicating key procedures to healthcare workers that generate and/or manage hazardous waste pharmaceuticals.

EPA is seeking comment on whether documentation of training is necessary in order to verify compliance with the training requirement. Based on the comments received, we may include a requirement in the final rule for documenting and retaining records of healthcare personnel training. Finally, the Agency wants to reiterate that these proposed personnel training requirements only apply to staff generating and/or managing hazardous waste pharmaceuticals. The training requirements of 40 CFR part 262 will continue to apply to staff generating and/or managing other types of hazardous wastes at the healthcare facility.

## 3. Making a Hazardous Waste Determination for Non-Creditable Hazardous Waste Pharmaceuticals

Similar to the current RCRA Subtitle C generator requirements, healthcare facilities will still be required to make a hazardous waste determination on pharmaceutical wastes prior to managing them under the proposed cradle-to-grave standards. Therefore, when a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the

pharmaceutical waste is listed in 40 CFR part 261, subpart D and if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261, subpart C. However, unlike the existing generator requirements, the healthcare facility does not need to identify the specific waste codes applying to the pharmaceutical wastes. If the pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the hazardous waste pharmaceuticals in accordance with these proposed requirements instead of 40 CFR part 262. Pharmaceutical wastes not meeting the definition of a hazardous waste (*i.e.*, non-hazardous waste pharmaceuticals) must be managed in compliance with applicable federal, state and local regulations.

EPA understands that healthcare facilities utilize various approaches when making hazardous waste determinations. For example, healthcare facilities may hire contractors to review their formularies and identify those pharmaceuticals that are hazardous wastes when discarded. These facilities may then identify hazardous waste pharmaceuticals at the pharmacy level, marking these pharmaceuticals with a special label so that healthcare personnel know how to properly dispose of the pharmaceutical when it becomes a waste. Other healthcare facilities may instruct personnel to dispose of all pharmaceutical wastes into one RCRA hazardous waste collection container. These facilities may then choose to manage all of the contents of the container as hazardous waste or they may choose to sort the hazardous waste portion from the non-hazardous waste pharmaceutical portion in the central accumulation area. Due to the various ways that healthcare facilities make the hazardous waste determination, the Agency is not proposing that a specific approach be utilized when making the determination, only that the facility performs the waste determination. However, healthcare facilities may choose to manage all of their pharmaceutical wastes as hazardous, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their waste pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 CFR part 266, subpart P.

#### 4. No Central Accumulation Area and Satellite Accumulation Area Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Hazardous waste pharmaceuticals are generated at numerous locations across a healthcare facility. Under the current RCRA Subtitle C requirements, each location at the healthcare facility with a RCRA hazardous waste receptacle for the disposal of hazardous waste pharmaceuticals is considered a satellite accumulation area and is subject to volume accumulation limits and other requirements.<sup>68</sup> Of particular concern regarding the satellite accumulation requirements for healthcare facilities is the one quart accumulation limit for acute hazardous wastes (*i.e.*, P-listed wastes). Under the December 2008 Pharmaceutical Universal Waste proposal, no accumulation areas, central or satellite, were proposed to be established for hazardous waste pharmaceuticals. This proposed approach was consistent with the current federal universal waste program, since facilities are not required to designate a special centralized area for the accumulation of universal wastes nor are they required to have satellite accumulation areas for universal wastes. Nevertheless, EPA understands that facilities that handle universal wastes will often accumulate their universal wastes within their 90- or 180-day hazardous waste accumulation areas.

For the reasons articulated in the Pharmaceutical Universal Waste proposal, the Agency has decided that a healthcare facility accumulating hazardous waste pharmaceuticals will not be subject to the satellite accumulation area regulations or the central accumulation area regulations (also sometimes called less than 90- or 180-day areas), but rather to the proposed accumulation time limits and container standards.

A healthcare facility may choose to accumulate hazardous waste pharmaceuticals within its 90- or 180-day central accumulation area if it has one established for its other hazardous wastes as long as it maintains compliance with the proposed accumulation time limit and container requirements of 40 CFR part 266,

<sup>68</sup> See § 262.34(c) for the satellite accumulation requirements. For additional information on satellite accumulation areas, please see the memorandum from Robert Springer to the EPA Regional RCRA Directors, "Frequently Asked Questions about Satellite Accumulation Areas" (RCRA Online #14703) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/0AC9E15424B2897D8525770600609793/\\$file/14703.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/0AC9E15424B2897D8525770600609793/$file/14703.pdf).

subpart P. The Agency notes that even if the hazardous waste pharmaceuticals are accumulated in a 90- or 180-day central accumulation area, these hazardous waste pharmaceuticals are not subject to the 90- or 180-day requirements. EPA solicits public comment on its decision to not require hazardous waste pharmaceutical-specific central and satellite accumulation area requirements.

#### 5. Container Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The container standards discussed in this section apply to those containers used by healthcare facilities to accumulate, store and transport non-creditable hazardous waste pharmaceuticals.<sup>69</sup> First, we would note that due to the relatively small quantities of hazardous waste pharmaceuticals that are typically accumulated and stored at a healthcare facility, the Agency understands that other types of waste management units, such as tanks, are not used for the management of waste pharmaceuticals. Therefore, we are only proposing standards for containers. However, the Agency solicits comment as to whether other types of waste management units are also used by healthcare facilities to accumulate and store hazardous waste pharmaceuticals and whether EPA should establish technical standards for other types of waste management units.

The Agency is proposing to require that healthcare facilities pack hazardous waste pharmaceuticals into containers that are structurally sound and that are compatible with the hazardous waste pharmaceuticals that will be contained within them. EPA intends this requirement to mean that containers used for holding hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, or deterioration. Containers also must not have any evidence of leakage, spillage or damage that could result in the release of waste under reasonably foreseeable circumstances. Furthermore, the Agency is proposing to require that incompatible wastes not be placed in the same container, unless the commingling of incompatible hazardous wastes is conducted in such a way that it does not have the potential to (1) generate extreme heat or pressure, fire or explosion, or violent reaction; (2) produce uncontrolled toxic mists,

<sup>69</sup> The container standards proposed do not apply to the various packaging, blister packs, bottles, vials, IV bags, etc., in which pharmaceuticals are stored prior to being dispensed or administered.

fumes, dusts, or gases in sufficient quantities to threaten human health; (3) produce uncontrollable flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the facility or container containing the hazardous waste pharmaceuticals; or (5) through other like means threaten human health or environment. For example, the majority of a healthcare facility's non-creditable hazardous waste pharmaceuticals are likely organic in nature, and thus, compatible with each other and can be accumulated together, especially since they will most likely be incinerated once they are transported to a TSDF. However, some non-creditable hazardous waste pharmaceuticals, such as metal bearing wastes not containing sufficient organics, are prohibited from being incinerated (*e.g.*, P012, arsenic trioxide). The hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration.

The Agency believes that these technical standards, like similar technical standards that EPA has promulgated in § 265.17 for interim status TSDFs, would ensure that hazardous waste pharmaceuticals are properly managed and would not be released into the environment, while at the same time providing flexibility to the healthcare facility in selecting those containers that are most appropriate for their situation.

In addition to the proposed container standards, the Agency is also proposing that accumulation containers for hazardous waste pharmaceuticals be secured in a manner that prevents unauthorized access to the contents in order to prevent the pilfering of hazardous waste pharmaceuticals or inadvertent exposures to them. As we have noted previously, hazardous waste pharmaceuticals still retain considerable value and can easily be diverted for illicit purposes. To ensure this does not occur, we believe it is important to propose a requirement that would prevent the unauthorized access to the contents of these containers. EPA intends this requirement to be performance-based and does not intend to propose prescriptive regulatory requirements for this standard. The Agency believes that healthcare facilities can choose to utilize containers that have built-in mechanisms to prevent access to their contents or can choose to store containers in locked storage lockers, closets or rooms where the public does not have access to the containers or their contents.

The Agency is seeking comment on the appropriateness of the proposed container management standards. In addition, the EPA is soliciting comment on the proposed requirement for ensuring that the hazardous waste pharmaceuticals contained in collection containers remain secure.

#### 6. Labeling Standards on Containers for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

During the period of accumulation and storage, the Agency is proposing that containers of hazardous waste pharmaceuticals be marked with the words "Hazardous Waste Pharmaceuticals." The Agency is not proposing to require that the hazardous waste numbers (often referred to as hazardous waste codes) of the container's contents be listed on the label. The personnel at healthcare facilities that typically generate the hazardous waste pharmaceuticals will be healthcare workers (*e.g.*, nurses). Healthcare workers are not usually intimately familiar with RCRA and its regulations and are primarily focused on patients and their health. In addition, while a healthcare facility may have an environmental compliance manager or environmental consultant that is knowledgeable about RCRA and its regulations and can make hazardous waste determinations, this individual cannot be present to assign a hazardous waste code and label the collection receptacle each time a pharmaceutical waste is generated. For these reasons, EPA does not believe it is necessary to require individual waste codes on the hazardous waste pharmaceutical collection container at the healthcare facility. The Agency is soliciting comment on the appropriateness of the proposed general labeling requirement. The Agency also requests comment on security concerns regarding having the word "pharmaceutical" marked on the containers.

#### 7. Accumulation Time Limits for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Several hazardous waste pharmaceuticals are P-listed, acute hazardous wastes (*e.g.*, nicotine, warfarin, etc.). Under current regulations, if a generator generates more than 1 kg of acute hazardous waste per calendar month or accumulates more than 1 kg of acute hazardous waste at any time, the generator is regulated as an LQG. Due to this low generation/accumulation threshold associated with P-listed wastes, healthcare facilities are

often LQGs. However, while healthcare facilities can generate enough P-listed waste to become LQGs, they often do not generate sufficient amounts of hazardous waste pharmaceuticals within the allowed accumulation period of 90 days to make off-site shipments using a hazardous waste transporter cost-effective.

Under the 2008 Pharmaceutical Universal Waste proposal, universal waste handlers would have had one year for accumulation of its hazardous waste pharmaceuticals in order to facilitate proper treatment and disposal. Commenters on the 2008 Universal Waste proposed rule indicated support for the one-year accumulation time limit. Thus, the Agency is proposing to allow healthcare facilities to accumulate hazardous waste pharmaceuticals for up to one year, without having interim status or a RCRA permit. As with Universal Waste, one year is an appropriate timeframe because it strikes a balance between allowing healthcare facilities enough time to accumulate amounts of hazardous waste pharmaceuticals to make it economically viable for transporting their hazardous waste pharmaceuticals off-site while ensuring that the hazardous wastes are not accumulated beyond the one year storage limit under the land disposal restrictions programs (see § 268.50).<sup>70</sup>

Healthcare facilities will have various approaches to demonstrate the length of time that hazardous waste pharmaceuticals are accumulated on-site. For example, a healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, identify in the central accumulation area<sup>71</sup> the earliest date that a hazardous waste pharmaceutical became a waste, or any other method that clearly demonstrates the length of time that the hazardous waste pharmaceutical has been accumulated from the date it became a hazardous waste. The Agency assumes that any accumulation for up to one year is for the purpose of facilitating proper treatment and disposal. EPA proposes to require that any healthcare facility needing a longer accumulation time for any unforeseen circumstances beyond the control of the healthcare facility

(*e.g.*, a recall or litigation) request an extension from the appropriate EPA Regional Administrator. This request must be sent in writing (electronic or paper) explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals accumulated beyond the one year, and the amount of extra time requested. An extension period will be granted at the discretion of the Regional Administrator on a case-by-case basis.

Finally, the Agency reiterates that the one-year accumulation time limit only applies to a healthcare facility's non-creditable hazardous waste pharmaceuticals and does not apply to any other types of hazardous waste generated on-site or to potentially creditable hazardous waste pharmaceuticals. EPA solicits comment on the proposed accumulation time limit of one year in order to allow healthcare facilities to generate enough non-creditable hazardous waste pharmaceuticals for cost-effective shipment, and solicits comment on the proposed mechanism to request a time extension.

#### 8. Land Disposal Restrictions for Non-Creditable Hazardous Waste Pharmaceuticals

Similar to the current RCRA Subtitle C generator requirements, healthcare facilities must comply with the land disposal restrictions (LDR) prior to land disposal of the hazardous waste pharmaceuticals they generate. Since healthcare facilities are generators, even though they are not subject to the 40 CFR part 262 requirements for the management of hazardous waste pharmaceuticals, they must comply with the land disposal restrictions found at 40 CFR part 268. The land disposal restrictions are in place to ensure that toxic constituents present in hazardous waste are properly treated to reduce their mobility or toxicity before hazardous waste is placed into or onto the land (*i.e.*, land disposed). With limited exceptions, hazardous waste must be treated by a RCRA permitted or interim status TSDF. Again, EPA notes that autoclaving is not an acceptable method of treating hazardous waste.

In general, generators of hazardous waste assign the appropriate hazardous waste numbers codes to allow TSDFs to determine the specific treatment standard(s) for each prohibited waste. The Agency is proposing that healthcare facilities generating non-creditable hazardous waste pharmaceuticals do not have to assign hazardous waste codes to these wastes, but rather label them as "hazardous waste pharmaceuticals". They do, however, need to be aware that

<sup>70</sup> See the preamble to the Universal Waste final rule: May 11, 1995; 60 FR 25492 (page 25526).

<sup>71</sup> While the proposed rules do not require healthcare facilities to comply with the central accumulation requirements under 262.34, a healthcare facility may have a central accumulation area for the other hazardous wastes that it generates.

while most of the hazardous waste pharmaceuticals are likely organic in nature and will be incinerated, some of their hazardous waste pharmaceuticals may not be suitable for incineration and therefore must be segregated from the organic wastes. The pharmaceutical hazardous wastes not suitable for incineration include characteristic metal wastes prohibited from being combusted because of the dilution prohibition of

§ 268.3(c), as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon. In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic pharmaceutical hazardous wastes so that they can be properly treated by the TSDF. The Agency seeks comment on whether it is necessary to

incorporate into the regulations a requirement to segregate these wastes and whether additional labeling requirements are necessary to identify the hazardous waste pharmaceuticals that are not suitable for incineration.

Tables 2 through 4 list the hazardous waste pharmaceuticals with their hazardous waste codes and their LDR treatment standards.

**Table 2: Waste Codes of Characteristic Hazardous Waste Pharmaceuticals**

<b>Waste Code</b>	<b>Description</b>	<b>Non-Wastewater Treatment Standard</b>
D001	Ignitable	
	Ignitable All D001, except high TOC D001 261.21(a)(1)	DEACT and UTS or RORGS or CMBST
	Ignitable High TOC D001 based on 261.21(a)(1)	RORGS or CMBST or POLYM
D002	Corrosivity	DEACT and UTS
D004 *	Arsenic	5.0 mg/L TCLP and UTS
D005 *	Barium	21 mg/L TCLP and UTS
D006 *	Cadmium	0.11 mg/L TCLP and UTS
D007 *	Chromium	0.60 mg/L TCLP and UTS
D008 *	Lead	0.75 mg/L TCLP and UTS
D009*	Mercury	
	Mercury $\geq$ 260 mg/kg total Hg (high mercury organics)	IMERC or RMERC
	<b>Mercury &lt; 260 mg/kg total Hg &amp; are not residues from RMERC (low mercury)</b>	<b>0.025 mg/L TCLP and UTS</b>
D010 *	Selenium	5.7 mg/L TCLP and UTS
D011 *	Silver	0.14 mg/L TCLP and UTS
<b>D013</b>	<b>Lindane</b>	
	<b>Lindane alpha-BHC</b>	<b>0.066 mg/kg and UTS</b>
	<b>Lindane beta-BHC</b>	<b>0.066 mg/kg and UTS</b>
	<b>Lindane delta-BHC</b>	<b>0.066 mg/kg and UTS</b>
	<b>Lindane gamma-BHC</b>	<b>0.066 mg/kg and UTS</b>
<b>D022</b>	<b>Chloroform</b>	<b>6.0 mg/kg and UTS</b>

Waste Code	Description	Non-Wastewater Treatment Standard
<b>D024</b>	<b>m-Cresol</b>	<b>5.6 mg/kg and UTS</b>

\*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

**BOLD** indicates that the waste is an organic waste with a concentration-based treatment standard  
UTS = Universal Treatment Standards in § 268.48

**Table 3: P-listed Hazardous Waste Pharmaceuticals**

Waste Code	Description	Non-Wastewater Treatment Standard
P001	Warfarin (concentration > 0.3%)	CMBST
P012 *	Arsenic trioxide	5.0 mg/L TCLP
P042	Epinephrine	CMBST
P046	Phentermine	CMBST
P075	Nicotine	CMBST
P081	Nitroglycerin	CMBST
P188	Physostigmine salicylate	1.4 mg/kg or CMBST
P204	Physostigmine	1.4 mg/kg or CMBST

\*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

**Table 4: U-listed Hazardous Waste Pharmaceuticals**

Waste Code	Description	Non-Wastewater Treatment Standard
U010	Mitomycin	CMBST
U015	Azaserine	CMBST
U034	Chloral hydrate	CMBST
U035	Chlorambucil	CMBST
<b>U044</b>	<b>Chloroform</b>	<b>6.0 mg/kg</b>
U058	Cyclophosphamide	CMBST
U059	Daunomycin	CMBST
<b>U075</b>	<b>Dichlorodifluoromethane</b>	<b>7.2 mg/kg</b>

Waste Code	Description	Non-Wastewater Treatment Standard
U089	Diethylstilbestrol	CMBST
<b>U121</b>	<b>Trichloromonofluoromethane</b>	<b>30 mg/kg</b>
U122	Formaldehyde	CMBST
<b>U129</b>	<b>Lindane</b>	
	<b>Lindane alpha-BHC</b>	<b>0.066 mg/kg</b>
	<b>Lindane beta-BHC</b>	<b>0.066 mg/kg</b>
	<b>Lindane delta-BHC</b>	<b>0.066 mg/kg</b>
	<b>Lindane gamma-BHC</b>	<b>0.066 mg/kg</b>
U132	Hexachlorophene	CMBST
U150	Melphalan	CMBST
U151*	Mercury	
	Mercury $\geq 260$ mg/kg total Hg (high mercury organics)	IMERC or RMERC
	<b>Mercury &lt; 260 mg/kg total Hg &amp; are not residues from RMERC (low mercury)</b>	<b>0.025 mg/L TCLP and UTS</b>
U182	Paraldehyde	CMBST
<b>U187</b>	<b>Phenacetin</b>	<b>16 mg/kg</b>
<b>U188</b>	<b>Phenol</b>	<b>6.2 mg/kg</b>
U200	Reserpine	CMBST
U201	Resorcinol	CMBST
U205 *	Selenium sulfide	5.7 mg/L TCLP
U206	Streptozotocin	CMBST
U237	Uracil mustard	CMBST
U248	Warfarin (Concentration $\leq 0.3\%$ )	CMBST

\*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

**BOLD** indicates that the waste is an organic waste with a concentration-based treatment standard  
 UTS = Universal Treatment Standards in § 268.48

The organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA permitted or interim status hazardous waste combustors. As noted in Tables 2–4, most of the organic wastes have a specified treatment standard of combustion (CMBST). The remaining seven organics (lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane, phenacetin and phenol) have numerical treatment standards, such that no particular treatment technology is specified or required in order to achieve

the numerical treatment standards. While these wastes may be incinerated, the incinerator residue (ash) must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be disposed.

As mentioned earlier, because this proposed rule does not require that healthcare facilities label their waste with the hazardous waste codes, the TSDF must always analyze the incinerator ash for these seven constituents—lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane,

phenacetin, and phenol—according to their waste analysis plan, as they could possibly be present in any shipment of organic hazardous waste pharmaceuticals.

*a. Alternative treatment standards considered.* In their comments to the 2008 Universal Waste proposal, Environmental Technology Council (ETC) suggested revising the treatment standards for the organic hazardous waste pharmaceuticals that have numerical treatment standards to the specified treatment standard of

combustion.<sup>72</sup> Specifying combustion would relieve the TSDFs from demonstrating compliance with the numerical treatment standards. EPA explored the feasibility of making combustion an alternative treatment standard for the seven organic hazardous waste pharmaceuticals that currently have numeric treatment standards. In fact, EPA notes that the numerical treatment standards were developed based on levels achieved through combustion. However, in order to allow maximum flexibility, EPA has indicated a preference for numerical treatment standards over specifying treatment standards whenever possible. Furthermore, it is not clear that pharmaceuticals would be the sole source of the seven organic constituents in question. Therefore, even if we proposed an alternative treatment standard of combustion for the seven organic pharmaceuticals, hazardous waste incinerators would still be required to test their ash for these constituents to demonstrate compliance with numeric treatment standards if they received the organics from another, non-pharmaceutical source.

*b. Incineration of mercury-containing hazardous waste pharmaceuticals.* It is rare, but some pharmaceuticals contain mercury (e.g., thimerosal, a mercury-containing preservative). When discarded, a mercury-containing pharmaceutical would be a D009 hazardous waste if the leachate generated by the toxicity characteristic leaching procedure (TCLP), or if the pharmaceutical itself (when the waste contains < 0.5% filterable solids), contains  $\geq 0.2$  mg/L mercury (see § 261.24).<sup>73</sup> As indicated in Table 2, a D009 hazardous waste with mercury content  $\geq 260$  mg/kg of total mercury and that also contains organics, must be treated by IMERC (incineration) or RMERC (mercury retorting). However, hazardous waste pharmaceuticals that are D009 are expected to have mercury content < 260 mg/kg, in which case the treatment standards are numeric and treatment by RMERC or IMERC is not required. With numeric treatment standards, the generator has flexibility regarding which hazardous waste treatment method to use to meet the treatment standard. As explained previously, incineration of mercury-bearing hazardous waste with >1% total organic carbon is not considered impermissible dilution (see § 268.3(c))

and therefore is an allowable form of treatment.

Emissions from combustion units that burn hazardous waste<sup>74</sup> are regulated under RCRA and the Clean Air Act (CAA). The implementing regulations under these statutory authorities include emission limits for new and existing combustion units for mercury, semi-volatile metals (cadmium and lead), low volatility metals (arsenic, beryllium, and chromium), particulate matter, chlorinated dioxins and furans, other toxic organic compounds, hydrogen chloride and chlorine. The regulations also (1) specify when and how combustion sources must comply with the emission standards and operating requirements, (2) prescribe detailed monitoring requirements to show continuous compliance with the emission standards, and (3) prescribe performance testing requirements to demonstrate compliance with the emission standards (see 40 CFR part 63, subpart EEE).

To ensure continuous compliance with the emission limits, hazardous waste combustors are required to establish limits on (1) the feedrate of metals (including mercury), chlorine, and (for some types of hazardous waste combustors) ash; (2) combustor operating parameters such as minimum combustion chamber temperature; and (3) operating parameters of the air pollution control device. For mercury, continuous compliance requirements would generally include a limit on the total feedrate of mercury in all feedstreams to the combustion unit, limits on the operation of a wet scrubber (depending on the species of mercury in the combustion gases, wet scrubbers can be efficient at removing mercury), and operating limits on the activated carbon injection or carbon bed system, if such systems are used.

In addition, RCRA directs permitting authorities to impose additional terms and conditions on a site-specific basis as may be necessary to protect human health and the environment (see § 270.32(b)). Thus, if the mercury emission limits specified previously are not protective in an individual instance, the permit writer will establish permit limits that are protective.

Nevertheless, EPA is aware that some stakeholders are concerned about the risks associated with incinerating mercury-bearing hazardous wastes and we encourage healthcare facilities and pharmaceutical reverse distributors to

consider the use of treatment technologies other than incineration for meeting the numeric treatment standards for mercury-bearing hazardous waste pharmaceuticals. Thimerosal-containing pharmaceuticals are expected to be non-wastewaters as defined by § 268.2, because they have more than 1% total organic carbon. For low mercury non-wastewaters, the numeric treatment standard can be achieved by stabilization/solidification, either with or without subsequent encapsulation.<sup>75</sup>

#### 9. Shipments of Non-Creditable Hazardous Waste Pharmaceuticals Off-site From Healthcare Facilities

The Agency is proposing to maintain the current RCRA Subtitle C tracking requirement by requiring that a hazardous waste manifest be prepared for each off-site shipment of non-creditable hazardous waste pharmaceuticals from healthcare facilities. Accordingly, each off-site shipment of hazardous waste pharmaceuticals must be transported to an interim status or permitted TSDF via a hazardous waste transporter. However, the Agency is proposing that for hazardous waste pharmaceuticals shipped by healthcare facilities, the RCRA hazardous waste codes do not need to be listed on the manifest. This is intended to accommodate the fact that healthcare providers generating the hazardous waste pharmaceuticals are generally unfamiliar with RCRA and are focused on providing healthcare to patients. One function of the hazardous waste codes is to determine the appropriate hazardous waste treatment standards under the land disposal restrictions (part 268). However, virtually all hazardous waste pharmaceuticals sent for off-site treatment are sent to hazardous waste incinerators, even when the treatment standard does not require incineration. The fact that EPA is proposing to not require hazardous waste codes for shipping hazardous waste pharmaceuticals is not intended to alter or impact any Department of Transportation (DOT) requirements for the shipment of these hazardous wastes. For a more detailed discussion of these proposed requirements, as well as the basis for these requirements, please see Section V.F.1 of this document.

<sup>75</sup> EPA is not aware of any testing done to demonstrate the effectiveness of this treatment method specifically for thimerosal-containing hazardous wastes, so vendors performing such treatment may need to do treatability studies to identify optimal use of stabilization/solidification treatment technologies.

<sup>72</sup> See comment number 0125 in the docket for this rulemaking. EPA-HQ-RCRA-2007-0932.

<sup>73</sup> The Agency is not aware of any hazardous waste pharmaceuticals that would be considered U151 because mercury would have to be the sole active ingredient.

<sup>74</sup> Combustors that burn hazardous waste include the following types of combustion units: Incinerators, cement kilns, lightweight aggregate kilns, industrial boilers and process heaters, and hydrochloric acid production furnaces.

#### 10. Rejected Shipment From Healthcare Facilities of Non-creditable Hazardous Waste Pharmaceuticals

In rare circumstances, a healthcare facility may send its non-creditable hazardous waste pharmaceuticals to a designated facility that is unable to manage the hazardous waste. For such situations, we are proposing that healthcare facilities follow the same procedures listed in 40 CFR part 262 (see § 262.23(f)). Specifically, if a designated facility is unable to accept the hazardous waste pharmaceuticals, and it returns the hazardous waste pharmaceuticals to the healthcare facility, the healthcare facility must sign the manifest that was used to return the shipment, provide the transporter a copy of the manifest, send a copy of the manifest within thirty days to the designated facility that returned the shipment and retain a copy of the manifest for three years from the date of delivery of the returned shipment. EPA believes that it is appropriate to continue current practices for rejected shipments that are part of the generator regulations of 40 CFR part 262 because rejected shipments are relatively rare and the procedures currently used for rejected shipments is relatively straightforward. In addition, healthcare facilities should be familiar with these procedures already.

#### 11. Reporting Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The Agency is proposing that healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to SQGs regulated under 40 CFR part 262—that is, the exception reporting requirement under § 262.44(b) and the additional reporting requirement under § 262.44(c). In addition, we are proposing that healthcare facilities that are LQGs would no longer be required to include their hazardous waste pharmaceuticals on their biennial report (BR). Each of these reporting requirements for healthcare facilities is discussed below.

First, as part of the current RCRA Subtitle C generator requirements, healthcare facilities that are LQGs must submit a BR to the Regional Administrator by March 1st of every even numbered year (see § 262.41). Among other requirements, the BR must include a description (EPA hazardous waste number and DOT hazard class) and quantity of each hazardous waste shipped off-site to a TSDF during each odd numbered year. If a healthcare

facility is an LQG due to its non-pharmaceutical hazardous waste, it will continue to be required to submit a BR. However, it need not include its hazardous waste pharmaceuticals in its BR. As discussed previously, the Agency is no longer requiring healthcare facilities to count hazardous waste pharmaceuticals when determining their generator category. Instead, all healthcare facilities, with the exception of CESQGs, will be subject to this proposed rule. The Agency has determined that it does not need the information to be included in the BR because this proposed rule will bring a consistent approach to managing pharmaceutical hazardous wastes. Nevertheless, the Agency is soliciting public comment on whether the Agency should require healthcare facilities—that is, all healthcare facilities subject to the 40 CFR part 266, subpart P requirements—to submit a BR, and if so, the type of information that should be included.

Second, the Agency is proposing that healthcare facilities follow the same reporting procedures for exception reporting that generators operating under the 40 CFR part 262 must follow. We are proposing to incorporate the generator exception reporting procedures in this new subpart. Specifically, if a healthcare facility does not receive a copy of the hazardous waste manifest from the designated facility within 60 days, the healthcare facility must submit to the EPA Regional Administrator a copy of the manifest with a statement that the healthcare facility did not receive confirmation of the hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the hazardous waste pharmaceuticals and the results of those efforts. Likewise, if a shipment of hazardous waste pharmaceuticals from a healthcare facility is rejected by the designated facility and it is shipped to an alternate facility and if the healthcare facility does not receive a signed copy of the hazardous waste manifest from the alternate facility within 60 days, it must submit to the EPA Regional Administrator a copy of the hazardous waste manifest with a statement that the healthcare facility did not receive confirmation of the hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the hazardous waste pharmaceuticals and the results of those efforts. Again, the Agency believes it is advantageous to use established procedures that should be familiar to healthcare facilities, especially given that rejected shipments are relatively rare.

Finally, the Agency proposes that the Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of hazardous waste pharmaceuticals. This is already the case for generators operating under the 40 CFR part 262 requirements. As with 40 CFR part 262, it is a codification of statutory authority under §§ 2002(a) and 3002(a)(6) that provides the Agency some flexibility in what reports may be required. The Agency solicits public comment on the proposed reporting requirements for healthcare facilities managing their hazardous waste pharmaceuticals in accordance with the standards proposed in this document.

#### 12. Recordkeeping Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The Agency is proposing that healthcare facilities managing non-creditable hazardous waste pharmaceuticals maintain records similar to the records that must be kept by generators regulated under 40 CFR part 262 (see § 262.40). Specifically, healthcare facilities must keep a signed copy of each hazardous waste manifest as a record for three years from the date that the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter. If the healthcare facility is required to file an exception report because it does not receive a signed copy of the manifest from the designated facility within 60 days of the date that the hazardous waste pharmaceutical was accepted by the initial transporter, then the healthcare facility must keep a copy of the each exception report for a period of at least three years from the due date of the report.<sup>76</sup> In addition, EPA is proposing that a healthcare facility must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals regarding which pharmaceuticals are hazardous wastes for three years from the date of the test, analysis, or other determination.

<sup>76</sup> § 262.40 requires that generators keep a copy of each BR for a period of at least three years from the due date of the report. However, since we are not requiring a healthcare facility to include its hazardous waste pharmaceuticals on its a BR, the Agency is also not including in subpart P a requirement that a BR be kept at the healthcare facility. If healthcare facility must submit a BR due to its non-pharmaceutical hazardous waste, the § 262.40 recordkeeping requirements will apply (see the discussion under Reporting Requirement for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals for the Agency's basis of not requiring healthcare facilities to include hazardous waste pharmaceuticals on the BR.

The Agency is also proposing that any of the retention periods be extended during the course of enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action. The Agency solicits public comment on the proposed recordkeeping requirements for healthcare facilities managing their non-creditable hazardous waste pharmaceuticals in accordance with the standards proposed in this document.

### 13. Response to Releases by Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

For hazardous waste pharmaceuticals generated and managed by healthcare facilities under the proposed standards, the Agency is proposing basic release responses, including the requirement that healthcare facilities immediately contain all releases of, and other residues from, hazardous waste pharmaceuticals. In addition, this proposal would require healthcare facilities to determine whether any material, residue, or debris resulting from the release is or contains a hazardous waste pharmaceutical and, if so, to manage it under the management standards for hazardous waste pharmaceuticals proposed in this document. These proposed release response procedures are the same as those under the Universal Waste program (see § 273.17 for small quantity universal waste handlers, and § 273.37 for large quantity universal waste handlers). Commenters to the 1993 proposed rule that established the Universal Waste program overwhelmingly supported the release response measures (60 FR 25528; May 11, 1995). Thus, we believe it is appropriate to include it again in this proposal.

Any releases of hazardous waste pharmaceuticals not cleaned up immediately would generally constitute illegal disposal, which may result in further action by EPA or an authorized state under RCRA. In addition, hazardous wastes under RCRA are included in the definition of hazardous substances for purposes of the Comprehensive Environmental Response Compensation, and Liability Act (CERCLA) (see CERCLA Section 101(14)<sup>77</sup>). Thus, any releases into the environment of hazardous substances above the reportable quantity (RQ) thresholds must be reported under

CERCLA (see CERCLA Section 103). That is, since hazardous waste pharmaceuticals are hazardous wastes and, hazardous substances under CERCLA, reporting for hazardous waste pharmaceutical releases is required when RQs are exceeded (see 40 CFR 302.4 for a list of RQs and hazardous substances). Such reports provide notification to the Agency (through the National Response Center) concerning releases into the environment and help inform whether EPA should take action, if necessary, under either RCRA or CERCLA.

The Agency solicits comment regarding the proposed standard for the response to releases of hazardous waste pharmaceuticals at healthcare facilities.

### 14. Long-Term Care Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Long-term care facilities differ in one respect from other types of healthcare facilities subject to these proposed standards. Unlike hospitals, who own the pharmaceuticals they dispense to patients, many of the hazardous waste pharmaceuticals generated at long-term care facilities belong to the residents of the facility. That is, the pharmaceuticals are dispensed under the patient's name. However, as previously discussed in this preamble, EPA is proposing to no longer allow hazardous waste pharmaceuticals generated at long-term care facilities (as defined under this proposed regulation) to be eligible for the household hazardous waste exemption. As a result, long-term care facilities must manage all hazardous waste pharmaceuticals generated on-site, regardless of ownership, in accordance with these same proposed management standards for healthcare facilities. EPA understands that while long-term care facilities often maintain each individual's pharmaceuticals in a centralized location, such as a pharmaceutical cart, there are instances where some individuals may keep and self-administer their own pharmaceuticals. EPA is proposing that the long-term care facilities collect and manage all hazardous waste pharmaceuticals generated at their facilities in accordance with these proposed requirements. This requirement means that in addition to the hazardous waste pharmaceuticals kept in the centralized location, long-term care facilities will need to collect all other hazardous waste pharmaceuticals from individuals that self-administer these pharmaceuticals and manage them in accordance with these proposed standards, which, among other things, prohibits the

sewering of hazardous waste pharmaceuticals. The Agency solicits comment on the extent to which long-term care facilities keep an inventory of the pharmaceuticals that individuals self-administer, as this would facilitate the collection of the hazardous waste pharmaceuticals for proper disposal.

Although long-term care facilities would not be required under this rule to collect non-hazardous waste pharmaceuticals, or hazardous waste pharmaceuticals from the independent living portion of a continuing care facility, EPA recommends that long-term care facilities collect all waste pharmaceuticals to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse. As discussed later in this preamble, DEA regulations govern the management of controlled substances (see Section V.E.2.a of the preamble for a discussion of DEA's 2014 final rule for the disposal of controlled substances and the implications of that rule and this proposed rule for long-term care facilities.<sup>78</sup>) Also discussed later in more detail, EPA is proposing to exempt from RCRA those hazardous waste pharmaceuticals that are also controlled substances, provided they are combusted at a permitted or interim status hazardous waste incinerator or permitted municipal solid waste incinerator and managed in compliance with applicable DEA regulations (see Section V.E.2 of the preamble for a detailed discussion of the exemption).

The Agency solicits comment regarding this requirement, and specifically requests comment on the various approaches that long-term care facilities use, or could use in collecting hazardous waste pharmaceuticals from individuals that self-administer their pharmaceuticals.

### 15. Healthcare Facilities That Accept Hazardous Waste Pharmaceuticals From Off-Site Conditionally Exempt Small Quantity Generators (CESQGs)<sup>79</sup>

Typically, hazardous waste pharmaceuticals from healthcare facilities are transported either to a reverse distributor, if it is potentially creditable,<sup>80</sup> or to a permitted or interim

<sup>78</sup> DEA's final rule for disposal of controlled substances: 79 FR 53520; September 9, 2104.

<sup>79</sup> Unlike other sub-sections of Section V.C., which discusses the proposed standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals, this sub-section addresses both non-creditable and creditable hazardous waste pharmaceuticals.

<sup>80</sup> Potentially creditable hazardous waste pharmaceuticals include pharmaceuticals that are: (1) Unused or un-administered. (2) unexpired or

<sup>77</sup> <http://www.epw.senate.gov/cercla.pdf>.

status hazardous waste TSD. However, stakeholders have informed EPA that in some cases, hazardous waste pharmaceuticals are transported to another healthcare facility. We are aware of at least two situations in which this is occurring. First, patients at long-term care facilities who receive their pharmaceuticals from an off-site long-term care pharmacy sometimes return their unused pharmaceuticals to the long-term care pharmacy.<sup>81</sup> Upon return, the long-term care pharmacy sorts through the returned pharmaceuticals to determine whether they will be disposed or restocked for reuse. Due to many factors, such as Medicare regulations and the cost of the pharmaceutical as compared to the cost of repackaging and restocking, only a small fraction of the returned pharmaceuticals are restocked for potential reuse. One long-term care pharmacy estimated that approximately 10 percent of the pharmaceuticals it sends to long-term care facilities come back as returns.<sup>82</sup> Some portion of the returns would be considered hazardous waste pharmaceuticals when discarded.<sup>83</sup> In the second situation, the Army has established off-post health clinics to provide easier access to healthcare for military personnel, including veterans. The pharmacies at the off-post clinics receive their pharmaceutical products via couriers that deliver the pharmaceuticals from the on-post, main pharmacy. The off-post pharmacies also return their unused pharmaceuticals to the on-post, main pharmacy via courier.

EPA data indicates that the majority of long-term care facilities are CESQGs<sup>84</sup> and the Army has informed EPA that their off-post clinics are generally CESQGs, as well.<sup>85</sup> The

less than one year past the expiration date; or (3) in unopened or opened packaging or containers.

<sup>81</sup> DEA controlled substances can be returned to a long-term care pharmacy only if they are subject to a recall (see 21 CFR 1317.85(a)).

<sup>82</sup> See notes from 11–15–12 site visit to Omnicare, Inc. in the docket for this proposed rule (EPA–HQ–RCRA–2007–0932).

<sup>83</sup> Due to the DEA regulations, a DEA registered long term care pharmacy may not accept returns of a controlled substances. DEA regulations define “reverse distribute” and reverse distributor” in 21 CFR 1300.01. A pharmacy is not authorized to accept returns of controlled substances from patients or reverse distribute (see 21 CFR 1301.13(e)(1)(iv)).

<sup>84</sup> Under these proposed requirements, hazardous waste pharmaceuticals will not count towards a facility’s generator category. Therefore, EPA expects that long-term care facilities will remain CESQGs, even though the Agency is proposing that all hazardous waste pharmaceuticals generated on the premises must be managed in accordance with these proposed requirements.

<sup>85</sup> See notes from 11–28–12 meeting with U.S. Army Institute of Public Health in the docket for this proposed rule (EPA–HQ–RCRA–2007–0932).

existing CESQG regulations do not allow a generator to send its hazardous waste off-site to another hazardous waste generator, unless the receiving generator is also one of the seven types of facilities listed in § 261.5(f)(3) for acute hazardous waste or § 261.5(g)(3) for hazardous waste, including municipal and non-municipal non-hazardous solid waste landfills. The Agency does not think that disposal in landfills is the best option for hazardous waste pharmaceuticals. Limited studies have shown active pharmaceutical ingredients are present in landfill leachate that is collected in municipal solid waste landfill leachate collection systems.<sup>86</sup> Landfill leachate is then typically transported to a wastewater treatment plant for treatment; however, active pharmaceutical ingredients can pass through the treatment system and into our Nation’s waters.

EPA thinks it would be preferable to allow healthcare facilities that are CESQGs to send their hazardous waste pharmaceuticals to another healthcare facility rather than send it to a municipal or non-municipal non-hazardous solid waste landfill. Therefore, EPA is proposing to allow healthcare facilities that are CESQGs operating under this subpart to send their hazardous waste pharmaceuticals to an off-site healthcare facility, without a hazardous waste manifest, provided four conditions are met. First, the receiving healthcare facility must be contracted to supply pharmaceutical products to the CESQG long-term care facility, or the CESQG healthcare facility and the receiving healthcare facility must both be under the control<sup>88</sup> of the same person, as defined by § 260.10 (e.g., the Army). Second, the receiving healthcare facility must be managing its hazardous waste pharmaceuticals in accordance with the regulations of this proposed rule.<sup>89</sup> Third, the hazardous

<sup>86</sup> Barnes, K. K., Christenson, S. C., Kolpin, D. W., Focazio, M. J., Furlong, E. T., Zaugg, S. D., Meyer, M. T. and Barber, L. B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. *Groundwater Monitoring & Remediation*, 24: 119–126.

<sup>87</sup> Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (June 2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. *Bulletin of Environmental Contamination and Toxicology*, V82.6:635–659.

<sup>88</sup> For purposes of this provision, “control” means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

<sup>89</sup> This condition is only applicable if the receiving healthcare facility is also a CESQG, since

waste pharmaceuticals from the CEQSG must be managed by the receiving healthcare facility as hazardous waste pharmaceuticals in accordance with the regulations of this proposed rule once it arrives at the receiving healthcare facility. Fourth, the receiving healthcare facility must keep and maintain records of the hazardous waste pharmaceuticals received from the off-site CESQG healthcare facilities for three years from receipt of shipment. These conditions should ensure the proper management of the hazardous waste pharmaceuticals, in that once they are received by the healthcare facility, they are subject to the same management standards EPA is proposing for hazardous waste pharmaceuticals managed by healthcare facilities, while at the same time would not impose an undue burden on healthcare facilities that are CESQGs, especially since these healthcare facilities always have the option of sending their hazardous waste pharmaceuticals to a municipal or non-municipal solid waste landfill.

The Agency solicits comment on this new provision under this subpart, including whether any additional conditions should be imposed. In recommending any additional conditions, the Agency requests that commenters provide their rationale for the additional condition(s), as well as why such additional condition(s) would not pose an undue burden on healthcare facilities that are CESQGs. In addition, the Agency solicits comment on whether it might be appropriate to allow facilities, other than those meeting the proposed definition of a healthcare facility, to accept hazardous waste pharmaceuticals from an off-site CESQG (e.g., a military medical logistics facility).

*D. How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors?*

#### 1. Potentially Creditable Hazardous Waste Pharmaceuticals Are Not Products

One difference between this proposal and the 2008 Pharmaceutical Universal Waste proposal is the proposed interpretation of how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturers’ credit. Two previous agency policy memos set out EPA’s existing understanding of the status of these “creditable” pharmaceuticals. The

healthcare facilities that are SQGs and LQGs must comply with the requirements proposed in 40 CFR part 266 subpart P.

first, a letter to Merck Sharp & Dohme in 1981, explained that pharmaceuticals sent for credit may be reclaimed and are not wastes since the decision to discard a particular material does not occur until after the product has been returned to the manufacturing plant.<sup>90</sup> The second, a letter to BFI Pharmaceutical Services, Inc. in 1991 states, “to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them.”<sup>91</sup> In addition to these letters, EPA’s 2008 Pharmaceutical Universal Waste proposal stated, “Because unused or expired pharmaceuticals are returned (via the reverse distributor) for possible manufacturer’s credit, they still have potential value to the pharmacy or hospital and are thus not considered wastes.”<sup>92</sup>

In this action, we are proposing to modify EPA’s position regarding the waste status of creditable pharmaceuticals. Because we understand that many participants in this sector have relied on the interpretations in the two letters and the 2008 Pharmaceutical Universal Waste preamble, we are providing notice of a change in EPA’s position and providing an opportunity for public comment. Until this rule is final and effective, however, EPA’s previous interpretations will continue to be in effect.

In terms of the concept that returned pharmaceuticals have value and are not waste, EPA confirms the general rule under RCRA that materials that are discarded are solid wastes, regardless of the economics of the system in which those discarded materials are handled. Therefore, the fact that a material may have monetary value (e.g., through a manufacturer’s credit) does not determine whether that material is a solid waste. Rather, the “decision point” on whether a pharmaceutical is a solid waste is when it has been discarded, or the decision has been made to discard the material. That is, a discarded pharmaceutical may retain value in the reverse distribution system, but still be considered a solid waste.

Additionally, the economic value of hazardous waste can be one important consideration in determining whether a hazardous waste is legitimately recycled (see, for example, the discussion of *Useful Economic Information* in the 2008 Definition of Solid Waste final rule, 73 FR 84706–07, October 30, 2008) and therefore excluded from being a solid waste. The definition of legitimate recycling is codified at 40 CFR 260.43 and is discussed in the 2015 Definition of Solid Waste final rule (80 FR 1694, January 13, 2015).

Commenters to the 2008 Pharmaceutical Universal Waste proposal, the 2014 Retail Notice of Data Availability (NODA), stakeholders, and pharmaceutical reverse distributors themselves have informed EPA that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused. One commenter wrote, “. . . EPA’s belief that reverse distributors first arrange to transport and receive the drugs, and then determine whether the drugs are useful products or wastes, is pure fiction.”<sup>93</sup> Another commenter wrote, “. . . the vast majority of the returned pharmaceuticals are to be collected for disposal or destruction once credit has been given.”<sup>94</sup> A third commenter wrote, “. . . drugs sent through reverse distribution are not reused or recycled due to economic and safety reasons.”<sup>95</sup> Regulations pertaining to the repurposing of pharmaceuticals vary by state, as they are established by each state’s Board of Pharmacy. However, stakeholders have overwhelmingly declared that state Boards of Pharmacy only allow pharmaceuticals to be repurposed under very narrow circumstances—that is, when a specific set of conditions are followed to ensure the viability and integrity of the pharmaceutical. The set of conditions vary by state; however, states have some restrictions in common when it comes to repurposing drugs. According to the National Conference of State Legislatures (NCSL), “Virtually all [state] laws include some restrictions designed to assure purity, safety and freshness of the products. Unless otherwise noted, all programs require:

- All donated drugs must not be expired and must have a verified future expiration date.
- Controlled substances, defined by the federal Drug Enforcement Administration (DEA) usually be excluded and prohibited.

- A state-licensed pharmacist or pharmacy to be part of the verification and distribution process.

- Each patient who is to receive a drug must have a valid prescription form in his/her own name.”<sup>96</sup>

Thus, in most, if not all cases, pharmaceuticals that are transported back to a reverse distributor for credit are discarded by the reverse distributor.<sup>97</sup> For that reason, the decision to send a pharmaceutical to a reverse distributor is essentially a decision to discard the pharmaceutical.

Therefore, EPA is proposing to reinterpret its position such that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. As a result, once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility. In this document, EPA is proposing to define the term “potentially creditable hazardous waste pharmaceutical.” A portion of the potentially creditable pharmaceuticals at healthcare facilities that are transported to reverse distributors will likely meet the definition of hazardous waste. Of the set of pharmaceuticals that are hazardous wastes, only “potentially creditable” hazardous waste pharmaceuticals may be transported to a reverse distributor for manufacturer’s credit (see definition Section V.A.3).

The Agency notes that the management standards discussed below pertain only to potentially creditable hazardous waste pharmaceuticals that are managed via reverse distribution and do not apply to the reverse distribution or reverse logistics systems that may exist for other consumer products. In addition to the standards discussed in this section, EPA is proposing standards for shipping potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors as well as associated recordkeeping (see Section V.F.2. of the preamble).

## 2. Hazardous Waste Determination for Potentially Creditable Hazardous Waste Pharmaceuticals

As with non-creditable hazardous waste pharmaceuticals discussed

<sup>96</sup> Content is copied from <http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx> (accessed May 13, 2015).

<sup>97</sup> Any facility, including a pharmaceutical manufacturer engaged in processing pharmaceutical hazardous waste for facilitation or verification of manufacturer’s credit would be considered a pharmaceutical reverse distributor under the proposed rule with respect to those operations, and would be subject to the proposed regulations for pharmaceutical reverse distributors.

<sup>90</sup> Alan Corson to Steven Wittner on May 13, 1981 (RCRA Online #11012) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/B630CD51DC85EDC8525670F006BCE84/\\$file/11012.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/B630CD51DC85EDC8525670F006BCE84/$file/11012.pdf).

<sup>91</sup> Sylvia Lowrance to Mark J. Schulz on May 16, 1991 (RCRA Online #11606) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A3A7A7A8F297438B8525670F006BE5D8/\\$file/11606.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A3A7A7A8F297438B8525670F006BE5D8/$file/11606.pdf).

<sup>92</sup> 73 FR 73525; December 2, 2008.

<sup>93</sup> Comment EPA–HQ–RCRA–2007–0932–0125.

<sup>94</sup> Comment EPA–HQ–RCRA–2007–0932–0068.

<sup>95</sup> Comment EPA–HQ–RCRA–2012–0426–0025.

previously, a healthcare facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart. Potentially creditable hazardous waste pharmaceuticals must be managed under this subpart, while pharmaceuticals that do not meet the definition of hazardous waste but are potentially creditable, do not have to be managed under this subpart. However, a healthcare facility may choose to manage all of its potentially creditable pharmaceuticals (both hazardous and non-hazardous) as potentially creditable hazardous waste pharmaceuticals while accumulating on-site and when shipping off-site. If a healthcare facility chooses this approach, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their potentially creditable waste pharmaceuticals are hazardous and manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 CFR part 266, subpart P.

### 3. Accumulation Time, Container Management, and Labeling for Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

Typically, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable hazardous waste pharmaceuticals appear to pose lower environmental risk of release than patient care hazardous waste pharmaceuticals or traditional industrial hazardous waste. The risk of release is lower for several reasons. First, potentially creditable hazardous waste pharmaceuticals that are prepared for shipment to a reverse distributor are usually in their original containers as well as outer packaging, providing two layers of protection from leaks or spills.<sup>98</sup> Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment. EPA anticipates that this

relatively quick timing is largely driven by the economic value of the manufacturer's credit for the returned pharmaceuticals. Therefore, because of the lower risk these pharmaceuticals pose, EPA is not proposing specific management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals. For the same reasons, we also are not proposing a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals. EPA requests comment on the assumption that healthcare facilities promptly remove potentially creditable hazardous waste pharmaceuticals from pharmacy shelves and send them to reverse distributors. EPA asks for comment on whether the expectation of credit provides sufficient incentive to ensure that the hazardous waste pharmaceuticals will be managed appropriately or whether it is necessary to establish management standards and/or a maximum time limit for the accumulation of potentially creditable hazardous waste pharmaceuticals prior to off-site shipment.

In the 2008 Pharmaceutical Universal Waste proposal, EPA specifically solicited comment on whether stakeholders have knowledge of problems with mixing incompatible pharmaceuticals during accumulation. In response, one commenter indicated that there were no issues encountered with the compatibility of pharmaceuticals during storage.<sup>99</sup> Since then, a 2011 article by Charlotte Smith states, "oxidizers, acids, and bases also are incompatible, but they occur infrequently as finished dosage forms."<sup>100</sup> It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk than solid pills due to possible spillage or leakage. However, EPA believes that the small quantities in which the liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), would likely obviate these risks. In addition, to further mitigate the potential for spillage or leakages, as a best management practice, EPA encourages healthcare facilities to place the original containers and packaging containing liquids and aerosols

pharmaceuticals in separate individual containers, such as a sealed storage bag before placing them in the container that will be shipped.

EPA also is proposing not to require specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals, while they accumulate on-site. EPA does not want to deter the practice of co-mingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported to a reverse distributor together.

In addition, due to concerns regarding diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor waste or patient care pharmaceutical waste, or most hazardous waste, the hazardous waste pharmaceuticals returned to a reverse distributor often have high street value that makes them susceptible to diversion. Thus, EPA is not proposing to require a label for potentially creditable hazardous waste pharmaceuticals during accumulation at a healthcare facility. The Agency seeks comment on its proposal not to require specific accumulation, container management or labeling standards for potentially creditable hazardous waste pharmaceuticals that will be transported to a reverse distributor, including no specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals on-site prior to shipment off-site.

#### *E. What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?*

##### 1. Sewer Disposal Prohibition

*a. Regulatory background on the domestic sewage exclusion.* Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, "Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment" is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that "Mixed waste streams that pass through sewer systems to publicly-owned treatment works (POTW's) will be subject to controls under the Clean

<sup>99</sup> Commenter #EPA-HQ-RCRA-2007-0932-0091.

<sup>100</sup> Charlotte Smith, RPH, MS; Managing Pharmaceutical Waste: A New Implementation Blueprint; Pharmacy Practice News, Special Edition, 2011.

<sup>98</sup> See 73 FR 73529; December 2, 2008.

Water Act. The Agency's construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency's pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems" (45 FR 33097).

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended by RCRA. HSWA included a new Section 3018, entitled Domestic Sewage. This section directed EPA to do two things with respect to the 261.4(a)(1)(ii) exclusion for mixtures of domestic sewage and other wastes: (1) Submit a Report to Congress (RTC) that describes the types, size and number of generators which dispose of such wastes in this manner, the types and quantities of wastes disposed of in this manner, and identify significant generators, wastes and waste constituents not regulated under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the existing regulations that are necessary to "ensure that substances . . . which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment."

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking (ANPR) on August 22, 1986 (51 FR 30166); a response to comments on the ANPR on June 22, 1987 (52 FR 23477); a notice of proposed rulemaking (NPR) on November 23, 1988 (53 FR 47632); and a final rule on July 24, 1990 (55 FR 30082). That final rule prohibits the discharge of pollutants which create a fire or explosion hazard in the POTW, which includes, but is not limited to, wastestreams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Celsius using the test methods specified in 40 CFR 261.21" (55 FR 30087). Although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), the sewer ban of liquid ignitable hazardous wastes (*i.e.*, with the hazardous waste code D001) was established under 40 CFR 403.5(b)(1), which is under the Clean Water Act (CWA) regulations. The Agency seeks comment on whether it would be helpful to incorporate in 40 CFR

261.4(a)(1)(ii), a cross-reference to the CWA regulations prohibiting the sewerage of liquid ignitable hazardous wastes.

*b. Prevalence of flushing in lieu of hazardous waste management.* In the preamble to the July 1990 final rule, EPA stated its intent "to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs" (55 FR 30084). Since then, studies have found that many healthcare facilities, particularly long term-care facilities, use drain disposal as a routine disposal method for pharmaceutical wastes in lieu of collection and shipment off-site for management. For example,

- A 2008 study of 59 long-term care facilities showed that 46 percent of the long-term care facilities dispose of their pharmaceuticals by dumping them down the drain.<sup>101</sup>
- A 2003 King County, Washington survey of healthcare facilities showed that the vast majority of liquids, and nearly half of the pills, were disposed of down the drain.<sup>102</sup>
- In a study by The Albany Medical Center, funded by an EPA Pollution Prevention Grant, the author states, "up to now, toilet wasting has been the common practice for drug wasting by patient care staff."<sup>103</sup>
- In a detailed study about the waste management practices within the healthcare industry, EPA's Office of Water also found that sewerage of waste pharmaceuticals was common practice.<sup>104</sup>
- EPA staff from the Office of Research and Development (ORD) have published numerous articles on the subject of active pharmaceutical ingredients (APIs) in the environment. One such paper states that "unit-packaged pills are probably not frequently disposed via toilets, whereas liquids are probably routinely poured down drains," although the authors acknowledge that "gaining an understanding of the types and quantities of APIs introduced directly and purposefully to the environment by

<sup>101</sup> Kansas State University. January 31, 2008.

Nancy J. Larson. *Pharmaceutical Waste Outreach Project*.

<sup>102</sup> King County Pharmaceutical Waste Survey Final Report. King County, Washington. April 2003.

<sup>103</sup> The Albany Medical Center, October 29, 2009, Russell F. Mankes, Progress Report on the Source Reduction Demonstration Project, EPA Grant #X9-97256506-0.

<sup>104</sup> Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA-821-R-08-013.

the disposal of unwanted, leftover drugs has been more problematic because of a dearth of comprehensive or reliable data."<sup>105</sup>

*c. Inadequacy of POTW treatment to remove pharmaceuticals.* Under the Clean Water Act (CWA), EPA establishes national regulations (called effluent limitations guidelines and pretreatment standards) to reduce discharges of pollutants from industries to surface waters and POTWs. However, there are currently no national effluent limitations or pretreatment standards that apply to discharges of pharmaceuticals by healthcare facilities to POTWs. Furthermore, traditional wastewater treatment operations implemented in the 1970s and 1980s at POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds. They are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. While some POTWs may have implemented advanced treatment technologies at their facilities, these technologies are also not designed to remove pharmaceuticals. EPA released a study in 2009 in which over 100 chemicals (including some pharmaceuticals) were analyzed in the influent and effluent at nine POTWs.<sup>106</sup> Although it was a limited study and difficult to generalize the results to all POTWs, it does indicate that the capabilities of treatment technologies currently employed by POTWs does not include treatment to remove APIs.<sup>107</sup> In addition, as stated in the Health Services Industry study, "synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters."<sup>108</sup>

*d. Adverse impacts to human health and the environment due to pharmaceuticals in the environment.*

<sup>105</sup> Ruhoy and Daughton; Beyond the medicine cabinet: An analysis of where and why medications accumulate; Environment International 34(2008) 1157-1169.

<sup>106</sup> EPA, Occurrence of Contaminants of Emerging Concern in Wastewater from Nine Publicly Owned Treatment Works, August 2009; EPA-821-R-09-009.

<sup>107</sup> Eggen RI, Hollender J, Joss A, Schärer M, Stamm C, "Reducing the Discharge of Micropollutants in the Aquatic Environment: The Benefits of Upgrading Wastewater Treatment Plant." Environmental Science and Technology 2014, 48(14) 7683-7689.

<sup>108</sup> Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA-821-R-08-013.

The pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. The Regulatory Impact Analysis for this proposed rulemaking summarizes the scientific literature with regard to ecological effects (see the Regulatory Impact Analysis in the docket for this proposed rule EPA-HQ-RCRA-2007-0932). The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows:<sup>109</sup>

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they are potentially able to impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving co-administration.

*e. Banning sewerage of hazardous waste pharmaceuticals.* Given the demonstrated negative ecological effects and the potential for negative human health effects, EPA is proposing to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and pharmaceutical reverse distributors that are subject to this proposed rule—that is, they are prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (*i.e.*, ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (*e.g.*, sink, toilet, or floor drain).

In addition, while healthcare facilities that are CESQGs are generally not subject to this proposed rule, EPA is proposing that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are CESQGs. The vast majority of healthcare facilities are CESQGs (84 percent). Some particular types of healthcare facilities have an even larger proportion of CESQGs: Over 94 percent of dental offices are CESQGs, and 94 percent of continuing care retirement communities

are CESQGs (see the Regulatory Impact Analysis in the docket for this proposed rule EPA-HQ-RCRA-2007-0932).

EPA is concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are more than 145,000 healthcare facilities that are CESQGs. Given this large number, the combined impact of sewer disposal by healthcare facilities that are CESQGs has an even greater potential to provide a substantial impact on the environment, as well as human health.

EPA solicits comment on EPA's proposal to ban the sewer disposal of hazardous waste pharmaceuticals at all healthcare facilities, including healthcare facilities that are CESQGs that generate such wastes. As part of its solicitation of comments, the Agency especially requests comment on the risk-risk tradeoffs inherent in prohibiting sewer disposal, which extends the life cycle of pharmaceutical waste, resulting in additional opportunities for diversion and increasing the possibility of inadvertent exposures for certain workers (and possibly even patients or visitors) as a tradeoff for a reduction in aquatic risks. EPA also solicits comment on whether the ban on sewer disposal should be limited to those healthcare facilities that are currently LQGs and SQGs, and not extended to CESQGs.

Under 40 CFR 403.12(p) of the CWA regulations, industrial users that discharge a substance to a POTW that, if otherwise disposed of, would be a hazardous waste, must notify in writing the POTW, the EPA Regional Waste Management Division Director and State hazardous waste authorities. POTWs should be made aware that under this proposal, if made final, the notifications they receive from healthcare facilities will no longer include hazardous waste pharmaceuticals since the healthcare facilities will be prohibited from sewerage their hazardous waste pharmaceuticals.

We note that EPA's proposed ban on sewerage hazardous waste pharmaceuticals is consistent with other federal and state actions. For example, the Drug Enforcement Administration (DEA) has finalized new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 (September 9, 2014; 79 FR 53520). DEA's new regulations require a "non-retrievable" method of destruction of controlled substances. The preambles to DEA's proposed and final rules state that flushing does not meet the non-

retrievable standard for destruction.<sup>110</sup> According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against flushing controlled substances.<sup>111</sup> The comments supporting the prohibition against sewerage came from states, regional and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers and requested that DEA clearly state in the regulatory language, not just preamble, that sewerage is not allowable as a means of destruction.

In addition, three states and the District of Columbia have taken action to limit the sewerage of pharmaceuticals and a third has introduced a bill. In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any unused medication into public sewers or septic systems.<sup>112</sup> In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.<sup>113</sup> In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper "Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts" state that "This is the first time that a pharmaceutical has been outlawed to protect water quality."<sup>114</sup> After researching and documenting environmental benefits of the ban, the authors conclude, "This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals." And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical products.<sup>115</sup> The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private waste water collection systems or septic

<sup>110</sup> Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803) and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).

<sup>111</sup> September 9, 2014; 79 FR 53520 (see page 53548).

<sup>112</sup> Illinois Public Act 096-0221.

<sup>113</sup> Nicknamed Bateman's Law, after Senator Christopher "Kip" Bateman (R-Somerset) that sponsored the legislation.

<sup>114</sup> Humphreys, *et al.* Environmental Health Perspectives. 2008 March; 116(3) 297-302.

<sup>115</sup> Title 22-B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities.

<sup>109</sup> A. Ginebreda et al, Environmental risk assessment of pharmaceuticals in rivers: Relationships between hazard indexes and aquatic macroinvertebrate diversity indexes in the Llobregat River (NE Sapin). Environ Int. (2009), doi:10.1016/j.envint.2009.10.003.

systems, although it has not yet become law.<sup>116</sup>

Finally, we would note that although the sewer ban is limited to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (*i.e.*, hazardous or non-hazardous), except when sewerage is specifically directed by FDA guidance (as noted on pharmaceutical packaging).<sup>117</sup>

For household pharmaceutical waste, we refer the public to the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted

household pharmaceuticals. In summary, these guidelines are as follows:

- (1) Use a drug take-back event or program, when available;
- (2) Dispose in household trash, after mixing the unwanted medicines with an undesirable substance such as kitty litter or coffee grounds and placing in a sealed container; and
- (3) Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.<sup>118</sup>

## 2. Conditional Exemption for Hazardous Waste Pharmaceuticals That Are Also Controlled Substances

When a pharmaceutical that is discarded is both a hazardous waste and

a controlled substance, its management and disposal is regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA's or the authorized state's purview, and the Controlled Substances Act (CSA) and its implementing regulations, which is under DEA's purview. EPA understands that only a handful of pharmaceuticals are in common usage that are both hazardous waste and controlled substances and therefore subject to dual regulation by both EPA and the DEA. These are identified in Table 5:

**Table 5: Pharmaceuticals Still Used in Healthcare that Are DEA Controlled Substances & RCRA Hazardous Wastes**

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Chloral; chloral hydrate	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics
Fentanyl sublingual spray	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content
Testosterone gels	Androgel, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to gel base
Valium injectable	Diazepam	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content

Chloral hydrate, U034, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste. It is listed for toxicity (note that EPA's U034 listing includes chloral hydrate, see memo dated April 6, 1998; Brandes to Knauss, RCRA Online #14175). On the other hand, the remaining four dually regulated

hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitability (D001). However, the active ingredient is not ignitable, but these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 6.

<sup>116</sup> State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.

<sup>117</sup> <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf>.

<sup>118</sup> <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf>.

**Table 6: DEA Controlled Substances & RCRA Hazardous Wastes Pharmaceuticals that Are Not in Common Use**

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal	D001 ignitable	III	No longer in common use
Opium Tincture	Laudanam	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use

Similarly, as noted in Table 7, phentermine is a controlled substance, but the medical form is a phentermine

salt, and the salts are no longer considered to be within the scope of the P046 listing (see memo dated February

17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831).

**Table 7: Pharmaceuticals that are DEA Controlled Substances & RCRA Hazardous Wastes Salt(s) No Longer Considered Hazardous Waste**

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha, alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obex-Nix, Pentecot, Phentride, Pro-Fast, Raptre, Supramine, Tara-8, Termene, Termine, Zantryl	Appetite suppressant	P046 Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts

EPA requests comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, RCRA hazardous waste.

Common practices that healthcare facilities have used in the past in order to comply with the DEA regulations for destroying controlled substances include sewerage and incineration. However, DEA's new regulation requires that controlled substances must be destroyed, such that they are "non-retrievable." As discussed previously,

the preambles for DEA's proposed and final rules state that flushing will not meet their new non-retrievable standard, a position which EPA fully supports. However, EPA is concerned that flushing will continue to be used by healthcare facilities for eliminating their controlled substances. In part, this concern is due to a 2009 EPA report which concluded, "controlled substances are the pharmaceuticals most commonly poured down the drain, especially the partially-used IVs

containing controlled substances."<sup>119</sup> In addition, stakeholders have informed EPA that it is expensive and difficult to manage controlled substances that are also hazardous wastes under both DEA and EPA regulatory schemes and therefore the unintended consequence is that they are often sewerage on-site in order to avoid the expense of complying with dual regulation en route to incineration.

<sup>119</sup> Pathways for Environmental Releases of Unused Pharmaceuticals, October 12, 2009, Memo from ERG to EPA, EPA-HQ-OW-2008-0517-0518.

EPA wants to eliminate the flushing of pharmaceuticals in order to reduce potential environmental contamination. Sewering hazardous wastes that are ignitable (D001) is already banned and EPA is now proposing to eliminate the sewerage of all other hazardous waste pharmaceuticals.<sup>120</sup> To eliminate duplicative regulation and thereby further reduce the incidence of flushing, EPA is proposing to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA is proposing that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266, subpart P, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition is to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). The majority of the hazardous wastes that are also controlled substances are hazardous because they exhibit the characteristic of ignitability. The best demonstrated available technology (BDAT) developed for ignitable hazardous waste under the LDRs includes combustion (see § 268.40). In addition, although chloral hydrate (U034) is listed because of its toxicity, its BDAT is also combustion. Therefore, in an effort to eliminate the sewerage of these dually regulated hazardous wastes/controlled substances, and because combustion of these pharmaceuticals is a suitable technology for destruction, EPA is proposing to allow the few hazardous wastes pharmaceuticals that are also controlled substances to be combusted at municipal solid waste combustors, although as noted previously, a hazardous waste incinerator (permitted or interim status) would also be allowed.

We realize that DEA may allow a technology other than combustion to be used to destroy controlled substances. However, if the RCRA hazardous waste pharmaceuticals that are DEA controlled

substances are exempt from RCRA, the other destruction technologies may lack environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, is a condition of the exemption. EPA requests comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances. Under this proposal, if DEA allows a technology other than incineration for the destruction of controlled substances, it would be allowed only for DEA controlled substances, but not for those that are also RCRA hazardous wastes.

The second condition is to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA's hazardous waste and DEA's controlled substance regulatory programs are designed to track the regulated material from cradle to grave. DEA regulations have requirements similar to EPA's hazardous waste manifest. In particular, in order to ship a schedule II controlled substance, a DEA registrant must submit a DEA Form 222 to the supplier of the schedule II controlled substance. The DEA Form 222 is a numerically controlled form issued by the DEA to authorized registrants, containing certain pre-printed information. The supplier must indicate on the DEA Form 222, the quantity of packages shipped and the date the packages were shipped. Like a hazardous waste manifest, a copy of Form 222 must accompany the shipment and it must be kept by both the supplier and purchaser for at least two years (copies of manifests must be kept for three years). Suppliers and distributors may utilize the electronic version of the DEA Form 222, which requires the same information and retention period. Similarly, DEA Schedule III, IV and V controlled substances must be accompanied by an invoice, which also must include a detailed inventory of the contents shipped. A copy of the invoice must also be retained by the supplier and purchaser of the controlled substances for a period of two years. EPA believes that the DEA tracking and shipping requirements are sufficient to act in lieu of the RCRA hazardous waste manifest and hazardous waste transporter requirements. EPA requests comment on this assessment.

DEA has previously stated that controlled substance "pharmaceutical wastage" may be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, to include sewerage or putting down the drain.<sup>121</sup> The term "pharmaceutical wastage" refers to leftover, unadministered pharmaceuticals ("e.g., some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized"<sup>122</sup>). EPA is proposing that the few hazardous waste pharmaceuticals that are also controlled substances would be exempt from RCRA, but only on the condition that they are incinerated at a permitted hazardous waste or municipal solid waste incinerator and managed in accordance with DEA regulations. As a result, if pharmaceutical wastage is both hazardous waste and controlled substance it would not be allowed to be sewerage; it would have to be incinerated. Prior to incineration, the pharmaceutical wastage would be exempt from RCRA and could be collected in a container at the healthcare facility. As an alternative, we request comment on whether to allow the sewerage of the pharmaceutical wastage for the five hazardous wastes that are also controlled substances. We are concerned, however, that this alternative approach will lead to the sewerage of all pharmaceutical wastage as healthcare providers are unlikely to keep track of which hazardous waste pharmaceuticals are allowed to be sewerage and which are not. We request comment on these approaches for pharmaceutical wastage and request data on the impact on healthcare facilities of not allowing pharmaceutical wastage to be sewerage.

*a. Long-term care facilities and the DEA final rule.* As discussed previously, EPA is proposing that hazardous waste from long-term care facilities will no longer be considered exempt as household hazardous waste. Instead it will need to be managed as regulated hazardous waste. This interpretation will apply to all the hazardous waste generated by a long-term care facility, not just its hazardous waste pharmaceuticals, although the Agency expects that much of the hazardous waste generated by long-term care facilities consists of hazardous waste pharmaceuticals. However, there are

<sup>121</sup> See DEA letter to registrants re: clarifying disposal of pharmaceutical wastage dated Oct 17, 2014; [http://www.deadiversion.usdoj.gov/drug\\_disposal/dear\\_practitioner\\_pharm\\_waste\\_101714.pdf](http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf).

