Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

Board Meeting

August 23, 2017

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.*

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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NOTICE IS HEREBY GIVEN that a meeting of the Board has been ordered and called for 9:00 a.m. on Wednesday, August 23, 2017 at the Board office, for the purpose to wit:

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 08-09-2017

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 from Previous Meeting – May 10, 2017
6. Report on Action Items
7. Confirmation of Acts
8. Opportunity for Public Comment
9. Special Orders of the Day
   - A. Presentation of Pharmacist Gold Certificates
     - PST.009230 – Theodore Schwartz Carmichael, issued 08-30-1967
     - PST.009269 – William Wayne McCullar, issued 08-30-1967
     - PST.009289 – Lawrence Daryl Pourciau, issued 08-30-1967
     - PST.009333 – Alvin Dale Crane, issued 11-29-1967
10. Committee Reports
    - A. Finance – Mr. Pitre & Mr. Russell Champagne, CPA & Ms. Penny Scruggins, CPA, Kolder Champagne Slaven & Co.
      - Consideration of Final Report for Fiscal Year 2016-2017
      - Consideration of Budget Amendment No. 1 for Fiscal Year 2017-2018
    - B. Application Review – Mr. Soileau
      - Consideration of Committee Recommendations re Applications
    - C. Reciprocity – Ms. Hall
    - 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. Moore
    - H. Regulation Revision – Mr. McKay
      - Consideration of Comments & Testimony from Public Hearings
        - Regulatory Project 2015-9 ~ Pharmacy Technicians
        - Regulatory Project 2017-1 ~ Pharmacy Internship
        - Regulatory Project 2017-2 ~ Equivalent Drug Product Interchange
    - I. Executive – Mr. Aron
      - Consideration of Committee Recommendations
11. Staff Reports
    - J. Assistant Executive Director – Mr. Fontenot
      - Consideration of Requests for Waivers from PMP Reporting Requirement

(continued)

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11. Staff Reports (continued)
    K. General Counsel – Mr. Finalet
        - Consideration of Proposed Voluntary Consent Agreements
    L. Executive Director – Mr. Broussard
        - Consideration of Final Report for Fiscal Year 2016-2017
12. Request for Approval of Life Safety Training Program – EMS Safety Services, Inc.
13. Request for Approval of Alternative Pharmacist Verification Methodology in Central Fill System – Mr. Jim Cousineau, Mr. Mark Sullivan, & Mr. Ben Sims, Brookshire Grocery Co.
14. Request for Revision of Rules for Telepharmacy – Mr. Adam Chesler, Cardinal Health
15. Request for Revision of Pharmacist Licensure Requirements for PGY2 Residents – Dr. Stephanie Anders, Ochsner Health System
16. Request for Exception to USP <800> Standards Enforcement – Mr. Errol Duplantis, Lloyd's Remedies Pharmacy
17. Announcements
18. Recess

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Report of Assistant Executive Director

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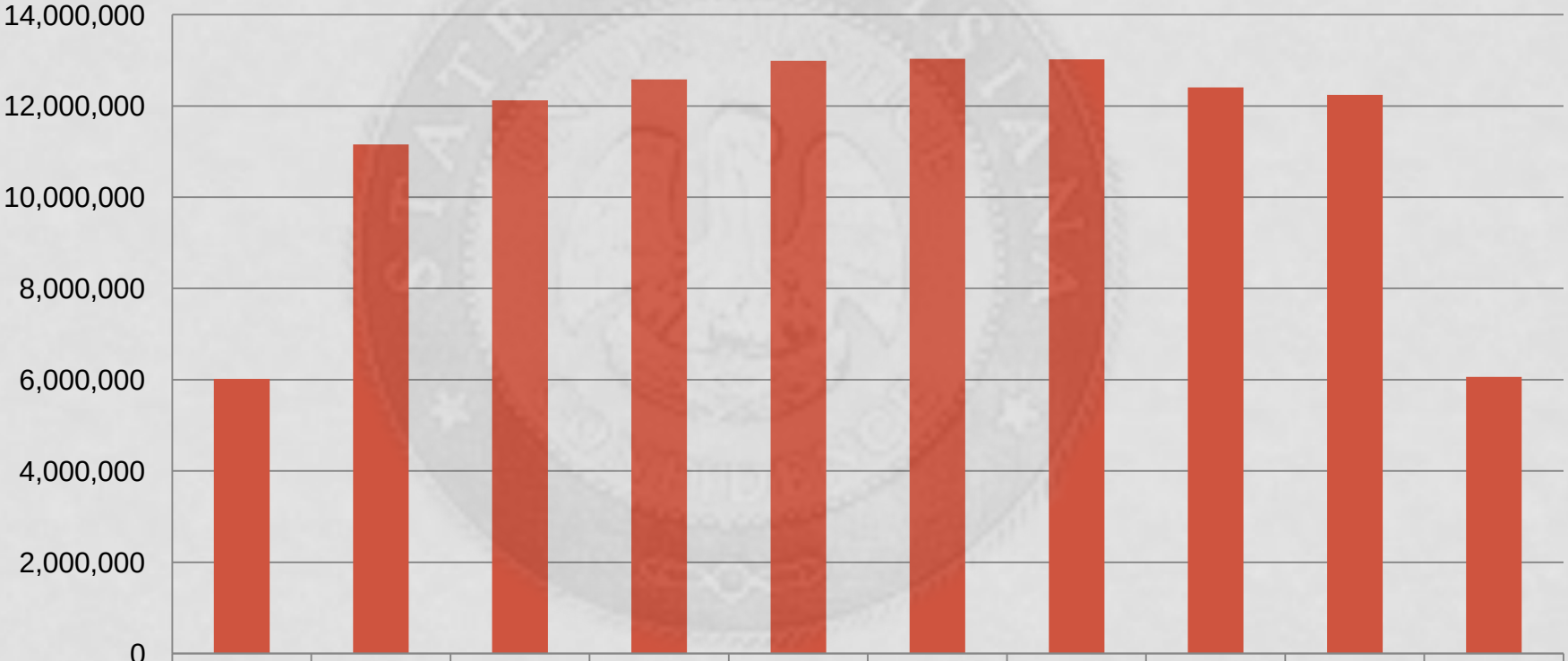
PRESCRIPTION MONITORING PROGRAM (PMP)

BOARD MEETING – AUGUST 23, 2017

NUMBER OF ELIGIBLE PRESCRIPTION TRANSACTIONS REPORTED TO THE PMP

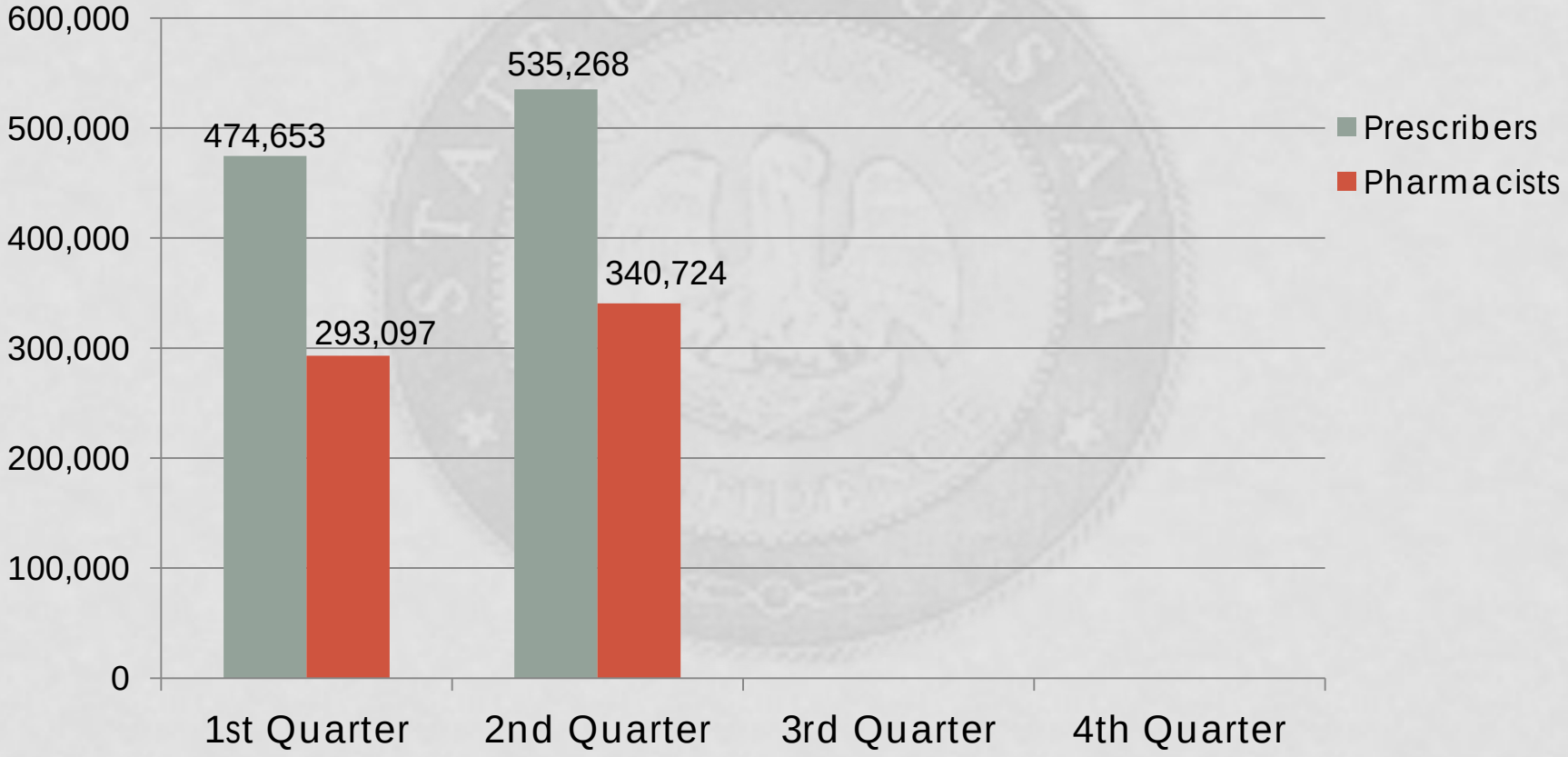
Total Reported: 111,634,838
(06/01/2008 through 06/30/2017)



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
RXs	6,019,931	11,154,837	12,124,061	12,584,423	12,989,950	13,032,083	13,020,364	12,403,123	12,241,613	6,064,453

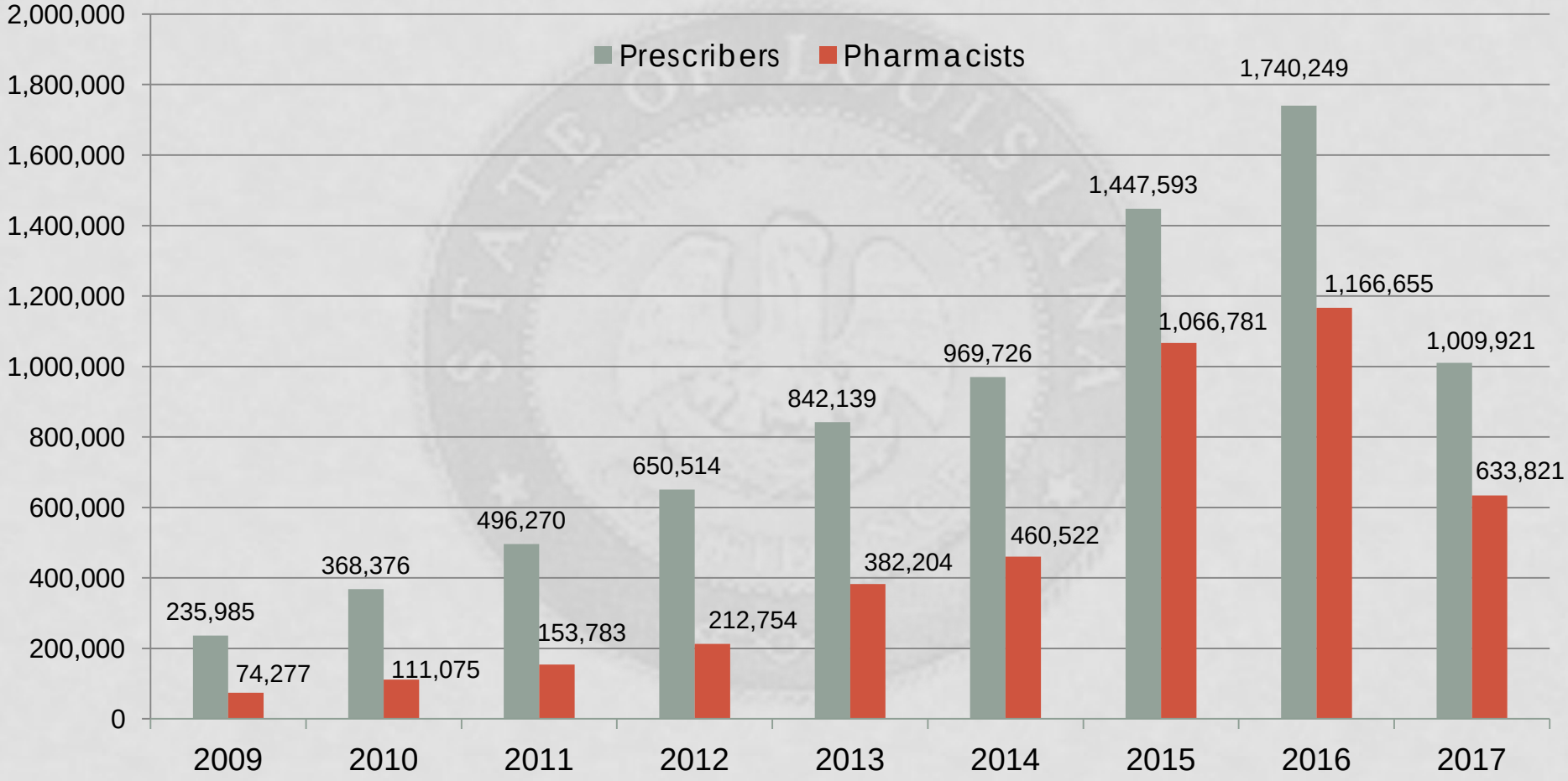
PRESCRIBER & PHARMACIST SEARCHES – 2017

Total for 2017: 1,643,742



PRESCRIBER & PHARMACIST SEARCHES
(01/01/2009 THROUGH 06/30/2017)

Overall Search Total: 12,022,645



PMP User Statistics for 2017Q2 (04/01/2017 through 06/30/2017)

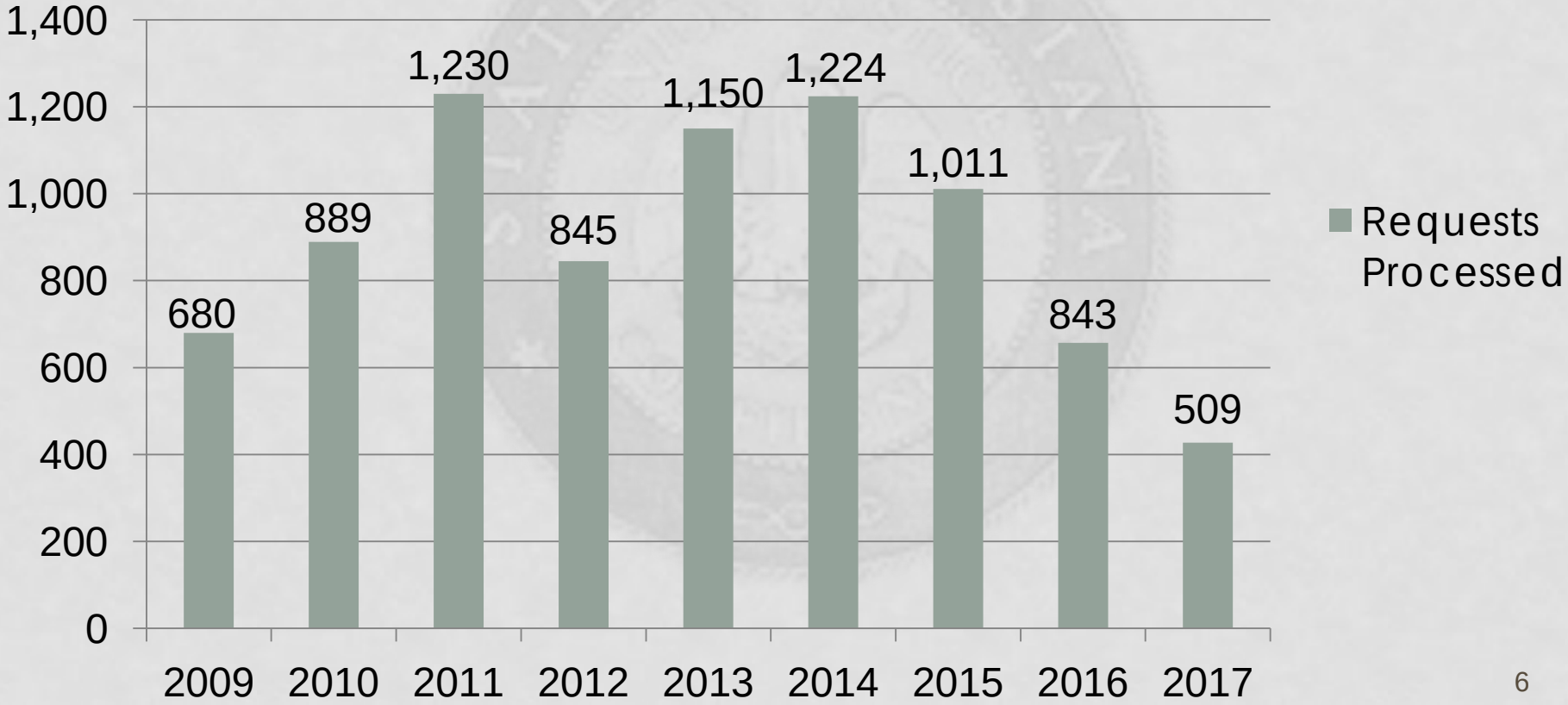
PMP Role Title - Healthcare Provider	Number of Providers Eligible for PMP Access (as of 06/30/2017)	Number of Providers Approved for PMP Access (as of 06/30/2017)	Number of PMP Searches by Approved Providers During 2017Q2 (Percentage of Total)
Physician (MD, DO)	12,482	4,528	308,906 (35.26%)
Nurse Practitioner (APRN)	2,595	1,326	48,838 (5.56%)
Dentist (DDS)	2,119	557	1,770 (0.20%)
Physician Assistant (PA)	721	287	11,913 (1.36%)
Optometrist (OD)	338	13	0
Podiatrist (DPM)	151	34	118 (0.01%)
Medical Psychologist (MP)	87	65	3,048 (0.34%)
Prescriber's Delegate	NA	1,284	160,675 (18.34%)
Pharmacist (PST)	8,577	3,721	302,883 (34.57%)
Pharmacist's Delegate	NA	484	37,841 (4.31%)
Totals	**27,070**	**12,299**	**875,992**

PMP User Statistics for 2017Q1 (01/01/2017 through 03/31/2017)

PMP Role Title - Healthcare Provider	Number of Providers Eligible for PMP Access (as of 03/31/2017)	Number of Providers Approved for PMP Access (as of 03/31/2017)	Number of PMP Searches by Approved Providers During 2017Q1 (Percentage of Total)
Physician (MD, DO)	12,436	4,438	270,670 (35.25%)
Nurse Practitioner (APRN)	2,532	1,263	45,261 (5.90%)
Dentist (DDS)	2,116	541	1,725 (0.22%)
Physician Assistant (PA)	705	270	10,995 (1.43%)
Optometrist (OD)	339	13	0
Podiatrist (DPM)	150	34	132 (0.02%)
Medical Psychologist (MP)	85	59	2,132 (0.28%)
Prescriber's Delegate	NA	1,590	143,738 (18.72%)
Pharmacist (PST)	8,499	3,666	266,869 (34.76%)
Pharmacist's Delegate	NA	560	26,228 (3.42%)
Totals	**26,862**	**12,434**	**767,750**

LAW ENFORCEMENT REQUESTS

Total Number of Law Enforcement Requests Processed: 8,381
01/01/2009 through 06/30/2017



Requests for Full Exemption from PMP Reporting
August 23, 2017

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
6472	NR	Advanced Pharmacy, LLC	Mail Order Pharmacy	Yes	Piedmont	SC
7147	IR	AlphaMED Pharmacy	Specialty Pharmacy	Yes	Marrero	LA
7433	NR	BrooksideRx, LLC	Mail Order Pharmacy	Yes	Omaha	NE
6678	NR	CarePoint Pharmacy	Specialty Pharmacy	Yes	Schaumburg	IL
7423	NR	Carepoint Pharmacy	Specialty Pharmacy	Yes	Schaumburg	IL
6649	OS	Carie Boyd's Prescription Shop	Outsourcing Facility	Yes	Hurst	TX
7242	NR	Cedra Pharmacy, Inc.	Specialty Pharmacy	Yes	Bronx	NY
7492	NR	Chemistry Rx	Specialty Pharmacy	Yes	Philadelphia	PA
7469	NR	Choice Rx Pharmacy	Mail Order Pharmacy	Yes	Doral	FL
1060	HOS	Christus Health Southwestern Louisiana	Hospital Pharmacy	Yes	Lake Charles	LA
7387	HOS	Cobalt Rehabilitation Hospital New Orleans	Hospital Pharmacy	Yes	New Orleans	LA
6760	NR	Conversio Health	Specialty Pharmacy	Yes	San Luis Obispo	CA
7493	NR	Cottrill's Pharmacy, Inc.	Specialty Pharmacy	Yes	Orchard Park	NY
7426	HOS	Curahealth Hospital New Orleans	Hospital Pharmacy	Yes	New Orleans	LA
7215	NR	Decillion Healthcare	Specialty Pharmacy	Yes	Dublin	OH
6978	NR	Diplomat Specialty Infusion Group	Mail Order Pharmacy	Yes	Raleigh	NC
7265	NR	Diplomat Specialty Infusion Group	Mail Order Pharmacy	Yes	Scottsdale	AZ
7175	NR	Diplomat Specialty Infusion Group	Mail Order Pharmacy	Yes	Urbandale	IA
269	HOS	East Carroll Parish Hospital Pharmacy	Hospital Pharmacy	Yes	Lake Providence	LA
7280	NR	Geesons Pharmacy	Specialty Pharmacy	Yes	Arlington	TX
7498	NR	Geneva Pharmacy	Retail Pharmacy	Yes	Elkhorn	NE
6880	NR	Genoa Healthcare	Specialty Pharmacy	Yes	Ladue	MO
6862	IR	Genoa, a QoL Healthcare Company	Specialty Pharmacy	Yes	New Orleans	LA
7164	NR	Heartland Medical	Specialty Pharmacy	Yes	Overland Park	KS
7001	IR	Lafayette General Pinhook Pharmacy	Hospital Pharmacy	Yes	Lafayette	LA

7232	HOS	Lafayette General Southwest Pharmacy	Hospital Pharmacy	Yes	Lafayette	LA
6389	HOS	Lafayette Surgical Specialty Hospital	Hospital Pharmacy	Yes	Lafayette	LA
7499	HOS	Lakeview Regional Medical Center	Hospital Pharmacy	Yes	Covington	LA
7372	NR	Life Tree Pharmacy	Non-Resident Pharmacy	Yes	Collegeville	PA
6903	NR	LMC Medical Supplies, Inc.	Mail Order Pharmacy	Yes	Boca Raton	FL
6883	NR	Matlock Pharmacy	Retail Pharmacy	Yes	Arlington	TX
7491	NR	MediSuite Pharmacy	Mail Order Pharmacy	Yes	Cary	NC
7005	HOS	North Oaks Rehabilitation Hospital Pharmacy	Hospital Pharmacy	Yes	Hammond	LA
7515	NR	Paragon Healthcare Inc.	Specialty Pharmacy	Yes	Dallas	TX
7203	NR	Pathstone Health Services	Specialty Pharmacy	Yes	Jacksonville	FL
7048	NR	Physician Specialty Pharmacy	Mail Order Pharmacy	Yes	Pensacola	FL
7487	HOS	Physicians Medical Center	Hospital Pharmacy	Yes	Houma	LA
7504	NR	RTS Americas, Inc.	Specialty Pharmacy	No	Deerfield	IL
7095	IR	Rx 2 Geaux Pharmacy	Retail Pharmacy	Yes	Baton Rouge	LA
6848	NR	Soleo Health	Infusion Pharmacy	Yes	Sharon Hill	PA
7177	NR	Synergy Pharmacy Services	Retail Pharmacy	Yes	Palm Harbor	FL
6478	HOS	The NeuroMedical Center Rehabilitation Hospital Pharmacy	Hospital Pharmacy	Yes	Baton Rouge	LA
5533	HOS	Touro Infirmary (TI) Department of Pharmacy	Hospital Pharmacy	Yes	New Orleans	LA
1833	HOS	Union General Hospital Pharmacy	Hospital Pharmacy	Yes	Farmerville	LA
7434	NR	VitalRx	Mail Order Pharmacy	Yes	Pelham	AL
7457	NR	Walgreens #02445	Mail Service	Yes	Orlando	FL
7093	NR	Woodland Hills Pharmacy	Specialty Pharmacy	Yes	Woodland Hills	CA
5096	NR	ZooPharm, Inc.	Veterinary Pharmacy	Yes	Laramie	WY

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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August 23, 2017

Agenda Item 11-L: Report of Executive Director

1. Meeting Activity
2. Reports
3. Examinations
4. Operations
5. State Activities
6. Regional & 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.

May 20-23	NABP Annual Meeting – Orlando, FL
May 25-27	LSHP Annual Meeting – New Orleans, LA
July 25-26	Tri-Regulator Symposium – Chicago, IL
Aug. 15	P-1 Orientation at ULM School of Pharmacy – Monroe, LA
Aug. 16-17	NABP Task Force on Long-Term Care Pharmacy Rules – Mount Prospect, IL
Aug. 1-30	Annual Review of MPJE Item Bank & New Items

2. Reports

A. Internal Reports (posted in Boardroom Library)
   1. Census – Compliance Division – Practitioner Recovery Program & Discipline
   2. Census – Credentials Division – CDS & Pharmacy Programs
   3. Credentials Division – Licensure Activity Report
   4. Credentials Division – Application Activity Report
   5. Credentials Division – Exceptions Report
   6. Compliance Division – Annual Statistical Report

B. External Reports
   1. Office of the Governor
      a. Annual Report – ***This is an action item; it requires Board approval.***
   2. La. Div. of Administration – Boards & Commissions
      a. Monthly Report of Member Per Diem
      b. Quarterly Report of Member Expense Reimbursements
   3. La. Div. of Administration – Office of Facility Planning & Control
      a. Semiannual Report of Leased Office Space
   4. La. Div. of Administration – Property Assistance Agency
      a. Annual Agency Fleet Mileage Report
      b. Annual Inventory of Property & Equipment
      c. Annual Asset Certification Report
      d. Report of Annual Audit of Property & Equipment
   5. La. Div. of Administration – Office of Risk Management
      a. Monthly Loss Claims Report

b. Monthly Report re Transitional Return to Work
c. Quarterly Risk Exposure Report
d. Quarterly Property Safety & Maintenance Inspections
e. Semiannual Property Exposure Report

6. La. Div. of Administration – Office of Statewide Reporting & Accounting Policy
   a. Quarterly Report of Accounts Receivable
7. La. Dept. of Culture, Recreation & Tourism – State Library of Louisiana
   a. Annual Report of Agency Publications
8. La. Dept. of Health – Bureau of Health Services Financing
   a. Monthly Report of Pharmacy Openings & Closures
9. La. Dept. of Insurance
   a. Annual Report of Referral Investigations
10. La. Dept. of Justice – Office of the Attorney General
    a. Quarterly Report of Private Legal Fees Paid
11. La. Dept. of Revenue
    a. Quarterly Employer's Return of State Withholding Tax
12. La. Dept. of State – Div. of Archives
    a. Annual Designation of Agency Records Officer
13. La. Dept. of Treasury – Cash Management Review Board
    a. Quarterly Report of Agency Bank Accounts
    b. Annual Report of Agency Reserve Accounts
14. La. State Employees Retirement System
    a. Monthly Report of Employer & Employee Contributions
15. La. Workforce Commission
    a. Quarterly Report of Employer's Unemployment Tax
16. La. Legislative Auditor
    a. Annual Inventory of Property & Equipment
    b. Annual Asset Certification Report
17. U.S. Dept. of Health & Human Services – Office of Public Health
    a. Quarterly Report to ESAR-VHP
18. U.S. Dept. of Labor – Bureau of Labor Statistics
    a. Monthly Survey of Current Employment Statistics
19. U. S. Dept. of Treasury – Internal Revenue Service
    a. Quarterly Employer's Federal Tax Return

3. Examinations

A. MPJE – the results for the first trimester of 2017 are available.

B. NAPLEX – the results for the first trimester of 2017 are available.
   1. NABP Memo re NAPLEX Exam Integrity
   2. NAPLEX Case Study

C. PARE – our last administration of this test was in July 2014.

D. PTCB – the results for the first half of 2017 are available.

4. Operations

A. Credentials Division

The June 30 census reports for the Pharmacy and CDS programs were posted in the Boardroom Library. Within the Pharmacy program, we had 24,766 credentials, which represents a 0.5% growth from the previous June 30 census. Although we had minor increases in the pharmacist and intern numbers, there were minor decreases in the number of pharmacy technicians and pharmacy permits. Within the CDS Program, we had 20,193 credentials, which is a 5.1% reduction from the previous year. Although there were slight increases in nurses and physician assistants, there was a 6.4% decrease in physicians, with other smaller decreases in dentists, veterinarians, researchers, as well as pharmacies and hospitals. As of June 30, 2017, we had 44,959 active credentials under

management, a 2.2% reduction from the previous fiscal year. This marks the first reduction since 2012, when we completed the removal of ineligible CDS credentials. In addition to the census reports, the production reports detailing pending applications and new credentials issued were also posted in the Boardroom Library.

We opened the renewal cycle on May 1 for pharmacy technicians as well as AMS and EDK credentials. Those credentials expire on June 30 unless renewed timely. We opened the renewal cycle for DME permits on July 1; those credentials expire on August 31 unless renewed timely.

- **CPT:** We printed 7,136 renewal reminder notices, held 18 of them back for defaulted student loan issues and pending disciplinary matters, then mailed the reminder on April 28. 92% of them renewed their credentials in a timely manner, and of that number, 93% did so online. We mailed expiration notices to 530 technicians in mid-July.
- **AMS:** We printed and mailed 502 renewal reminders on April 28. All but 34 of them were renewed; we mailed those expiration notices in mid-July.
- **EDK:** We printed and mailed 458 renewal reminders on April 28. All but 17 of them were renewed; we mailed those expiration notices in mid-July.
- **DME:** We printed and mailed 632 renewal reminder notices on June 30. Since that date, 5 new permits have been issued. Of the 637 active DME permits, 73% of them have renewed, and of that number, 88% have renewed online.