<sup>122</sup> *Ibid.*

<sup>120</sup> See 40 CFR 403.5 for specific pretreatment prohibitions.

two exceptions. First, hazardous waste pharmaceuticals that are also controlled substances will not be subject to RCRA, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances. Second, as discussed previously, EPA estimates that only 28% of long-term care facilities generate hazardous waste pharmaceuticals and of those, 85% generate small enough quantities of hazardous waste that they will qualify as CESQGs and will be subject to the reduced regulatory requirements of 40 CFR 261.5, and only the sewer ban provision of this new subpart.<sup>123</sup>

DEA's new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are expected to help alleviate the problem that long-term care facilities face when discarding controlled substances. DEA's new regulations allow retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations and become "collectors" to place collection receptacles at long-term care facilities (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users (*i.e.*, consumers).

Under the new DEA regulations, long-term care facilities have three options, two of which are new, for managing their patients' controlled substances. First, if a DEA registered retail

pharmacy or hospital/clinic with an on-site pharmacy places a collection container at a long-term care facility, the staff from the long-term care facility may place the patients' controlled substances in the collection receptacles. Second, although long-term care facilities will not be able to conduct collection events for their patients' controlled substances for mail-back programs, they will be allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement will continue to be allowed to pick up patients' controlled substances for disposal. With these changes to DEA's regulation, long-term care facilities can now dispose of patients' controlled substances in a more environmentally protective way. Because we are proposing that hazardous waste pharmaceuticals that are also controlled substances are conditionally exempt from RCRA, these wastestreams may also be managed in any of these three ways allowed by DEA, provided the waste is managed to meet the conditions of the RCRA conditional exemption.

The new DEA regulations do not mandate the placement of collection receptacles or patient participation in mail-back programs or take-back events. However, if long-term care facilities are prohibited from disposing of pharmaceuticals down the toilet or drain under RCRA (and as a method of destruction under DEA regulations), then the only way for patients at long-term care facilities to lawfully dispose of DEA controlled substances that are

also RCRA hazardous wastes would be through participation in one of DEA's collection methods. Long-term care facilities are allowed to place patients' hazardous waste pharmaceuticals that are controlled substances in the DEA collection receptacles; the other hazardous waste pharmaceuticals generated by long-term care facilities must be managed under the proposed RCRA management standards for healthcare facilities. However, we note that if the long-term care facility is a CESQG, we are proposing as an acceptable method of disposal of the long-term care facility's hazardous waste pharmaceuticals would be to place them in a DEA collection receptacle, even if they are not controlled substances (see § 266.504(b)). DEA already allows controlled substances to be co-mingled with non-controlled substances. Therefore, EPA believes it is consistent to allow CESQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of CESQGs' hazardous wastes as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors and workers at long-term care facilities to have the hazardous waste pharmaceuticals in DEA collection receptacles rather than in the regular trash. See Table 8 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at long-term care facilities:

TABLE 8—RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES

Types of pharmaceutical waste at long-term care facilities	Regulatory requirements	
	RCRA	DEA Authorized collection methods allowed for <i>patients'</i> pharmaceuticals
Hazardous Waste Pharmaceuticals that are also Controlled Substances.	Conditionally exempt from RCRA .....	Yes.
Hazardous Waste Pharmaceuticals that are not Controlled Substances.	.....	
if LTCF is a CESQG .....	261.5 and sewer ban .....	Yes.
if LTCF is not a CESQG .....	Part 266, subpart P .....	No.

*b. Household hazardous waste collected in DEA authorized collection receptacles.* In response to questions that EPA has received since the DEA rule was published, we are taking this opportunity to clarify the current RCRA regulatory status of the pharmaceuticals

collected in DEA authorized collection receptacles. DEA's regulations allow the co-mingling of controlled substances and non-controlled substances in its collection receptacles. In some instances, the pharmaceuticals that are collected by retail pharmacies and law

enforcement in DEA authorized collection receptacles may contain pharmaceuticals that are RCRA hazardous waste. However, as household wastes, these hazardous waste pharmaceuticals would be excluded from regulation by

<sup>123</sup> See the docket for this rulemaking for data about long-term care facilities which was developed

using data in the economic analysis: EPA-HQ-RCRA-2007-0932.

§ 261.4(b)(1) because the exclusion applies even when the household hazardous wastes are collected. It is important to note that in order to maintain the exclusion, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.<sup>124</sup> Furthermore, states generally regulate non-hazardous waste and they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the collection receptacles.

Under this proposal, pharmaceuticals collected in DEA authorized collection receptacles will continue to be excluded from regulation as household hazardous waste, with some conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste. We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not *require* an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we are proposing that pharmaceuticals that are household hazardous waste (*i.e.*, “household waste pharmaceuticals”) and are collected in DEA authorized collection receptacles

where they may be co-mingled<sup>125</sup> with controlled substances continue to be excluded from RCRA regulation, provided they are:

(1) Combusted at a municipal solid waste or hazardous waste combustor, and

(2) managed in accordance with all applicable DEA regulations (see § 266.506(a)(2)). The Agency solicits comments on all these provisions.

On a separate, but related matter, EPA has received a number of inquiries about the exemption in the Clean Air Act regulations for Other Solid Waste Incinerator (OSWI) “units that combust contraband or prohibited goods” (see the exemption at 40 CFR 60.2887(p) for new OSWIs and 40 CFR 60.2993(p) for existing OSWIs). As indicated in a previous guidance memo, EPA does not consider pharmaceuticals, voluntarily collected from ultimate users in a take-back program, to be contraband or prohibited goods.<sup>126</sup> Likewise, EPA will not consider pharmaceuticals that are voluntarily dropped off at collection receptacles to be contraband or prohibited goods. Therefore, the OSWI exemption does not apply and law enforcement may not destroy voluntarily collected pharmaceuticals in the same way that it is allowed to destroy contraband or prohibited goods.

### 3. Management of Residues in Pharmaceutical Containers

*a. Regulatory background.* Over the years, EPA has received numerous inquiries regarding the regulatory status of various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded because of the hazardous waste residue in the containers. Stakeholders have been particularly concerned about containers that once held pharmaceuticals that are on the “P-list” of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month or accumulates more than 1 kg of acute hazardous waste at any time.<sup>127</sup> The current regulatory status of acute and non-acute commercial chemical product

residues remaining in a container are specifically addressed in § 261.33:

The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded

(c) Any *residue* remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in § 261.7(b). [emphasis added]

According to § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered “empty”:

A container or an inner liner removed from a container that has held any hazardous waste, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter is empty if:

(i) All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *e.g.*, pouring, pumping, aspirating, *and*

(ii) No more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, *or*

(iii) (A) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; *or*

(B) No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice *and* either has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,<sup>128</sup> then the container is *not* considered “RCRA empty,” even though the pharmaceutical may have been fully dispensed. If the container is not “RCRA empty,” then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste). On the other hand, if the contents of the container have been removed by a commonly employed

<sup>125</sup> DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

<sup>126</sup> Rudzinski to RCRA Division Directors, September 26, 2012, RCRA Online #14833 <http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/fcb11dd6f61d4b1685257afe005eb5ce!OpenDocument>.

<sup>127</sup> Additionally, acute hazardous wastes are included on the F-list of § 261.31; however none of those acute hazardous wastes are pharmaceuticals.

<sup>128</sup> We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.

<sup>124</sup> DEA regulations also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

practice *and* either have one inch or less of residue remaining, or 3 percent or less of weight of the total capacity of the container remaining, then the container is considered “RCRA empty,” and may be managed as non-hazardous waste.

Likewise, according to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered “empty”:

A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§ 261.31 or 261.33(e) is “empty” if:

(i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

Therefore, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered “RCRA empty,” even though the pharmaceutical may have been fully dispensed. If the container is not “RCRA empty,” then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals<sup>129</sup> that provides three possible regulatory approaches for generators:

(1) Count only the weight of the residue toward generator category

(2) Demonstrate an equivalent removal method to render containers RCRA empty

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration.

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations and EPA indicated at the time that a more comprehensive solution would require notice and public comment that occurs during a rulemaking. We are proposing to amend the regulations that pertain to

containers that once held pharmaceuticals that are RCRA hazardous wastes. We are proposing different regulatory solutions for different types of containers found in healthcare settings. Specifically, we address the following three types of containers: (1) Unit-dose containers (*e.g.*, packets, cups, wrappers, blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices. If finalized, these new regulations for pharmaceutical containers would replace the November 2011 guidance; however, in the meantime, the guidance remains in effect.

*b. Unit-dose containers.* First, with regard to unit-dose containers and dispensing bottles and vials up to 1 liter or 1000 pills, we are proposing a conditional exemption from the empty container regulations of § 261.7 for containers from which the pharmaceuticals have been fully dispensed. Specifically, we are proposing that the removal of the pharmaceuticals from the unit-dose containers, and dispensing bottles and vials (up to 1 liter or 1000 pills), is equivalent to rendering the container “RCRA empty.” Therefore, for containers that once held non-acute hazardous wastes, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous wastes, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method. Rather, if the contents of the container have been fully dispensed by removing all pharmaceuticals that can be removed using the practices commonly employed to remove materials from that type of container, the residues (and therefore the container) may be disposed of as non-hazardous waste.

We are proposing this conditional exemption for two reasons. First, we want to eliminate the sewerage of pharmaceuticals. We are particularly concerned that in a healthcare setting, when containers are triple rinsed, the rinsate will be poured down the drain which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as municipal solid waste management—rather than poured down the drain. Second, although the “empty container”

regulations of § 261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals range in size from a few milliliters (*e.g.*, packaging for nicotine gum, paper cups used to dispense pharmaceuticals to in-patients) to a liter (*e.g.*, bottles that hold bulk quantities of pills). In rare circumstances, containers with pharmaceuticals are as large as two or three liters (*e.g.*, powders that are reconstituted with water). This differs significantly from the 55-gallon drums that are typically used in other sectors that generate hazardous waste. Consequently, the amount of residues in the containers was anticipated to be much more substantial than is the case for containers typically used for pharmaceuticals.

EPA has received data from three stakeholders demonstrating that there is very little residue remaining in fully dispensed containers of pharmaceuticals. In addition, EPA’s ORD conducted similar research. The results from each of the four sources are summarized below; the full results are included in the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

*i. Consulting Firm.* One stakeholder, with a hazardous medical materials consulting firm, provided some laboratory testing. They had the residues from single-unit dose packaging of four different P-listed pharmaceuticals tested using gas chromatography/mass spectrometry (GC/MS) and high performance liquid chromatography/ultraviolet detector (HPLC/UV). The amount of active pharmaceutical ingredient in the residues remaining in containers was quantified and the results from containers that had been triple rinsed were compared with containers that had not been triple rinsed. For the containers that were triple rinsed, the active ingredient in the residues was non-detect in all cases. For the containers that were not triple rinsed, the highest level detected was 35.8 µg (or 0.0358 mg). The laboratory results submitted to EPA are summarized in Table 9; the full laboratory results are included in the docket for this rulemaking (EPA-HQ-RCRA-2007-0932).

<sup>129</sup> Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827 <http://>

[yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/)

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**Table 9: Active Pharmaceutical Ingredient in Residues in Single-Unit Dose Packaging**

Drug (packaging type)	HW Code	Active pharmaceutical ingredient in Triple-Rinsed Packaging ( $\mu\text{g}$ )	Active pharmaceutical ingredient in Non-Triple-Rinsed Packaging ( $\mu\text{g}$ )	Reporting Limit ( $\mu\text{g}$ )
Nicotine gum* (blister pack)	P075	ND	ND	0.00005
Nicotine patch* (single use packet)	P075	ND	35.8	0.00005
Warfarin** (blister pack)	P001	ND	6.4	5.0
Physostigmine** (ampoule)	P204	ND	ND	100

\*Method EPA 8720B

\*\*HPLC/UV

ND = non-detect

ii. *Large Retailer*. The second stakeholder that submitted data to EPA was a large retailer. Their data provide the weight of active pharmaceutical ingredient residues remaining in bulk

containers (*i.e.*, 100-count) of various dosage strengths of warfarin. The residues were quantified using HPLC–UV/Vis (high performance liquid chromatography/ultraviolet/visible light

detector). The data are summarized in Table 10; the full results submitted to EPA are included in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

**Table 10: Warfarin Residues in 100-Count Dispensing Bottles**

Warfarin Dose	Number of Bottles Tested	Total Warfarin Residue in all Containers (mg)	Average Warfarin Residue/Bottle (mg)
Low (1 - 3 mg)	17	2.638	0.155
Medium (5 - 7.5 mg)	18	12.820	0.712
High (10 mg)	18	21.530	1.196

The results from each of the first two stakeholders reflect only the weight of the active pharmaceutical ingredient, not the full weight of the hazardous waste residues. Since it is the Agency's position that it is the full weight of the hazardous waste residues and not just the weight of the active pharmaceutical ingredients that must be counted in determining generator status, we have used the results to calculate the weight of the total residues. In the retailer's case, they have informed EPA that a typical pill with a 10 mg dose of Coumadin (brand name of warfarin) weighs 200 mg. The active ingredient represents 10 mg, or 5% of the weight of the pill, while 190 mg, or 95% of the weight of the pill, consists of ingredients other than the active ingredient. As indicated in Table 10, the average weight of warfarin residue remaining in a fully dispensed bottle of

the high dose of warfarin (10 mg) is 1.196 mg. If we assume that the residue in the container has the same proportions of ingredients (*i.e.*, 5% of the residue is warfarin and 95% of the residue are other ingredients), then there would be an average of 23.92 mg of total hazardous waste residue remaining in a 100-count bottle of 10 mg pills of warfarin. The amount of hazardous waste residue remaining in a 100-count bottle of pills is very small compared with the residue that would remain in a 55-gallon drum, which is what the regulations for container residues envisaged.

iii. *Riverside County*. The third stakeholder that provided data to EPA was the Riverside County Department of Environmental Health, Hazardous Materials Management Branch. The county received a grant from the California Certified Unified Program

Agency (CUPA) Forum Board to conduct a study of residues remaining in pharmaceutical containers. Researchers at the University of California, Riverside (UCR) conducted the study and provided their results in a report to Riverside County entitled, *Residue Analysis of P-Listed Pharmaceutical Containers for Warfarin and Nicotine*. The results are summarized below, but UCR's full results are in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).<sup>130</sup>

The intent of the study was to investigate the third regulatory approach suggested in the November 2011 memo discussed previously. That

<sup>130</sup> See Exhibit 2 of the CUPA Forum Board Trust Fund Grant Report submitted by the Riverside County Department of Environmental Health at the conclusion of the grant.

is, the study investigated whether the concentration of warfarin in the residues of warfarin pill bottles was greater than 0.3% and therefore met the listing criteria for P001 or whether the residues were at or below 0.3% and therefore met the listing criteria for U248. Although nicotine is not a concentration-based P-listing, packaging from nicotine-containing products were also investigated to determine total remaining residues.

The researchers collected a total of 59 samples containers, including 44 sample containers that had held warfarin pills but had been fully dispensed and another 15 sample containers from nicotine-containing products. The samples included warfarin and nicotine from several manufacturers, in a range of dose strengths and in various container types. The residues were solvent-extracted and then dried by rotary evaporation to determine the total weight of residues. Subsequently, the residues were re-dissolved in methanol and analyzed using HPLC to determine the concentration of the active pharmaceutical within the residues.

The majority of warfarin containers were plastic bottles, but some containers were blister packs and three samples were 30-pill blister packs, sometimes

referred to as a “bingo card.” The results indicate that the concentration of the active pharmaceutical ingredient warfarin in the residues in plastic bottles was usually over the 0.3% concentration. However, the concentration of warfarin in the residues on blister packs, including the 30-pack blister pack, was consistently below 0.3%. Overall, in the majority of cases, the warfarin within the residues was present at a high enough concentration to be considered P001 (33 of 44 samples, 75 percent of the samples).

However, the results also confirm the results from the first two stakeholders. That is, the total weight of residues remaining in the containers after they were emptied of the warfarin pills is negligible. For the plastic bottles, the total weight of residue ranged from 4.3–82.3 mg. For the single-dose blister packs, the total weight of residue ranged from 3.5–7.6 mg. And for the 30-pack blister pack, the total weight ranged from 134.8–273 mg. Taking the smallest amount of residue of 3.5 mg, it would take close to 300,000 containers per month to exceed the 1 kg threshold to be an LQG. Even on the conservative side, taking the largest amount of residue of 273 mg, it would take close

to 4000 containers per month to exceed the 1 kg threshold to be an LQG.

The results for nicotine residues were similar. For containers of gum and patches, the weight of total residues ranged from 9–111.2 mg, although the two containers of liquid nicotine solution contained more residues—1301 and 1616 mg. Although nicotine is not a concentration-based listing, it is worth noting that the active pharmaceutical ingredient of nicotine in the residues was below the quantifiable limit of 1.5 µg/ml in 8 of the 15 samples and for the other 7 samples, the concentration of nicotine ranged from 0.01–0.09%.

iv. EPA’s Office of Research and Development. Finally, EPA’s ORD conducted an analysis to evaluate whether simply removing a drug from the container is equivalent to triple rinsing the container. ORD’s results are summarized in Table 11, but the Final Project Report containing the full results is in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932). ORD analyzed three different P-listed pharmaceuticals: Warfarin, nicotine and physostigmine salicylate. Table 11 lists the 18 different combinations of active pharmaceutical ingredients, form, dosage strengths and packaging combinations that ORD analyzed.

TABLE 11—PHARMACEUTICAL COMBINATIONS TESTED BY EPA’S ORD

Active pharmaceutical ingredient	Manufacturer/Brand name	Form	Dosage	Packaging type	
Warfarin	Taro Pharmaceutical Industries, Ltd.	Tablet	1 mg	Plastic bottle.	
		Tablet	5 mg	Plastic bottle.	
		Tablet	10 mg	Plastic bottle.	
		Tablet	2 mg	Single-dose blister pack.	
Nicotine	Upsher-Smith/Jantoven	Tablet	1 mg	Single-dose blister pack	
		Tablet	10 mg	Single-dose blister pack.	
		Tablet	2 mg	Single-dose blister pack.	
	GlaxoSmithKline/Nicorette	Gum	2 mg	Single-dose blister pack.	
		Gum	4 mg	Single-dose blister pack.	
		Rugby Laboratories	Gum	2 mg	Single-dose blister pack.
		Gum	4 mg	Single-dose blister pack.	
		GlaxoSmithKline/Nicorette	Lozenge	2 mg	Plastic vial
Physostigmine Salicylate.	Akron Inc.	Lozenge	4 mg	Plastic vial.	
		Patch	7 mg	Peel-off plastic.	
		Patch	14 mg	Peel-off plastic.	
		Patch	21 mg	Peel-off plastic.	
		Pfizer/Nicotrol	Spray	10 mg/ml	Glass vial.
Physostigmine Salicylate.	Akron Inc.	Inhaler	10 mg	Plastic container.	
		Liquid	1 mg/ml	Glass ampoule.	

All combinations in Table 11 were analyzed in triplicate using the following three-step approach:

(1) After removing the tablets, gum, lozenges, etc from the containers, the amount of total residuals remaining in the container was determined using a sensitive balance to weigh the container before and after triple rinsing,

(2) The “maximum possible weight of residual drug/total residual/container” was calculated for each compound and packaging combination. This calculated result was used to infer a theoretical upper limit for the amount of active pharmaceutical compound in the total residue remaining in the container, and

(3) Thermal gravimetric analysis (TGA) was used to qualitatively evaluate the presence of active pharmaceutical ingredient in the residuals removed from the containers before and after triple-rinsing.

With respect to the weight of the remaining residuals in the containers, ORD’s results are similar to the results

from the first three sources. That is, the weight of the total residuals remaining in the packaging of P-listed pharmaceuticals is minimal. For single-dose blister packs, lozenge vials and the peel-off plastic from nicotine patches the weight of the residuals was negligible and within the range of error of the balance, but all results were below 0.0002 grams. For plastic containers that held tablets, the weight of residuals were higher, but still very low, ranging from 0.0152–0.0157 grams. For containers that held liquids, the weight of residuals was the highest, but still very low, ranging from 0.0472 grams for glass vials of nicotine spray, to 0.0651 grams for glass ampoules that held liquid physostigmine salicylate. The residuals in the nicotine inhaler were not experimentally determined; rather, the manufacturer (Pfizer) states on the packaging that the 10 mg cartridge delivers a 4 mg dose, so the residuals are assumed to be 6 mg (or 0.006 grams).<sup>131</sup>

Unlike the quantitative results from the HPLC analyses from outside stakeholders, the results from the TGA are qualitative only. That is, the TGA was only intended to evaluate the presence of the API and compare the results from containers that had been triple rinsed with those that had not been triple rinsed. Using TGA, the API was not detected in the residuals, with one exception: The liquid nasal spray (note that TGA was not used on the nicotine inhaler residuals). In most cases, the TGA detected other, unspecified ingredients in the residuals, but not the active pharmaceutical ingredient on the P-list. The total weight of the residuals was well under a gram and the active pharmaceutical ingredient is a small proportion of the total weight of the tablet, gum, etc. As a result, with the exception of the nicotine nasal spray, the TGA was not sensitive enough to detect the presence of the active pharmaceutical ingredient, regardless of whether the container had been triple rinsed or not.

EPA is aware that there are certain limitations with the data from the four sources. For instance, in the case of the

consulting firm, no replicate samples were tested. In the case of the retailer, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency is proposing to allow the residues in single-unit dose containers/packaging and dispensing bottles, vials and ampules that once held pharmaceuticals to be managed as non-hazardous waste pharmaceuticals provided the pharmaceutical product has been fully dispensed (*e.g.*, all pills have been removed). EPA is soliciting comment on whether these studies are representative of the spectrum of formulations and containers that might be encountered.

Finally, we note that the Agency is concerned about the potential for diversion of the pharmaceutical containers that may occur when the pharmaceutical residues and containers are discarded in the municipal waste stream. In such instances, we are concerned that the containers could be diverted from the municipal waste stream and used for illicit purposes, such as packaging counterfeit pharmaceuticals. Therefore, EPA is proposing that “RCRA empty” pharmaceutical containers that are original pharmaceutical packages (and therefore are susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing single doses to patients. The means of destruction could include crushing or shredding the container. We do not believe that simply defacing the label would be sufficient to avoid diversion, since labels could be replaced if the container is intact.

We request comment on these proposed provisions, including whether it is necessary to limit the size of the dispensing bottle to which this provision would apply. In our observation, EPA has rarely seen pharmaceutical dispensing bottles that are larger than 1000-count, which are approximately 1 liter in size. EPA requests comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes apply. We also seek comment as to whether “RCRA empty” pharmaceutical containers that are the original pharmaceutical packages should be destroyed prior to placing them in the trash.

*c. Dispensed syringes.* With regard to dispensed syringes, EPA is proposing a conditional exemption for syringes that have been used to administer pharmaceuticals that are listed or characteristic hazardous waste when discarded. The residues remaining in a dispensed syringe would not be regulated as hazardous waste provided the syringe has been used to administer a pharmaceutical to a patient and the syringe is placed in a sharps container (if appropriate) and is managed in accordance with all applicable state and federal medical waste regulations. This would apply to syringes used to administer pharmaceuticals that are P- or U-listed, or exhibit a hazardous waste characteristic.

EPA issued guidance regarding the regulatory status of residues in syringes in December 1994<sup>132</sup> and April 2008.<sup>133</sup> In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine in a discarded syringe would be P042, EPA stated, “Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste.”<sup>134</sup>

In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe. This proposed conditional exemption for syringes, in large part, would maintain the existing interpretation. The primary difference is that under the proposed conditional exemption, healthcare facilities would not be required to determine if the residues in the syringes meet a listing description or exhibit a hazardous waste characteristic.

<sup>132</sup> December 1994, RCRA Online #13718 [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/\\$file/13718.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/$file/13718.pdf).

<sup>133</sup> Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788 [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/\\$file/14788.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/$file/14788.pdf).

<sup>134</sup> Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778)

<sup>131</sup> Optimizing drug dose is a major factor in improving the sustainability of healthcare. The prescriber needs to be cognizant that prescribed treatments can have unanticipated, collateral impacts that reach far beyond the healthcare setting. See: Daughton and Ruhoy, *Lower-dose prescribing: Minimizing “side effects” of pharmaceuticals on society and the environment*; *Sci Total Environ*, 443(2013), pp. 324–336, which presents a critical examination of the multi-faceted potential role of drug dose in reducing the ambient levels of APIs in the environment and in reducing the incidence of drug wastage, which ultimately necessitates disposal of leftovers. (<http://sciencedirect.com/science/article/pii/S004896712013927#>)

EPA believes this conditional exemption is important to minimize the potential for exposures to healthcare workers, which can happen if they are accidentally stuck with a needle. Typically, sharps containers are more readily available to a medical practitioner than a hazardous waste container. Therefore, the used syringe will be discarded more quickly into a sharps container and there will be less opportunity for accidental sticks to occur en route to disposing the sharp.

However, we also note that syringes in sharps containers are typically autoclaved prior to disposal. EPA is concerned that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks (via pulmonary exposure) to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.<sup>135</sup> EPA seeks comment on the extent of risks associated with autoclaving hazardous waste residues leftover in syringes and whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this conditional exemption would apply or whether any other conditions would be appropriate. For instance, stakeholders have informed us that they will squirt the residues remaining in a syringe onto a gauze pad prior to placing the syringe in the sharps container. Then, if the residues on the gauze pad are hazardous waste, the gauze pad is managed as hazardous waste, while allowing the syringe to be fully dispensed before placing it in the sharps container. In EPA's view, this method of managing excess residues is preferred over another practice that is commonly used: The disposal of excess residues down the drain.

*d. Other containers, including delivery devices.* With regard to other containers, including delivery devices, EPA is proposing that the residues remaining in unused or used containers (such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels, or creams) would be regulated as hazardous waste if the residues are a P- or U-listed hazardous waste or exhibit a hazardous waste characteristic. In some cases, such as with IV bags, the volume of hazardous waste is much larger than with residues contained in syringes or

unit-dose containers. Stakeholders have stated that it is common practice for the leftover contents of IV bags and tubing to be emptied into a sink, which is a practice we are striving to eliminate. It is extremely difficult to determine how much residue remains in tubes of ointment, gel or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since hazardous waste pharmaceuticals managed under this proposed rule would not be counted towards a facility's generator category, managing these residues and containers as hazardous waste under proposed 40 CFR part 266, subpart P should not pose the same burden that generators currently face with keeping track of the monthly amount of residues in containers that are not "RCRA empty." Further, comments on the 2008 Pharmaceutical Universal Waste proposal indicated that stakeholders prefer clear distinctions in regulating the hazardous waste from healthcare facilities and this proposed standard for container residues responds to that comment. EPA seeks comment on whether these proposed provisions address stakeholder concerns, while protecting human health and the environment.

*F. What are the proposed standards for shipping hazardous waste pharmaceuticals?*

1. Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals to Treatment, Storage, and Disposal Facilities

a. Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals From Healthcare Facilities to TSDFs

Typically, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable (e.g., patient care) hazardous waste pharmaceuticals and (2) potentially creditable hazardous waste pharmaceuticals. This section discusses the proposed requirements for shipping of non-creditable, patient care/floor hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and pharmaceutical reverse distributors, see Section V.F.2 of the preamble.

Generally, patient care/floor hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have

been partially administered and often are not in their original packaging. In addition, patient care/floor hazardous waste pharmaceuticals cannot receive manufacturer's credit and therefore may not be shipped to a reverse distributor. EPA is proposing that patient care/floor hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off-site, must be shipped to a designated facility (i.e., an interim status or permitted hazardous waste TSDF), as currently required (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste). Specifically, EPA proposes that non-creditable hazardous waste pharmaceuticals must continue to comply with the existing pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who are unfamiliar with RCRA, EPA proposes that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA is proposing that the words, "hazardous waste pharmaceuticals" must be entered in the "special handling and additional information" box on the manifest (box # 14). All existing RCRA recordkeeping requirements regarding hazardous waste manifesting continue to apply, (see Section V.C.12), as well as all applicable DOT shipping requirements. EPA requests comment on this proposed approach for manifesting non-creditable hazardous waste pharmaceuticals from a healthcare facility.

b. Shipping Standards for Evaluated Hazardous Waste Pharmaceuticals From Pharmaceutical Reverse Distributors to TSDFs

For pharmaceutical reverse distributors, once potentially creditable hazardous waste pharmaceuticals have been deemed non-creditable or credit has been issued and they do not require any additional verification of credit, EPA is proposing that the hazardous waste pharmaceuticals be referred to as "evaluated hazardous waste pharmaceuticals." As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA is proposing that they must be shipped in accordance

<sup>135</sup> Daughton CG, *Drugs and the Environment: Stewardship & Sustainability*, National Exposure Research Laboratory, Environmental Sciences Division, U.S. EPA, Las Vegas, NV; NERL-LV-ES 10/081, EPA/600/R-10/106; September 2010 (<http://www.epa.gov/nerled1/bios/daughton/APM200-2010.pdf>).

with the existing pre-transport requirements for packaging, labeling and marking, and that evaluated hazardous waste pharmaceuticals must be shipped via a hazardous waste transporter using a hazardous waste manifest to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA believes that use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals has been issued and verified, the potential for mismanagement is greater. This is because the pharmaceuticals have lost their value and will cost the reverse distributor money to dispose. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA is proposing that the pharmaceutical reverse distributor list the appropriate hazardous waste codes on the manifest (even though the healthcare facility is not required to provide such information to the reverse distributor). Hazardous waste pharmaceuticals received by pharmaceutical reverse distributors are in their original packaging with their label, so the information to determine the appropriate hazardous waste codes should be readily available. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare workers lack. As described in Section V.G.3 (pharmaceutical reverse distributor management standards), reverse distributors must keep copies of hazardous waste manifests for three years from the date of shipment.

EPA requests comment regarding the proposed manifest and transportation requirements for non-creditable hazardous waste pharmaceuticals from healthcare facilities and evaluated hazardous waste pharmaceuticals from pharmaceutical reverse distributors.

#### c. Importing/Exporting Non-Creditable or Evaluated Hazardous Waste Pharmaceuticals

Under the existing regulations, a healthcare facility or pharmaceutical reverse distributor may not import

hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept hazardous waste from off-site and complies with the requirements for importing hazardous waste in 40 CFR part 262, subpart F. This proposal does not change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under existing regulations, a healthcare facility or pharmaceutical reverse distributor may not export (non-creditable or evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262, subpart E. This proposal also does not change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals.<sup>136</sup>

EPA requests comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA does not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262, subpart H; however, we also request comment on whether this is the case.

#### 2. Shipping Standards for Potentially Creditable Hazardous Waste Pharmaceuticals

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from healthcare facilities to pharmaceutical reverse distributors and between pharmaceutical reverse distributors. The return of potentially creditable pharmaceuticals (hazardous and non-hazardous) to reverse distributors can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA's request for information,<sup>137</sup> pharmaceutical reverse

distributors explained various scenarios that require extra shipping steps. For example, a healthcare facility typically sends pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer's credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility's reverse distributor must send the pharmaceuticals on to the manufacturer's reverse distributor for the manufacturer's credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the returned pharmaceuticals to the manufacturer so that the manufacturer itself can verify pharmaceutical amounts and credits. The estimate of the amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors have indicated that the percent of potentially creditable pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent, depending on the contractual agreement between the reverse distributor and the manufacturer. Both of the scenarios described previously happen routinely and are part of the business of returning pharmaceuticals to reverse distributors (including manufacturers) for manufacturer's credit.

As explained in Section V.D.1, EPA is proposing that pharmaceuticals transported to pharmaceutical reverse distributors for credit are solid wastes, some of which will also be considered hazardous wastes. Under the current RCRA Subtitle C regulations, hazardous waste, including hazardous waste pharmaceuticals must be manifested to a permitted or interim status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous wastes pharmaceuticals during accumulation and transport are relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which is typically in small, individually packaged doses (such as with many tablets and capsules) or small vials.

<sup>136</sup> The Controlled Substances Import and Export Act prohibits controlled substances from being imported or exported unless permitted by DEA, even when the controlled substances are wastes. See 21 U.S.C. 952 and 953.

<sup>137</sup> EPA sent nine pharmaceutical reverse distributors a letter asking for more information about their business practices in an effort to more fully understand reverse distribution of pharmaceuticals. The seven responses representing the views of eight reverse distributors can be found in the docket of this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when transported to a reverse distributor.<sup>138</sup> Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA's recommendation regarding liquids and aerosols in Section V.D.2.). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk of release to the environment described previously, EPA is proposing to allow potentially creditable hazardous waste pharmaceuticals to be shipped *without* a hazardous waste manifest and *without* the use of hazardous waste transporters. However, this exemption from manifesting and use of hazardous waste transporters only applies if the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, or if a pharmaceutical reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor. Further, DOT shipping requirements continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals.

In lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters, EPA is proposing an alternate type of tracking for potentially creditable hazardous waste pharmaceuticals—with two requirements. First, for each shipment, healthcare facilities and pharmaceutical reverse distributors must provide in writing (via letter or electronic communication), advance notice of the shipment to the pharmaceutical reverse distributor. Second, for each shipment, the receiving pharmaceutical reverse distributors must provide confirmation to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous

waste pharmaceuticals has arrived. One way to comply with this requirement would be for the receiving reverse distributor to require the healthcare facility or pharmaceutical reverse distributor that initiates the shipment of potentially creditable hazardous waste pharmaceuticals to utilize some form of "delivery confirmation" mechanism that is provided by the shipper that confirms that a shipment to a reverse distributor has reached its destination and is under the custody and control of the recipient (e.g. delivery confirmation tracking with return receipt). This "delivery confirmation" notice can be paper-based or electronic. As part of the delivery confirmation system, a signature (paper or electronic) or other confirmation from a representative of the receiving pharmaceutical reverse distributor would be required. The signature by the pharmaceutical reverse distributor would provide assurance that the shipment was received by the reverse distributor. Without the signature or other confirmation of a representative of the pharmaceutical reverse distributor, it is possible for the shipper to state that delivery to the location has occurred, but it would not necessarily indicate that the recipient was there to receive the shipment. This proposed requirement is in direct response to concerns expressed by commenters over the lack of tracking of pharmaceuticals in the 2008 Pharmaceutical Universal Waste proposal.

Alternatively, EPA has learned that some stakeholders use bar-coding on the pharmaceuticals or on the boxes to track shipments. The barcodes contain detailed information, including the exact quantities and types of pharmaceuticals included in the shipment. Typically, when a reverse distributor receives a barcoded shipment, it will scan in the shipment and the sender will receive electronic notification that the shipment has arrived. This type of bar-code tracking would meet the delivery confirmation requirement of this proposed rule, but other mechanisms of "delivery confirmation" that are offered by common carriers, such as the U.S. Postal Service, FedEx or United Parcel Service (UPS), would also be acceptable.

Under this proposal, healthcare facilities and reverse distributors may use common carriers, such as the U.S. Postal Service, United Parcel Service, or FedEx<sup>139</sup> for shipments of potentially creditable hazardous waste pharmaceuticals to and between

pharmaceutical reverse distributors. EPA believes that common carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low transportation risk. We note that healthcare facilities and pharmaceutical reverse distributors must meet the applicable Pipeline and Hazardous Materials Safety Administration (PHMSA) Hazardous Materials Regulation (HMR; 49 CFR parts 171–180) shipping requirements, including preparing proper shipping papers when shipping potentially creditable hazardous waste pharmaceuticals. A RCRA hazardous waste that does not meet DOT hazard classes 1–8 in the HMR, are only Class 9 hazardous materials when defined as a RCRA hazardous wastes that requires a manifest. As a result, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to pharmaceutical reverse distributors only when the hazardous wastes are DOT class 1–8 hazardous materials.

EPA notes that a pharmaceutical reverse distributor is not required to sort the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not sorted, the pharmaceutical reverse distributor must follow the tracking procedures in this proposal for the entire shipment. On the other hand, if a pharmaceutical reverse distributor chooses to sort the potentially creditable hazardous waste pharmaceuticals from the creditable non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these proposed standards. EPA asks for comment on whether the proposed tracking system and controls are sufficient to protect human health and the environment.

a. What Happens if a Healthcare Facility or Pharmaceutical Reverse Distributor Initiates a Shipment and Does Not Get Confirmation of Delivery?

If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation from the intended recipient within seven calendar days, EPA is proposing that the healthcare facility or pharmaceutical reverse

<sup>138</sup> Pharmaceutical Universal Waste proposal, 73 FR 73529; December 2, 2008.

<sup>139</sup> Note EPA is not endorsing the use of any of the shipping companies cited.

distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped. The Agency requests comment on whether any additional requirements, such as reporting to the implementing agency, are necessary in such cases.

#### b. Importing/Exporting Potentially Creditable Hazardous Waste Pharmaceuticals

If a healthcare facility or pharmaceutical reverse distributor imports potentially creditable hazardous waste pharmaceuticals, then it must comply with the proposed requirements for the shipment of potentially creditable hazardous waste pharmaceuticals. The proposed requirements would be in lieu of those for manifested hazardous waste imports found at 40 CFR part 262, subpart F. EPA requests comment on whether potentially creditable hazardous waste pharmaceuticals are imported into the U.S. and, if so, how they are currently declared to customs when imported.

If a healthcare facility or pharmaceutical reverse distributor exports potentially creditable hazardous waste pharmaceuticals then it must generally comply with 40 CFR part 262, subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals.<sup>140</sup>

#### c. Recordkeeping for Shipments of Potentially Creditable Hazardous Waste Pharmaceuticals

EPA is proposing to require healthcare facilities and reverse distributors to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we are proposing that healthcare facilities and reverse distributors that initiate a shipment to another pharmaceutical reverse distributor keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) shipping papers, and (3) confirmation of receipt of shipment for three years after the shipment was initiated. These records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals are reaching their intended destination and not diverted.

In most cases, retaining records for 3 years should be sufficient for inspection purposes; however, we are proposing that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency seeks comment on whether additional recordkeeping is necessary to document the cases when the pharmaceutical reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within 7 calendar days and the steps must be taken to locate the shipment.

#### G. What are the proposed standards for pharmaceutical reverse distributors?

##### 1. Background on Pharmaceutical Reverse Distributor Operations

Pharmaceutical reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. From stakeholder input and EPA site visits, EPA's understanding is that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers' return goods policies, the pharmaceutical reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can be credited, as well as which must be sent on to another reverse distributor for completion of the crediting process.

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer's credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific pharmaceutical reverse distributor may facilitate credit for a particular manufacturer's pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving pharmaceutical reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the credit process.

Because manufacturers' return goods policies change over time, sometimes a pharmaceutical reverse distributor receives a potentially creditable hazardous waste pharmaceutical that is not eligible for credit immediately, and the pharmaceutical reverse distributor retains the potentially creditable hazardous waste pharmaceutical on-site until it is credit eligible. EPA requests comment on how often this happens and how long the potentially creditable hazardous waste pharmaceuticals are kept on-site at reverse distributors to await changes in manufacturers' return goods policies.

In some cases, even after the pharmaceutical reverse distributor has awarded credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to inventory and verify the amount of pharmaceuticals and credit. In developing this proposed rule, EPA considered all of the previous scenarios as part of the crediting process.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent onward to another pharmaceutical reverse distributor, the pharmaceutical reverse distributor awards the manufacturer's credit to the healthcare facility and then manages the hazardous waste pharmaceuticals on-site until they are sent off-site for treatment and disposal. As discussed previously in this proposal, after a potentially creditable hazardous waste pharmaceutical has been evaluated and either credited or deemed non-creditable and no additional pharmaceutical reverse distributors will be involved in the crediting process, EPA proposes to use the term "evaluated hazardous waste pharmaceutical." This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus credited and non-creditable hazardous waste pharmaceuticals that have been through the reverse distributor process and are destined to be managed by a permitted or interim status TSDF. Both are considered hazardous waste pharmaceuticals, but they are managed differently under the proposed regulations.

EPA is not aware of any pharmaceutical reverse distributors that facilitate manufacturer's credit that also has interim status or a permit to treat or dispose of hazardous waste on-site. Therefore, EPA anticipates that pharmaceutical reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off-site for

<sup>140</sup> The Controlled Substances Import and Export Act prohibits controlled substances from being imported or exported unless permitted by DEA, even when the controlled substances are wastes. See 21 U.S.C. 952 and 953.

treatment and disposal. EPA requests comment on whether the processes described previously are representative of the pharmaceutical reverse distribution process.

## 2. EPA's Rationale for Proposing New RCRA Management Standards for Pharmaceutical Reverse Distributors

This proposed rule is establishing standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that pharmaceutical reverse distributors receive and manage. The Agency notes that the management standards discussed in this section apply only to reverse distributors of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals and do not apply to reverse distribution or reverse logistics systems that may exist for other consumer products.

The current federal RCRA hazardous waste regulations at 40 CFR part 262 provide that only RCRA-permitted and interim status TSDFs may receive hazardous waste from off-site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for pharmaceutical reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA proposes a new category under RCRA called a "pharmaceutical reverse distributor," which we proposed to define as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. The definition specifies that any person, including forward distributors and pharmaceutical manufacturers, which processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor. EPA is proposing that pharmaceutical reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off-site provided they comply with the proposed standards in this rule. Pharmaceutical reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed previously, EPA's existing interpretation allows pharmaceutical reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made

about whether the pharmaceuticals will be repurposed. As a generator, a pharmaceutical reverse distributor currently must comply with the LQG, SQG, or CESQG generator requirements, depending on the total volume of hazardous waste generated in a calendar month. Some smaller pharmaceutical reverse distributors might stay under the hazardous waste quantity limits for CESQGs, which would mean that under the federal RCRA requirements, these CESQG pharmaceutical reverse distributors would not have to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 261.5). However, the Agency has concerns with CESQG pharmaceutical reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about pharmaceutical reverse distributors that currently qualify as CESQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems.<sup>141 142</sup> Landfill leachate is generally transported to a wastewater treatment plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation's waters.

EPA is proposing to revise its position regarding potentially creditable hazardous waste pharmaceuticals, such that they will be first considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a

pharmaceutical reverse distributor is a decision to discard the pharmaceutical (as discussed previously in Section V.D.1). Other comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by pharmaceutical reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

As previously discussed, only between 2–6 percent of the potentially creditable hazardous wastes that are received by pharmaceutical reverse distributors are listed or characteristic hazardous wastes.<sup>143</sup> Therefore, the vast majority of the potentially creditable pharmaceutical waste that a pharmaceutical reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, which primarily manages hazardous waste. As a result, a pharmaceutical reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

In addition, because the pharmaceuticals in the reverse distribution system are receiving credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately \$1 billion a year.<sup>144</sup> Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging. Since there is a low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting

<sup>141</sup> Barnes, K. K., Christenson, S. C., Kolpin, D. W., Focazio, M. J., Furlong, E. T., Zaugg, S. D., Meyer, M. T. and Barber, L. B. (2004). Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. *Groundwater Monitoring & Remediation*, 24: 119–126.

<sup>142</sup> Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (2009). Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. *Bulletin of Environmental Contamination and Toxicology*, 82.6:635–659.

<sup>143</sup> See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA-HQ-RCRA-2007-0932.

<sup>144</sup> Meeting with representatives from CVS/Caremark (November 8, 2012); see the docket for meeting notes (EPA-HQ-RCRA-2007-0932).

in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially creditable hazardous waste pharmaceuticals.

Thus, EPA is proposing to take a “middle-of-the-road” approach to regulating pharmaceutical reverse distributors by regarding them as a new type of RCRA hazardous waste entity—a pharmaceutical reverse distributor. This proposed approach addresses comments that EPA received on the December 2008 Pharmaceutical Universal Waste proposal and reflects EPA’s proposed revised interpretation that the point of generation for potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor.

EPA proposes to establish management standards for pharmaceutical reverse distributors in 40 CFR part 266, subpart P. These entities would not be subject to 40 CFR parts 262, 264, or 265. Generally, EPA is proposing that pharmaceutical reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all pharmaceutical reverse distributors, regardless of the amount of potentially creditable hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for pharmaceutical reverse distributors to comply with the new proposal, since the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA proposes that a pharmaceutical reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the proposed pharmaceutical reverse distributor standards. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a pharmaceutical reverse distributor must either obtain a RCRA permit or have interim status. This proposal requires pharmaceutical reverse distributors to comply with standards that are similar to LQG standards for on-site accumulation of

hazardous waste that are found in § 262.34(a) and (b). We are proposing these requirements because, as discussed previously, the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the risk of release is low. Furthermore, many pharmaceutical reverse distributors are already LQGs and therefore this proposed rule should not represent a large shift in current practices or increased burden. However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, we are proposing that pharmaceutical reverse distributors have additional standards for the management of evaluated hazardous waste pharmaceuticals. Note that while the LQG accumulation standards are found in §§ 262.34(a) and (b), these generator regulations reference many interim status TSDF standards in part 265. However, in the regulatory text and preamble for this rule, we reference the standards in part 265 directly for the applicable accumulation standards for pharmaceutical reverse distributors (rather than § 262.34(a) which would then simply refer the reader to part 265). However, the Agency requests comment as to whether we should include the regulatory standard directly in 40 CFR part 266, subpart P, instead of providing a cross-reference to the standard in 40 CFR part 265 in an effort to make the rules easier to follow and comply with.

### 3. Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards

The proposed standards for pharmaceutical reverse distributors are organized into three sections. The first section applies to the pharmaceutical reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another pharmaceutical reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals. The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another pharmaceutical reverse distributor, but instead will be sent to a permitted or interim status TSDF.

#### a. Standards for Pharmaceutical Reverse Distributors

This portion of the preamble discusses the proposed standards that apply to pharmaceutical reverse distributors for the management of all hazardous waste pharmaceuticals on-site. Unlike the following two sections, the standards discussed in this section apply to all pharmaceutical reverse distributors, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a pharmaceutical reverse distributor must follow the proposed standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262.

i. *Notification.* The first proposed requirement is that a pharmaceutical reverse distributor must notify EPA of its hazardous waste pharmaceutical activities via the Site ID form (EPA form 8700–12). Under the current RCRA Subtitle C program, both LQGs and TSDFs must submit a Site ID form to EPA. Thus, EPA believes it is appropriate, and in line with comments received on the 2008 Pharmaceutical Universal Waste proposal, to require pharmaceutical reverse distributors to notify EPA. A pharmaceutical reverse distributor that does not have an EPA ID number will be required to submit the Site ID form to obtain one. If this proposal is finalized, the Agency plans on revising the Site ID form to include a box to allow notifications by pharmaceutical reverse distributors. For those pharmaceutical reverse distributors that already have an EPA ID number, they will need to re-notify EPA as a pharmaceutical reverse distributor. Some pharmaceutical reverse distributors may also be generators of other types of hazardous waste (e.g., from cleaning and maintenance operations). Therefore, it is possible that a pharmaceutical reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a pharmaceutical reverse distributor.

ii. *Inventory.* EPA is proposing a new provision that is specific to pharmaceutical reverse distributors: the requirement is to keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on-site. The inventory must include the identity (e.g., name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. EPA

also recommends as a best management practice that pharmaceutical reverse distributors also keep an inventory of their non-hazardous waste pharmaceuticals as well. An inventory is a key requirement to protect public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the pharmaceutical reverse distributor to know which pharmaceuticals they have on-site at any time. The Agency believes that in many cases, pharmaceutical reverse distributors already maintain inventories and this proposed requirement is not expected to be burdensome for the pharmaceutical reverse distributors to implement. In fact, according to responses from pharmaceutical reverse distributors to a request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state.<sup>145</sup> However, EPA requests comment on whether this practice is already commonly followed.

iii. *Security of the pharmaceutical reverse distributor.* EPA is proposing that pharmaceutical reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Specifically, due to increased thefts of narcotics from pharmacies reported in recent years in major media outlets,<sup>146</sup> EPA is concerned that pharmaceutical reverse distributors could also face such thefts since they accumulate unused pharmaceuticals or those that have exceeded their expiration date. Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agrees with the commenters that the requirements that appear in the interim status TSDF security regulations would be appropriate to adopt and apply to pharmaceutical reverse distributors to prevent the illicit use of these pharmaceuticals and safeguard human health and thus, has included this requirement for pharmaceutical reverse distributors. The security of the facility requirement of § 265.14(a) requires a facility to “prevent the unknowing

entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.” EPA is proposing a similar requirement for pharmaceutical reverse distributors: they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (e.g., a receiving area and accumulation area).

Based on site visits, EPA recognizes that many pharmaceutical reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the pharmaceutical reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some pharmaceutical reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but pharmaceutical reverse distributors are not limited to the examples provided. Further, if a pharmaceutical reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA’s regulations, then the pharmaceutical reverse distributor would not need to install additional security.

iv. *Maximum 90 days for on-site accumulation and petition for an extension of accumulation time.*

EPA is proposing that, like LQGs, pharmaceutical reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency has decided not to propose specific container management standards.

The 90-day time limit begins when the potentially creditable hazardous waste pharmaceuticals initially arrive at the pharmaceutical reverse distributor. The 90-day time limit follows the potentially creditable pharmaceutical, even after it becomes an evaluated hazardous waste pharmaceutical. That is, there is a single 90-day accumulation limit for the hazardous waste pharmaceutical at each pharmaceutical reverse distributor. However, some potentially creditable hazardous waste pharmaceuticals travel through more than one pharmaceutical reverse

distributor to receive manufacturer’s credit. In such cases, each pharmaceutical reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 90-day accumulation limit. EPA requests comment on the 90-day timeframe and whether this timeframe is sufficient, or whether an alternative timeframe should be allowed.

As discussed previously, EPA is proposing that a pharmaceutical reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals upon arrival. Many pharmaceutical reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives. Current inventory systems may be adapted to provide verification of the time limits. For example, if a pharmaceutical reverse distributor includes the date of arrival in the inventory, then the pharmaceutical reverse distributor will be able to use the inventory to verify that potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are not accumulated on-site for more than 90 calendar days. EPA is not proposing a specific method that pharmaceutical reverse distributors must use to document that accumulation does not exceed 90 calendar days. We anticipate that most pharmaceutical reverse distributors would use the inventory system to verify the 90-calendar day timeframe rather than using an additional requirement of labeling containers with dates for verification, but we request comment on this issue. We also request comment on whether EPA needs to specify a method of documenting that 90 calendar days is not exceeded.

Pharmaceutical reverse distributors have informed EPA that there are times when pharmaceutical returns may need to be consolidated for longer periods because they are subject to litigation and the pharmaceutical reverse distributor is not allowed to move them. Pharmaceutical reverse distributors may also need to handle large recalls of hazardous waste pharmaceuticals and might not be able to process all of the returned items within 90 calendar days. Therefore, EPA is proposing to allow a pharmaceutical reverse distributor to request from EPA an extension of the 90-day accumulation time limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the pharmaceutical reverse distributor. A pharmaceutical reverse distributor

<sup>145</sup> See all the responses EPA received from pharmaceutical reverse distributors in the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

<sup>146</sup> “Pharmacies Besieged by Addicted Thieves” by Abby Goodnough Published: February 6, 2011 <http://www.nytimes.com/2011/02/07/us/07pharmacies.html>.

seeking an extension must submit a written request to the EPA Regional Administrator (in writing or electronically), explaining the reason for the extension, the approximate volume or weight of the hazardous waste pharmaceuticals that will be stored for more than 90-days and the amount of additional time requested. Under the existing RCRA subtitle C regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA is proposing to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis. EPA requests comment on whether it is necessary to place a limit on the length of time for which an extension may be granted.

v. *Contingency plan and emergency procedures.* The Agency is proposing to require that pharmaceutical reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265, subpart D. EPA believes that a pharmaceutical reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many pharmaceutical reverse distributors are already LQGs, they should already have contingency plans to address the hazards on-site. It may be possible that the pharmaceutical reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but we believe that such modifications should not impose much burden.

vi. *Closure.* Due to the generally low risk of release of the hazardous waste pharmaceuticals that pharmaceutical reverse distributors will accumulate on-site, as well as the value of the hazardous waste pharmaceuticals, EPA is proposing to require a performance-based closure standard that is based on the federal LQG closure standard found at § 265.111. Specifically, when a pharmaceutical reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of hazardous waste pharmaceuticals (both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals) from the facility before closure.

vii. *Reporting.* In some instances, a pharmaceutical reverse distributor may receive a shipment from a healthcare facility that includes items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (e.g., IV tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Pharmaceutical reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility directly to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a pharmaceutical reverse distributor; rather they should be manifested to a designated facility, such as a permitted or interim status TSDF. Nevertheless, a healthcare facility might incorrectly ship non-creditable hazardous wastes to a pharmaceutical reverse distributor.

EPA is proposing that if a pharmaceutical reverse distributor receives a shipment from a healthcare facility that includes hazardous waste that it is not authorized to receive, such as non-creditable hazardous waste or hazardous waste that is not a pharmaceutical, the pharmaceutical reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days of receiving the hazardous waste. We have adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.76, respectively) to make it appropriate for pharmaceutical reverse distributors that receive unauthorized hazardous waste. However, we are also proposing two additional requirements for pharmaceutical reverse distributors that receive inappropriate hazardous waste. First, the pharmaceutical reverse distributor must send a copy of the unauthorized hazardous waste report to the healthcare facility that sent the unauthorized hazardous waste. This requirement is intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste. Second, the pharmaceutical reverse distributor must manage the unauthorized hazardous waste that it receives in accordance with all applicable regulations. The Agency expects that the pharmaceutical reverse

distributor will likely pass these additional costs (e.g., medical waste incineration) on to the healthcare facility for the management of the hazardous waste and this will act as an incentive for the healthcare facility to take measures to prevent further shipments of unauthorized hazardous waste. We request comment on whether EPA's understanding regarding this type of situation is representative.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that pharmaceutical reverse distributors avoid sorting through shipments that contain non-creditable waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste. As a result, it is possible that a pharmaceutical reverse distributor receiving a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the pharmaceutical reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. Further, we recommend that pharmaceutical reverse distributors work with their clients to reduce the occurrence of inappropriate shipments.

viii. *Recordkeeping.* EPA is proposing three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, a pharmaceutical reverse distributor must keep a copy of its notification (EPA form 8700-12) to EPA to indicate that it is a pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P. A pharmaceutical reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, a pharmaceutical reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of the advance notification from the healthcare facility or other pharmaceutical reverse distributor, a copy of delivery confirmation, shipping papers and any unauthorized waste reports. We propose that these shipping records must be kept for three years from the date the pharmaceutical reverse distributor receives the shipment. We request comment on whether additional recordkeeping is necessary to document cases when shipments of potentially creditable hazardous waste pharmaceuticals do not reach their intended destination within 7 calendar

days. Third, a pharmaceutical reverse distributor must keep a copy of its current inventory at all times as long as the pharmaceutical reverse distributor remains in operation. The inventory is a living document that will constantly be updated and must be available for inspection. Finally, we propose that periods of record retention indicated previously for a pharmaceutical reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Note that additional recordkeeping requirements may also pertain to pharmaceutical reverse distributors. For example, a pharmaceutical reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to pharmaceutical reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor and others that apply to pharmaceutical reverse distributors for the management of evaluated hazardous waste pharmaceuticals.

ix. *Evaluating potentially creditable hazardous waste pharmaceuticals within 21 days.* Based on stakeholder input and site visits, EPA has learned that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system. The pharmaceutical reverse distributor then determines which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be credited and then sent off-site for treatment and disposal. EPA is proposing that this evaluation process must be completed within 21 days of arriving at the pharmaceutical reverse distributor. Likewise, if the pharmaceutical reverse distributor is a manufacturer, EPA is proposing that the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA has chosen to propose 21 calendar days to ensure that the pharmaceutical reverse distributor has a long enough of time to make the

evaluation, yet a short enough time to ensure that potentially creditable hazardous waste pharmaceuticals do not linger awaiting evaluation. The Agency requests comment on this timeframe and whether it should be shortened or lengthened. We also want to emphasize that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on-site.

Once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another pharmaceutical reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this proposal at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals (discussed in Section V.G.3.b.). If, however, they are destined for an interim status or permitted TSDF, they are considered “evaluated hazardous waste pharmaceuticals.” There are additional regulations in this proposal at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals (discussed in Section V.G.3.c.).

b. *Additional Standards for Pharmaceutical Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Pharmaceutical Reverse Distributor*

This section discusses the additional standards that apply to a pharmaceutical reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer’s credit at another pharmaceutical reverse distributor. These hazardous waste pharmaceuticals continue to be considered potentially creditable hazardous waste pharmaceuticals. Until manufacturer’s credit is finalized, the potentially creditable hazardous waste pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer’s credit. Therefore, EPA is proposing few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another pharmaceutical reverse distributor.

i. *Where potentially creditable hazardous waste pharmaceuticals can be sent.* The proposed regulations for

pharmaceutical reverse distributors are structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with pharmaceutical reverse distributors and reviewing information submitted via EPA’s request for information, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the pharmaceutical hazardous waste is ultimately transported to a TSDF. The three possible types of transfers are:<sup>147</sup>

(1) a healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, which may or may not be a manufacturer;

(2) the first pharmaceutical reverse distributor may send the potentially creditable hazardous waste to another pharmaceutical reverse distributor, which may or may not be a manufacturer

(3) the second pharmaceutical reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a pharmaceutical reverse distributor that is a manufacturer.

EPA anticipates that healthcare facilities that are CESQGs will send their potentially creditable hazardous waste pharmaceuticals directly to pharmaceutical reverse distributors, and that the accumulation mechanism that we are proposing will be used to send only non-creditable hazardous waste pharmaceuticals to off-site healthcare facilities (see Section V.C.15.). However, EPA requests comment on whether CESQG healthcare facilities would benefit from being able to consolidate potentially creditable hazardous waste pharmaceuticals off-site, as well. Depending on comments, EPA will consider allowing a fourth transfer (for this limited situation) when potentially creditable hazardous waste pharmaceuticals are sent from a CESQG healthcare facility to an off-site healthcare facility for accumulation, as would also be allowed by proposed § 266.504(a).

<sup>147</sup> A healthcare facility or pharmaceutical reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA permitted or interim status TSDF.

This chain of transfers ensures that the potentially creditable hazardous waste pharmaceuticals will be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal (assuming no accumulation time extensions are granted). EPA requests comment as to whether the three-transfer and 90-day limits are appropriate and whether more or fewer transfers are necessary for verification of manufacturer's credit.

Put another way, if a pharmaceutical reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the pharmaceutical reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under proposed § 266.510(c). However, a pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another pharmaceutical reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c).

Regardless of the destination, each pharmaceutical reverse distributor must make an evaluation of the hazardous waste pharmaceuticals within 21 calendar days and may only accumulate the hazardous waste pharmaceuticals on-site for a maximum of 90 calendar days, unless an extension is granted by the Regional Administrator before it ships them off-site to another pharmaceutical reverse distributor or a RCRA-permitted or interim status TSDF. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to proposed § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to proposed § 266.509.

ii. *Recordkeeping for pharmaceutical reverse distributors shipping of potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor.* Pharmaceutical reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to

another pharmaceutical reverse distributor (whether it is a manufacturer or not). This includes a copy of the advance notification provided to the other pharmaceutical reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. We propose that these shipping records must be kept for 3 years from the date it initiates the shipment.

c. *Additional Standards for Pharmaceutical Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals*

This section discusses the additional standards that apply to a pharmaceutical reverse distributor for the management of evaluated hazardous waste pharmaceuticals (*i.e.*, a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification). Evaluated hazardous waste pharmaceuticals have been through the entire crediting process. In order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals.

i. *Accumulation area.* As discussed previously, EPA is proposing that a pharmaceutical reverse distributor must complete its evaluation of a potentially creditable hazardous waste pharmaceuticals within 21 calendar days of arriving at the pharmaceutical reverse distributor. Once the evaluation has been completed and the pharmaceutical reverse distributor knows that it is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another pharmaceutical reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. Under the proposal, a pharmaceutical reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals.

ii. *Weekly inspections.* EPA is proposing that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at

least weekly to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for pharmaceutical reverse distributors, we are proposing that a pharmaceutical reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

iii. *Personnel training.* EPA is proposing to require that pharmaceutical reverse distributors meet the same federal classroom or on-the-job personnel training requirements that LQGs must meet (§ 265.16). However, we specify in this proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA believes that these personnel are the individuals handling and managing the hazardous waste pharmaceuticals and must have appropriate hazardous waste training. The Agency requests comment on whether the training standards are appropriate for the specific reverse distributor personnel.

iv. *Labeling and management of containers in on-site accumulation area.* EPA is proposing container labeling similar to what was proposed under the 2008 pharmaceutical universal waste proposed rule. While containers of hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, "Hazardous Waste Pharmaceuticals." We are proposing this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are still considered potentially creditable. We are not proposing to require an accumulation start date on the label for the containers, because the reverse distributor's inventory will likely be used to verify the accumulation start date. However, a pharmaceutical reverse distributor may choose an alternate method, such as marking the date on each container as it arrives, to ensure that the hazardous waste pharmaceuticals are not accumulated at the pharmaceutical reverse distributor for more than 90 days, provided an extension is not granted. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 90-day accumulation time rather than require dating on the container labels, but we request comment regarding this requirement and whether

it is necessary to specify a method for how a pharmaceutical reverse distributor must verify that the 90-day maximum accumulation time is not exceeded.

In terms of container management standards, the Agency is proposing requirements that are similar to the container management standards for LQGs—that is, the standards in 40 CFR part 265, but the Agency is also proposing to include some additional management requirements specific to hazardous waste pharmaceuticals. Specifically, under 40 CFR 262.34(a)(1)(i), LQGs must comply with the container management standards in 40 CFR part 265, subpart I, which includes a requirement that containers of hazardous waste must be kept closed, except when adding or removing waste. In this document, EPA is proposing to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release for those hazardous waste pharmaceuticals that are in a solid form. However, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (e.g., for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard. EPA requests comment on whether additional forms of hazardous waste pharmaceuticals (other than liquids and gels) need to be specified in the regulations and subject to the closed container requirement.

EPA is also proposing that containers of hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, we are proposing to require that a pharmaceutical reverse distributor that manages ignitable or reactive evaluated hazardous waste pharmaceuticals or that mixes or comingles incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes.

Similar to healthcare facilities that accumulate non-creditable hazardous waste pharmaceuticals, pharmaceutical reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the

dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

There are also several existing LQG accumulation unit management standards in § 262.34(a) that EPA believes are not necessary to include for the management of evaluated hazardous waste pharmaceuticals. For instance, this proposal only sets standards for the accumulation of evaluated hazardous waste pharmaceuticals in containers. EPA does not think it is necessary to include accumulation units such as tanks, containment buildings, or drip pads because pharmaceutical reverse distributors do not currently use these types of accumulation units. However, if EPA is mistaken in this understanding and commenters indicate they would like to be able to use tanks, containment buildings, or drip pads, EPA would consider including in this proposal the LQG standards for accumulation in these units. The Agency solicits comment on this matter.

In addition, the Agency is not proposing to require pharmaceutical reverse distributors to meet the air emission standards found in 40 CFR part 265, subpart CC as required in § 262.34(a)(1)(i) because we anticipate that they will not be applicable. Specifically, § 265.1083(c) exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) exempts containers with a capacity of less than 0.1 m<sup>3</sup> (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265, subpart CC, air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because hazardous waste pharmaceuticals are often in their original packaging, and we are proposing to require that liquid and gel hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging and containers for hazardous waste pharmaceuticals will often have a capacity less than 0.1 m<sup>3</sup> (26 gallons)

further limiting the applicability of the container air emission standards.

Similarly, EPA does not anticipate that the 40 CFR part 265, subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are applicable to the activities of a pharmaceutical reverse distributor and its management of hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265, subpart CC discussed previously, EPA is not proposing to require that 40 CFR part 265, subparts AA and BB apply to pharmaceutical reverse distributors. EPA requests comments on whether its current understanding is correct and whether the 40 CFR part 265, subparts AA, BB, and CC RCRA air emission standards should be applied to pharmaceutical reverse distributors.

v. *Hazardous waste numbers (codes)*. EPA is proposing to require that the containers of evaluated hazardous waste pharmaceuticals be labeled with the appropriate RCRA hazardous waste numbers. The hazardous waste numbers may be placed on the container label at any time during on-site accumulation, but they must be added prior to when the evaluated hazardous waste pharmaceuticals are transported off-site. The hazardous waste numbers must be marked on the container label in order to ensure that it is readily visible and cannot be separated from the hazardous waste. The hazardous waste numbers are necessary so that transporters, transfer facilities, and TSDFs to know how to properly transport, consolidate, treat, store and dispose of the hazardous waste in compliance with the applicable RCRA regulations. We are not requiring that the pharmaceutical reverse distributor be the party that adds the hazardous waste numbers to the containers. The proposed regulations allow a vendor to perform this duty on behalf of the pharmaceutical reverse distributor. In practice, however, if a vendor is responsible for assigning hazardous waste numbers, personnel from the pharmaceutical reverse distributor may need to assist in the process.

vi. *Shipping evaluated hazardous waste pharmaceuticals*. Although it is already stated in § 266.508(a) under the section of the regulations that pertains to shipping standards, for clarity, we propose to repeat in § 266.510 (the pharmaceutical reverse distributor section of the regulations) the requirement that pharmaceutical reverse distributors that ship evaluated hazardous waste pharmaceuticals off-site must do so in accordance with the proposed shipping requirements in

§ 266.508(a). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

vii. *Rejected shipments.* The Agency is proposing to require in § 266.510(c)(7) that pharmaceutical reverse distributors meet the same procedures as LQGs must meet for rejected shipments in § 262.42(c). If a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor and the TSDF returns the shipment to the pharmaceutical reverse distributor, the pharmaceutical reverse distributor must sign the applicable item on the manifest. In addition, the pharmaceutical reverse distributor may consolidate the rejected hazardous waste pharmaceuticals on-site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with this proposal's pharmaceutical reverse distributor standards for evaluated hazardous waste pharmaceuticals. The reporting requirements associated with rejected shipments are discussed separately under the reporting section.

viii. *Land disposal restrictions.* EPA is proposing in § 266.510(c)(8) that pharmaceutical reverse distributors are subject to the same land disposal restrictions (LDRs) that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is proposing to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, "pharmaceutical reverse distributors" to the title of that section to make the applicability of the treatment standards clear.

ix. *Reporting by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.*

(1) *Biennial report.* EPA is proposing that pharmaceutical reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. However, the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a pharmaceutical reverse distributor sends to another pharmaceutical reverse distributor. Specifically, we are proposing in § 266.510(c)(9)(i) that a pharmaceutical

reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which includes the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The reason we are not requiring the pharmaceutical reverse distributor to provide such information is that they do not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from the healthcare facility, and thus have no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals. Thus, EPA is not requiring the pharmaceutical reverse distributor to report this information in its BR.

(2) *Exception reporting.* For the reasons that EPA requires exception reporting generally—that is, to maintain the cradle to grave tracking system, EPA is proposing in § 266.510(c)(9)(ii)(A) that pharmaceutical reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the pharmaceutical reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility. Likewise, we are proposing in § 266.510(c)(9)(ii)(B) that pharmaceutical reverse distributors meet LQG exception reporting when a shipment from a pharmaceutical reverse distributor is rejected by the designated facility and forwarded onto an alternate facility.

x. *Recordkeeping by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* Many of the proposed recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity, it is useful to restate them in this recordkeeping section, so that pharmaceutical reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In particular, we are proposing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors. First, EPA is proposing that a pharmaceutical reverse distributor keeps a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that we are proposing in § 266.510(c)(10) for pharmaceutical reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.40–42 and § 265.16; these include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation.

EPA believes that these recordkeeping requirements are appropriate for pharmaceutical reverse distributors, many of whom are currently LQGs, but requests comment on this requirement.

EPA asks commenters to review the standards EPA is proposing for pharmaceutical reverse distributors and provide specific comment on whether the standards are appropriate and sufficient to protect human health and the environment.

#### d. When a Pharmaceutical Reverse Distributor Must Have a RCRA Hazardous Waste Permit

EPA is proposing to not require that a pharmaceutical reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the pharmaceutical reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a pharmaceutical reverse distributor would be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, a pharmaceutical reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on-site or if it accepts manifested hazardous waste from off-site. A pharmaceutical reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off-site because a pharmaceutical reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste via a manifest. EPA believes that this approach to regulation of pharmaceutical reverse distributors that accumulate hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that pharmaceutical reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

## VI. Implementation and Enforcement

### A. Healthcare Facilities

#### 1. Determining Whether a Healthcare Facility is Subject to Part 266, Subpart P

EPA is proposing that healthcare facilities that are currently considered LQGs or SQGs are subject to the new 40 CFR part 266, subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates (or accumulates)

more than 100 kg hazardous waste per calendar month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266, subpart P requirements. In addition, healthcare facilities that are CESQGs are subject to the prohibition on sewerage hazardous waste pharmaceuticals in § 266.5052.

To determine whether a healthcare facility is a subject to 40 CFR part 266, subpart P, or a CESQG regulated under § 261.5, a healthcare facility must count all the hazardous waste—pharmaceutical and non-pharmaceutical—it generates in a calendar month. In counting the amount of hazardous waste generated per calendar month, we note that EPA is proposing to change which pharmaceuticals will be considered hazardous wastes (*i.e.*, potentially creditable hazardous waste pharmaceuticals). Specifically, EPA is proposing that potentially creditable hazardous waste pharmaceuticals transported to a pharmaceutical reverse distributor will be considered solid waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a CESQG regulated under § 261.5, or whether it is regulated under 40 CFR part 266, subpart P. This differs from current practice where, although a healthcare facility must count the non-creditable hazardous waste pharmaceuticals it generates each calendar month toward its hazardous waste generator category, it does not count the potentially creditable hazardous waste pharmaceuticals it sends to a pharmaceutical reverse distributor. Therefore, although a healthcare facility *currently* may be considered a CESQG, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a CESQG. In that case, the healthcare facility would be subject to the 40 CFR part 266, subpart P requirements.

## 2. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals Under Part 266, Subpart P

EPA is proposing that all healthcare facilities, with the exception of CESQGs, will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste

pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward the facility's monthly hazardous waste generator category. In addition, if a healthcare facility does not want to keep track of the amount of hazardous waste it generates to ensure it does not exceed the CESQG quantity limits, it could choose to operate under this proposed rule. If it chooses to operate under this proposed rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

### B. Pharmaceutical Reverse Distributors

#### 1. Pharmaceuticals Sent to Pharmaceutical Reverse Distributors Are Solid Wastes

One difference between this proposal and the 2008 Pharmaceutical Universal Waste proposal is how RCRA would apply to pharmaceuticals returned to pharmaceutical reverse distributors to obtain manufacturer's credit. EPA is proposing to change its existing position on this issue. If this rule is finalized, this change would mean that the decision by a healthcare facility to send a pharmaceutical to a pharmaceutical reverse distributor is the decision to discard the pharmaceutical. Therefore, under this proposed rule, once the healthcare facility makes the decision to send a pharmaceutical to a pharmaceutical reverse distributor for credit, it is a solid waste at the healthcare facility. It is likely that a portion of the potentially creditable solid waste pharmaceuticals at healthcare facilities that are destined for a pharmaceutical reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste pharmaceuticals would need to be managed in accordance with the standards proposed in this document. However, until this rule is final and effective, EPA's current position will remain in effect.