B. Compliance Division

Our 6 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 1,459 pharmacies within the state, as well as approximately 1,400 various types of facilities and persons 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 224 cases pending from the prior fiscal year. We entered 391 new cases and closed 468, leaving 147 cases still open for the new fiscal year. The number of open cases is a 40% reduction from the previous year. Of the 468 cases closed this fiscal year, 54% were disposed of through staff activities and the balance through committee and Board action.

C. Administrative Division

Three new employees started working for the Board on June 12:

- Mamie Smith is a licensing assistant for the Pharmacy program;
- Arielle Shelton is the receptionist; and
- Tiffany Brumfield is the administrative assistant in the executive office.

Danielle Hartzog has been our receptionist since September 2015. She transferred to the new position in the PMP office and is working with Lindsey Schultz to implement the new automatic prescriber registration law adopted in the 2017 legislature. We still have a need for another licensing assistant and plan to hire for that position. However, we are limited in available office space and plan to increase the number of student workers to process the paper records for the Credentials Division.

As previously authorized by the Executive Committee, we have engaged the Office of Facility Planning & Control in the Div. of Administration to serve as a general contractor for a project to maintain and update the interior and exterior of the office building. The Cooperative Endeavor Agreement (CEA) for this project carries a total estimated price of $375,000. We have included this project in the proposed budget amendment to be considered at this meeting.

The successful bidder for the financial audit contract issued by the Office of the Legislative Auditor was Pinell & Martinez, a CPA firm in Covington. They will perform the annual financial audit of the Board for three fiscal years, beginning with FY 16-17. The supervising auditor is Mr. Chris Pinell, CPA. The draft copy of the audit report was presented to the Executive Committee during their meeting yesterday.

Finally, you may recall we reported at your last meeting the Legislative Auditor had placed their planned performance audit on hold due to the departure of the auditors

assigned to the audit. We recently met their new auditors and they have resumed their data collection phase of the performance audit.

5. State Activities

A. Louisiana Legislature

The Regular Session of the 2017 Legislature convened on April 10 and adjourned on June 8. There were 949 bills introduced, of which 429 were passed and signed into law by the Governor. A copy of the Final Legislative Brief is posted in the Boardroom Library. The Board is required to take formal notice of the new laws affecting matters under the Board's jurisdiction and take any necessary action to implement those laws. If the Board determines rulemaking is required, those items shall be referred to the Board's Regulation Revision Committee.

B. La. State Board of Medical Examiners

The board published a Final Rule in the June 2017 edition of the *Louisiana Register*, amending their rules for physician assistants. Among other topics, the rule amended the list of schedules of controlled substances which physician assistants may prescribe to include Schedules II through V, as authorized by Act 453 of the 2016 Legislature. In addition, all physician assistants authorized to prescribe controlled substances shall obtain access privileges to the state's Prescription Monitoring Program and then access patient records within the PMP as appropriate.

The board has appointed a new executive director. Dr. Vincent A. Culotta, Jr. completed his medical education at LSU in 1974. He has practiced medicine in the Metairie, La. area as a specialist in obstetrics and gynecology.

C. La. State Board of Nursing

The board published a Final Rule in the July 2017 edition of the *Louisiana Register*, amending their rules for the composition of the board. Of the 11 member positions on that board, two seats have historically been allocated to physicians as ex-officio and non-voting members. The 2016 Legislature amended the nursing law to convert those two positions to consumer member positions with full voting privileges. The Final Rule amended their rules to comply with the 2016 legislation.

D. La. Dept. of Health – Office of Public Health

The Secretary of LDH exercised her statutory authority to place two designer chemicals in Schedule I of the state list of controlled substances – cyclopropylfentanyl and deschloroketamine. This temporary scheduling action will expire at the end of the 2018 legislative session unless the legislature passes a bill updating the state list.

We have drafted a legislative proposal for the 2018 legislative session for the Board to sponsor our usual controlled substance schedule update. These two chemicals were added to that legislative proposal.

E. La. Dept. of Agriculture & Forestry

The department is part of the statewide medical marijuana program; it licenses the grower of the marijuana and the producer of the marijuana products. The department published its Final Rule for medical marijuana in the July 2017 edition of the *Louisiana Register*. A copy of the rule was posted in the Boardroom Library.

6. Regional & National Activities

A. National Association of Boards of Pharmacy (NABP)

The annual meeting of this association is one of the three meetings for which certain of 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.

During the 2017 meeting in Orlando, FL, the delegates elected new leaders and members of the association's executive committee:

Chair: Hal Wand (AZ)
President: Jeanne Waggener (TX)
President-elect: Susan Ksiazek (NY)
Treasurer: Jay Campbell (NC)

District 1:	Tim Fensky (MA)	District 5 :	Gary Dewhirst (ND)
District 2:	Caroline Juran (VA)	District 6:	Gay Dodson (TX)
District 3:	Reggie Dilliard (TN)	District 7:	Mark Johnston (ID)
District 4:	Phil Burgess (IL)	District 8:	Richard Mazzoni (NM)

The delegates also voted to adopt several resolutions. Copies of the adopted resolutions were posted in the Boardroom Library.

For your planning purposes, the 2018 Annual Meeting is scheduled for May 5-8, 2018 at the Hyatt Regency Denver Hotel in Denver, CO.

B. NABP-AACP District 6

The annual meeting of this association is one of the three meetings for which certain of 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. For your planning purposes, the 2017 meeting will be held October 8-11 at the Marriott Riverwalk Hotel in San Antonio, TX. Districts 7 and 8 will be joining District 6 for that meeting.

We have already distributed the conference and hotel registration materials to you. Please keep in mind the deadlines contained in those materials, including the closure of the conference hotel room block on September 17.

C. MALTAGON

The annual meeting of this association is one of the three meetings for which certain of 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. For your planning purposes, the 2017 conference will be held in Charleston, SC on October 22-25.

We have already distributed the conference and hotel registration materials to you. Please keep in mind the deadlines contained in those materials, including the closure of the conference hotel room block on September 22.

D. Accreditation Council for Pharmacy Education (ACPE)

During their June meeting, ACPE placed four schools of pharmacy on probation for substantial non-compliance with accreditation standards:

- Hampton University College of Pharmacy (Hampton, VA)
- MCPHS University School of Pharmacy (Boston, MA)
- Touro College of Pharmacy (New York, NY)
- ULM School of Pharmacy (Monroe, LA)

With respect to the probation decision for ULM School of Pharmacy, ACPE cited four accreditation standards found to be in substantial non-compliance:

- *Standard No. 8 – Organization and Governance*
  The college or school is organized and staffed to advance its vision and facilitate the accomplishment of its goals and objectives. Key elements evaluated:
  8.1 – Leadership collaboration
  8.2 – Qualified dean
  8.3 – Qualified administrative team
  8.4 – Dean's other substantial administrative responsibilities
  8.5 – Authority, collegiality, and resources
  8.6 – College or school participation in university governance
  8.7 – Faculty participation in college or school governance
  8.8 – Systems failures
  8.9 – Alternate pathway equitability
- *Standard No. 11 – Interprofessional Education (IPE)*
  The curriculum prepares all students to provide entry level, patient-centered care in a variety of practice settings as a contributing member of an interprofessional

team. In the aggregate, team exposure includes prescribers as well as other healthcare professionals. Key elements evaluated:
11.1 – Interprofessional team dynamics
11.2 – Interprofessional team education
11.3 – Interprofessional team practice

- *Standard No. 18 – Faculty and Staff ~ Quantitative Factors*
  The college or school has a cohort of faculty and staff with the qualifications and experience needed to effectively deliver and evaluate the professional degree program. Key elements evaluated:
  18.1 – Sufficient faculty
  18.2 – Sufficient staff
- *Standard No. 23 – Financial Resources*
  The college or school has current and anticipated financial resources to support the stability of the educational program and accomplish its mission, goals, and strategic plan. Key elements evaluated:
  23.1 – Enrollment support
  23.2 – Budgetary input
  23.3 – Revenue allocation
  23.4 – Equitable allocation

A copy of the Proceedings from the June meeting of ACPE was posted in the Boardroom Library.

In addition to its accreditation of professional pharmacy degree programs, ACPE is also charged with accreditation of providers of continuing pharmacy education. To assist in the governance of that activity, ACPE created the Continuing Pharmacy Education Commission (CPEC). The CPEC is comprised of ten members from various sectors of CPE stakeholders, including one member from the pharmacy regulatory community. The CPEC members are appointed by the ACPE Board of Directors and serve three year terms. They meet twice per year, approximately one month prior to the meetings of the ACPE Board of Directors. Joe Fontenot was recently appointed to the CPEC for a three year term concluding in December 2019. A copy of the ACPE Spring 2017 Update was posted in the Boardroom Library.

E. U. S. Drug Enforcement Administration (DEA)

The DEA has published a policy statement relative to the transfer of unfilled prescriptions for controlled substances from one pharmacy to another pharmacy. A copy of the policy statement was posted in the Boardroom Library. The Board's Executive Committee is reviewing that policy to determine the appropriate revision to the Board's policy adopted at its last meeting prohibiting that practice.

The U.S. Congress passed the Comprehensive Addiction & Recovery Act of 2016, a portion of which amended the Controlled Substances Act to permit the partial filling of Schedule II prescriptions. The DEA has not yet amended its rules to implement the new provision of the CSA, and the Board has not yet amended its corresponding rules. However, Act 82 of the 2017 Louisiana Legislature specifically referenced the amended section of the CSA to permit the partial filling of Schedule II prescriptions. A copy of the relevant portion of the law was posted in the Boardroom Library.

F. U.S. Centers for Disease Control & Prevention (CDC)

The CDC collaborated with representatives from pharmacy, medical, and nursing organizations to develop a resource guide for constructing and using collaborative practice agreements between pharmacists and physicians. *Advancing Team-Based Care Through Collaborative Practice Agreements – A Resource and Implementation Guide for Adding Pharmacists to the Care Team* was released earlier this month; a copy was posted in the Boardroom Library.

7. International Activities

A. International Pharmaceutical Federation (FIP)

FIP will convene its 77th World Congress of Pharmacy and Pharmaceutical Sciences on Sep. 10-14, 2017 in Seoul, South Korea. The theme for the conference

selected by the host, Korean Pharmaceutical Association, is *Medicines and beyond! – the soul of pharmacy.* Presentations will center on the five main topics selected for the conference: (1) Nurturing the soul of pharmacy, (2) Precision pharmacotherapy, (3) Pharmacy services; going beyond prescriptions, (4) Smart pharmacy, and (5) Targeting special interests. The registration portal for the congress, including conference and housing options, is open at www.fip.org.

For your planning purposes, the 2018 congress will be held Sep. 2-6 in Glasgow, Scotland.

B. .Pharmacy

.Pharmacy is a generic top level domain (gTLD) on the Internet. Although it is owned by NABP, the application to the Internet Corporation for Assigned Names & Numbers (ICANN) for the .Pharmacy domain was endorsed by several international organizations, including the World Health Organization (WHO), Interpol, the Pharmaceutical Group of the European Union (PGEU), the International Pharmaceutical Federation (FIP), and the National Association of Pharmacy Regulatory Authorities (NAPRA). .Pharmacy is different from most TLDs in that access to a website on .Pharmacy is restricted to applicants whose legitimacy has been verified by NABP or one of its international partners. The vision for .Pharmacy is to create an online pharmacy community where patients can go to safely order prescription drugs, knowing the sites have already been verified as legitimate pharmacies, licensed by the appropriate pharmacy regulatory authority. In addition to pharmacies, the plan is to create a presence for a number of related organizations, including professional membership organizations, colleges of pharmacy, boards of pharmacy, drug manufacturers, and consumer-oriented drug information organizations. .Pharmacy began accepting applications for website registrations in June 2015.

By July 2017, the end of December 2016, there were 353 registered domains, 261 of which were held by pharmacy organizations representing approximately 40% of the physical pharmacy locations in the U.S. More information, including a list of registered domains, is available at www.safe.pharmacy.

Respectfully submitted,
Malcolm J Broussard
Executive Director

Louisiana Board of Pharmacy

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Compliance Division Census Report

August 23, 2017

Practitioner Recovery Program

- Probation Completion Report

  [*none since last Board meeting*]

• Active Probation	42	Pharmacist
	1	Pharmacy intern
	5	Technician
• Active Suspension	40	Pharmacist
	2	Pharmacy intern
	16	Technician
	4	Technician candidate

Disciplinary Restrictions

- Probation Completion Report

05-18-2017	PTC.023402	Larry Wade
05-18-2017	PTC.023403	LaTashua Yvette Mitchell
08-25-2017	PTC.023681	Tracey Deshawn Green

• Active Probation	14	Pharmacist
	1	Pharmacy intern
	4	Technician
	1	Technician candidate
	6	Pharmacy permit
	1	CDS-PHY license
	1	DME permit
• Active Suspension	55	Pharmacist
	1	Pharmacy intern
	78	Technician
	19	Technician candidate
	12	Pharmacy permit
	4	CDS-PHY license
	81	CDS license for practitioners

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	06/30/16	06/30/17
PST.VI	LA	0	0	0	0	12	10	9	9	13	16	18
	NR	0	0	0	0	9	10	15	14	15	16	24
	Total	*0*	*0*	*0*	*0*	*21*	*20*	*24*	*23*	*28*	*32*	*42*
PST-GVI	LA	0	0	0	0	0	6	13	13	12	15	26
	NR	0	0	0	0	0	0	3	5	5	5	10
	Total	*0*	*0*	*0*	*0*	*0*	*6*	*16*	*18*	*17*	*20*	*36*
PST-M	LA	0	0	0	0	3	5	3	1	2	1	0
	NR	0	0	0	0	11	11	11	13	10	10	9
	Total					*14*	*16*	*14*	*14*	*12*	*11*	*9*
PST-G	LA	0	0	0	0	158	157	164	166	186	204	216
	NR	0	0	0	0	30	35	32	31	31	35	30
	Total	*0*	*0*	*0*	*0*	*188*	*192*	*196*	*197*	*217*	*239*	*246*
PST	LA	4,522	4,612	4,750	4,860	4,654	4,933	4,981	5,140	5,408	5,304	5,372
	NR	1,975	1,964	2,029	2,098	2,079	2,212	2,527	2,479	2,471	2,835	2,950
	Total	*6,497*	*6,576*	*6,779*	*6,958*	*6,733*	*7,145*	*7,508*	*7,619*	*7,879*	*8,139*	*8,322*
	PST	***6,497***	***6,576***	***6,779***	***6,958***	***6,935***	***7,353***	***7,758***	***7,871***	***8,108***	***8,441***	***8,655***
PNT	LA	1,079	1,074	1,035	965	907	938	942	948	952	957	946
	NR	117	67	84	153	137	128	128	127	143	127	145
	Total	*1,196*	*1,141*	*1,119*	*1,118*	*1,044*	*1,066*	*1,070*	*1,075*	*1,095*	*1,084*	*1,091*
PNT-FPG	Total	0	0	0	0	5	0	3	6	2	4	3
	PNT	***1,196***	***1,141***	***1,119***	***1,118***	***1,049***	***1,066***	***1,073***	***1,081***	***1,097***	***1,088***	***1,094***
CPT	LA	4,587	4,780	4,733	5,363	5,720	5,509	5,751	6,463	6,584	6,815	6,418
	NR	152	144	109	144	145	120	112	138	141	152	141
	Total	*4,739*	*4,924*	*4,842*	*5,507*	*5,865*	*5,629*	*5,863*	*6,601*	*6,725*	*6,967*	*6,559*
CPT-M	Total	0	0	0	0	1	0	1	2	1	2	2
	CPT	***4,739***	***4,924***	***4,842***	***5,507***	***5,866***	***5,629***	***5,864***	***6,603***	***6,726***	***6,969***	***6,561***
PTC	LA	1,389	1,446	1,510	1,679	1,574	1,665	1,658	1,870	1,929	1,813	1,971
	NR	32	23	32	35	35	39	37	37	52	48	54
	PTC	***1,421***	***1,469***	***1,542***	***1,714***	***1,609***	***1,704***	***1,695***	***1,907***	***1,981***	***1,861***	***2,052***
PHY	CH	12	11	12	14	12	12	12	12	12	12	11
	HOS	164	167	167	165	151	154	158	164	163	160	163
	HOX	0	0	0	0	19	18	14	11	8	7	6
	IN	36	37	37	27	14	10	12	12	11	11	12
	INX	0	0	0	0	11	14	13	11	10	10	11
	IR	620	588	592	587	570	568	558	583	588	576	577
	IRX	0	0	0	0	21	19	17	10	10	7	6
	NR	240	250	256	286	318	361	387	422	473	513	515
	NRN	0	0	0	0	0	0	0	9	9	8	7
	NRP	0	0	0	0	0	0	0	1	2	2	2
	NU	16	16	16	16	15	15	15	15	14	15	14
	PEN	0	0	0	0	0	0	0	0	0	0	0
	PEX	0	0	0	0	0	0	1	2	2	2	2
	SAT	0	0	0	0	0	0	0	1	3	6	6
	RC	491	534	545	562	576	587	597	619	649	671	651
	PHY	***1,579***	***1,603***	***1,625***	***1,657***	***1,707***	***1,758***	***1,784***	***1,872***	***1,954***	***2,000***	***1,983***
AMS	AMS	212	255	306	361	55	64	349	92	456	113	104
	AMS-X	0	0	0	0	301	302	289	359	356	367	335
	AMS	***212***	***255***	***306***	***361***	***356***	***366***	***638***	***451***	***812***	***480***	***439***
EDK	EDK	412	439	388	503	417	435	421	464	474	454	402
	EDK-X	0	0	0	0	13	13	10	10	10	10	9
	EDK	***412***	***439***	***388***	***503***	***430***	***448***	***431***	***474***	***484***	***464***	***411***
DME	LA						223	160	209	336	345	346
	NR							218	281	267	287	291
	DME							***378***	***490***	***603***	***622***	***637***
CDTM								41	41	52	59	66
MAR								1,617	2,037	2,383	2,603	2,820
SWP						58	78	126	38	54	48	48
TOTAL								**21,405**	**22,865**	**24,254**	**24,635**	**24,766**

Louisiana Board of Pharmacy
Credentials Division
CDS Program

	Classification	06/30/09	06/30/10	06/30/11	06/30/12	06/30/13	06/30/14	06/30/15	06/30/16	06/30/17
AMS	Automated Medication Sys	0	0	0	0	0	26	29	22	28
AMX	Automated Medication Sys - Exempt	0	0	0	0	0	2	1	0	0
APN	APRN	607	758	889	1,015	1,103	1,479	1,954	2,296	2,343
DDS	Dentist	2,267	2,363	2,027	2,048	1,902	2,123	2,133	2,134	1,929
DET	Drug Detection / Canine	20	22	14	12	10	11	11	9	8
DEX	Drug Detection / Canine - Exempt						1	1	0	
DIS	Distributor	363	400	279	288	273	324	319	301	284
DPM	Podiatrist	161	165	139	136	118	133	142	152	136
DVM	Veterinarian	1,000	1,065	922	901	852	1,002	1,045	1,085	1,007
ETC	Animal Euthanasia Tech - Cert	44	49	16	7	6	6	5	5	1
ETL	Animal Euthanasia Tech - Lead	0	0	12	20	21	23	23	22	24
HOS	Hospital	405	438	280	267	263	272	271	289	278
HOX	Hospital - Exempt	0	0	12	14	5	6	6	5	5
LAB	Laboratory	14	15	8	6	7	8	8	8	7
LAX	Laboratory - Exempt	0	0	4	5	5	5	5	4	4
MD	Physician	14,599	15,269	12,362	11,727	10,698	11,913	12,124	12,360	11,575
MFR	Manufacturer	52	58	48	50	45	42	42	37	38
MP	Medical Psychologist	50	58	65	67	69	78	82	86	84
OD	Optometrist	269	278	275	287	279	309	316	326	297
PA	Physician Assistant	232	272	294	326	344	449	487	610	667
PHX	Pharmacy - Exempt	0	0	50	47	41	30	24	21	20
PHY	Pharmacy	0	0	1,307	1,318	1,329	1,357	1,379	1,367	1,339
REP	Sales Representative	66	88	29	20	7	0	0	0	0
RES	Researcher	119	156	109	110	98	113	113	108	100
ROF	Registered Outsourcing Facility	0	0	0	0	0	0	8	14	13
SAC	Substance Abuse Clinic	14	17	7	9	9	9	9	7	6
SAX	Subst. Abuse Clinc - Exempt	0	0	0	0	0	0	1	0	0
	Total	20,282	21,471	19,148	18,680	17,484	19,721	20,538	21,268	20,193

Total Credentials Under Management

Pharmacy	16,601	17,818	18,260	18,625	21,405	22,865	24,254	24,635	24,766
CDS	20,698	21,916	19,148	18,680	17,745	20,009	20,809	21,316	20,193
Total	***37,299***	***39,734***	***37,408***	***37,305***	***39,150***	***42,874***	***45,063***	***45,951***	***44,959***

Louisiana Board of Pharmacy
Census Report

Type of Credential	6/30/1996	3/19/1997	6/30/1998	6/30/1999	6/30/2000	6/30/2001	6/30/2002	6/30/2003	6/30/2004	6/30/2005	6/30/2006
Pharmacists											
In-state	3,660	4,143	4,247	4,269	4,830	3,887	4,386	4,435	4,486	4,532	4,460
Out-of-state	446	1,339	1,435	1,421	944	1,901	1,453	1,455	1,484	1,686	1,915
TOTAL	*4,106*	*5,482*	*5,682*	*5,690*	*5,774*	*5,788*	*5,839*	*5,890*	*5,970*	*6,218*	*6,375*
Pharmacy Interns											
In-state											980
Out-of-state											109
TOTAL						*957*	*976*	*929*	*995*	*1,154*	*1,089*
Pharmacy Technicians											
In-state											4,552
Out-of-state											163
TOTAL						*3,216*	*3,453*	*3,505*	*4,114*	*4,455*	*4,715*
Pharmacy Technician Candidates											
In-state											1,081
Out-of-state											32
TOTAL						*2,896*	*2,372*	*1,336*	*1,069*	*1,074*	*1,113*
Pharmacy Permits											
IR	634	636	609	621	585	584	576	573	633	729	681
RC	473	471	493	505	520	528	535	541	555	473	430
H	174	171	175	172	171	171	174	179	181	181	167
IN	45	38	39	19		17	18	19	27	36	35
NU	10	10	9	10		12	14	13	13	13	17
CH	4	4	7	4		8	9	11	12	12	12
PEN											
OS	152	168	175	216	223	262	313	353	339	200	226
PE	104	102	120	102			95	94	0		
CO	12	12	12	12		12	13	13	0		
TOTAL	*1,608*	*1,612*	*1,639*	*1,668*	*1,663*	*1,717*	*1,771*	*1,818*	*1,760*	*1,644*	*1,568*
Equipment Permits											
AMS						0	109	136	158	174	173
EDK						468	461	474	444	471	428

Louisiana Board of Pharmacy
Census Report

Type of Credential		6/30/2007	6/30/2008	6/30/2009	6/30/2010	6/30/2011	6/30/2012	6/30/2013	6/30/2014	6/30/2015	6/30/2016	6/30/2017
Pharmacists												
In-state		4,522	4,612	4,750	4,860	5,000	5,095	5,170	5,329	5,596	5,540	5,632
Out-of-state		1,975	1,964	2,029	2,098	2,179	2,258	2,588	2,542	2,512	2,901	3,023
TOTAL		*6,497*	*6,576*	*6,779*	*6,958*	*7,179*	*7,353*	*7,758*	*7,871*	*8,108*	*8,441*	*8,655*
Pharmacy Interns												
In-state		1,079	1,074	1,035	965	917	938	945	950	953	959	948
Out-of-state		117	67	84	153	137	128	128	131	144	129	146
TOTAL		*1,196*	*1,141*	*1,119*	*1,118*	*1,054*	*1,066*	*1,073*	*1,081*	*1,097*	*1,088*	*1,094*
Pharmacy Technicians												
In-state		4,587	4,780	4,733	5,363	5,722	5,509	5,752	6,463	6,585	6,815	6,419
Out-of-state		152	144	109	144	145	120	112	138	141	152	142
TOTAL		*4,739*	*4,924*	*4,842*	*5,507*	*5,867*	*5,629*	*5,864*	*6,601*	*6,726*	*6,967*	*6,561*
Pharmacy Technician Candidates												
In-state		1,389	1,446	1,510	1,679	1,574	1,665	1,658	1,870	1,929	1,813	1,971
Out-of-state		32	23	32	35	35	39	31	37	52	48	54
TOTAL		*1,421*	*1,469*	*1,542*	*1,714*	*1,609*	*1,704*	*1,695*	*1,907*	*1,981*	*1,861*	*2,025*
Pharmacy Permits												
IR		620	588	592	587	591	587	575	583	598	583	583
RC		491	534	545	562	576	587	597	619	649	671	651
H		164	167	167	165	170	172	172	175	174	173	175
IN		36	37	37	27	25	24	25	23	21	21	23
NU		16	16	16	16	15	15	15	15	14	15	14
CH		12	11	12	14	12	12	12	12	12	12	11
PEN								1	2	2	2	2
NR		240	250	256	286	318	361	387	432	484	523	524
TOTAL		*1,579*	*1,603*	*1,625*	*1,657*	*1,707*	*1,758*	*1,784*	*1,861*	*1,954*	*2,000*	*1,983*
Equipment Permits												
AMS		212	255	306	361	356	366	638	451	812	480	439
EDK		412	439	388	503	430	448	431	474	484	464	411
DME							223	378	490	603	622	637
Special Activity	CDTM							41	41	52	59	66
	MAR							1,617	2,037	2,383	2,603	2,820
Special Work Permit						58	78	126	38	54	48	48

Louisiana Board of Pharmacy
CDS Program - Census Report

	Classification	6/30/2009	6/30/2010	6/30/2011	6/30/2012	6/30/2013	6/30/2014	6/30/2015	6/30/2016	6/30/2017
AMS	Automated Medication System	0	0	0	0	0	28	30	22	28
APN	Advanced Practice Registered Nurse	607	758	889	1,015	1,103	1,479	1,954	2,296	2,343
DDS	Dentist	2,267	2,363	2,027	2,048	1,902	2,123	2,133	2,134	1,929
DET	Drug Detection Canine	20	22	14	12	10	11	12	9	8
DIS	Distributor	363	400	279	288	273	324	319	301	284
DPM	Podiatrist	161	165	139	136	118	133	142	152	136
DVM	Veterinarian	1,000	1,065	922	901	852	1,002	1,045	1,085	1,007
ETC	Animal Euthanasia Tech - Cert	44	49	28	27	27	29	28	27	25
HOS	Hospital	405	438	292	281	268	278	277	294	283
LAB	Analytical Laboratory	14	15	12	11	12	13	13	12	11
MD	Physician	14,599	15,269	12,362	11,727	10,698	11,913	12,124	12,360	11,575
MFR	Manufacturer	52	58	48	50	45	42	42	37	38
MP	Medical Psychologist	50	58	65	67	69	78	82	86	84
OD	Optometrist	269	278	275	287	279	309	316	326	297
PA	Physician's Assistant	232	272	294	326	344	449	487	610	667
PHY	Pharmacy	0	0	1357	1,365	1,370	1,387	1,403	1,388	1,359
RES	Researcher	119	156	109	110	98	113	113	108	100
ROF	Registered Outsourcing Facility	0	0	0	0	0	0	8	14	13
SAC	Substance Abuse Clinic	14	17	7	9	9	9	10	7	6
	TOTAL	*20,202*	*21,916*	*19,119*	*18,660*	17,477	*20,009*	*20,809*	*21,268*	*20,193*

Total Credentials Under Board Management

Pharmacy Program	16,601	17,818	18,260	18,625	21,405	22,865	24,254	24,635	24,766
CDS Program	20,698	21,916	19,119	18,660	17,477	20,009	20,809	21,316	20,193
TOTAL	***37,299***	***39,734***	***37,379***	***37,285***	***38,882***	***42,874***	***45,063***	***45,951***	***44,959***

New Credentials Issued

FYE 2016 - 2017

July 1, 2016 - June 30, 2017

Prefix	Subcategory	CredentialType	Total
AMS		Automated Medication System	25
AMS	X	Automated Medication System - Exempt	27
		Prefix Totals	52
CDS	AMS	CDS License - Automated Medication System	13
CDS	APN	CDS License - APRN	375
CDS	DDS	CDS License - Dentist	86
CDS	DET	CDS License - Drug Detection / Canine	2
CDS	DIS	CDS License - Distributor	33
CDS	DPM	CDS License - Podiatrist	5
CDS	DVM	CDS License - Veterinarian	76
CDS	ETL	CDS License - Animal Euthanasia Technician, Lead (AET-L)	5
CDS	HOS	CDS License - Hospital	29
CDS	MD	CDS License - Physician	749
CDS	MFR	CDS License - Manufacturer	8
CDS	MP	CDS License - Medical Psychologist	4
CDS	OD	CDS License - Optometrist	19
CDS	PA	CDS License - Physician Assistant	138
CDS	PHX	CDS License - Pharmacy - Exempt	1
CDS	PHY	CDS License - Pharmacy	58
CDS	RES	CDS License - Researcher	10
CDS	ROF	CDS License - Registered Outsourcing Facility	7
		Prefix Totals	1618
CDTM		Collaborative Drug Therapy Management (V)	8
		Prefix Totals	8
CPT		Certified Pharmacy Technician	555
DME		Durable Medical Equipment (DME) Provider	83
EDK		Emergency Drug Kit	64
MA		Medication Administration (V)	343
PHY	HOS	Pharmacy - Hospital Inpatient	7
PHY	IN	Pharmacy - Institutional	1
PHY	IR	Pharmacy - Community ~ Independent	43
PHY	NR	Pharmacy - Nonresident	87
PHY	RC	Pharmacy - Community ~ Chain	12
PHY	RPP	Pharmacy - Remote Processor	1
PHY	SAT	Pharmacy - Hospital Off-Site Satellite	2
PHY	SPL	Pharmacy - Special Event	1
		Prefix Totals	154
PIC		Pharmacist-in-Charge (V)	191

PMP	CDS	PMP - CDS Credential (V)	1109
PMP	PHY	PMP - PHY Dispenser Account (V)	119
PMP	PST	PMP - Pharmacist (V)	236
PNT		Pharmacy Intern	284
PNT	FPG	Pharmacy Intern - Foreign Pharmacy Graduate	3
PST		Pharmacist	452
PTC		Pharmacy Technician Candidate	1477
SWP		Special Work Permit	47
		Grand Totals	6795