In addition, the Agency notes that the proposed change in EPA's position concerning reverse distribution and the management standards discussed in this document pertain only to the reverse distribution of hazardous waste pharmaceuticals and does not apply to reverse distribution or reverse logistics systems that may exist for other consumer products. This limitation is because EPA has studied and collected

data for reverse distribution systems for hazardous waste pharmaceuticals, and not all consumer products.<sup>148</sup>

#### 2. Pharmaceutical Reverse Distributors Managing Hazardous Waste Pharmaceuticals Under Part 266, Subpart P

Under this proposal, all pharmaceutical reverse distributors are subject to 40 CFR part 266, subpart P and will be subject to the same standards with respect to their hazardous waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even pharmaceutical reverse distributors that are currently CESQGs will be regulated under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals. Therefore, as with healthcare facilities, a pharmaceutical reverse distributor subject to 40 CFR part 266, subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.

### C. Healthcare Facilities and Pharmaceutical Reverse Distributors Managing Non-Pharmaceutical Hazardous Waste in Accordance With 40 CFR Part 262 or Part 273

Most, if not all, healthcare facilities and pharmaceutical reverse distributors generate hazardous wastes other than pharmaceuticals. These, non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). However, because a healthcare facility or pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P no longer has to count its hazardous waste pharmaceuticals, including acute hazardous waste pharmaceuticals such as warfarin, it could result in a change in the facility's overall generator category and thus change how its non-pharmaceutical hazardous waste must be managed. For example, the generator category for a healthcare facility or pharmaceutical reverse distributor may be reduced from an LQG to an SQG or even a CESQG, when it stops counting its hazardous waste pharmaceuticals, especially acute hazardous waste pharmaceuticals, toward its generator category.

If finalized, the standards established by this rulemaking apply only to the management of hazardous waste

<sup>148</sup> EPA is examining the reverse logistics of non-pharmaceutical hazardous wastes as part of its analysis of comments received on the Retail Notice of Data Availability that was published on February 14, 2014 (79 FR 8926).

pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. Healthcare facilities and pharmaceutical reverse distributors likely generate or manage other types of wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the RCRA Subtitle C requirements (such as the RCRA satellite accumulation regulations (§ 262.34(c)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262, subpart K). Retail pharmacies in retail stores and grocery stores may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 requirements and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For pharmaceutical reverse distributors, this proposed rule only applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some pharmaceutical reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA requirements will apply to those non-pharmaceutical hazardous wastes.

#### D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding pharmaceutical hazardous wastes. One major goal of this proposed rule is to provide clarity on this topic, and thereby promote national consistency, which, in turn, should promote better compliance among healthcare facilities, including pharmacies.

California has taken numerous enforcement actions against national retail chains with pharmacies for not complying with the RCRA hazardous waste regulations. In recent years, the state took enforcement actions and imposed fines on the following chains: Kmart (2009), Walmart (2010), Target (2011), CVS (2012), Costco (2012), Walgreens (2012) and Rite-Aid (2013). In at least two settlement agreements, California directed the defendants (CVS and Costco) to “initiate work with appropriate stakeholders from business and government, including the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, and the DTSC [Department of Toxic Substances Control], and thereafter either directly or through trade

associations or informal coalitions of interested parties, undertake to promote federal regulatory reform regarding the proper management of nondispensable pharmaceuticals, including over-the-counter medications, through “reverse distribution.”<sup>149</sup> Through these settlement agreements, California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems.

In 2012, Connecticut’s Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from Connecticut DEEP direct CVS stores in the state to follow a set of best management practices.<sup>150</sup> A number of the practices developed in these consent orders mirror some of the practices we are proposing in this rule, particularly with regard to pharmaceuticals destined for a pharmaceutical reverse distributor. Connecticut DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for pharmaceutical reverse distributors by applying specific practices to their management. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a pharmaceutical reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the pharmaceutical reverse distributor receiving them. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a pharmaceutical reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for pharmaceutical reverse distribution.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, Interim Enforcement Policy:

<sup>149</sup> <http://www.calepa.ca.gov/enforcement/orders/2012/CVSStipFinal.pdf> and <http://www.calepa.ca.gov/enforcement/orders/2012/CostcoFinal.pdf> or see the docket for this rulemaking EPA-HQ-RCRA-2007-0932.

<sup>150</sup> <http://www.ct.gov/deep/lib/deep/enforcement/consentorder/COWSWDH13005.pdf>. or see the docket for this rulemaking EPA-HQ-RCRA-2007-0932.

Pharmaceutical Waste in Healthcare.<sup>151</sup> Like Connecticut’s consent orders with CVS, this enforcement discretion policy has some elements in common with this proposed rule for hazardous waste pharmaceuticals. For instance, a healthcare facility must notify the Department of Ecology that it is operating under the policy and must train its staff involved in pharmaceutical waste management. Only a time limit, rather than a quantity limit, applies to the accumulation of the hazardous waste pharmaceuticals on-site. Of particular note is that Washington State prohibits disposing of most hazardous waste pharmaceuticals down the toilet or drain.

In 2011, Minnesota’s Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers.<sup>152</sup> In this guidance, Minnesota states, “Whether a pharmaceutical is eligible for return credit does not affect its *product* or *waste* status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a *waste*. The MPCA considers health care practitioners and pharmacies to be *generators* of these pharmaceutical wastes. Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.” This is similar to the approach that EPA is proposing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA’s proposed rule, MPCA does not require hazardous waste pharmaceuticals destined for a pharmaceutical reverse distributor to be counted toward determining a healthcare facility’s generator category, and MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a pharmaceutical reverse distributor. By adopting a rule that is consistent with state approaches, EPA is bringing national consistency to the management

<sup>151</sup> See the interim enforcement policy in the docket for this rulemaking (EPA-HQ-RCRA-2007-0932) or see it online at <https://fortress.wa.gov/ecy/publications/documents/0704024.pdf>.

<sup>152</sup> See the guidance document in the docket for this rulemaking (EPA-HQ-RCRA-2007-0932) or see it online at <http://www.pca.state.mn.us/index.php/view-document.html?gid=4004>.

of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

### VII. Request for Comment on EPA's Efforts To Identify Additional Pharmaceutical Hazardous Wastes

Some of the comments EPA received in response to the 2008 Universal Waste proposal recommended that EPA add additional pharmaceutical wastes to the P and U hazardous waste lists (see § 261.33). Some commenters suggested that EPA assess the hazards from all discarded pharmaceuticals (especially chemotherapy drugs) that have come into the market since the promulgation of the original P and U hazardous waste lists<sup>153</sup> and that EPA update these lists to include discarded pharmaceuticals that are hazardous. In response to these comments, the Agency began gathering and reviewing information related to pharmaceuticals that may exhibit hazardous properties. EPA identified 204 drugs, which include 172 drugs that the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) identified as hazardous, and 32 drugs that NIOSH proposed for addition to its hazardous drug list.<sup>154</sup> EPA also collected toxicity data and other information for these 204 drugs. These findings, along with additional information regarding the management of pharmaceutical wastes, are presented in the final report entitled *Data Collection on the Toxicity, Use, and Disposal of Hazardous Drugs Report* (September 2011) placed in the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

Commenters specifically referred to EPA's P and U hazardous waste lists under the RCRA subtitle C regulations. Generally, in its hazardous waste determinations, EPA has evaluated both "production wastes" (from specific or non-specific sources; see §§ 261.31 and 261.32) and "commercial chemical products" that, when discarded, become wastes (§ 261.33). This latter category (commercial chemical products that are discarded) is the most relevant of the listed hazardous wastes to the

pharmaceutical wastes discussed elsewhere in this preamble, and to which commenters referred in the 2008 Universal Waste proposal. As discussed in Section IV.A. of this preamble, commercial chemical products listed in § 261.33 are (when discarded) defined as either P-listed "acute" hazardous wastes, or U-listed (non-acute) hazardous wastes. The criteria for listing a solid waste as hazardous under RCRA Subtitle C are described in § 261.11. A waste may be identified as a P-listed waste if it is shown to be fatal to humans or animals at low doses (see § 261.11(a)(2)). Thus, lethality data for any chemical is the principal factor for making a determination that a discarded commercial chemical product is a P-listed hazardous waste.<sup>155</sup>

In contrast, a waste may be identified as a U-listed waste if it contains any of the toxic constituents listed in Appendix VIII of 40 CFR part 261, and if, after examining each of 10 factors in § 261.11(a)(3), it is determined that the waste is capable of posing a "substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."<sup>156</sup> Examples of these 10 factors include the toxicity and concentration of the hazardous constituent in the waste, the plausible types of improper management to which the waste could be subjected, the quantities of the waste generated at individual generation sites or on a regional or national basis, the nature and severity of the human health and environmental damage that has occurred as a result of the improper management of wastes, and action taken by other governmental agencies or regulatory programs based on the health or environmental hazard posed by the waste or waste constituent. EPA may

<sup>155</sup> § 261.11(a)(2) states "The Administrator shall list a solid waste as a hazardous waste only upon determining that the solid waste . . . has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD 50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness. (Waste listed in accordance with these criteria will be designated Acute Hazardous Waste.)"

<sup>156</sup> The Agency cannot list hazardous wastes under section § 261.11(a)(3) based on inherent toxicity alone without considering exposure factors, particularly the likelihood of mismanagement. That is, EPA needs to examine each of the 10 factors and, to the extent it does not use one or more of them, must explain why they are irrelevant or unimportant. See *Dithiocarbamate Task Force v. EPA* (No. 95-1249).

only revise either of these lists of commercial chemical products through notice-and-comment rulemaking.

In its September 2011 report, EPA found that 11 drugs on the NIOSH or OSHA lists of hazardous drugs meet the specific criteria for acute toxicity in § 261.11(a)(2) (identified as "Tier 1" drugs in the report). An additional 114 drugs on the NIOSH or OSHA lists did *not* meet the specific criteria in § 261.11(a)(2) for acute toxicity, but did have lethal doses for other animals or humans ("Tier 2" drugs). The remaining 79 drugs had limited human or animal toxicity data, and no lethality data, and were designated "Tier 3" in the report. Thus, the vast majority of the NIOSH/OSHA hazardous drugs evaluated in the EPA 2011 report do not meet the criteria for listing as acute hazardous waste under RCRA subtitle C.<sup>157</sup> As discussed previously, to include a drug on the U-list, the Agency must demonstrate that a discarded drug would be "capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed." Therefore, for the NIOSH/OSHA drugs that do not meet the listing criteria for inclusion on the P-list, the Agency would have to examine the 10 factors in § 261.11(a)(3) to determine whether a drug meets the criteria to be included on the U-list. In addition to toxicity data (which is lacking in particular for the drugs identified as Tier 3), the types of information that would be relevant include waste volumes, plausible management scenarios, exposure potential, damage cases, and actions taken by other governmental agencies or regulatory programs. To obtain this information for this class of materials poses a challenge. While EPA has some information—the September 2011 report includes summaries of drug management practices and references to others—there remain significant gaps.

In addition, as discussed in Section IV.D. of this preamble, the EPA's OIG has recommended that EPA identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste, and establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste. While EPA has an existing process generally for defining whether or not a solid waste is a listed hazardous

<sup>157</sup> EPA emphasizes that this finding reflects the manner in which EPA defines acute hazardous waste under the RCRA subtitle C program; the NIOSH/OSHA lists are based upon different criteria related to preventing occupational exposure to these drugs.

<sup>153</sup> May 19, 1980 *Federal Register* (45 FR 33084) and November 25, 1980 *Federal Register* (45 FR 78525).

<sup>154</sup> See NIOSH's Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings (<http://www.cdc.gov/niosh/docs/2004-165/>) and OSHA Technical Manual Section VI: Chapter 2—Controlling Occupational Exposure to Hazardous Drugs ([https://www.osha.gov/dts/osta/otm/otm\\_vi\\_otm\\_vi\\_2.html](https://www.osha.gov/dts/osta/otm/otm_vi_otm_vi_2.html)). Note that the "hazardous" classification used by NIOSH and OSHA is not the same as the definition of hazardous under the RCRA subtitle C regulations.

waste (*i.e.*, EPA has regulatory criteria for defining listed hazardous waste described previously; EPA has established policies for evaluating risk and other factors in making listing determinations;<sup>158</sup> and EPA must use the notice-and-comment rulemaking process when proposing listing determinations), the OIG observed that EPA's hazardous waste program has not kept pace with the large number of pharmaceuticals that have been developed since 1980. EPA plans to regularly review the NIOSH/OSHA lists of hazardous drugs, as they represent a source of valuable information on pharmaceuticals that have already been identified as having the possibility of posing risks that might warrant regulation as hazardous waste.

EPA is also exploring ways to identify new sources of information, along with alternative approaches that can most efficiently address these concerns. EPA is using the opportunity in this preamble to seek stakeholders' input on the best course of action concerning regulation of additional pharmaceuticals as hazardous wastes. It is also an opportunity for stakeholders to provide additional information that they may have about potentially hazardous pharmaceuticals. Thus, before deciding on a possible proposal to list additional pharmaceuticals as hazardous wastes, we request comment on the September 2011 final report, and solicit information regarding additional potentially hazardous pharmaceuticals. We request information on the sources and identity of additional potentially hazardous pharmaceuticals along with annual product generation data, annual waste generation data, use information, toxicity data, waste storage and handling information, and disposal information.

In addition, we request stakeholder input for alternative approaches to making hazardous waste listing determinations for pharmaceuticals that do not meet the acute hazardous criteria. Based on the existing listing determination process described previously for non-acute wastes, there is no single toxicity effect (*e.g.*, LD<sub>50</sub>) to readily determine whether or not the waste is hazardous under RCRA subtitle C. As such, we are seeking ideas on alternative approaches to more efficiently evaluate potentially hazardous non-acute discarded pharmaceuticals. For example, should EPA develop and promulgate new

criteria specific to discarded pharmaceuticals that would allow it to establish a single hazardous waste listing for all discarded pharmaceuticals that meet the new criteria? Such approaches could also include consideration of whether discarded pharmaceuticals are already managed under a regulatory scheme that prevents mismanagement that a hazardous waste designation would otherwise address (similar to the hazardous waste listing factor that takes into account "actions taken by other governmental agencies or regulatory programs"). We also are seeking information on any innovative processes or programs that states may have for identifying, reviewing, and making a hazardous waste determination for discarded pharmaceuticals.

The Agency emphasizes that no regulatory action is being proposed with respect to expanding the number of pharmaceuticals that are considered hazardous waste. We will use the comments we receive to help inform how to proceed with evaluating discarded pharmaceuticals as listed or characteristic hazardous wastes. Any action taken would be part of a separate, proposed rulemaking in the future.

#### **VIII. Request for Comment on EPA's Efforts To Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)**

##### *A. Background*

In 1980, as part of its final and interim final regulations implementing Section 3001 of RCRA, EPA promulgated the list of commercial chemical products or manufacturing chemical intermediates (40 CFR 261.33) that are hazardous wastes if they are discarded or intended to be discarded, which included nicotine and salts (45 FR 33124; May 19, 1980). The phrase "commercial chemical product or manufacturing chemical intermediate" refers to a "chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient" (see the *Comment* following 40 CFR 261.33(d)). A chemical substance is listed in 40 CFR 261.33(e) as an acutely hazardous waste if it meets any of the criteria in 40 CFR 261.11(a)(2), which states that the waste "has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD 50 toxicity

(rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness."

##### *B. Basis for Original Listing*

EPA listed nicotine and salts (referred to commonly as just nicotine) as acutely hazardous waste (P075) in § 261.33(e) based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg.<sup>159</sup> As discussed previously, for humans, the standard in the regulations for acute toxicity is "fatal to humans in low doses" (see § 261.11(a)(2)). EPA's Background Document for Section 261.33 from 1981 provides a basis for what is meant by "fatal to humans in low doses" for chemicals that have been given through the oral route ("fatal to humans upon ingestion of ≤100 mg/kg"). The estimated oral LD50 to humans of 1 mg/kg falls within the criteria for "fatal to humans in low doses." However, the background listing document and its references do not provide sufficient detail to determine the concentration of nicotine that was used to establish the estimated oral LD50 in humans.

##### *C. Rationale for EPA's Efforts To Amend the P075 Listing*

On February 14, 2014, EPA published a Notice of Data Availability (NODA) and Request for Comment (79 FR 8926) entitled "Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the RCRA Program." EPA received 44 comments in response to this NODA, many of which included comments related to pharmaceuticals, in particular comments concerning expired or returned low-concentration nicotine-containing smoking cessation products and e-cigarettes. The most detailed comments concerning the unsold low-concentration nicotine products were jointly submitted by the Retail Industry Leaders Association (RILA), the Food Marketing Institute (FMI), the National Association of Chain Drug Stores (NACDS), the National Retail Federation, and their members (referred to as the retail associations, retailers, or

<sup>158</sup> EPA's policy statement on hazardous waste listing determinations is contained in the **Federal Register** preamble to the first proposed Dyes and Pigments Listing Determination (59 FR 66072, December 22, 1994).

<sup>159</sup> See EPA's listing Background Document for Section 261.33, April 1981, in the docket for this proposed rule (EPA-HQ-RCRA-2007-0932).

commenters).<sup>160</sup> In their comments, the retail associations, representing a broad range of retailers within the retail industry, asked EPA to undertake a rulemaking to remove low-concentration nicotine products from the acute hazardous waste P075 classification under RCRA. The retailers believe these products do not meet RCRA's requirements for acute hazardous waste. Thus, according to the retailers, the acute hazardous classification is inappropriately making them subject to RCRA's LQG requirements, which become applicable when someone generates more than 1 kg/month of acute hazardous waste. The retailers also expressed concern that they are subject to increased economic burdens and reporting requirements because they are subject to RCRA's LQG requirements.

The commenters, to support their request to EPA, state that EPA's listing for nicotine and salts warrants a reevaluation, because in more recent literature concerning nicotine toxicity, doubts have been expressed about the estimated oral LD50 toxicity to humans of 1 mg/kg, used as a key basis for the listing. According to information provided by commenters, the estimated oral LD50 toxicity to humans of 1 mg/kg was based on extrapolations from toxicological effects observed as result of "self-experiments" performed with nonfatal doses of nicotine. However, according to the commenters, there are doubts about the 1 mg/kg estimate because people have survived after ingesting much larger amounts of nicotine.

The commenters also state that in 1980, when EPA listed nicotine and salts as acute hazardous wastes, the nicotine products in the market contained a high concentration of the chemical (e.g., pesticides which contained 40 percent nicotine sulfate), but that these products are no longer on the market. The commenters stressed that the current nicotine products on the market are low-concentration nicotine products that do not meet the regulatory criteria for acutely hazardous wastes. The low-concentration nicotine-containing products that are currently on the market were identified by commenters as nicotine replacement therapy products (e.g., gums, lozenges, patches, inhalers, and nasal sprays) and e-cigarettes. These products, according to the commenters, generally contain less than 3 percent nicotine.

<sup>160</sup> See comments by the retail associations in response to EPA's Retail NODA in the docket for the Retail NODA (EPA-HQ-RCRA-2012-0426-0019).

While it may be reasonable for the commenters to conclude that toxicity is higher at higher concentrations of a chemical and lower at lower concentrations of a chemical, EPA currently lacks sufficient information to conclude that low-concentration nicotine-containing products are not acutely toxic as defined under 40 CFR 261.11(a)(2). In addition, except for warfarin and zinc phosphide, the listings for commercial chemical products under 40 CFR 261.33(e) are not concentration-based listings. The warfarin and zinc phosphide listings were changed to concentration-based listings because companies using products containing lower concentration formulations of warfarin and zinc phosphide petitioned EPA to amend the listings and provided LD50 data for animals for the lower concentration products to support their petition (see 49 FR 19922; May 10, 1984). The Agency does not think that linear extrapolations from toxicity levels determined using higher-concentration nicotine products can be used to characterize the acute toxicity of low-concentration nicotine-containing products. Furthermore, although nicotine pesticides are no longer available, high concentration nicotine products still exist. For example, manufacturers of nicotine-containing products, such as e-cigarettes, buy concentrated nicotine solutions and dilute them for consumer use.

In summary, nicotine and salts are P075 listed acute hazardous wastes if the waste arises from the discard of an unused commercial chemical product, manufacturing chemical intermediate, or off-specification material. Additionally, the P075 waste code applies only if the nicotine is present in pure or technical grade form, or is the sole active ingredient in the chemical formulation when discarded. As such, unused (unsold, expired, or returned) nicotine-containing products, including patches, gums, lozenges,<sup>161</sup> inhalers, nasal sprays and e-cigarettes,<sup>162</sup> are classified as P075 listed acute hazardous wastes when discarded. When discarded, these unsold products are causing many retailers to notify and operate as LQGs, which has resulted in increased economic burdens and reporting requirements for retailers. EPA

<sup>161</sup> See memo from Dellinger to Smith, dated August 23, 2010, RCRA Online # 14817 regarding unused patches, gums and lozenges [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD44ECDC852577ED00624E8F/\\$file/14817.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD44ECDC852577ED00624E8F/$file/14817.pdf).

<sup>162</sup> See memo from Johnson to DeWitt, May 8, 2015, regarding e-cigarettes, RCRA Online # 17850.

is aware that this is an issue of great concern to the retail associations and their members and would like to address the issue, if possible, by amending the P075 listing to conditionally exempt certain low-concentration nicotine-containing products. The Agency is considering two possible approaches, described below, for amending the P075 listing.

#### *D. Two Possible Approaches for Amending the P075 Listing*

##### **1. Exemption from P075 Listing for FDA-Approved Over-the-Counter Nicotine-Containing Smoking Cessation Products**

The over-the-counter (OTC) nicotine-containing smoking cessation products, referred to also as nicotine replacement therapy (NRT) products (*i.e.*, nicotine patches, gums, and lozenges) are approved by the Food and Drug Administration (FDA), which ensures that the risk to the public using these products have been evaluated. EPA is currently trying to obtain the risk evaluation data for these products from FDA, which may provide data on the exact concentration of nicotine in the NRT products and any animal and/or human toxicity data associated with use of these products. The Agency is also trying to gather any publicly available animal and/or human toxicity data for these products, in particular toxicity data that could be compared to EPA's acute toxicity criteria under § 261.11(a)(2). If the Agency is successful in obtaining the toxicity data to support the conclusion that FDA-approved over-the-counter nicotine-containing smoking cessation products do not meet the criteria for listing as an acutely hazardous waste, then the Agency will propose to exempt these products from the P075 listing.

Since e-cigarettes have not been approved by the FDA as smoking cessation products, we do not anticipate being able to obtain animal or human toxicity data from the FDA on nicotine concentrations in e-cigarettes. To complicate matters, the concentration of nicotine in e-cigarettes is not limited by any regulation or approval process and is therefore unpredictable. As a result, this option would likely be limited to excluding FDA-approved over-the-counter nicotine-containing smoking cessation products from the P075 listing and would not include e-cigarettes.

##### **2. Concentration-Based Exemption From P075 Listing for Low-Concentration Nicotine-Containing Products**

The comments from the retail associations have stressed that the low

concentration nicotine products currently in the market (generally containing less than 3 percent nicotine) should not be classified as acutely hazardous wastes under RCRA. However, they did not submit any human toxicological data or animal LD50 data for these products to demonstrate that these products are not acutely toxic as defined under § 261.11(a)(2). Without these data, it is difficult for the Agency to justify exempting these products from the P075 listing. Furthermore, in order for the Agency to consider a concentration-based exemption for low-concentration nicotine-containing products from the P075 listing, the Agency needs human toxicological data and animal LD50 data for nicotine-containing products at maximum concentrations of nicotine in these products (e.g., 3 percent nicotine). If the toxicological data for nicotine-containing products at maximum concentrations of nicotine in these products show that these products are not acutely toxic as defined under § 261.11(a)(2), then the Agency could propose a concentration-based exemption for these products (including e-cigarettes) from the P075 listing. However, depending on the toxicity data, the Agency may also propose to list the P075 exempt nicotine-containing products as non-acute hazardous wastes (U-listed wastes) under 40 CFR 261.33(f). In that case, the concentration-based exemption for nicotine-containing products from the P075 listing would be similar to what the Agency proposed for warfarin and zinc phosphide listings (see 48 FR 7714; February 23, 1983).

#### *E. Request for Comments*

EPA invites comments on all possible approaches to amend the acute hazardous waste listing for nicotine and salts, including the two approaches discussed above in Section VIII.D. We also request toxicity information for low-concentration nicotine-containing products that could help determine whether or not these products meet the criteria for acute hazardous wastes under § 261.11(a)(2). The Agency emphasizes that no regulatory language is currently being proposed with respect to amending the P075 listing to exempt the low-concentration nicotine-containing products. However, depending on the information received during the comment period, EPA could finalize one of the approaches discussed previously without a separate proposed rulemaking in the future.

In addition, we request comments on whether we should exempt other low-concentration nicotine-containing

smoking cessation products, such as inhalers and nasal sprays, from the P075 listing under approach 1, described in the Section VIII.D, above. These products are also FDA-approved, but require a prescription to purchase. The nicotine-containing patches, gums, and lozenges are sold over-the-counter, so they do not require a prescription for purchase. We are interested in finding out what the differences are between nicotine-containing smoking cessation products requiring a prescription and those products that do not require a prescription (e.g., in concentrations of nicotine, amount of nicotine delivered over time, health effects).

Finally, we request comment on whether we should include e-cigarettes and nicotine-containing e-liquids for the e-cigarettes within the scope of the definition of pharmaceutical. As described in this proposal, pharmaceutical hazardous wastes do not count toward generator category. Therefore, since e-cigarettes and nicotine-containing e-cigarette refill liquids (sometimes referred to as e-liquids or e-juice) are P075, if they are considered pharmaceuticals, they would not impact the hazardous waste generator category of the retailers. The retailers, however, would have to manage e-cigarettes and nicotine-containing liquids as hazardous waste pharmaceuticals under part 266, subpart P. We will use the comments we receive to help us decide whether and how to proceed with amending the scope of the definition of pharmaceutical to include e-cigarettes and nicotine-containing e-liquids.

### **IX. State Authorization**

#### *A. Applicability of Rules in Authorized States*

Under Section 3006 of RCRA, EPA may authorize a qualified State to administer its own hazardous waste program within the State in lieu of the Federal program. Following authorization, EPA retains enforcement authority under Sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that

State, since only the State was authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified time frames. However, the new federal requirements did not take effect in an authorized State until the State adopted the federal requirement as State law.

In contrast, under RCRA Section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. The statute directs EPA to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While the State must still adopt HSWA related provisions as State law in order to retain final authorization, EPA implements the HSWA provisions in authorized States until the States do so.

Authorized States are required to modify their program only when EPA enacts federal requirements that are more stringent or broader in scope than the existing federal requirements. RCRA Section 3009 allows the States to impose standards more stringent than those in the federal program (see also § 271.1).<sup>163</sup> Therefore, authorized States may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

#### *B. Effect on State Authorization*

This action proposes to add a new subpart P to 40 CFR part 266, and it is being proposed in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266, subpart P is being proposed under non-HSWA authority. Thus, when finalized, the amendments promulgated under non-HSWA authority would be applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. However, the prohibition of sewerage pharmaceutical hazardous wastes (§ 266.504) is being proposed under HSWA authority in section 3018 of RCRA. Thus, when finalized, the amendments promulgated under the authority of HSWA would be applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify

<sup>163</sup> EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes state programs.

their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. This proposed rule is considered, on the whole, to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt the amendments, when finalized. When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart.

*C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program*

The Universal Waste program allows states to add wastestreams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because this proposed rule is considered more stringent than either the “traditional RCRA” standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the

amendments, if this rule is finalized. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future.

**X. Adding and Reserving Part 266, Subpart O**

In addition to proposing new standards for the management of hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors, EPA is proposing to add and reserve 40 CFR part 266, subpart O. Specifically, on May 22, 2001, EPA finalized a Project XL rule in 40 CFR part 266, subpart O (66 FR 28066) for US Filter Recovery Services. However, on July 2, 2008, EPA published a rule that withdrew 40 CFR part 266, subpart O (73 FR 37858). Generally, in order to avoid the potential for confusion that might be caused by reusing a subpart, EPA reserves a subpart that has already been used and removed. In 2008, when we removed 40 CFR part 266, subpart O, we neglected to reserve it. Consequently, we are proposing to add and reserve 40 CFR part 266, subpart O.

**XI. Summary of Regulatory Impact Analysis**

In order to meet the Office of Management and Budget (OMB) Circular A-4 requirement that EPA analyze the costs and benefits of regulations, we conducted an economic analysis of the proposed rule. The economic analysis follows OMB guidelines and estimates the costs and benefits of the rule. The economic analysis is titled “Regulatory Impact Analysis for EPA’s Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals” and is hereafter referred to as the Regulatory Impact Analysis (RIA). The RIA is summarized here while the full RIA can be found at regulations.gov under docket number EPA-HQ-RCRA-2007-0932.

This proposed rule may affect several different types of healthcare facilities, including hospitals, physicians’ offices, dentists’ offices, outpatient care centers, pharmacies, veterinary clinics, nursing care facilities, coroners’ offices, other health practitioners, other ambulatory care services, and pharmaceutical reverse distributors. Based on data from the 2007 Economic Census and a limited number of states, the RIA estimates that the rule will affect approximately 174,000 facilities. Table 12 lists the number of facilities (by NAICS code) expected to be affected by the proposed rule. The vast majority of these (83.6%) are CESQGs, followed by SQGs (13.4%), and LQGs (3.0%).

TABLE 12: PROPOSED PHARMACEUTICALS RULE FACILITIES CLASSIFIED BY NAICS CODES AND TYPE OF FACILITY		
NAICS	FACILITY TYPE	NUMBER OF FACILITIES
<b>HEALTHCARE FACILITIES AS DEFINED BY THIS PROPOSED RULE</b>		
44611	Pharmacies	11,617
54194	Veterinary Clinics	7,847
6211	Physicians' Offices	60,823
6212	Dentists' Offices	35,106
6213	Other Health Practitioners (e.g., chiropractors)	34,555
6214	Outpatient Care Centers	8,227
6219	Other Ambulatory Health Care Services	2,586
622	Hospitals	6,505
6231	Nursing Care Facilities	4,508
623311	Continuing Care Retirement Communities	1,641
Subset of 92219	Medical Examiners and Coroners' Offices	552
<b>Reverse Distributors</b>		
Various NAICS	Reverse Distributors	56
<b>TOTAL</b>		<b>174,023</b>

We estimate that there is a total of approximately 139,000 tons of RCRA hazardous waste generated by healthcare facilities annually. Approximately 36,200 tons (26%) of this total are hazardous waste pharmaceuticals.

#### A. Costs of the Proposed Rule

The estimated costs of the proposed rule are the incremental costs over and above the "baseline" (*i.e.*, assumptions about the way in which healthcare facilities currently dispose of their hazardous waste pharmaceuticals). The base case set of baseline assumptions reflects "full compliance" with the current RCRA hazardous waste requirements for the management of hazardous waste pharmaceuticals. A sensitivity analysis of baseline assumptions was also conducted that reflects only "partial compliance" with current regulations. To see the results for the partial compliance baseline sensitivity analysis, please see the RIA.

The estimated cost of the proposed rule, including the proposed prohibition on sewerage of hazardous waste pharmaceuticals is estimated at \$37 million annually under the full compliance baseline. However, there are also significant cost savings under the proposed rule: \$24.3 million annually under the full compliance baseline.

Therefore the net cost of the rule is \$13 million annually (\$37million cost minus \$24.3 million cost savings = \$13 million net costs). Please see the RIA for more detailed analysis and results regarding the cost of the rule and the regulatory options analyzed.

#### B. Benefits of the Proposed Rule

The proposed rule for the management of hazardous waste pharmaceuticals is expected to yield a range of environmental benefits as hospitals, medical clinics, and other healthcare facilities divert hazardous waste pharmaceuticals currently disposed in sewers, municipal solid waste landfills (MSWLFs), municipal waste combustors (MWCs), and medical waste autoclaves and incinerators, to hazardous waste incinerators. The rule reduces the amount of hazardous waste pharmaceuticals sewerage into waterways, provides regulatory clarity for industry and provides healthcare facilities and pharmaceutical reverse distributors with cost savings.

The largest quantified benefit is from avoided sewerage of hazardous waste pharmaceuticals. Disposal of hazardous waste pharmaceuticals through sewerage is believed to be a widespread practice of disposal. Sewerage is believed to be one of the most deleterious disposal methods because

active pharmaceutical ingredients (APIs) entering surface waters, often untreated by municipal wastewater treatment plants, pose the potential for adverse human health and environmental effects since they may be absorbed by humans and other organisms. Under the proposed rule, the Agency anticipates preventing approximately 6,400 tons of hazardous waste pharmaceuticals annually into waterways via a sewerage ban. While the Agency was not able to quantify the human health and environmental benefits of reducing or eliminating the sewerage of hazardous waste pharmaceuticals, EPA did estimate the cost savings of eliminating the wastewater treatment costs associated with sewerage such pharmaceuticals. The estimated cost savings of eliminated wastewater treatment related to the prevented sewerage of hazardous waste pharmaceuticals is estimated to be \$4.3 million annually.

The proposed rule will yield other benefits beyond the reduction in sewerage of hazardous waste pharmaceuticals. For example, under the proposed rule, healthcare facilities will no longer be required to count hazardous waste pharmaceuticals toward their RCRA generator category. This, in turn, will lead to changes in a healthcare facility's generator category,

enabling them to realize an additional cost savings. The extent to which such changes in generator category will occur under the proposed rule is uncertain, but these changes would be most likely for those healthcare facilities for which hazardous waste pharmaceuticals make up a large portion of their overall hazardous waste generation. Please see the RIA for a breakout of cost savings by regulatory requirement.

## XII. Statutory and Executive Order Reviews

### A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735; October 4, 1993), this action is a “significant regulatory action” because it is likely to raise novel legal or policy issues under section 3(f)(4). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821; January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action (EPA–HQ–RCRA–2007–0932).

Findings for the RIA indicate that the rule, as proposed, is projected to result in an aggregate annual cost of approximately \$37 million based on a discount rate of 7%. However, the proposed rule will also achieve an annual cost savings, which is estimated to be \$24.3 million. Therefore, the net cost of the rule is estimated at \$13 million annually. The costs, which represents annualized incremental costs relative to the full compliance baseline, is below the \$100 million threshold established under part 3(f)(1) of the Order.

In addition to calling for an assessment of regulatory costs, Executive Order 12866 also requires Federal agencies to assess benefits and, “recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.” As discussed previously, the cost savings for the rule are estimated to be \$24.3 million annually. These cost savings are considered benefits of the rule. Also, EPA estimates that the proposed rule will lead to the diversion of approximately 6,440 tons annually of hazardous waste pharmaceuticals from sewer disposal to alternate forms of disposal. This reduction in sewerage will likely reduce the concentration of

active pharmaceutical ingredients in the nation’s waterways, potentially benefiting both ecosystems and human populations. Please see the RIA for more details on the benefits of the proposed rule.

### B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2486.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is proposing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and pharmaceutical reverse distributors managing hazardous waste pharmaceuticals. These proposed requirements, which are also identified in the ICR supporting this action, will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. The healthcare facilities must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals for three years from the date of analyses. In addition, the proposed requirements include provisions for improved tracking of hazardous waste pharmaceuticals that are routed through pharmaceutical reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. In addition, during a facility inspection, information kept in facility records will help EPA and state environmental regulatory agencies determine whether or not regulatory requirements are being followed. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipment.

EPA has carefully considered the burden imposed upon the regulated

community by the proposed regulations. EPA is confident that those activities required of respondents are necessary and, to the extent possible, has attempted to minimize the burden imposed. EPA believes strongly that if the minimum requirements specified under the proposed regulations are not met, neither the facilities nor EPA can ensure that hazardous waste pharmaceuticals are managed in a manner protective of human health and the environment.

EPA estimates that the total annual respondent burden for the new paperwork requirements in the proposed rule is approximately 54,857 hours, and the annual respondent cost for the new paperwork requirements in the rule is approximately \$3,457,478. The estimated annual hourly burden ranges from 0.1 to 3.5 hours per response for the 28,637 respondents. However, in addition to estimating the annual respondent burden associated with new paperwork requirements in the proposed rule, the Agency also estimated the annual benefits (hours and cost savings) to respondents from the new paperwork requirements in comparison to complying with the existing RCRA hazardous waste information collection requirements for hazardous waste pharmaceuticals (e.g., preparation of biennial reports, recordkeeping, etc.). Taking both the new proposed and existing RCRA requirements into account, EPA expects the proposed rule would result in a net annual paperwork burden to the 28,637 respondents of approximately 28,660 hours or \$2,301,873. The net cost to EPA of administering the rule is expected to be negligible, since the Agency is not required to review and approve any information submitted by respondents. Burden is defined at 5 CFR 1320.3(b).

*Respondents/affected entities:* Private entities.

*Respondent’s obligation to respond:* Mandatory per 40 CFR part 266, subpart P.

*Estimated number of respondents:* 28,637.

*Frequency of response:* Once.

*Total estimated burden:* 54,857 hours.

*Total estimated cost:* \$3,457,478, includes \$1,038,856 annualized capital or operation & maintenance costs.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA’s regulations in 40 CFR are listed in 40 CFR part 9. Submit your comments on the Agency’s need for this information, the accuracy of the

provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to [oria\\_submissions@omb.eop.gov](mailto:oria_submissions@omb.eop.gov), Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October

26, 2015. The EPA will respond to any ICR-related comments in the final rule.

### C. Regulatory Flexibility Small Business Analysis

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are indicated in Table 13. The Agency has determined that costs of the

regulation for a facility are less than 1 percent of annual revenue.

To assess the number of small entities in the regulated universe, EPA consulted NAICS-level data from the 2007 Economic Census and tallied the number of facilities, by NAICS code, owned by entities with revenues below SBA's threshold for consideration as small. Entities in revenue categories above the SBA threshold are *not* considered small. See Table 12 for the SBA thresholds and revenues.

TABLE 13: SBA 2014 SMALL BUSINESS SIZE STANDARDS (USING 2007 NAICS CODES)			
FACILITY TYPE	SBA SIZE STANDARD (FIRM-LEVEL, ANNUAL REVENUE)	PERCENTAGE OF GENERATORS CONSIDERED "SMALL" UNDER SBA STANDARD	NUMBER OF GENERATORS THAT ARE SMALL
Pharmacies	\$27.5 million	46%	5,390
Veterinary Clinics	\$7.5 million	95%	7,416
Physicians' Offices	\$11.0 million	88%	53,577
Dentists' Offices	\$7.5 million	97%	33,932
Other Health Practitioners (e.g., chiropractors)	\$7.5 million	93%	32,036
Outpatient Care Centers (ex-kidney dialysis centers)	\$15.0 million	68%	4,787
Outpatient Care Centers (kidney dialysis centers)	\$38.5 million	14%	161
Other Ambulatory Health Care Services	\$15.0 million	66%	1,707
Hospitals	\$38.5 million	25%	1,634
Nursing Care Facilities (e.g., assisted living facilities, nursing homes, U.S. veterans domiciliary centers)	\$15.0 million	44%	1,985
Continuing Care Retirement Communities	\$27.5 million	62%	1,023
Medical Examiners and Coroners' Offices	Size standards not established	100%	552
Reverse Distributors	Various NAICS	50%	28
<b>Total Number of Small Facilities</b>			<b>144,228</b>
<u>Source:</u> U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, effective July 14, 2014.			

The percentage of facilities that qualify as small under SBA's thresholds were estimated for each industry affected by the proposed rule. These

percentages were applied to the number of facilities in the regulatory universe, as presented in the RIA. After estimating the number of small entities by NAICS

code, the average cost per small entity was estimated based on the model facility costs presented in the RIA. Next, the EPA determined whether the per

facility costs incurred by small entities represent more than 1% of annual revenues, which required estimating small entities' average annual revenues. For each NAICS code, the average per facility revenue of entities considered small under the SBA standard was estimated based on data from the 2007 Economic Census.

The proposed rule is expected to impact a total of 144,228 small entities (1,634 hospitals, 142,566 other healthcare facilities (*i.e.*, healthcare facilities that are not hospitals) and 28 pharmaceutical reverse distributors). The highest cost impact to small entities is estimated to be 0.013% of revenues at other healthcare facilities and 0.002% of revenues at hospitals. Because pharmaceutical reverse distributors are in various NAICS codes, the Agency was not able to obtain revenue data for pharmaceutical reverse distributors. However the estimated cost impact to small entity pharmaceutical reverse distributors is estimated at \$5,300 annually, which the Agency does not anticipate will cause significant hardship on pharmaceutical reverse distributors that are small entities. However, the Agency requests comment on the cost impacts on small entity pharmaceutical reverse distributors that process creditable hazardous waste pharmaceuticals.

In the RIA, small entity impacts are presented incremental to the full compliance baseline. The annual per facility costs incremental to both baselines are estimated to be much less than 1% of average annual revenues. Since the incremental impact to the smallest healthcare facilities in terms of revenue is less than 1% of average annual revenues, the proposed rule is not expected to cause a significant impact to a substantial number of small businesses. Please see the RIA for a detailed analysis of cost impacts on small entities.

Although this proposed rule will not have a significant economic impact on

a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

#### *D. Unfunded Mandates Reform Act (UMRA)*

This rule does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost is estimated to be \$13 million annually after cost savings (\$37 million cost minus \$24.3 million in cost savings). Thus, this proposed rule is not subject to the requirements of sections 202 or 205 of UMRA.

This proposed rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals and coroners' offices are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rule. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

#### *E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the relationship between the national government and the states, or on the distribution of power and

responsibilities among the various levels of government.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action may have tribal implications. However, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law.

To assess the potential tribal implications of the proposed rule, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of the proposed rule for these facilities. Estimates of tribally run healthcare facilities were obtained from the U.S. Department of Health and Human Services' Indian Health Service (IHS), as summarized in Table 14.<sup>164</sup> Data were not readily available on the size or hazardous waste generation amounts for the tribally run healthcare facilities identified by the IHS. To estimate the potential costs of each regulatory option, per facility costs derived in the RIA were applied to the IHS facility counts. Based on these values, Table 14 summarizes the costs that tribally run healthcare facilities are expected to incur under the proposed rule. OMB has not issued guidance on what constitutes a substantial burden on tribal governments under this executive order. The relatively low costs estimated for tribally run healthcare facilities in Table 14, however, suggest that the proposed rule will not impose a substantial burden on tribal governments. EPA welcomes comments on the proposed rule's impact on tribal governments. EPA specifically solicits additional comment on this proposed action from tribal officials.

<sup>164</sup> Indian Health Service (IHS), U.S. Department of Health and Human Services, IHS Year 2013 Profile, available at <http://www.ihs.gov/PublicAffairs/IHSBrochure/Profile.asp>, accessed December 20, 2012.

**TABLE 14: COST IMPACTS FOR HEALTHCARE FACILITIES OWNED AND OPERATED BY NATIVE AMERICAN TRIBES USING A 7 PERCENT DISCOUNT RATE (MILLIONS OF YEAR 2011\$)**

FACILITY TYPE	NUMBER OF FACILITIES <sup>1</sup>	PROPOSED RULE
<b>Total Annual Costs Incremental to Full Compliance Baseline</b>		
Hospitals	16	\$0.019
Tribal Operated Facilities	16	\$0.088
Health Centers	258	
Alaska Village Clinics	164	
Health Stations	75	
<b>TOTAL</b>	<b>529</b>	<b>\$0.107</b>

Notes:

1. Indian Health Service (IHS), U.S. Department of Health and Human Services, IHS Year 2013 Profile, available at <http://www.ihs.gov/PublicAffairs/IHSBrochure/Profile.asp>, accessed December 20, 2012.
2. Estimate reflects annual cost impact for tribal operated facilities, health centers, Alaska village clinics, and health stations combined.

The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation is provided in the docket for this proposed rule (see EPA-HQ-RCRA-2007-0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this proposed rule (see EPA-HQ-RCRA-2007-0932).

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

This proposed rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks

addressed by this action present a disproportionate risk to children.

To examine whether the proposed rule has a disproportionate impact on children, the RIA uses a geographic analysis of demographics near wastewater treatment plants and hazardous waste combustion facilities. Table 15 summarizes the results of this analysis. As indicated in the table, this analysis finds that children (*i.e.*, individuals under the age of 18) account for a slightly larger share of the population (28.5%) in the one-mile radius around wastewater treatment plants than they account for nationally (25.3%). Among the catchment zones of wastewater treatment plants, however, children make up a much smaller portion of the population (9.8%). Within both the one- and three-mile buffers around hazardous waste combustion facilities, children's share of the population slightly exceeds their share nationally.

These data suggest that the proposed rule will not result in a disproportionate adverse impact on children. Because the

children's share of the population near hazardous waste combustion facilities is near the national average, any increase in the combustion of hazardous waste combustion that occurs as a result of the proposed rule is unlikely to have a significant disproportionate impact on children's health. The data in Table 15 also show that the number of children living in close proximity to wastewater treatment plants, in areas likely to benefit from the rule, far exceeds the number of children who live near hazardous waste combustion facilities. This suggests that the diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities will benefit a much greater number of children than it may put at greater risk of adverse health effects. See Table 15 for the demographics of children surrounding wastewater treatment plants and hazardous waste combustion facilities. Please see the RIA for a detailed methodology of the children's health analysis.

<b>TABLE 15: SUMMARY OF CHILDREN'S HEALTH ASSESSMENT</b>		
<b>GEOGRAPHIC AREA</b>	<b>NUMBER OF CHILDREN IN AREA</b>	<b>NATIONAL % OF POPULATION UNDER THE AGE OF 18</b>
Wastewater treatment plants, one-mile radius	7.8 million (28.5%) <sup>1</sup>	25.3%
Wastewater treatment plants, catchment areas	4.4 million (9.8%) <sup>1</sup>	
Hazardous waste combustion facilities, one-mile radius	5,012 (26.1%) <sup>1</sup>	
Hazardous waste combustion facilities, three-mile radius	64,710 (25.6%) <sup>1</sup>	
<b>GEOGRAPHIC AREA</b>	<b>NUMBER OF FACILITIES WHERE CHILDREN'S SHARE OF THE LOCAL POPULATION EXCEEDS NATIONAL AVG. %</b>	
Wastewater treatment plants, one-mile radius	8,908	
Wastewater treatment plants, catchment areas	5,171	
Hazardous waste combustion facilities, one-mile radius	13	
Hazardous waste combustion facilities, three-mile radius	11	
<b>GEOGRAPHIC AREA</b>	<b>NUMBER OF FACILITIES WHERE CHILDREN'S SHARE OF THE LOCAL POPULATION EXCEEDS STATE AVG. %</b>	
Wastewater treatment plants, one-mile radius	8,992	
Wastewater treatment plants, catchment areas	5,149	
Hazardous waste combustion facilities, one-mile radius	14	
Hazardous waste combustion facilities, three-mile radius	11	
<u>Notes:</u>		
1. Values in parentheses represent children's proportion of the population.		
Sources: RTI International, U.S. Synthesized Population 2005–2009 Version 2.0, August 2012; U.S. EPA Clean Watershed Needs Database; and U.S. EPA, Assessment of the Potential Costs, Benefits, & Other Impacts of the Hazardous Waste Combustion MACT Final Rule Standards, September 2005.		

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not a “significant energy action” as defined in Executive Order 13211, (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

The proposed rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in the proposed rule are not expected to

impact energy production or distribution. Similarly, the management requirements outlined in the proposed rule will have minimal impact on energy consumption (e.g., from transporting hazardous waste pharmaceuticals that otherwise would have been sewerred). Because the changes in energy production and consumption under the proposed rule are likely to be minimal, the proposed rule is not expected to have a significant adverse effect on energy supply, distribution, or use. In addition, no measurable adverse impacts are

expected on energy prices or foreign supplies.

*I. National Technology Transfer and Advancement Act (NTTAA)*

This proposed rulemaking does not involve technical standards.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects

on minority, low-income or indigenous populations. The results of this evaluation are summarized in the following paragraphs. The evaluation is contained in the Regulatory Impact Analysis (RIA), which can be found at [regulations.gov](http://regulations.gov) under docket number EPA-HQ-RCRA-2007-0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewerage of

hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, the proposed rule may result in positive environmental justice impacts. See Table 16 for the results of the Environmental Justice analysis.

Overall, EPA expects that the proposed rule may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. As suggested by Table 16, the reduction in sewerage expected under the proposed rule may benefit relatively large

minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities greatly exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the proposed rule may benefit environmental justice populations.

<b>TABLE 16: DEMOGRAPHICS FOR POPULATIONS NEAR WASTEWATER TREATMENT FACILITIES &amp; COMMERCIAL HAZARDOUS WASTE COMBUSTION FACILITIES</b>				
<b>GEOGRAPHIC AREA</b>	<b>MINORITY POPULATION</b>	<b>LOW-INCOME POPULATION</b>	<b>% OF NATIONAL POPULATION</b>	
			<b>RACIAL &amp; ETHNIC MINORITIES</b>	<b>LOW-INCOME POPULATION</b>
Wastewater treatment plants, one-mile radius	6.2 million (22.6%) <sup>1</sup>	3.8 million (14.0%) <sup>1</sup>	24.7%	11.4%
Wastewater treatment plants, catchment areas	3.8 million (8.6%) <sup>1</sup>	2.2 million (4.9%) <sup>1</sup>		
Hazardous waste combustion facilities, one-mile radius	3,578 (18.7%) <sup>1</sup>	3,130 (16.3%) <sup>1</sup>		
Hazardous waste combustion facilities, three-mile radius	67,329 (26.6%) <sup>1</sup>	42,782 (16.9%) <sup>1</sup>		
	<b>NO. OF FACILITIES EXCEEDING:</b>			
<b>GEOGRAPHIC AREA</b>	<b>NATIONAL AVG. MINORITY %.</b>		<b>NATIONAL AVG. LOW-INCOME %.</b>	
Wastewater treatment plants, one-mile radius	3,233		7,886	
Wastewater treatment plants catchment areas	3,151		7,358	
Hazardous waste combustion facilities, one-mile radius	6		4	
Hazardous waste combustion facilities, three-mile radius	7		4	
	<b>NO. OF FACILITIES EXCEEDING:</b>			
<b>GEOGRAPHIC AREA</b>	<b>STATE AVG. MINORITY %.</b>		<b>STATE AVG. LOW-INCOME %.</b>	
Wastewater treatment plants, one-mile radius	3,596		7,949	
Wastewater treatment plants, catchment areas	3,562		7,391	
Hazardous waste combustion facilities, one-mile radius	7		13	
Hazardous waste combustion facilities, three-mile radius	8		16	
<u>Notes:</u>				
1. Values in parentheses represent the proportion of the population considered a racial or ethnic minority or below the Federal Poverty Level.				
Sources: RTI International, U.S. Synthesized Population 2005–2009 Version 2.0, August 2012; U.S. EPA Clean Watershed Needs Database; and U.S. EPA, Assessment of the Potential Costs, Benefits, & Other Impacts of the Hazardous Waste Combustion MACT Final Rule Standards, September 2005.				

**List of Subjects***40 CFR Part 261*

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

*40 CFR Part 262*

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

*40 CFR Part 266*

Environmental protection, Energy, Hazardous Waste, Recycling, Reporting and recordkeeping requirements.

**40 CFR Part 268**

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

**40 CFR Part 273**

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: August 31, 2015.

**Gina McCarthy,**  
Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is proposed to be amended as follows:

**PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE**

■ 1. The authority citation for part 261 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 2. Amend § 261.5 by adding paragraph (c)(8) to read as follows:

**§ 261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators.**

\* \* \* \* \*

(c) \* \* \*

(8) Is a hazardous waste pharmaceutical managed under 40 CFR part 266, subpart P.

\* \* \* \* \*

■ 3. Amend § 261.7 by adding paragraph (c) to read as follows:

**§ 261.7 Residues of hazardous waste in empty containers.**

\* \* \* \* \*

(c) Healthcare facilities and pharmaceutical reverse distributors operating under 40 CFR part 266, subpart P are subject to § 266.507 for the management of hazardous waste pharmaceutical residues in containers, in lieu of this section.

**PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE**

■ 4. The authority citation for part 262 continues to read as follows:

**Authority:** 42 U.S.C 6906, 6912, 6922–6925, 6937, and 6938.

■ 5. Amend § 262.10 by adding paragraphs (m) and (n) to read as follows:

**§ 262.10 Purpose, scope and applicability.**

\* \* \* \* \*

(m) All pharmaceutical reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including pharmaceutical hazardous waste and non-pharmaceutical hazardous waste). Healthcare facilities that generate (or accumulate) more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, waste, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), are subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

**PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES**

■ 6. The authority citation for part 266 continues to read as follows:

**Authority:** 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

**Subpart O—[Reserved]**

■ 7. Add reserved subpart O:

■ 8. Add subpart P to read as follows:

**Subpart P—Hazardous Waste Pharmaceuticals**

Sec.

266.500 Definitions for this subpart.

266.501 Applicability.

266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

266.504 Healthcare facilities that are conditionally exempt small quantity generators (CESQGs).

266.505 Prohibition of sewerage hazardous waste pharmaceuticals.

266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances.

266.507 Management of hazardous waste pharmaceutical residues in containers.

266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor.

266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a pharmaceutical reverse distributor to a pharmaceutical reverse distributor.

266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

**Subpart P—Hazardous Waste Pharmaceuticals****§ 266.500 Definitions for this subpart.**

The following definitions apply to this subpart:

*Evaluated hazardous waste pharmaceutical* means a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification.

*Hazardous waste pharmaceutical* means a pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C.

*Healthcare facility* means:

(1) Any person that:

(i) Provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(ii) Sells or dispenses over-the-counter or prescription pharmaceuticals.

(2) This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals.

*Household waste pharmaceutical* means a pharmaceutical that is a solid waste, as defined in § 261.2, but is exempt from being a hazardous waste under § 261.4(b)(1).

*Long-term care facility* means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care

portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

*Non-creditable hazardous waste pharmaceutical* means a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer's credit.

*Non-hazardous waste pharmaceutical* means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261, subpart D, and does not exhibit a characteristic identified in 40 CFR part 261, subpart C.

*Non-pharmaceutical hazardous waste* means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261, subpart D, or exhibits one or more characteristics identified in 40 CFR part 261, subpart C, but is not a pharmaceutical, as defined in this section.

*Pharmaceutical* means any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals.

*Pharmaceutical reverse distributor* means any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor.

*Potentially creditable hazardous waste pharmaceutical* means:

(1) A hazardous waste pharmaceutical that has the potential to receive manufacturer's credit and is:

- (i) Unused or un-administered; and
- (ii) Unexpired or less than one year past expiration date.

(2) The term does not include "evaluated hazardous waste pharmaceuticals," residues of pharmaceuticals remaining in

containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals.

#### **§ 266.501 Applicability.**

(a) A healthcare facility that is a conditionally exempt small quantity generator remains subject to § 261.5 and is *not* subject to this subpart, except for §§ 266.504, 266.505, and 266.507(a) and (b).

(b) A healthcare facility that is a conditionally exempt small quantity generator has the option of complying with this subpart for the management of its hazardous waste pharmaceuticals, as an alternative to complying with the conditional exemption of § 261.5.

(c) A healthcare facility or pharmaceutical reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to:

(1) Sections 266.502 and 266.504 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a pharmaceutical reverse distributor.

(2) Sections 266.503 through 266.507 and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are destined for a pharmaceutical reverse distributor.

(e) A pharmaceutical reverse distributor is subject to §§ 266.505 through 266.510 of this subpart with respect to the management of hazardous waste pharmaceuticals.

(f) This subpart does not apply to the management of hazardous waste pharmaceuticals that are generated or managed by entities other than healthcare facilities and pharmaceutical reverse distributors.

#### **§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.**

(a) *Notification and withdrawal from this subpart for healthcare facilities managing non-creditable hazardous waste pharmaceuticals*—(1)

*Notification.* A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous

Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA Identification Number.

(i) A healthcare facility that already has an EPA identification number must re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification form (EPA form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) *Withdrawal.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a conditionally exempt small quantity generator under § 261.5, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA form 8700–12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA Identification Number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 261.5(b).

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) *Training of employees managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure that all employees that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar

with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) *Hazardous waste determination for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility that generates a solid waste that is a pharmaceutical must determine whether the solid waste pharmaceutical is a hazardous waste pharmaceutical (*i.e.*, it exhibits a characteristic identified in 40 CFR part 261, subpart C or is listed in 40 CFR part 261, subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its solid waste pharmaceuticals as hazardous waste pharmaceuticals under this subpart even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive hazardous waste pharmaceuticals, or that mixes or commingles incompatible hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

- (i) Generate extreme heat or pressure, fire or explosion, or violent reaction;
- (ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;
- (iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;
- (iv) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or
- (v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate hazardous waste pharmaceuticals and non-hazardous pharmaceutical waste in the same container, except that hazardous waste pharmaceuticals prohibited from being combusted because of the dilution

prohibition of § 268.3(c) must be accumulated in separate containers.

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.*

(1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on-site for one year or less without a permit or having interim status. A healthcare facility may accumulate for more than one year without a permit or having interim status, only if the requirements of paragraph (f)(3) of this section are met.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceutical being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste; or

(iv) Any other method which clearly demonstrates the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating from the date it first became a waste.

(3) A healthcare facility may request from the EPA Regional Administrator an extension beyond the one year accumulation time limit for non-creditable hazardous waste pharmaceuticals involved in litigation, a recall, or unforeseen circumstances beyond the control of the healthcare facility.

(i) A request must be sent to the EPA Regional Administrator in writing (paper or electronic). The request for an extension must include an explanation of the reason an extension is requested, the approximate volume or weight of

the hazardous waste pharmaceuticals that will be accumulated more than 90 days, and the amount of additional time requested.

(ii) The amount of time extension granted is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals.* The hazardous waste pharmaceuticals generated by a healthcare facility are subject to the Land Disposal Restrictions of 40 CFR part 268. A healthcare facility that generates hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (codes).

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned hazardous waste pharmaceuticals on-site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of delivery of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals—(1) Biennial report by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception report by healthcare facilities for a missing copy of the manifest.* (i) For shipments from a

healthcare facility to a designated facility: If a healthcare facility does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(A) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(B) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(ii) For shipments rejected by the designated facility and shipped to an alternate facility: If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the handwritten signature of the owner or operator of the alternate facility within 60 days of the date the waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(A) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(B) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(3) *Additional reports.* The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.* (1) A healthcare facility must keep a copy of each manifest signed in accordance with

§ 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) for at least three years from the date of the test, analysis, or other determination.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(k) *Response to releases of non-creditable hazardous waste pharmaceuticals at healthcare facilities.*

(1) A healthcare facility must immediately contain all releases of non-creditable hazardous waste pharmaceuticals and other residues from non-creditable hazardous waste pharmaceuticals.

(2) A healthcare facility must determine whether any material resulting from the release is a non-creditable hazardous waste pharmaceutical, and if so, must manage the non-creditable hazardous waste pharmaceutical residues and spill clean-up materials in accordance with the requirements of this subpart.

(l) *Long-term care facilities that manage non-creditable hazardous waste pharmaceuticals.* A healthcare facility that is a long-term care facility and that has individuals that administer their own pharmaceuticals must collect any unused non-creditable hazardous waste pharmaceuticals from those self-administering individuals and manage them in accordance with this subpart.

(m) *Accepting creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a CESQG.* A healthcare facility may accept creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a conditionally exempt small quantity generator under § 261.5, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the conditionally exempt small quantity

generator healthcare facility that is sending the hazardous waste pharmaceuticals off-site or has a contractual relationship whereby the receiving healthcare facility supplies pharmaceuticals to the conditionally exempt small quantity generator healthcare facility,

(2) Is operating under this subpart for the management of its hazardous waste pharmaceuticals,

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off-site in compliance with this subpart, and

(4) Keeps records of the hazardous waste pharmaceuticals shipments it receives from off-site for 3 years from the date that the shipment is received.

**§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.**

(a) *Hazardous waste determination for creditable hazardous waste pharmaceuticals at the healthcare facility.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.*, it listed in 40 CFR part 261, subpart D or exhibits a characteristic identified in 40 CFR part 261, subpart C). A healthcare facility may choose to manage its potentially creditable solid waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under § 266.509 even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D.

(b) Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor.

(c) *Biennial Report by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(d) *Recordkeeping.* (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for 3 years from the date of shipment:

(i) A copy of the advance notification provided to the pharmaceutical reverse distributor;

(ii) The confirmation of delivery; and

(iii) The shipping papers or bill of lading.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

**§ 266.504 Healthcare facilities that are conditionally exempt small quantity generators (CESQGs).**

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a conditionally exempt small quantity generator may send its potentially creditable hazardous waste pharmaceuticals to a pharmaceuticals reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a CESQG.* A healthcare facility that is a conditionally exempt small quantity generator may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided the receiving healthcare facility meets the conditions in § 266.502(m) of this subpart.

(c) *Long-term care facilities that are CESQGs.* A long-term care facility that is a conditionally exempt small quantity generator may dispose of its hazardous waste pharmaceuticals in a collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

**§ 266.505 Prohibition of sewerage hazardous waste pharmaceuticals.**

All healthcare facilities and pharmaceutical reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly-owned treatment works does not apply to a hazardous waste pharmaceutical.

**§ 266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances.**

(a) The following are exempt from 40 CFR parts 260 through 273, provided the conditions of paragraph (b) of this section are met:

(1) A hazardous waste pharmaceutical that is also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) An authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that collects controlled substances collected from an ultimate user (as defined by the Drug Enforcement Administration) and co-mingles them with hazardous waste pharmaceuticals that are exempt as a household waste under § 261.4(b)(1).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances, and combusted at one of the following:

(1) A permitted large municipal waste combustor (LMWC), subject to 40 CFR part 62, subpart FFF for existing LMWCs, or 40 CFR part 60, subparts Ea and Eb for new LMWCs, or

(2) A permitted small municipal waste combustor (SMWC), subject to 40 CFR part 62, subpart JJJ for existing SMWCs, or 40 CFR part 60, subparts AAAA and BBBB for new SMWCs, or

(3) A unit that has a permit or interim status to burn hazardous waste and is covered by 40 CFR part 63, subpart EEE. A unit that is exempt from 40 CFR part 63, subpart EEE as specified in § 63.1200(b) of this chapter is not covered by subpart EEE.

**§ 266.507 Management of hazardous waste pharmaceutical residues in containers.**

(a) *Dispensing and unit-dose containers.* A dispensing bottle, vial, or ampule (not to exceed 1 liter or 1000 pills); or a unit-dose container, (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided:

(1) All pharmaceuticals have been removed from the dispensing bottle, vial or ampule; or the unit-dose container, (e.g., unit-dose packet, cup, wrapper, blister pack, or delivery device) using the practices commonly employed to remove materials from that type of container, and

(2) Any dispensing bottle or unit-dose container that is an original manufacturer's product package is

destroyed prior to disposal in such a manner as would prevent further use of the container.

(b) *Dispensed syringes.* The residues remaining in a syringe are not regulated as hazardous waste provided:

(1) The syringe has been used to administer the pharmaceutical to a patient, and

(2) The syringe is placed in a sharps container that is managed in accordance with all applicable federal, state, and local medical waste requirements.

(c) *Other containers, including delivery devices.* The residues remaining in all other types of unused or used containers that once held pharmaceuticals must be managed as hazardous waste pharmaceuticals, if the residues are listed in 40 CFR part 261, subpart D or exhibit a characteristic identified in 40 CFR part 261, subpart C. This includes, but is not limited to, the residues in intravenous (IV) bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels or creams.

**§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor.**

(a) A healthcare facility or pharmaceutical reverse distributor that ships either non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, respectively, off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility), must comply with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart E.

(iii) *Marking.* (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety

authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Pharmaceutical Reverse Distributor's Name and Address\_\_.

Healthcare Facility's or Pharmaceutical Reverse Distributor's EPA Identification Number\_\_.

Manifest Tracking Number\_\_.

(iv) *Placarding*. Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172, subpart F.

(v) *Shipping papers*. Prepare shipping papers in accordance with 49 CFR part 172, subpart C.

(2) The manifest requirements of 40 CFR part 262, subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list hazardous waste codes in box 13 of EPA Form 8700-22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the words "hazardous waste pharmaceuticals" in Box 14 (the special handling instructions and additional information) of EPA Form 8700-22.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals*. A healthcare facility or pharmaceutical reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262, subpart E.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals*. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262, subpart F. A healthcare facility or pharmaceutical reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, unless they have a permit or interim status that allows them to accept hazardous waste from off-site.

**§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a pharmaceutical reverse distributor to a pharmaceutical reverse distributor.**

(a) A healthcare facility or a pharmaceutical reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a pharmaceutical reverse distributor must:

(1) Provide advance notice (paper or electronic) to the pharmaceutical

reverse distributor of the intent to ship potentially creditable hazardous waste pharmaceuticals to the receiving pharmaceutical reverse distributor before each shipment of potentially creditable hazardous waste pharmaceuticals is sent, and

(2) Comply with the pre-transport requirements of § 266.508(a)(1)(i) through (v).

(b) Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving pharmaceutical reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived.

(c) If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor and does not receive delivery confirmation within seven calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or pharmaceutical reverse distributor that initiated the shipment must contact the shipper and the intended recipient (*i.e.*, the pharmaceutical reverse distributor) promptly to report that the confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals*. (1) A healthcare facility or pharmaceutical reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the following requirements in addition to paragraphs (a) through (c) of this section:

(i) Comply with the requirements applicable to a primary exporter at 40 CFR 262.53, 262.56(a)(1) through (4), (a)(6), and (b) and 262.57;

(ii) Export such potentially creditable hazardous waste pharmaceuticals only upon consent of the receiving country and in conformance with the EPA Acknowledgement of Consent as defined in 40 CFR part 262, subpart E; and

(iii) Provide a copy of the EPA Acknowledgement of Consent for the shipment to the transporter transporting the shipment for export.

(2) A transporter of potentially creditable hazardous waste pharmaceuticals to a foreign destination other than those OECD countries specified 40 CFR 262.58(a)(1) (in which case the transporter is subject to the

requirements of 40 CFR part 262, subpart H) may not accept a shipment if the transporter knows the shipment does not conform to the EPA Acknowledgment of Consent. In addition the transporter must ensure that:

(i) A copy of the EPA Acknowledgement of Consent accompanies the shipment; and

(ii) The shipment is delivered to the facility designated by the person initiating the shipment.

(e) *Importing potentially creditable hazardous waste pharmaceuticals*. Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262, subpart F.

**§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.**

A pharmaceutical reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off-site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on-site without a permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for pharmaceutical reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals*.

(1) *Notification*. A pharmaceutical reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a pharmaceutical reverse distributor operating under this subpart.

(i) A pharmaceutical reverse distributor that already has an EPA identification number must re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A pharmaceutical reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(2) *Inventory by the pharmaceutical reverse distributor.* A pharmaceutical reverse distributor must maintain an inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on-site.

(i) A pharmaceutical reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the pharmaceutical reverse distributor.

(ii) The inventory must include the identity (*e.g.*, name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(3) *Security at the pharmaceutical reverse distributor facility.* A pharmaceutical reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize unauthorized entry include, but are not limited to:

(A) 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) Means to control entry, such as keycard access.

(ii) If the pharmaceutical reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration regulations, the facility is not required to provide separate security measures pursuant to this section.

(4) *Maximum accumulation time for hazardous waste pharmaceuticals at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for 90 calendar days or less. The 90 days start when the potentially creditable hazardous waste pharmaceutical arrives at the pharmaceutical reverse distributor and applies to all hazardous waste pharmaceuticals accumulated on-site, regardless of whether they are destined for another pharmaceutical reverse distributor (*i.e.*, potentially creditable hazardous waste pharmaceuticals), or a permitted or interim status treatment, storage or disposal facility (*i.e.*, evaluated hazardous waste pharmaceuticals).

(5) *Extension of 90-day accumulation time limit at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor may request an extension of its 90-day accumulation time limit for hazardous waste pharmaceuticals from the EPA Regional Administrator due to unforeseen circumstances beyond the control of the pharmaceutical reverse distributor, or if the potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are involved in litigation or a recall.

(i) A written request must be sent to the EPA Regional Administrator (paper or electronic). The request for an extension must include an explanation of the reason an extension is requested, the approximate volume or weight of the hazardous waste pharmaceuticals that will be accumulated more than 90 days, and the amount of additional time requested.

(ii) The amount of time granted for an extension is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(6) *Contingency plan and emergency procedures at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 CFR part 265, subpart D.

(7) *Closure of a pharmaceutical reverse distributor.* When closing an area where a pharmaceutical reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the pharmaceutical reverse distributor must control, minimize, or eliminate to the extent necessary to protect human health and the environment, post-closure escape of hazardous waste, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere.

(8) *Reporting by a pharmaceutical reverse distributor—(i) Unauthorized waste report.* A pharmaceutical reverse distributor must submit an unauthorized hazardous waste report if the pharmaceutical reverse distributor receives hazardous waste from off-site that it is not authorized to receive (*e.g.*, non-creditable hazardous waste pharmaceuticals, non-pharmaceutical hazardous waste). The pharmaceutical reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 15 days after receiving the unauthorized hazardous waste and the

pharmaceutical reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized hazardous waste. The pharmaceutical reverse distributor must manage the unauthorized hazardous waste in accordance with all applicable regulations for generators of non-pharmaceutical hazardous waste. The unauthorized waste report must be signed by the owner or operator of the pharmaceutical reverse distributor, or his authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the pharmaceutical reverse distributor;

(B) The date the pharmaceutical reverse distributor received the hazardous waste;

(C) The EPA identification number, name and address of the healthcare facility that shipped the hazardous waste, if available;

(D) A description and the quantity of each unauthorized hazardous waste the pharmaceutical reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized hazardous waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The EPA Regional Administrator may require pharmaceutical reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(9) *Recordkeeping by pharmaceutical reverse distributors.* A pharmaceutical reverse distributor must keep the following records (paper or electronic):

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the advance notification, delivery confirmation, the shipping papers or bill of lading for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date it receives the shipment;

(iii) A copy of its inventory for as long as the facility is subject to this subpart; and

(iv) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(10) A pharmaceutical reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 21 calendar days of arriving at the pharmaceutical reverse distributor to establish whether it is destined for another pharmaceutical reverse distributor for further evaluation or verification of manufacturer's credit or for a permitted or interim status treatment, storage or disposal facility. This 21 calendar days is part of the 90 calendar days allowed for on-site accumulation.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another pharmaceutical reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceuticals that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with paragraph (c) of this section.