Pending Applications

PHARMACY CREDENTIALS

Prefix	Subcat.	CredentialType	02/12/16	04/26/16	08/03/16	11/07/16	01/13/17	05/03/17	8/16/2017
AMS		Automated Medication System	2	5	3	3	7	11	13
CPT		Certified Pharmacy Technician	30	40	54	53	41	48	30
DME		Durable Medical Equipment	15	16	27	23	23	18	23
EDK		Emergency Drug Kit							7
PHY	CH	Pharmacy - Charitable							
PHY	HOS	Pharmacy - Hospital Inpatient	3	2	3	6	7	7	9
PHY	IN	Pharmacy - Institutional		1		1			
PHY	IR	Pharmacy - Community ~ Independent	17	19	16	20	21	21	23
PHY	NR	Pharmacy - Nonresident	92	96	89	89	94	67	92
PHY	NRN	Pharmacy - Nonresident Nuclear							2
PHY	NU	Pharmacy - Nuclear							
PHY	PEN	Pharmacy - Penal							
PHY	RC	Pharmacy - Community ~ Chain	13	7	4		3	1	
PHY	RPP	Pharmavy - Remote Processor					1	1	
PHY	SAT	Pharmacy - Hospital Off-Site Satellite	1						
PIC		Pharmacist-in-Charge	1	1	1	1	1		
PNT	FPG	Pharmacy Intern - Foreign Graduate			1	2	3	3	4
PNT		Pharmacy Intern	31	30	58	101	89	43	65
PST		Pharmacist	257	254	419	294	272	282	374
PTC		Pharmacy Technician Candidate	358	353	346	480	515	405	502
		Subtotal	**820**	**824**	**1021**	**1073**	**1077**	**907**	**1144**

CDS CREDENTIALS

Prefix	Subcat.	CredentialType	02/12/16	04/26/16	08/03/16	11/07/16	01/13/17	05/03/17	8/16/2017
CDS	AMS	CDS - Automated Medication System							
CDS	APN	CDS - APRN	13	7	6	7	7	12	12
CDS	DDS	CDS - Dentist	1	1	1			1	1
CDS	DET	CDS - Drug Detection / Canine					2	2	3
CDS	DIS	CDS - Distributor	11	4	6	10		8	8
CDS	DPM	CDS - Podiatrist							
CDS	DVM	CDS - Veterinarian	3			1			2
CDS	ETC	CDS - Animal Euthanasia Tech, Certified							
CDS	ETL	CDS - Animal Euthanasia Tech, Lead				1	1		
CDS	HOS	CDS - Hospital			7	7	11	14	18
CDS	MD	CDS - Physician	8	10	9	10	8	13	19
CDS	MFR	CDS - Manufacturer				1	1	2	1
CDS	MP	CDS - Medical Psychologist							1
CDS	OD	CDS - Optometrist	1		2	2	2	1	2
CDS	PA	CDS - Physician Assistant	8	3	4	13	6	6	6
CDS	PHY	CDS - Pharmacy	31	23	20	23	25	26	23
CDS	PHX	CDS - Pharmacy - Exempt							
CDS	REP	CDS - Sales Representative							
CDS	RES	CDS - Researcher		8	6	10	8	8	7
CDS	ROF	CDS - Registered Outsourcing Facility			3	1	1	1	1
CDS	SAC	CDS - Substance Abuse Clinic	1	2	1				
		Subtotal	**77**	**58**	**65**	**86**	**72**	**94**	**104**

OTHER CREDENTIALS

Prefix	Subcat.	CredentialType	02/12/16	04/26/16	08/03/16	11/07/16	01/13/17	05/03/17	8/16/2017
CDTM		Collaborative Drug Therapy Management							
LB		Law Book	6						
MA		Medication Administration	3	4	3	5	10	9	7
PMP		PMP - CDS Credential	62	61	55	34	33	65	266
PMP		PMP - MIS Credential							
PMP		PMP - PST Credential	8	6	7	5	5	70	3
SWP		Special Work Permit	46	48	62	71	52	31	11
		Subtotal	**125**	**119**	**127**	**115**	**100**	**175**	**287**

TOTAL	**1022**	**1001**	**1213**	**1274**	**1249**	**1176**	**1535**

Louisiana Board of Pharmacy

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August 23, 2017

Agenda Item 11-L: Report of Executive Director

Section 2 – A – 5 ~ 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.

- *(None since last report.)*

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.

- *(None since last report.)*

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 June 12, 2017, Mr. Aron and Mr. Finalet concurred to grant a request from Alisha Ardoin Morein. She had previously obtained PTC.014511 which expired on February 26, 2016. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On June 26, 2017, Mr. Aron and Mr. Finalet concurred to grant a request from Edward Wayne Briggs. He had previously obtained PTC.014511 which expired on April 21, 2010. He is PTCB-certified, has been a practicing technician in Texas and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On June 28, 2017, Mr. Aron and Mr. Finalet concurred to grant a request from Kierra Deshawn Springfield. She had previously obtained PTC.023407 which expired on May 23, 2017. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On June 29, 2017, Mr. Aron and Mr. Finalet concurred to grant a request from Demetrich Johnise Thomas. She had previously obtained PTC.017931 which expired on March 14, 2013. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On June 29, 2017, Mr. Aron and Mr. Finalet concurred to grant a request from Kara Elizabeth Martin. She had previously obtained PTC.021731 which expired on February 13, 2016. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On July 11, 2017, Mr. Aron and Mr. Finalet concurred to grant a request from Johneisha Kiera Spears. She had previously obtained PTC.019393 which expired on April 25, 2014. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600

hours of practical experience.

- On July 18, 2017, Mr. Aron and Mr. Finalet concurred to grant a request from Keirra Michelle Dangerfield. She had previously obtained PTC.021576 which expired on December 27, 2015. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.
- On July 18, 2017, Mr. Aron and Mr. Finalet concurred to grant a request from Sarena Lada Lavan. She had previously obtained PTC.021517 which expired on December 10, 2015. She is PTCB-certified and was issued a Special Work Permit for one year to earn 600 hours of practical experience.

Louisiana Board of Pharmacy - Compliance Division
Statistical Summary for Fiscal Year 2016-2017

Individual Performance Data

		Inspections			Investigations		
		CDS	Rx	Total	Cases Assigned	Audits Completed	Reports Submitted
> Compliance Officers							
Aaron, Cary D.							
1st Qtr.		7	49	56	3	0	6
2nd Qtr.		9	59	68	13	0	15
3rd Qtr.		12	65	77	11	1	10
4th Qtr.		20	35	55	8	0	9
	Total	*48/86*	*208/277*	*256/363*	*35*	*1*	*40*
Completion Rate:		*56%*	*75%*	*71%*			
Dennis, Daniel M.	*Decrease in total permits due to territory change in Qtr. 3.						
1st Qtr		17	79	96	4	0	6
2nd Qtr		6	86	92	8	0	8
3rd Qtr		9	89	98	13	0	9
4th Qtr		13	76	89	10	0	15
	Total	*45/78*	*330/268*	*375/346*	*35*	*0*	*38*
Completion Rate:		*58%*	**100%*	**100%*			
Gross, Nicole L.	(Started 03-06-2017)						
1st Qtr		0	0	0	0	0	0
2nd Qtr		0	0	0	0	0	0
3rd Qtr		2	4	6	2	0	0
4th Qtr		29	35	64	6	0	4
	Total	*31/98*	*39/215*	*70/313*	*8*	*0*	*4*
Completion Rate:		*31%*	*18%*	*22%*			
Savoie, Huey J.							
1st Qtr		3	48	51	5	0	3
2nd Qtr		3	48	51	6	0	4
3rd Qtr		20	66	86	2	0	19
4th Qtr		2	56	58	4	1	17
	Total	*28/69*	*218/296*	*246/365*	*17*	*1*	*43*
Completion Rate:		*41%*	*74%*	*67%*			
Trisler, Rayland M.							
1st Qtr		7	43	50	3	0	4
2nd Qtr		2	74	76	0	0	3
3rd Qtr		11	40	51	4	0	4
4th Qtr		8	46	46	3	0	2
	Total	*28/62*	*203/265*	*223/285*	*10*	*0*	*13*
Completion Rate:		*45%*	*77%*	*78%*			
Whaley, Benjamin S.							
1st Qtr		9	50	59	11	0	8
2nd Qtr		15	32	47	10	0	9
3rd Qtr		20	49	69	9	0	12
4th Qtr		21	28	49	6	0	7
	Total	*65/86*	*159/190*	*224/276*	*36*	*0*	*36*
Completion Rate:		*76%*	*84%*	*81%*			
	TOTAL	***245/479***	***1157/1477***	***1394/1948***			
Completion Rate		***51%***	***78%***	***75%***			

Louisiana Board of Pharmacy - Compliance Division
Statistical Summary for Fiscal Year 2016-2017

Individual Performance Data				*Investigations*		
		Inspections		Cases	Audits	Reports
	CDS	Rx	Total	Assigned	Completed	Submitted
> Administrative Officers						
Fontenot, M. Joseph						
1st Qtr	0	0	0	2	0	6
2nd Qtr	0	0	0	3	0	2
3rd Qtr	0	0	0	7	0	5
4th Qtr	0	0	0	0	0	2
Total	*0*	*0*	*0*	*12*	*0*	*15*
Finalet, Carlos M.						
1st Qtr	0	0	0	54	0	42
2nd Qtr	0	0	0	17	0	26
3rd Qtr	0	0	0	43	0	25
4th Qtr	0	0	0	22	0	30
Total	*0*	*0*	*0*	*136*	*0*	*123*
Broussard, Malcolm J.						
1st Qtr	0	0	0	9	0	6
2nd Qtr	0	0	0	5	0	4
3rd Qtr	0	0	0	1	0	1
4th Qtr	0	0	0	0	0	0
Total	*0*	*0*	*0*	*15*	*0*	*11*
Agency Summary						
1st Qtr	43	269	312	91	0	81
2nd Qtr	35	299	334	62	0	71
3rd Qtr	74	313	387	92	1	85
4th Qtr	93	276	369	59	1	86
TOTAL				***304***	***2***	***323***

Summary of Investigations and Adjudications	
Number of Cases Pending from Prior Fiscal Year(s)	224
Number of Complaints Received during Current Fiscal Year:	391
Number of Complaints Closed during Current Fiscal Year:	468
Number of Complaints Pending at End of Fiscal Year:	147

Disposition of Closed Complaints:		
Withdrawn	10	
No violations found	76	
Administrative/Field corrections	118	
Referred to another agency	16	
Administrative sanction	4	
Termination of previously imposed probationary periods	27	
Referred to appropriate Board Committee	217	
	468	*Total*

Louisiana Board of Pharmacy - Compliance Division
Statistical Summary for Fiscal Year 2016-2017

Committee Action on Referrals

26 Case dismissed

159 Voluntary Consent Agreement
- 12 Assessment
- 4 Denial / Refusal to Issue
- 9 Letter of Noncompliance
- 5 Letter of Warning
- 29 Letter of Reprimand
- 12 Voluntary Surrender
- 17 Probation
- 4 Suspension
- 10 Revocation
- 57 Other decisions

32 Formal Hearing
- 1 Refusal to Issue
- 20 Suspension
- 11 Revocation

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Analysis of Adjudications by Type of Credential

	PST	PNT	CPT	PTC	PHY	CDS	***TOTAL***
Denial / Refusal to Issue	0	0	0	4	1	0	***5***
Reinstatement	4	0	16	0	2	7	***29***
Modification of Previous Orders	5	0	0	0	0	0	***5***
Assessment	1	0	0	1	10	0	***12***
Letter of Noncompliance	7	0	0	0	2	0	***9***
Letter of Warning	0	0	2	0	3	0	***5***
Letter of Reprimand	14	0	12	0	3	0	***29***
Voluntary Surrender	7	0	3	1	1	0	***12***
Probation	10	1	3	1	3	0	***18***
Suspension	4	0	7	0	1	12	***24***
Revocation	1	0	14	3	3	0	***21***
TOTAL	***53***	***1***	***57***	***10***	***29***	***19***	***169***

Louisiana Board of Pharmacy

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Annual Report

Fiscal Year 2016-2017

July 1, 2017

Mission

Created by the Louisiana Legislature in 1888, the mission of the Louisiana Board of Pharmacy remains unchanged over a century later: to regulate the practice of pharmacy in such a manner as to protect the public health, safety, and welfare of the citizens of Louisiana. Toward that goal, the Louisiana Pharmacy Practice Act specifically authorizes the Board to restrict the practice of pharmacy to qualified persons, as well as to control and regulate all persons and sites that sell prescription drugs or devices or provide pharmacy care services to consumers in this state.

Membership

The Board is composed of seventeen members: two pharmacists from each of eight districts and one public member at large. The district representatives are nominated by pharmacists, appointed by the governor, confirmed by the state senate, and serve six year terms. The public member is selected by, and serves at the pleasure of, the governor. The current members of the Board are:

District 1	Diane G. Milano, Richard M. Indovina, Jr.
District 2	Jacqueline L. Hall, Raymond J. Strong
District 3	Blake P. Pitre, Richard A. Soileau
District 4	Douglas E. Robichaux, Rhonny K. Valentine
District 5	Carl W. Aron, T. Morris Rabb
District 6	Richard Mannino, Ronald E. Moore
District 7	Allen W. Cassidy, Chris B. Melancon
District 8	Brian A. Bond, Marty R. McKay
Public	Don L. Resweber

Licensure

In order to facilitate the restriction of practice to qualified persons, the Board has established educational, experiential, and examination requirements for pharmacist licensure. As authorized by the legislature, the Board has contracted its high-stakes examination procedures with professional testing services.

A. Examinations for Pharmacists

The North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) are administered by the National Association of Boards of Pharmacy (NABP). These computer adaptive tests are administered in continuous window opportunities at multiple sites throughout the state. A minimum scaled score of 75 is required on each test to qualify for pharmacist licensure. The results for all Louisiana-based NAPLEX and MPJE candidates from the School of Pharmacy at University of Louisiana in Monroe as well as the College of Pharmacy at Xavier University in New Orleans in Calendar Year 2016 are summarized here:

NAPLEX

	Jan – Apr		May – Aug		Sept – Dec	
	ULM	XU	ULM	XU	ULM	XU
Total No. of Candidates	4	16	94	123	18	43
Mean Scaled Score – School	60	62	87	90	84	75
Mean Scaled Score – State	67	67	89	89	77	77
Mean Scaled Score – National	75	75	95	95	81	81
School Pass Rate [%]	0	25	77	78	78	51
State Pass Rate	22	22	78	78	55	55
National Pass Rate	49	49	86	86	65	65

MPJE

	Jan – Apr		May – Aug		Sept – Dec	
	ULM	XU	ULM	XU	ULM	XU
Total No. of Candidates	80	111	143	182	66	130
Mean Scaled Score – School	84	79	79	77	79	77
Mean Scaled Score – State	81	81	77	77	77	77
Mean Scaled Score – National	81	81	78	78	77	77
School Pass Rate [%]	99	83	80	74	80	78
State Pass Rate	90	90	78	78	75	75
National Pass Rate	88	88	83	83	75	75

B. Examinations for Technicians

The Pharmacy Technician Certification Board (PTCB) administers a national certification examination; this computer adaptive test is administered in continuous window opportunities at multiple sites throughout the state. A minimum scaled score of 75 is required to successfully complete the examination. The Louisiana Board of Pharmacy accepts the PTCB examination score result as part of the licensure requirements for pharmacy technicians. The results for all Louisiana-based PTCB candidates for Calendar Year 2016 are summarized here:

No. of State Candidates	1,329
State Pass Rate [%]	45
No. of National Candidates	53,177
National Pass Rate [%]	58

C. Census Data

At the close of the fiscal year on June 30, 2017, a review of our records yielded the following census information:

	2017	*2016*	*2015*
• Pharmacy Program			
1. Pharmacists			
> Number of active licenses	8,655	8,389	8,108
> Number of licensees within the state	5,372	5,509	5,596
2. Pharmacy Interns			
> Number of active registrations	1,094	1,088	1,097

3.	Pharmacy technicians				
	> Number of active certificates		6,561	6,969	6,726
4.	Pharmacy technician candidates				
	> Number of active registrations		2,052	1,861	1,981
5	Pharmacies				
	> Number of active permits		1,983	2,000	1,954
	- Community – Independent	583		583	598
	- Community – Chain	651		671	649
	- Hospital	175		173	174
	- Institutional	23		21	21
	- Nuclear	14		15	14
	- Charitable	11		12	12
	- Penal	2		2	2
	- Nonresident	524		523	484
6.	Equipment Permits				
	> Emergency drug kit (EDK)		411	464	484
	> Automated medication systems (AMS)		439	480	812
	> Durable medical equipment (DME)		637	622	603
7.	Special Activity Credentials				
	> CDTM Registration		66	59	52
	> Med. Administration Registration		2,820	2,603	2,383
	> Special Work Permits		48	48	54
	Subtotal of Credentials in Pharmacy Program		*24,766*	*24,635*	*24,254*

- CDS Program

		2017	*2016*	*2015*
1.	Animal Control Shelter	0	0	1
2.	Automated Medication System (AMS)	28	22	30
3.	Advanced Practice RN (APRN)	2,343	2,296	1,954
4.	Ambulatory Surgical Center (ASC)	0	21	87
5.	Correctional Center	0	1	4
6.	Dentist	1,929	2,134	2,133
7.	Drug Detection / Canine	8	9	12
8.	Distributor	284	301	327
9.	Podiatrist	136	152	142
10.	Veterinarian	1,007	1,085	1,045
11.	Emergency Medical Center	0	5	26
12.	Emergency Medical Service	0	16	49
13.	Animal Euthanasia Technician	25	27	28
14.	Hospital	283	294	277
15.	Laboratory	11	12	13
16.	Physician	11,575	12,360	12,125
17.	Medical Clinic	0	3	81
18.	Manufacturer	38	37	42
19.	Miscellaneous	0	0	11
20.	Medical Psychologist	84	86	82
21.	Optometrist	297	316	309

22.	Pharmacies	1,359	1,388	1,403
23.	Physician Assistant	667	610	487
24.	Registered Outsourcing Facility	13	14	8
25.	Researcher	100	108	113
26.	Rural Health Clinic	0	2	11
27.	Substance Abuse Clinic	6	7	10
	Subtotal of Credentials in CDS Program	*20,193*	*21,316*	*20,809*
Total Credentials under Management		**44,959**	**45,951**	**45,063**

D. New Credentials

During the past fiscal year, the Board issued 5,177 new credentials in the Pharmacy Program and 1,618 new credentials in the CDS Program. Of note within the Pharmacy Program, we issued 452 new pharmacist licenses, 555 new pharmacy technician certificates, and 1,477 new pharmacy technician candidate registrations during the past fiscal year. Of note within the CDS Program, we issued new CDS licenses to 749 physicians, 375 advanced practice registered nurses, and 138 physician assistants.

E. License Transfer (Reciprocity)

Persons already licensed as a pharmacist by any other state (except California) who wish to obtain a license in Louisiana must successfully complete the MPJE as well as the application and criminal background check. Of the 452 new pharmacist licenses issued this past fiscal year, 252 were issued subsequent to successful completion of the reciprocity process.

Compliance

A. Enforcement

In order to control and regulate the practice of pharmacy in Louisiana, the Board employs five pharmacist compliance officers to perform routine inspections and special investigations throughout the year in all places under the Board's jurisdiction. In addition to pharmacies, the compliance officers also inspect healthcare facilities to monitor compliance with controlled substance requirements. The compliance officers visited just under 1,400 pharmacies and other facilities during the year to perform routine inspections, site visits for permit changes and other calls for assistance. The compliance and administrative officers began the fiscal year with 224 cases from the previous fiscal year, received 391 new cases, and closed 468 cases, leaving 147 cases for the next fiscal year. Of the 468 cases closed during the fiscal year: 10 of the original complaints were withdrawn, 27 resulted from termination of previously imposed probationary periods, 76 were determined to be without violation, 16 cases were referred to other agencies, 118 resulted in field/administrative corrections, 4 resulted in administrative sanctions, and 217 cases were referred to the Board's committees. The committees took no action in 26 of their cases, issued approvals for 57 non-disciplinary petitions, and recommended voluntary consent agreements for 102 cases. Of that number, all but 32 accepted the proposed discipline; those 32 respondents were referred for formal administrative hearings. The decisions from the formal hearings resulted in one denial of licensure, suspension of 20 credentials, and 11 revocations.

Compliance officers coordinate other investigative activities with a wide range of agencies, including local police departments, parish sheriff departments, other state regulatory

and law enforcement agencies, and federal agencies such as the Drug Enforcement Administration, the Food and Drug Administration, and the Consumer Product Safety Commission. Though the compliance officers utilize the educational approach as the fundamental mechanism to achieve compliance, certain circumstances warrant formal board action.

B. Adjudications

During the past fiscal year, the Board conducted four administrative hearings and levied formal disciplinary action against several credentials. A summary of that activity is presented here:

Sanction	Pharmacist	Intern	Technician	Candidate	Permit	CDS
Denial / Refusal	0	0	0	4	1	0
Reinstatement	4	0	16	0	2	7
Change Previous Orders	5	0	0	0	0	0
Assessment	1	0	0	1	10	0
Letter of Warning	7	0	2	0	5	0
Letter of Reprimand	14	0	12	0	3	0
Voluntary Surrender	7	0	3	1	1	0
Probation	10	1	3	1	3	0
Suspension	4	0	7	0	1	12
Revocation	1	0	14	3	3	0

C. Practitioner Recovery Program

The Board established its program in 1988 to assist practitioners obtain treatment for their impairment, maintain their recovery, and assist their re-entry into professional practice. As of July 1, 2017 there were 42 pharmacists, one pharmacy intern, and five pharmacy technicians actively engaged in the recovery program. They surrendered their credentials while in treatment; following treatment and upon favorable recommendation by board-certified addiction medicine specialists, they applied for the reinstatement of their credentials. The Board reinstated their credentials on probation, and the licensees practice under various restrictions designed to monitor their re-entry to professional practice. In addition, the credentials for 42 pharmacists, two interns, 16 technicians, and four technician candidates were still on active suspension for impairment reasons.

Board Activity

A. Regulatory

The Board's Regulation Revision Committee is tasked with the continuous review of the Board's rules and their revision as appropriate. The committee initiated and the Board completed several regulatory projects during the fiscal year.

- Controlled Substance Prescriptions, amending LAC 46:LIII.Chapters 25 and 27;
- Pharmacist-in-Charge of Nonresident Pharmacy; amending LAC 46:LIII.Chapter 23;
- Medication Synchronization, amending, amending LAC 46:LIII.2519;
- Standing Orders for Distribution of Naloxone, amending LAC 46:LIII.2541; and
- Reinstatement of CDS License, amending LAC 46:LIII.2707.

The Board has four additional regulatory projects not yet completed; the progress of these regulatory initiatives may be monitored at the Board's website:

- Pharmacy Technicians, amending LAC 46:LIII.Chapter 9;
- Marijuana Pharmacy, amending LAC 46:LIII.Chapter 24;
- Pharmacy Internship Requirements, amending LAC 46:LIII.Chapter 7; and
- Equivalent Drug Product Interchange, amending LAC 46:LIII.Chapter 25.

B. Legislative

During the 2017 regular session, the Board sponsored two bills, both of which were successful. Act 100 amended the state list of controlled substances to harmonize the state list with the federal list. Act 241 amended the prescription monitoring program law to add additional categories of persons authorized to access prescription monitoring information, including coroners, substance abuse counselors, as well as probation and parole officers.

C. Operations

We have also completed seven years of service with our website's content management system and its mass communication capabilities. We have increased the frequency of communications to our licensees through the use of targeted email, alerts, and bulletins. Through avoided postage and labor costs of mass snail mail notices, we have already recouped the cost of our investment and will continue our savings going forward. In response to requests from users of mobile communication devices, we have updated our website to be responsive to access requests from mobile devices.

Our licensing information system was acquired and placed into service in 2010. We have scheduled a major upgrade for the system in the next fiscal year; that upgrade is essential to allow the expansion of online services. In addition, we are planning a major project to scan our licensure files which will allow further automation of our credentialing processes.

Finally, the Board continued its operation of Louisiana's Prescription Monitoring Program (PMP). The initial contract for the program vendor reached the end of its five year life, and the contract was released for public bid. The new vendor, Optimum Technology, Inc. based in Columbus, OH, was awarded the second contract in December 2013. During this fiscal year, that firm was acquired by Appriss, Inc. based in Louisville, KY. Appriss agreed to honor the terms of the 2013 contract, and further, transitioned the Louisiana program to its operating platform (Aware) in June 2016. The number of prescribers and dispensers authorized to access the program's database continues to increase, as has the average number of queries per day. Since the program is required to file an annual report to the legislature, we have appended that report to this one to facilitate its separation.

D. Physical Plant

The Board purchased its office building in December 2010 and moved to its current location in May 2011. We continue to make minor improvements to the building and grounds. The Board has planned a significant renovation of the office building during the next fiscal year. The loan for the purchase of the building was retired in December 2015.

Board Office

The Board currently employs 20 people on a full-time basis in a variety of professional, technical, and clerical roles; the Board also supports the local Cooperative Office Education

(COE) program in Baton Rouge area high schools by hiring high school senior students on a temporary basis. The physical and mailing address of the board office is:

Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Telephone (225) 925-6496
Telecopier (225) 925-6499

The board's website address is www.pharmacy.la.gov and general email is received at info@pharmacy.la.gov.

Conclusion

The board has had an active year on several fronts, and all of these activities have contributed to the overall mission of the board. The officers and members of the board, as well as the entire office staff, are committed to achieving our goal of protecting the public's health, safety and welfare through appropriate regulation of the practice of pharmacy in this state. We understand that public service is a privilege, and we endeavor to render that service honorably.

Prepared by:
Malcolm J Broussard
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Prescription Monitoring Program
Annual Report

Fiscal Year 2016-2017

July 1, 2017

Introduction

Act 676 of the 2006 Louisiana Legislature authorized the development, implementation, operation, and evaluation of an electronic system for the monitoring of controlled substances and other drugs of concern that are dispensed within the state or dispensed by a licensed pharmacy outside the state to an address within the state. The goal of the program is to improve the state's ability to identify and inhibit the diversion of controlled substances and drugs of concern in an efficient and cost-effective manner and in a manner that shall not impede the appropriate utilization of these drugs for legitimate medical purposes.

The Prescription Monitoring Program (PMP) was implemented in August 2008. We notified pharmacies of their requirement to report all eligible prescription transactions to the program, and further, required them to report all historical data retroactive to June 1, 2008 no later than December 31, 2008. In December 2008, the Board notified all prescribers and dispensers wishing to acquire direct access privileges of the requirement to complete the web-based orientation program prior to receiving their access privileges. The web portal to the program database was opened to queries on January 1, 2009, and the program remains fully functional.

The initial vendor selected pursuant to the original public bid in 2008 was Health Information Designs, Inc. from Auburn, AL. When that contract was re-bid in 2013, the successful bidder was Optimum Technology, Inc. from Columbus, OH. In 2015, that firm was acquired by Appriss, Inc. based in Louisville, KY. During Fiscal Year 2015-2016, Appriss transitioned the Louisiana program from the Optimum Technology platform to its own Aware platform. Among other benefits will be an enhanced reporting capability.

Advisory Council

The enabling legislation created the PMP Advisory Council to assist the Board in the development and operation of the program. The Board shall seek, and the advisory council shall provide, information and advice regarding: (1) which controlled substances should be monitored, (2) which drugs of concern demonstrate a potential for abuse and should be monitored, (3) design and implementation of educational courses required by the PMP law, (4) methodology to be used for analysis and interpretation of prescription monitoring information, (5) design and implementation of a program evaluation component, and (6) identification of potential additional members to the advisory council. The original legislation specifically identified the 25 organizations named to the council and further, named the leader of the organization but permitted the leader to name a designee to function in the absence of the appointee. The organizations represented on the council include the licensing agencies for the prescribers and dispensers, the professional membership organizations for the prescribers and dispensers, organizations representing federal, state, and local law enforcement agencies, as well as representatives from the legislature. The advisory council has elected its own leadership, adopted policies and procedures for its operations, and meets on a quarterly basis.

The council actively reviews the program's operations and makes recommendations for the improvement of the program. Those recommendations are forwarded to the Board of Pharmacy, resulting in regulatory or legislative initiatives designed to implement the council's recommendations.

Legislative Mandates

The 2014 Legislature adopted a number of measures which will serve to improve the program. Beginning August 1, 2014, pharmacies and other dispensers will be required to report their eligible prescription transactions to the program database no later than the next business day following the date of dispensing, instead of the previous seven day allowance. In addition, the Board has recently completed the rulemaking process authorized by the 2013 Legislature that will allow authorized prescribers and dispensers to appoint delegates for the purpose of retrieving data from the program's database.

The 2015 Legislature also adopted a measure that will require prescribers of certain controlled substances for the treatment of certain conditions to access the patient's history in the program database prior to initiating such treatment. The same measure will require pharmacists dispensing certain controlled substances to certain patients to access the patient's history in the program database prior to dispensing such medications.

The 2017 Legislature amended the state controlled substance law to require the automatic issuance of PMP access privileges to all practitioners with prescriptive authority for controlled substances except veterinarians. Another measure amended the PMP law to enable additional categories of authorized users, e.g., medical examiners, substance abuse counselors, and probation and parole officers, as well as judicially supervised specialty courts.

Program Highlights

- September 2016 – began sharing information with Texas.
- October 2016 – began sharing information with Alaska, Kansas, Massachusetts, Nevada, North Dakota, South Dakota, and Tennessee.
- December 2016 – began sharing information with Minnesota and Oklahoma.
- April 2017 – began sharing information with Alabama.
- June 2017 – began sharing information with Pennsylvania.

Program Metrics

The data on the following pages provide summary data for the operational aspects of the program – number of prescription transactions reported to the program database, number of prescribers and dispensers and their delegates registered to access the program data, the number of queries performed by those authorized prescribers and dispensers and their delegates as well as law enforcement agencies and regulatory agencies, and finally, the average number of queries per day. In addition, we present the top ten controlled substances dispensed, by label name, for the past four years, both number of prescriptions and the number of units dispensed.