(11) A pharmaceutical reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer's credit within 21 calendar days of arriving at the facility and must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section. This 21 calendar days is part of the 90 calendar days allowed for on-site accumulation.

(b) *Additional standards for pharmaceutical reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another pharmaceutical reverse distributor for further evaluation or verification of manufacturer's credit:

(1) A pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor within 90 days from when the potentially creditable hazardous waste

pharmaceuticals arrived or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another pharmaceutical reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is a pharmaceutical manufacturer within 90 days from when the potentially creditable hazardous waste pharmaceuticals arrived or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A pharmaceutical reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor in accordance with § 266.509.

(4) *Recordkeeping.* A pharmaceutical reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another pharmaceutical reverse distributor, for at least three years from the date of shipment:

(i) A copy of the advance notification provided to the pharmaceutical reverse distributor;

(ii) The confirmation of delivery; and

(iii) The shipping papers or bill of lading.

(c) *Additional standards for pharmaceutical reverse distributors managing evaluated hazardous waste pharmaceuticals.* A pharmaceutical reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the pharmaceutical reverse distributor.* A pharmaceutical reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Weekly inspections of on-site accumulation area.* A pharmaceutical reverse distributor must inspect its on-site accumulation area at least weekly, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a pharmaceutical reverse distributor.* Personnel at a pharmaceutical reverse distributor that handle evaluated

hazardous waste pharmaceuticals are subject to the training requirements of § 265.16.

(4) *Labeling and management of containers at on-site accumulation area.* A pharmaceutical reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, "hazardous waste pharmaceuticals";

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) A pharmaceutical reverse distributor that manages ignitable or reactive evaluated hazardous waste pharmaceuticals, or that mixes or commingles incompatible evaluated hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the pharmaceutical reverse distributor.

(5) *Hazardous waste numbers.* Containers of evaluated hazardous waste pharmaceuticals must be marked with the applicable hazardous waste number(s) (i.e., hazardous waste code(s)) prior to transport off-site.

(6) *Shipments.* A pharmaceutical reverse distributor must ship evaluated hazardous waste pharmaceuticals that

are destined for a permitted or interim status treatment, storage or disposal facility, in accordance with § 266.508(a).

(7) *Procedures for a pharmaceutical reverse distributor for managing rejected shipments.* A pharmaceutical reverse distributor who sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned hazardous waste pharmaceuticals on-site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with paragraph (a) of this section. Upon receipt of the returned shipment, the pharmaceutical reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of delivery of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the pharmaceutical reverse distributor; and

(iv) Transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the shipping standards of § 266.508(b).

(8) *Land disposal restrictions.* Evaluated hazardous waste pharmaceuticals are subject to the Land Disposal Restrictions of 40 CFR part 268. A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) *Biennial report by a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41, except § 262.41(a)(7).

(ii) *Exception reporting by a pharmaceutical reverse distributor for a missing copy of the manifest.* (A) For shipments from a pharmaceutical reverse distributor to a designated facility:

(1) If a pharmaceutical reverse distributor does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the pharmaceutical reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(2) A pharmaceutical reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the pharmaceutical reverse distributor is located if it has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(i) A legible copy of the manifest for which the pharmaceutical reverse distributor does not have confirmation of delivery; and

(ii) A cover letter signed by the pharmaceutical reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B) For shipments rejected by the designated facility and shipped to an alternate facility:

(1) A pharmaceutical reverse distributor that does not receive a copy of the manifest with the handwritten signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35 day timeframe begins the date the waste is accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(2) A pharmaceutical reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the pharmaceutical reverse distributor is located if it has not received a copy of the manifest with the handwritten signature of the owner or operator of the

alternate facility within 45 days of the date the hazardous waste was accepted by the initial transporter. The 45-day timeframe begins the date the hazardous waste is accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility. The Exception Report must include:

(i) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(ii) A cover letter signed by the pharmaceutical reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) *Recordkeeping by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) A pharmaceutical reverse distributor must keep a log (written or electronic) of the weekly inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A pharmaceutical reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A pharmaceutical reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A pharmaceutical reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A pharmaceutical reverse distributor must keep records to document personnel training, in accordance with § 265.16.

(d) *When a pharmaceutical reverse distributor must have a permit.* A pharmaceutical reverse distributor is an operator of a hazardous waste treatment, storage or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the pharmaceutical reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off-site; or

(3) Treats or disposes of hazardous waste on-site.

**PART 268—LAND DISPOSAL RESTRICTIONS**

■ 9. The authority citation for part 268 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 10. Amend Section 268.7 by revising the section heading and the paragraph (a) subject heading to read as follows:

**§ 268.7 Testing, tracking, and recordkeeping requirements for generators, pharmaceutical reverse distributors, treaters, and disposal facilities.**

(a) *Requirements for generators and pharmaceutical reverse distributors:*

\* \* \*

■ 11. Amend § 268.50 by adding paragraphs (a)(4) and (5) to read as follows:

**§ 268.50 Prohibitions on storage of restricted wastes.**

(a) \* \* \*

(4) A healthcare facility accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the requirements in § 266.502 of this chapter.

(5) A pharmaceutical reverse distributor accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the pharmaceutical reverse distributor complies with § 266.510 of this chapter.  
\* \* \* \* \*

**PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT**

■ 12. The authority citation for part 273 continues to read as follows:

**Authority:** 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 13. Amend § 273.80 by revising paragraph (a) and adding paragraph (d) to read as follows:

**§ 273.80 General.**

(a) Except as provided in paragraph (d), any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

\* \* \* \* \*

(d) Pharmaceutical hazardous waste is regulated by 40 CFR part 266, subpart P and may not be added as a category of hazardous waste for management under this part.

[FR Doc. 2015-23167 Filed 9-24-15; 8:45 am]

**BILLING CODE 6560-50-P**

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## BRIEFING

**(797) Pharmaceutical Compounding—Sterile Preparations**, *USP 39* page 626. It is proposed to revise this chapter to improve clarity, respond to stakeholder input, and reflect new science. Major edits to the chapter include:

1. Reorganized existing chapter to group similar topics together, eliminate redundancies, and clarify requirements. Key procedural information is placed in boxes so that it can be easily referenced and followed.
2. Collapsed compounded sterile preparations (CSP) microbial risk categories from three to two and changed terminology. No sterile compounding is inherently “low risk” and preparation of all CSPs must be done carefully. Categories were renamed neutrally as Category 1 and 2 CSPs, which are distinguished primarily by the conditions under which they are made and the time within which they are used. Category 1 CSPs have a shorter beyond use date (BUD) and may be prepared in a segregated compounding area; Category 2 CSPs have a longer BUD and must be prepared in a cleanroom environment.
3. Removed specific information on handling of hazardous drugs and added references to [Hazardous Drugs—Handling in Healthcare Settings \(800\)](#).
4. Introduced terminology for “in-use time” to refer to the time before which a conventionally manufactured product used to make a CSP must be used after it has been opened or punctured, or a CSP must be used after it has been opened or punctured.

Additionally, the chapter was revised to add requirements for maintaining master formulation and compounding records, provide guidance on use of isolators, and add guidance for sterility testing of CSP prepared in batch sizes of less than 40.

The proposed chapter is posted online at [www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision](http://www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision) with line numbers. Please provide the line numbers corresponding to your comments when submitting comments to [CompoundingSL@usp.org](mailto:CompoundingSL@usp.org).

Additionally, minor editorial changes have been made to update the chapter to current *USP* style.

(CMP: J. Sun.)  
Correspondence Number—C163428

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# **<797> PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS**

**Change to read:**

## **INTRODUCTION**

The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see “official” and “article” in the *General Notices and Requirements*) or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* (85)), they are potentially most hazardous to patients when administered into the central nervous system.

Despite the extensive attention in this chapter to the provision, maintenance, and evaluation of air quality, the avoidance of direct or physical contact contamination is paramount. It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 (see *Table 1*) areas.

To achieve the above five conditions and practices, this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this chapter do not pertain to the *clinical administration* of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. Sterile compounding differs from nonsterile compounding (see *Pharmaceutical Compounding—Nonsterile Preparations* (795) <sup>•</sup> (CN 1 May 2016)) primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components (i.e., with immediate-use CSPs, low-risk level CSPs, and medium-risk level CSPs) and the achievement of sterility when compounding with nonsterile ingredients and components (i.e., with high-

risk level CSPs). Some differences between standards for sterile compounding in this chapter and those for nonsterile compounding in *Pharmaceutical Compounding—Nonsterile Preparations* (795) include, but are not limited to, ISO-classified air environments (see *Table 1*); personnel garbing and gloving; personnel training and testing in principles and practices of aseptic manipulations and sterilization; environmental quality specifications and monitoring; and disinfection of gloves and surfaces of ISO Class 5 (see *Table 1*) sources.

**Table 1. ISO Classification of Particulate Matter in Room Air** (limits are in particles of 0.5 µm and larger per cubic meter [current ISO] and cubic feet [former Federal Standard No. 209E, FS 209E])<sup>a</sup>

Class Name		Particle Count	
ISO Class	U.S. FS 209E	ISO, m <sup>3</sup>	FS 209E, ft <sup>3</sup>
3	Class 1	35.2	1
4	Class 10	352	10
5	Class 100	3,520	100
6	Class 1,000	35,200	1,000
7	Class 10,000	352,000	10,000
8	Class 100,000	3,520,000	100,000

<sup>a</sup> Adapted from former Federal Standard No. 209E, General Services Administration, Washington, DC, 20407 (September 11, 1992) and ISO 14644-1:1999, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness. For example, 3,520 particles of 0.5 µm per m<sup>3</sup> or larger (ISO Class 5) is equivalent to 100 particles per ft<sup>3</sup> (Class 100) (1 m<sup>3</sup> = 35.2 ft<sup>3</sup>).

The standards in this chapter are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians. These terms recognize that most sterile compounding is performed by or under the supervision of pharmacists in pharmacies and also that this chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of this chapter, CSPs include any of the following:

1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.
2. Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package inserts) or prepared differently than published in such labeling. [Note—The FDA states that “Compounding does not include mixing, reconstituting, or similar

acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling" [21 USC 321 (k) and (m)]. However, the FDA approved labeling (product package insert) rarely describes environmental quality (e.g., ISO Class air designation, exposure durations to non-ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration). Beyond-use exposure and storage dates or times (see *General Notices and Requirements and Pharmaceutical Compounding—Nonsterile Preparations (795)*) for sterile products that have been either opened or prepared for administration are not specified in all package inserts for all sterile products. Furthermore, when such durations are specified, they may refer to chemical stability and not necessarily to microbiological purity or safety.]

## **ORGANIZATION OF THIS CHAPTER**

The sections in this chapter are organized to facilitate the practitioner's understanding of the fundamental accuracy and quality practices for preparing CSPs. They provide a foundation for the development and implementation of essential procedures for the safe preparation of low-risk, medium-risk, and high-risk level CSPs and immediate-use CSPs, which are classified according to the potential for microbial, chemical, and physical contamination. The chapter is divided into the following main sections:

- Responsibility of Compounding Personnel
- CSP Microbial Contamination Risk Levels
- Personnel Training and Evaluation in Aseptic Manipulation Skills
- Immediate-Use CSPs
- Single-Dose and Multiple-Dose Containers
- Hazardous Drugs as CSPs
- Radiopharmaceuticals as CSPs
- Allergen Extracts as CSPs
- Verification of Compounding Accuracy and Sterility
- Environmental Quality and Control
- Suggested Standard Operating Procedures (SOPs)
- Elements of Quality Control
- Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding
- Finished Preparation Release Checks and Tests
- Storage and Beyond-Use Dating
- Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs
- Patient or Caregiver Training
- Patient Monitoring and Adverse Events Reporting
- Quality Assurance (QA) Program
- Abbreviations and Acronyms
- Glossary
- Appendices I–V

The requirements and recommendations in this chapter are summarized in *Appendix I*. A list of abbreviations and acronyms is included at the end of the main text, before the *Appendices*.

All personnel who prepare CSPs shall be responsible for understanding these fundamental practices and precautions, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

## **RESPONSIBILITY OF COMPOUNDING PERSONNEL**

Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. These performance responsibilities include maintaining appropriate cleanliness conditions and providing labeling and supplementary instructions for the proper clinical administration of CSPs.

Compounding supervisors shall ensure, through either direct measurement or appropriate information sources, that specific CSPs maintain their labeled strength within monograph limits for *USP* articles, or within 10% if not specified, until their BUDs. All CSPs are prepared in a manner that maintains sterility and minimizes the introduction of particulate matter.

A written quality assurance procedure includes the following in-process checks that are applied, as appropriate, to specific CSPs: accuracy and precision of measuring and weighing; the requirement for sterility; methods of sterilization and purification; safe limits and ranges for strength of ingredients, bacterial endotoxins, and particulate matter; pH; labeling accuracy and completeness; BUD assignment; and packaging and storage requirements. The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved:

1. Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:
  - a. perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces;
  - b. select and appropriately don protective garb;
  - c. maintain or achieve sterility of CSPs in ISO Class 5 (see [Table 1](#)) PEC devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic, and chemotoxic drugs (see *Hazardous Drugs as CSPs* and *Radiopharmaceuticals as CSPs*);
  - d. identify, weigh, and measure ingredients; and
  - e. manipulate sterile products aseptically, sterilize high-risk level CSPs, and label and quality inspect CSPs.
2. Ingredients have their correct identity, quality, and purity.
3. Opened or partially used packages of ingredients for subsequent use in CSPs are properly stored under restricted access conditions in the compounding facility. Such packages cannot be used when visual inspection detects

~~unauthorized breaks in the container, closure, and seal; when the contents do not possess the expected appearance, aroma, and texture; when the contents do not pass identification tests specified by the compounding facility; and when either the BUD or expiration date has been exceeded.~~

- ~~4. Water-containing CSPs that are nonsterile during any phase of the compounding procedure are sterilized within 6 hours after completing the preparation in order to minimize the generation of bacterial endotoxins.~~
- ~~5. Sterilization methods achieve sterility of CSPs while maintaining the labeled strength of active ingredients and the physical integrity of packaging.~~
- ~~6. Measuring, mixing, sterilizing, and purifying devices are clean, appropriately accurate, and effective for their intended use.~~
- ~~7. Potential harm from added substances and differences in rate and extent of bioavailability of active ingredients for other than oral route of administration are carefully evaluated before such CSPs are dispensed and administered.~~
- ~~8. Packaging selected for CSPs is appropriate to preserve the sterility and strength until the BUD.~~
- ~~9. While being used, the compounding environment maintains the sterility or the presterilization purity, whichever is appropriate, of the CSP.~~
- ~~10. Labels on CSPs list the names and amounts or concentrations of active ingredients, and the labels or labeling of injections (see *Preservation, Packaging, Storage, and Labeling* in the *General Notices and Requirements*) list the names and amounts or concentrations of all ingredients (see <sup>a</sup> *Labeling* (7) <sub>(CN 1 May 2016)</sub>). Before being dispensed or administered, the clarity of solutions is visually confirmed; also, the identity and amounts of ingredients, procedures to prepare and sterilize CSPs, and specific release criteria are reviewed to ensure their accuracy and completeness.~~
- ~~11. BUDs are assigned on the basis of direct testing or extrapolation from reliable literature sources and other documentation (see *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* (795)).~~
- ~~12. Procedures for measuring, mixing, dilution, purification, sterilization, packaging, and labeling conform to the correct sequence and quality established for the specified CSP.~~
- ~~13. Deficiencies in compounding, labeling, packaging, and quality testing and inspection can be rapidly identified and corrected.~~
- ~~14. When time and personnel availability so permit, compounding manipulations and procedures are separated from postcompounding quality inspection and review before CSPs are dispensed.~~

~~This chapter emphasizes the need to maintain high standards for the quality and control of processes, components, and environments and for the skill and knowledge of personnel who prepare CSPs. The rigor of in-process quality-control checks and of postcompounding quality inspection and testing increases with the potential hazard of the route of administration. For example, nonsterility, excessive bacterial endotoxin contamination, large errors in strength of correct ingredients, and incorrect ingredients in CSPs are potentially more dangerous to patients when the CSPs are administered~~

into the vascular and central nervous systems than when administered by most other routes.

### **CSP MICROBIAL CONTAMINATION RISK LEVELS**

The three contamination categories for CSPs described in this section are assigned primarily according to the potential for microbial contamination during the compounding of low-risk level CSPs and medium-risk level CSPs or the potential for not sterilizing high-risk level CSPs, any of which would subject patients to risk of harm, including death. High-risk level CSPs must be sterilized before being administered to patients. The appropriate risk level—low, medium, or high—is assigned according to the corresponding probability of contaminating a CSP with (1) microbial contamination (e.g., microbial organisms, spores, endotoxins) and (2) chemical and physical contamination (e.g., foreign chemicals, physical matter). Potential sources of contamination include, but are not limited to, solid and liquid matter from compounding personnel and objects; nonsterile components employed and incorporated before terminal sterilization; inappropriate conditions within the restricted compounding environment; prolonged presterilization procedures with aqueous preparations; and nonsterile dosage forms used to compound CSPs.

The characteristics described below for low-, medium-, and high-risk level CSPs are intended as a guide to the breadth and depth of care necessary in compounding, but they are neither exhaustive nor prescriptive. The licensed healthcare professionals who supervise compounding are responsible for determining the procedural and environmental quality practices and attributes that are necessary for the risk level they assign to specific CSPs.

These risk levels apply to the quality of CSPs immediately after the final aseptic mixing or filling or immediately after the final sterilization, unless precluded by the specific characteristics of the preparation. Upon subsequent storage and shipping of freshly finished CSPs, an increase in the risks of chemical degradation of ingredients, contamination from physical damage to packaging, and permeability of plastic and elastomeric packaging is expected. In such cases, compounding personnel are responsible for considering the potential additional risks to the integrity of CSPs when assigning BUDs. The pre-administration storage duration and temperature limits specified in the following subsections apply in the absence of direct sterility testing results that justify different limits for specific CSPs.

#### **Low-Risk Level CSPs**

CSPs compounded under all the following conditions are at a low risk of contamination.

#### **Low-Risk Conditions—**

1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 (see [Table 1](#)) or better air quality using only sterile ingredients, products, components, and devices.
2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile

products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.

3. Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.
4. For a low-risk level preparation, in the absence of passing a sterility test (see *Sterility Tests (71)*), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 14 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between  $-25^{\circ}$  and  $-10^{\circ}$ .

### **Examples of Low-Risk Compounding—**

1. Single-volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampuls should be passed through a sterile filter to remove any particles.
2. Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

**Low-Risk Level CSPs with 12-Hour or Less BUD—**If the PEC is a CAI or CACI that does not meet the requirements described in *Placement of Primary Engineering Controls* or is a laminar airflow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 7 (see [Table 1](#)) buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician's order for a specific patient may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. Low-risk level CSPs with a 12-hour or less BUD shall meet all of the following four criteria:

1. PECs (LAFWs, BSCs, CAIs, CACIs,) shall be certified and maintain ISO Class 5 (see [Table 1](#)) as described in *Facility Design and Environmental Controls* for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.
2. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all inclusive.
3. Personnel shall follow the procedures described in *Personnel Cleansing and Garbing* and *Additional Personnel Requirements* prior to compounding. Sinks

should not be located adjacent to the ISO Class 5 (see [Table 1](#)) PEC. Sinks should be separated from the immediate area of the ISO Class 5 (see [Table 1](#)) PEC device.

4. The specifications in *Cleaning and Disinfecting the Sterile Compounding Areas*, *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*, and *Viable and Nonviable Environmental Sampling (ES) Testing* shall be followed as described in the chapter.

Compounding personnel must recognize that the absence of an ISO Class 7 (see [Table 1](#)) buffer area environment in a general uncontrolled environment increases the potential of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization, and thus for patient harm, especially in critically ill or immunocompromised patients.

**Quality Assurance**—Quality assurance practices include, but are not limited to the following:

1. Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 (see [Table 1](#)) air quality.
2. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks.
3. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.
4. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

**Media-Fill Test Procedure**—This test or an equivalent test is performed at least annually by each person authorized to compound in a low-risk level environment under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level CSPs. Once begun, this test is completed without interruption. *Example of test procedure:* within an ISO Class 5 (see [Table 1](#)) air quality environment, three sets of four 5-mL aliquots of sterile Soybean–Casein Digest Medium (also known as trypticase soy broth or trypticase soy agar [TSA]) are transferred with the same sterile 10-mL syringe and vented needle combination into separate sealed, empty, sterile 30-mL clear vials (i.e., four 5-mL aliquots into each of three 30-mL vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)). Inspect for microbial growth over 14 days as described in

*Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*

**Medium-Risk Level CSPs**

When CSPs are compounded aseptically under *Low-Risk Conditions* and one or more of the following conditions exists, such CSPs are at a medium risk of contamination.

**Medium-Risk Conditions—**

1. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.
2. The compounding process includes complex aseptic manipulations other than the single-volume transfer.
3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.
4. For a medium-risk preparation, in the absence of passing a sterility test (see *Sterility Tests (71)*), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 9 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between  $-25^{\circ}$  and  $-10^{\circ}$ .

**Examples of Medium-Risk Compounding—**

1. Compounding of total parenteral nutrition fluids using manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.
2. Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed.
3. Transfer of volumes from multiple ampuls or vials into one or more final sterile containers.

**Quality Assurance—**Quality assurance procedures for medium-risk level CSPs include all those for low-risk level CSPs, as well as a more challenging media-fill test passed annually or more frequently.

**Media-Fill Test Procedure—**This test or an equivalent test is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. Once begun, this test is completed without interruption. *Example of test procedure:* within an ISO Class 5 (see [Table 1](#)) air quality environment, six 100-mL aliquots of sterile Soybean-Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-

mL syringe and 18-gauge needle combination is used to exchange two 5-mL aliquots of medium from one container to the other container in the pair. For example, after a 5-mL aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-mL aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-mL aliquot is transferred from it back to the second container in the pair. Following the two 5-mL aliquot exchanges in each pair of containers, a 5-mL aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-mL clear vial, using a sterile 10-mL syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*.

### High-Risk Level CSPs

CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated.

#### High-Risk Conditions—

1. Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral), are incorporated or a nonsterile device is employed before terminal sterilization.
2. Any of the following are exposed to air quality worse than ISO Class 5 (see [Table 1](#)) for more than 1 hour (see *Immediate-Use CSPs*):
  - o sterile contents of commercially manufactured products,
  - o CSPs that lack effective antimicrobial preservatives, and
  - o sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.
3. Compounding personnel are improperly garbed and gloved (see *Personnel Cleansing and Use of Barrier Protective Equipment*).
4. Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.
5. It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients (see *Ingredient Selection under Pharmaceutical Compounding—Nonsterile Preparations* (795)).

For a sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 3 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid

frozen state between  $-25^{\circ}$  and  $-10^{\circ}$ . [Note—Sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units.]

All nonsterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk level CSP solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not larger than  $1.2\ \mu\text{m}$  preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level CSPs by filtration shall be performed with a sterile  $0.2\ \mu\text{m}$  or  $0.22\ \mu\text{m}$  nominal pore size filter entirely within an ISO Class 5 (see [Table 1](#)) or superior air quality environment.

### **Examples of High-Risk Conditions—**

1. Dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized.
2. Exposing the sterile ingredients and components used to prepare and package CSPs to room air quality worse than ISO Class 5 (see [Table 1](#)) for more than 1 hour (see *Immediate-Use CSPs*).
3. Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed.
4. Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

**Quality Assurance—**Quality assurance procedures for high-risk level CSPs include all those for low-risk level CSPs. In addition, a media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs.

**Media-Fill Test Procedure for CSPs Sterilized by Filtration—**This test or an equivalent test is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level CSPs. Once begun, this test is completed without interruption. *Example of test procedure*(in the following sequence):

1. Dissolve 3 g of nonsterile commercially available Soybean-Casein Digest Medium in 100 mL of nonbacteriostatic water to make a 3% nonsterile solution.
2. Draw 25 mL of the medium into each of three 30-mL sterile syringes. Transfer 5 mL from each syringe into separate sterile 10-mL vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.
3. Under aseptic conditions and using aseptic techniques, affix a sterile  $0.2\ \mu\text{m}$  or  $0.22\ \mu\text{m}$  nominal pore size filter unit and a 20-gauge needle to each syringe. Inject the next 10 mL from each syringe into three separate 10-mL sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at  $20^{\circ}$  to  $25^{\circ}$  or at  $30^{\circ}$  to  $35^{\circ}$  for a minimum of 14 days. If two temperatures are used for incubation of

media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*.

## **PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS**

Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio-video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see [Table 1](#)) environmental conditions before they begin to prepare CSPs. Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

**Media-Fill Challenge Testing**—The skill of personnel to aseptically prepare CSPs may be evaluated using sterile fluid bacterial culture media fill verification<sup>4</sup> (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare particular risk level CSPs and when sterilizing high-risk level CSPs. Media-fill challenge tests that simulate high-risk level compounding are also used to verify the capability of the compounding environment and process to produce a sterile preparation.

Commercially available sterile fluid culture media, such as Soybean-Casein Digest Medium (see *Sterility Tests* (71)), shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment. Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)). Failure is indicated by visible turbidity in the medium on or before 14 days.

## **IMMEDIATE-USE CSPS**

The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for *Low Risk Level CSPs* subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or

batch-compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs.

Immediate-use CSPs are exempt from the requirements described for *Low-Risk Level CSPs* only when all of the following criteria are met:

1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.
2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
4. Administration begins not later than 1 hour following the start of the preparation of the CSP.
5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.
6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

Compounding in worse than ISO Class 5 (see [Table 1](#)) conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.

### **SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS**

Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see [Table 1](#)) air quality (see *Immediate-Use CSPs*), and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 (see [Table 1](#)) or cleaner air may be used up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* (51)) unless otherwise specified by the manufacturer.

## HAZARDOUS DRUGS AS CSPPS

Although the potential therapeutic benefits of compounded sterile hazardous drug preparations generally outweigh the risks of their adverse effects in ill patients, exposed healthcare workers risk similar adverse effects with no therapeutic benefit. Occupational exposure to hazardous drugs can result in (1) acute effects, such as skin rashes; (2) chronic effects, including adverse reproductive events; and (3) possibly cancer (see Appendix A of NIOSH Publication no. 2004-165).

Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Many hazardous drugs have sufficient vapor pressures that allow volatilization at room temperature; thus storage is preferably within a containment area such as a negative pressure room. The storage area should have sufficient general exhaust ventilation, at least 12 air changes per hour (ACPH)<sup>2</sup> to dilute and remove any airborne contaminants.

Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal. Hazardous drugs shall be prepared in an ISO Class 5 (see [Table 1](#)) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter. Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation.

All hazardous drugs shall be prepared in a BSC<sup>3</sup> or a CACI that meets or exceeds the standards for CACI in this chapter. The ISO Class 5 (see [Table 1](#)) BSC or CACI shall be placed in an ISO Class 7 (see [Table 1](#)) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see [Table 1](#)) or better ante areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization. The BSC and CACI optimally should be 100% vented to the outside air through HEPA filtration.

If a CACI that meets the requirements of this chapter is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 ACPHs.

When closed-system vial transfer devices (CSTDs) (i.e., vial transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within the ISO Class 5 (see [Table 1](#)) environment of a BSC or CACI. The use of a CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with

~~sterile chemo type gloves, and compliance with manufacturers' recommendations when using a CACI.~~

~~All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. The training shall include at least the following: (1) safe aseptic manipulation practices; (2) negative pressure techniques when utilizing a BSC or CACI; (3) correct use of CSTD devices; (4) containment, cleanup, and disposal procedures for breakages and spills; and (5) treatment of personnel contact and inhalation exposure.~~

~~NOTE—Because standards of assay and unacceptable quantities of contamination of each drug have not been established in the literature, the following paragraph is a recommendation only. Future standards will be adopted as these assay methods are developed and proven.~~

~~In order to ensure containment, especially in operations preparing large volumes of hazardous drugs, environmental sampling to detect uncontained hazardous drugs should be performed routinely (e.g., initially as a benchmark and at least every 6 months or more often as needed to verify containment). This sampling should include surface wipe sampling of the working area of BSCs and CACIs; counter tops where finished preparations are placed; areas adjacent to BSCs and CACIs, including the floor directly under the working area; and patient administration areas. Common marker hazardous drugs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, and fluorouracil. If any measurable contamination (cyclophosphamide levels greater than 1.00 ng per cm<sup>2</sup> have been found to cause human uptake) is found by any of these quality assurance procedures, practitioners shall make the decision to identify, document, and contain the cause of contamination. Such action may include retraining, thorough cleaning (utilizing high-pH soap and water), and improving engineering controls. Examples of improving engineering controls are (1) venting BSCs or CACIs 100% to the outside, (2) implementing a CSTD, or (3) re-assessing types of BSCs or CACIs.~~

~~Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.~~

## **RADIOPHARMACEUTICALS AS CSPS**

~~In the case of production of radiopharmaceuticals for positron emission tomography (PET), general test chapter *Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses* (823) supersedes this chapter. Upon release of a PET radiopharmaceutical as a finished drug product from a production facility, the~~

further handling, manipulation, or use of the product will be considered compounding, and the content of this section and chapter is applicable.

For the purposes of this chapter, radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single dose injection or not more than 30 mL taken from a multiple dose container (see

<sup>a</sup> *Packaging and Storage Requirements* (659) (CN-1 May 2016) shall be designated as, and conform to, the standards for *Low-Risk Level CSPs*.

These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see [Table 1](#)) PEG located in an ISO Class 8 (see [Table 1](#)) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.

Radiopharmaceutical vials designed for multi use, compounded with technetium-99m, exposed to ISO Class 5 (see [Table 1](#)) environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations. Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 (see [Table 1](#)) or cleaner air environment to permit special handling, shielding, and air flow requirements. To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA.

Radiopharmaceuticals prepared as *Low-Risk Level CSPs with 12-Hour or Less BUD* shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment area shall not cross a line of demarcation into the segregated compounding area.

## **ALLERGEN EXTRACTS AS CSPS**

Allergen extracts as CSPs are single dose and multiple dose *intra-dermal or subcutaneous injections* that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all *CSP Microbial Contamination Risk Levels* in this chapter only when all of the following criteria are met:

1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).
2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.

3. ~~Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water.~~
4. ~~Compounding personnel don hair covers, facial hair covers, gowns, and face masks.~~
5. ~~Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.~~
6. ~~Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.~~
7. ~~Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.~~
8. ~~Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.~~
9. ~~The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).~~
10. ~~The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.~~
11. ~~Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.~~

~~Personnel who compound allergen extracts as CSPs must be aware of greater potential risk of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for *CSP Microbial Contamination Risk Levels*. Although contaminated allergen extracts as CSPs can pose health risks to patients when they are injected *intradermally or subcutaneously*, these risks are substantially greater if the extract is inadvertently injected *intravenously*.~~

### **VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY**

~~The compounding procedures and sterilization methods for CSPs correspond to correctly designed and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility, accuracy, and purity of finished CSPs. For example, sterility testing (see *Test for Sterility of the Product To Be Examined* under *Sterility Tests (71)*) may be applied to specimens of low and medium risk level CSPs, and standard self-contained biological indicators (BI) shall be added to nondispensable~~

~~specimens of high-risk level CSPs before terminal sterilization for subsequent evaluation to determine whether the sterilization cycle was adequate (see *Biological Indicators for Sterilization* (1035)). Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount. The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers. When the correct identity, purity, strength, and sterility of ingredients and components of CSPs cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampuls, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling), such ingredients and components shall be discarded immediately.~~

~~Some individual ingredients, such as bulk drug substances, are not labeled with expiration dates when they are stable indefinitely in their commercial packages under their labeled storage conditions. However, despite retaining full chemical stability, such ingredients may gain or lose moisture during storage and use. Changes in moisture content may require testing (see *Loss on Drying* (731)) to determine the correct amount to weigh for accurate content of active chemical moieties in CSPs (see *Pharmaceutical Calculations in Prescription Compounding* (1160)).~~

~~Although not required, a quantitative stability indicating chemical assay is recommended to ensure compounding accuracy of CSPs, especially those that contain drug ingredients with a narrow therapeutic plasma concentration range.~~

### **Sterilization Methods**

~~The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method (see *Methods of Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* (1211)) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs. The selected sterilization process is obtained from experience and appropriate information sources (e.g., see *Sterilization and Sterility Assurance of Compendial Articles* (1211))—and, preferably, verified wherever possible—to achieve sterility in the particular CSPs. General guidelines for matching CSPs and components to appropriate sterilization methods include the following:~~

- ~~1. CSPs have been ascertained to remain physically and chemically stable when subjected to the selected sterilization method.~~
- ~~2. Glass and metal devices may be covered tightly with aluminum foil, then exposed to dry heat in an oven at a mean temperature of 250° for 30 minutes to achieve sterility and depyrogenation (see *Dry-Heat Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* (1211) and *Bacterial Endotoxins Test* (85)). Such items are either used immediately or stored until use in an environment suitable for compounding *Low-Risk Level CSPs* and *Medium-Risk Level CSPs*.~~
- ~~3. Personnel ascertain from appropriate information sources that the sterile microporous membrane filter used to sterilize CSP solutions, during either~~

compounding or administration, is chemically and physically compatible with the CSP.

#### STERILIZATION OF HIGH-RISK LEVEL CSPS BY FILTRATION

Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids. Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22  $\mu\text{m}$ . They shall be certified by the manufacturer to retain at least  $10^7$  microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see *High-Risk Conditions in High-Risk Level CSPs*).

The compounding supervisor shall ensure, directly or from appropriate documentation, that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality, including strength of ingredients of the specific CSP. The filter dimensions and liquid material to be sterile filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process. When CSPs are known to contain excessive particulate matter, a prefilter of larger nominal pore size membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants in order to maximize the efficiency of the sterilizing filter.

Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test.

Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized. Large deviations from usual or expected chemical and physical properties of CSPs (e.g., water-miscible alcohols) may cause undetectable damage to filter integrity and shrinkage of microorganisms to sizes smaller than filter nominal pore size.

#### STERILIZATION OF HIGH-RISK LEVEL CSPS BY STEAM

The process of thermal sterilization employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed (see *Steam Sterilization under Sterilization and Sterility Assurance of Compendial Articles (1211)*). To achieve sterility, all materials are to be exposed to steam at  $121^\circ$  under a pressure of about 1 atmosphere or 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for CSPs. An allowance shall be made for the time required for the material to reach  $121^\circ$  before the sterilization exposure duration is timed.

Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores. Before their sterilization, plastic, glass, and metal devices are tightly wrapped in low particle shedding paper or fabrics or sealed in envelopes that prevent poststerilization microbial penetration. Immediately before filling ampuls and vials that will be steam sterilized, solutions are passed through a filter having a nominal pore size not larger than 1.2  $\mu\text{m}$  for removal of particulate matter. Sealed containers shall be able to generate steam internally; thus, stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.

The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of steam sterilization shall be verified using appropriate BIs of *Bacillus stearothermophilus* (see *Biological Indicators* (1035)) and other confirmation methods such as temperature-sensing devices (see *Sterilization and Sterility Assurance of Compendial Articles* (1211) and *Sterility Tests* (71)).

#### STERILIZATION OF HIGH-RISK LEVEL CSPS BY DRY HEAT

Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. Heated filtered air shall be evenly distributed throughout the chamber by a blower device. The oven should be equipped with a system for controlling temperature and exposure period. Sterilization by dry heat requires higher temperatures and longer exposure times than does sterilization by steam. Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable. During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air. The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate BIs of *Bacillus subtilis* (see *Biological Indicators* (1035)) and other confirmation methods such as temperature-sensing devices (see *Sterilization and Sterility Assurance of Compendial Articles* (1211) and *Sterility Tests* (71)). [Note—Dry heat sterilization may be performed at a lower temperature than may be effective for depyrogenation] .

#### Depyrogenation by Dry Heat

Dry heat depyrogenation shall be used to render glassware or containers such as vials free from pyrogens as well as viable microbes. A typical cycle would be 30 minutes at 250°. The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs). The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin (see *Sterilization and Sterility Assurance of Compendial Articles* (1211) and *Bacterial Endotoxins Test* (85)).

### ENVIRONMENTAL QUALITY AND CONTROL

Achieving and maintaining sterility and overall freedom from contamination of a CSP is dependent on the quality status of the components incorporated, the process utilized, personnel performance, and the environmental conditions under which the process is performed. The standards required for the environmental conditions depend on the amount of exposure of the CSP to the immediate environment anticipated during processing. The quality and control of environmental conditions for each risk level of operation are explained in this section. In addition, operations using nonsterile components require the use of a method of preparation designed to produce a sterile preparation.

## Exposure of Critical Sites

Maintaining the sterility and cleanliness (i.e., freedom from sterile foreign materials) of critical sites is a primary safeguard for CSPs. Critical sites are locations that include any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. The risk of, or potential for, critical sites to be contaminated with microorganisms and foreign matter increases with increasing exposed area of the critical sites, the density or concentration of contaminants, and exposure duration to worse than ISO Class 5 (see [Table 1](#)) air. Examples include an opened ampul or vial stopper on a 10-mL or larger vial or an injection port on a package of intravenous solution having an area larger than the point of a needle or the tip of a syringe.

The nature of a critical site also affects the risk of contamination. The relatively rough, permeable surface of an elastomeric closure retains microorganisms and other contaminants after swabbing with a sterile 70% IPA pad more readily than does the smoother glass surface of the neck of an ampul. Therefore, the surface disinfection can be expected to be more effective for an ampul.

Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. Airborne contaminants, especially those generated by sterile compounding personnel, are much more likely to reach critical sites than are contaminants that are adhering to the floor or other surfaces below the work level. Furthermore, large and high-density particles that are generated and introduced by compounding manipulations and personnel have the potential to settle on critical sites even when those critical sites are exposed within ISO Class 5 (see [Table 1](#)) air.

### ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas

The most common sources of ISO Class 5 (see [Table 1](#)) air quality for exposure of critical sites are horizontal and vertical LAFWs, CAIs, and CACIs. A clean room (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)) is a compounding environment that is supplied with HEPA or HEPA-filtered air that meets ISO Class 7 (see [Table 1](#)), the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning. A buffer area is an area that provides at least ISO Class 7 (see [Table 1](#)) air quality.

[Figure 1](#) is a conceptual representation of the placement of an ISO Class 5 (see [Table 1](#)) PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD. This plan depicts the most critical operation area located within the PEC in a designated area (see definition of *Segregated Compounding Area*) separated from activities not essential to the preparation of CSPs. Placement of devices (e.g., computers, printers) and objects (e.g., carts, cabinets) that are not essential to compounding in the segregated area should be restricted or limited, depending on their effect on air quality in the ISO Class 5 (see [Table 1](#)) PEC.

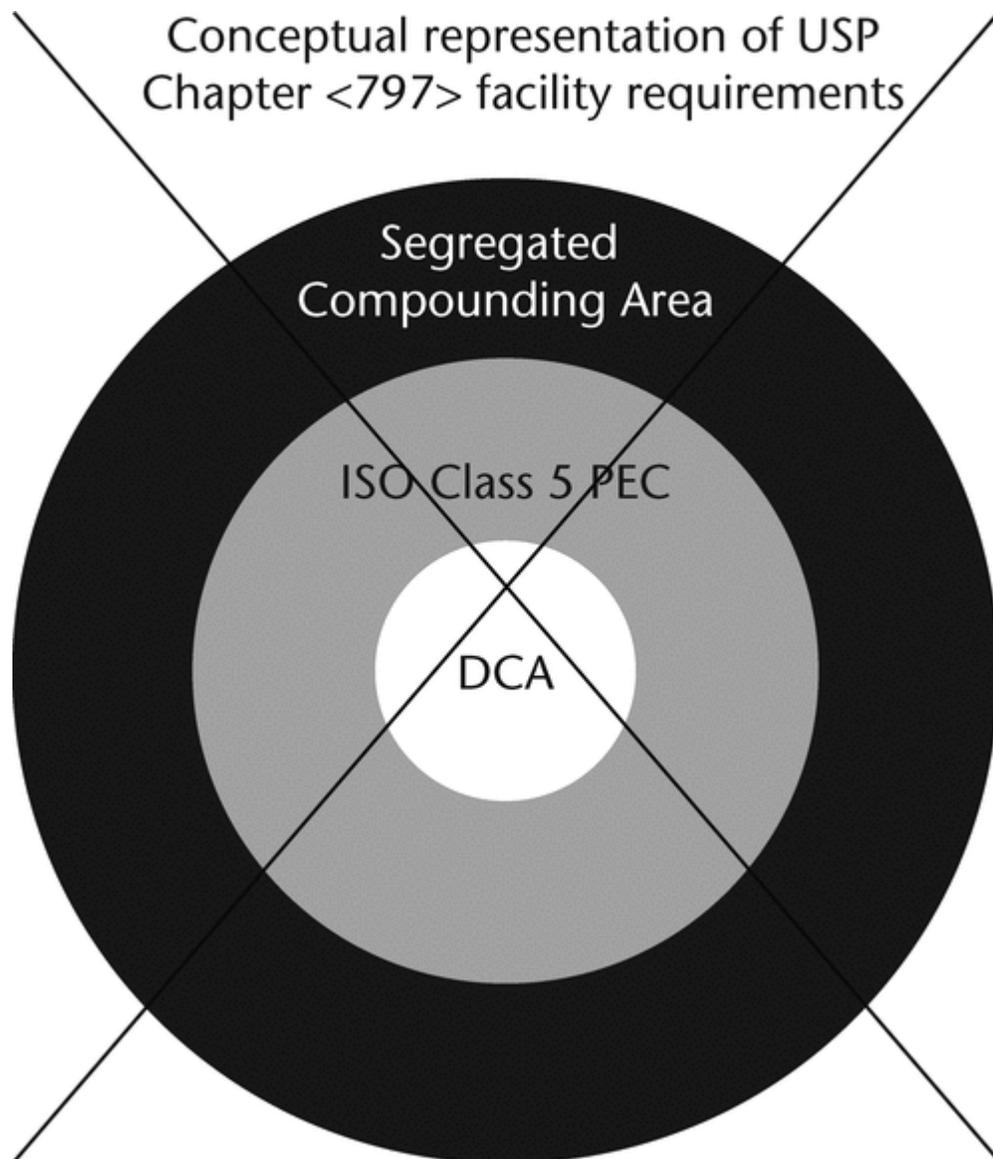


Figure 1. Conceptual representation of the placement of an ISO Class 5 PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD.

[Figure 2](#) is a conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level. The quality of the environmental air increases with movement from the outer boundary to the direct compounding area (DCA). Placement of devices in ante-areas and buffer areas is dictated by their effect on the designated environmental quality of atmospheres and surfaces, which shall be verified by monitoring (see *Viable and Nonviable Environmental Sampling (ES) Testing*). It is the responsibility of each compounding facility to ensure that each source of ISO Class 5 (see [Table 1](#)) environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

## Conceptual representation of USP Chapter <797> facility requirements

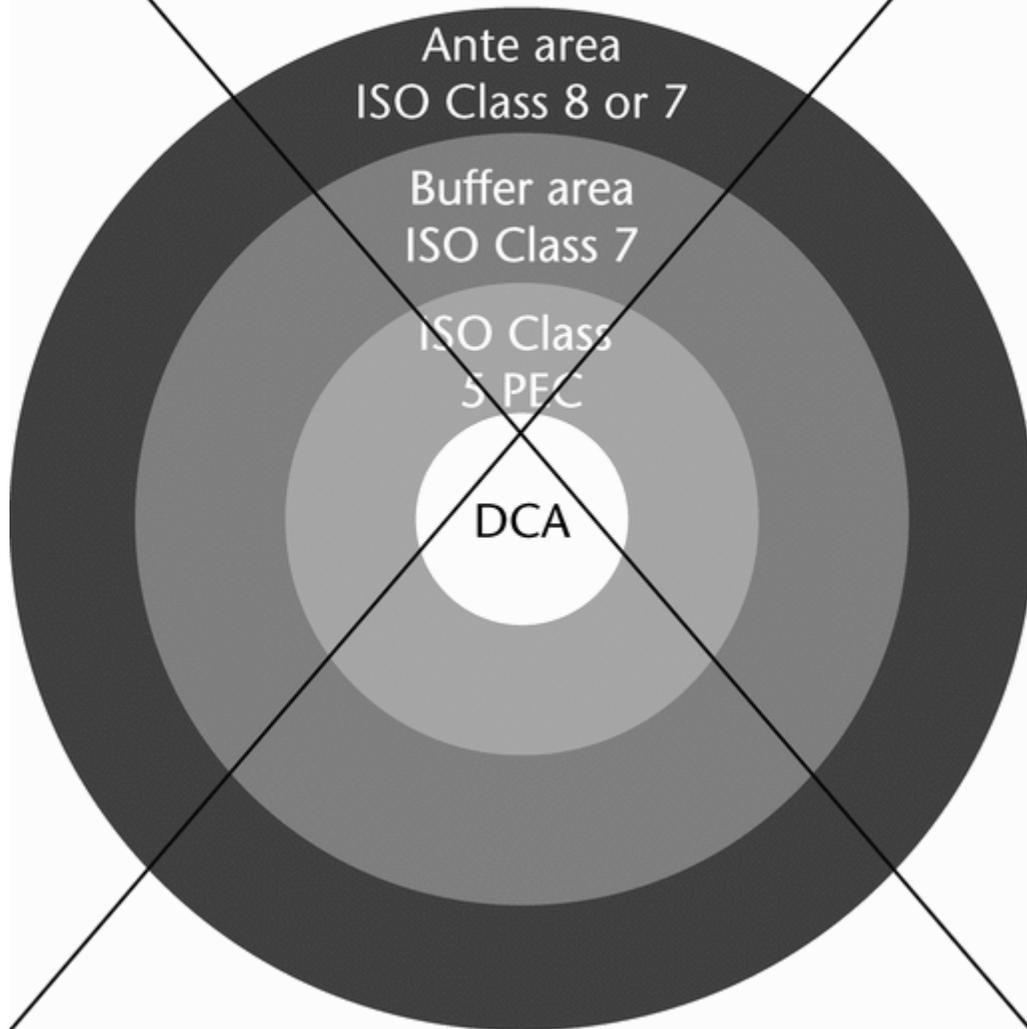


Figure 2. Conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level.

Placement of devices (e.g., computers, printers) and objects (e.g., carts, cabinets) that are not essential to compounding in buffer areas is dictated by their effect on the required environmental quality of air atmospheres and surfaces, which shall be verified by monitoring (see *Viable and Nonviable Environmental Sampling (ES) Testing*). It is the responsibility of each compounding facility to ensure that each source of ISO Class 5 (see [Table 1](#)) environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

### **Facility Design and Environmental Controls**

Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. These facilities shall also provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler, to maintain comfortable conditions for compounding personnel to perform flawlessly when attired in the required aseptic compounding garb. PECs typically include, but are not limited to, LAFWs, BSCs, CAIs, and CACIs, which provide an ISO Class 5 (see [Table 1](#)) environment for the exposure of critical sites. PECs shall maintain ISO Class 5 (see [Table 1](#)) or better conditions for 0.5-µm particles (dynamic operating conditions) while compounding CSPs. Secondary engineering controls such as buffer areas and ante-areas generally serve as a core for the location of the PEC. Buffer areas are designed to maintain at least ISO Class 7 (see [Table 1](#)) conditions for 0.5-µm particles under dynamic conditions and ISO Class 8 (see [Table 1](#)) conditions for 0.5-µm and larger particles under dynamic conditions for the ante-areas. Airborne contamination control is achieved in the PEC through the use of HEPA filters. The airflow in the PEC shall be unidirectional (laminar flow), and because of the particle collection efficiency of the filter, the “first air” at the face of the filter is, for the purposes of aseptic compounding, free from airborne particulate contamination. HEPA-filtered air shall be supplied in critical areas (ISO Class 5, see [Table 1](#)) at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations. Proper design and control prevents turbulence and stagnant air in the critical area. In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.

The principles of HEPA filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions. Policies and procedures for maintaining and working within the PEC area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs. The CSP work environment is designed to have the cleanest work surfaces (PEC) located in a buffer area. The buffer area shall maintain at least ISO Class 7 (see [Table 1](#)) conditions for 0.5-µm and larger particles under dynamic operating conditions. The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area.

The displacement concept shall not be used for high-risk compounding.<sup>4</sup> The PEC shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC systems can disrupt the unidirectional airflow in open-faced workbenches. The operators may also create disruptions in airflow

by their own movements and by the placement of objects onto the work surface. The PEC shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross-drafts. Room air exchanges are typically expressed as ACPHs. Adequate HEPA filtered airflow supplied to the buffer area and ante area is required to maintain cleanliness classification during operational activity through the number of ACPHs. Factors that should be considered when determining air change requirements include number of personnel working in the room and compounding processes that generate particulates, as well as temperature effects. An ISO Class 7 (see [Table 1](#)) buffer area and ante area supplied with HEPA filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA filtered air. If the area has an ISO Class 5 (see [Table 1](#)) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA filtered make-up air. Ceiling-mounted returns are not recommended. All HEPA filters should be efficiency tested using the most penetrating particle size and should be leak tested at the factory and then leak tested again in situ after installation.<sup>5</sup>

Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants. Whenever such items are brought into the area, they shall first be cleaned and disinfected. Whenever possible, equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing, or other activities associated with the proper maintenance of the item.

The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents. Junctures of ceilings to walls shall be covered or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame. Walls may be constructed of flexible material (e.g., heavy gauge polymer), panels locked together and sealed, or of epoxy-coated gypsum board. Preferably, floors are overlaid with wide sheet vinyl flooring with heat welded seams and coving to the sidewall. Dust collecting overhangs, such as ceiling utility pipes, and ledges, such as windowsills, should be avoided. The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls shall be sealed. The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. Carts should be of stainless steel wire, nonporous plastic, or sheet metal

construction with good quality, cleanable casters to promote mobility. Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection.

### **Placement of Primary Engineering Controls**

PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see [Table 1](#)) buffer area (see [Figure 1](#)), with the following CAI/CACI exceptions below:

- Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area.
- Presterilization procedures for high risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see [Table 1](#)) environment.
- PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

CAIs and CACIs shall be placed in an ISO Class 7 (see [Table 1](#)) buffer area *unless* they meet all of the following conditions:

- The isolator shall provide isolation from the room and maintain ISO Class 5 (see [Table 1](#)) during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 (see [Table 1](#)) levels during compounding operations.
- Not more than 3520 particles (0.5  $\mu\text{m}$  and larger) per  $\text{m}^3$  shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.<sup>6</sup>

It is incumbent on the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 (see [Table 1](#)) for 0.5  $\mu\text{m}$  and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see [Table 1](#)) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 (see [Table 1](#)) buffer area, then only low risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

### **Viable and Nonviable Environmental Sampling (ES) Testing**

The ES program should provide information to staff and leadership to demonstrate that the PEC is maintaining an environment within the compounding area that consistently ensures acceptably low viable and nonviable particle levels. The compounding area includes the ISO Class 5 (see [Table 1](#)) PEC (LAFWs, BSCs, CAIs, and CACIs), buffer areas, ante areas, and segregated compounding areas.

Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally under any of the following conditions:

- as part of the commissioning and certification of new facilities and equipment;
- following any servicing of facilities and equipment;
- as part of the re-certification of facilities and equipment (i.e., every 6 months);
- in response to identified problems with end products or staff technique; or
- in response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection).

#### ENVIRONMENTAL NONVIAIBLE PARTICLE TESTING PROGRAM

A program to sample nonviable airborne particles differs from that for viable particles in that it is intended to directly measure the performance of the engineering controls used to create the various levels of air cleanliness, for example, ISO Class 5, 7, or 8 (see [Table 1](#)).

**Engineering Control Performance Verification**—PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. Certification procedures such as those outlined in *Certification Guide for Sterile Compounding Facilities (CAG-003-2006)*<sup>7</sup> shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.

**Total Particle Counts**—Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see [Table 1](#)), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante area has been altered. Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following:

- ISO Class 5: not more than 3520 particles 0.5 µm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI;
- ISO Class 7: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area;
- ISO Class 8: not more than 3,520,000 particles or 0.5 µm size and larger per cubic meter of air for any ante area.

All certification records shall be maintained and reviewed by supervising personnel or other designated employees to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs.

#### PRESSURE DIFFERENTIAL MONITORING

A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 (see [Table 1](#)) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low and medium risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.

#### ENVIRONMENTAL VIABLE AIRBORNE PARTICLE TESTING PROGRAM

The risk of contaminating a CSP prepared under low risk level and medium risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and the presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class 5 (see [Table 1](#)) PEC and secondary engineering controls, ISO Class 7 (see [Table 1](#)) buffer area, and ISO Class 8 (see [Table 1](#)) ante-area. High risk level CSPs pose the greatest threat to patients because compounding personnel are tasked with the requirement of processing nonsterile components and devices in order to achieve sterility.

A sampling program in conjunction with an observational audit is designed to evaluate the competency of compounding personnel work practices, allowing for the implementation of corrective actions on an ongoing basis (see *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*).

**Sampling Plan**—An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.

Selected sampling sites shall include locations within each ISO Class 5 (see [Table 1](#)) environment and in the ISO Class 7 and 8 (see [Table 1](#)) areas and in the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 [see [Table 1](#)] environment, counters near doors, pass-through boxes). The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

Review of the data generated during a sampling event may detect elevated amounts of airborne microbial bioburden; such changes may be indicative of adverse changes within the environment. It is recommended that compounding personnel refer to *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116) and the CDC's "Guidelines for Environmental Infection Control in Healthcare Facilities, 2003" for more information.

**Growth Medium**—A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria. Malt extract agar or some other media that supports the growth of fungi shall be used in high-risk level compounding environments. Media used for surface sampling must be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

**Viable Air Sampling**—Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments (LAFWs, CAIs, clean room or buffer areas, and ante-areas) shall be performed by properly trained individuals for all compounding risk levels.

Impaction shall be the preferred method of volumetric air sampling. Use of settling plates for qualitative air sampling may not be able to determine adequately the quality of air in the controlled environment. The settling of particles by gravity onto culture plates depends on the particle size and may be influenced by air movement. Consequently, the number of colony forming units (cfu) on a settling plate may not always relate to the concentrations of viable particles in the sampled environment.

For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within LAFW and other areas where air backwash turbulence may enter the compounding area (doorways, in and around ISO Class 5 [see [Table 1](#)] PEC and environments). Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.

For low-risk level GSPs with 12-hour or less BUD prepared in a PEC (LAFWs, BSCs, CAIs) that maintains an ISO Class 5 (see [Table 1](#)), air sampling shall be performed at locations inside the ISO Class 5 (see [Table 1](#)) environment and other areas that are in close proximity to the ISO Class 5 (see [Table 1](#)) environment during the certification of the PEC.

**Air Sampling Devices**—There are a number of manufacturers of electronic air sampling equipment. It is important that personnel refer to the manufacturer's recommended procedures when using the equipment to perform volumetric air sampling procedures. The instructions in the manufacturer's user's manual for verification and use of electric air samplers that actively collect volumes of air for evaluation must be followed. A sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity. The volumetric air sampling devices need to be serviced and calibrated as recommended by the manufacturer.

It is recommended that compounding personnel also refer to *Methodology and Instrumentation for Quantitation of Viable Airborne Microorganisms* under *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116), which provides more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.

**Air Sampling Frequency and Process**—Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment. If compounding occurs in multiple locations within an institution (e.g., main

pharmacy, satellites), environmental sampling is required for each individual compounding area. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. Any facility construction or equipment servicing may require that air sampling be performed during these events.

**Incubation Period**—At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured (e.g., taped), and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. TSA should be incubated at 30° to 35° for 48 to 72 hours. Malt extract agar or other suitable fungal media should be incubated at 26° to 30° for 5 to 7 days. The number of discrete colonies of microorganisms are counted and reported as cfu and documented on an environmental sampling form. Counts from air sampling need to be transformed into cfu per cubic meter of air and evaluated for adverse trends.

**Action Levels, Documentation, and Data Evaluation**—The value of viable microbial sampling of the air in the compounding environment is realized when the data are used to identify and correct an unacceptable situation. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

Any cfu count that exceeds its respective action level (see [Table 2](#)) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in [Table 2](#) should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

**Table 2. Recommended Action Levels for Microbial Contamination<sup>‡</sup>**  
<sup>‡</sup>(cfu per cubic meter [1000 liters] of air per plate)

Classification	Air Sample <sup>‡</sup>
ISO Class 5	>1
ISO Class 7	>10

<b>Classification</b>	<b>Air Sample†</b>
ISO Class 8 or worse	> 100

† -Guidance for Industry Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practice US HHS, FDA September 2004.

### **Additional Personnel Requirements**

Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present. When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross-contamination. Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small and large volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA), when possible in an ante-area of ISO Class 8 (see [Table 1](#)) air quality, before being passed into the buffer areas. Personnel hand hygiene and garbing procedures are also performed in the ante-area, which may contain a sink that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. There shall be some demarcation designation that separates the ante-area from the buffer area. Adequate provision for performing antiseptic hand cleansing using an alcohol-based surgical hand scrub with persistent activity followed by the donning of sterile gloves should be provided after entry into the buffer area.

### **Cleaning and Disinfecting the Compounding Area**

Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination.

The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 (see [Table 1](#)) compounding areas for exposure of critical sites as well as buffer areas, ante-areas, and segregated compounding areas. Compounding personnel are responsible for ensuring that the frequency of cleaning is in accordance with the requirements stated in [Table 3](#) and determining the cleaning and disinfecting products to be used (see [Appendix II](#)). Any organizational or institutional policies regarding disinfectant selection should be considered by compounding personnel. All cleaning and disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.

**Table 3. Minimum Frequency of Cleaning and Disinfecting Compounding Areas**

<b>Site</b>	<b>Minimum Frequency</b>
ISO Class 5 (see <a href="#">Table 1</a> ) Primary Engineering Control (e.g., LAFW, BSC, CAI, CACI)	At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or

Site	Minimum Frequency
	suspected
Counters and easily cleanable work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

The selection and use of disinfectants in healthcare facilities is guided by several properties, such as microbicidal activity, inactivation by organic matter, residue, and shelf life (see *Appendix II*). In general, highly toxic disinfectants, such as glutaraldehyde, are not used on housekeeping surfaces (e.g., floors, countertops). Many disinfectants registered by the EPA are one-step disinfectants. This means that the disinfectant has been formulated to be effective in the presence of light to moderate soiling without a pre-cleaning step.

Surfaces in LAFWs, BSCs, CAIs, and CACIs, which are intimate to the exposure of critical sites, require disinfecting more frequently than do housekeeping surfaces such as walls and ceilings. Disinfecting sterile compounding areas shall occur on a regular basis at the intervals noted in [Table 3](#) when spills occur, when the surfaces are visibly soiled, and when microbial contamination is known to have been or is suspected of having been introduced into the compounding areas.

When the surface to be disinfected has heavy soiling, a cleaning step is recommended prior to the application of the disinfectant. Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs. Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; for example, water-soluble solid residues are removed with sterile water (for injection or irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins.

Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.

Work surfaces in the ISO Class 7 (see [Table 1](#)) buffer areas and ISO Class 8 (see [Table 1](#)) ante areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see [Table 1](#)) air quality (see *Disinfectants and Antiseptics* (1072)).

Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly. In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents are to be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues (see *Appendix II*). Their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial or compounding personnel.

All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation. If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.

Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.

Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages (or a comparable method) is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.

When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 (see [Table 1](#)) PEC (LAFW, BSC, CAI, CACI) without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer or clean area or segregated compounding area.

### **Personnel Cleansing and Garbing**

The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs. Squamous cells are normally shed from the human body at a rate

of 10<sup>6</sup> or more per hour, and those skin particles are laden with microorganisms.<sup>8,9</sup> When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see [Table 1](#)) and ISO Class 7 (see [Table 1](#)) compounding areas until their conditions are remedied.

Before entering the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), compounding personnel shall remove personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.

Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields. Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs.

After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-area. The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lint-free disposable towels or an electronic hand dryer. After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned. Gowns designated for buffer area use shall be worn, and preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use.

Once inside the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity<sup>10</sup> following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves.

Sterile gloves shall be the last item donned before compounding begins. Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Only use gloves that have been tested for compatibility with alcohol disinfection by the manufacturer. Routine application of sterile 70% IPA shall occur throughout the compounding process and whenever nonsterile surfaces (e.g.

vials, counter tops, chairs, carts) are touched. Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected. Antiseptic hand cleansing shall be performed as indicated above. Compounding personnel shall be trained and evaluated in the avoidance of touching critical sites.

When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face masks/eye shields, and gloves shall be replaced with new ones before re-entering the compounding area, and proper hand hygiene shall be performed.

During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 (see [Table 1](#)) environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 (see [Table 1](#)) shall re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 (see [Table 1](#)) buffer area. When CAIs and GAGIs are the source of the ISO Class 5 (see [Table 1](#)) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.

### **Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures**

Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 (see [Table 1](#)) environmental conditions, and cleaning and disinfection procedures. This training shall be completed and documented before any compounding personnel begin to prepare CSPs. Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing (see *Appendices III–V*).

Media fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding and semiannually for high-risk level compounding.

Compounding personnel who fail written tests or observational audits or whose media-fill test vials have one or more units showing visible microbial contamination shall be re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations. In addition to didactic evaluation and aseptic media fill, compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures.

In the event that cleaning and disinfecting procedures are also performed by other support personnel (e.g., institutional environmental services, housekeeping), thorough

training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.

#### COMPETENCY EVALUATION OF GARBING AND ASEPTIC WORK PRACTICE

The risk of contaminating a CSP prepared under low-risk level and medium-risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and the presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class 5 (see [Table 1](#)) PEC and secondary engineering controls, ISO Class 7 (see [Table 1](#)) buffer area, and ISO Class 8 (see [Table 1](#)) ante-area. High-risk level CSPs pose the greatest threat to patients because compounding personnel are tasked with the requirement of processing nonsterile components and devices in order to achieve sterility. Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a form such as the *Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* (see [Appendix III](#)) and the personnel glove fingertip sampling procedures indicated below.

**Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling**—Sampling of compounding personnel glove fingertips shall be performed for all CSP risk level compounding because direct touch contamination is the most likely source of introducing microorganisms into CSPs prepared by humans. Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices, which include frequent and repeated glove disinfection using sterile 70% IPA during actual compounding of CSPs. All personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).

Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media fill preparation (without applying sterile 70% IPA) in order to assess the adequacy of aseptic work practices prior to being initially allowed to prepare CSPs for human use and for more experienced personnel to maintain their qualifications to prepare CSPs for human use.

**Garbing And Gloving Competency Evaluation**—Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures (see *Personnel Cleansing and Garbing under Personnel Training and Evaluation in Aseptic Manipulation Skills* above). The visual observation shall be documented on a form such as the *Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* (see [Appendix III](#)) and maintained to provide a permanent record and long-term assessment of personnel competency.

**Gloved Fingertip Sampling**—All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use. Immediately after the compounding employee completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature (see *Incubation Period*). After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use.

Immediately prior to sampling, gloves shall not be disinfected with sterile 70% IPA. Disinfecting gloves immediately before sampling will provide false negative results. Plates filled with nutrient agar with neutralizing agents such as lecithin and polysorbate 80 added shall be used when sampling personnel fingertips. Personnel shall “touch” the agar with the fingertips of both hands in separate plates in a manner to create a slight impression in the agar. The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below (see *Incubation Period*). Results should be reported separately as number of cfu per employee per hand (left hand, right hand). The cfu action level for gloved hands will be based on the total number of cfu on both gloves, not per hand.

**Incubation Period**—At the end of the designated sampling period for compounding personnel competency assessment activities (surface or personnel), the agar plates are recovered and covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. TSA with lecithin and polysorbate 80 shall be incubated at 30° to 35° for 48 to 72 hours.

**Aseptic Manipulation Competency Evaluation**—After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the *Media-Fill Test Procedure* and subsequent annual or semi-annual *Media-Fill Test Procedures*. Records of these evaluations will be maintained using a form such as the *Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel* (see *Appendix IV*) and maintained to provide a permanent record of and long-term assessment of personnel competency.

**Media-Fill Test Procedure**—The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media fill verification, (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media-fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests shall represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare low- and medium-risk level CSPs and when sterilizing high-risk level CSPs. Media fill challenge tests are also used to verify

the capability of the compounding environment and processes to produce sterile preparations.

A commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium (see *Sterility Tests* (71)), that is able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment is commonly used. For high-risk level CSPs nonsterile commercially available Soybean–Casein Digest Medium may be used to make a 3% solution. Normal processing steps, including filter sterilization, shall be mimicked. Media filled vials shall be incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)). Failure is indicated by visible turbidity in any one of the media-fill units on or before 14 days. Other methodologies recommended by a competent microbiologist to enhance recovery time and sensitivity to detect microbial contamination may be considered (see *CSP Microbial Contamination Risk Levels* for examples of media-fill procedures).

#### SURFACE CLEANING AND DISINFECTION SAMPLING AND ASSESSMENT

Surface sampling is an important component of the maintenance of a suitable microbially controlled environment for compounding CSPs, especially since transfer of microbial contamination from improperly disinfected work surfaces via inadvertent touch contact by compounding personnel can be a potential source of contamination into CSPs. It is useful for evaluating facility and work surface cleaning and disinfecting procedures and employee competency in work practices such as disinfection of component/vial surface cleaning. Surface sampling shall be performed in all ISO classified areas on a periodic basis. Sampling can be accomplished using contact plates or swabs, and it shall be done at the conclusion of compounding. Locations to be sampled shall be defined in a sample plan or on a form. The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm<sup>2</sup>. Contact plates are filled with general solid agar growth medium and neutralizing agents above the rim of the plate, and they are used for sampling regular or flat surfaces. Swabs may be used for sampling irregular surfaces, especially for equipment (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)).

**Cleaning and Disinfecting Competency Evaluation**—Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures, during initial personnel training on cleaning procedures, during changes in cleaning staff, and at the completion of any media-fill test procedure (see *Cleaning and Disinfecting of Compounding Areas*).

The visual observation shall be documented using a form such as the *Sample Form for Assessing Cleaning and Disinfection Procedures* (see *Appendix V*) and maintained to provide a permanent record and long term assessment of personnel competency.

**Surface Collection Methods**—To sample surfaces using a contact plate, gently touch the sample area with the agar surface and roll the plate across the surface to be sampled. The contact plate will leave a growth media residue behind; therefore, immediately after sampling with the contact plate, the sampled area shall be thoroughly wiped with a nonshedding wipe soaked in sterile 70% IPA.

If an area is sampled via the swab method, collection of the sample is processed by using appropriate procedures that will result in the surface location equivalent to that of a contact plate. After swabbing the surface to be sampled, swabs are placed in an appropriate diluent; an aliquot is planted on or in the specified nutrient agar. Results should be reported as cfu per unit of surface area.

### **Action Levels, Documentation, and Data Evaluation**

The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

Any cfu count that exceeds its respective action level (see [Table 4](#)) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or working practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

When gloved fingertip sample results exceed action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented. Employee training may be required to correct the source of the problem.

Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in [Table 4](#) should be used only as guidelines. Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

**Table 4. Recommended Action Levels for Microbial Contamination<sup>5</sup>**

<b>Classification</b>	<b>Fingertip Sample</b>	<b>Surface Sample (Contact Plate) (cfu per plate)</b>
ISO Class 5	>3	>3
ISO Class 7	N/A	>5
ISO Class 8 or worse	N/A	>100

<sup>5</sup> - Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products Annexes PE-009-6, 5 April 2007.

## **SUGGESTED STANDARD OPERATING PROCEDURES (SOPS)**

The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared. The following procedures are recommended:

1. ~~Access to the buffer area is restricted to qualified personnel with specific responsibilities or assigned tasks in the compounding area.~~
2. ~~All cartoned supplies are decontaminated in the area by removing them from shipping cartons and wiping or spraying them with a nonresidue-generating disinfecting agent while they are being transferred to a clean and properly disinfected cart or other conveyance for introduction into the buffer area. Manufacturers' directions or published data for minimum contact time will be followed. Individual pouched sterile supplies need not be wiped because the pouches can be removed as these sterile supplies are introduced into the buffer area.~~
3. ~~Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift are decontaminated and stored on shelving in the ante-area.~~
4. ~~Carts used to bring supplies from the storeroom cannot be rolled beyond the demarcation line in the ante-area, and carts used in the buffer area cannot be rolled outward beyond the demarcation line unless cleaned and disinfected before returning.~~
5. ~~Generally, supplies required for the scheduled operations of the shift are wiped down with an appropriate disinfecting agent and brought into the buffer area, preferably on one or more movable carts. Supplies that are required for back-up or general support of operations may be stored on the designated shelving in the buffer area, but excessive amounts of supplies are to be avoided.~~
6. ~~Nonessential objects that shed particles shall not be brought into the buffer area, including pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads).~~
7. ~~Essential paper-related products (e.g., paper syringe overwraps, work records contained in a protective sleeve) shall be wiped down with an appropriate disinfecting agent prior to being brought into the buffer area.~~
8. ~~Traffic flow in and out of the buffer area shall be minimized.~~
9. ~~Personnel preparing to enter the buffer area shall remove all personal outer garments, cosmetics (because they shed flakes and particles), and all hand, wrist, and other visible jewelry or piercings that can interfere with the effectiveness of PPE.~~
10. ~~Personnel entering the ante-area shall don attire as described in *Personnel Cleansing and Garbing* and *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*.~~
11. ~~Personnel shall then thoroughly wash hands and forearms to the elbow with soap and water for at least 30 seconds. An air dryer or disposable nonshedding towels are used to dry hands and forearms after washing.~~

12. Personnel entering the buffer area shall perform antiseptic hand cleansing prior to donning sterile gloves using a waterless alcohol-based surgical hand scrub with persistent activity.
13. Chewing gum, drinks, candy, or food items shall not be brought into the buffer area or ante area. Materials exposed in patient care and treatment areas shall never be introduced into areas where components and ingredients for CSPs are present.
14. At the beginning of each compounding activity session, and whenever liquids are spilled, the surfaces of the direct compounding environment are first cleaned with USP Purified Water to remove water-soluble residues. Immediately thereafter, the same surfaces are disinfected with a nonresidue-generating agent using a nonlinting wipe.
15. Primary engineering controls shall be operated continuously during compounding activity. When the blower is turned off and before other personnel enter to perform compounding activities, only one person shall enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and disinfecting the work surfaces.
16. Traffic in the area of the DCA is minimized and controlled.
17. Supplies used in the DCA for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surface with sterile 70% IPA or removing the outer wrap at the edge of the DCA as the item is introduced into the aseptic work area.
18. All supply items are arranged in the DCA so as to reduce clutter and provide maximum efficiency and order for the flow of work.
19. After proper introduction into the DCA of supply items required for and limited to the assigned operations, they are so arranged that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures. That is, no objects may be placed between the first air from HEPA filters and an exposed critical site.
20. All procedures are performed in a manner designed to minimize the risk of touch contamination. Gloves are disinfected with adequate frequency with an approved disinfectant such as sterile 70% IPA.
21. All rubber stoppers of vials and bottles and the necks of ampuls are disinfected by wiping with sterile 70% IPA and waiting for at least 10 seconds before they are used to prepare CSPs.
22. After the preparation of every CSP, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects.
23. After procedures are completed, used syringes, bottles, vials, and other supplies are removed, but with a minimum of exit and re-entry into the DCA so as to minimize the risk of introducing contamination into the aseptic workspace.

### **ELEMENTS OF QUALITY CONTROL**

A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile

products shall be developed for each site. This program equips personnel with the appropriate knowledge and trains them in the required skills necessary to perform the assigned tasks. Each person assigned to the aseptic area in the preparation of sterile products shall successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs (see *Personnel Training and Evaluation in Aseptic Manipulation Skills* and *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*).

### **Ingredients and Devices**

Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality using the following information: vendor labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding facility storage conditions.

#### **STERILE INGREDIENTS AND DEVICES**

Commercially available sterile drug products, sterile ready-to-use containers, and devices are examples of sterile components. A written procedure for unit-by-unit physical inspection preparatory to use is followed to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use.

#### **NONSTERILE INGREDIENTS AND DEVICES**

If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk. Nonsterile active ingredients and added substances or excipients for CSPs should preferably be official *USP* or *NF* articles. When nonofficial ingredients are used, they shall be accompanied by certificates of analysis from their suppliers to aid compounding personnel in judging the identity, quality, and purity in relation to the intended use in a particular CSP. Physical inspection of a package of ingredients is necessary in order to detect breaks in the container, looseness in the cap or closure, and deviation from the expected appearance, aroma, and texture of the contents.

Bulk or unformulated drug substances and added substances or excipients shall be stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers. The date of receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient. After receipt by the compounding facility, packages of ingredients that lack a supplier's expiration date cannot be used after 1 year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.

Careful consideration and evaluation of nonsterile ingredient sources is especially warranted when the CSP will be administered into the vascular system, central nervous system, or eyes.

Upon receipt of each lot of the bulk drug substance or excipient used for CSPs, the individual compounding the preparation performs a visual inspection of the lot for evidence of deterioration, other types of unacceptable quality, and wrong identification. For bulk drug substances or excipients, visual inspection is performed on a routine basis as described in the written protocol.

### **Equipment**

It is necessary that equipment, apparatus, and devices used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits. Written procedures outlining required equipment calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities are established and followed. Routine maintenance and frequencies shall be outlined in these SOPs. Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment. Personnel are prepared through an appropriate combination of specific training and experience to operate or manipulate any piece of equipment, apparatus, or device they may use when preparing CSPs. Training includes gaining the ability to determine whether any item of equipment is operating properly or is malfunctioning.

## **VERIFICATION OF AUTOMATED COMPOUNDING DEVICES (ACDs) FOR PARENTERAL NUTRITION COMPOUNDING**

ACDs for the preparation of parenteral nutrition admixtures are widely used by pharmacists in hospitals and other healthcare settings. They are designed to streamline the labor-intensive processes involved in the compounding of these multiple-component formulations by automatically delivering the individual nutritional components in a predetermined sequence under computerized control. Parenteral nutrition admixtures often contain 20 or more individual additives representing as many as 50 or more individual components (e.g., 15 to 20 crystalline amino acids, dextrose monohydrate, and lipids; 10 to 12 electrolyte salts; 5 to 7 trace minerals; and 12 vitamins). Thus, ACDs can provide improved accuracy and precision of the compounding process over the traditional manual compounding methods.

### **Accuracy**

The accuracy of an ACD can be determined in various ways to ensure that the correct quantities of nutrients, electrolytes, or other nutritional components are delivered to the final infusion container. Initially, the ACD is tested for its volume and weight accuracy. For volume accuracy, a suitable volume of Sterile Water for Injection, USP, which represents a typical additive volume (e.g., 40 mL for small-volume range of 1 to 100 mL, 300 mL for large-volume range of 100 to 1000 mL), is programmed into the ACD and delivered to the appropriate volumetric container. The compounding personnel should then consult *Volumetric Apparatus* (31) for appropriate parameters to assess the volumetric performance of the ACD. For gravimetric accuracy, the balance used in conjunction with the ACD is tested using various weight sizes that represent the amounts typically used to deliver the various additives. Compounding personnel should consult <sup>\*</sup>*Balances* (41) <sub>(CN 1 May 2016)</sub> for acceptable tolerances of the weights used. In addition, the same volume of *Sterile Water for Injection* used to assess volumetric accuracy is then weighed on the balance used in conjunction with the ACD. For example, if 40 mL of water was used in the volumetric assessment, its corresponding weight should be about 40 g (assuming the relative density of water is 1.0). In addition, during the use of the ACD, certain additives, such as potassium chloride (corrected for density differences), can also be tested in the same manner as with an in-process test.

Finally, additional tests of accuracy may be employed that determine the content of certain ingredients in the final volume of the parenteral nutrition admixture. Generally, pharmacy departments do not have the capability to routinely perform chemical analyses such as analyses of dextrose or electrolyte concentrations. Consequently, hospital or institutional laboratories may be called upon to perform these quality assurance tests. However, the methods in such laboratories are often designed for biological, not pharmaceutical, systems. Thus, their testing procedures shall be verified to meet the *USP* requirements stated in the individual monograph for the component being tested. For example, under *Dextrose Injection*, the following is stated: It contains not less than 95.0% and not more than 105.0% of the labeled amount of  $C_6H_{12}O_6 \cdot H_2O$ . The hospital or institutional chemistry laboratories must validate their methods to apply to this range and correct for their typical measurement of anhydrous dextrose versus dextrose monohydrate. Similar ranges and issues exist, for example, for injections of calcium gluconate, magnesium sulfate, and potassium chloride. The critical point is the use of *USP* references and possible laboratory procedural differences.

### **Precision**

The intermediate precision of the ACD can be determined on the basis of the day-to-day variations in performance of the accuracy measures. Thus, compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant cumulative errors over time. This is especially true for additives with a narrow therapeutic index, such as potassium chloride.

## **FINISHED PREPARATION RELEASE CHECKS AND TESTS**

The following quality metrics shall be performed for all CSPs before they are dispensed or administered.

### **Inspection of Solution Dosage Forms and Review of Compounding Procedures**

All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed. The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.

#### **PHYSICAL INSPECTION**

Finished CSPs are individually inspected in accordance with written procedures after compounding. If not distributed promptly, these CSPs are individually inspected just prior to leaving the storage area. Those CSPs that are not immediately distributed are stored in an appropriate location as described in the written procedures. Immediately after compounding, and as a condition of release, each CSP unit, where possible, should be inspected against lighted white or black background or both for evidence of visible particulates or other foreign matter. Prerelease inspection also includes container closure integrity and any other apparent visual defect. CSPs with observed

defects should be immediately discarded or marked and segregated from acceptable products in a manner that prevents their administration. When CSPs are not distributed promptly after preparation, a predistribution inspection is conducted to ensure that a CSP with defects, such as precipitation, cloudiness, and leakage, which may develop between the time of release and the time of distribution, is not released.

### **Compounding Accuracy Checks**

Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release. The double-check system should meet state regulations and include label accuracy and accuracy of the addition of all drug products or ingredients used to prepare the finished product and their volumes or quantities. The used additive containers and, for those additives for which the entire container was not expended, the syringes used to measure the additive should be quarantined with the final products until the final product check is completed. Compounding personnel shall visually confirm that ingredients measured in syringes match the written order being compounded. Preferably, a person other than the compounder can verify that correct volumes of correct ingredients were measured to make each CSP. For example, compounding personnel would pull the syringe plunger back to the volume measured.

When practical, the accuracy of measurements is confirmed by weighing a volume of the measured fluid, then calculating that volume by dividing the weight by the accurate value of the density, or specific gravity, of the measured fluid. Correct density or specific gravity values programmed in ACDs, which measure by weight using the quotient of the programmed volume divided by the density or specific gravity, shall be confirmed to be accurate before and after delivering volumes of the liquids assigned to each channel or port. These volume accuracy checks and the following additional safety and accuracy checks in this section shall be included in the SOP manual of the CSP facility.

### **Sterility Testing**

All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see *Sterility Tests* (71)) before they are dispensed or administered. The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration* method or the *USP Direct Inoculation of the Culture Medium* method where the *Membrane Filtration* method is not feasible.

When high-risk level CSPs are dispensed before receiving the results of their sterility tests, there shall be a written procedure requiring daily observation of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens. In addition, the patient and the physician of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. Positive sterility test results should prompt a rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance

controls to identify sources of contamination and correct problems in the methods or processes.

### **Bacterial Endotoxin (Pyrogen) Testing**

All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* (85) and *Pyrogen Test* (151)). In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in *Bacterial Endotoxins Test* (85) referenced above for the appropriate route of administration.

### **Identity and Strength Verification of Ingredients**

Compounding facilities shall have at least the following written procedures for verifying the correct identity and quality of CSPs before they are dispensed and administered:

1. That labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.
2. That there are correct identities, purities, and amounts of ingredients by comparing the original written order with the written compounding record for the CSP.
3. That correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients.

### **STORAGE AND BEYOND-USE DATING**

BUDs for compounded preparations are usually assigned on the basis of professional experience, which should include careful interpretation of appropriate information sources for the same or similar formulations (see *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* (795)). BUDs for CSPs are rarely based on preparation-specific chemical assay results, which are used with the Arrhenius equation to determine expiration dates (see *General Notices and Requirements*) for manufactured products. The majority of CSPs are aqueous solutions in which hydrolysis of dissolved ingredients is the most common chemical degradation reaction. The extent of hydrolysis and other heat-catalyzed degradation reactions at any particular time point in the life of a CSP represents the thermodynamic sum of exposure temperatures and durations. Such lifetime stability exposure is represented in the mean kinetic temperature calculation (see *Pharmaceutical Calculations in Prescription Compounding* (1160)). Drug hydrolysis rates increase exponentially with arithmetic

temperature increase; thus, exposure of a beta-lactam antibiotic solution for 1 day at controlled room temperature (see *General Notices and Requirements*) will have an equivalent effect on the extent of hydrolysis of approximately 3 to 5 days in cold temperatures (see *General Notices and Requirements*).

Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs. When CSPs are known to have been exposed to temperatures warmer than the warmest labeled limit or to temperatures exceeding 40° (see *General Notices and Requirements*) for more than 4 hours, such CSPs should be discarded unless direct assay data or appropriate documentation confirms their continued stability.

### **Determining Beyond-Use Dates**

BUDs and expiration dates are not the same (see *General Notices and Requirements*). Expiration dates for the chemical and physical stability of manufactured sterile products are determined from results of rigorous analytical and performance testing, and they are specific for a particular formulation in its container and at stated exposure conditions of illumination and temperature. When CSPs deviate from conditions in the approved labeling of manufactured products contained in CSPs, compounding personnel may consult the manufacturer of particular products for advice on assigning BUDs based on chemical and physical stability parameters. BUDs for CSPs that are prepared strictly in accordance with manufacturers' product labeling shall be those specified in that labeling or from appropriate literature sources or direct testing. BUDs for CSPs that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* (795).

In addition, compounding personnel may refer to applicable publications to obtain relevant stability, compatibility, and degradation information regarding the drug or its congeners. When assigning a beyond-use date, compounding personnel should consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy (see *Expiration Date and Beyond-Use Date* under *Labeling* in the *General Notices and Requirements*). Stability information must be carefully interpreted in relation to the actual compounded formulation and conditions for storage and use. Predictions based on other evidence, such as publications, charts, and tables, would result in theoretical BUDs. Theoretically predicted beyond-use dating introduces varying degrees of assumptions and, hence, a likelihood of error or at least inaccuracy. The degree of error or inaccuracy would be dependent on the extent of differences between the CSPs' characteristics (e.g., composition, concentration of ingredients, fill volume, container type and material) and the characteristics of the products from which stability data or information is to be extrapolated. The greater the doubt of the accuracy of theoretically predicted beyond-use dating, the greater the need to determine dating periods experimentally. Theoretically predicted beyond-use dating periods should be carefully considered for CSPs prepared from nonsterile bulk active ingredients having therapeutic activity, especially where these CSPs are expected to be compounded routinely. When CSPs will be distributed to and administered in residential locations other than healthcare facilities, the effect of potentially uncontrolled and

unmonitored temperature conditions shall be considered when assigning BUDs. It must be ascertained that CSPs will not be exposed to warm temperatures (see *General Notices and Requirements*) unless the compounding facility has evidence to justify stability of CSPs during such exposure.

It should be recognized that the truly valid evidence of stability for predicting beyond-use dating can be obtained only through product-specific experimental studies. Semiquantitative procedures such as thin-layer chromatography (TLC) may be acceptable for many CSPs. However, quantitative stability-indicating assays such as high-performance liquid chromatographic (HPLC) assays would be more appropriate for certain CSPs. Examples include CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity; where a theoretically established beyond-use dating period is supported by only marginal evidence; or where a significant margin of safety cannot be verified for the proposed beyond-use dating period. In short, because beyond-use dating periods established from product-specific data acquired from the appropriate instrumental analyses are clearly more reliable than those predicted theoretically, the former approach is strongly urged to support dating periods exceeding 30 days.

To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products. When attempting to predict a theoretical BUD, a compounded or an admixed preparation should be considered as a unique system that has physical and chemical properties and stability characteristics that differ from its components. For example, antioxidant, buffering, or antimicrobial properties of a sterile vial for injection (SVI) might be lost upon its dilution, with the potential of seriously compromising the chemical stability of the SVI's active ingredient or the physical or microbiological stability of the SVI formulation in general. Thus, the properties stabilized in the SVI formulation usually cannot be expected to be carried over to the compounded or admixed preparation. Preparation-specific, experimentally determined stability data evaluation protocols are preferable to published stability information.

Compounding personnel who assign BUDs to CSPs when lacking direct chemical assay results must critically interpret and evaluate the most appropriate available information sources to determine a conservative and safe BUD. The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions.

When manufactured MDVs (see *Multiple-Dose Container* under *Preservation, Packaging, Storage, and Labeling* in the *General Notices and Requirements*) of sterile ingredients are used in CSPs, the stoppers of the MDVs are inspected for physical integrity and disinfected by wiping with a sterile 70% IPA swab before each penetration with a sterile withdrawal device. When contaminants or abnormal properties are suspected or observed in MDVs, such MDVs shall be discarded. The BUD after initially entering or opening (e.g., needle puncturing) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* (51)) unless otherwise specified by the manufacturer.

### **Proprietary Bag and Vial Systems**

The sterility storage and stability beyond-use times for attached and activated (where activated is defined as allowing contact of the previously separate diluent and drug

contents) container pairs of drug products for intravascular administration (e.g., ADD-Vantage®, Mini Bag Plus®) shall be applied as indicated by the manufacturer. In other words, follow manufacturers' instructions for handling and storing ADD-Vantage®, Mini Bag Plus®, Add A Vial®, Add Ease® products, and any others.

### **Monitoring Controlled Storage Areas**

To ensure that product potency is retained through the manufacturer's labeled expiration date, compounding personnel shall monitor the drug storage areas within the compounding facility. Controlled temperature areas in compounding facilities include controlled room temperature, 20° to 25° with mean kinetic temperature 25°; controlled cold temperature, 2° to 8° with mean kinetic temperature 8°; cold temperature, 2° to 8°; freezing temperature, -25° and -10° (see *General Notices and Requirements*) if needed to achieve freezing, and the media-specific temperature range for microbial culture media. A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations. Suitable temperature recording devices may include a calibrated continuous recording device or a National Institute of Standards and Technology (NIST) calibrated thermometer that has adequate accuracy and sensitivity for the intended purpose, and it shall be properly calibrated at suitable intervals. If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly.

The temperature-sensing mechanisms shall be suitably placed in the controlled temperature storage space to reflect accurately its true temperature. In addition, the compounding facility shall adhere to appropriate procedures of all controlled storage spaces to ensure that such spaces are not subject to significantly prolonged temperature fluctuations as may occur, for example, by leaving a refrigerator door open too long.

### **MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPS**

This section summarizes the responsibilities of compounding facilities for maintaining quality and control of CSPs that are dispensed and administered within their parent healthcare organizations.

Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients. In fulfilling this general responsibility, the compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions.

Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility. Where noncompounding personnel are assigned tasks

involving any of these responsibilities, the policies and procedures encompassing those tasks should be developed by compounding supervisors. The quality and control activities related to distribution of CSPs are summarized in the following five subsections. Activities or concerns that should be addressed as the compounding facility fulfills these responsibilities are as follows.

### **Packaging, Handling, and Transport**

Inappropriate processes or techniques involved with packaging, handling, and transport can adversely affect quality and package integrity of CSPs. Although compounding personnel routinely perform many of the tasks associated with these functions, some tasks, such as transport, handling, and placement into storage, may be fulfilled by noncompounding personnel who are not under the direct administrative control of the compounding facility. Under these circumstances, appropriate SOPs shall be established by the compounding facility with the involvement of other departments or services whose personnel are responsible for carrying out those CSP-related functions for which the compounding facility has a direct interest. The performance of the noncompounding personnel is monitored for compliance to established policies and procedures.

The critical requirements that are unique to CSPs and that are necessary to ensure CSP quality and packaging integrity shall be addressed in SOPs. For example, techniques should be specified to prevent the depression of syringe plungers or dislodging of syringe tips during handling and transport. Additionally, disconnection of system components (e.g., where CSPs are dispensed with administration sets attached to them) shall be prevented through the BUD of the CSP. Foam padding or inserts are particularly useful where CSPs are transported by pneumatic tube systems. Regardless of the methods used, the compounding facility must evaluate their effectiveness and the reliability of the intended protection. Evaluation should be continuous—for example, through a surveillance system, including a system of problem reporting to the compounding facility.

Inappropriate transport and handling can adversely affect the quality of certain CSPs having unique stability concerns. For example, the physical shaking that might occur during pneumatic tube transport or undue exposure to heat or light must be addressed on a preparation-specific basis. Alternative transport modes or special packaging measures might be needed for the proper assurance of quality of these CSPs. The use of tamper-evident closures and seals on CSP ports can add an additional measure of security to ensure product integrity regardless of the transport method used.

Chemotoxic and other hazardous CSPs require safeguards to maintain the integrity of the CSP and to minimize the exposure potential of these products to the environment and to personnel who may come in contact with them. Transportation by pneumatic tube should be discouraged because of potential breakage and contamination. Special requirements associated with the packaging, transport, and handling of these agents include the prevention of accidental exposures or spills and the training of personnel in the event of an exposure or spill. Examples of special requirements of these agents also include exposure-reducing strategies such as the use of Luer-lock syringes and connections, syringe caps, the capping of container ports, sealed plastic bags, impact-resistant containers, and cautionary labeling.

## **Use and Storage**

The compounding facility is responsible for ensuring that CSPs in the patient-care setting maintain their quality until administered. The immediate labeling of the CSP container will display prominently and understandably the requirements for proper storage and expiration dating. Delivery and patient care setting personnel shall be properly trained to deliver the CSP to the appropriate storage location. Outdated and unused CSPs shall be returned to the compounding facility for disposition.

SOPs must exist to ensure that storage conditions in the patient care setting are suitable for the CSP specific storage requirements. Procedures include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8° and the monthly inspection of all drug storage locations by compounding personnel. Inspections shall confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of MDVs, and the avoidance of using single-dose products as MDVs. CSPs, as well as all other drug products, shall be stored in the patient care area in such a way as to secure them from unauthorized personnel, visitors, and patients.

## **Readying for Administration**

Procedures essential for generally ensuring quality, especially sterility assurance, when readying a CSP for its subsequent administration include proper hand washing, aseptic technique, site care, and change of administration sets. Additional procedures may also be essential for certain CSPs, devices, or techniques. Examples where such special procedures are needed include in-line filtration, the operation of automated infusion control devices, and the replenishment of CSPs into the reservoirs of implantable or portable infusion pumps. When CSPs are likely to be exposed to warmer than 30° for more than 1 hour during their administration to patients, the maintenance of their sterility and stability should be confirmed from either relevant and reliable sources or direct testing.

## **Redispensed CSPs**

The compounding facility shall have the sole authority to determine when unopened, returned CSPs may be redispensed. Returned CSPs may be redispensed only when personnel responsible for sterile compounding can ensure that such CSPs are sterile, pure, and stable (contain labeled strength of ingredients). The following may provide such assurance: the CSPs were maintained under continuous refrigeration and protected from light, if required, and no evidence of tampering or any readying for use outside the compounding facility exists. Assignment of new storage times and BUDs that exceed the original dates for returned CSPs is permitted only when there is supporting evidence from sterility testing and quantitative assay of ingredients. Thus, initial preparation and thaw times should be documented and reliable measures should have been taken to prevent and detect tampering. Compliance with all procedures associated with maintaining product quality is essential. The CSPs shall not be redispensed if there is not adequate assurance that preparation quality and packaging integrity (including the connections of devices, where applicable) were continuously maintained between the time the CSPs left and the time they were returned.

Additionally, CSPs shall not be redispensed if redispensing cannot be supported by the originally assigned BUD.

### **Education and Training**

The assurance of CSPs' quality and packaging integrity is highly dependent on the proper adherence of all personnel to the pertinent SOPs. Compounding personnel shall design, implement, and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed in the foregoing sections and all personnel to whom such functions and tasks are assigned. This program includes the assessment and documentation of procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration, such as extravasation. This program should be coordinated with the institution's adverse events and incident reporting programs.

### **Packing and Transporting CSPs**

The following sections describe how to maintain sterility and stability of CSPs until they are delivered to patient care locations for administration.

#### **PACKING CSPS FOR TRANSIT**

When CSPs are distributed to locations outside the premises in which they are compounded, compounding personnel select packing containers and materials that are expected to maintain physical integrity, sterility, and stability of CSPs during transit. Packing is selected that simultaneously protects CSPs from damage, leakage, contamination, and degradation, and protects personnel who transport packed CSPs from harm. The SOP manual of the compounding facility specifically describes appropriate packing containers and insulating and stuffing materials, based on information from product specifications, vendors, and experience of compounding personnel. Written instructions that clearly explain how to safely open containers of packed CSPs are provided to patients and other recipients.

#### **TRANSIT OF CSPS**

Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile, and stable condition to recipients.

Compounding personnel should ascertain that temperatures of CSPs during transit by the selected mode will not exceed the warmest temperature specified on the storage temperature range on CSP labels. It is recommended that compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that CSPs may encounter.

Compounding personnel shall include specific handling and exposure instructions on the exteriors of containers packed with CSPs to be transported and obtain reasonable assurance of compliance therewith from transporters. Compounding personnel shall periodically review the delivery performance of couriers to ascertain that CSPs are being efficiently and properly transported.

### **Storage in Locations Outside Compounding Facilities**

Compounding facilities that ship CSPs to patients and other recipients outside their own premises shall ascertain or provide, whichever is appropriate, the following assurances:

1. Labels and accessory labeling for CSPs include clearly readable BUDs, storage instructions, and disposal instructions for out-of-date units.
2. Each patient or other recipient is able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage.

### **PATIENT OR CAREGIVER TRAINING**

A formal training program is provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling, and administration of CSPs. The instructional objectives for the training program include all home care responsibilities expected of the patient or caregiver and is specified in terms of patient or caregiver competencies.

Upon the conclusion of the training program, the patient or caregiver should, correctly and consistently, be able to do the following:

1. Describe the therapy involved, including the disease or condition for which the CSPs are prescribed, goals of therapy, expected therapeutic outcome, and potential side effects of the CSPs.
2. Inspect all drug products, CSPs, devices, equipment, and supplies on receipt to ensure that proper temperatures were maintained during transport and that goods received show no evidence of deterioration or defects.
3. Handle, store, and monitor all drug products, CSPs, and related supplies and equipment in the home, including all special requirements related to same.
4. Visually inspect all drug products, CSPs, devices, and other items the patient or caregiver is required to use immediately prior to administration in a manner to ensure that all items are acceptable for use. For example, CSPs must be free from leakage, container cracks, particulates, precipitate, haziness, discoloration, or other deviations from the normal expected appearance, and the immediate packages of sterile devices must be completely sealed, with no evidence of loss of package integrity.
5. Check labels immediately prior to administration to ensure the right drug, dose, patient, and time of administration.
6. Clean the in-home preparation area, scrub hands, use proper aseptic technique, and manipulate all containers, equipment, apparatus, devices, and supplies used in conjunction with administration.
7. Employ all techniques and precautions associated with CSP administration; for example, preparing supplies and equipment, handling of devices, priming the tubing, and discontinuing an infusion.
8. Care for catheters, change dressings, and maintain site patency as indicated.
9. Monitor for and detect occurrences of therapeutic complications such as infection, phlebitis, electrolyte imbalance, and catheter misplacement.

10. Respond immediately to emergency or critical situations such as catheter breakage or displacement, tubing disconnection, clot formation, flow blockage, and equipment malfunction.
11. Know when to seek and how to obtain professional emergency services or professional advice.
12. Handle, contain, and dispose of wastes, such as needles, syringes, devices, biohazardous spills or residuals, and infectious substances.

Training programs include a hands-on demonstration and practice with actual items that the patient or caregiver is expected to use, such as CSP containers, devices, and equipment. The patient or caregiver practices aseptic and injection technique under the direct observation of a health professional.

The compounding facility, in conjunction with nursing or medical personnel, is responsible for ensuring initially and on an ongoing basis that the patient or caregiver understands, has mastered, and is capable of and willing to comply with all of these home care responsibilities. This is achieved through a formal, written assessment program. All specified competencies in the patient or caregiver training program are formally assessed. The patient or caregiver is expected to demonstrate to appropriate healthcare personnel mastery of assigned activities before being allowed to administer CSPs unsupervised by a health professional.

Printed material such as checklists or instructions provided during training may serve as continuing post-training reinforcement of learning or as reminders of specific patient or caregiver responsibilities. Post-training verbal counseling can also be used periodically, as appropriate, to reinforce training and to ensure continuing correct and complete fulfillment of responsibilities.

### **PATIENT MONITORING AND ADVERSE EVENTS REPORTING**

Compounding facilities shall clinically monitor patients treated with CSPs according to the regulations and guidelines of their respective state healthcare practitioner licensure boards or of accepted standards of practice. Compounding facilities shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.

The SOP manuals of compounding facilities shall describe specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs. Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences. Compounding personnel are encouraged to participate in adverse event reporting and product defects programs of the FDA and USP.

### **QUALITY ASSURANCE (QA) PROGRAM**

A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter. Emphasis in the QA program is placed on maintaining and improving the quality of systems and the provision of patient care. In

addition, the QA program ensures that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions were performed.<sup>44</sup>

Characteristics of a QA program include the following:

1. Formalization in writing;
2. Consideration of all aspects of the preparations and dispensing of products as described in this chapter, including environmental testing and verification results;
3. Description of specific monitoring and evaluation activities;
4. Specification of how results are to be reported and evaluated;
5. Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded; and
6. Delineation of the individuals responsible for each aspect of the QA program.

In developing a specific plan, focus is on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone. In general, the selection of indicators and the effectiveness of the overall QA program is reassessed on an annual basis.

## ABBREVIATIONS AND ACRONYMS

ACD	automated compounding device
AGPH	air changes per hour
ALARA	as low as reasonably achievable
ASHRAE	American Society of Heating, Refrigerating and Air Conditioning Engineers
BI	biological indicator
BSC	biological safety cabinet
BUD	beyond use date
CAGI	compounding aseptic containment isolator
CAI	compounding aseptic isolator
CDC	Centers for Disease Control and Prevention
CETA	Controlled Environment Testing Association
cfu	colony forming unit(s)
CSP	compounded sterile preparation
CSTD	closed system vial transfer device
DCA	direct compounding area
ECV	endotoxin challenge vial
EU	Endotoxin Unit

FDA	Food and Drug Administration
HEPA	high-efficiency particulate air
HICPAC	Healthcare Infection Control Practices Advisory Committee
HVAC	heating, ventilation, and air conditioning
IPA	isopropyl alcohol
ISO	International Organization for Standardization
LAFW	laminar airflow workbench
MDVs	multiple-dose vials
MMWR	Morbidity and Mortality Weekly Report
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
PEC	primary engineering control
PET	positron emission tomography
PPE	personnel protective equipment
psi	pounds per square inch
QA	quality assurance
SOP	standard operating procedure
SVI	sterile vial for injection
TSA	trypticase soy agar
USP	United States Pharmacopeia

## GLOSSARY

**Ante-Area:** An ISO Class 8 (see [Table 1](#)) or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.<sup>42</sup>

**Aseptic Processing:** (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)) A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package (containers—closures or packaging material for medical devices) and the transfer of the product into the container and its closure under at least ISO Class 5 (see [Table 1](#)) conditions.

**Beyond-Use Date (BUD):** (see *General Notices and Requirements and Pharmaceutical Compounding—Nonsterile Preparations* (795)) For the purpose of this chapter, the date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.

**Biological Safety Cabinet (BSC):** A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

**Buffer Area:** An area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.

**Clean Room:** (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116) and also the definition of *Buffer Area*) A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

**Compounding Aseptic Containment Isolator (CACI):** A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

**Compounding Aseptic Isolator (CAI):** A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum).<sup>43</sup>

**Critical Area:** An ISO Class 5 (see [Table 1](#)) environment.

**Critical Site:** A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

**Direct Compounding Area (DCA):** A critical area within the ISO Class 5 (see [Table 1](#)) primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

**Disinfectant:** An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

**First Air:** The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

**Hazardous Drugs:** Drugs are classified as hazardous if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs. (See current NIOSH publication.)

**Labeling:** [see *General Notices and Requirements* and 21 USC 321 (k) and (m)] A term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term “label” designates that part of the labeling on the immediate container.

**Media-Fill Test:** (see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)) A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.<sup>4</sup> The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

**Multiple-Dose Container:** (see *General Notices and Requirements* and <sup>6</sup>(659)<sub>2016</sub>)<sup>(CN-1-May-2016)</sup> A multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. The beyond-use date (BUD) for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is 28 days (see *Antimicrobial Effectiveness Testing* (51)), unless otherwise specified by the manufacturer.

**Negative Pressure Room:** A room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is *into* the room.<sup>42</sup>

**Pharmacy Bulk Package:** (see <sup>6</sup>(659)<sub>2016</sub>)<sup>(CN-1-May-2016)</sup> A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

Where a container is offered as a pharmacy bulk package, the label shall (a) state prominently “Pharmacy Bulk Package—Not for Direct Infusion,” (b) contain or refer to information on proper techniques to help ensure safe use of the product, and (c) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

**Primary Engineering Control (PEC):** A device or room that provides an ISO Class 5 (see [Table 1](#)) environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

**Preparation:** A preparation, or a CSP, that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

**Product:** A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

**Positive Pressure Room:** A room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out of* the room.<sup>42</sup>

**Single-Dose Container:** (see *General Notices and Requirements* and <sup>659</sup>)<sub>(CN 1 May 2016)</sub> A single-dose container is a single-unit container for articles (see *General Notices and Requirements*) or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

**Segregated Compounding Area:** A designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 (see [Table 1](#)) air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

**Sterilizing Grade Membranes:** Membranes that are documented to retain 100% of a culture of 10<sup>7</sup> microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22 µm or 0.2 µm nominal pore size, depending on the manufacturer's practice.

**Sterilization by Filtration:** Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

**Terminal Sterilization:** The application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10<sup>-6</sup>, or a probability of less than one in one million of a nonsterile unit.<sup>43</sup>

**Unidirectional Flow** (see footnote 3): An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

## APPENDICES

### Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († “shall”) and Recommended (‡ “should”) in USP Chapter <797>

NOTE—This tabular appendix selectively abstracts and condenses the full text of <797> for rapid reference only. Compounding personnel are responsible for reading, understanding and complying with the full text and all official USP terminology, content, and conditions therein.

#### INTRODUCTION

‡ Chapter purpose is to prevent harm and death to patients treated with CSPs.

† Chapter pertains to preparation, storage, and transportation, but not administration, of CSPs.

† Personnel and facilities to which <797> applies; therefore, for whom and which it may be enforced by regulatory and accreditation authorities.

† Types of preparations designated to be CSPs according to their physical forms, and their sites and routes of administration to patients.

† Compounding personnel must be meticulously conscientious to preclude contact contamination of CSPs both within and outside ISO Class 5 areas.

#### ORGANIZATION

† All compounding personnel shall be responsible for understanding fundamental practices and precautions within USP <797>, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

#### RESPONSIBILITY OF COMPOUNDING PERSONNEL

† Practices and quality assurances required to prepare, store, and transport CSPs that are sterile, and acceptably accurate, pure, and stable.

#### CSP MICROBIAL CONTAMINATION RISK LEVELS

† Proper training and evaluation of personnel, proper cleansing and garbing of personnel, proper cleaning and disinfecting of compounding work environments, and proper maintenance and monitoring of controlled environmental locations (all of which are detailed in their respective sections).

#### Low-Risk Level CSPs

† Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and entries into any container.

† In absence of passing sterility test, store not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at  $-25^{\circ}$  to

~~=10° or colder.~~

~~† Media-fill test at least annually by compounding personnel.~~

#### **Low-Risk Level CSPs with 12-Hour or Less BUD**

~~† Fully comply with all four specific criteria.~~

~~‡ Sinks should not be located adjacent to the ISO Class 5 primary engineering control.~~

~~‡ Sinks should be separated from the immediate area of the ISO Class 5 primary engineering control device.~~

#### **Medium-Risk Level CSPs**

~~† Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs.~~

~~† In absence of passing sterility test, store not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in solid frozen state at -25° to -10° or colder.~~

~~† Media fill test at least annually by compounding personnel.~~

#### **High-Risk Level CSPs**

~~† Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization.~~

~~† Sterilization method verified to achieve sterility for the quantity and type of containers.~~

~~† Meet allowable limits for bacterial endotoxins.~~

~~† Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization.~~

~~† In absence of passing sterility test, store not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in solid frozen state at -25° to -10° or colder.~~

~~† Media-fill test at least semiannually by compounding personnel.~~

#### **PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATIONS SKILLS**

~~† Pass didactic, practical skill assessment and media fill testing initially, followed by an annual assessment for a low- and medium-risk level compounding and semi-annual assessment for high-risk level compounding.~~

~~† Compounding personnel who fail written tests, or whose media-fill test vials result in gross microbial colonization, shall be immediately reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.~~

#### **IMMEDIATE-USE CSPs**

~~† Fully comply with all six specified criteria.~~

#### **SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS**

~~† Beyond use date 28 days, unless specified otherwise by the manufacturer, for closure sealed multiple-dose containers after initial opening or entry.~~

~~† Beyond use time of 6 hours, unless specified otherwise by the manufacturer, for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry.~~

~~† Beyond use time of 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air.~~

~~† Storage of opened single-dose ampuls is not permitted.~~

#### ~~HAZARDOUS DRUGS AS CSPs~~

~~† Appropriate personnel protective equipment.~~

~~† Appropriate primary engineering controls (BSCs and CACIs) are used for concurrent personnel protection and exposure of critical sites.~~

~~† Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.~~

~~† At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located.~~

~~† Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal.~~

~~† Hazardous drugs shall be prepared in an ISO Class 5 environment with protective engineering controls in place, and following aseptic practices specified for the appropriate contamination risk levels.~~

~~† Access to drug preparation areas shall be limited to authorized personnel.~~

~~† A pressure indicator shall be installed that can readily monitor room pressurization, which is documented daily.~~

~~† Annual documentation of full training of personnel regarding storage, handling, and disposal of hazardous drugs.~~

~~† When used, a CSTD shall be used in an ISO Class 5 primary engineering control device.~~

~~† At least 0.01 inch water column negative pressure is required for compounding of hazardous drugs.~~

~~‡ Negative-pressure buffer area is not required for low-volume compounding operations when CSTD is used in BSC or CACI.~~

~~† Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.~~

~~† Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations.~~

~~‡ Total external exhaust of primary engineering controls.~~

~~‡ Assay of surface wipe samples every 6 months.~~

## ~~RADIOPHARMACEUTICALS AS CSPs~~

~~† Positron Emission Tomography is according to USP chapter (823).~~

~~† Appropriate primary engineering controls and radioactivity containment and shielding.~~

~~† Radiopharmaceuticals compounded from sterile components, in closed sterile containers, with volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container shall be designated as and conform to the standards for low-risk level CSPs.~~

~~† Radiopharmaceutical vials, designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations.~~

~~† Location of primary engineering controls permitted in ISO Class 8 controlled environment.~~

~~† Technetium-99m/Molybdenum-99 generators used according to manufacturer, state, and federal requirements.~~

~~† Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD shall be prepared in a segregated compounding area.~~

~~† Materials and garb exposed in patient care and treatment area shall not cross a line of demarcation into the segregated compounding area.~~

~~† Technetium-99m/Molybdenum-99 generators must be eluted in ISO Class 8 conditions.~~

~~† Segregated compounding area will be designated with a line of demarcation.~~

~~‡ Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.~~

## ~~ALLERGEN EXTRACTS AS CSPs~~

~~† Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels when certain criteria are met.~~

## ~~VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY~~

~~† Review labels and document correct measurements, aseptic manipulations, and sterilization procedures to confirm correct identity, purity, and strength of ingredients in, and sterility of, CSPs.~~

~~‡ Assay finished CSPs to confirm correct identity and, or, strength of ingredients.~~

~~‡ Sterility test finished CSPs.~~

## ~~Sterilization Methods~~

~~† Verify that methods achieve sterility while maintaining appropriate strength, purity, quality, and packaging integrity.~~

~~‡ Prove effectiveness by USP chapter (71), equivalent, or superior sterility testing.~~

### **Sterilization of High-Risk Level CSPs by Filtration**

† Nominal 0.2- $\mu\text{m}$  pore size sterile membranes that are chemically and physically compatible with the CSP.

† Complete rapidly without filter replacement.

† Subject filter to manufacturer's recommended integrity test (e.g., bubble point test) after filtering CSPs.

### **Sterilization of High-Risk Level CSPs by Steam**

† Test to verify the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave.

† Ensure live steam contacts all ingredients and surfaces to be sterilized.

† Pass solutions through a 1.2- $\mu\text{m}$  or smaller nominal pore size filter into final containers to remove particulates before sterilization.

† Heated filtered air shall be evenly distributed throughout the chamber by a blower device.

† Dry heat shall only be used for those materials that cannot be sterilized by steam, when the moisture would either damage or be impermeable to the materials.

† Sufficient space shall be left between materials to allow for good circulation of the hot air.

† The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and other confirmation.

‡ The oven should be equipped with a system for controlling temperature and exposure period.

### **Depyrogenation by Dry Heat**

† Dry heat depyrogenation shall be used to render glassware or containers, such as vials free from pyrogens as well as viable microbes.

† The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility.

† The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs).

‡ The bacterial endotoxin test should be performed on the ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxin.

## **ENVIRONMENTAL QUALITY AND CONTROL**

### **Exposure of Critical Sites**

† ISO Class 5 or better air.

† Preclude direct contact (e.g., touch and secretions) contamination.

### **ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas**

† A buffer area is an area that provides at least ISO Class 7 air quality.

† New representations of facility layouts.

† Each compounding facility shall ensure that each source of ISO Class 5 environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

† Devices (e.g., computers and printers) and objects (e.g., carts and cabinets) can be placed in buffer areas and shall be verified by testing or monitoring.

### **Viable and Nonviable Environmental Sampling (ES) Testing**

† Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally when several conditions exist.

‡ The ES program should provide information to staff and leadership to demonstrate that the engineering controls are maintaining an environment within the compounding area that consistently maintains acceptably low viable and nonviable particle levels.

### **Environmental Nonviable Particle Testing Program**

† Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used.

### **Total Particle Counts**

† Certification that each ISO classified area (e.g., ISO Class 5, 7 and 8) is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer room or ante area has been altered.

† Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results meeting ISO Class 5, 7, or 8 depending on the requirements of the area.

† All certification records shall be maintained and reviewed by supervising personnel or other designated employee to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour.

### **Pressure Differential Monitoring**

† A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and ante area, and the ante area and the general environment outside the compounding area.

† The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device.

† The pressure between the ISO Class 7 and general pharmacy area shall not be less than 5 Pa (0.02 inch water column (w.c.)).

† In facilities where low and medium risk level CSPs are prepared, differential airflow

shall maintain a minimum velocity of 0.2 meter/second (40 fpm) between buffer area and ante-area.

### **Environmental Viable Airborne Particle Testing Program—Sampling Plan**

† An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.

† Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes).

† The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

‡ It is recommended that compounding personnel refer to USP Chapter *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116) and the CDC Guidelines for Environmental Infection Control in Healthcare Facilities-2003 for more information.

### **Growth Media**

† A general microbiological growth medium such as Soybean Casein Digest Medium (also known as trypticase soy broth (TSB) or agar (TSA)) shall be used to support the growth of bacteria.

† Malt extract agar (MEA) or some other media that supports the growth of fungi shall be used in high-risk level compounding environments.

† Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

### **Viable Air Sampling**

† Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels.

† Impaction shall be the preferred method of volumetric air sampling.

† For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities like staging, labeling, gowning, and cleaning.

† Locations shall include zones of air backwash turbulence within laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area.

† For low-risk level CSPs with 12-hour or less BUD, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment, during the certification of the primary engineering control.

‡ Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.

### **Air Sampling Devices**

† The instructions in the manufacturer's user manual for verification and use of electric air samplers that actively collect volumes of air for evaluation shall be followed.

† A sufficient volume of air (400–1000 liters) shall be tested at each location in order to maximize sensitivity.

‡ It is recommended that compounding personnel also refer to USP Chapter <1116>, which can provide more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.

### **Air Sampling Frequency and Process**

† Air sampling shall be performed at least semiannually (i.e. every 6 months), as part of the re-certification of facilities and equipment for area where primary engineering controls are located.

† A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed.

‡ Any facility construction or equipment servicing may require the need to perform air sampling during these events.

### **Incubation Period**

† The microbial growth media plates used to collect environmental sampling are recovered, covers secured (e.g., taped), inverted, and incubated at a temperature and for a time period conducive to multiplication of microorganisms.

† The number of discrete colonies of microorganisms shall be counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring need to be transformed into cfu/cubic meter of air and evaluated for adverse trends.

‡ TSA should be incubated at  $35^{\circ} \pm 2^{\circ}$  for 2–3 days.

‡ MEA or other suitable fungal media should be incubated at  $28^{\circ} \pm 2^{\circ}$  for 5–7 days.

### **Action Levels, Documentation and Data Evaluation**

† Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment.

† Competent microbiology personnel shall be consulted if an environmental sampling consistently shows elevated levels of microbial growth.

† An investigation into the source of the environmental contamination shall be conducted.

‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.

‡ Table titled, Recommended Action Levels for Microbial Contamination should only be used as a guideline

### **Facility Design and Environmental Controls**

† Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

† Compounding facilities shall provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb.

† Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.

† In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.

† Policies and procedures for maintaining and working within the primary engineering control area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities used during the preparation of the CSPs.

† The principles of HEPA filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions.

† Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour.

† Buffer areas maintain 0.02- to 0.05-inch water column positive pressure, and do not contain sinks or drains.

† Air velocity from buffer rooms or zones to ante areas is at least 40 feet/minute.

† The primary engineering controls shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation.

† The primary engineering controls shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross-drafts.

† HEPA filtered supply air shall be introduced at the ceiling.

† All HEPA filters shall be efficiency tested using the most penetrating particle size and shall be leak tested at the factory and then leak tested again in situ after installation.

† Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment.

† Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the room.

† Surfaces and essential furniture in buffer rooms or zones and clean rooms shall be nonporous, smooth, nonshedding, impermeable, cleanable, and resistant to disinfectants.

† The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability, and minimizing spaces in which

microorganisms and other contaminants may accumulate.

† The surfaces shall be resistant to damage by disinfectant agents.

† Junctures of ceilings to walls shall be covered or caulked to avoid cracks and crevices where dirt can accumulate.

† Ceiling tiles shall be caulked around each perimeter to seal them to the support frame.

† The exterior lens surface of ceiling lighting fixtures shall be smooth, mounted flush, and sealed.

† Any other penetrations through the ceiling or walls shall be sealed.

† The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected.

† Carts shall be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.

† Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable.

† Their number, design, and manner of installation the items above shall promote effective cleaning and disinfection.

‡ If ceilings consist of inlaid panels, the panels should be impregnated with a polymer to render them impervious and hydrophobic.

‡ Dust collecting overhangs, such as ceiling utility pipes, or ledges, such as windowsills, should be avoided.

‡ Air returns should be mounted low on the wall creating a general top-down dilution of room air with HEPA-filtered make-up air.

### **Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas**

† Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7.

† Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

† Primary engineering controls shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

† When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

† When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells),

~~the manipulations shall be clearly separated from routine material handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific standard operating procedures in order to avoid any cross-contamination.~~

~~† Food, drinks, and items exposed in patient care areas, and unpacking of bulk supplies and personnel cleansing and garbing are prohibited from buffer areas or rooms.~~

~~† Demarcation designation between buffer areas or rooms and ante-areas.~~

~~† Antiseptic hand cleansing and sterile gloves in buffer areas or rooms.~~

~~‡ Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small and large volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA) when possible in an ante-area, of ISO Class 8 air quality, before being passed into the buffer areas.~~

### **Cleaning and Disinfecting the Sterile Compounding Areas**

~~† Trained personnel write detailed procedures including cleansers, disinfectants, and non-shedding wipe and mop materials.~~

~~† Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.~~

~~† Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs.~~

~~† Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills, e.g., water soluble solid residues are removed with Sterile Water (for Injection or Irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins.~~

~~† Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily.~~

~~† Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies, using a method that does not degrade the ISO Class 7 or 8 air quality.~~

~~† Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs.~~

~~† IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs.~~

~~† Emptied shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly.~~

~~† Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs.~~

~~† Cleaning and disinfecting agents, their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial and/or compounding~~

personnel.

† All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, or ante area, and segregated compounding areas and shall not be removed from these areas except for disposal.

† If cleaning materials are reused (e.g., mops), procedures shall be developed (based on manufacturer recommendations) that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned.

† Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method.

† After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, and during this time the item shall not be used for compounding purposes.

† Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.

### **Personnel Cleansing and Garbing**

† Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs.

† Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, and cosmetics are prohibited from preparing CSPs.

† Compounding personnel shall remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck.

† Order of compounding garb and cleansing in ante area: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown.

† Order of cleansing and gloving in buffer room or area: hand cleansing with a persistently active alcohol-based product with persistent activity; allow hands to dry; don sterile gloves.

† Routinely disinfect gloves with sterile 70% IPA after contacting nonsterile objects.

† Inspect gloves for holes and replace when breaches are detected.

† Personnel repeat proper procedures after they are exposed to direct contact contamination or worse than ISO Class 8 air.

† These requirements are exempted only for immediate-use CSPs and CAIs for which manufacturers provide written documentation based on validated testing that such personnel practices are not required to maintain sterility in CSPs.

### **Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures**

~~† Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel, multi-media instructional sources, and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures.~~

~~† This training shall be completed and documented before any compounding personnel begin to prepare CSPs.~~

~~† Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media fill testing.~~

~~† Media fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding; and semiannually for high-risk level compounding.~~

~~† Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, shall be reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies.~~

~~† Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations.~~

~~† Compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures in addition to didactic evaluation and aseptic media fill.~~

~~† Cleaning and disinfecting procedures performed by other support personnel shall be thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert.~~

~~† Support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.~~

### **Competency Evaluation of Garbing and Aseptic Work Practices**

~~† Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and the personnel glove fingertip sampling procedures.~~

### **Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling**

~~† Monitoring of compounding personnel glove fingertips shall be performed for all CSP risk level compounding.~~

~~† Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices.~~

~~† All personnel shall demonstrate competency in proper hand hygiene and garbing~~

procedures in addition to aseptic work practices.

† Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing to assess garbing competency and after completing the media fill preparation.

† Gloves shall not be disinfected with sterile 70% IPA immediately prior to sampling.

### **Garbing and Gloving Competency Evaluation**

† Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures.

† The visual observation shall be documented on a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and maintained to provide a permanent record of and long term assessment of personnel competency.

### **Gloved Fingertip Sampling**

† Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator shall collect a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates by lightly pressing each finger tip into the agar.

† The plates shall be incubated for the appropriate incubation period and at the appropriate temperature.

† All employees shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use.

† After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs.

† Gloves shall not be disinfected with sterile 70% IPA prior to testing.

† The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below.

† The cfu action level for gloved hands shall be based on the total number of cfu on both gloves and not per hand.

‡ Results should be reported separately as number of cfu per employee per hand (left hand, right hand).

### **Incubation Period**

† At the end of the designated sampling period, the agar plates are recovered, covers secured, inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Trypticase soy agar (TSA) with lecithin and polysorbate 80 shall be incubated at  $35^{\circ} \pm 2^{\circ}$  for 2–3 days.

### **Aseptic Manipulation Competency Evaluation**

† All compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the media fill test procedure and subsequent

~~annual or semiannual media fill test procedures on the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel.~~

#### **~~Media-Fill Test Procedure~~**

~~† The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media fill verification.~~

~~† Media filled vials shall be incubated within a range of  $35^{\circ} \pm 2^{\circ}$  for 14 days.~~

#### **~~Surface Cleaning and Disinfection Sampling and Assessment~~**

~~† Surface sampling shall be performed in all ISO classified areas on a periodic basis and can be accomplished using contact plates and/or swabs and shall be done at the conclusion of compounding.~~

~~† Locations to be sampled shall be defined in a sample plan or on a form.~~

#### **~~Cleaning and Disinfecting Competency Evaluation~~**

~~† Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures during initial personnel training on cleaning procedures, changes in cleaning staff and at the completion of any Media Fill Test Procedure.~~

~~† Visual observation shall be documented on a Sample Form for Assessing Cleaning and Disinfection Procedures and maintained to provide a permanent record of, and long term assessment of, personnel competency.~~

#### **~~Surface Collection Methods~~**

~~† Immediately after sampling a surface with the contact plate, the sampled area shall be thoroughly wiped with a non-shedding wipe soaked in sterile 70% IPA.~~

~~‡ Results should be reported as cfu per unit of surface area.~~

#### **~~Action Levels, Documentation, and Data Evaluation~~**

~~† Environmental sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment.~~

~~† If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.~~

~~† An investigation into the source of the contamination shall be conducted.~~

~~† When gloved fingertip sample results exceeds action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented.~~

~~‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.~~

#### **~~SUGGESTED STANDARD OPERATING PROCEDURES~~**

~~† All facilities are required to have these, and they must include at least the items enumerated in this section.~~

#### **~~FINISHED PREPARATION RELEASE CHECKS AND TESTS~~**

### **Inspection of Solution Dosage Forms and Review of Compounding Procedures**

† Review procedures and documents to ensure sterility, purity, correct identities and amounts of ingredients, and stability.

† Visually inspect for abnormal particulate matter and color, and intact containers and seals.

### **Sterility Testing**

† High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized.

### **Bacterial Endotoxin (Pyrogen) Testing**

† High-risk level CSPs, excluding those for inhalation and ophthalmic administration, prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized.

### **Identity and Strength Verification of Ingredients**

† Written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs.

† Written procedures to ensure labels of CSPs contain correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration.

### **STORAGE AND BEYOND-USE DATING**

#### **Determining Beyond-Use Dates**

† Use the general criteria in USP (795) in the absence of direct stability-indicating assays or authoritative literature that supports longer durations.

### **MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs**

† Written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs.

#### **Redispensed CSPs**

† When sterility, and acceptable purity, strength, and quality can be ensured.

† Assignment of sterility storage times and stability beyond-use dates that occur later than those of originally dispensed CSPs must be based on results of sterility testing and quantitative assay of ingredients.

#### **Packaging and Transporting CSPs**

† Packaging maintains physical integrity, sterility, stability, and purity of CSPs.

† Modes of transport that maintain appropriate temperatures and prevent damage to CSPs.

### **PATIENT OR CAREGIVER TRAINING**

† Multiple component formal training program to ensure patients and caregivers

understand the proper storage, handling, use, and disposal of CSPs.

**PATIENT MONITORING AND ADVERSE EVENTS REPORTING**

† Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.

‡ Adverse events and defects with CSPs reported to FDA's MedWatch and USP's MEDMARX programs.

**GLOSSARY**

† Twenty eight terms are defined and integral to complying with USP <797>.

**Appendix II. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties<sup>1</sup>**

Chemical Category of Disinfectant							
		Isopropyl alcohol	Accelerated hydrogen peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone-iodine)
Concentration Used		60–95%	0.5% <sup>2</sup>	0.4–1.6% aq	0.4–1.6% aq	100–5000 ppm	30–50 ppm
Microbial Inactivation <sup>2</sup>	Bacteria	±	±	±	±	±	±
	Lipophilic viruses	±	±	±	±	±	±
	Hydrophilic viruses	±	±	±	±	±	±
	M.tuberculosis	±	±	±	±	±	±
	Mycotic agents (fungi)	±	±	±	±	±	±
	Bacterial Spores	=	=	=	=	±	=
Important Chemical & Physical Properties	Shelf life >1 week	±	±	±	±	±	±
	Corrosive or deleterious effects	±	=	=	=	±	±
	Non-evaporable	=	=	±	±	=	±

### Chemical Category of Disinfectant

		Isopropyl alcohol	Accelerated hydrogen peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone-iodine)
<b>Concentration Used</b>		<b>60–95%</b>	<b>0.5%<sup>3</sup></b>	<b>0.4–1.6% aq</b>	<b>0.4–1.6% aq</b>	<b>100–5000 ppm</b>	<b>30–50 ppm</b>
	residue						
	Inactivated by organic matter	±	±	±	±	±	±
	Skin irritant	±	=	±	±	±	±
	Eye irritant	±	=	±	±	±	±
	Respiratory irritant	=	=	=	=	±	=
	Systemic toxicity	±	=	±	±	±	±

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; = = no; ± = variable results.

<sup>1</sup> Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA, "Antisepsis, disinfection and sterilization in the hospital and related institutions," *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, DC, 1995, pages 227-245.

<sup>2</sup> Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm chlorine solution against *C. difficile* spores). Reference: Perez J, Springthorpe VS, Sattar SA, "Activity of selected oxidizing microbicides against the spores of *Clostridium difficile*: Relevance to environmental control," *American Journal of Infection Control*, August 2005, pages 320-325.

<sup>3</sup> Accelerated hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

### Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

Printed name and position/title of person assessed:	
Name of facility or location:	
<p><b>Hand Hygiene and Garbing Practices:</b> The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity; prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*</p>	

	Presents in a clean appropriate attire and manner.
	Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante areas.
	Brings no food or drinks into or stored in the ante areas or buffer areas.
	Is aware of the line of demarcation separating clean and dirty sides and observes required activities.
	Does shoe covers or designated clean area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.
	Does beard cover if necessary.
	Does head cover assuring that all hair is covered.
	Does face mask to cover bridge of nose down to include chin.
	Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.
	Dries hands and forearms using lint free towel or hand dryer.
	Selects the appropriate sized gown examining for any holes, tears, or other defects.
	Does gown and ensures full closure.
	Disinfects hands again using a waterless alcohol based surgical hand scrub with persistent activity and allows hands to dry thoroughly before donning sterile gloves.
	Does appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.
	Examines gloves ensuring that there are no defects, holes, or tears.
	While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.

	Removes PPE on the clean side of the ante-area.	
	Removes gloves and performs hand hygiene.	
	Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.	
	Removes and discards mask, head cover, and beard cover (if used).	
	Removes shoe covers or shoes one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is exited).	
<b>*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.</b>		
Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

**Appendix IV. Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel**

Printed name and position/title of person assessed:	
Name of facility or location:	
<b>Aseptic Technique, Safety, and Quality Assurance Practices:</b> The qualified evaluator checks each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*	
	Completes the Hand Hygiene and Garbing Competency Assessment Form.
	Performs proper hand hygiene, garbing, and gloving procedures according to SOPs.
	Disinfects ISO Class 5 device surfaces

	with an appropriate agent.
	Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area.
	Introduces only essential materials in a proper arrangement in the ISO Class 5 work area.
	Does not interrupt, impede, or divert flow of first air to critical sites.
	Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in ISO Class 5 work area.
	Performs manipulations only in the appropriate DCA of the ISO Class 5 device.
	Does not expose critical sites to contact contamination or worse than ISO Class 5 air.
	Disinfects stoppers, injection ports, and ampul necks by wiping with sterile 70% IPA and allows sufficient time to dry.
	Affixes needles to syringes without contact contamination.
	Punctures vial stoppers and spikes infusion ports without contact contamination.
	Labels preparation(s) correctly.
	Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.
	Cleans, sets up, and calibrates automated compounding device (e.g., "TPN compounder") according to manufacturer's instructions.
	Disposes of sharps and waste according to institutional policy or recognized guidelines.

**\*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

**Appendix V. Sample Form for Assessing Cleaning and Disinfection Procedures**

Printed name and position/title of person assessed:	
Name of facility or location:	

**Cleaning and Disinfection Practices:** The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.\*

**Daily Tasks:**

	Prepares correct concentration of disinfectant solution according to manufacturer's instructions.
	Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.).
	Documents disinfectant solution preparation.
	Follows garbing procedures when performing any cleaning activities.
	At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, IV bar, automated compounders, and work surface.
	Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.
	Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.
	Cleans all counters and easily cleanable work surfaces.
	Mops floors, using the mop labeled "floors," starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves

	<p>carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.</p>
	<p>In the ante-area, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.</p>
<b>Monthly Tasks:</b>	
	<p>Performs monthly cleaning on a designated day. Prepares a disinfectant solution as stated in daily tasks that is appropriate for the surfaces to be cleaned.</p>
	<p>Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.</p>
	<p>Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.</p>
	<p>Cleans all buffer area totes and storage shelves by removing contents and using a germicidal detergent soaked lint free wipe, cleans the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allows totes to dry. Prior to replacing contents into tote, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.</p>
	<p>Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint free wipe to remove any disinfectant residue. Uses new wipe as needed.</p>
	<p>Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.</p>
	<p>Documents all cleaning activities as to who performed such activities with date and time noted.</p>
<p><b>*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific</b></p>	

**corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

# 1. INTRODUCTION AND SCOPE

This chapter describes the minimum practices and quality standards to be followed when preparing compounded sterile human and animal drugs (compounded sterile preparations, or CSPs). These practices and standards must be used to prevent harm, including death, to human and animal patients that could result from 1) microbial contamination (nonsterility), 2) excessive bacterial endotoxins, 3) variability from the intended strength of correct ingredients, 4) chemical and physical contaminants, and/or 5) use of ingredients of inappropriate quality.

## 1.1 Scope

### CSP AFFECTED

The requirements and standards described in this chapter must be used to ensure the sterility of any CSP. Although the list below is not exhaustive, the following must be sterile:

- Injections
- Aqueous bronchial inhalations
- Baths and soaks for live organs and tissues
- Irrigations for internal body cavities (i.e., any space that does not freely communicate with the environment outside of the body)
- Ophthalmics
- Implants

For the compounding of hazardous drugs, see [Hazardous Drugs—Handling in Healthcare Settings \(800\)](#).

### PERSONNEL AND SETTINGS AFFECTED

This chapter applies to all persons who prepare CSPs (e.g., pharmacists, pharmacy technicians, physicians, veterinarians, and nurses) at all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarians' practice sites).

The compounding organization's leadership and all employees involved in preparing, storing, and transporting CSPs are responsible for 1) ensuring that the applicable practices and quality standards in this chapter are continually and consistently applied to their operations, and 2) proactively identifying and remedying potential problems within their operations.

### SPECIFIC PRACTICES

**Administration of medications:** This chapter is not intended to address administration of sterile medications. Administration of sterile medications should be performed in accordance with the Centers for Disease Control and Prevention's Safe Injection Practices<sup>4</sup> and the manufacturer's or compounder's labeling of the sterile medication.

**Proprietary bag and vial systems:** Docking and activation of proprietary bag and vial systems (e.g., ADD-Vantage®, Mini Bag Plus®, addEASE®) strictly in accordance

41 with the manufacturer's instructions for immediate administration to an individual patient  
42 is not considered compounding. However, aseptic technique must be followed when  
43 attaching the proprietary bag and vial system.

44 Docking of the proprietary bag and vial systems for future activation and administration  
45 is considered compounding and must be performed in accordance with this chapter,  
46 with the exception of *12. Establishing Beyond-Use Dates and In-Use Times*. Beyond-  
47 use dates (BUDs) for proprietary bag and vial systems must be assigned in accordance  
48 with the manufacturer's instructions provided in product labeling.

49 **Reconstitution or dilution:** Reconstituting or diluting a conventionally manufactured  
50 sterile product with no intervening steps strictly in accordance with the manufacturer's  
51 labeling for administration to an individual patient is not considered compounding.  
52 However, aseptic technique must be followed during preparation, and procedures must  
53 be in place to minimize the potential for contact with nonsterile surfaces and introduction  
54 of particulate matter or biological fluids.

55 Any other reconstitution or dilution of a conventionally manufactured sterile product is  
56 considered compounding and must be performed in accordance with this chapter.

57 **Repackaging:** Repackaging of a conventionally manufactured sterile product from its  
58 original primary container into another primary container must be performed in  
59 accordance with the requirements in this chapter for CSPs, including assignment of  
60 BUDs and in-use times as described in *12. Establishing Beyond-Use Dates and In-Use*  
61 *Times*.

## 62 **1.2 Factors Affecting the Risks Associated with CSPs**

63 CSPs can be compounded using only sterile starting ingredients or using some or all  
64 nonsterile starting ingredients. If all of the components used to compound a drug are  
65 sterile to begin with, the sterility of the components must be maintained during  
66 compounding to produce a sterile compounded preparation. If one or more of the  
67 starting components being used to compound is not sterile, the sterility of the  
68 compounded preparation must be achieved through a sterilization process, such as  
69 terminal sterilization in the final sealed container or sterile filtration, and then maintained  
70 through subsequent manipulations of the preparation. When compounding with  
71 nonsterile starting ingredients, the quality of the components and the effectiveness of  
72 the sterilization step are particularly critical to achieving a sterile preparation. In all  
73 cases, failure to achieve and/or maintain sterility of CSPs can lead to serious harm,  
74 including death. Personnel engaged in compounding and handling CSPs must strictly  
75 adhere to the standards in this chapter throughout the compounding process and until  
76 the preparation reaches the intended patient(s).

77 The risks to the sterility associated with a particular CSP depend on a number of  
78 factors, including the following:

- 79 • Batch size
- 80 • Complexity of the compounding process (e.g., number of manipulations involved;  
81 whether starting with nonsterile or sterile components)

- 82 • Inherent nature of the drug being compounded (e.g., whether the drug is  
83 susceptible to microbial growth; whether the preparation will be preservative  
84 free)
- 85 • Complexity of the compounding operation (e.g., multiple people in the cleanroom  
86 at the same time; multiple CSPs being prepared at the same time; activity in the  
87 surrounding areas)
- 88 • Length of time between the start of compounding (including making a stock  
89 solution) and administration of the drug to the patient

90 Ultimately, the risk to the population of patients is lower if the compounding is done for  
91 an individual patient as compared to when the compounding is done in a batch for  
92 multiple patients. When applying the standards in this chapter, the risks of a particular  
93 compounding operation must be considered, and steps commensurate with these risks  
94 must be taken to ensure a quality CSP.

### 95 1.3 Risk Categories

96 Consistent with this risk-based approach, this chapter distinguishes between two  
97 categories of CSPs, Category 1 and Category 2, primarily by the conditions under which  
98 they are made and the time within which they will be used. Category 1 CSPs are those  
99 assigned a maximum BUD of 12 hours or less at controlled room temperature or 24  
100 hours or less if refrigerated if made in accordance with all of the applicable standards for  
101 Category 1 CSPs in this chapter. Category 2 CSPs are those that may be assigned a  
102 BUD of greater than 12 hours at room temperature or greater than 24 hours if  
103 refrigerated (see *12. Establishing Beyond-Use Dates and In-Use Times*) if made in  
104 accordance with all of the applicable standards for Category 2 CSPs in this chapter.  
105 See [Table 1](#) for a summary comparison of the minimum requirements in this chapter for  
106 Category 1 and 2 CSPs.

107 This chapter describes minimum requirements that apply to compounding of all CSPs,  
108 and also to repackaging of sterile products. If a compounder does not meet all of the  
109 Category 2 requirements, the CSP or repackaged sterile product will be considered a  
110 Category 1, and the shorter BUD applicable to Category 1 CSPs must be assigned. The  
111 minimum requirements not specifically described as applicable to Category 1 or  
112 Category 2, such as minimum training and competency testing and personal hygiene for  
113 personnel, are applicable to compounding of all CSPs and repackaging of sterile  
114 products.

115 **Table 1. Summary Comparison of Minimum Requirements for Category 1 and**  
116 **Category 2 CSPs<sup>a</sup>**

	Category 1 CSPs	Category 2 CSPs
<b>Personnel Qualifications</b>		
Visual observation of hand hygiene and garbing	Quarterly	Quarterly
Gloved fingertip sampling	Quarterly	Quarterly

	Category 1 CSPs	Category 2 CSPs
Media fill testing	Quarterly	Quarterly
<b>Personal Protective Equipment</b>		
See <a href="#">Table 2</a> .		
<b>Buildings and Facilities</b>		
Primary engineering control (PEC)	Not required to be placed in a classified area	Required to be placed in a classified area
Recertification	Every 6 months	Every 6 months
<b>Environmental Monitoring</b>		
Nonviable airborne monitoring	Every 6 months	Every 6 months
Viable airborne monitoring	Monthly	Monthly
Surface sampling	Monthly	Monthly
<b>Release Testing</b>		
Physical inspection	Required	Required
Sterility testing	Not required	Based on assigned BUD
Endotoxin testing	Not required	Required if prepared from nonsterile ingredient(s) <sup>b</sup>
<b>BUD</b>		
BUD assignment	≤12 hours at controlled room temperature or ≤24 hours if refrigerated	>12 hours at controlled room temperature or >24 hours if refrigerated
<p><sup>a</sup> This table summarizes the requirements that apply specifically to Category 1 and Category 2 CSPs. There are numerous requirements in the chapter that are not summarized in this table because they apply to all CSPs, regardless of whether they are Category 1 or Category 2.</p> <p><sup>b</sup> See exemptions in <i>10.3 Bacterial Endotoxins Testing</i>.</p>		

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#### 1.4 Urgent-Use CSPs

118 A CSP may be prepared in worse than International Organization for Standardization  
119 (ISO) Class 5 air quality (see *4.1 Protection from Airborne Contaminants*) in rare  
120 circumstances when a CSP is needed urgently (e.g., cardiopulmonary resuscitation) for  
121 a single patient, and preparation of the CSP under conditions described for Category 1  
122 or Category 2 would subject the patient to additional risk due to delays in therapy. In  
123 these circumstances, the compounding procedure must be a continuous process not to  
124 exceed 1 hour, and administration of the CSP must begin immediately upon completion  
125 of preparation of the CSP. Aseptic technique must be followed during preparation, and  
126 procedures must be in place to minimize the potential for contact with nonsterile  
127 surfaces, introduction of particulate matter or biological fluids, and mix-ups with other  
128 CSPs.

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## 1.5 Roadmap through Chapter

The chapter is organized as follows:

- [1. Introduction and Scope](#)
  - [2. Personnel Qualifications—Training, Evaluation, and Requalification](#)
  - [3. Personal Hygiene and Personal Protective Equipment](#)
  - [4. Buildings and Facilities](#)
  - [5. Environmental Monitoring](#)
  - [6. Cleaning and Disinfecting Compounding Areas](#)
  - [7. Equipment and Components](#)
  - [8. Sterilization and Depyrogenation](#)
  - [9. SOPs and Master Formulation and Compounding Records](#)
  - [10. Release Testing](#)
  - [11. Labeling](#)
  - [12. Establishing Beyond-Use Dates and In-Use Times](#)
  - [13. Quality Assurance and Quality Control](#)
  - [14. CSP Storage, Handling, Packaging, and Transport](#)
  - [15. Complaint Handling and Adverse Event Reporting](#)
  - [16. Documentation](#)
  - [17. Radiopharmaceuticals as CSPs](#)
- [Glossary](#)  
[Appendices](#)  
[Appendix 1. Acronyms](#)  
[Appendix 2. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties](#)

## 2. PERSONNEL QUALIFICATIONS—TRAINING, EVALUATION, AND REQUALIFICATION

Because the failure of compounding personnel to follow procedures and adhere to quality standards poses the greatest risk of CSP contamination, all personnel involved in the preparation and handling of CSPs must be trained and qualified and must undergo annual refresher training and requalification in appropriate sterile compounding standards and practices. Training, qualification, and requalification of personnel must be documented.

Each compounding facility must develop a written training program that describes the required training, the frequency of training, and the process for evaluating the performance of individuals involved in sterile compounding. This program should equip personnel with the appropriate knowledge and train them in the required skills necessary to perform their assigned tasks. This section describes the minimum qualifications for personnel preparing and handling CSPs, including the training, evaluation, and requalification of such personnel.

Separate from the formal competency testing and requalification described in this section, supervisors of compounding personnel should observe compounding activities on a daily basis and take immediate corrective action if deficient practices are observed.