Louisiana Board of Pharmacy
Prescription Monitoring Program

Calendar Year:	2008	2009	2010	2011	2012	2013	2014	2015	2016	6/30/2017
Prescription Database:										
Transactions Reported (in Millions)	6.015	11.144	12.117	12.775	12.99	13.032	13.02	12.403	12.245	6.062
Access to Program Data:										
New prescribers registered:		1,526	721	548	574	640	1,093	958	766	413
Total prescribers registered:		*1,526*	*2,247*	*2,795*	*3,369*	*4,009*	*5,102*	*6,060*	*6,826*	*7,239*
New prescriber delegates registered:							473	709	364	239
Total prescriber delegates registered:							*473*	*1,182*	*1,546*	*1,785*
New pharmacists registered:		728	483	361	494	509	466	418	353	117
Total pharmacists registered:		*728*	*1,211*	*1,572*	*2,066*	*2,575*	*3,041*	*3,459*	*3,812*	*3,929*
New pharmacist delegates registered:							143	236	166	126
Total pharmacist delegates registered:							*143*	*379*	*545*	*671*
Searches Performed by Users:										
Solicited by prescribers:		235,985	368,376	496,270	650,514	842,139	942,733	1,178,446	1,740,249	1,009,921
Solicited by prescriber delegates:							26,993	269,147		
Solicited by pharmacists:		74,277	111,075	153,783	212,754	382,204	456,568	1,015,496	1,166,655	633,821
Solicited by pharmacist delegates:							3,954	51,285		
Solicited by law enforcement:		680	889	1,230	845	1,150	1,224	1,011	843	509
Solicited by regulatory agencies:		833	1,401	1,612	1,584	1,364	1,675	1,477	1,663	1,136
Average queries per day:		854	1,319	1,788	2,372	3,361	3,926	6,896	7,971	9,016

Louisiana Board of Pharmacy
Prescription Monitoring Program

Top Controlled Substance Drugs Dispensed, by Label Name

2013	Drug Name	# Rx	Qty
	Hydrocodone/APAP 10-500	853,416	58,549,294
	Tramadol 50mg	765,440	52,645,565
	Zolpidem 10mg	611,493	18,844,825
	Hydrocodone/APAP 7.5-500	503,602	19,435,356
	Hydrocodone/APAP 5-500	460,105	14,821,532
	Hydrocodone/APAP 10-325	444,618	32,776,638
	Alprazolam 0.5mg	443,306	23,845,024
	Alprazolam 1mg	325,623	20,685,013
	Carisoprodol 350mg	320,099	21,833,430
	Clonazepam 1mg	261,320	14,447,060

2014	Drug Name	# Rx	Qty
	Hydrocodone/APAP 10-325	1,270,652	91,205,954
	Tramadol 50mg	900,872	60,641,816
	Hydrocodone/APAP 7.5-325	708,467	29,507,180
	Hydrocodone/APAP 5-325	616,995	19,932,033
	Zolpidem 10mg	526,666	16,493,087
	Alprazolam 0.5mg	416,194	22,424,375
	Alprazolam 1mg	303,529	19,330,194
	Oxycodone/APAP 10-325	268,583	21,420,793
	Clonazepam 0.5mg	253,289	12,559,739
	Clonazepam 1mg	252,646	14,018,210

2015	Drug Name	# Rx	Qty
	Hydrocodone/APAP 10-325	1,134,284	85,692,900
	Tramadol 50mg	939,808	64,608,114
	Hydrocodone/APAP 7.5-325	599,864	26,098,294
	Hydrocodone/APAP 5-325	551,317	18,432,786
	Zolpidem 10mg	512,297	16,049,100
	Alprazolam 0.5mg	416,972	22,514,399
	Oxycodone/APAP 10-325	329,285	26,347,048
	Alprazolam 1mg	303,200	19,385,621
	Clonazepam 1mg	264,126	14,859,779
	Clonazepam 0.5mg	258,410	12,986,657

2016	Drug Name	# Rx	Qty
	Hydrocodone/APAP 10-325	1,134,992	84,713,832
	Tramadol 50mg	975,537	65,742,114
	Hydrocodone/APAP 7.5-325	599,483	25,362,244
	Hydrocodone/APAP 5-325	575,255	18,417,263
	Zolpidem 10mg	512,753	16,157,638
	Alprazolam 0.5mg	437,175	23,594,764
	Oxycodone/APAP 10-325	377,013	30,248,215
	Alprazolam 1mg	316,590	20,207,395
	Clonzepam 1mg	279,482	15,813,361
	Clonzepam 0.5mg	276,798	13,951,268

Outlook for Next Fiscal Year

The program will continue the implementation of the legislative mandate to issue access privileges to all practitioners with prescriptive authority for controlled substances, except veterinarians. The current contract for the program vendor is slated to expire in late 2018. The program staff will collaborate with the state procurement office to facilitate the issuance of a new bid invitation.

Conclusion

The program has completed approximately eight years of operation. Based on feedback from authorized users, it appears to represent an efficient and cost-effective use of resources. Data from the program suggests we have made some early contributions to the reduction of diversion of controlled substances. Our interstate collaborations have yielded high marks for our program design and operation. We look forward to fully developing the potential of our program to identify and inhibit the diversion of controlled substances in Louisiana.

We acknowledge the contributions from Ms. Lindsey Schultz and Ms. Danielle Hartzog, our administrative coordinators, and Mr. Joseph Fontenot, Program Manager, for their operation of the program and the development of this report.

Prepared by:
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Multistate Pharmacy Jurisprudence Examination (MPJE™)

January 1 – April 30, 2017

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

August 23, 2017

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.

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

University of Louisiana at Monroe

Test Window: January 1, 2017 - April 30, 2017

This MPJE score report provides summary information for first-time examinees from ACPE-accredited schools/colleges and for all examinees, regardless of repeater status and/or the educational institution. Tables 1 and 2 contain school, state, and national pass rate information as well as total score means.

MPJE in-state: Examinees taking the MPJE for the same jurisdiction as respective pharmacy program
MPJE out of state: Examinees testing in different jurisdiction than respective pharmacy program

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

	Candidates	Pass Rate %	Total Scaled Score Mean	Standard Deviation
In-state	4	50.00%	74.75	4.35
Out of state	36	94.44%	78.67	3.08
State	94	80.85%	78.28	4.02
National	3983	82.10%	78.31	4.22

Table 2 All Candidates

	Candidates	Pass Rate %	Total Scaled Score Mean	Standard Deviation
In-state	6	50.00%	74.50	3.89
Out of state	39	94.87%	78.67	2.98
State	131	75.57%	77.39	4.11
National	5525	76.90%	77.59	4.25

Table 3 contains information on the range of scaled scores achieved by FT ACPE (First-Time, ACPE-Accredited) candidates as well as the pool of all candidates. It also shows the boundaries of the Scaled Score Range.

Table 3 Total Scaled Score Min/Max

	Min	Max
FT ACPE	59	96
All Candidates	59	96
Scaled Score Range	0	100

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.

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

Table 4 & Graph 1 School Frequency Distribution of Scaled Scores

Based on First-Time Candidates from ACPE-Accredited Programs N = 4

Scaled Score Range	Frequency	Cumulative Percent of the Upper Limit of the Interval
[0,4]	0	0%
[5,9]	0	0%
[10,14]	0	0%
[15,19]	0	0%
[20,24]	0	0%
[25,29]	0	0%
[30,34]	0	0%
[35,39]	0	0%
[40,44]	0	0%
[45,49]	0	0%
[50,54]	0	0%
[55,59]	0	0%
[60,64]	0	0%
[65,69]	0	0%
[70,74]	2	50%
[75,79]	2	100%
[80,84]	0	100%
[85,89]	0	100%
[90,94]	0	100%
[95,100]	0	100%

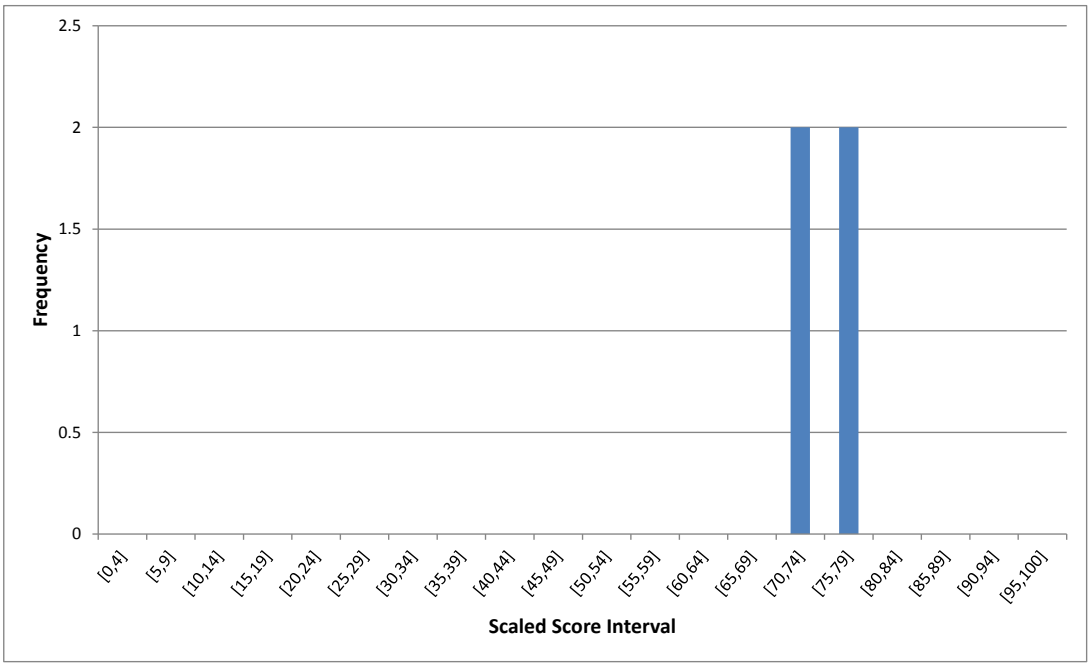
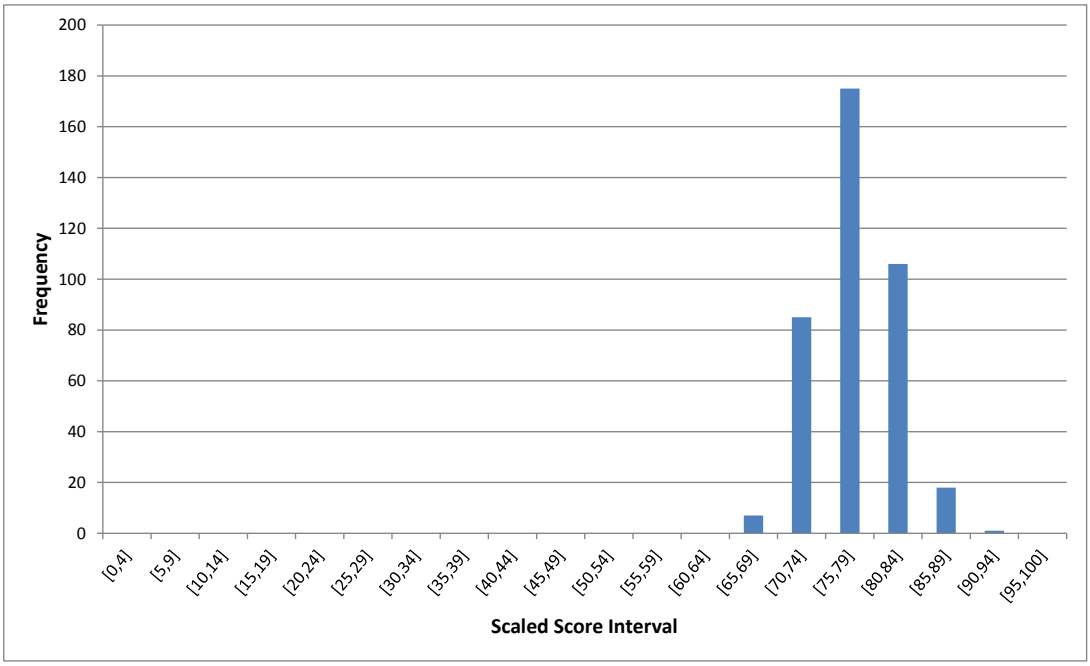


Table 5 & Graph 2 National Frequency Distribution of Scaled Scores

Based on First-Time Candidates from ACPE-Accredited Programs N = 392

Scaled Score Range	Frequency	Cumulative Percent of the Upper Limit of the Interval
[0,4]	0	0%
[5,9]	0	0%
[10,14]	0	0%
[15,19]	0	0%
[20,24]	0	0%
[25,29]	0	0%
[30,34]	0	0%
[35,39]	0	0%
[40,44]	0	0%
[45,49]	0	0%
[50,54]	0	0%
[55,59]	0	0%
[60,64]	0	0%
[65,69]	7	2%
[70,74]	85	23%
[75,79]	175	68%
[80,84]	106	95%
[85,89]	18	100%
[90,94]	1	100%
[95,100]	0	100%



Multistate Pharmacy Jurisprudence Examination (MPJE)

Xavier College of Pharmacy

	2000		***2001***		***2002***		***2003***	
	Jan - Jun	Jul - Dec	Jan - Jun	Jul - Dec	Jan - Jur	Jul - Dec	Jan - Jun	Jul - Dec
TOTAL CANDIDATE GROUP								
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
FIRST-TIME CANDIDATE GROUP								
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

	2004		***2005***		***2006***		***2007***	
	Jan - Jun	Jul - Dec	Jan - Jun	Jul - Dec	Jan - Jur	Jul - Dec	Jan - Jun	Jul - Dec
TOTAL CANDIDATE GROUP								
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
FIRST-TIME CANDIDATE GROUP								
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

	2008		***2009***			***2010***			***2011***		
	Jan - Jun	Jul - Dec	Jan - Ap	May - Aug	Sep - Dec	Jan - Ap	May - Aug	Sep - Dec	Jan - Ap	May - Aug	Sep - Dec
TOTAL CANDIDATE GROUP											
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
FIRST-TIME CANDIDATE GROUP											
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

	2012			***2013***			***2014***			***2015***		
	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep -Doc
TOTAL CANDIDATE GROUP												
No. of Candidates	13	181	87	53	188	115	52	193	128	81	215	103
** testing in same/different state*		94 / 87	23 / 65	6 / 47	95 / 93	46 / 69	12 / 40	82 / 111	43 / 85	26 / 55	105 / 110	33 / 70
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	78.36/80.64
** testing in same/different state*												
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	80.05
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	80.91
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	78.79/85.71
** testing in same/different state*												
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	86.55
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	87.78
FIRST-TIME CANDIDATE GROUP												
No. of Candidates	9	163	70	43	171	86	43	176	98	65	193	73
** testing in same/different state*		87 / 76	11 / 54	3 / 40	89 / 82	31 / 55	8 / 35	76 / 100	24 / 74	14 / 51	94 / 99	14 / 59
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	79.00/81.47
** testing in same/different state*												
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	80.81
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	81.60
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	92.86/91.53
** testing in same/different state*												
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	91.06
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	90.35

Multistate Pharmacy Jurisprudence Examination (MPJE)

Xavier College of Pharmacy

	2016			***2017***			***2018***			***2019***		
	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep -Doc
TOTAL CANDIDATE GROUP												
No. of Candidates	111	182	130	61								
** testing in same/different state*	13 / 98	92 / 90	51 / 79	18 / 43								
Mean Scaled Score - School *	75.15/79.34	75.93/77.13	75.16/76.56	74.00/75.63								
** testing in same/different state*												
Mean Scaled Score - State	80.92	77.12	76.91	77.39								
Mean Scaled Score - National	81.10	78.08	77.08	77.59								
School Pass Rate: *	53.85/82.65	64.13/74.44	56.86/78.48	44.44/65.12								
** testing in same/different state*												
State Pass Rate:	90.23	77.93	75.14	75.57								
National Pass Rate:	87.62	82.66	74.77	76.90								
FIRST-TIME CANDIDATE GROUP												
No. of Candidates	94	163	77	42								
** testing in same/different state*	10 / 84	83 / 80	16 / 61	6 / 36								
Mean Scaled Score - School *	74.90/79.99	76.04/77.46	73.19/76.64	75.17/75.64								
** testing in same/different state*												
Mean Scaled Score - State	81.58	77.10	77.33	78.28								
Mean Scaled Score - National	81.84	78.24	77.61	78.31								
School Pass Rate: *	50.00/88.10	65.06/76.25	31.25/77.05	50.00/66.67								
** testing in same/different state*												
State Pass Rate:	92.79	77.21	77.88	80.85								
National Pass Rate:	90.71	83.77	78.24	82.10								

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

Xavier University of Louisiana

Test Window: January 1, 2017 - April 30, 2017

This MPJE score report provides summary information for first-time examinees from ACPE-accredited schools/colleges and for all examinees, regardless of repeater status and/or the educational institution. Tables 1 and 2 contain school, state, and national pass rate information as well as total score means.