### 2.1 Demonstrating Proficiency in Core Competencies

174 Before beginning to prepare CSPs, personnel must complete training and be able to  
175 demonstrate proficiency in the theoretical principles and hands-on skills of sterile  
176 manipulations and in achieving and maintaining appropriate environmental conditions.  
177 Successful completion must be demonstrated through written testing and hands-on  
178 demonstration of skills. Proficiency must be demonstrated in at least the following core  
179 competencies:

- 180 • Hand hygiene and garbing
- 181 • Cleaning and disinfection
- 182 • Measuring and mixing
- 183 • Aseptic manipulation
- 184 • Proper cleanroom behavior
- 185 • Methods of sterilization and depyrogenation, if applicable
- 186 • Use of equipment
- 187 • Documentation of the compounding process (e.g., master formulation and  
188 compounding records)
- 189 • Understanding the direction of the HEPA-filtered unidirectional airflow within the  
190 ISO Class 5 area
- 191 • Proper use of PECs
- 192 • The potential impact of personnel activities such as moving materials into and out  
193 of the compounding area

194 The following sections describe in detail the competency testing that must be conducted  
195 initially for all sterile compounding personnel in garbing and hand hygiene and aseptic  
196 manipulation, and the requirements for retraining and requalification.

## 197 **2.2 Competency Testing in Garbing and Hand Hygiene**

198 Gloved fingertip/thumb sampling is important because direct touch contamination is  
199 the most likely source of microorganisms. Gloved fingertip sampling evaluates a  
200 compounding person's competency in correctly performing hand hygiene and garbing  
201 (see [Box 2-1](#)). All persons performing compounding must successfully complete an  
202 initial competency evaluation, including visual observation and gloved fingertip/thumb  
203 sampling [zero colony-forming units (CFUs)] no fewer than three times before being  
204 allowed to compound CSPs, to demonstrate that they can perform the procedure  
205 consistently. After the initial competency evaluation, compounding personnel must  
206 successfully complete gloved fingertip/thumb sampling quarterly (no more than a total of  
207 three CFUs). Each fingertip/thumb evaluation must occur after separate, full hand  
208 hygiene and garbing procedures.

209 Compounding personnel must be visually observed by competent personnel while  
210 performing hand hygiene and garbing procedures (see *3. Personal Hygiene and*  
211 *Personal Protective Equipment*). The visual audit must be documented and the  
212 documentation maintained to provide a permanent record and long-term assessment of  
213 personnel competency.

214 Sampling must be performed on sterile gloves inside of an ISO Class 5 PEC. If  
215 conducting gloved fingertip/thumb sampling in a Restricted Access Barrier System  
216 (RABS) [e.g., Compounding Aseptic Isolator (CAI) or Compounding Aseptic  
217 Containment Isolator (CACI)] or an isolator, samples must be taken from the sterile

218 gloves placed over the gauntlet gloves. In addition, gloved fingertip/thumb sampling  
219 must be performed after completing the media-fill preparation without applying sterile  
220 alcohol or any other agent that could interfere with the ability of the gloved fingertip test  
221 to assess the adequacy of aseptic work practices.

222 **Box 2-1 Gloved Fingertip Sampling and Testing Procedures**

- Use two plates filled with nutrient agar containing neutralizing agents (e.g., lecithin and polysorbate 80) in a size range of 24- to 30-cm<sup>2</sup> in size.
- Do NOT disinfect gloves with sterile 70% isopropyl alcohol (IPA) or any other disinfectant immediately before touching the agar plate because this could cause a false-negative result.
- Collect a gloved fingertip and thumb sample from both hands by lightly pressing each fingertip into the agar. Use a separate plate for each hand.
- Re-cover the agar plates without further contact with agar. Label the plates with a personnel identifier, right or left hand, date, and time.
- Immediately discard the gloves after sampling.
- Invert the plates and incubate them at a temperature and for a time period conducive to multiplication of microorganisms (e.g., 20°–35° for 5 days).
- Record the number of CFU per hand (left hand, right hand).
- Determine whether the CFU action level for gloved hands (i.e., zero CFU initially or three CFU thereafter) is exceeded by counting the total number of CFUs on both gloves, not per hand.

223 **2.3 Competency Testing in Aseptic Manipulation**

224 After successful completion of the initial hand hygiene and garbing competency  
225 evaluation, all sterile compounding personnel must have their sterile technique and  
226 related practices evaluated during a media-fill test (see [Box 2-2](#)). Evaluation results  
227 must be documented and the documentation maintained to provide a permanent record  
228 and long-term assessment of personnel competency.

229 **Box 2-2 Media-Fill Testing Procedures**

- When performing these testing procedures, use the most difficult and challenging compounding procedures and processing conditions encountered by the person during a work shift (e.g., the most manipulations, most complex flow of materials, longest time to compound), replacing all the components used in the CSPs with microbial growth medium.
- Include all normal processing steps and incorporate worst-case conditions, including sterilizing filtration if used.
- Do not interrupt the test once it has begun, unless the normal work day involves interruptions.
- If all of the starting components are sterile to begin with, transfer sterile fluid microbial culture medium, such as sterile soybean-casein digest, into the same types of container–closure systems commonly used at the facility to evaluate a person’s skill at aseptically processing CSPs into finished dosage forms.
- If some of the starting components are nonsterile to begin with, use a nonsterile commercially available medium, such as soybean-casein digest powder, to make a 3% solution. Prepare the nonsterile culture medium according to the manufacturer’s instructions and manipulate it in a manner that reflects nonsterile-to-sterile compounding activities.
- Incubate media-filled vials at 20°–35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, incubate the filled containers for at least 7 days at the lower temperature (20°–25°) followed by 7 days at 30°–35°. Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in one or more container–closure unit(s) on or before 14 days. Investigate media-fill failures to determine possible causes (e.g., sterilizing filter failure). Document and discuss investigational findings with personnel before any re-testing.
- If using a purchased pre-prepared microbial growth medium, either verify that the growth medium is growth promoting, or obtain a certificate of analysis (COA) from the supplier of the growth medium to ensure that it will support the growth of microorganisms.
- If using a microbial growth medium prepared in-house, the growth promotion capability of the medium must be demonstrated and documented (see [Sterility Tests \(71\)](#)).
- Always store microbial growth media in accordance with manufacturer instructions and use them before their expiration date.

230

## 2.4 Reevaluation, Retraining, and Requalification

231

### REQUALIFICATION AFTER FAILURE

232

Persons who fail written tests; visual observation of hand hygiene, garbing, and aseptic technique; gloved fingertip/thumb sampling; or media-fill tests must undergo

233

immediate requalification through additional training by competent compounding

234

personnel. Personnel who fail visual observation of hand hygiene, garbing, and aseptic

235

technique; gloved fingertip/thumb sampling; or media-fill tests must pass three

236

237 successive reevaluations in the deficient area before they can resume compounding of  
238 sterile preparations.

239 REFRESHER TRAINING PROGRAM

240 Compounding personnel must successfully complete annual refresher training in the  
241 core competencies listed in *2.1 Demonstrating Proficiency in Core Competencies*.  
242 Successful completion must be demonstrated through written testing and hands-on  
243 demonstration of skills.

244 TIMING OF REEVALUATION AND REQUALIFICATION

245

- 246 • Visual observation—Compounding personnel must be visually observed while  
247 performing hand hygiene and garbing procedures initially and then at least  
248 quarterly.
- 249 • Gloved fingertip sampling—Compounding personnel must perform  
250 fingertip/thumb sampling three times initially and then quarterly to confirm their  
251 competency and work practices. Fingertip sampling conducted as part of a  
252 routine media-fill test can be counted in fulfilling these reevaluation  
253 requirements.
- 254 • Media-fill testing—After initial qualification, conduct media-fill tests of all  
255 personnel engaged in compounding CSPs at least quarterly to evaluate aseptic  
256 technique and requalify them.
- 257 • Cleaning and disinfecting—Retrain and requalify personnel in cleaning and  
258 disinfecting compounding areas after a change in cleaning and disinfecting  
259 procedures.
- 260 • After a pause in compounding—Personnel who have not compounded CSPs in  
261 more than 3 months must be requalified in all core competencies before  
262 resuming compounding duties.

263 If compounding is done less frequently than the frequencies specified above (e.g.,  
264 quarterly), personnel reevaluation and requalification must occur before each  
265 compounding session begins.

266

267 **3. PERSONAL HYGIENE AND PERSONAL PROTECTIVE EQUIPMENT**

268 Because personnel preparing CSPs are the most likely cause of CSP contamination,  
269 compounding personnel must maintain proper personal hygiene and use personal  
270 protective equipment (PPE).

271 Personnel suffering from rashes, sunburn, oozing tattoos or sores, conjunctivitis, active  
272 respiratory infection, or other active communicable disease must be excluded from  
273 working in compounding areas until their conditions are resolved.

274

**3.1 Personnel Preparation**

275 Compounding personnel must take appropriate steps to prevent microbial  
276 contamination of CSPs. Squamous cells are normally shed from the human body at a  
277 rate of 10<sup>6</sup> or more per hour, and those skin particles are laden with microorganisms.<sup>2,3</sup>  
278 Before entering a designated compounding area, compounding staff must remove any

279 items that are not easily cleanable and that are not necessary for compounding. For  
280 example, personnel must:

- 281 • Remove personal outer garments (e.g., bandanas, coats, hats, jackets, scarves,  
282 sweaters, and vests)
- 283 • Remove all cosmetics because they shed flakes and particles
- 284 • Remove all hand, wrist, and other exposed jewelry or piercings (e.g., rings,  
285 watches, bracelets, earrings, and lip or eyebrow rings) that can interfere with  
286 the effectiveness of PPE (e.g., fit of gloves, cuffs of sleeves, and eye  
287 protection). Cover any jewelry that cannot be removed (e.g., surgically  
288 implanted jewelry)
- 289 • Remove ear buds, headphones, and cell phones, or other similar devices
- 290 • Keep natural nails clean and neatly trimmed to minimize particle shedding and  
291 avoid glove punctures. Nail polish, artificial nails, and extenders must be  
292 removed.

### 293 **3.2 Hand Hygiene**

294 Hand hygiene is required before initiating any compounding activities and when re-  
295 entering the ante-area after a break in compounding activity. After donning shoe covers,  
296 head and facial hair covers, and face masks, hand hygiene must be conducted (see  
297 [Box 3-1](#)). Hands must be washed with unscented soap and water. Alcohol hand  
298 sanitizers alone are not sufficient. Do not combine antimicrobial soaps and handrubs  
299 with alcohol-based products because of potential adverse dermatologic reactions.  
300 Brushes are not recommended for hand hygiene because of the potential for skin  
301 irritation and increased bacterial shedding. Dry hands and forearms with either low-lint  
302 disposable towels or wipes. After hands are washed and dried, perform hand antisepsis  
303 using a suitable alcohol-based handrub with sustained antimicrobial activity immediately  
304 before donning sterile gloves. Follow the manufacturer's instructions for application  
305 times, and apply the product to dry hands only. [NOTE—Soap must not be added to a  
306 partially empty soap dispenser. This practice of "topping off" dispensers can lead to  
307 bacterial contamination of soap.]

#### 308 **Box 3-1 Hand Hygiene Procedures**

- Remove debris from underneath fingernails, if present, using a nail cleaner under warm running water.
- Wash hands and forearms up to the elbows with unscented soap and water for at least 30 seconds.
- Dry hands and forearms to the elbows completely with low-lint disposable towels or wipes.
- Immediately prior to donning sterile gloves, apply a suitable alcohol-based handrub with sustained antimicrobial activity, following the manufacturer's instructions for application times, and use a sufficient amount of product to keep the hands wet for the duration of the application time.
- Allow hands to dry thoroughly before donning sterile gloves.

309

### 3.3. Garb and Glove Requirements

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The garb and glove requirements for CSPs depend on the category of CSP and type of PEC used. [Table 2](#) summarizes the minimum garb and glove requirements for CSPs.

311

**Table 2. Minimum Garb and Glove Requirements**

312

CSP Category	PEC type	Minimum Requirement
Category 1	Any	<ul style="list-style-type: none"> <li>• Non-cotton, low-lint, disposable gown or coveralls</li> <li>• Low-lint, disposable covers for shoes</li> <li>• Low-lint, disposable covers for head and facial hair that cover the ears and forehead</li> <li>• Sterile gloves and sterile sleeves<sup>a</sup></li> </ul>
Category 2	Laminar airflow system (LAFS) and biological safety cabinet (BSC)	<ul style="list-style-type: none"> <li>• Non-cotton, low-lint, disposable gowns or coveralls</li> <li>• Low-lint, disposable covers for shoes</li> <li>• Low-lint, disposable covers for head and facial hair that cover the ears and forehead</li> <li>• Mask</li> <li>• Sterile gloves and sterile sleeves<sup>a</sup></li> <li>• Eye shield is optional</li> </ul>
Category 2	RABS (CAI or CACI) or isolator	<ul style="list-style-type: none"> <li>• Non-cotton, low-lint, disposable gowns or coveralls</li> <li>• Low-lint, disposable covers for shoes and hair</li> <li>• Sterile gloves</li> </ul>

<sup>a</sup> If a sterile gown is used, the use of sterile sleeves is optional.

313

Personnel intending to enter a buffer area or segregated compounding area must put on protective clothing. Protective clothing must be put on in an order that eliminates the greatest risk of contamination. As noted previously, put on shoe covers, head and facial hair covers, face masks, and gown, before completing hand cleansing procedures and then put on sterile gloves and sterile sleeves (if used). If sterile gowns are used, put on sterile gloves and gowns after hand cleansing procedures. Garbing and degarbing should not occur in the ante-area at the same time.

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#### GOWNS

320

Visibly soiled gowns must be changed immediately. Gowns and other garbing items must be segregated and stored before use in an enclosure to prevent contamination (e.g., away from sinks to avoid splashing). Coveralls and sterile gowns must not be reused.

321

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323

324

#### GLOVES

325

326 Gloves must be sterile and powder free. Use only gloves that have been tested by the  
327 manufacturer for compatibility with alcohol disinfection. Before putting on gloves,  
328 perform hand hygiene as described in [Box 3-1](#). Hands must be completely dry before  
329 putting on sterile gloves. Unless donning a sterile gown, sterile gloves must be the last  
330 item put on before handling anything in the buffer or segregated compounding area and  
331 before compounding begins in the PEC. If donning a sterile gown, put on the gloves  
332 first, then the sterile gown.

333 Routine application of sterile 70% IPA to gloves must occur throughout the  
334 compounding process and whenever nonsterile surfaces (e.g., vials, counter tops,  
335 chairs, carts) are touched. Contaminated gloved hands can be disinfected by rubbing  
336 sterile 70% IPA solution onto all contact surface areas of the gloves and letting the  
337 gloved hands dry thoroughly.

338 Gloves on hands and gauntlet sleeves on RABS and isolators must be inspected  
339 routinely by the personnel using them for holes, punctures, or tears and must be  
340 replaced immediately if such defects are detected. Sterile gloves must be placed over  
341 the gauntlet gloves of the RABS and isolators.

#### 342 EXITING AND REENTERING COMPOUNDING AREAS

343 When compounding personnel exit the buffer or segregated compounding area during  
344 a work shift, a nonsterile gown can be removed and retained in the ante or segregated  
345 compounding area if not visibly soiled, to be re-donned during that same work shift only.  
346 Coveralls and sterile gowns may not be reused and must be replaced with new ones.  
347 Shoe covers, hair and facial hair covers, face masks, head covering, gloves, and  
348 sleeves may not be reused and must be replaced with new ones. Goggles must be  
349 either sterilized or disinfected with sterile 70% IPA before each use. Hand hygiene must  
350 be performed before resuming sterile compounding.

#### 351 COMPOUNDING HAZARDOUS DRUGS

352 For PPE requirements when handling hazardous drugs, refer to [\(800\)](#).

353

354

### 4. BUILDINGS AND FACILITIES

355 Buildings and facilities in which compounding will be taking place must be designed,  
356 built, outfitted, and maintained properly to prevent airborne contamination of CSPs.  
357 Areas related to compounding operations in such facilities (i.e., ante-area, buffer area,  
358 segregated compounding area, and PEC) must be separated from areas not directly  
359 related to compounding and must be appropriately controlled to achieve and maintain  
360 required air quality classification levels (see [Table 3](#)), depending on the nature of the  
361 operation being performed in the specific area.

362 A facility's design must ensure that the movement of personnel, equipment, and  
363 components into and out of the compounding area does not disrupt air quality in the  
364 area or create a route of contamination. The number of operations being performed, the  
365 number of personnel in the compounding area (and in adjacent areas), and the  
366 complexity of the compounding procedures are critical factors that determine whether a  
367 facility will be able to maintain control of environmental conditions. All of these factors  
368 must be taken into account when designing and outfitting a facility in which sterile  
369 compounding will be performed.

370 This section describes applicable air quality standards and the appropriate design of  
371 buildings and facilities intended for the preparation of CSPs. It describes in detail the  
372 materials to be used and the steps to be taken in designing facilities to ensure suitable  
373 conditions. This section also discusses the environmental controls that must be in place  
374 to ensure achievement and maintenance of sterility for CSPs.

#### 375 4.1 Protection from Airborne Contaminants

376 Buildings and facilities used in compounding must be designed to prevent airborne  
377 contamination of the area in which sterile compounding occurs. Without proper design  
378 and controls, airborne contaminants are likely to reach the area where compounding  
379 occurs, increasing the risk that CSPs will be exposed to microbial contamination.

#### 380 APPLICABLE AIR QUALITY STANDARDS

381 The internationally accepted standards for air quality in controlled environments are  
382 described in [Table 3](#) and referenced throughout this chapter.

383 **Table 3. ISO Classification of Particulate Matter in Room Air**

ISO Class	Particle Count <sup>a</sup> /m <sup>3</sup>
3	35.2
4	352
5	3,520
6	35,200
7	352,000
8	3,520,000

<sup>a</sup> Limits for number of particles  $\geq 0.5 \mu\text{m}$  measured under typical operating conditions.

#### 384 DESIGN REQUIREMENTS TO MAINTAIN AIR QUALITY

385 For compounding Category 1 or 2 CSPs, buildings and facilities intended for  
386 compounding CSPs must be designed so that air quality increases with movement  
387 through separate operational areas to the PEC. Separate areas of operation must be  
388 appropriately controlled, depending on the necessary level of air quality. Classified  
389 areas in which the air quality is controlled include ante-areas, buffer areas, and PECs.

- 390 • Ante-areas must meet at least ISO Class 8 standards. Typically, personnel hand  
391 hygiene and garbing procedures, staging of components, order entry, CSP  
392 handling, and other activities that potentially generate high levels of particulates  
393 are performed in this area. Ante-areas are also transition areas to ensure that  
394 proper air pressure relationships are maintained between designated areas.
- 395 • A buffer area must provide at least ISO Class 7 air quality. Activities in this area  
396 must be especially carefully controlled to avoid affecting the air quality in the  
397 area where CSP preparation occurs.
- 398 • Areas intended for CSP preparation must meet ISO Class 5 standards. ISO  
399 Class 5 standards are achieved through use of a PEC, such as a LAFS, BSC,  
400 CAI, CACI, or isolator.

401 A PEC used for compounding may be placed in an unclassified, segregated  
402 compounding area (see below) if only Category 1 CSPs are compounded in the PEC.

#### 403 **4.2 Facility Design and Environmental Controls**

404 In addition to minimizing airborne contamination and protecting CSPs, compounding  
405 facilities must be designed and controlled to provide a well-lit and comfortable working  
406 environment, with appropriate temperature and humidity for compounding personnel  
407 wearing the required garb. The room must be maintained at a temperature of 20° or  
408 cooler and a humidity below 60% at all times. Temperature and humidity must be  
409 controlled through an efficient heating, ventilation, and air conditioning (HVAC) system  
410 rather than through use of humidifiers and dehumidifiers, which can contain standing  
411 water that can contribute to microbial contamination.

412 It is the responsibility of compounding facility management to ensure that each  
413 operational area related to CSP preparation meets the ISO-classified air quality  
414 standard appropriate for the activities to be conducted there and, specifically, that the  
415 ISO Class 5 areas are optimally located, operated, maintained, monitored, and verified  
416 to have appropriate air quality.

#### 417 **DESIGN OF A COMPOUNDING FACILITY**

418 A compounding facility generally consists of separate, designated operational clean  
419 areas, including an ante-area, a buffer area, and a PEC, or a segregated compounding  
420 area containing a PEC where CSPs are prepared. See *Placement and Use of Primary*  
421 *Engineering Controls* for the requirements for a segregated compounding area. The  
422 ante-area must be separated from the surrounding, unclassified sections of the building  
423 to reduce the risk of contaminants being blown, dragged, tracked, or otherwise  
424 introduced into the high-efficiency particulate air (HEPA)-filtered clean environment.  
425 This separation must be continuously maintained and monitored (see 5. *Environmental*  
426 *Monitoring*). When compounding Category 2 CSPs, the ISO Class 8 ante-area and the  
427 ISO Class 7 buffer area must be separate rooms, with walls and doors between them  
428 and controls to prevent the flow of lower-quality air into the more controlled areas.

429 The PEC must be located in the buffer area or the segregated compounding area so  
430 as to avoid conditions that could adversely affect their separate operations. For  
431 example, strong air currents from opened doors, personnel traffic, or air streams from  
432 the HVAC system(s) can disrupt the unidirectional airflow of an open-faced PEC such  
433 as a laminar airflow workbench (LAFW). Compounding personnel can also create  
434 disruptions in airflow by their own movements adjacent to the PEC, their manipulations  
435 within the PEC, and by placing objects onto work surfaces within the PEC. Access of  
436 personnel to controlled areas must be limited. For example, only authorized personnel  
437 and materials required for compounding and cleaning should be permitted in the buffer  
438 area.

439 Due to the interdependence of the various rooms or areas that make up a  
440 compounding facility, it is essential to carefully define and control the dynamic  
441 interactions permitted between areas and rooms. When designing doors, consider door  
442 closures, door surfaces, and the swing of the door, all of which can affect airflow.

443 Airlocks and interlocking doors can be used to facilitate better control of air balance  
444 between a higher classified area and an area of lesser air quality (e.g., between the  
445 buffer area and ante-area), or between a classified area and an unclassified area (e.g.,

446 between the ante-area and an uncontrolled area such as a hallway). If a pass-through is  
447 used, it must only be opened one door at a time; both doors must never be opened at  
448 the same time.

449 It is critical to adequately control materials (e.g., supplies, equipment, and utensils) as  
450 they move from lesser to higher classified areas to prevent the influx of contaminants.  
451 For this reason, when designing a facility, consider the movement of materials.

452 When designing the facility, consider whether all materials used can be easily cleaned.  
453 Avoid using door seals and sweeps that are difficult to clean. Hands-free access doors  
454 are preferred. Do not use tacky mats in ISO-classified areas.

#### 455 THE CSP PROCESSING ENVIRONMENT

456 All CSPs must be prepared in a PEC, which provides an ISO Class 5 environment  
457 (with the exception of Urgent-Use CSPs, see *1.4 Urgent-Use CSPs*). The compounding  
458 environment must continuously meet ISO Class 5 or better conditions for 0.5- $\mu$ m  
459 particles and must exclude microbial contamination during compounding of CSPs  
460 (typical operating conditions).

461 HEPA filters and unidirectional (laminar) airflow are used to maintain the appropriate  
462 airborne particulate classification of the area. Unidirectional airflow must be maintained  
463 in the PEC at all times. HEPA-filtered air must be supplied to the PEC at a velocity  
464 sufficient to sweep particles away from critical sites and maintain unidirectional airflow  
465 during operations. Proper design and control prevents turbulence and creation of eddies  
466 or stagnant air in the PEC.

467 Air must be introduced through HEPA filters located at the ceiling of the buffer area  
468 containing the PEC, and returns should be mounted low on the wall, creating a general  
469 top-down dilution of area air through HEPA-filtered air.

#### 470 PLACEMENT AND USE OF PRIMARY ENGINEERING CONTROLS

471 Proper placement of the PEC is critical to ensuring an ISO Class 5 environment for  
472 compounding CSPs.

473 **LAFS:** Provides an ISO Class 5 or better environment for sterile compounding. A  
474 LAFS provides smooth, unidirectional HEPA-filtered airflow that is designed to prevent  
475 contamination of a sterile compounding environment. The LAFS can consist of either a  
476 LAFW or a HEPA filter alone creating an ISO Class 5 zone within an ISO Class 7 room,  
477 as long as unidirectional airflow is maintained.

478 The LAFS must be located out of traffic patterns and away from room air currents that  
479 could disrupt the intended airflow patterns. If used to prepare only Category 1 CSPs, the  
480 ISO Class 5 environment can be obtained by placing a LAFW in a segregated  
481 compounding area. If used to prepare Category 2 CSPs, the LAFS must be located  
482 within a restricted access buffer area with an ISO Class 7 or better air quality.

483 **BSC:** A ventilated cabinet with an open front and inward and downward HEPA-filtered  
484 airflow and HEPA-filtered exhaust. A BSC must be located out of traffic patterns and  
485 away from room air currents that could disrupt the intended airflow patterns. A BSC  
486 used to prepare only Category 1 CSPs can be placed in an unclassified area. If used to  
487 prepare Category 2 CSPs, the BSC must be located within a restricted access buffer  
488 area with an ISO Class 7 or better air quality. If a BSC is used to prepare hazardous  
489 drugs, see [\(800\)](#).

490 **RABS:** Can include a CAI or a CACI, and can be used to provide an ISO Class 5  
491 environment for preparing CSPs (see [Microbiological Control and Monitoring of Aseptic](#)  
492 [Processing Environments \(1116\)](#)). A RABS is different from an isolator (see description  
493 of isolators below). In a RABS, glove ports are used to provide physical separation  
494 between the surrounding area and the aseptic manipulations. If used to prepare  
495 Category 2 CSPs, the area surrounding the RABS must meet ISO Class 7 or better air  
496 quality.

497 All transport ports on the RABS must be closed during compounding. When a RABS is  
498 used, the recovery time after opening to achieve ISO Class 5 air quality must be  
499 documented, and internal procedures must be developed to ensure that adequate  
500 recovery time is allowed after opening and closing the RABS, both before and during  
501 compounding operations.

502 **Isolator:** Provides isolation from the surrounding area and maintains ISO Class 5 air  
503 quality during typical operating conditions. The following standards must be met to  
504 qualify as an isolator:

- 505 • High-integrity transfer ports are used to move supplies, ingredients, components,  
506 and devices into and out of the isolator.
- 507 • The isolator is decontaminated using a generator that distributes a sporicidal  
508 chemical agent throughout the isolator chamber.
- 509 • The isolator maintains constant overpressure of at least 0.05-inch water column.
- 510 • The manufacturer has provided documentation that the isolator will continuously  
511 meet ISO Class 5 conditions, including during material transfer.

512 If ISO Class 5 classification is achieved using an isolator that meets the requirements  
513 above, the isolator can be located in an ISO Class 8 area and used to prepare Category  
514 2 CSPs. In addition, when using an isolator, some functions, such as hand washing, can  
515 be done in the ISO Class 8 area. Water sources such as sinks and drains must be  
516 located at least 1 meter from the isolator. If the isolator does not meet the requirements  
517 above, it is considered a RABS that must be located within at least an ISO Class 7 area  
518 to prepare Category 2 CSPs, or within a segregated compounding area to prepare  
519 Category 1 CSPs.

520 **Segregated Compounding Areas:** In some situations, a PEC may be located within  
521 an unclassified area, without a buffer or ante-area. This type of design is called a  
522 segregated compounding area. Category 2 CSPs must never be compounded in  
523 segregated compounding areas; only Category 1 CSPs can be compounded in facilities  
524 with such designs. It is critical to locate a segregated compounding area away from  
525 unsealed windows, doors that connect to the outdoors, and significant traffic flow. A  
526 segregated compounding area must not be located adjacent to construction sites,  
527 warehouses, food preparation areas, or other environmental control challenges. The  
528 impact of activities that will be conducted around or adjacent to the segregated  
529 compounding area must be considered carefully when designing such an area, and the  
530 perimeter of the segregated compounding area must be defined.

531

ACTIVITIES IN RELATION TO THE PEC

532 The facility where CSPs are prepared must be designed so that activities such as hand  
533 hygiene and gowning will not adversely affect the ability of the PEC to function as  
534 designed. In facilities with ante-areas and buffer areas, the sink used for hand hygiene  
535 must not be placed in the buffer area. The sink should be placed in the ante-area to  
536 allow for hand washing before entering the buffer area. In a segregated compounding  
537 area, the sink must be located at least 1 meter from the PEC.

538 AIR-EXCHANGE REQUIREMENTS

539 For facilities designed with ante-areas and buffer areas, adequate HEPA-filtered  
540 airflow to the buffer and ante-areas is required to maintain the appropriate cleanliness  
541 classification during compounding activities. Airflow adequacy is measured in terms of  
542 the number of air changes per hour (ACPH). Factors that should be considered when  
543 determining appropriate air-exchange requirements for an area include the maximum  
544 number of personnel permitted to work in the area, the number of particulates that may  
545 be generated from activities and processes in the area, and the effects of temperature.

546 An ISO Class 7 buffer or ante-area supplied with HEPA-filtered air must measure an  
547 ACPH of not less than 30, and the ACPH may need to be higher to maintain the  
548 classification, depending on the factors previously described. The ACPH of 30 can  
549 include recirculated HEPA-filtered air, but at least half (a minimum of 15 ACPH) must be  
550 HEPA-filtered fresh air.

551 If an isolator that meets the specifications described above is used to achieve ISO  
552 Class 5 air quality, air exchange requirements in the room where the isolator is located  
553 can be reduced to 15 ACPH.

554 ESTABLISHING AND MAINTAINING PRESSURE DIFFERENTIALS

555 To prevent the flow of poorer quality air from one area to another area of higher air  
556 quality classification, except when a segregated compounding area is used, a minimum  
557 differential positive pressure of 0.02-inch water column is required to separate each  
558 ISO-classified area. The pressure differential between the ISO Class 7 area and the  
559 general pharmacy area must not be less than 0.02-inch water column.

560 A pressure gauge or velocity meter must be used to monitor the pressure differential or  
561 airflow between the ante-area and buffer area and between the ante-area and the  
562 general environment outside the classified areas. The results must be reviewed and  
563 documented on a log at least daily or by a continuous recording device.

564 **4.3 Constructing Areas to Achieve Easily Cleanable Conditions**

565 The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in a  
566 classified area or in a segregated compounding area must be smooth, impervious, free  
567 from cracks and crevices, and non-shedding, thereby promoting cleanability and  
568 minimizing spaces in which microorganisms and other contaminants can accumulate.  
569 Surfaces must be resistant to damage by disinfectants. Junctures between the ceiling  
570 and the walls must be coved or sealed to eliminate cracks and crevices where dirt can  
571 accumulate. If ceilings consist of inlaid panels, the panels must be impregnated with a  
572 polymer to render them impervious and hydrophobic, and they must be sealed.

573 Walls must be constructed of durable material (e.g., heavy-gauge polymer). Panels  
574 must be locked together and sealed. If gypsum board is used, it must be epoxy-coated.  
575 Floors must be overlaid with wide sheet vinyl flooring with heat-welded seams and  
576 coving to the sidewall. Classified areas and segregated compounding areas must not

577 contain dust-collecting overhangs, such as utility pipes, or ledges, such as windowsills.  
578 The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and  
579 sealed. Any other penetrations through the ceiling or walls must be sealed. The buffer  
580 area or area inside the perimeter of a segregated compounding area cannot contain  
581 water sources (e.g., sinks) or floor drains.

582 Work surfaces must be constructed of smooth, impervious materials, such as stainless  
583 steel or molded plastic, so that they can be easily cleaned and disinfected.

#### 584 **4.4 Placement and Movement of Materials**

585 Only furniture, storage shelving, counters, cabinets, supplies, and other materials  
586 necessary for performing compounding activities are permitted in buffer or segregated  
587 compounding areas. Any objects located in buffer or segregated compounding areas  
588 must be smooth, impervious, free from cracks and crevices, non-shedding, and easily  
589 cleaned and disinfected. Their number, design, and manner of installation must promote  
590 effective cleaning and disinfecting. Certain items are not permitted in buffer areas.  
591 These include, but are not limited to, coarse cardboard, external shipping containers,  
592 and nonessential paper (e.g., paper towels and tissues).

593 Carts used to transport components or equipment into classified areas must be  
594 constructed from stainless steel, nonporous plastic, or sheet metal, with good quality,  
595 cleanable casters to promote mobility and ensure ease of disinfection.

596 Certain devices (e.g., computers) and objects (e.g., carts and cabinets) essential to  
597 compounding can be located in the segregated compounding area, but must be located  
598 at an appropriate distance from the PEC so that they have no detrimental effects on the  
599 air quality inside the PEC. The appropriate distance must be determined by considering  
600 the surrounding environment and the activities conducted in it.

601 Before being brought into a buffer area or segregated compounding area, objects must  
602 be cleaned and disinfected. Equipment and other items used in a buffer area or a  
603 segregated compounding area should not be removed except for calibration, servicing,  
604 or other activities associated with proper maintenance. If removed, these items must be  
605 cleaned and disinfected before they are returned to the buffer area or segregated  
606 compounding area.

#### 607 **4.5 Certification and Recertification of Facilities**

608 Before a facility is used to compound either Category 1 or Category 2 CSPs, it must be  
609 certified by an independent, qualified individual as meeting its design and air quality  
610 specifications (see [Table 3](#)). It is important to place special emphasis on certifying the  
611 ISO Class 5 areas. During certification of ISO Class 5 areas, air sampling must be  
612 performed inside the PEC and the surrounding ISO-classified areas. Routine staff  
613 activity during compounding-related processes must be simulated during certification.

614 Certification of the PEC must include:

- 615 • **Airflow Testing** to determine acceptability of the air velocity and volume, the air  
616 exchange rate, and room pressure cascade to ensure that air consistently flows  
617 from clean to dirty areas, and that the appropriate quality of air is maintained  
618 under typical operating conditions.

- 619 • **HEPA Filter Integrity Testing** using the most penetrating particle size. HEPA  
620 filters must be leak tested at the factory and then leak tested again after  
621 installation and as part of recertification.
- 622 • **Total Particle Counts Testing** under typical operating conditions by qualified  
623 operators using current, state-of-the-art electronic equipment.
- 624 • **Smoke Studies** for each PEC under full operational processing conditions to  
625 demonstrate unidirectional airflow and sweeping action over and away from the  
626 product(s).

627 Certification of other ISO-classified areas must include:

- 628 • **Airflow Testing** to determine acceptability of the air velocity and volume, the air  
629 exchange rate, and room pressure cascade to ensure that air consistently flows  
630 from clean to dirty areas and that the appropriate quality of air is maintained  
631 under typical operating conditions.

632 Classified areas must be recertified if there are changes to the area such as redesign,  
633 construction, or replacement or relocation of the PEC, or alteration in the configuration  
634 of the room that could affect airflow or air quality. Recertification must be done at least  
635 every 6 months.

636 All certification and recertification records must be reviewed by supervising personnel  
637 or other designated employees to ensure that the controlled environments comply with  
638 the proper standards and records must be maintained in accordance with the  
639 requirements in *16. Documentation*.

#### 640 **4.6 Design and Construction of Facilities for Compounding with Hazardous Drugs**

641 For design of facilities in which compounding with hazardous drugs will occur, see  
642 [\(800\)](#).

643

644

### **5. ENVIRONMENTAL MONITORING**

645 An effective environmental monitoring program provides meaningful information on the  
646 quality of the compounding environment and any environmental trends in surrounding  
647 areas. In addition, an effective environmental monitoring program will identify potential  
648 routes of contamination, allowing for implementation of corrections to prevent CSP  
649 contamination. Sterile compounding facilities must develop and implement written  
650 environmental monitoring procedures (see *9. SOPs and Master Formulation and*  
651 *Compounding Records*). All environmental sampling and results must be documented,  
652 and records must be maintained in accordance with the requirements in *16.*  
653 *Documentation*.

654

#### **5.1 General Monitoring Requirements**

655 Sterile compounding facilities must be qualified initially using environmental air and  
656 surface sampling as described below to establish a baseline level of environmental  
657 quality. After initial qualification, the environment in which sterile compounding activities  
658 are performed must be monitored regularly to ensure that the environment remains  
659 suitable for sterile compounding.

660 Environmental monitoring involves the collection and review of environmental samples  
661 from various air and surface locations to detect airborne and surface contaminants.  
662 Data from sampling are then used to assess airborne nonviable particulate and  
663 microbial contamination risks, potential routes of contamination, and the adequacy of  
664 disinfection procedures. Data collected from environmental sampling must be reviewed  
665 regularly to detect elevated levels of microbial bioburden, elevated levels of nonviable  
666 particulates, or other adverse changes within the environment.

667 Data from air and surface sampling must be reviewed in conjunction with personnel  
668 data to assess the state of environmental control and to identify CSP contamination  
669 risks. Prompt corrective action in response to any adverse data is essential to maintain  
670 the necessary environmental quality for CSP preparation. Data must also be reviewed  
671 following corrective actions to confirm that the actions taken have been effective in  
672 achieving the required air and surface quality levels (see [Table 3](#) and [Table 5](#)).

673 Routine environmental sampling during compounding operations must be conducted to  
674 confirm that the environmental quality in ISO-classified areas is maintained. Sampling  
675 also must be performed in any of the following circumstances.

- 676 • As part of the certification of new facilities and equipment
- 677 • As part of recertification, following any servicing of facilities or equipment (see 4.  
678 *Buildings and Facilities*)
- 679 • In response to identified problems (e.g., sterility failures; a complaint of patient  
680 infection when the CSP is considered to be a potential source of the infection)
- 681 • In response to identified trends (e.g., repeated positive fingertip sampling results  
682 or failed media fill simulations; repeated observations of air or surface  
683 contamination)

684 The sampling program must include: 1) nonviable airborne particulate sampling; 2)  
685 viable airborne particulate sampling; and 3) surface sampling, including but not limited  
686 to equipment, work surfaces, and room surfaces.

687 To obtain an environmental sample that is representative of the full operating  
688 conditions at the facility, environmental air sampling (both viable and nonviable) must be  
689 conducted during periods of typical activity (i.e., when compounding is occurring).  
690 However, the sampling program must be designed and conducted in a manner that  
691 minimizes the chance that the sampling itself will contribute to contamination of the  
692 CSP, the operator, or the environment.

693 The sampling program must be developed based on an understanding of risk factors,  
694 including but not limited to criticality of the environment sampled, number and types of  
695 activities conducted in the room being monitored, maximum number of personnel that  
696 may be working in the room at one time, and how the CSPs will be exposed to the  
697 immediate environment during compounding. The sampling program must contain a  
698 listing of the sample locations, procedures for collecting samples, frequency of  
699 sampling, size of sample (e.g., surface area, volume of air), time of day sampled in  
700 relation to activities in the compounding area, and levels that will trigger corrective  
701 action. Sampling timing and locations should be carefully selected based on their  
702 relationship to the operation performed in the area. Sampling locations, frequencies,  
703 and timing must be clearly described in a facility's established Standard Operating

704 Procedure (SOP). It is important to sample locations posing the most contamination risk  
705 to the CSP (i.e., the PEC), and sampling locations should be selected that are likely to  
706 be representative of the conditions throughout the area.

707 Graphic presentation of the results collected over a period of time can be useful in  
708 identifying trends, or for indicating that a significant change has occurred, even when  
709 the results fall within the specified limits.

710 It is important that personnel be trained in the proper operation of the air sampling  
711 equipment used to ensure reproducible sampling. All air sampling devices must be  
712 serviced and calibrated at appropriate intervals (i.e., as recommended by the  
713 manufacturer).

## 714 **5.2 Monitoring Air Quality for Nonviable Airborne Particles**

715 Because maintaining appropriate air quality is essential to the overall contamination  
716 prevention strategy for sterile compounding, it is imperative that all engineering control  
717 equipment function as designed and that the levels of airborne particles remain within  
718 acceptable limits during compounding operations (see [Table 3](#)). A monitoring program  
719 for nonviable airborne particles must be developed and implemented to measure the  
720 performance of the engineering controls that are being used to provide the specified  
721 levels of air cleanliness (e.g., in the PEC and ISO Class 7 and 8 areas).

### 722 AIR SAMPLING TIMING AND LOCATIONS

723 Air sampling sites must be selected in all classified areas. Measurements of air  
724 cleanliness must be taken in each PEC, at locations where there is greatest risk to the  
725 exposed CSPs, containers, and closures. Measurements of air cleanliness in other  
726 classified areas, including the buffer area and ante-area, should be taken at  
727 representative locations that reflect the quality of air in the area. When conducting  
728 sampling of the PEC, care should be taken to avoid disturbing the unidirectional airflow.

729 Total particle counts of all ISO-classified areas must be conducted during typical  
730 operations every 6 months.

### 731 DATA EVALUATION AND ACTION LEVELS

732 If levels measured during the nonviable air sampling program exceed the criteria in  
733 [Table 3](#) for the appropriate ISO classification levels of the area sampled when  
734 measured under typical operating conditions, an investigation of the cause must be  
735 conducted and corrective action must be taken to prevent future deviations. When  
736 nonviable air sampling results for an ISO Class 5 PEC exceed the criteria in [Table 3](#), all  
737 compounding activities must cease in that PEC and a corrective action plan must be  
738 implemented immediately. When nonviable air sampling results for ISO Class 7 or 8  
739 areas exceed the criteria in [Table 3](#), a corrective action plan must be implemented  
740 immediately. In such a case, if compounding is continued, the BUDs for any CSPs  
741 compounded must not exceed the BUDs for Category 1 CSPs until the area is  
742 successfully recertified. Some examples of corrective action include a procedural  
743 improvement, such as enhanced disinfection; a process or facility improvement; or  
744 HEPA filter replacement or repair. The extent of the investigation should be consistent  
745 with the type of excursion, and should include an evaluation of trends.

## 746 **5.3 Monitoring Air Quality for Viable Airborne Particles**

747 An environmental sampling program for viable airborne particles must be developed  
748 and implemented to assess microbiological air quality in all classified areas. The goals  
749 of an environmental sampling program are to determine whether contamination is  
750 present at unacceptable levels and to assess whether proper personnel practices are  
751 being followed and proper environmental conditions maintained.

#### AIR SAMPLING TIMING AND LOCATIONS

752  
753 Air sampling sites must be selected in all classified areas. When conducting sampling  
754 of the PEC, care should be taken to avoid disturbing unidirectional airflow. See [Box 5-1](#)  
755 for active air sampling procedures. Active air sampling of all ISO-classified areas must  
756 be conducted during typical operating conditions at least monthly. Active air sampling is  
757 required in each ISO-classified area (e.g., PEC and ISO Class 7 and 8 areas). A  
758 general microbiological growth medium that supports the growth of bacteria and fungi,  
759 such as trypticase soy agar (TSA) or soybean-casein digest medium, must be used.  
760 Samples must be incubated at 20°–25° for 5–7 days and then at 30°–35° for 2–3  
761 additional days. A microbiological incubator that is monitored to maintain the required  
762 temperature must be used to incubate the samples. The microbiological incubator must  
763 be placed in a location outside of a cleanroom or segregated compounding area. All  
764 sampling activities must be performed by properly trained individuals.

#### **Box 5-1 Active Air Sampling Procedures for Viable Airborne Monitoring**

- Decontaminate sampling equipment according to the manufacturer's instructions and handle aseptically.
- When media are brought into an ISO-classified area, wipe the wrapping with sterile 70% IPA using a low-lint sterile wipe before removing the media from their packaging.
- Examine media used to collect samples for damage or contamination, and handle in an aseptic manner. Discard contaminated or damaged media and conduct an investigation to determine the cause of the damage or contamination. If a damaged sampling device or packaging is identified (e.g., cracks or foreign bodies on the media surface, or discoloration), examine the entire lot of devices from that vendor to determine whether other devices are damaged or contaminated.
- Using an active air sampling device, test at least 1 cubic meter or 1,000 liters of air from each area sampled.
- At the end of the designated sampling, retrieve the medium and cover it to protect it from external contamination. Protect media from physical damage and keep at appropriate temperatures during transport to the incubator.
- Invert the media plates and incubate the medium at 20°–25° for 5–7 days and then at 30°–35° for 2–3 additional days.
- Examine the media plates for growth daily during normal business hours and record the total number of discrete colonies of microorganisms as CFU per cubic meter of air on an environmental sampling form based on sample type, sample location, and sample date.

767 Evaluate counts against the action levels in [Table 4](#), and examine counts in relation to  
 768 previous data to identify adverse results or trends. If levels measured during the viable  
 769 air sampling program reach or exceed the levels in [Table 4](#), corrective actions must be  
 770 taken, including repeat air sampling. If a CFU count is identified below the action levels  
 771 in [Table 4](#), primary screening and characterization must be performed (see [Microbial  
 772 Characterization, Identification, and Strain Typing \(1113\)](#)). Highly pathogenic  
 773 microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus, molds  
 774 and yeasts) are potentially fatal to patients receiving CSPs and must be immediately  
 775 remedied through cleaning and disinfection, regardless of CFU count. If levels  
 776 measured during viable air sampling exceed the levels in [Table 4](#), the genus must be  
 777 identified, and when possible, identify the species of any microorganism recovered, with  
 778 the assistance of a credentialed microbiology laboratory.

779 **Table 4. Action Levels for Viable Airborne Particle Air Sampling<sup>a</sup>**

ISO Class	Air Sampling Action Levels (CFU/m <sup>3</sup> ) <sup>b</sup>
5	≥1
7	≥10
8	≥100

<sup>a</sup> Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice—US Dept of Health and Human Services, Food and Drug Administration, (FDA) September 2004.

<sup>b</sup> All action levels must be based on sampling in the vicinity of exposed materials/articles during compounding operations.

780 **5.4 Sampling Surfaces for Contamination**

781 Surface sampling is an important component of the maintenance of a suitably  
 782 controlled environment for compounding CSPs, especially because transfer of microbial  
 783 contamination from improperly disinfected work surfaces via inadvertent touch contact  
 784 by compounding personnel is a potential source of contamination of CSPs. Surface  
 785 sampling is useful for evaluating facility and work surface cleaning and disinfecting  
 786 procedures, and employee competency in work practices such as cleaning and  
 787 disinfection of component/vial surfaces.

788 Surface sampling for microbial contamination must be performed in all ISO-classified  
 789 areas. All sampling sites and procedures must be described in the facility's SOP.

790 **SAMPLING TIMING AND LOCATIONS**

791 When conducted, surface sampling must be performed at the conclusion of  
 792 compounding activities, but before the area has been cleaned and disinfected. Media  
 793 used for surface sampling must be supplemented with additives to neutralize the effects  
 794 of any residual disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

795 Multiple locations must be sampled at least monthly within each ISO-classified area,  
 796 including the following (see [\(1116\)](#)):

- 797 • The interior of the PEC and equipment contained in it

- 798 • Staging or work areas near the PEC
- 799 • Frequently touched surfaces
- 800 • Pass-through chambers

801 SAMPLING PROCEDURES

802 Contact sampling devices (e.g., plates, paddles, or slides) containing microbial growth  
803 media must be used for sampling flat surfaces. Sterile swabs wetted with sterile water  
804 can be used when sampling irregular surfaces and difficult-to-reach locations in  
805 classified areas, such as crevices, corners, and spaces between surfaces.

806 Surface sampling devices must contain general microbial growth media (e.g., soybean  
807 casein digest media) supplemented with neutralizing additives (e.g., lecithin and  
808 polysorbate 80). Use a surface sampling device (e.g., plates, paddles, or slides) in the  
809 size range of 24- to 36-cm<sup>2</sup>. Contact sampling devices must be certified by the  
810 manufacturer to meet growth promotion tests in [Microbial Enumeration Tests \(61\)](#).  
811 Contact plates must have a raised convex surface. Plates must be stored according to  
812 the manufacturer's recommendation. See [Box 5-2](#) for the procedures for conducting  
813 surface sampling with contact sampling devices. Follow the manufacturer's instructions  
814 for using sampling swabs.

815 **Box 5-2 Using Devices for Flat Surface Sampling**

- Examine media used to collect samples for damage or contamination and handle in an aseptic manner. Discard contaminated or damaged media and conduct an investigation to determine the cause of the damage or contamination. If a damaged sampling device or packaging is identified (e.g., cracks or foreign bodies on the media surface, or discoloration), examine the entire lot of devices from that vendor to determine whether other devices are damaged or contaminated.
- If using commercially prepared devices, wipe the wrapping with sterile 70% IPA using a low-lint sterile cloth before removing the devices from their packaging.
- Remove the cover from the contact sampling device and firmly press the media surface onto the surface to be sampled. The contact sampling device will leave a residue of growth medium on the sample site. After sampling, use a low-lint sterile wipe to thoroughly clean the sampled area with sterile water and disinfect with sterile 70% IPA.
- After exposure, cover each contact sampling device to protect it from further contamination.
- Invert the plates and incubate the contact sampling devices at 20°–25° for 5–7 days and then at 30°–35° for 2–3 additional days.
- Examine the sampling devices for growth daily during normal business hours, and record the observed count at each time point. At the final time point, record the total number of discrete colonies of microorganisms (CFU/sample) on the environmental sampling record based on sample type, sample location and sample date.

817 If levels measured during surface sampling exceed the criteria in [Table 5](#), an  
 818 investigation of the cause must be conducted and corrective action must be taken to  
 819 prevent future deviations. When surface sampling results for an ISO Class 5 PEC  
 820 exceed the criteria in [Table 5](#), all compounding activities must cease in that PEC. When  
 821 surface sampling results for ISO Class 7 or 8 areas exceed the criteria in [Table 5](#), a  
 822 corrective action plan must be implemented immediately. In such a case, if  
 823 compounding is continued, the BUDs for any CSPs compounded must not exceed the  
 824 BUDs for Category 1 CSPs until the surfaces are retested and the results fall below  
 825 action levels in [Table 5](#). Some examples of corrective action include a procedural,  
 826 facility, or equipment improvement. The extent of the investigation should be consistent  
 827 with the type of excursion and should include an evaluation of trends.

828 **Table 5. Action Levels for Surface Sampling**

ISO Class	Work Surfaces Sampled Using Contact Plates (CFU/plate) <sup>a</sup>	Work Surfaces Sampled Using Swabs (CFU/25 cm <sup>2</sup> or per sample) <sup>a</sup>	Non-work Surfaces Sampled Using Contact Plates (CFU/plate) <sup>b</sup>	Non-work Surfaces Sampled Using Swabs (CFU/25 cm <sup>2</sup> or per sample) <sup>b</sup>
5	>3	>3	N/A <sup>c</sup>	N/A <sup>c</sup>
7	>5	>5	>10	>10
8	>25	>25	>50	>50

<sup>a</sup> Work surfaces are those surfaces that are in direct contact with materials used in compounding. These action levels are based on the expectation that materials will be disinfected before introduction to an ISO Class 5 area.

<sup>b</sup> Non-work surfaces are those surfaces that do not come into direct contact with materials used in compounding.

<sup>c</sup> All surfaces within the ISO Class 5 area are considered work surfaces.

829  
830

**6. CLEANING AND DISINFECTING COMPOUNDING AREAS**

831 Surfaces in compounding areas are a major source of microbial contamination of  
 832 CSPs. Therefore, scrupulous attention must be paid to cleaning and disinfection.  
 833 Cleaning and disinfecting the surfaces in sterile compounding areas must occur on a  
 834 regular basis at the intervals noted in [Table 6](#). Cleaning and disinfection must be  
 835 repeated when spills occur; when surfaces, floors, and walls are visibly soiled; and  
 836 when microbial contamination is known to have been, or is suspected of having been,  
 837 introduced into the compounding areas.

838 If compounding is done less frequently than the cleaning frequencies specified below  
 839 (e.g., once a week or once a month), cleaning must occur before each compounding  
 840 session begins, instead of according to the frequencies described in [Table 6](#).

841 **Table 6. Minimum Frequency for Cleaning and Disinfecting Surfaces in Classified**  
 842 **and Segregated Compounding Areas**

Site	Minimum Frequency
------	-------------------

Site	Minimum Frequency
PEC (except for an isolator)	At the beginning and end of each shift; before each batch; no longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring; after spills; and when surface contamination is known or suspected
Isolator (as defined in 4. <i>Buildings and Facilities</i> )	Clean the isolator each time it is opened; decontaminate the isolator once it is closed after each time it has been opened, or after each cleaning cycle, if cleaning occurs without opening
Work surfaces outside the PEC (e.g., buffer area and/or segregated compounding area)	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

843

### 6.1 Disinfectants

844 Cleaning and disinfection agents must be selected and used with careful consideration  
845 of compatibilities, effectiveness, and inappropriate or toxic residues (see *Appendix 2*  
846 and [Disinfectants and Antiseptics \(1072\)](#)). The selection and use of disinfectants must  
847 be guided by microbicidal activity, inactivation by organic matter, residue, and shelf life.  
848 Sporocidal agents must be used at least weekly to clean all ISO-classified and  
849 segregated compounding areas (see [Disinfectants and Antiseptics \(1072\)](#),  
850 [Classification of Disinfectants, Table 2, General Classification of Antiseptics,](#)  
851 [Disinfectants, and Sporocidal Agents](#)).

852 The frequency, methods, and locations of disinfection agent use must be established  
853 in written SOPs, in accordance with the manufacturer's instructions, and followed by  
854 environmental services (i.e., custodial) or compounding personnel.

855

### 6.2 Cleaning Tools

856 All cleaning tools (e.g., wipes, sponges, and mop heads) must be sterile and low-lint,  
857 preferably composed of synthetic microfibers and dedicated for use in buffer or ante-  
858 areas or segregated compounding areas. All cleaning tools must be cleaned and re-  
859 sterilized after each use. They must be discarded after an appropriate amount of time,  
860 to be determined based on the condition of the materials. Disposal must involve  
861 collecting them in suitable plastic bags and removing them from classified and  
862 segregated compounding areas, with minimal agitation so as not to disperse  
863 contaminants into the air.

864

### 6.3 Cleaning and Disinfecting Floors, Ceilings, Walls, and Shelving

865 Floors in all ISO-classified and segregated compounding areas should be cleaned by  
866 mopping with a cleaning and disinfection agent once daily at a time when no aseptic  
867 operations are in progress. Mopping should be in the direction of clean to dirty areas.  
868 Mopping must be performed by trained personnel using approved agents and  
869 procedures, which must be described in written SOPs. In all ISO-classified and  
870 segregated compounding areas, the walls, ceilings, and shelving must be cleaned and  
871 disinfected monthly.

## 872 **6.4 Cleaning and Disinfecting Work Surfaces**

873 For both Category 1 and Category 2 CSPs, cleaning and disinfecting work surfaces in  
874 the PEC are the most critical steps before preparing CSPs. These surfaces must be  
875 cleaned and disinfected more frequently than other surfaces such as walls and ceilings.  
876 With the exception of isolators (as defined in *4. Buildings and Facilities*), all surfaces in  
877 the PEC must be cleaned at the beginning and end of each work shift; no longer than  
878 30 minutes following the previous surface disinfection when ongoing compounding  
879 activities are occurring; when there are spills; and when surface contamination is known  
880 or suspected from procedural breaches. Additionally, surfaces in the PEC in direct  
881 contact with materials used in compounding must be cleaned before starting each batch  
882 of CSPs. When using an isolator, cleaning must be done when the isolator is opened.  
883 Decontaminate the isolator once it is closed after each time it has been opened, or after  
884 each cleaning cycle, if cleaning occurs without opening. See [Box 6-1](#) for a summary of  
885 procedures for cleaning and disinfecting visibly soiled areas in the PEC.

### 886 **Box 6-1 Procedures for Cleaning and Disinfecting Visibly Soiled Areas in the PEC**

- Remove all items on the surface and remove loose material and residue from spills using a suitable cleaning agent.
- Use sterile water for injection or irrigation and sterile low-lint wipes to remove water-soluble solid residues.
- Wipe the affected area with a disinfectant (e.g., sterile 70% IPA).
- Allow the surface to dry before beginning compounding.

887 Work surfaces in the buffer, ante, and segregated compounding areas must be  
888 cleaned and disinfected at least daily, and storage sites for compounding ingredients  
889 and supplies must remain free from dust and debris. This must be achieved using a  
890 method that does not diminish the ISO Class 7 or 8 air quality.

## 891 **6.5 Cleaning and Disinfecting Compounding Supplies**

892 No shipping or other external cartons are allowed into the buffer or ante-areas or  
893 segregated compounding areas. Before compounding supplies are introduced into  
894 buffer areas, they must be wiped with a suitable disinfectant (e.g., sterile 70% IPA) that  
895 is delivered from a spray bottle or other suitable delivery method. After the disinfectant  
896 is sprayed or wiped on the surface to be disinfected, the disinfectant must be allowed to  
897 dry, during which time the item cannot be used.

## 898 **6.6 Disinfecting Critical Sites**

899 Critical sites (e.g., vial stoppers, ampul necks, and intravenous bag septums) must be  
900 disinfected by wiping them with sterile 70% IPA swabs that are commercially available

901 in individual foil-sealed packages (or a comparable method). The IPA must be allowed  
902 to dry before piercing stoppers with sterile needles or breaking the necks of ampuls.  
903 The sterile 70% IPA swabs used for disinfecting critical sites and devices must not  
904 contact any other object before contacting the critical site.

905  
906

## 7. EQUIPMENT AND COMPONENTS

907

### 7.1 Equipment

908 The equipment used for compounding CSPs must be of appropriate design and  
909 adequate size. The equipment also must be of suitable composition such that the  
910 surfaces that contact components are not reactive, additive, or sorptive, and therefore,  
911 will not affect or alter the purity of the CSP. Equipment in direct contact with the CSP  
912 and container–closure system must be sterilized and depyrogenated using methods  
913 appropriate for the equipment and container–closure system (see 8. *Sterilization and*  
914 *Depyrogenation*, and [Sterilization and Sterility Assurance of Compendial Articles](#)  
915 [\(1211\)](#), [Methods of Sterilization](#)).

916 Equipment must be suitably located to facilitate sterile compounding operations. It  
917 must be consistently capable of operating properly and within acceptable tolerance  
918 limits. Compounding personnel must establish, maintain, and follow written procedures  
919 for the calibration, maintenance, and use of the equipment, as well as monitoring it for  
920 proper function. Personnel must also maintain results from equipment calibration,  
921 annual maintenance reports, and other routine maintenance records in accordance with  
922 the requirements in 16. *Documentation*.

923 Automated compounding devices (ACDs) are designed to streamline the labor-  
924 intensive processes involved in the compounding of multiple-ingredient preparations  
925 (e.g., parenteral nutrition) by automatically delivering the individual ingredients in a  
926 predetermined sequence under computerized control. ACDs can improve the accuracy  
927 and precision of the compounding process, compared with manual compounding  
928 methods.

929 When using ACDs, compounding personnel must conduct an accuracy assessment of  
930 the ACD each day it is used to compound CSPs. The volume and weight accuracy of  
931 the ACD must be determined, based on manufacturer recommendations, to ensure that  
932 the correct quantities of ingredients are delivered to the final container. The precision of  
933 the ACD can be monitored based on an assessment of day-to-day variations in its  
934 accuracy measures. Compounding personnel must keep a daily record of the accuracy  
935 measures and must review the results at least weekly to identify trends over time.

936

### 7.2 Components

937 Compounding personnel must establish, maintain, and follow written procedures for  
938 the selection and inventory control of all CSP components, including all ingredients (i.e.,  
939 bulk active pharmaceutical ingredients (APIs) and inactive ingredients), containers, and  
940 closures. These written procedures must be followed for all components, from receipt to  
941 consumption.

942

#### COMPONENT SELECTION

943 Compounders must use qualified vendors. A vendor is qualified when there is  
944 evidence to support its ability to supply a material that consistently meets all quality  
945 specifications. Qualification must include an evaluation of the vendor's reputation and  
946 reliability.

947 Ingredients that are the subject of a *USP* or *NF* monograph must be used when  
948 available. APIs used in compounding must be manufactured by an FDA-registered  
949 facility. Each API must be accompanied by a valid COA that includes the specifications  
950 and test results and shows that the API meets the monograph, if one exists, and any  
951 additional specifications required to appropriately compound the CSP. Other bulk  
952 ingredients should be accompanied by a valid COA that shows that the ingredient  
953 meets the monograph, if one exists, and any additional specifications for the ingredient.

954 When ingredients other than APIs cannot be obtained from an FDA-registered facility,  
955 compounders must use professional judgment in selecting an acceptable and reliable  
956 source. When ingredients are obtained from an unregistered facility, the compounder  
957 must establish the identity, strength, purity, and quality of the ingredients obtained from  
958 that supplier by reasonable means. These means may include checking each lot of the  
959 component when received, or periodically verifying quality by testing a sample of  
960 components obtained from that supplier to determine whether the COAs for ingredients  
961 sourced from that supplier accurately reflect the characteristics of the ingredients.

962 When components of compendial quality are not obtainable, components of high  
963 quality such as those that are chemically pure, analytical reagent grade, or American  
964 Chemical Society (ACS)–certified may be used. However, these components should be  
965 used cautiously because the standards for analytical reagents or ACS–grade materials  
966 do not consider whether the presence of any impurity raises human or animal safety  
967 concerns.

968 Careful consideration and evaluation of nonsterile ingredient sources is especially  
969 warranted when the CSP will be administered into the vascular system, central nervous  
970 system, or eyes.

971 Each lot of commercially available sterile, depyrogenated containers and container–  
972 closure systems must be accompanied by a COA or other documentation showing  
973 conformance with established specifications.

#### 974 COMPONENT RECEIPT

975 Upon receipt of each lot of a component, a visual inspection must be performed to  
976 ensure that the ingredient appears to be what it is represented to be; the lot must also  
977 be examined for evidence of deterioration and other aspects of unacceptable quality.  
978 Facility personnel must verify the labeling and condition of the component [e.g., whether  
979 the outer packaging is damaged and whether temperature-sensing indicators show that  
980 the component has been exposed to excessive temperature(s)].

981 Analytical results in the vendor-supplied COA for each lot of incoming ingredient must  
982 be inspected against the compounding facility's current specification sheet to ensure  
983 that the acceptance criteria are met. If there is a compendial monograph for any  
984 ingredient received, facility personnel must verify that the COA for the ingredient  
985 demonstrates that the ingredient has met the acceptance criteria of all specified  
986 monograph tests for that lot and includes the test results.

987 Any ingredients found to be of unacceptable quality must be promptly rejected, clearly  
988 labeled as rejected, and segregated to prevent their use before appropriate disposal.

989 Any other lots of that ingredient from that vendor must be examined to determine  
990 whether other lots have the same defect.

991 The date of receipt by the compounding facility must be clearly and indelibly marked  
992 on each ingredient package, except for finished dosage forms obtained from FDA-  
993 registered manufacturers. For each ingredient, information including receipt date,  
994 quantity received, supplier's name, lot number, expiration date, and results of any in-  
995 house or third-party testing performed must be recorded. Compounding personnel must  
996 keep a written record of each shipment of components received, in accordance with the  
997 recordkeeping requirements described in *16. Documentation*.

#### 998 COMPONENT EVALUATION BEFORE USE

999 Before use, all components must be re-inspected. Ingredient packages must be  
1000 inspected to detect container breaks, looseness of the cap or closure, and deviation  
1001 from the expected appearance, aroma, and texture of the contents that might have  
1002 occurred during storage. Sterile container–closures and sterile devices must be visually  
1003 inspected to ensure that they are free from defects that could compromise sterility, and  
1004 are otherwise suitable for their intended use.

1005 Compounding personnel must ascertain before use that ingredients for CSPs are of  
1006 the correct identity and appropriate quality and have been stored under appropriate  
1007 conditions. The following information should be used to make this determination:  
1008 prescription or medication order, compounding record, master formulation record (if  
1009 used), vendor labels and COAs, product labeling, and knowledge of the compounding  
1010 facility storage conditions and practices.

1011 If the correct identity, purity, strength, and sterility of ingredients and other components  
1012 intended for preparation of CSPs cannot be confirmed (e.g., containers of ingredients  
1013 with incomplete labeling, unlabeled syringes, opened ampuls, punctured vial stoppers,  
1014 flexible intravenous bags), they must be promptly rejected, clearly labeled as rejected,  
1015 and segregated to prevent their use before appropriate disposal.

#### 1016 COMPONENT HANDLING AND STORAGE

1017 All components must be handled and stored in a manner that prevents contamination,  
1018 mix-ups, and deterioration. Ingredients must be stored in tightly closed containers under  
1019 temperature, humidity, and lighting conditions consistent with those indicated in official  
1020 monographs or specified by the suppliers/manufacturer. Moisture-sensitive ingredients  
1021 must be stored in tight, well-closed containers.

1022 Packages of ingredients that lack a vendor's expiration date must not be used after 1  
1023 year from receipt by the compounding facility, unless appropriate inspection and testing  
1024 indicates that the ingredient has retained its purity and quality for use in CSPs.

1025 For information on handling and storage of hazardous drugs, see [\(800\)](#).

1026

1027

### 8. STERILIZATION AND DEPYROGENATION

1028 Each CSP must be sterile and pyrogen-free before release. When selecting the  
1029 sterilization method for each CSP, personnel must take into consideration the nature of  
1030 the components, its physical and chemical properties, and the intended container–  
1031 closure system. The sterilization method used must sterilize the CSP while maintaining  
1032 its physical and chemical stability (i.e., appropriate strength, purity, quality), and the

1033 packaging integrity of the CSP. Utensils and materials in direct contact with the  
1034 components, the CSP, and the container–closure system must be sterilized and  
1035 depyrogenated using appropriate methods (see [Sterilization of Compendial Articles](#)  
1036 [\(1229\)](#)). If sterilization and depyrogenation of container–closure systems is performed  
1037 on site, the efficacy of each process must be established and documented, and the  
1038 process must be shown to be reproducible. CSPs that are terminally sterilized are  
1039 expected to use a process that achieves a sterility assurance level (SAL) of  $10^{-6}$ . An  
1040 SAL of  $10^{-6}$  is equivalent to a probability that 1 unit in a million is nonsterile. Generally,  
1041 an SAL value cannot be applied to CSPs that are aseptically filled into a sterile  
1042 container following sterilization.

1043 The following must be considered when selecting an appropriate sterilization method:

- 1044 • Terminal sterilization (e.g., dry heat, steam, or irradiation) is the preferred  
1045 method, unless the specific CSP or container–closure system cannot tolerate  
1046 terminal sterilization.
- 1047 • Filtration is not an option if compounding a suspension when the suspended  
1048 particles are removed by the filter being used, which could affect the strength of  
1049 the CSP.
- 1050 • Dry heat is not an option if a CSP component is labile when exposed to the  
1051 temperatures used.
- 1052 • Steam sterilization is not an option if moisture, pressure, or the temperatures  
1053 used would degrade the CSP.

1054 A description of the sterilization and depyrogenation process, including the  
1055 temperature, pressure (if applicable), duration, and permissible load conditions for each  
1056 cycle, must be included in the facility’s written SOPs (see 9. *SOPS and Master*  
1057 *Formulation and Compounding Records*.)

1058 In addition, the SOPs must include a schedule and method for establishing and  
1059 periodically verifying the effectiveness of the sterilization and depyrogenation methods  
1060 selected, as well as the method for maintaining and cleaning the sterilizers and  
1061 depyrogenation equipment.

1062 The following sections provide general guidance on specific sterilization methods.

### 1063 **8.1 Sterilization by Filtration**

1064 See [Sterilizing Filtration of Liquids \(1229.4\)](#). Commercially available sterile filters must  
1065 be certified by the manufacturer as suitable for pharmaceutical use when used to  
1066 sterilize CSPs. Sterilizing filters must be sterile and pyrogen-free and have a nominal  
1067 pore size of 0.2 or 0.22  $\mu\text{m}$ . They must be certified by the manufacturer to retain at least  
1068  $10^7$  microorganisms of a strain of *Brevundimonas diminuta* per square centimeter of  
1069 upstream filter surface area under conditions similar to those in which the CSPs will be  
1070 filtered (i.e., pressure, flow rate, and volume filtered).

1071 The person responsible for selecting the sterilization method must ascertain from  
1072 appropriate information sources that the sterilizing-grade membrane filter selected is  
1073 chemically and physically compatible with the specific formulation of the CSP. For  
1074 example, CSPs containing water-miscible alcohols may cause undetectable damage to  
1075 filter integrity and shrinkage of microorganisms to sizes smaller than the filter’s nominal  
1076 pore size.

1077 The responsible person must ensure, directly or from appropriate documentation from  
1078 the supplier, that the filters 1) are chemically and physically stable at the pressure and  
1079 temperature conditions that will be used; 2) have enough capacity to filter the required  
1080 volumes; and 3) will yield a sterile filtrate while maintaining pre-filtration pharmaceutical  
1081 quality, including strength of ingredients of the specific CSP. The filter dimensions and  
1082 the preparation to be sterilized by filtration should permit the sterilization process to be  
1083 completed without the need for replacement of the filter during the process. When CSPs  
1084 are known to contain excessive particulate matter, to maximize the efficiency of the final  
1085 sterilizing filtration, a pre-filtration step should be performed using a filter of larger  
1086 nominal pore size, or a separate filter of larger nominal pore size should be placed  
1087 upstream of (i.e., prior to) the sterilizing filter to remove gross particulate contaminants  
1088 before the CSP is passed through the sterilizing grade filter. Excessive particulate  
1089 matter requiring a prefiltration step also could be a signal of an inappropriate  
1090 formulation, and therefore the formulation and the process should be assessed to  
1091 ensure that they are appropriate; if necessary, they should be modified. Filter units used  
1092 to sterilize CSPs must be subjected to the manufacturers' recommended post-use  
1093 integrity test, such as a bubble point test.

## 1094 **8.2 Sterilization by Steam Heat**

1095 See [Steam Sterilization by Direct Contact \(1229.1\)](#). The process of thermal  
1096 sterilization using saturated steam under pressure (i.e., autoclaving) is the preferred  
1097 method for terminal sterilization of aqueous preparations in their final, sealed container-  
1098 closure system. Steam heat sterilization is not an option if moisture, pressure, or the  
1099 temperatures used would degrade the CSP. Steam heat sterilization is also used to  
1100 sterilize many components (e.g., elastomeric closures) and some types of equipment.  
1101 To achieve sterility, all materials must be directly exposed to steam under adequate  
1102 pressure for the length of time necessary, as determined by use of appropriate  
1103 biological indicators, to render the items sterile (i.e., kill any microorganisms, including  
1104 bacterial spores that might be present). This is usually between 20 and 60 minutes at  
1105 121° saturated steam under a pressure of 15 psi. The duration of the exposure period  
1106 must include sufficient time for the CSP or other items to reach the sterilizing  
1107 temperature. The CSP and other items must remain at the sterilizing temperature for the  
1108 duration of the sterilization period. The sterilization cycle should be designed to achieve  
1109 a SAL of 10<sup>-6</sup>.

1110 CSPs must be placed in suitable trays to allow steam to reach the CSPs without  
1111 entrapment of air. Flat, stainless steel trays with low sides or ventilated bottoms will  
1112 permit steam contact. When preparing plastic, glass, and metal devices or other items  
1113 for steam sterilization, the items must be wrapped in low-lint protective fabric or paper or  
1114 sealed in envelopes that will permit steam penetration and prevent post sterilization  
1115 microbial contamination. Immediately before filling ampuls and vials that will be steam  
1116 sterilized, solutions must be passed through a filter having a nominal pore size of not  
1117 larger than 1.2 µm for removal of particulate matter.

1118 Sealed containers must be able to generate steam internally. Stoppered and crimped  
1119 empty vials must contain a small amount of moisture to generate steam. Deep  
1120 containers, such as beakers and graduated cylinders, should be placed on their sides to  
1121 prevent air entrapment, or should have a small amount of water placed in them when  
1122 steam sterilized. Porous materials and those items with occluded pathways (e.g.,

1123 tubing) should only be sterilized by steam if the autoclave chamber has suitable cycles  
1124 for dry goods, such as a pre-vacuum process to remove air before steam is sent into the  
1125 chamber. Elastomeric closures and many other dry goods will need a drying cycle after  
1126 steam exposure to remove condensed or absorbed moisture.

1127 The effectiveness of steam sterilization must be established and verified with each  
1128 sterilization run or load by using appropriate biological indicators, such as spores of  
1129 *Geobacillus stearothermophilus*, ATCC 12980, ATCC 7953 or equivalent (see [Biological](#)  
1130 [Indicators for Sterilization \(1035\)](#)), and other confirmation methods such as  
1131 physicochemical indicators and integrators (see [Sterilization—Chemical and](#)  
1132 [Physicochemical Indicators and Integrators \(1209\)](#)).

1133 The steam supplied must be free of contaminants and generated using clean water.  
1134 The seals on the doors of autoclave chambers should be examined visually every day  
1135 they are used for cracks or other damage, and the seal surfaces should be kept clean.  
1136 A data recorder or chart must be used to monitor each cycle and to examine for cycle  
1137 irregularities (e.g., deviations in temperature or pressure).

1138 Because the temperatures used to achieve sterilization by steam heat are lower than  
1139 those used to achieve depyrogenation, materials in direct contact with the CSP (e.g.,  
1140 the container–closure system) must first undergo a depyrogenation process (e.g., dry  
1141 heat or rinsing with pyrogen-free water) before being sterilized using steam heat, unless  
1142 the materials used are certified to be pyrogen-free (see [Depyrogenation \(1228\)](#)).

### 1143 **8.3 Sterilization by Dry Heat**

1144 See [Dry Heat Sterilization \(1229.8\)](#). Dry heat can be used only for those items that  
1145 cannot be sterilized by steam or other means, when either the moisture would damage  
1146 the material or the wrapping material is impermeable. Sterilization by dry heat requires  
1147 higher temperatures and longer exposure times than sterilization by steam. The  
1148 duration of the exposure period must include sufficient time for the CSP or other items  
1149 to reach the sterilizing temperature. The CSP and other items must remain at the  
1150 sterilizing temperature for the duration of the sterilization period.

1151 Dry heat sterilization is usually done in an oven designed for sterilization at a  
1152 temperature of 160° or higher, although sterilization processes at lower temperatures  
1153 have been developed and validated. If lower temperatures are used, they must be  
1154 shown to achieve effective sterilization (see [Dry Heat Sterilization \(1229.8\)](#), [Validation](#)  
1155 [of Dry Heat Sterilization, Biological Indicators](#)).

1156 Heated air must be evenly distributed throughout the chamber, which is typically done  
1157 by an air blower. The oven must be equipped with temperature controls and a timer.  
1158 During sterilization, sufficient space must be left between materials to allow for good  
1159 circulation of the hot air. A data recorder or chart must be used to monitor each cycle  
1160 and the data must be reviewed to identify cycle irregularities (e.g., deviations in  
1161 temperature or exposure time).

1162 The effectiveness of the dry heat sterilization method must be established and verified  
1163 with each sterilization run or load using appropriate biological indicators such as spores  
1164 of *Bacillus atrophaeus*, ATCC 9372, (see [\(1035\)](#)) and other confirmation methods (e.g.,  
1165 temperature-sensing devices).

1166 Because the temperatures used to achieve sterilization by dry heat are lower than  
1167 those used to achieve depyrogenation, materials in direct contact with the CSP (e.g.,

1168 the container–closure system) must first undergo a depyrogenation process (e.g., dry  
1169 heat or rinsing with pyrogen-free water) before being sterilized using dry heat, unless  
1170 the materials used are certified to be pyrogen-free (see [\(1228\)](#)).

#### 1171 **8.4 Depyrogenation by Dry Heat**

1172 See [\(1228\)](#). Dry heat depyrogenation must be used to render glassware and other  
1173 thermostable containers pyrogen-free. Depyrogenation processes typically operate at a  
1174 range of temperatures from approximately 170° up to about 400°, depending on the  
1175 exposure time. For example, a typical cycle would hold the items at 250° for 30 minutes.  
1176 The duration of the exposure period must include sufficient time for the items to reach  
1177 the depyrogenation temperature. The items must remain at the depyrogenation  
1178 temperature for the duration of the depyrogenation period.

1179 The effectiveness of the dry heat depyrogenation cycle must be established and  
1180 verified annually using endotoxin challenge vials (ECVs) to demonstrate that the cycle is  
1181 capable of achieving a ≥3-log reduction in endotoxins (see [Bacterial Endotoxins Test](#)  
1182 [\(85\)](#)).

### 1183 **9. SOPS AND MASTER FORMULATION AND COMPOUNDING RECORDS**

1185 Every compounding facility must establish and follow written SOPs for sterile  
1186 compounding. The SOPs must ensure that the entire compounding operation is well  
1187 designed, functions as designed, and will yield CSPs that are safe for administration to  
1188 patients. The compounding process for CSPs must be described in SOPs.

1189 A Master Formulation Record is required when CSPs are prepared in a batch for  
1190 multiple patients or when CSPs are prepared from nonsterile ingredients. A Master  
1191 Formulation Record documents the ingredients, specific procedures, equipment to be  
1192 used, and testing required for each CSP. A Compounding Record is required for every  
1193 CSP prepared and requires documentation by all individuals involved in the actual  
1194 preparation of the CSP.

#### 1195 **9.1 Creating and Following SOPs**

1196 Facilities preparing CSPs must develop SOPs on all aspects of the compounding  
1197 operation. All personnel who conduct or oversee compounding activities must be trained  
1198 in the SOPs and are responsible for ensuring that they are followed. All compounding  
1199 personnel must:

- 1200 • Be able to immediately recognize potential problems, deviations, or errors  
1201 associated with preparing a CSP (e.g., related to equipment, facilities,  
1202 materials, personnel, compounding process, or testing) that could potentially  
1203 result in contamination or other adverse impact on CSP quality
- 1204 • Report any problems, deviations, or errors to the compounding supervisor or  
1205 designee, who must take corrective actions

1206 Compounding supervisors must ensure that SOPs are appropriate and are fully  
1207 implemented, which includes ensuring that staff demonstrate consistency and  
1208 competency in performing every procedure that relates to their job function.

1209 Compounding supervisors must also ensure that appropriate follow-up occurs if  
1210 problems, deviations, or errors are identified.

### 1211 **9.2 Creating Master Formulation Records**

1212 A Master Formulation Record must be created for CSPs prepared in a batch for  
1213 multiple patients or for CSPs prepared from nonsterile ingredients. Any changes or  
1214 alterations to the Master Formulation Record must be performed only by authorized  
1215 personnel and must be documented. [Box 9-1](#) lists the information that must be included  
1216 in a Master Formulation Record.

#### 1217 **Box 9-1 Master Formulation Record**

A Master Formulation Record must include at least the following information:

- Name, strength, and dosage form of the CSP
- Physical description of the final preparation
- Identities and amounts of all ingredients and appropriate container–closure systems
- Complete instructions for preparing the CSP, including equipment, supplies, and a description of the compounding steps
- BUD and storage requirements
- Quality control procedures (e.g., pH, filter integrity, and visual inspection)
- Sterilization method, if applicable (e.g., filter, steam, or dry heat)
- Any other information needed to describe the operation and ensure its repeatability (e.g., adjusting pH and tonicity and temperature)

### 1218 **9.3 Creating Compounding Records**

1219 A Compounding Record must be created by the compounder preparing the CSP to  
1220 document the compounding process. The Compounding Record or inventory control  
1221 system must permit traceability of all ingredients. The Master Formulation Record (when  
1222 used) can be used as the basis for preparing the Compounding Record. For example, a  
1223 copy of the Master Formulation Record can be made that contains spaces for recording  
1224 the information needed to complete the Compounding Record. It is critical that the  
1225 Compounding Record document in detail any deviations from the process outlined in  
1226 the Master Formulation Record and any problems or errors experienced during the  
1227 compounding of the CSP. [Box 9-2](#) lists the information that must be included in a  
1228 Compounding Record.

1229 Each Compounding Record must be reviewed and approved before the CSP is  
1230 released (signature or initials and date).

#### 1231 **Box 9-2 Compounding Records**

Compounding Records must include at least the following information:

- Name, strength, and dosage form of the CSP
- Master Formulation Record reference for the preparation, when used
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription or lot number)
- Signature or initials of individuals involved in each step (e.g., technician or pharmacist)
- Name, vendor or manufacturer, lot number, and expiration date of each ingredient and container–closure system
- Weight or measurement of each ingredient
- Documentation of the calculations made to determine and verify quantities and/or concentrations of components, if appropriate
- Documentation of quality control procedures in accordance with the SOP (e.g., filter integrity, pH, and visual inspection)
- Any deviations from the Master Formulation Record, if used, and any problems or errors experienced during the compounding of the CSP
- Total quantity compounded
- Assigned BUD
- Duplicate container label if prepared in a batch

1232  
1233

## 10. RELEASE TESTING

1234 At the completion of compounding, before release and dispensing, the CSP must be  
1235 inspected as described below to determine whether the physical appearance of the  
1236 CSP is as it should be and to confirm that the CSP and its labeling match the  
1237 prescription or medication order.

1238 The physical inspection described in *10.1 Physical Inspection of CSP* must be  
1239 performed on all CSPs before they are released. In addition, sterility and bacterial  
1240 endotoxin testing must be performed in some cases (see *12. Establishing Beyond-Use*  
1241 *Dates and In-Use Times*), as described in *10.2 Sterility Testing* and *10.3 Bacterial*  
1242 *Endotoxins Testing*. All checks and inspections, and any other tests or checks  
1243 necessary to ensure the quality of the CSP (e.g., assays), must be included in the  
1244 facility's SOP (see *9. SOPS and Master Formulation and Compounding Records*).  
1245 Additional quality assurance and quality control activities are discussed in *13. Quality*  
1246 *Assurance and Quality Control*.

1247

### 10.1 Physical Inspection of CSP

1248 After compounding, and as a condition of release, each individual CSP unit must be  
1249 inspected to identify any apparent physical defect. Each individual injectable CSP unit  
1250 must be inspected against a lighted white background and a black background for  
1251 evidence of visible particulates or other foreign matter, or discoloration. Some CSPs  
1252 also must be visually checked for certain characteristics (e.g., emulsions must be  
1253 checked for phase separation). Pre-release inspection also must include a visual  
1254 inspection of container–closure integrity (e.g., checking for leakage, cracks in the

1255 container, or improper seals). CSPs with observed defects must be immediately  
1256 discarded, or marked and segregated from acceptable units in a manner that prevents  
1257 them from being released or dispensed.

1258 When a CSP will not be released or dispensed promptly after preparation, a pre-  
1259 release inspection must be conducted immediately before it is released or dispensed to  
1260 make sure that the CSP does not exhibit any defects, such as precipitation, cloudiness,  
1261 or leakage, which may develop during storage. A CSP with such defects must be  
1262 immediately discarded, or marked and segregated from acceptable units in a manner  
1263 that prevents it from being released or dispensed.

## 1264 **10.2 Sterility Testing**

1265 Category 1 CSP BUDs apply regardless of whether sterility testing is conducted (see  
1266 [Table 7](#)). If a Category 2 CSP is assigned a BUD that requires sterility testing (see  
1267 [Table 8](#)), the testing must be performed in a manner consistent with [\(71\)](#), with the  
1268 exception, in some cases, of the batch sizes specified in [Sterility Tests \(71\), Table 3.](#)  
1269 [Minimum Number of Articles to be Tested in Relation to the Number of Articles in the](#)  
1270 [Batch](#). If the number of units of CSPs to be prepared in a single batch is less than the  
1271 number of units needed for testing, additional units may be required to be compounded  
1272 to be able to conduct sterility testing. For batch sizes of 1–39 units, each sterility test  
1273 must be performed using a number of units equal to 10% of the batch size, rounded up  
1274 to the next whole number. For batch sizes of 40 or more units, the sample sizes  
1275 specified in [Sterility Tests \(71\), Table 3](#) must be used.

1276 When the CSP formulation permits, the Membrane Filtration method is the method of  
1277 choice for sterility testing. The preferred alternative is the Direct Inoculation of the  
1278 Culture Medium method; both methods are described in [\(71\)](#).

1279 If sterility testing will be conducted, ideally the results should be obtained before  
1280 dispensing to patient(s). If it is anticipated that there will be situations in which there  
1281 may be an urgent need to dispense a CSP before the results of the sterility testing are  
1282 known, a written procedure (SOP) must be developed and followed; this SOP must  
1283 describe how these situations will be handled. In addition, this SOP must require  
1284 frequent observation of the incubating test specimen and must require immediate recall  
1285 of the dispensed CSP (if possible) or immediate notification of the patient's prescriber, if  
1286 any evidence of microbial growth is found during the test.

1287 Positive sterility test results must prompt a rapid and systematic investigation into the  
1288 causes of the sterility failure, including identification of the contaminating organism (at  
1289 least to the genus level) and any aspects of the facility, process, or personnel that may  
1290 have contributed to the sterility failure. The source of the contamination, if identified,  
1291 must be corrected, and the facility should determine whether the conditions causing the  
1292 sterility failure affect other CSPs. The investigation and resulting corrective actions  
1293 must be documented.

## 1294 **10.3 Bacterial Endotoxins Testing**

1295 All Category 2 CSPs made from one or more nonsterile ingredients, except those for  
1296 inhalation and topical ophthalmic administration, must be tested to ensure that they do  
1297 not contain excessive bacterial endotoxins (see [\(85\)](#) and [Pyrogen Test \(151\)](#)). A CSP  
1298 does not need to be tested for bacterial endotoxins if the COA for the nonsterile  
1299 ingredient lists the endotoxins burden, or if the compounding facility has predetermined

1300 the endotoxins burden of the nonsterile ingredient and found it acceptable, and the  
1301 material is stored under cool and dry conditions.  
1302 In the absence of a bacterial endotoxins limit in an official monograph or other CSP  
1303 formula source, the CSP must not exceed the endotoxins limit calculated as described  
1304 in [\(85\)](#) for the appropriate route of administration.

1305  
1306

## 11. LABELING

1307 CSPs must be labeled with adequate, legible identifying information to prevent errors  
1308 during storage, dispensing, and use. The term labeling designates all labels and other  
1309 written, printed, or graphic matter on an article's immediate container or on, or in, any  
1310 package or wrapper in which it is enclosed, except any outer shipping container. The  
1311 term label designates that part of the labeling on the immediate container. See [Labeling](#)  
1312 [\(7\), Labels and Labeling for Products and Other Categories, Compounded](#)  
1313 [Preparations](#).

1314 The label must, at a minimum, display prominently and understandably the following  
1315 information:

- 1316 • Assigned internal identification number (e.g., prescription or lot number)
- 1317 • Brand and/or generic name(s), or active ingredient(s) and amounts or  
1318 concentrations
- 1319 • Dosage form
- 1320 • Total amount, if it is not obvious from the container
- 1321 • Storage conditions
- 1322 • BUD and when appropriate, an in-use time (see *12. Establishing Beyond-Use*  
1323 *Dates and In-Use Times*)
- 1324 • Whether it is a single-dose or multiple-dose container
- 1325 • Indication that the preparation is compounded

1326 The labeling must, at a minimum, display prominently and understandably the  
1327 following information:

- 1328 1. Patient name, or for animal drugs, owner's name and species of patient
- 1329 2. Route of administration, if known
- 1330 3. Any special handling instructions
- 1331 4. Any warning statements that are applicable
- 1332 5. Name, address, and contact information of the compounder if the CSP is to be  
1333 sent outside of the facility in which it was compounded

1334 Labeling operations must be controlled to prevent labeling errors and CSP mix-ups. A  
1335 final check must be conducted to verify that the correct and complete label has been  
1336 affixed to the finished CSP. All labels must also comply with applicable state laws and  
1337 regulations.

1338  
1339

## 12. ESTABLISHING BEYOND-USE DATES AND IN-USE TIMES

1340 Each CSP label must state the date beyond which the preparation cannot be used and  
1341 must be discarded. A CSP may also be labeled with an in-use time within which it must  
1342 be used after it has been opened or punctured. A number of critical parameters must be  
1343 considered before establishing these dates. It is also important to understand the  
1344 various terms that are used in discussion of these dates.

## 1345 **12.1 Terminology**

1346 A number of terms are used to describe the time period during which a drug is  
1347 considered to retain its desired characteristics so that it can be safely administered to a  
1348 patient to achieve the desired therapeutic effect.

1349 The expiration date identifies the time during which a conventionally manufactured  
1350 drug product may be expected to maintain its labeled identity, strength, quality, and  
1351 purity, provided it is kept under the labeled storage conditions. The expiration date limits  
1352 the time during which a conventionally manufactured product may be dispensed or  
1353 used. Expiration dates are determined based on product-specific studies that evaluate  
1354 the specific formulation of a drug product in the specific container in which it is to be  
1355 stored and under the conditions to which it could be exposed. Temperature, humidity,  
1356 and light are some of the factors that can affect whether and how much a product  
1357 degrades over time. An expiration date is determined by taking representative samples  
1358 from batches and placing them in storage under controlled conditions and then testing  
1359 them at scheduled intervals to determine whether they meet specifications throughout  
1360 their labeled shelf lives. When an expiration date is stated only in terms of the month  
1361 and the year, it is a representation that the intended expiration date is the last day of the  
1362 stated month.

1363 A BUD is included on the label of each CSP to indicate the date or date and hour after  
1364 which the CSP must not be used, because its required quality characteristics (e.g.,  
1365 sterility, strength, purity) cannot be ensured. The term expiration date is not appropriate  
1366 for CSPs, because the types of full stability studies conducted by manufacturers to  
1367 establish expiration dates for conventionally manufactured products are not typically  
1368 performed for CSPs. BUDs for CSPs are calculated in terms of hours or days.

1369 An in-use time refers to the time before which a conventionally manufactured product  
1370 or a CSP must be used after it has been opened or needle punctured (e.g., after a  
1371 container closure of a vial has been penetrated).

## 1372 **12.2 Critical Parameters to Be Considered in Establishing a BUD**

1373 Time is a critical factor in establishing a BUD. The more time that passes between the  
1374 compounding of a CSP and its administration to a patient, the greater the risk of harm to  
1375 the patient if the stability or sterility of the CSP has been compromised. With respect to  
1376 sterility, this is especially the case if microbial contamination is present from the outset.  
1377 BUDs for CSPs should be established conservatively to ensure that the drug maintains  
1378 its required characteristics until administration to reduce the risk to patients of receiving  
1379 a contaminated or degraded preparation. Both sterility and stability considerations must  
1380 be taken into account when establishing a BUD.

1381 **STERILITY CONSIDERATIONS**

1382 Microbial contamination of a CSP poses a significant risk to patients, and if the CSP is  
1383 contaminated during preparation, the risk increases the longer the time the CSP is  
1384 stored before administration.

1385 When establishing a BUD for a CSP, it is critical that compounding personnel carefully  
1386 consider all of the possible ways that the sterility of the CSP could be compromised  
1387 over time. The following factors related to sterility must be carefully considered:

- 1388 • Whether the CSP will be tested for sterility, and the results will be known, before  
1389 the CSP is released or dispensed
- 1390 • Whether the CSP will be terminally sterilized in its final container (provided the  
1391 drug and its container–closure can withstand the terminal sterilization process)  
1392 (see 8. *Sterilization and Depyrogenation*)
- 1393 • Whether the CSP contains a preservative, or is inherently susceptible to  
1394 microbial survival or growth, if contaminated
- 1395 • Whether the container–closure system and sealing method will ensure the  
1396 integrity of the CSP until administration to the patient

#### 1397 STABILITY CONSIDERATIONS

1398 Over time, active ingredient(s) in a CSP may degrade, reducing the strength of the  
1399 preparation and/or producing harmful impurities. Additionally, the container–closure  
1400 system may degrade, which can lead to several potential deleterious effects, such as: 1)  
1401 reducing the integrity of the CSP; 2) leaching of harmful chemicals into the preparation  
1402 from the container–closure system; and/or 3) absorption of the active ingredient onto  
1403 the container, thereby reducing potency. When establishing a BUD for a CSP, it is  
1404 critical that compounding personnel carefully consider all of the possible ways that the  
1405 physical or chemical characteristics of the CSP could change over time. The following  
1406 issues must be carefully considered:

- 1407 • The chemical and physical stability properties of the drug and/or its formulation  
1408 (i.e., if the drug and its formulation are known to degrade over time and/or  
1409 under certain storage conditions)
- 1410 • The compatibility of the container–closure system with the finished preparation  
1411 (e.g., consider leachables, interactions, and storage conditions of the  
1412 components)

1413 In addition:

- 1414 • If the CSP includes components from conventionally manufactured product(s),  
1415 the BUD of the CSP must not exceed the shortest remaining expiration date of  
1416 any of the starting components.
- 1417 • If the CSP includes components from other compounded preparations, the BUD  
1418 of the final CSP must not exceed the shortest remaining BUD of any of the  
1419 starting CSP components.

### 1420 12.3 Establishing a BUD for a CSP

1421 BUDs for CSPs must be established in accordance with [Table 7](#) for Category 1 CSPs  
1422 and [Table 8](#) for Category 2 CSPs. The BUDs specified in the tables indicate the hours  
1423 or days after the CSP is prepared and beyond which the CSP cannot be used. The BUD  
1424 is determined from the time the CSP is compounded. One day is equivalent to 24 hours.  
1425 The BUDs in [Table 7](#) and [Table 8](#) for CSPs are based on the risk of microbial  
1426 contamination, not the physical or chemical stability of the CSP, and involve the  
1427 following assumptions:

- 1428 1. The CSP and its components can remain chemically and physically stable for the  
1429 BUD period
- 1430 2. None of the factors identified in *12.2 Critical Parameters to Be Considered in*  
1431 *Establishing a BUD*, would require a shorter BUD

1432 If there is any indication, based on the factors described in *12.2. Critical Parameters to*  
1433 *be Considered in Establishing a BUD*, that the particular CSP formulation will not remain  
1434 chemically or physically stable for the specified period, a shorter BUD must be assigned  
1435 based on the time period during which the CSP is expected to remain chemically and  
1436 physically stable.  
1437 [Table 8](#) establishes the longest permitted BUDs for Category 2 CSPs, based the  
1438 following variables:

#### 1439 METHOD OF ACHIEVING STERILITY

1440 Because terminal sterilization using a verified method provides reasonable assurance  
1441 that a CSP will be sterile, [Table 8](#) allows longer BUDs for CSPs that are terminally  
1442 sterilized and not sterility tested than for aseptically prepared CSPs that are not sterility  
1443 tested. Not all CSPs can be terminally sterilized, and if the CSP is aseptically prepared  
1444 (e.g., using only sterile products or sterilized by filtration), the shorter BUDs in [Table 8](#)  
1445 for aseptically prepared CSPs that are not sterility tested must not be exceeded.

#### 1446 STARTING COMPONENTS

1447 An aseptically prepared CSP compounded from one or more nonsterile starting  
1448 component has a higher risk of microbial contamination than an aseptically prepared  
1449 CSP compounded only from sterile starting components. [Table 8](#) allows for longer  
1450 BUDs for CSPs aseptically prepared from only sterile starting components.

#### 1451 WHETHER THE CSP WILL BE STERILITY TESTED AND THE RESULTS KNOWN BEFORE THE DRUG IS 1452 RELEASED OR DISPENSED

1453 Sterility testing (see *10.2 Sterility Testing*) before releasing or dispensing a CSP can  
1454 provide additional assurance of the absence of contamination. When the results of  
1455 sterility testing are known before dispensing, a longer BUD is permitted in [Table 8](#). If  
1456 sterility testing is not performed, a shorter BUD is required in [Table 8](#).

1457 If a sterility test is performed and there is an urgent need to dispense the CSP before  
1458 sterility test results become available, a CSP can be dispensed to a patient before the  
1459 end of the sterility testing period if:

- 1460 • The prescriber specifically requests dispensing before completion of the sterility  
1461 test, and the request is documented

- The patient and the prescriber are notified of any microbial growth during the sterility testing. The species of microbial contaminant is reported to the prescriber to ensure appropriate medical therapy following exposure to a contaminated CSP

PRESENCE OF A PRESERVATIVE

Although a preservative must not be considered a substitute for good aseptic practices, preservatives can be added to multiple-dose CSPs because they may inhibit the growth of microorganisms for short periods of time. If a CSP contains a preservative whose effectiveness for the length of the BUD has been verified based on antimicrobial effectiveness testing (see [Antimicrobial Effectiveness Testing \(51\)](#)), the BUD in [Table 8](#) for a CSP containing a preservative can be assigned. Shorter BUDs are required for preservative-free CSPs, as compared to CSPs that contain a verified preservative. The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with [\(51\)](#) at the completion of the sterility test (if conducted) or at the time of preparation (if sterility testing is not performed). The test must be completed and the results obtained on the specific formulation before any of the CSP is released or dispensed. The test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

STORAGE CONDITIONS

The specified conditions under which a CSP will be stored are important in determining an appropriate BUD. Storage in a refrigerator or in a freezer (see [Packaging and Storage Requirements \(659\)](#)) has been shown to slow the growth of microorganisms. Therefore, [Tables 7](#) and [8](#) allow for longer BUDs for CSPs stored in colder conditions than when stored at controlled room temperature.

Storage under frozen conditions places the container–closure under physical stress, and the degree of stress may depend on the formulation and other factors. Therefore, if a Category 2 CSP is to be stored in a freezer, the integrity of the CSP in the particular container–closure system in which it will be stored must have been demonstrated for 45 days at frozen storage. A container–closure integrity test needs to be conducted only once on each formulation and fill volume in the particular container–closure system in which it will be stored or released/dispensed. Once the CSP is thawed, the CSP must not be re-frozen.

It must be recognized that CSPs may be stored under different storage conditions before they are used (e.g., they may first be frozen, and then thawed in the refrigerator, and finally kept at controlled room temperature before administration). The storage time of a CSP must not exceed the original BUD placed on the CSP for its labeled storage conditions, and BUDs are not additive. For example, a CSP cannot be stored for 4 days at controlled room temperature, then 7 days refrigerated, and then 45 days in a freezer, for a total of 56 days. Once a CSP is stored under a condition that would require a shorter BUD (i.e., controlled room temperature), the CSP must be used within the shorter timeframe for that storage condition (in this example, 4 days).

**Table 7. BUDs for Category 1 CSPs<sup>a</sup>**

	Storage Conditions
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Storage Conditions		
	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)
BUD	≤12 hours	≤24 hours

<sup>a</sup> The BUDs specified in the table indicate the hours after the Category 1 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded.

**Table 8. BUDs for Category 2 CSPs<sup>a</sup>**

Preparation Characteristics				Storage Conditions			
Method of Achieving Sterility	Sterility Testing Performed	Preservative Added		Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°) <sup>b</sup>	
BUD	Aseptically prepared CSPs	No	No	Prepared from one or more nonsterile starting component 4 days	Prepared from one or more nonsterile starting component 7 days	Prepared from one or more nonsterile starting component 45 days	
			Yes <sup>c</sup>	28 days	42 days	45 days	
		Yes	No	28 days	42 days	45 days	
			Yes <sup>d</sup>	42 days	42 days	45 days	
		Terminally Sterilized CSPs	No	No	14 days	28 days	45 days
				Yes <sup>e</sup>	28 days	42 days	45 days
Yes	No	28 days	42 days	45 days			
	Yes <sup>d</sup>	42 days	42 days	45 days			

<sup>a</sup> The BUDs specified in the table indicate the days after the Category 2 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded. One day is equivalent to 24 hours.

<sup>b</sup> The integrity of the container–closure system with the particular CSP in it must have been demonstrated for 45 days at frozen storage. The container–closure integrity test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

<sup>c</sup> The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at the time of preparation. The test must be completed and the results obtained on the specific formulation before any of the CSP is dispensed. The test needs to be conducted only once on each formulation in the

Preparation Characteristics			Storage Conditions		
Method of Achieving Sterility	Sterility Testing Performed	Preservative Added	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°) <sup>b</sup>

particular container–closure system in which it will be stored or released/dispensed.

<sup>d</sup> The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at the completion of sterility test (i.e., 14 days after preparation). The test must be completed and the results obtained on the specific formulation before any of the CSP is dispensed. The test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

1505

## 12.4 Establishing In-Use Times

1506 The in-use time is the time before which a conventionally manufactured product or a  
 1507 CSP must be used after it has been opened or needle-punctured. The in-use time  
 1508 assigned cannot exceed the expiration date of the conventionally manufactured product  
 1509 or the BUD of a CSP. The in-use time may be dependent on the type of product or CSP  
 1510 and the environment where the manipulations occur (e.g., ISO Class 5, or worse than  
 1511 ISO Class 5). [Table 9](#) specifies the in-use times for conventionally manufactured  
 1512 products and CSPs that are opened, stored, and used for sterile compounding in ISO  
 1513 Class 5 or better air quality. [Table 10](#) specifies the in-use times for conventionally  
 1514 manufactured products and CSPs that are opened and/or stored in worse than ISO  
 1515 Class 5 air quality.

1516 **Table 9. In-Use Times for Conventionally Manufactured Products and CSPs**  
 1517 **Opened, Stored, and Used for Sterile Compounding in ISO Class 5 or Better Air**  
 1518 **Quality**

Components	In-Use Time
<b>Conventionally Manufactured Sterile Product</b>	
Ampuls	Use <i>immediately</i> after opening and passing through a sterile particulate filter
Pharmacy Bulk Package	As specified by the manufacturer
Single-dose container (e.g., bag, bottle, syringe, or vial)	6 hours
Multiple-dose container	28 days, unless otherwise specified by the manufacturer
<b>CSP</b>	
Compounded single-dose container	6 hours
Compounded stock solutions	6 hours
Compounded multiple-dose container <sup>a</sup>	28 days, unless otherwise specified by the original compounder

<sup>a</sup> The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at

Components	In-Use Time
<b>Conventionally Manufactured Sterile Product</b>	
the completion of the sterility test (if conducted) or at the time of preparation (if sterility testing is not performed). The test must be completed and the results obtained on the specific formulation before any of the CSP is released or dispensed. The test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.	

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**Table 10. In-Use Times for Conventionally Manufactured Products and CSPs Opened and/or Stored in Worse than ISO Class 5 Air<sup>a</sup>**

Components	In-Use Time
<b>Conventionally Manufactured Sterile Product</b>	
Ampuls	Use <i>immediately</i> after opening and passing through a sterile particulate filter
Pharmacy Bulk Package	Not applicable. Contents of pharmacy bulk packages must be used only in an ISO Class 5 or better environment.
Single-dose container (e.g., bag, bottle, syringe, vial)	Use for a single patient within the time specified by the manufacturer, or by the end of the case or procedure, whichever comes first. Discard remainder.
Multiple-dose container	28 days, unless otherwise specified by the manufacturer
<b>CSP</b>	
Compounded single-dose container	Use for a single patient immediately. Discard remainder.
Compounded multiple-dose container <sup>b</sup>	28 days, unless otherwise specified by the original compounder
<sup>a</sup> Compounding or repackaging must not occur in worse than ISO Class 5 air. <sup>b</sup> The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with (51) at the completion of the sterility test (if conducted) or at the time of preparation (if sterility testing is not performed). The test must be completed and the results obtained on the specific formulation before any of the CSP is released or dispensed. The test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.	

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### 13. QUALITY ASSURANCE AND QUALITY CONTROL

1523 A quality assurance (QA) and quality control (QC) program is necessary to ensure that  
1524 consistently high-quality CSPs are prepared. QA is a set of written processes that, at a  
1525 minimum, verifies, monitors, and reviews the adequacy of the compounding process.  
1526 QC is the observation of techniques and activities that demonstrate that requirements  
1527 are met.

1528 Each facility must have a formal, written QA and QC program that establishes a  
1529 system of adherence to procedures, prevention and detection of errors and other quality  
1530 problems, and appropriate corrective actions when needed. A facility's QA program  
1531 must be formally established and documented in SOPs that ensure that all aspects of

1532 the preparation of CSPs are conducted in accordance with this chapter and applicable  
1533 federal, state, and local laws and regulations.

1534 The QA program must, at a minimum, address the following functions:

- 1535 • Personnel qualifications and training:
  - 1536 ○ Periodically review personnel files for each employee to determine
  - 1537 whether personnel continue to meet basic qualifications, are obtaining
  - 1538 required training, and are getting qualified and requalified in
  - 1539 accordance with the specified frequencies (e.g., gloved fingertip/thumb
  - 1540 sampling)
  - 1541 ○ Assess staff performance, including aseptic techniques, cleanroom
  - 1542 behavior, and other critical activities (e.g., media-fill testing)
- 1543 • Component selection and handling:
  - 1544 ○ Carefully select, and ensure ongoing qualification of suppliers and
  - 1545 service providers (e.g., chemical vendors and external testing
  - 1546 laboratories)
  - 1547 ○ Select ingredients that are the subject of a *USP* or *NF* monograph and
  - 1548 that are manufactured at an FDA-registered facility, when available
  - 1549 ○ Inspect incoming components against their COAs to ensure that they
  - 1550 meet their specifications
  - 1551 ○ Quarantine, properly dispose of, and investigate components that do
  - 1552 not meet their specifications
- 1553 • Design and maintenance of the building, facility, and equipment:
  - 1554 ○ Review the adequacy of the design of the building, facility, and
  - 1555 equipment; when changes are made, assess their effects to make sure
  - 1556 they do not adversely affect the operation (e.g., certification)
  - 1557 ○ Ensure that facilities and equipment used in compounding are installed,
  - 1558 operated, and maintained properly per appropriate and pre-established
  - 1559 specifications
  - 1560 ○ Detect adverse trends in environmental monitoring data to take
  - 1561 preventive action and corrective action
- 1562 • Compounding process:
  - 1563 ○ Approve Master Formulation Records (when used), or any changes to
  - 1564 them, before they are implemented
  - 1565 ○ Review Compounding Records for accuracy, completeness, and
  - 1566 conformance to established specifications
  - 1567 ○ Review final labeling against prescription or medication orders
  - 1568 ○ Ensure that all errors, process problems, or deviations from procedures
  - 1569 are documented
  - 1570 ○ Investigate any error, deviation, out-of-specification result, or complaint,
  - 1571 and implement, oversee, and document appropriate corrective action to
  - 1572 prevent recurrence
- 1573 • Final CSP release:
  - 1574 ○ Assess the final CSP before release (e.g., physical inspection, sterility
  - 1575 testing, and analytical testing)

- 1576                   ○ Review internal or external testing programs (if used) for conformance  
1577                   with applicable standards (e.g., sterility testing and endotoxin testing)  
1578                   • Documentation:  
1579                   ○ Establish SOPs and assess conformance to SOPs  
1580                   ○ Establish and assess conformance with document control and records  
1581                   management procedures  
1582                   ○ Establish, maintain, and follow written procedures for handling all  
1583                   written and oral complaints regarding a CSP

1584                   The roles and duties of personnel responsible for each aspect of the QA program must  
1585                   be described in the SOPs. Designated personnel responsible for the QA program must  
1586                   have adequate training, experience, responsibility, and authority to perform these  
1587                   duties.

1588                   The overall QA program must be assessed annually.

1589

## 1590                   **14. CSP STORAGE, HANDLING, PACKAGING, AND TRANSPORT**

1591                   Appropriate processes or techniques for storing, handling, packaging, and transporting  
1592                   CSPs must be in place and must also be outlined in SOPs. Personnel who will be  
1593                   storing, handling, packaging, and transporting CSPs within the facility must be properly  
1594                   trained in accordance with the relevant SOPs.

### 1595                   **14.1 Storing CSPs within the Compounding Facility**

1596                   To help ensure that CSP quality is retained while the CSP is stored at the  
1597                   compounding facility, compounding personnel must monitor conditions in the drug  
1598                   storage areas. A controlled temperature area must be checked at least once daily to  
1599                   determine whether the temperature remains within the appropriate range, and the  
1600                   results must be documented on a temperature log. If the compounding facility uses a  
1601                   continuous temperature recording device, compounding personnel must verify at least  
1602                   once daily that the recording device is functioning properly. In addition, the  
1603                   compounding facility must adhere to appropriate procedures for all controlled  
1604                   temperature areas to ensure that such spaces are not subject to prolonged temperature  
1605                   fluctuations (e.g., by leaving a refrigerator door open too long).

1606                   When it is known that a CSP has been exposed to temperatures that exceed storage  
1607                   temperature limits, (i.e., temperatures warmer than the warmest labeled limit or  
1608                   temperatures exceeding 40° for more than 4 hours), the CSP should be discarded.

### 1609                   **14.2 Handling of CSPs**

1610                   CSPs must be handled properly while in the compounding facility to maintain CSP  
1611                   quality and packaging integrity. For example, techniques should be in place to prevent  
1612                   the depression of syringe plungers or dislodging of syringe tips. Additionally,  
1613                   disconnection of system components (e.g., where CSPs are dispensed with  
1614                   administration sets attached to them) must be prevented throughout the BUD or until  
1615                   administration of the CSP.

### 1616                   **14.3 Packaging of CSPs**

1617 Compounding personnel must select and use packaging materials that will maintain  
1618 the physical integrity, sterility, and stability of the CSPs. Packaging materials must  
1619 protect CSPs from damage, leakage, contamination, degradation, and adsorption, while  
1620 simultaneously protecting transport personnel from harm. The facility must have written  
1621 SOPs that describe appropriate shipping containers and insulating and stuffing  
1622 materials based on the product specifications, information from vendors, and knowledge  
1623 of the mode of transport. For example, when CSPs are transported within the facility  
1624 through pneumatic tube systems, foam padding or inserts may be useful for preventing  
1625 breakage and spills. Compounding personnel must continuously monitor the  
1626 effectiveness and reliability of the packaging materials.

1627 Alternative modes of transport and/or special packaging may be needed to protect the  
1628 quality of CSPs. The use of tamper-evident closures and seals on CSP ports can  
1629 provide an additional measure of security that can help ensure product integrity,  
1630 regardless of the transport method used. If the CSP is sensitive to light, light-resistant  
1631 packaging materials must be used. In some cases, the CSP should be packaged in a  
1632 special container (e.g., a cooler) to protect it from temperature fluctuations.

#### 1633 **14.4 Transporting CSPs**

1634 Compounding personnel must select modes of transport that are expected to deliver  
1635 properly packed CSPs in an undamaged, sterile, and stable condition. Inappropriate  
1636 handling and transport can adversely affect the quality of CSPs in general, particularly  
1637 certain CSPs with unique stability concerns. For example, the physical shaking that  
1638 might occur during pneumatic tube transport, or undue exposure to heat or light, must  
1639 be considered and addressed on a preparation-specific basis. Compounding personnel  
1640 must include specific handling instructions on the exteriors of containers that are used  
1641 to transport CSPs.

#### 1642 **14.5 Handling of Hazardous Drugs**

1643 For information on the storage, packaging, handling, and transport of hazardous drugs,  
1644 see [\(800\)](#).

### 1645 **15. COMPLAINT HANDLING AND ADVERSE EVENT REPORTING**

1647 Compounding facilities must provide patients and other CSP recipients with a way to  
1648 submit questions and report any concerns or complaints they may have regarding a  
1649 CSP. SOPs must be developed, implemented, and followed for the receipt,  
1650 acknowledgment, and handling of all complaints about the quality and labeling of, or  
1651 possible adverse reactions to, a specific CSP.

#### 1652 **15.1 Complaint Handling**

1653 A qualified individual must review all complaints to determine whether the complaint  
1654 indicates a potential quality problem with the CSP. If so, a thorough investigation into  
1655 the cause of the problem must be initiated and completed promptly. The investigation  
1656 must consider whether the quality problem extends to other batches of the same CSP,  
1657 or to other CSPs that could have been affected. Corrective action, if necessary, must be  
1658 implemented immediately for all potentially affected CSPs. When warranted, consider  
1659 whether to initiate a recall of potentially affected CSPs and whether to cease sterile

1660 compounding operations until all underlying problems have been identified and  
1661 corrected.

1662 A written record of each complaint must be kept, regardless of the source (e.g., e-mail,  
1663 telephone, mail). The record must contain the name of the complainant, the date the  
1664 complaint was received, the nature of the complaint, and the response to the complaint.  
1665 In addition, to the extent that the information is known, the following should be recorded:  
1666 the name and strength of the CSP, the prescription or medication order number, and the  
1667 lot number, if one is assigned. The record must also include the findings of any  
1668 investigation and any follow-up. Complaint records must be easily retrievable for review  
1669 and evaluation for possible trends and must be retained in accordance with the  
1670 recordkeeping requirements in *16. Documentation*. A CSP that is returned in connection  
1671 with a complaint must be quarantined until it is destroyed after completion of the  
1672 investigation and in accordance with applicable federal, state, and local laws and  
1673 regulations.

## 1674 **15.2 Adverse Event Reporting**

1675 Reports of potential adverse events involving a CSP must be reviewed promptly and  
1676 thoroughly by compounding personnel. The reports must be handled in accordance with  
1677 the procedures for handling complaints as described in section *15.1 Complaint*  
1678 *Handling*, as well as the record retention requirements described in *16. Documentation*.  
1679 Relevant healthcare professionals and patients must be informed as appropriate. If  
1680 required, adverse events must be reported in accordance with applicable state and local  
1681 laws and regulations. In addition, serious or unexpected adverse events associated with  
1682 a CSP should be reported to the FDA through the MedWatch program for human drugs  
1683 and Form FDA 1932a for animal drugs.

1684

## 1685 **16. DOCUMENTATION**

1686 All facilities where CSPs are prepared must have and maintain written documentation  
1687 to demonstrate compliance with this chapter, including all SOPs, Master Formulation  
1688 Records (when used), Compounding Records, laboratory and equipment records,  
1689 prescriptions or medication orders, and all information related to complaints.

1690 All records must be legible and stored in a manner that prevents their deterioration  
1691 and/or loss. Records can be kept electronically. Records must be maintained either at  
1692 the facility or at another location that is readily accessible within a reasonable period of  
1693 time.

1694 All records specific to the compounding of a particular CSP (e.g., Master Formulation  
1695 Record, Compounding Record, and testing results) must be kept for at least 3 years  
1696 after the BUD of the CSP, or as required by state laws and regulations, whichever is  
1697 longer. Facility design and initial qualification records must be kept as long as the facility  
1698 is in operation. All other records must be kept for at least 3 years, or as required by  
1699 state laws and regulations, whichever is longer. Examples include records related to  
1700 personnel training and qualification, equipment maintenance and calibration, receipt of  
1701 components, environmental monitoring, complaints, and quality assurance.

1702 Recordkeeping must also comply with all applicable federal laws and regulations.

1703  
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## 17. RADIOPHARMACEUTICALS AS CSPS

1705 Radiopharmaceuticals are associated with risks of radiation exposure to healthcare  
1706 practitioners and unintentional radiation exposure to patients. Compounding of  
1707 radiopharmaceuticals must comply with applicable federal, state, and local laws and  
1708 regulations such as those from the Nuclear Regulatory Commission (NRC), FDA, and  
1709 State Boards of Pharmacy.

1710 Unless done in strict conformance with the manufacturer's package insert, any further  
1711 use or handling and manipulation of conventionally manufactured radiopharmaceutical  
1712 product is considered compounding and must follow the standards in this chapter and  
1713 applicable federal, state, and local laws and regulations. Radiation exposures must be  
1714 kept as low as reasonably achievable (the ALARA principle). Therefore, appropriate  
1715 shielding must be used to help minimize radiation exposure. Additional equipment  
1716 needed for radiation control when compounding may include, but is not limited to:

- 1717 • Radiation detectors
- 1718 • Static and handheld monitors
- 1719 • Handheld monitors
- 1720 • Lead (or other appropriate) shielding
- 1721 • Shielded waste cans
- 1722 • Non-shedding absorbent mats
- 1723 • L-Blocks
- 1724 • Tongs
- 1725 • Syringe, vial, and elution shields
- 1726 • Syringe re-cappers
- 1727 • Final unit dose containment shielding
- 1728 • Dose calibrators
- 1729 • Dippers and dipper lifts

1730 Radioisotope generator systems (e.g., Tc-99m/Mo-99, Rb-82/Sr-82, Ga-68/Ge-68)  
1731 must be stored and eluted (operated) under conditions recommended by the  
1732 manufacturer and applicable state and federal regulations. The generators must be  
1733 eluted in an ISO Class 8 or cleaner air environment that allows special generator  
1734 shielding, airflow requirements, and the use of lifting devices (e.g., cranes and/or  
1735 wenchers) due to the weight of the generator and shielding. Radioisotope generators  
1736 producing radioisotopes with a half-life of 15 minutes or less (e.g., Rb-82/Sr-82) can be  
1737 eluted in accordance with the manufacturer's instructions at the point of care (e.g., at  
1738 the bedside or in the patient care area). Visual inspection of radiopharmaceutical CSPs  
1739 containing high concentrations of radioactivity (e.g., for color and absence of particulate  
1740 material) must be performed in accordance with ALARA principles to limit acute and  
1741 chronic radiation exposure of the inspecting personnel.

1742 All compounding personnel must be properly gowned and garbed as described in 3.  
1743 *Personal Hygiene and Personal Protective Equipment*. However, personnel  
1744 compounding radiopharmaceuticals are permitted to use personal radiation dosimeters.  
1745 Personal radiation dosimeters can be film, thermoluminescent, or electronic. Whole-  
1746 body badge radiation dosimeters must be worn underneath the gown, whereas

1747 ring/wrist badges that measure the dose at the extremities must be worn under gloves.  
1748 If personnel are going from a cleanroom to a patient care area, all PPE must be  
1749 changed before leaving one area and entering the other.

1750 When compounding activities require the manipulation of a patient's blood-derived or  
1751 other biological material (e.g., radiolabeling of white blood cells), the manipulation must  
1752 be performed in a separate, dedicated ISO Class 7 area that contains a PEC. All blood  
1753 manipulations in the radiolabeling process, except for the centrifuge steps, must be  
1754 performed inside the dedicated PEC. Dedicated equipment must be used for all blood  
1755 manipulations. Strict SOPs must be developed and implemented to minimize the risk of  
1756 patient-to-patient cross-contamination.

1757 Some radiopharmaceutical preparations (e.g., volatile or gaseous preparations such  
1758 as iodine or xenon) may require pressurization configurations that are different from  
1759 those described in 4. *Buildings and Facilities*. In these cases, the facility must comply  
1760 with applicable federal, state, and local laws and regulations.

1761 Nonradioactive compounds may be compounded in the same compounding area in  
1762 which radioactive compounds have been prepared, provided the following takes place:

- 1763 • The ISO Class 5 area is decontaminated and monitored for radioactivity above  
1764 background levels.
- 1765 • The dose calibrator is left inside the PEC.
- 1766 • The PEC is operated in accordance with all the standards in this chapter when  
1767 nonradioactive CSPs are being prepared.

## 1768 GLOSSARY

1769 **Airlock:** A space with interlocked doors, constructed to maintain air pressure control  
1770 when items move between two adjoining areas (generally with different air cleanliness  
1771 standards). The intent of an airlock is to prevent ingress of particulate matter and  
1772 microbial contamination from a lesser-controlled area.

1773 **Ante-area:** An ISO Class 8 or cleaner area where personnel hand hygiene and  
1774 garbing procedures and other activities that generate high particulate levels are  
1775 performed. The ante-area is the transition area between the unclassified area of the  
1776 facility and the buffer area. [NOTE—The ante-area is sometimes referred to as an ante-  
1777 room when solid doors and walls are present.]

1778 **Aseptic processing or preparation:** A process by which separate, sterile  
1779 components (e.g., drugs, containers, or closures) are brought together under conditions  
1780 that maintain their sterility. The components can either be purchased as sterile or, when  
1781 starting with nonsterile components, can be separately sterilized prior to combining  
1782 (e.g., by membrane filtration, autoclave).

1783 **Batch:** More than one unit of CSP prepared in a single process and intended to have  
1784 uniform characteristics and quality, within specified limits.

1785 **Beyond-use date (BUD):** The date or time after which a CSP cannot be used and  
1786 must be discarded. The date or time is determined from the date or time when the  
1787 preparation was compounded.

1788 **Biological safety cabinet (BSC):** A ventilated cabinet with unidirectional HEPA-  
1789 filtered airflow and HEPA-filtered exhaust to protect the worker from hazardous drugs. A  
1790 BSC used to prepare a CSP must be capable of providing an ISO Class 5 environment  
1791 for preparation of the CSP.

1792 **Buffer area:** An ISO Class 7 (or ISO Class 8 if using an isolator) or cleaner area  
1793 where the PEC that generates and maintains an ISO Class 5 environment is physically  
1794 located.

1795 **Category 1 CSP:** A CSP assigned a BUD of 12 hours or less at controlled room  
1796 temperature or 24 hours or less refrigerated.

1797 **Category 2 CSP:** A CSP assigned a BUD of greater than 12 hours at controlled room  
1798 temperature or greater than 24 hours refrigerated that is compounded in accordance  
1799 with all applicable standards for Category 2 CSPs in this chapter.

1800 **Certificate of analysis (COA):** A report from the supplier of a component, container,  
1801 or closure that accompanies the supplier's material and contains the specifications and  
1802 results of all analyses and a description of the material.

1803 **Classified space:** A space that maintains an air cleanliness classification based on  
1804 the International Organization for Standardization (see also definition for ISO Class).

1805 **Cleanroom:** An ISO-classified room in which the concentration of airborne particles is  
1806 controlled to meet a specified airborne-particulate cleanliness class to prevent particle  
1807 and microbial contamination of CSPs.

1808 **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is  
1809 created by combining, diluting, pooling, or otherwise altering a drug product or bulk drug  
1810 substance. A product produced by reconstituting a conventionally manufactured product  
1811 for an individual patient strictly in accordance with the directions contained in the  
1812 approved labeling provided by the product manufacturer is not considered a CSP for the  
1813 purposes of this chapter.

1814 **Compounding aseptic containment isolator (CACI):** A type of RABS that uses  
1815 HEPA filtration to provide an ISO Class 5 clean air environment designed for the  
1816 compounding of sterile hazardous drugs.

1817 **Compounding aseptic isolator (CAI):** A type of RABS that uses HEPA filtration to  
1818 provide an ISO Class 5 clean air environment designed for compounding of sterile non-  
1819 hazardous drugs.

1820 **Compounded stock solution:** A compounded solution to be used in the preparation  
1821 of multiple units of a finished CSP.

1822 **Container-closure system:** The sum of packaging components that together  
1823 contain and protect the dosage form. This includes primary packaging components and  
1824 secondary packaging components, if the latter are intended to provide additional  
1825 protection.

1826 **Conventionally manufactured product:** A pharmaceutical dosage form, usually the  
1827 subject of an FDA-approved application, and manufactured under current good

1828 manufacturing practice conditions. Conventionally manufactured products are not  
1829 compounded preparations.

1830 **Critical site:** A location that includes any component or fluid pathway surfaces (e.g.,  
1831 vial septa, injection ports, and beakers) or openings (e.g., opened ampuls and needle  
1832 hubs) that are exposed and at risk of direct contact with air (e.g., ambient room or  
1833 HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.

1834 **Direct compounding area:** A critical area within the ISO Class 5 PEC where critical  
1835 sites are exposed to unidirectional HEPA-filtered air, also known as first air.

1836 **Disinfectant:** A chemical agent used on inanimate surfaces and objects to destroy  
1837 fungi, viruses, and bacteria, but not necessarily their spores.

1838 **Expiration date:** Date placed on a conventionally manufactured product to limit the  
1839 time during which it can be used.

1840 **Filter integrity test:** A test (e.g., bubble point test) of the integrity of a sterilizing  
1841 grade filter performed after the filtration process to detect whether the integrity of the  
1842 filter has been compromised.

1843 **First air:** The air exiting the HEPA filter in a unidirectional air stream.

1844 **Hazardous drug:** Any drug identified by at least one of the following six criteria:  
1845 carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans,  
1846 organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic  
1847 existing hazardous drugs in structure or toxicity.

1848 **In-use time:** The time before which a conventionally manufactured product or a CSP  
1849 must be used after it has been opened or needle punctured (e.g., after a container  
1850 closure of a vial has been penetrated).

1851 **ISO Class:** An air quality classification from the International Organization for  
1852 Standardization.

1853 **Isolator:** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air  
1854 operated at a continuously higher pressure than its surrounding environment and is  
1855 decontaminated using an automated system. It uses only decontaminated interfaces or  
1856 rapid transfer ports for materials transfer.

1857 **Label:** A display of written, printed, or graphic matter on the immediate container of  
1858 any article.

1859 **Labeling:** All labels and other written, printed, or graphic matter that are 1) on any  
1860 article or any of its containers or wrappers, or 2) accompanying such an article.

1861 **Laminar airflow system (LAFS):** A device or zone within a buffer area that provides  
1862 an ISO Class 5 or better environment for sterile compounding. The system provides a  
1863 unidirectional HEPA-filtered airflow.

1864 **Laminar airflow workbench (LAFW):** A device that is a type of LAFS that provides  
1865 an ISO Class 5 or better environment for sterile compounding. The device provides a  
1866 unidirectional HEPA-filtered airflow.

1867 **Media fill test:** A simulation used to qualify processes and personnel engaged in  
1868 sterile compounding to ensure that the processes and personnel are able to produce  
1869 sterile CSPs without microbial contamination.

1870 **Microbial contamination:** The presence of microorganisms in, or on, an item.

1871 **Multiple-dose container:** A container of sterile medication for parenteral  
1872 administration (e.g., injection or infusion) that is designed to contain more than one  
1873 dose of the medication. A multiple-dose container is usually required to meet the  
1874 antimicrobial effectiveness testing criteria. See [Container Content for Injections \(697\)](#),  
1875 [Determination of Volume of Injection in Containers, Multi-Dose Containers](#).

1876 **Pass-through:** An enclosure with seals on interlocking doors that are positioned  
1877 between two spaces for the purpose of minimizing particulate transfer while moving  
1878 materials from one space to another.

1879 **Pharmacy bulk package:** A conventionally manufactured sterile product for  
1880 parenteral use that contains many single doses intended for use in a pharmacy  
1881 admixture program. A pharmacy bulk package may either be used to prepare  
1882 admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile  
1883 syringes.

1884 **Positive-pressure room:** A room that is maintained at higher pressure than the  
1885 adjacent spaces, and therefore the net airflow is out of the room.

1886 **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5  
1887 environment for sterile compounding.

1888 **Preservative:** A substance added to inhibit microbial growth or to prevent  
1889 decomposition or undesirable chemical changes.

1890 **Pyrogen:** A substance that induces a febrile reaction in a patient.

1891 **Pyrogen-free:** A substance lacking sufficient endotoxins or other fever-inducing  
1892 contamination to induce a febrile or pyrogenic response.

1893 **Quality assurance (QA):** A system of procedures, activities, and oversight that  
1894 ensures that operational and quality standards are consistently met.

1895 **Quality control (QC):** The sampling, testing, and documentation of results that, taken  
1896 together, ensure that specifications have been met before release of the preparation.

1897 **Reconstitution:** The process of adding a diluent to a powdered medication to  
1898 prepare a sterile solution or suspension.

1899 **Release testing:** Testing performed to ensure that a preparation meets appropriate  
1900 quality characteristics.

1901 **Repackaging:** The act of removing a conventionally manufactured sterile product  
1902 from its original primary container and placing it into another primary container, usually  
1903 of smaller size.

1904 **Responsible person:** The individual accountable for an activity.

- 1905 **Restricted access barrier system (RABS):** An enclosure that provides HEPA-  
1906 filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of  
1907 materials through defined openings that have been designed and validated to preclude  
1908 the transfer of contamination, and that generally are not to be opened during operations.  
1909 Examples of RABS include CAIs and CACIs.
- 1910 **Segregated compounding area:** A designated, unclassified space, area, or room  
1911 that contains a PEC and is suitable for preparation of Category 1 CSPs only.
- 1912 **Single-dose containers:** A container of sterile medication for parenteral  
1913 administration (e.g., injection or infusion) that is designed for use with a single patient as  
1914 a single injection/infusion. A single-dose container usually does not contain a  
1915 preservative.
- 1916 **Specification:** The tests, analytical methods, and acceptance criteria to which a drug  
1917 substance, drug product, CSP, component, container–closure system, equipment, or  
1918 other material used in drug preparation must conform to be considered acceptable for  
1919 its intended use.
- 1920 **Stability:** The extent to which a CSP retains physical and chemical properties and  
1921 characteristics within specified limits throughout its BUD.
- 1922 **Sterility:** The freedom from viable microorganisms.
- 1923 **Sterility testing:** A documented and established laboratory procedure for detecting  
1924 viable microbial contamination in a sample or preparation.
- 1925 **Sterilizing-grade membranes:** Filter membranes that are documented to retain  
1926 100% of a culture of  $10^7$  microorganisms of a strain of *Brevundimonas diminuta* per  $\text{cm}^2$   
1927 of membrane surface under a pressure of not less than 30 psi. Such filter membranes  
1928 are nominally 0.22- $\mu\text{m}$  or 0.2- $\mu\text{m}$  pore size.
- 1929 **Sterilization by filtration:** Passage of a gas or liquid through a sterilizing-grade  
1930 membrane to consistently yield filtrates that are sterile.
- 1931 **Terminal sterilization:** The application of a lethal process (e.g., dry heat, steam,  
1932 irradiation) to sealed containers for the purpose of achieving a predetermined SAL of  
1933 greater than  $10^{-6}$  or a probability of less than one in one million of a nonsterile unit.
- 1934 **Unclassified space:** A space not required to meet any air cleanliness classification  
1935 based on the International Organization for Standardization (ISO).
- 1936 **Unidirectional airflow:** Air within a PEC moving in a single direction in a uniform  
1937 manner and at sufficient speed to reproducibly sweep particles away from the direct  
1938 compounding area or testing area.
- 1939 **Verification:** Confirmation that a method, process, or system will perform as  
1940 expected under the conditions of actual use.

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## APPENDICES

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### Appendix 1. Acronyms

ACD	Automated compounding device
ACPH	Air changes per hour
ALARA	As low as reasonably achievable
API	Active pharmaceutical ingredient
BSC	Biological safety cabinet
BUD	Beyond-use date
CACI	Compounding aseptic containment isolator
CAI	Compounding aseptic isolator
CFU	Colony-forming units
COA	Certificate of analysis
CSP	Compounded sterile preparation
ECV	Endotoxin challenge vial
FDA	Food and Drug Administration
HEPA	High-efficiency particulate air
HVAC	Heating, ventilation, and air conditioning
IPA	Isopropyl alcohol
ISO	International Organization for Standardization
LAFS	Laminar airflow system
LAFW	Laminar airflow workbench
NRC	Nuclear Regulatory Commission
PEC	Primary engineering control
PPE	Personal protective equipment
QA	Quality assurance
QC	Quality control
RABS	Restricted access barrier system
SAL	Sterility assurance level
SOP	Standard operating procedure
TSA	Trypticase soy agar

## Appendix 2. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties<sup>a</sup>

### Chemical Category of Disinfectant

		Isopropyl Alcohol	Accelerated Hydrogen Peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone-iodine)
Concentration Used		60%–95%	0.5% <sup>b</sup>	0.4%–1.6% aq	0.4%–1.6% aq	100–5000 ppm	30–50 ppm
Microbial Inactivation <sup>c</sup>	Bacteria	+	+	+	+	+	+
	Lipophilic viruses	+	+	+	+	+	+
	Hydrophilic viruses	±	+	±	±	+	±
	M. tuberculosis	+	+	±	+	+	±
	Mycotic agents (fungi)	+	+	+	+	+	±
	Bacterial spores	–	–	–	–	+	–
Important Chemical and Physical Properties	Shelf life >1 week	+	+	+	+	+	+
	Corrosive or deleterious effects	±	–	–	–	±	±
	Non-evaporable residue	–	–	+	+	–	+
	Inactivated by organic matter	+	±	+	±	+	+
	Skin irritant	±	–	+	+	+	±
	Eye irritant	+	–	+	+	+	+
	Respiratory irritant	–	–	–	–	+	–
	Systemic toxicity	+	–	+	+	+	+

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.

Chemical Category of Disinfectant							
		Isopropyl Alcohol	Accelerated Hydrogen Peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone-iodine)

<sup>a</sup> Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA. Antisepsis, disinfection and sterilization in the hospital and related institutions. *Man Clin Microbiol.* Washington D.C.: American Society for Microbiology;1995, 227–245.

<sup>b</sup> Accelerated hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

<sup>c</sup> Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of  $\leq 1$  minute; inactivation of spores requires longer contact times (e.g., 5–10 minutes for 5,000 ppm chlorine solution against *C. difficile* spores). Perez J, Springthorpe VS, Sattar SA. Activity of selected oxidizing microbicides against the spores of *Clostridium difficile*: relevance to environmental control. *Am J Infect Con.* 2005;33(6):320–325.

1948 ▲ USP40

### 1949 SWS WORKFLOW VALIDATION

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XML Attribute	XML Value	SWS Attribute	SWS Value	Notes
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS

1951 <sup>1</sup> U.S. Food and Drug Administration, Guidance for Industry, *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice*, September 2004.

1953 <sup>2</sup> Guidelines for Environmental Infection Control in Health-Care Facilities, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), MMWR, vol. 52, no. RR-10, June 6, 2003, figure 3, pg. 12-

1956 <sup>3</sup> NSF/ANSI 49.

1957 <sup>4</sup> ISO 14644 4:2001 Cleanrooms and associated controlled environments—Design, construction, and start-up, *Case Postale 56*, CH-1211 Geneve 20, Switzerland, tel. +41 22 749 01 11.

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<sup>5</sup> By definition (IEST RP-CC-001.4), HEPA filters are a minimum of 99.97% efficient when tested using 0.3-µm thermally generated particles and a photometer or rated at their most penetrating particle size using a particle counter.

<sup>6</sup> Sample procedures are detailed in CETA Applications Guide CAG-002-2006 section 2.09.

<sup>7</sup> Controlled Environment Testing Association, 1500 Sunday Drive, Ste. 102, Raleigh, NC 27607; [www.CETAinternational.org](http://www.CETAinternational.org).

<sup>8</sup> Agalloco J, Akers JE. Aseptic Processing: A Vision of the Future. *Pharmaceutical Technology*, 2005. Aseptic Processing supplement, s16.

<sup>9</sup> Eaton T. Microbial Risk Assessment for Aseptically Prepared Products. *Am Pharm Rev.* 2005; 8 (5, Sep/Oct): 46–51.

<sup>10</sup> *Guideline for Hand Hygiene in Health-care Settings*, MMWR, October 25, 2002, vol. 51, No. RR-16 available on the Internet at <http://www.cdc.gov/handhygiene/>.

<sup>11</sup> The use of additional resources, such as the Accreditation Manual for Home Care from the Joint Commission on Accreditation of Healthcare Organizations, may prove helpful in the development of a QA plan.

<sup>12</sup> See *American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE), Laboratory Design Guide*.

<sup>13</sup> *CETA Applications Guide for the Use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities*, CAG-001-2005, Controlled Environment Testing Association (CETA), November 8, 2005.

<sup>1</sup> Centers for Disease Control and Prevention and the Safe Injection Practices Coalition, One & Only Campaign, [http://www.oneandonlycampaign.org/safe\\_injection\\_practices](http://www.oneandonlycampaign.org/safe_injection_practices). <sup>▲</sup> USP40

<sup>2</sup> Agalloco J, Akers JE. Aseptic processing: a vision of the future. *Pharm Technol.* 2005; Aseptic Processing supplement, s16. <sup>▲</sup> USP40

<sup>3</sup> Eaton T. Microbial risk assessment for aseptically prepared products. *Am Pharm Rev.* 2005;8(5):46–51. <sup>▲</sup> USP40

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## BRIEFING

⟨ 800 ⟩ **Hazardous Drugs—Handling in Healthcare Settings**, *PF* 40(3) [May–Jun. 2013]. Based on the public comments received for the proposed ⟨ 800 ⟩ in *PF* 40(3), the USP Compounding Expert Committee has developed a revised chapter. This chapter has been created to identify the requirements for receipt, storage, compounding, dispensing, and administration of hazardous drugs (HDs) to protect the patient, healthcare personnel, and environment. Facility requirements that differ from [Pharmaceutical Compounding—Sterile Preparations](#) ⟨ 797 ⟩ and this chapter will be harmonized through an upcoming revision of ⟨ 797 ⟩, which will include the following:

- Elimination of the current allowance in ⟨ 797 ⟩ for facilities that prepare a low volume of HDs that permits placement of a Biological Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI) in a non-negative pressure room. All HD compounding must be done in a separate area designated for HD compounding.
- Addition of an allowance in ⟨ 800 ⟩ for a Containment Segregated Compounding Area (C-SCA), a separate, negative pressure room with at least 12 air changes per hour (ACPH) for use when compounding HDs. Low- and medium-risk HD compounded sterile preparation (CSP) may be prepared in a BSC or compounding aseptic containment isolator (CACI) located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours.

Major changes from the proposal of ⟨ 800 ⟩ in *PF* 40(3) include:

- Clarified wording in many sections.
- Removed statement concerning no acceptable level of HDs.
- Revised section on list of HDs, to allow entities to perform an assessment of risk for non-antineoplastic drugs and final dosage forms to determine alternative containment strategies and/or work practices.
- Clarified that HDs may be unpacked in either a neutral/normal or negative pressure area.
- Allowance for either external venting or redundant high-efficiency particulate air (HEPA) filtration of containment primary engineering controls (C-PECs) used for nonsterile compounding.

The proposed chapter is posted online at [www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings](http://www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings) with line numbers. Please provide the line numbers corresponding to your comments when submitting comments to [CompoundingSL@usp.org](mailto:CompoundingSL@usp.org).

(CMP: J. Sun.) Correspondence Number—C151881

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*Add the following:*

# ◁ 800 ▷ HAZARDOUS DRUGS— HANDLING IN HEALTHCARE SETTINGS

## 1. INTRODUCTION AND SCOPE

This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.

This chapter applies to all healthcare personnel who handle HD preparations and all entities which store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices). Personnel who may potentially be exposed to HDs include, but are not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians.

Entities that handle HDs must incorporate the standards in this chapter into their occupational safety plan. The entity's health and safety management system must, at a minimum, include:

- Engineering controls
- Competent personnel
- Safe work practices
- Proper use of appropriate Personal Protective Equipment (PPE)
- Policies for HD waste segregation and disposal

The chapter is organized into the following main sections:

1. [Introduction and Scope](#)
2. [List of Hazardous Drugs](#)
3. [Types of Exposure](#)
4. [Responsibilities of Personnel Handling Hazardous Drugs](#)
5. [Facilities](#)
6. [Environmental Quality and Control](#)
7. [Personal Protective Equipment](#)
8. [Hazard Communication Program](#)
9. [Personnel Training](#)
10. [Receiving](#)
11. [Labeling, Packaging, and Transport](#)
12. [Dispensing Final Dosage Forms](#)
13. [Compounding](#)

- 37 14. [Administering](#)
- 38 15. [Deactivation/Decontamination, Cleaning, and Disinfection](#)
- 39 16. [Spill Control](#)
- 40 17. [Disposal](#)
- 41 18. [Documentation and Standard Operating Procedures](#)
- 42 19. [Medical Surveillance](#)

43 [Appendix A: Acronyms and Definitions](#)

44 [Appendix B: Examples of Design for Hazardous Drugs Compounding Areas](#)

45 [Appendix C: Types of Biological Safety Cabinets](#)

46 [Appendix D: Bibliography](#)

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## 2. LIST OF HAZARDOUS DRUGS

49 The National Institute for Occupational Safety and Health (NIOSH) maintains a list of  
50 antineoplastic and other HDs used in healthcare. An entity must maintain a list of HDs,  
51 which may include items on the current NIOSH list in addition to other agents not on the  
52 NIOSH list. The entity's list must be reviewed at least annually and whenever a new  
53 agent or dosage form is used.

54 The NIOSH list of antineoplastic and other HDs provides the criteria used to identify  
55 HDs. These criteria must be used to identify HDs that enter the market after the most  
56 recent version of the NIOSH list, or that enter the entity as an investigational drug. If the  
57 information available on this drug is deemed insufficient to make an informed decision,  
58 consider the drug hazardous until more information is available.

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### Box 1: Containment Requirements

- Any antineoplastic HD requiring manipulation and HD Active Pharmaceutical Ingredients (API) on the NIOSH list must follow the requirements in this chapter.
  - Final antineoplastic dosage forms that do not require any further manipulation other than counting final dosage forms may be dispensed without any further requirements for containment unless required by the manufacturer.
- For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and/work practices.

60 Some dosage forms of drugs defined as hazardous may not pose a significant risk of  
61 direct occupational exposure because of their dosage formulation (e.g., tablets or  
62 capsules—solid, intact medications that are administered to patients without modifying  
63 the formulation). However, dust from tablets and capsules may present a risk of  
64 exposure by skin contact and/or inhalation. An assessment of risk may be performed for  
65 these dosage forms to determine alternative containment strategies and/or work  
66 practices.

67 The assessment of risk must, at a minimum, consider the following:

- 68 • Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk)
- 69 • Risk of exposure
- 70 • Packaging
- 71 • Manipulation

72 If an assessment of risk approach is taken, the entity must document what alternative  
 73 containment strategies and/or work practices are being employed for specific dosage  
 74 forms to minimize occupational exposure. If used, the assessment of risk must be  
 75 reviewed at least annually and the review documented.

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### 3. TYPES OF EXPOSURE

78 Routes of unintentional entry of HDs into the body include dermal and mucosal  
 79 absorption, inhalation, injection, and ingestion (e.g., contaminated foodstuffs, spills, or  
 80 mouth contact with contaminated hands). Both clinical and nonclinical personnel may be  
 81 exposed to HDs when they handle HDs or touch contaminated surfaces. [Table 1](#) lists  
 82 examples of potential routes of exposure based on activity.

83 **Table 1. Examples of Potential Routes of Exposure Based on Activity**

Activity	Potential Route of Exposure
Dispensing	<ul style="list-style-type: none"> <li>• Counting tablets and capsules from bulk containers</li> </ul>
Compounding	<ul style="list-style-type: none"> <li>• Crushing tablets or opening capsules</li> <li>• Pouring oral or topical liquids from one container to another</li> <li>• Weighing or mixing components</li> <li>• Constituting or reconstituting powdered or lyophilized HDs</li> <li>• Withdrawing or diluting injectable HDs from parenteral containers</li> <li>• Expelling air or HDs from syringes</li> <li>• Contacting HD residue present on PPE or other garments</li> <li>• Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs</li> <li>• Maintenance activities for potentially contaminated equipment and devices</li> </ul>
Administration	<ul style="list-style-type: none"> <li>• Generating aerosols during administration of HDs by various routes (e.g. injection, irrigation, oral, inhalation, or topical application)</li> <li>• Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation)</li> <li>• Priming an IV administration set</li> </ul>
Patient-care activities	<ul style="list-style-type: none"> <li>• Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other</li> </ul>

Activity	Potential Route of Exposure
	materials
Spills	<ul style="list-style-type: none"> <li data-bbox="508 333 1154 367">• Spill generation, management, and disposal</li> </ul>
Receipt	<ul style="list-style-type: none"> <li data-bbox="508 415 1386 520">• Contacting with HD residues present on drug container, individual dosage units, outer containers, work surfaces, or floors</li> </ul>
Transport	<ul style="list-style-type: none"> <li data-bbox="508 575 1084 609">• Moving HDs within a healthcare setting</li> </ul>

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#### 4. RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS

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Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas. The designated individual must thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of non-compliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team. The designated individual must also be responsible for the continuous monitoring of the facility and maintaining reports of testing/sampling performed in facilities.

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All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and care environment.

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#### 5. FACILITIES

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HDs must be handled under conditions that promote patient safety, worker safety, environmental protection, and infection prevention. Access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling. HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients, or visitors to reduce risk of exposure. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas.

Designated areas must be available for:

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- Receipt and unpacking of antineoplastic HDs or HD API
- Storage of HDs
- Nonsterile HD compounding (if performed by the entity)
- Sterile HD compounding (if performed by the entity)

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### 5.1 Receipt

115 Antineoplastic HDs and APIs must be unpacked (i.e., removal from external shipping  
116 containers) in an area that is neutral/normal or negative pressure relative to the  
117 surrounding areas. HDs must not be unpacked from their shipping containers in sterile  
118 compounding areas or in positive pressure areas.

119

### 5.2 Storage

120 HDs must be stored in a manner that prevents spillage or breakage if the container  
121 falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters  
122 (e.g., earthquakes) the manner of storage must meet applicable safety precautions,  
123 such as secure shelves with raised front lips.

124 Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic  
125 HDs may be stored with other inventory. Antineoplastic HDs requiring manipulation  
126 other than counting final dosage forms and any HD API must be stored separately from  
127 non-HDs in a manner that prevents contamination and personnel exposure. These HDs  
128 must be stored in a negative-pressure room with at least 12 air changes per hour  
129 (ACPH).

130 Sterile and nonsterile HDs may be stored together. Depending upon facility design,  
131 HDs may be stored within a negative pressure buffer room with at least 12 ACPH.  
132 However, only HDs used for sterile compounding may be stored in the negative  
133 pressure buffer room.

134 Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a  
135 negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or  
136 containment segregated compounding area (C-SCA)]. If a refrigerator is placed in a  
137 negative pressure buffer room, an exhaust located adjacent to the refrigerator's  
138 compressor and behind the refrigerator should be considered.

139

### 5.3 Compounding

140 Engineering controls are required to protect the preparation from cross-contamination  
141 and microbial contamination (if preparation is intended to be sterile) during all phases of  
142 the compounding process. Engineering controls for containment are divided into three  
143 categories representing primary, secondary, and supplementary levels of control. A  
144 containment primary engineering control (C-PEC) is a ventilated device designed to  
145 minimize worker and environmental HD exposure when directly handling HDs.  
146 Containment secondary engineering controls (C-SEC) is the room in which the C-PEC  
147 is placed. Supplemental engineering controls [e.g., closed-system drug-transfer device  
148 (CSTD)] are adjunct controls to offer additional levels of protection. *Appendix B* provides  
149 examples for designs of HD compounding areas.

150 Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC.  
151 The C-SEC used for sterile and nonsterile compounding must:

- 152 • Be externally vented through high-efficiency particulate air (HEPA) filtration
- 153 • Be physically separated (i.e., a different room from other preparation areas)
- 154 • Have a negative pressure between 0.01 and 0.03 inches of water column

155 The C-PEC must operate continuously if used for sterile compounding or if the C-PEC  
156 supplies the negative pressure. If there is any loss of power to the unit, or if repair or  
157 moving occurs, all activities occurring in the C-PEC must be suspended immediately. If  
158 necessary, protect the unit by covering it appropriately per the manufacturer's  
159 recommendations. Once the C-PEC can be powered on, decontaminate, clean, and  
160 disinfect (if used for sterile compounding) all interior surfaces and wait the  
161 manufacturer-specified recovery time before resuming compounding.

162 A sink must be available for hand washing as well as emergency access to water for  
163 removal of hazardous substances from eyes and skin. An eyewash station and/or other  
164 emergency or safety precautions that meet applicable laws and regulations must be  
165 readily available. However, care must be taken to locate them in areas where their  
166 presence will not interfere with required ISO classifications.

167 For entities that compound both nonsterile and sterile HDs, the respective C-PECs  
168 must be placed in segregated rooms separate from each other, unless those C-PECs  
169 used for nonsterile compounding are sufficiently effective that the room can  
170 continuously maintain ISO 7 classification throughout the nonsterile compounding  
171 activity. If the C-PECs used for sterile and nonsterile compounding are placed in the  
172 same room, they must be placed at least 1 meter apart and particle-generating activity  
173 must not be performed when sterile compounding is in process.

#### 174 5.3.1 NONSTERILE COMPOUNDING

175 In addition to this chapter, nonsterile compounding must follow standards in  
176 [Pharmaceutical Compounding—Nonsterile Preparations](#) ( 795 ). A C-PEC is not  
177 required if manipulations are limited to handling of final dosage forms (e.g., tablets and  
178 capsules) that do not produce particles, aerosols, or gasses.

179 The C-PECs used for manipulation of nonsterile HDs must be either externally vented  
180 (preferred) or redundant–HEPA filtered in series. Nonsterile HD compounding must be  
181 performed in a C-PEC that provides personnel and environmental protection, such as a  
182 Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A  
183 Class II BSC or a compounding aseptic containment isolator (CACI) may be also be  
184 used. For occasional nonsterile HD compounding, a C-PEC used for sterile  
185 compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated,  
186 cleaned, and disinfected before resuming sterile compounding in that C-PEC. A C-PEC  
187 used only for nonsterile compounding does not need to have unidirectional airflow  
188 because the critical environment does not need to be ISO classified.

189 The C-PEC must be placed in a C-SEC that has at least 12 ACPH. [Table 2](#)  
190 summarizes the engineering controls required for nonsterile HD compounding.

191 Due to the difficulty of cleaning HD contamination from surfaces, the architectural  
192 finish requirements (e.g., smooth, seamless, and impervious surfaces) described in  
193 [Pharmaceutical Compounding—Sterile Preparations](#) ( 797 ) also apply to nonsterile  
194 compounding areas.

195 **Table 2. Engineering Controls for Nonsterile HD Compounding**

C-PEC	C-SEC Requirements
• Externally vented (preferred) or redundant–HEPA filtered in series	• 12 ACPH • Externally vented

C-PEC	C-SEC Requirements
<ul style="list-style-type: none"> <li>Examples: CVE, Class I or II BSC, CACI</li> </ul>	<ul style="list-style-type: none"> <li>Negative pressure between 0.01 and 0.03 inches of water column</li> </ul>

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### 5.3.2 STERILE COMPOUNDING

In addition to this chapter, applicable sterile compounding standards in [\( 797 \)](#) must be followed.

All C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides a Class 5 or better air quality, such as a Class II or III BSC, or CACI. Class II BSC types A2, B1, or B2 are all acceptable. For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile components. *Appendix C* describes the different types of BSCs.

A laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) must not be used for the compounding of an antineoplastic HD. A BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.

The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room (preferred) or an unclassified containment segregated compounding area (C-SCA). If the C-PEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared must be limited as defined in [\( 797 \)](#) for CSPs prepared in a segregated compounding area. *Table 3* summarizes the engineering controls required for sterile HD compounding.

**Table 3. Engineering Controls for Sterile HD Compounding**

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 Buffer Room	<ul style="list-style-type: none"> <li>Externally Vented</li> <li>Examples: Class II BSC or CACI</li> </ul>	<ul style="list-style-type: none"> <li>30 ACPH</li> <li>Externally vented</li> <li>Negative pressure between 0.01 and 0.03 inches of water column</li> </ul>	As described in <a href="#">( 797 )</a>
C-SCA	<ul style="list-style-type: none"> <li>Externally Vented</li> <li>Examples: Class II BSC or CACI</li> </ul>	<ul style="list-style-type: none"> <li>12 ACPH</li> <li>Externally vented</li> <li>Negative pressure between 0.01 and 0.03 inches of water column</li> </ul>	As described in <a href="#">( 797 )</a> for segregated compounding area

218 **ISO class 7 buffer room:** The C-PEC may be placed in an ISO Class 7 buffer room  
219 that has a negative pressure between 0.01 and 0.03 inches of water column and has a  
220 minimum of 30 ACPH of HEPA-filtered supply air.

221 Because the room through which entry into the HD buffer room (e.g., ante-area or non-  
222 HD buffer room) plays an important role in terms of total contamination control, the  
223 following is required:

- 224 • Minimum of 30 ACPH of HEPA-filtered supply air
- 225 • Maintain a positive pressure of 0.02 inches of water column relative to all  
226 adjacent unclassified spaces
- 227 • Maintain an air quality of ISO Class 7 or better

228 This provides for inward air migration of equal cleanliness classified air into the  
229 negative pressure buffer room to contain any airborne HD. A hand-washing sink must  
230 be placed at least 1 meter from the entrance of the buffer room to avoid contamination  
231 migration into the negative pressure HD buffer room.

232 Although not a recommended facility design, if the negative-pressure HD buffer room  
233 is entered though the positive-pressure non-HD buffer room, the following is required:

- 234 • A line of demarcation must be defined within the negative-pressure buffer area  
235 for garbing and degarbing
- 236 • A method to transport HDs, CSPs, and waste into and out of the negative  
237 pressure buffer room to minimize the spread of HD contamination. This may be  
238 accomplished by use of a pass-through between the negative-pressure buffer  
239 area and adjacent space. The pass-through must be included in the facility's  
240 certification to ensure that particles are not compromising the air quality of the  
241 negative-pressure buffer room. Do not use a refrigerator pass-through. Other  
242 methods of containment (such as sealed containers) may be used if the entity  
243 can demonstrate HD containment and appropriate environmental control.

244 HD CSPs prepared in an ISO Class 7 buffer room may use the BUDs described in {  
245 [797](#)}, based on the categories of CSP, sterility testing, and storage temperature.  
246

247 **Containment segregated compounding area (C-SCA):** The C-PEC may be placed  
248 in an unclassified C-SCA that has a negative pressure between 0.01 and 0.03 inches of  
249 water column relative to all adjacent spaces and has a minimum of 12 ACPH of HEPA-  
250 filtered supply air. A hand-washing sink must be placed at least 1 meter from C-PEC.

251 Only low- and medium-risk HD CSPs may be prepared in a C-SCA. HD CSPs  
252 prepared in the C-SCA must not exceed the BUDs described in { [797](#) } for CSPs  
253 prepared in a segregated compounding area.

#### 254 **5.4 Containment Supplemental Engineering Controls**

255 Containment supplemental engineering controls, such as CSTDs, provide adjunct  
256 controls to offer additional levels of protection during compounding or administration.  
257 Some CSTDs have been shown to limit the potential of generating aerosols during  
258 compounding. However, there is no certainty that all CSTDs will perform adequately.

259 Since there is no published universal performance standard for evaluation of CSTD  
260 containment, users should carefully evaluate the performance claims associated with  
261 available CSTDs based on independent studies and demonstrated containment  
262 reduction.

263 A CSTD must not be used as a substitute for a C-PEC when compounding. CSTDs  
264 should be used when compounding HDs when the dosage form allows. CSTDs must be  
265 used when administering HDs when the dosage form allows.

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## 6. ENVIRONMENTAL QUALITY AND CONTROL

268 Environmental wipe sampling should be performed routinely (e.g., initially as a  
269 benchmark and at least every 6 months, or more often as needed, to verify  
270 containment). Surface wipe sampling should include:

- 271 • Interior of the C-PEC and equipment contained in it
- 272 • Staging or work areas near the C-PEC
- 273 • Areas adjacent to C-PECs (e.g., floors directly under staging and dispensing  
274 area)
- 275 • Patient administration areas

276 There are currently no studies demonstrating the effectiveness of a specific number or  
277 size of wipe samples in determining levels of HD contamination. Wipe sampling kits  
278 should be verified before use to ensure the method and reagent used have been tested  
279 to recover a specific percentage of known marker drugs from various surface types  
280 found in the sampled area. There are currently no certifying agencies for vendors of  
281 wipe sample kits.

282 There is currently no standard for acceptable limits for HD surface contamination.  
283 Common marker HDs that can be assayed include cyclophosphamide, ifosfamide,  
284 methotrexate, fluorouracil, and platinum-containing drugs. An example of measurable  
285 contamination would be cyclophosphamide levels  $>1.00 \text{ ng/cm}^2$ , which were shown in  
286 some studies to result in uptake of the drug in exposed workers. If any measurable  
287 contamination is found, the compounding supervisor must identify, document, and  
288 contain the cause of contamination. Such action may include reevaluating work  
289 practices, re-training personnel, performing thorough deactivation/decontamination and  
290 cleaning, and improving engineering controls. Repeat the wipe sampling to validate that  
291 the deactivation/decontamination and cleaning steps have been effective.

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## 7. PERSONAL PROTECTIVE EQUIPMENT

294 Personal Protective Equipment (PPE) provides worker protection to reduce exposure  
295 to HD aerosols and residues. When performing a task in situations where C-PECs are  
296 not generally available, such as treating a patient or cleaning a spill, additional PPE may  
297 be required. The NIOSH list of antineoplastic and other HDs provides some general  
298 guidance on PPE for possible scenarios that may be encountered in healthcare  
299 settings.

300 Gloves, gowns, head, hair, and shoe covers are required for compounding sterile and  
301 nonsterile HDs. Gloves are required for administering antineoplastic HDs. Gowns are

302 required when administering injectable antineoplastic HDs. For all other activities, the  
303 entity's SOP must describe the appropriate PPE to be worn based on its occupational  
304 safety plan and assessment of risk (if used). The entity must develop SOPs for PPE  
305 based on the risk of exposure (see *Types of Exposure*) and activities performed.

306 Appropriate PPE must be worn when handling HDs including during:

- 307 • Receipt
- 308 • Storage
- 309 • Transport
- 310 • Compounding (sterile and nonsterile)
- 311 • Administration
- 312 • Deactivation/Decontamination, Cleaning, and Disinfecting
- 313 • Spill Control

### 314 **7.1 Gloves**

315 When required, chemotherapy gloves must be tested to American Society for Testing  
316 and Materials (ASTM) standard D6978 (or its successor). Chemotherapy gloves must  
317 be powder-free because powder can contaminate the work area and can adsorb and  
318 retain HDs. Gloves must be inspected for physical defects before use. Do not use  
319 gloves with pin holes or weak spots.

320 Chemotherapy gloves must be changed every 30 min or when torn, punctured, or  
321 contaminated.

### 322 **7.2 Gowns**

323 When required, disposable gowns must be tested and shown to resist permeability by  
324 HDs. Gowns must be selected based on the HDs handled. Disposable gowns made of  
325 polyethylene-coated polypropylene or other laminate materials offer better protection  
326 than those made of uncoated materials. Gowns must close in the back (i.e., no open  
327 front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns must not  
328 have seams or closures that could allow HDs to pass through.

329 Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials  
330 are not appropriate outerwear when handling HDs because they permit the permeation  
331 of HDs and can hold spilled drugs against the skin, thereby increasing exposure.  
332 Clothing may also retain HD residue from contact, and may transfer to other healthcare  
333 workers or various surfaces. Washing of non-disposable clothing contaminated with HD  
334 residue may transfer drug residue to other clothing.

335 Gowns must be changed per the manufacturer's information for permeation of the  
336 gown. If no permeation information is available for the gowns used, change them every  
337 2–3 hours or immediately after a spill or splash. Gowns worn in HD handling areas must  
338 not be worn to other areas in order avoid spreading HD contamination and exposing  
339 other healthcare workers.

### 340 **7.3 Head, Hair, Shoe, and Sleeve Covers**

341 Head and hair covers (including beard and moustache, if applicable) and shoe covers  
342 provide protection from contact with HD residue on surfaces and floors. When  
343 compounding sterile HDs, a second pair of shoe covers must be donned before entering

344 the buffer room and removed when exiting the buffer room. Shoe covers worn in HD  
345 handling areas must not be worn to other areas to avoid spreading HD contamination  
346 and exposing other healthcare workers.

347 Disposable sleeve covers constructed of coated materials may be used to protect  
348 areas of the arm that may come in contact with HDs. If used, sleeve covers must be  
349 carefully removed and properly disposed of after the task is completed.

#### 350 **7.4 Eye and Face Protection**

351 Many HDs are irritating to the eyes and mucous membranes. Appropriate eye and face  
352 protection must be worn when there is a risk for spills or splashes of HDs or HD waste  
353 materials when working outside of a C-PEC (e.g., administration in the surgical suite,  
354 working at or above eye level, or cleaning a spill). A full-facepiece respirator provides  
355 eye and face protection. Goggles must be used when eye protection is needed. Eye  
356 glasses alone or safety glasses with side shields do not protect the eyes adequately  
357 from splashes. Face shields in combination with goggles provide a full range of  
358 protection against splashes to the face and eyes. Face shields alone do not provide full  
359 eye and face protection.

#### 360 **7.5 Respiratory Protection**

361 For most activities requiring respiratory protection, a fit-tested NIOSH-certified N95 or  
362 more protective respirator is sufficient to protect against airborne particles. However,  
363 N95 respirators offer no protection against gases and vapors and little protection  
364 against direct liquid splashes (see the Centers for Disease Control and Prevention's  
365 (CDC's) Respirator Trusted-Source Information).

366 Surgical masks do not provide respiratory protection from drug exposure and must not  
367 be used when respiratory protection is required. A surgical N95 respirator provides the  
368 respiratory protection of an N95 respirator, and like a surgical mask, provides a barrier  
369 to splashes, droplets, and sprays around the nose and mouth.

370 Personnel who are unpacking HDs that are not contained in plastic should wear an  
371 elastomeric half-mask with a multi-gas cartridge and P100-filter. If the type of drug can  
372 be better defined, then a more targeted cartridge can be used.

373 Fit test the respirator and train workers to use respiratory protection. Follow all  
374 requirements in the Occupational Safety and Health Administration (OSHA) respiratory  
375 protection standard (29 CFR 1910.134). An appropriate full-facepiece, chemical  
376 cartridge-type respirator must be worn when attending to HD spills larger than what can  
377 be contained with a spill kit, or when there is a known or suspected airborne exposure  
378 to powders or vapors.

#### 379 **7.6 Disposal of Used Personal Protective Equipment**

380 Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace  
381 quantities of HDs. PPE must be placed in an appropriate waste container and further  
382 disposed of per local, state, and federal regulations. PPE used during compounding  
383 should be disposed of in the proper waste container before leaving the C-SEC.  
384 Chemotherapy gloves worn during compounding must be carefully removed and  
385 discarded immediately in an approved HD waste container inside the C-PEC or  
386 contained in a sealable bag for discarding outside the C-PEC. Potentially contaminated  
387 clothing must not be taken home under any circumstances.

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## 8. HAZARD COMMUNICATION PROGRAM

390 Entities are required to establish policies and procedures that ensure worker safety  
391 during all aspects of HD handling. The entity must develop SOPs to ensure effective  
392 training regarding proper labeling, transport, and storage of the HDs and use of Safety  
393 Data Sheets (SDS), based on the Globally Harmonized System of Classification and  
394 Labeling of Chemicals (GHS).

395 Elements of the plan must include:

- 396 • A written plan that describes how the standard will be implemented.
- 397 • All containers of hazardous chemicals must be labeled, tagged, or marked with  
398 the identity of the material and appropriate hazard warnings.
- 399 • Entities must have an SDS for each hazardous chemical they use.
- 400 • Entities must ensure that the SDSs for each hazardous chemical used are readily  
401 accessible to personnel during each work shift and when they are in their work  
402 areas.
- 403 • Personnel who may be exposed to hazardous chemicals when working must be  
404 provided information and training before the initial assignment to work with a  
405 hazardous chemical, and also whenever the hazard changes.

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## 9. PERSONNEL TRAINING

408 All personnel who handle HDs must be fully trained based on their job functions (e.g.,  
409 in the receipt, storage, handling, compounding, dispensing, and disposal of HDs).  
410 Training must occur before the employee independently handles HDs. The  
411 effectiveness of training for HD handling competencies must be demonstrated by each  
412 employee. Personnel competency must be reassessed at least every 12 months and  
413 when a new HD or new equipment is used or a new or significant change in process or  
414 SOP occurs. All training and competency assessment must be documented.

415 The training must include at least the following:

- 416 • Overview of entity's list of HDs and their risks
- 417 • Review of the entity's SOPs related to handling of HDs
- 418 • Proper use of PPE
- 419 • Proper use of equipment and devices (e.g., engineering controls)
- 420 • Spill management
- 421 • Response to known or suspected HD exposure

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## 10. RECEIVING

424 The entity must establish SOPs for receiving HDs. HDs should be received from the  
425 supplier sealed in impervious plastic to segregate them from other drugs and to improve  
426 safety in the receiving and internal transfer process. HDs must be delivered to the HD  
427 storage area immediately upon arrival.

428 PPE, including ASTM-tested, powder-free chemotherapy gloves, must be worn when  
 429 unpacking HDs (see *Personnel Protective Equipment*). A spill kit must be accessible in  
 430 the receiving area.

431 The entity must enforce policies that include a tiered approach, starting with visual  
 432 examination of the shipping container for signs of damage or breakage (e.g., visible  
 433 stains from leakage, sounds of broken glass containers). [Table 4](#) summarizes the steps  
 434 for receiving and handling of damaged shipping containers.

435 **Table 4. Summary of Requirements for Receiving and Handling Damaged HD**  
 436 **Shipping Containers**

If the shipping container appear damaged	<ul style="list-style-type: none"> <li>• Seal container without opening and contact the supplier for instructions</li> <li>• If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous"</li> <li>• If the supplier declines return, dispose of properly</li> </ul>
If a damaged shipping container must be opened	<ul style="list-style-type: none"> <li>• Seal the container in plastic or an impervious container</li> <li>• Transport it to a C-PEC and place on a plastic-backed preparation mat</li> <li>• Open the package and remove usable items.</li> <li>• Wipe the outside of the usable items with a disposable wipe.</li> <li>• Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous"</li> <li>• If the supplier declines return, dispose of properly</li> <li>• Decontaminate/deactivate and clean the C-PEC (see <i>Deactivation/Decontamination, Cleaning, and Disinfection</i>) and discard the mat and cleaning disposables as hazardous waste</li> </ul>

437 When opening damaged shipping containers, they should preferably be transported to  
 438 a C-PEC designated for nonsterile compounding. If a C-PEC designated for sterile  
 439 compounding is the only one available, it must be thoroughly disinfected after the  
 440 decontamination/deactivation and cleaning step before returning to any sterile  
 441 compounding activity.

442 Damaged packages or shipping cartons must be considered spills that must be  
 443 reported to the designated person and managed according to the entity's SOPs. Clean-  
 444 up must comply with established SOPs.

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## 11. LABELING, PACKAGING, AND TRANSPORT

447 The entity must establish SOPs for the labeling, handling, packaging, and transport of  
 448 HDs. The SOPs must address prevention of accidental exposures or spills, personnel  
 449 training on response to exposure, and use of a spill kit. Examples of special exposure-  
 450 reducing strategies include small-bore connectors (such as Luer Lock) and syringes,

451 syringe caps, CSTDs, the capping of container ports, sealed impervious plastic bags,  
452 impact-resistant and/or water-tight containers, and cautionary labeling.

### 453 **11.1 Labeling**

454 HDs identified by the entity as requiring special HD handling precautions must be  
455 clearly labeled at all times during their transport.

### 456 **11.2 Packaging**

457 Compounding personnel must select and use packaging containers and materials that  
458 will maintain physical integrity, stability, and sterility (if needed) of the HDs during  
459 transport. Packaging materials must protect the HD from damage, leakage,  
460 contamination, and degradation, while protecting healthcare workers who transport  
461 HDs. The entity must have written SOPs to describe appropriate shipping containers  
462 and insulating materials, based on information from product specifications, vendors,  
463 mode of transport, and experience of the compounding personnel.

### 464 **11.3 Transport**

465 HDs that need to be transported must be labeled, stored, and handled in accordance  
466 with applicable federal, state, and local regulations. HDs must be transported in  
467 containers that minimize the risk of breakage or leakage. Pneumatic tubes must not be  
468 used to transport any liquid or antineoplastic HDs because of the potential for breakage  
469 and contamination.

470 When shipping HDs to locations outside the entity, the entity must consult the  
471 Transport Information on the SDS. The entity must ensure that labels and accessory  
472 labeling for the HDs include storage instructions, disposal instructions, and HD category  
473 information in a format that is consistent with the courier's policies.

## 474 **12. DISPENSING FINAL DOSAGE FORMS**

476 HDs that do not require any further manipulation other than counting final dosage  
477 forms may be dispensed without any further requirements for containment unless  
478 required by the manufacturer or if visual indicators of HD exposure hazards (e.g., HD  
479 dust or leakage) are present.

480 Counting of HDs should be done carefully. Clean equipment should be dedicated for  
481 use with these drugs. Tablet and capsule forms of HDs must not be placed in  
482 automated counting or packaging machines, which subject them to stress and may  
483 introduce powdered contaminants into the work area.

## 484 **13. COMPOUNDING**

486 Entities and personnel involved in compounding HDs must be compliant with the  
487 appropriate USP standards for compounding including [\( 795 \)](#) and [\( 797 \)](#).  
488 Compounding must be done in proper engineering controls as described in  
489 *Compounding*. When compounding nonsterile and sterile HD preparations in a C-PEC,  
490 a plastic-backed preparation mat must be placed on the work surface of the C-PEC.  
491 The mat should be changed immediately if a spill occurs and regularly during use, and  
492 should be discarded at the end of the daily compounding activity. Disposable or clean

493 equipment for compounding (such as mortars and pestles, and spatulas) must be  
494 dedicated for use with HDs. Compounding personnel must ensure that the labeling  
495 processes for compounded preparations do not introduce contamination into non-HD  
496 handling areas.

497 When compounding nonsterile HD preparations, use commercially available products  
498 as starting ingredients whenever possible. Liquid formulations are preferred over  
499 crushing tablets or opening capsules. APIs should only be used when there are no other  
500 options. When compounding sterile HD preparations, APIs should be avoided if a  
501 suitable manufactured product is available and appropriate for use (e.g., use an  
502 injectable product rather than API).

503 Bulk containers of liquid and API HD must be handled carefully to avoid spills. If used,  
504 APIs should be handled in a C-PEC to protect against occupational exposure,  
505 especially during particle generating activities (such as crushing tablets, opening  
506 capsules, and weighing powder).

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#### 14. ADMINISTERING

509 HDs must be administered safely using protective medical devices and techniques.  
510 Examples of protective medical devices include needleless and closed systems.  
511 Examples of protective techniques include spiking or priming of IV tubing in a C-PEC  
512 and crushing tablets in plastic sleeves.

513 Appropriate PPE must be worn when administering HDs. After use, PPE must be  
514 removed and disposed of in an approved HD waste container at the site of drug  
515 administration. Equipment (such as tubing and needles) and packaging materials must  
516 be disposed of properly, such as in HD waste containers after administration.

517 CSTDs must be used for administration when the dosage form allows. Techniques and  
518 ancillary devices that minimize the risk posed by open systems must be used when  
519 administering HDs through certain routes. Administration into certain organs or body  
520 cavities (e.g., the bladder, eye, peritoneal cavity, or chest cavity) often requires  
521 equipment for which locking connections may not be readily available or possible.

522 Healthcare personnel should avoid manipulating HDs such as crushing tablets or  
523 opening capsules if possible. Liquid formulations are preferred if solid oral dosage forms  
524 are not appropriate for the patient. If HD dosage forms do require manipulation such as  
525 crushing tablet(s) or opening capsule(s) for a single dose, personnel must don  
526 appropriate PPE and use a plastic sleeve to contain any dust or particles generated.

527 The Oncology Nursing Society (ONS) Safe Handling of Hazardous Drugs publication  
528 contains additional information on handling HDs for administration.

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#### 15. DEACTIVATION/DECONTAMINATION, CLEANING, AND DISINFECTION

531 All areas where HDs are handled (e.g., such as during receiving, compounding,  
532 transport, administering, and disposal) and all reusable equipment and devices (e.g., C-  
533 PEC, carts, and trays) must be routinely deactivated/decontaminated and cleaned.  
534 Additionally, sterile compounding areas and devices must be subsequently disinfected.

535 All healthcare personnel who perform deactivation/decontamination, cleaning, and  
536 disinfection activities in HD handling areas must be trained in appropriate procedures to  
537 protect themselves and the environment from contamination. All personnel performing

538 these activities must wear appropriate PPE resistant to the cleaning agents used,  
539 including two pairs of ASTM-tested chemotherapy gloves and impermeable disposable  
540 gowns. Consult manufacturer or supplier information for compatibility with cleaning  
541 agents used. Additionally, eye protection and face shields must be used if splashing is  
542 possible. Respiratory protection must be used if warranted by the activity.

543 The entity must establish written procedures for decontamination, deactivation,  
544 cleaning, and disinfection (for sterile compounding areas). Cleaning of nonsterile and  
545 sterile compounding areas must also comply with < 795 > and < 797 >. Written  
546 procedures for cleaning must include procedures, agents used, dilutions used,  
547 frequency, and documentation requirements. [Table 5](#) summarizes the purpose and  
548 example agents for each step.

549 The deactivating, decontaminating, cleaning, and disinfecting agents selected must be  
550 appropriate for the type of HD contaminant(s), location, and surface materials. The  
551 products used must not contaminate the surfaces with substances that are toxic,  
552 volatile, corrosive, or otherwise harmful to the surface material. Perform cleaning in  
553 areas that are sufficiently ventilated to prevent accumulation of hazardous airborne drug  
554 concentrations and decontamination agents.

555

**Table 5. Summary of Cleaning Steps**

Cleaning Step	Purpose	Agents
Deactivation	Render compound inert or inactive	As listed in the HD labeling or if no specific information available, sodium hypochlorite or other Environmental Protection Agency (EPA)-registered oxidizer
Decontamination	Remove inactivated residue	Sterile alcohol, sterile water, peroxide, or sodium hypochlorite
Cleaning	Remove organic and inorganic material	Germicidal detergent and sterile water
Disinfection	Destroy microorganisms	Sterile alcohol or other EPA-registered disinfectant appropriate for use

556

### 15.1 Deactivation/Decontamination

557 Deactivation renders a compound inert or inactive. Decontamination occurs by  
558 physically removing HD residue from non-disposable surfaces and transferring it to  
559 absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area  
560 being cleaned. All disposable materials must be discarded as contaminated HD waste.

561 Chemical deactivation of HD residue is preferred, but no single process has been  
562 found to deactivate all currently available HDs. Studies have examined oxidizing agents  
563 such as potassium permanganate, hydrogen peroxide, and sodium hypochlorite;  
564 vaporized hydrogen peroxide and detergents; and high- and low-pH solutions, all with  
565 varying results. Some potential deactivators have produced byproducts that are as  
566 hazardous as the original drug. Other deactivators have respiratory effects or result in  
567 caustic damage to surfaces. Note that sodium hypochlorite is corrosive to stainless steel  
568 surfaces if left untreated; therefore, sodium hypochlorite must be neutralized with  
569 sodium thiosulfate or followed by use of a germicidal detergent.

570 A multi-component deactivation system is theoretically more efficient than a single-  
571 agent system because of the diverse nature of HDs. One commercially available  
572 product provides a system for decontamination and deactivation using sodium  
573 hypochlorite, surfactant, and thiosulfate neutralizer. This combination product, followed  
574 by rinsing, has been shown to be effective for cleaning HD-contaminated surfaces.  
575 Other products use combinations of deactivating agents and/or cleaning agents,  
576 followed by rinsing and disinfecting. Because of the growing number of assays available  
577 for HDs, additional surface wipe sampling is now possible and should be done to  
578 document the effectiveness of any agent used for decontamination of HD residue from  
579 work surfaces (see *Environmental Quality and Control*).

## 580 **15.2 Cleaning and Disinfection**

581 Cleaning is a process that results in the removal of contaminants (e.g., soil, microbial  
582 contamination, HD residue) from objects and surfaces using water, detergents,  
583 surfactants, solvents, and/or other chemicals. Disinfection is a process of destroying  
584 microorganisms. Disinfection must be done for areas intended to be sterile including the  
585 sterile compounding areas.

## 586 **15.3 Cleaning the Compounding Area**

587 The [Cleaning and Disinfecting the Compounding Area](#) section in ( 797 ) applies to both  
588 sterile and nonsterile HD compounding areas. Cleaning agents used on compounding  
589 equipment should not introduce microbial contamination.

590 All C-PEC used for either nonsterile or sterile compounding must be decontaminated  
591 between compounding of different HDs, any time a spill occurs, before and after  
592 certification, any time voluntary interruption occurs, and if the ventilation tool is moved.  
593 No cleaning step may be performed when compounding activities are occurring.

594 The amount of HD contamination introduced into the C-PEC may be reduced by  
595 surface decontamination (i.e., wiping down) of HD containers. Although no wipe-down  
596 procedures have been studied, the use of disposable material moistened with alcohol,  
597 sterile water, peroxide, or sodium hypochlorite solutions may be effective. To avoid  
598 spreading HD residue, spray the wiper, not the HD container. The solution used for  
599 wiping HD packaging must not alter the product label.

600 C-PECs may have areas under the work tray where contamination can build up. These  
601 areas must be cleaned at least monthly to reduce the contamination level in the C-PEC.  
602 Accessing this area may be difficult. Clean as much as possible of the C-PEC surfaces  
603 before accessing the area under the work tray. When cleaning the area under the work  
604 tray of a C-PEC, the containment airflows are compromised by opening the cabinets. To  
605 provide protection to the worker performing this task, respiratory protection may be  
606 required. An NIOSH-approved respirator worn by a worker who has been fit tested and  
607 cleared to use a respirator would be appropriate.

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## **16. SPILL CONTROL**

610 All personnel who may be required to clean-up a spill of HDs must receive proper  
611 training in spill management and the use of PPE and NIOSH-certified respirators (see  
612 *Personal Protective Equipment*). Spills must be contained and cleaned immediately only  
613 by qualified personnel with appropriate PPE. Qualified personnel must be available at

614 all times in entities handling HDs. Signs must be available for restricting access to the  
615 spill area. Spill kits containing all of the materials needed to clean HD spills must be  
616 readily available in all areas where HDs are routinely handled. If HDs are being  
617 prepared or administered in a non-routine healthcare area, a spill kit and respirator must  
618 be available. All spill materials must be disposed of as hazardous waste.

619 The circumstances and management of spills must be documented. Personnel who  
620 are potentially exposed during the spill or spill clean-up or who have direct skin or eye  
621 contact with HDs require immediate evaluation. Non-employees exposed to an HD spill  
622 should report to the designated emergency service for initial evaluation and also  
623 complete an incident report or exposure form.

624 SOPs must be developed to prevent spills and to direct the clean-up of HD spills.  
625 SOPs must address the size and scope of the spill and specify who is responsible for  
626 spill management and the type of PPE required. The management of the spill (e.g.,  
627 decontamination, deactivation, and cleaning) may be dependent on the size and type of  
628 spill. The SOP must address the location of spill kits and clean-up materials as well as  
629 the capacity of the spill kit. Written procedures should address use of appropriate full-  
630 facepiece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded  
631 or if there is known or suspected airborne exposure to vapors or gases.

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## 17. DISPOSAL

634 Disposal of all HD waste (including unused and unusable HDs) must comply with all  
635 applicable federal, state, and local regulations. All personnel who perform routine  
636 custodial waste removal and cleaning activities in HD handling areas must be trained in  
637 appropriate procedures to protect themselves and the environment to prevent HD  
638 contamination.

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## 18. DOCUMENTATION AND STANDARD OPERATING PROCEDURES

641 Activities that must be documented include, but are not limited to, the acquisition,  
642 preparation, and dispensing of an HD; personnel training; and the use and maintenance  
643 of equipment and supplies. These records must be available for review. Personnel who  
644 transport, compound, or administer HDs must document their training according to  
645 OSHA standards (see OSHA Standard 1910.120 Hazardous Waste Operations and  
646 Emergency Response) and other applicable laws and regulations.

647 The entity must maintain SOPs for the safe handling of HDs for all situations in which  
648 these HDs are used throughout a facility. The SOPs must be reviewed at least annually  
649 by the designated responsible individual, and the review must be documented.

650 Revisions in forms or records must be made as needed and communicated to all  
651 personnel handling HDs.

652 The SOPs for handling of HDs should include:

- 653 • Hazard communication program
- 654 • Occupational safety program
- 655 • Labeling of HDs
- 656 • Procurement of HDs
- 657 • Use of proper engineering controls (e.g., C-PECs, C-SECs)

- 658 • Use of PPE based on activity (e.g., receipt, transport, compounding,  
659 administration, spill, and disposal)
- 660 • Decontamination/deactivation, cleaning, and disinfection
- 661 • Transport
- 662 • Environmental monitoring
- 663 • Spill control
- 664 • Medical surveillance

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## 19. MEDICAL SURVEILLANCE

667 Medical surveillance is part of a comprehensive exposure control program  
668 complementing engineering controls, safe work processes, and use of PPE. Entities  
669 should ensure that healthcare workers who handle HDs as a regular part of their job  
670 assignment are enrolled in a medical surveillance program. The general purpose of  
671 surveillance is to minimize adverse health effects in personnel potentially exposed to  
672 HDs. Medical surveillance programs involve assessment and documentation of  
673 symptom complaints, physical findings, and laboratory values (such as a blood count) to  
674 determine whether there is a deviation from the expected norms.

675 Medical surveillance can also be viewed as a secondary prevention tool that may  
676 provide a means of early detection if a health problem develops. Tracking personnel  
677 through medical surveillance allows the comparison of health variables over time in  
678 individual workers, which may facilitate early detection of a change in a laboratory value  
679 or health condition. Medical surveillance programs also look for trends in populations of  
680 workers. Examining grouped data compared with data from unexposed workers may  
681 reveal a small alteration or increase in the frequency of a health effect that would be  
682 obscured if individual workers' results alone were considered.

683 Medical surveillance evaluates the protection afforded by engineering controls, other  
684 administrative controls, safe work processes, PPE, and worker education about the  
685 hazards of the materials they work with in the course of their duties. The data-gathering  
686 elements of a medical surveillance program are used to establish a baseline of workers'  
687 health and then to monitor their future health for any changes that may result from  
688 exposure to HDs.

689 Elements of a medical surveillance program should be consistent with the entity's  
690 Human Resource policies and should include:

- 691 • Development of an organized approach to identify workers who are potentially  
692 exposed to HDs on the basis of their job duties
- 693 • Use of an 'entity-based' or contracted employee health service to perform the  
694 medical surveillance while protecting the confidentiality of the employees'  
695 personal medical information
- 696 • Initial baseline assessment (pre-placement) of a worker's health status and  
697 medical history. Data elements collected include a medical (including  
698 reproductive) history and work history to assess exposure to HDs, physical  
699 examination, and laboratory testing. Methods used to assess exposure history  
700 include a review of:

- 701 - Records of HDs handled, with quantities and dosage forms
- 702 - Number of HD preparations/administrations per week
- 703 - Estimates of hours spent handling HDs per week and/or per month
- 704 - Performance of a physical assessment and laboratory studies linked to target  
705 organs of commonly used HDs, such as a baseline complete blood count.  
706 Note that biological monitoring to determine blood or urine levels of specific  
707 HDs is not currently recommended in surveillance protocols, but may have a  
708 role in the follow-up of acute spills with a specific agent.
- 709 • Medical records of surveillance should be maintained according to OSHA  
710 regulation concerning access to employee exposure and medical records
  - 711 • Monitoring workers' health prospectively through periodic surveillance using the  
712 elements of data gathering described above (updated health and exposure  
713 history, physical assessment, and laboratory measures, if appropriate)
  - 714 • Monitoring of the data to identify prevention failure leading to health effects; this  
715 monitoring may occur in collaboration with the employee health service
  - 716 • Development of a follow-up plan for workers who have shown health changes  
717 suggesting toxicity or who have experienced an acute exposure. This follow-up  
718 should include evaluation of current engineering and administrative controls and  
719 equipment to ensure that all systems are appropriately and accurately  
720 implemented (see *Follow-Up Plan* below).
  - 721 • Completion of an exit examination when a worker's employment at the entity  
722 ends, to document the information on the employee's medical, reproductive,  
723 and exposure histories. Examination and laboratory evaluation should be  
724 guided by the individual's history of exposures and follow the outline of the  
725 periodic evaluation.

## 726 **19.1 Follow-Up Plan**

727 The occurrence of exposure-related health changes should prompt immediate re-  
728 evaluation of primary preventive measures (e.g., administrative and engineering  
729 controls, PPE, and others). In this manner, medical surveillance acts as a check on the  
730 effectiveness of controls already in use.

731 The entity should take the following actions:

- 732 • Perform a post-exposure examination tailored to the type of exposure (e.g., spills  
733 or needle sticks from syringes containing HDs). An assessment of the extent of  
734 exposure should be conducted and included in a confidential database and in  
735 an incident report. The physical examination should focus on the involved area  
736 as well as other organ systems commonly affected (i.e., the skin and mucous  
737 membranes for direct contact or inhalation; the pulmonary system for  
738 aerosolized HDs). Treatment and laboratory studies will follow as indicated and  
739 be guided by emergency protocols.

- 740 • Compare performance of controls with recommended standards; conduct  
741 environmental sampling when analytical methods are available.
- 742 • Verify and document that all controls are in proper operating condition.
- 743 • Verify and document that the worker complied with existing policies. Review  
744 policies for the use of PPE and employee compliance with PPE use and  
745 policies. Review availability of appropriate PPE (see *Personal Protective*  
746 *Equipment*).
- 747 • Develop and document a plan of action that will prevent additional exposure of  
748 workers.
- 749 • Ensure confidential, two-way communication between the worker and the  
750 employee health unit(s) regarding notification, discussions about a change in  
751 health condition, or detection of an adverse health effect.
- 752 • Provide and document a follow-up medical survey to demonstrate that the plan  
753 implemented is effective.
- 754 • Ensure that any exposed worker receives confidential notification of any adverse  
755 health effect. Offer alternative duty or temporary reassignment.
- 756 • Provide ongoing medical surveillance of all workers at risk for exposure to HDs to  
757 determine whether the plan implemented is effective.

758 **APPENDIX A: ACRONYMS AND DEFINITIONS**

759

760 **Acronyms**

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ACPH	Air changes per hour
API	Active pharmaceutical ingredient
ASTM	American Society for Testing and Materials
BSC	Biological safety cabinet
BUD	Beyond-use date
CACI	Compounding aseptic containment isolator
CAI	Compounding aseptic isolator
CDC	Centers for Disease Control and Prevention
C-PEC	Containment primary engineering control
C-SCA	Containment segregated compounding area
C-SEC	Containment secondary engineering control
CSP	Compounded sterile preparation
CSTD	Closed-system drug-transfer device
CVE	Containment ventilated enclosure
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
HD	Hazardous drug

HEPA	High-efficiency particulate air
IV	Intravenous
LAFW	Laminar airflow workbench
NIOSH	National Institute for Occupational Safety and Health
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
PPE	Personal protective equipment
SDS	Safety Data Sheet
SOP	Standard operating procedure
ULPA	Ultra-low particulate air

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### Definitions

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**Active pharmaceutical ingredient (API):** Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

**Alternative duty:** Performance of other tasks that do not include the direct handling of HDs.

**Assessment of risk:** Evaluation of risk to determine alternative containment strategies and/or work practices.

**Beyond-use date (BUD):** The date or time after which a compounded preparation must not be used, stored, or transported (see [795](#) and [797](#)).

**Biological safety cabinet (BSC):** A ventilated cabinet often used for preparation of hazardous drugs. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, and Type B2). See *Appendix C* for details.

**Buffer room:** A type of C-SEC under negative pressure where the C-PEC is physically located. Activities that occur in this area are limited to the preparation and staging of components and supplies used when compounding HDs.

**Chemotherapy glove:** A medical glove that meets the ASTM Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (D6978) or its successor.

**Cleaning:** The removal of soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.

**Closed-system drug-transfer device (CSTD):** A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system.

**Compounded preparation:** A nonsterile or sterile drug or nutrient preparation that is compounded in a licensed pharmacy or other healthcare-related facility in response to or anticipation of a prescription or a medication order from a licensed prescriber.

794 **Compounding aseptic containment isolator (CACI):** A specific type of CAI that is  
795 designed for the compounding of sterile HDs. The CACI is designed to provide worker  
796 protection from exposure to undesirable levels of airborne drugs throughout the  
797 compounding and material transfer processes and to provide an aseptic environment  
798 with unidirectional airflow for compounding sterile preparations.

799 **Compounding aseptic isolator (CAI):** An isolator specifically designed for  
800 compounding sterile, non-hazardous pharmaceutical ingredients or preparations. The  
801 CAI is designed to maintain an aseptic compounding environment throughout the  
802 compounding and material transfer processes.

803 **Compounding personnel:** Individuals who participate in the compounding process.

804 **Compounding supervisor:** Individual(s) responsible for developing and implementing  
805 appropriate procedures; overseeing facility compliance with this chapter and other  
806 applicable laws, regulations, and standards; ensuring the competency of personnel;  
807 and maintaining environmental control of the compounding areas.

808 **Containment primary engineering control (C-PEC):** A ventilated device designed  
809 and operated to minimize worker and environmental exposures to HDs by controlling  
810 emissions of airborne contaminants through the following:

- 811 • The full or partial enclosure of a potential contaminant source
- 812 • The use of airflow capture velocities to trap and remove airborne contaminants  
813 near their point of generation
- 814 • The use of air pressure relationships that define the direction of airflow into the  
815 cabinet
- 816 • The use of HEPA filtration on all potentially contaminated exhaust streams

817 Examples of C-PECs include Class I, II, or III BSCs, CACIs, and CVE (e.g., powder  
818 hood). C-PECs used for nonsterile compounding do not need to have ISO Class 5 air  
819 quality, whereas C-PECs used for sterile compounding must have ISO Class 5 air  
820 quality (see [Table 2](#) and [3](#)).

821 **Containment secondary engineering control (C-SEC):** The C-SEC is the room in  
822 which the C-PEC is placed. It incorporates specific design and operational parameters  
823 required to contain the potential hazard within the compounding room.

824 **Containment segregated compounding area (C-SCA):** A type of C-SEC with  
825 nominal requirements for airflow and room pressurization as they pertain to HD  
826 compounding.

827 **Containment ventilated enclosure (CVE):** A full or partial enclosure that uses  
828 ventilation principles to capture, contain, and remove airborne contaminants through  
829 HEPA filtration and prevent their release into the work environment.

830 **Deactivation:** Treatment of an HD contaminant on surfaces with a chemical, heat,  
831 ultraviolet light, or another agent to transform the HD into a less hazardous agent.

832 **Decontamination:** Inactivation, neutralization, or removal of HD contaminants on  
833 surfaces, usually by chemical means.

834 **Disinfectant:** A chemical agent that destroys or inhibits the growth of microorganisms.

835 **Engineering control:** Primary, secondary, and supplemental devices designed to  
836 eliminate or reduce worker exposure to a chemical, biological, radiological, ergonomic,  
837 or physical hazard, and in the case of CSPs, to protect the compounded preparation

838 from environmental contamination.  
839 **Entity:** Pharmacy, hospital, physician's office, clinic, veterinary office, or other location  
840 where HDs are received, stored, prepared, dispensed, administered, and/or  
841 distributed.

842 **EPA-registered disinfectant:** Antimicrobial products registered with the  
843 Environmental Protection Agency (EPA) for healthcare use against pathogens  
844 specified in the product labeling.

845 **Externally vented:** Exhausted to the outside

846 **Globally Harmonized System of Classification and Labeling of Chemicals (GHS):**  
847 A system for standardizing and harmonizing the classification and labeling of  
848 chemicals.

849 **Goggles:** Tight-fitting eye protection that completely covers the eyes, eye sockets,  
850 and facial area that immediately surrounds the eyes. Goggles provide protection from  
851 impact, dust, and splashes. Some goggles fit over corrective lenses.

852 **Hazardous drug (HD):** Any drug identified as hazardous or potentially hazardous on  
853 the basis of at least one of the following six criteria:

- 854 • Carcinogenicity
- 855 • Teratogenicity or developmental toxicity
- 856 • Reproductive toxicity in humans
- 857 • Organ toxicity at low doses in humans or animals
- 858 • Genotoxicity
- 859 • New drugs that mimic existing HDs in structure or toxicity

860  
861 **High-efficiency particulate air (HEPA) filtration:** An extended-medium, dry-type  
862 filter in a rigid frame, having a minimum particle collection efficiency of 99.97% for  
863 particles with a mass median diameter of 0.3 µm when tested at a rated airflow in  
864 accordance with MIL STD 282 using IEST Recommended Standard RP-CC001.5.

865 **Negative-pressure room:** A room that is maintained at a lower pressure than the  
866 adjacent spaces; therefore the net flow of air is into the room.

867 **Pass-through:** An enclosure with interlocking doors that is positioned between two  
868 spaces for the purpose of reducing particulate transfer while moving materials from  
869 one space to another. A pass-through serving negative-pressure rooms needs to be  
870 equipped with sealed doors.

871 **Personal protective equipment (PPE):** Items such as gloves, gowns, respirators,  
872 goggles, faceshields, and others that protect individual workers from hazardous  
873 physical or chemical exposures.

874 **Positive-pressure room:** A room that is maintained at a higher pressure than the  
875 adjacent spaces; therefore, the net flow of air is out of the room.

876 **Safety data sheet (SDS):** An informational document that provides written or printed  
877 material concerning a hazardous chemical. The SDS is prepared in accordance with  
878 the HCS [previously known as a Material Safety Data Sheet (MSDS)].

879 **Spill kit:** A container of supplies, warning signage, and related materials used to  
880 contain the spill of an HD.

881 **Standard operating procedure (SOP):** Written procedures describing operations,

882 testing, sampling, interpretation of results, and corrective actions that relate to the  
883 operations that are taking place.

884 **Supplemental engineering control:** An adjunct control (e.g., CSTD) that may be  
885 used concurrently with primary and secondary engineering controls. Supplemental  
886 engineering controls offer additional levels of protection and may facilitate enhanced  
887 occupational protection, especially when handling HDs outside of primary and  
888 secondary engineering controls (e.g., during administering).

889 **Trace contaminated waste:** Items used in the handling, compounding, dispensing,  
890 administration, or disposal of antineoplastic agents that are not overtly contaminated  
891 (e.g., gowns, gloves, goggles, wipes).

892

893

## APPENDIX B: EXAMPLES OF DESIGNS FOR HAZARDOUS DRUGS COMPOUNDING AREAS<sup>A</sup>

894

895

Use	Optimal Primary and Secondary Control	Minimum ACPH	Limitations Primary and Secondary Control	Minimum ACPH	Notes for limitations	
Nonsterile HD compounding		12				
Sterile HD compounding		30		12	Maximum BUD as described in <797> for segregated compounding area.	
	OR			30	If this design is in place, measures must be taken to avoid contamination of the positive-pressure buffer room.	
	OR		<p>This design is not recommended</p>	30	Maximum BUD as described in <797>.	
Both sterile HD and nonsterile HD compounding	A separate room for sterile and nonsterile compounding is recommended			30	For rooms used for both sterile and nonsterile compounding, particle-generating activity must not be performed when sterile compounding is in process. C-PECs must be at least 1 meter apart.	
			OR		12	Maximum BUD as described in <797> for segregated compounding area.
			OR		12	Maximum BUD as described in <797> for segregated compounding area.

<sup>a</sup> The arrows indicate direction of airflow.

896

897

898

899

## APPENDIX C: TYPES OF BIOLOGICAL SAFETY CABINETS

900 **Class I:** A BSC that protects personnel and the environment but does not protect the  
901 product/preparation. A minimum velocity of 75 linear feet/min of unfiltered room air is  
902 drawn through the front opening and across the work surface, providing personnel  
903 protection. The air is then passed through a HEPA/ULPA (ultra-low particulate air)  
904 filter, either into the room or to the outside in the exhaust plenum, providing  
905 environmental protection.

906 **Class II:** Class II (Types A1, A2, B1, and B2) BSCs are partial barrier systems that  
907 rely on the movement of air to provide personnel, environmental, and  
908 product/preparation protection. Personnel and product/preparation protection are  
909 provided by the combination of inward and downward airflow captured by the front  
910 grille of the cabinet. Side-to-side cross-contamination of products/preparations is  
911 minimized by the internal downward flow of HEPA/ULPA filtered air moving toward the  
912 work surface and then drawn into the front and rear intake grilles. Environmental  
913 protection is provided when the cabinet exhaust air is passed through a HEPA/ULPA  
914 filter.

915 **Type A1 (formerly, Type A):** These Class II BSCs maintain a minimum inflow  
916 velocity of 75 feet/min; have HEPA-filtered, down-flow air that is a portion of the  
917 mixed down-flow and inflow air from a common plenum; may exhaust HEPA-filtered  
918 air back into the laboratory or to the environment through an exhaust canopy; and  
919 may have positive-pressure contaminated ducts and plenums that are not  
920 surrounded by negative-pressure plenums. Type A1 BSCs are not suitable for use  
921 with volatile toxic chemicals and volatile radionucleotides.

922 **Type A2 (formerly, Type B3):** These Class II BSCs maintain a minimum inflow  
923 velocity of 100 feet/min; have HEPA-filtered, down-flow air that is a portion of the  
924 mixed down-flow and inflow air from a common exhaust plenum; may exhaust HEPA-  
925 filtered air back into the laboratory or to the environment through an exhaust canopy;  
926 and have all contaminated ducts and plenums under negative pressure or  
927 surrounded by negative-pressure ducts and plenums. If these cabinets are used for  
928 minute quantities of volatile toxic chemicals and trace amounts of radionucleotides,  
929 they must be exhausted through properly functioning exhaust canopies.

930 **Type B1:** These Class II BSCs maintain a minimum inflow velocity of 100 feet/min;  
931 have HEPA-filtered, down-flow air composed largely of uncontaminated, recirculated  
932 inflow air; exhaust most of the contaminated down-flow air through a dedicated duct  
933 exhausted to the atmosphere after passing it through a HEPA filter; and have all  
934 contaminated ducts and plenums under negative pressure or surrounded by  
935 negative-pressure ducts and plenums. If these cabinets are used for work involving  
936 minute quantities of volatile toxic chemicals and trace amounts of radionucleotides,  
937 the work must be done in the directly exhausted portion of the cabinet.

938 **Type B2 (total exhaust):** These Class II BSCs maintain a minimum inflow velocity of  
939 100 feet/min; have HEPA-filtered, down-flow air drawn from the laboratory or the  
940 outside; exhaust all inflow and down-flow air to the atmosphere after filtration through  
941 a HEPA filter without recirculation inside the cabinet or return to the laboratory; and  
942 have all contaminated ducts and plenums under negative pressure or surrounded by  
943 directly exhausted negative-pressure ducts and plenums. These cabinets may be  
944 used with volatile toxic chemicals and radionucleotides.

945  
946 **Class III:** The Class III BSC is designed for work with highly infectious microbiological  
947 agents and other hazardous operations. It provides maximum protection for the  
948 environment and the worker. It is a gas-tight enclosure with a viewing window that is  
949 secured with locks and/or requires the use of tools to open. Both supply and exhaust  
950 air are HEPA/ULPA filtered. Exhaust air must pass through two HEPA/ULPA filters in  
951 series before discharge to the outdoors.

952  
953  
954

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1129 ■ 1S (USP39)



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Request to Delay Implementation of Requirement for National Accreditation of Pharmacy Technician Training Programs

(WalMart Stores)

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**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.

# Health and Wellness Practice Compliance

Tim Koch, R.Ph,

Sr. Director, Corporate Compliance

702 SW 8th Street  
Bentonville, AR 72716-0230  
Phone 479-204-8627  
Fax 479-273-8675  
Tim.Koch@walmart.com

September 10, 2015

Louisiana Board of Pharmacy  
Malcolm J. Broussard, Executive Director  
3388 Brentwood Drive  
Baton Rouge, LA 70809-1700

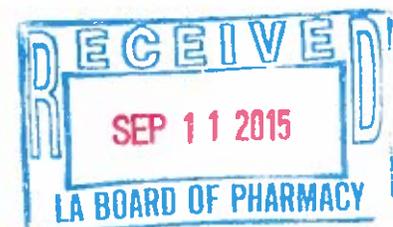
Dear Mr. Broussard,

On behalf of a group of concerned industry stakeholders, I would like to request to be placed on the Board's agenda to discuss the Board's requirement that an applicant for a pharmacy technician certificate shall demonstrate successful completion of a nationally-accredited and board-approved pharmacy technician training program. The request, specifically, would be that the Board consider delaying the January 1, 2016 deadline for meeting this requirement.

Industry stakeholders have come together with the national accrediting bodies, ASHP/ACPE, and the Pharmacy Technician Accreditation Commission (PTAC), in concert with PTCB to discuss the outcome goals addressed in the ASHP/ACPE accreditation standards. Of concern, are the length of the program (600 hours), the relevance of all of the goals to the employer's practice setting, the applicability of the required simulated activities to an employer's practice setting, and the requirement to place students into experiential rotation sites outside of the employer's business. Of further concern is the capacity, within the industry, to train enough technicians to these standards to maintain staffing levels of technicians appropriate to provide pharmacy care in a safe manner.

The concerns outlined above affect all practice settings, and the stakeholder meetings which have been held over the past year have been attended by, and input given by, a number of diverse national pharmacy associations.

I have included with this correspondence a letter which has been cosigned by the leadership of ASHP and ACPE which outlines the efforts between the accrediting bodies and the concerned industry stakeholders as it relates to the work being done to identify possible changes to the accreditation standards. The willingness of the accrediting bodies to listen to the concerns of the stakeholders and to take the concerns into consideration have been instrumental in the continued collaboration with the stakeholders, as I trust you will find evidenced in the letter.



Again, I request that the Board delay the January 1, 2016 deadline which requires technicians to complete a nationally-accredited training program. This delay would give the industry and the accrediting bodies the time necessary to work toward a meaningful outcome to the stakeholders' request that the accrediting bodies review the applicability of the current goals and standards to the employer-based training programs.

Yours in Pharmacy,



Timothy R. Koch, RPh, CHC  
Senior Director, Corporate Compliance  
Tim.Koch@walmart.com





Dear members of the Louisiana Board of Pharmacy,

The ASHP and ACPE collaboration in the accreditation of pharmacy technician education and training programs has a commitment to standards that address the preparation of technicians capable, on graduation, of practicing in an effective and safe manner and achieving certification by Pharmacy Technician Certification Board (PTCB). Through the formation of the jointly appointed, multi stakeholder Pharmacy Technician Accreditation Commission (PTAC), the ASHP and ACPE Boards receive recommendations on the accreditation decisions as well as feedback on possible desirable changes in the accreditation standards.

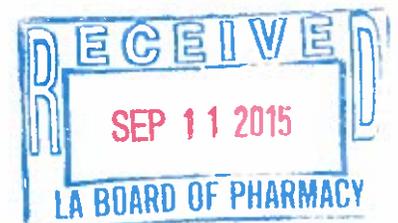
ASHP and ACPE technician accreditation staff have participated in several meetings and other discussions with representatives of employer based technician training programs over the past year. ASHP and ACPE have requested further survey information on the 45 technician graduate outcome goals addressed in the present ASHP/ACPE accreditation standards. Specifically, we have requested estimates of how and over what timeframe would employer based technician training programs achieve the goals they believe are applicable to their area of practice, as well as goals they believe are not relevant to their area of practice.

Once the survey results are received, ASHP and ACPE will discuss the findings with the employers and consider the implications for the present ASHP/ACPE accreditation standards and/or review procedures that would maintain the preparation of technicians practicing in an effective and safe manner and capable of achieving certification by Pharmacy Technician Certification Board (PTCB). The PTAC will discuss the survey results and possible changes, if needed, to the standards and/or the review process at their October 15-16, 2015 meeting and make recommendations, as needed, to the ASHP and ACPE Boards before the end of the year.

Sincerely,

**Janet A. Silvester, Pharm.D., M.B.A., FASHP**  
Vice President, Accreditation Services  
Accreditation Services Office  
ASHP

**Peter H. Vlases, PharmD, DSc (Hon), BCPS, FCCP**  
Executive Director  
Accreditation Council for Pharmacy Education (ACPE)





Walgreen Co.  
Government Relations  
104 Wilmot Rd. MS 1459  
Deerfield, IL 60015  
P 847-315-4653 F 847-315-4417  
walgreens.com

September 23, 2015

Mr. Malcolm J. Broussard  
Executive Director  
Louisiana Board of Pharmacy  
3388 Brentwood Drive  
Baton Rouge, LA 70809-1700

Dear Malcolm,

I think we both hold the common ideal of having highly trained pharmacy technicians in all Louisiana pharmacies. If pharmacists are to begin to maximize their value in the healthcare system, then these highly trained technicians will need to become an even more integral part of the pharmacy team. We share in these ideals; however, there are several potential hurdles which were uncovered recently upon our review of the upcoming changes to the PTCB standards.

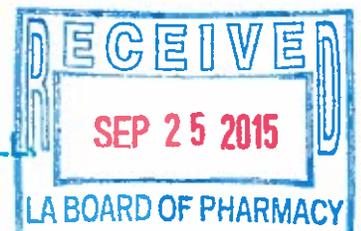
I write to you today in order to raise concern with the Louisiana Board of Pharmacy's January 1, 2016 deadline to require that an applicant for a pharmacy technician certificate demonstrate successful completion of a nationally-accredited and board approved pharmacy technician program.

First and foremost, the requirement to have 80 hours of offsite training is very problematic. In order to comply with this standard we would need to create new "preceptor" sites for these technicians. Based on the current college of pharmacy model for preceptor sites, there would not be enough capacity to add in all of these new required training hours. Secondly, offsite training may cause logistical difficulties and financial hardships for these newly hired employees in rural and remote areas.

In addition, the requirement of 600 hours of training would make it difficult to employ part-time technicians. These employees would need to have at least 12 hours of training per week in addition to any hours worked in the pharmacy, in order for them complete the training within the required 12 month period.

We have met with a stakeholder group representing ASHP / ACPE and PTCB. The key representatives of these organizations have all agreed to thoroughly examine and evaluate all of the concerns I have expressed to you. I believe they will ultimately work to identify possible changes to the accreditation standards.

EVERY DAY WE HELP PEOPLE GET, STAY AND LIVE WELL



Louisiana Board of Pharmacy  
September 24, 2015  
Page2

In short, Walgreens is respectfully requesting a delay of the January 1, 2016 deadline which requires technicians to complete a nationally-accredited training program. The discussion is ongoing with the aforementioned national organizations and everyone involved is willing to work together. This working group merely requires additional time to find a workable solution for all stakeholders.

Thank you for your consideration of this request.

Sincerely,



Dan Luce, BS Pharm, RPh, MBA, FAPhA  
National Director, Pharmacy Affairs  
847.315.4022

EVERY DAY WE HELP PEOPLE GET, STAY AND LIVE WELL.



October 30, 2015

Louisiana Board of Pharmacy

Malcolm J. Broussard, Executive Director  
3388 Brentwood Drive  
Baton Rouge, LA 70809-1700

Dear Mr. Broussard,

I am writing to you in my capacity as Senior Director, Pharmacy Regulatory Affairs for CVS Health, and a concerned industry stakeholder surrounding the pending January 1, 2016 implementation of the technician certification requirement for successful completion of a nationally-accredited and board-approved pharmacy technician training program.

CVS Health has come together with other industry stakeholders, the national accrediting bodies, ASHP/ACPE, and the Pharmacy Technician Accreditation Commission (PTAC), in collaboration with PTCB to discuss the outcome goals addressed in the ASHP/ACPE accreditation standards. CVS and other stakeholders have voiced our concerns to ASHP/ACPE in regards to the length of the program (600 hours), the relevance of all of the goals to the individual practice setting, the applicability of the required 80 hours of simulated activities to an individual's practice setting and the requirement to place students into two experiential rotation sites outside of the employer's business. In addition, we continue to have concerns surrounding how to train enough full-time and part-time technicians to these standards to maintain staffing levels of technicians appropriate to provide pharmacy care in a safe manner. Finally, these concerns not only affect community practice settings but they affect all practice settings.

CVS Health asks that the Louisiana Board of Pharmacy consider delaying the January 1, 2016 implementation of the technician certification requirements for at least one year while industry stakeholders and ASHP/ACPE leadership continue efforts to identify and change the accreditation standards to allow for a more robust program that will provide a highly qualified pharmacy technician while preventing any hardships on all pharmacies within Louisiana. Thank you.

Sincerely,

Al Carter  
CVS Health  
Senior Director, Pharmacy Regulatory Affairs



Michael A. Podgurski  
Vice President, Pharmacy Services

MAILING ADDRESS  
P.O. Box 3165  
Harrisburg, PA 17105

GENERAL OFFICE  
30 Hunter Lane  
Camp Hill, PA 17011

717.975.5888  
717.975.3760 Fax  
e-mail: [mpodgurski@riteaid.com](mailto:mpodgurski@riteaid.com)

November 3, 2015

Louisiana Board of Pharmacy  
Malcolm J. Broussard, Executive Director  
3388 Brentwood Drive  
Baton Rouge, LA 70809 - 1700

Dear Mr. Broussard:

On behalf of Rite Aid, with 62 pharmacies in Louisiana, I respectfully request that the Board consider delaying the January 1, 2016 implementation date of the rule that requires that an applicant for a pharmacy technician certificate "shall demonstrate successful completion of a nationally-accredited and board-approved pharmacy technician program."

I, and other industry stakeholders, have met with the national accrediting bodies, ASHP/ACPE, the Pharmacy Technician Accreditation Commission (PTAC), and the Pharmacy Technician Certification Board (PTCB) to discuss the outcome goals addressed in the ASHP/ACPE accreditation standards. Significant concerns include the length of the program (600 hours), the pertinence of the goals relating to the practice setting, the applicability and length of the simulated activities to the practice setting, and the placing of trainees into experiential sites that are not community pharmacies. Finding enough experiential sites will gravely impact the number of technicians that can be trained, which will impact staffing levels of properly trained technicians and could result in patient safety issues in all practice settings.

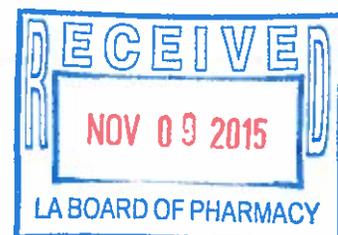
ASHP and ACPE have begun efforts, along with the concerned industry stakeholders which includes Rite Aid, to address possible changes to the accreditation standards. We will continue this collaboration until resolved.

While the accrediting bodies review the current outcome goals and standards, please delay the implementation date of this Board rule.

Sincerely,

A handwritten signature in black ink that reads "M.A. Podgurski".

Michael A. Podgurski, R.Ph  
Vice President, Pharmacy Services





# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



## Announcements

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**NOTE:** Pursuant to the Open Meetings Law, at LRS 42:6.1, the committee may, upon 2/3 affirmative vote of those members present and voting, enter into executive session for the limited purposes of (1) discussion of the character, professional competence, or physical or mental health of a licensee, (2) investigative proceedings regarding allegations of misconduct, (3) strategy sessions or negotiations with respect to litigation, or (4) discussions regarding personnel matters.



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



November 18, 2015

## Agenda Item 12: Announcements

Nov. 26	Thanksgiving Day – <i>Board office closed</i>
Nov. 27	Acadian Day – <i>Board office closed</i>
Dec. 6-10	ASHP MidYear Meeting – New Orleans, LA
Dec. 16-17	Violations Committee Informal Conference
Dec. 24	Christmas Eve – <i>Board office closed</i>
Dec. 25	Christmas Day – <i>Board office closed</i>
Dec. 31	New Year's Eve – <i>Board office closed</i>
Jan. 1	New Year's Day – <i>Board office closed</i>
Jan. 11	Gubernatorial Inauguration Day – <i>Board office closed</i>
Jan. 18	Martin Luther King, Jr. Day – <i>Board office closed</i>
Jan. 20	Prescription Monitoring Program (PMP) Advisory Council
Feb. 9	Mardi Gras Day – <i>Board office closed</i>
Feb. 23	Reinstatement & Impairment Committees
Feb. 24	Reciprocity Committee & Board Meeting
Feb. 25	Administrative Hearing

## Board Meeting Schedule for Calendar Year 2016

Feb. 23-25	May 3-5	Aug. 9-11	Nov. 15-17
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