MPJE in-state: Examinees taking the MPJE for the same jurisdiction as respective pharmacy program
MPJE out of state: Examinees testing in different jurisdiction than respective pharmacy program

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

	Candidates	Pass Rate %	Total Scaled Score Mean	Standard Deviation
In-state	6	50.00%	75.17	3.31
Out of state	36	66.67%	75.64	2.96
State	94	80.85%	78.28	4.02
National	3983	82.10%	78.31	4.22

Table 2 All Candidates

	Candidates	Pass Rate %	Total Scaled Score Mean	Standard Deviation
In-state	18	44.44%	74.00	4.07
Out of state	43	65.12%	75.63	2.88
State	131	75.57%	77.39	4.11
National	5525	76.90%	77.59	4.25

Table 3 contains information on the range of scaled scores achieved by FT ACPE (First-Time, ACPE-Accredited) candidates as well as the pool of all candidates. It also shows the boundaries of the Scaled Score Range.

Table 3 Total Scaled Score Min/Max

	Min	Max
FT ACPE	59	96
All Candidates	59	96
Scaled Score Range	0	100

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.

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

Table 4 & Graph 1 School Frequency Distribution of Scaled Scores

Based on First-Time Candidates from ACPE-Accredited Programs N = 6

Scaled Score Range	Frequency	Cumulative Percent of the Upper Limit of the Interval
[0,4]	0	0%
[5,9]	0	0%
[10,14]	0	0%
[15,19]	0	0%
[20,24]	0	0%
[25,29]	0	0%
[30,34]	0	0%
[35,39]	0	0%
[40,44]	0	0%
[45,49]	0	0%
[50,54]	0	0%
[55,59]	0	0%
[60,64]	0	0%
[65,69]	0	0%
[70,74]	3	50%
[75,79]	2	83%
[80,84]	1	100%
[85,89]	0	100%
[90,94]	0	100%
[95,100]	0	100%

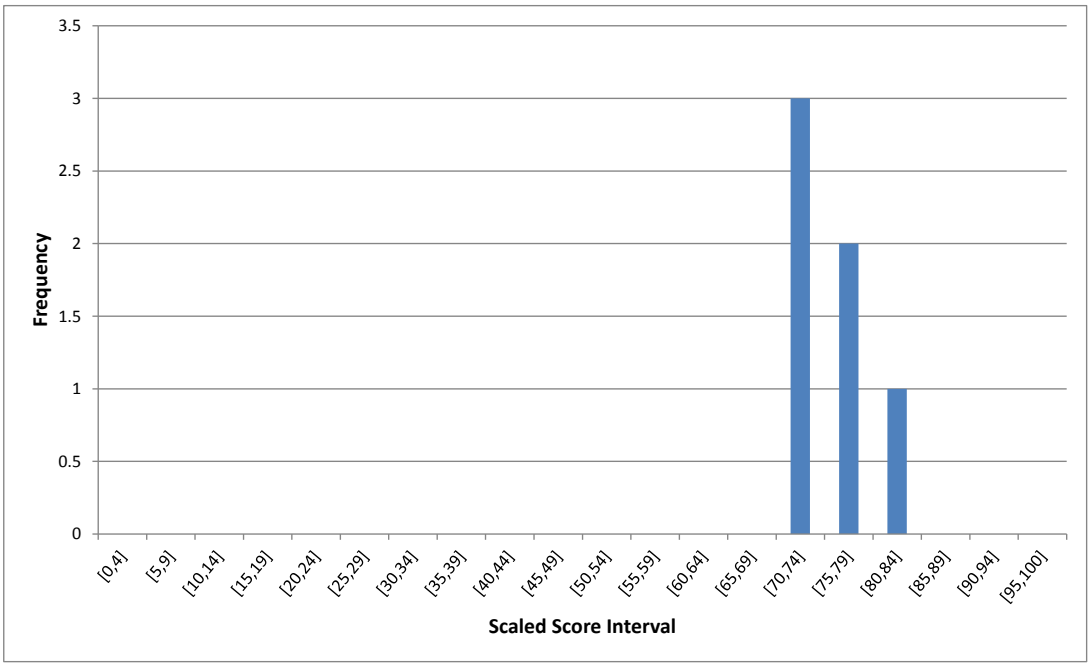
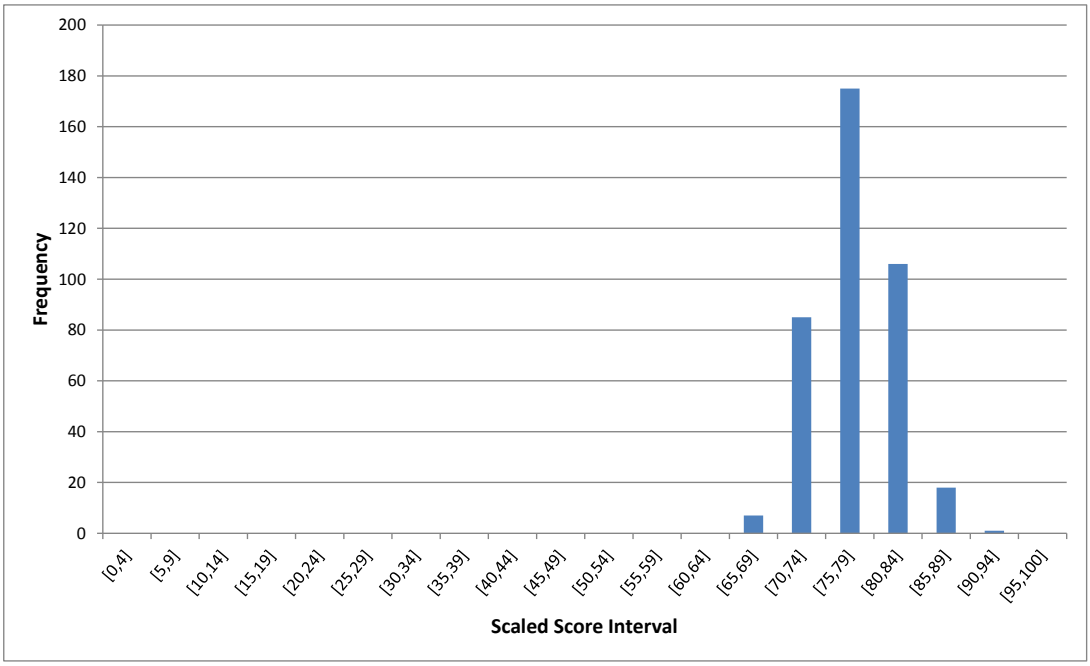


Table 5 & Graph 2 National Frequency Distribution of Scaled Scores

Based on First-Time Candidates from ACPE-Accredited Programs N = 392

Scaled Score Range	Frequency	Cumulative Percent of the Upper Limit of the Interval
[0,4]	0	0%
[5,9]	0	0%
[10,14]	0	0%
[15,19]	0	0%
[20,24]	0	0%
[25,29]	0	0%
[30,34]	0	0%
[35,39]	0	0%
[40,44]	0	0%
[45,49]	0	0%
[50,54]	0	0%
[55,59]	0	0%
[60,64]	0	0%
[65,69]	7	2%
[70,74]	85	23%
[75,79]	175	68%
[80,84]	106	95%
[85,89]	18	100%
[90,94]	1	100%
[95,100]	0	100%



Multistate Pharmacy Jurisprudence Examination (MPJE)

Xavier College of Pharmacy

	2000		***2001***		***2002***		***2003***	
	Jan - Jun	Jul - Dec	Jan - Jun	Jul - Dec	Jan - Jur	Jul - Dec	Jan - Jun	Jul - Dec
TOTAL CANDIDATE GROUP								
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
FIRST-TIME CANDIDATE GROUP								
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

	2004		***2005***		***2006***		***2007***	
	Jan - Jun	Jul - Dec	Jan - Jun	Jul - Dec	Jan - Jur	Jul - Dec	Jan - Jun	Jul - Dec
TOTAL CANDIDATE GROUP								
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
FIRST-TIME CANDIDATE GROUP								
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

	2008		***2009***			***2010***			***2011***		
	Jan - Jun	Jul - Dec	Jan - Ap	May - Aug	Sep - Dec	Jan - Ap	May - Aug	Sep - Dec	Jan - Ap	May - Aug	Sep - Dec
TOTAL CANDIDATE GROUP											
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
FIRST-TIME CANDIDATE GROUP											
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

	2012			***2013***			***2014***			***2015***		
	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep -Doc
TOTAL CANDIDATE GROUP												
No. of Candidates	13	181	87	53	188	115	52	193	128	81	215	103
** testing in same/different state*		94 / 87	23 / 65	6 / 47	95 / 93	46 / 69	12 / 40	82 / 111	43 / 85	26 / 55	105 / 110	33 / 70
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	78.36/80.64
** testing in same/different state*												
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	80.05
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	80.91
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	78.79/85.71
** testing in same/different state*												
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	86.55
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	87.78
FIRST-TIME CANDIDATE GROUP												
No. of Candidates	9	163	70	43	171	86	43	176	98	65	193	73
** testing in same/different state*		87 / 76	11 / 54	3 / 40	89 / 82	31 / 55	8 / 35	76 / 100	24 / 74	14 / 51	94 / 99	14 / 59
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	79.00/81.47
** testing in same/different state*												
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	80.81
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	81.60
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	92.86/91.53
** testing in same/different state*												
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	91.06
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	90.35

Multistate Pharmacy Jurisprudence Examination (MPJE)

Xavier College of Pharmacy

	2016			***2017***			***2018***			***2019***		
	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep - Dec	Jan - Apr	May - Aug	Sep -Doc
TOTAL CANDIDATE GROUP												
No. of Candidates	111	182	130	61								
** testing in same/different state*	13 / 98	92 / 90	51 / 79	18 / 43								
Mean Scaled Score - School *	75.15/79.34	75.93/77.13	75.16/76.56	74.00/75.63								
** testing in same/different state*												
Mean Scaled Score - State	80.92	77.12	76.91	77.39								
Mean Scaled Score - National	81.10	78.08	77.08	77.59								
School Pass Rate: *	53.85/82.65	64.13/74.44	56.86/78.48	44.44/65.12								
** testing in same/different state*												
State Pass Rate:	90.23	77.93	75.14	75.57								
National Pass Rate:	87.62	82.66	74.77	76.90								
FIRST-TIME CANDIDATE GROUP												
No. of Candidates	94	163	77	42								
** testing in same/different state*	10 / 84	83 / 80	16 / 61	6 / 36								
Mean Scaled Score - School *	74.90/79.99	76.04/77.46	73.19/76.64	75.17/75.64								
** testing in same/different state*												
Mean Scaled Score - State	81.58	77.10	77.33	78.28								
Mean Scaled Score - National	81.84	78.24	77.61	78.31								
School Pass Rate: *	50.00/88.10	65.06/76.25	31.25/77.05	50.00/66.67								
** testing in same/different state*												
State Pass Rate:	92.79	77.21	77.88	80.85								
National Pass Rate:	90.71	83.77	78.24	82.10								

Louisiana Board of Pharmacy

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Baton Rouge, Louisiana 70809-1700
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North American Pharmacist Licensure Examination (NAPLEX™)

January 1 – April 30, 2017

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

August 23, 2017

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.

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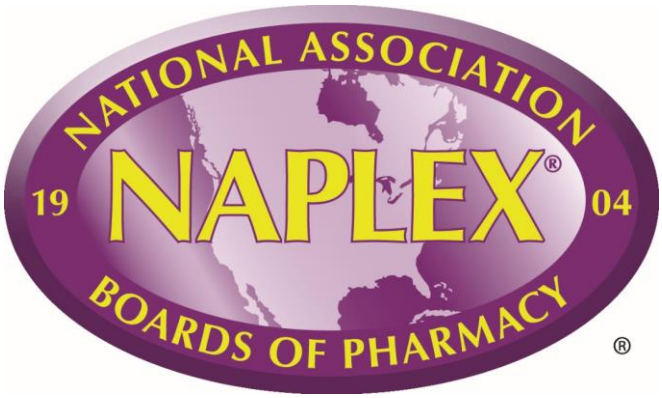


North American Pharmacist Licensure Examination® (NAPLEX®) School Summary Report

University of Louisiana at Monroe

Test Window: January 1, 2017 - April 30, 2017

This NAPLEX score report consists of two levels of scores: aggregated school scores and individual candidate scores. Beginning November 1, 2015, individual (unidentified) scores are reported in the NAPLEX Roster excel file. Summary information is provided separately for first-time examinees from ACPE-accredited schools/colleges and for all examinees, regardless of repeater status and/or the educational institution.

Tables 1 and 2 contain school, state, and national pass rate information as well as total score means and area score means for each of the two main NAPLEX content domains:

Area 1 - Ensure Safe and Effective Pharmacotherapy and Health Outcomes (67%)

Area 2 - Safe and Accurate Preparation, Compounding, Dispensing and Administration of Medications and Provision of Healthcare Products (33%)

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
School	2	50.00%	72.50	26.16	11.00	1.41	10.50	0.71
State	4	75.00%	87.50	27.91	11.75	1.50	12.25	2.06
National	189	76.19%	86.04	20.21	11.87	1.38	11.85	1.55

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
School	11	81.82%	87.45	16.85	11.73	1.01	12.00	1.41
State	34	70.59%	80.50	16.75	11.44	1.05	11.50	1.31
National	1277	62.73%	79.33	18.29	11.38	1.26	11.61	1.55

Table 3 contains information on the range of scaled scores achieved by FT ACPE (First-Time, ACPE-Accredited) candidates as well as the pool of all candidates. It also shows the boundaries of the Scaled Score Range.

Table 3 Total Scaled Score Min/Max

	Min	Max
FT ACPE	22	132
All Candidates	22	132
Scaled Score Range	0	150

Interpretation and Uses of Candidate Scores

At the candidate level, two sets of scores are produced: an overall, composite score and area scores. Only overall scores are used to make pass/fail decisions. Area scores are intended to provide insight into performances in each of the content area domains independent of one another.

There are a total of two area scores, one per main competency area. Area scores are 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 two content areas.

Table 4 shows the mean area scores for candidates scoring within the designated ranges of NAPLEX total scores. Data in this table includes outcomes from all candidates testing between January 1, 2016 and December 31, 2016.

Comparison Information

Total Scaled Score Range	*AREA 1*	*AREA 2*
0 - 24	8	7
25 - 49	9	9
50 - 74	11	11
75 - 99	12	12
100 - 124	13	13
125 - 150	15	15

The following tables and graphs 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 5 & Graph 1 School Frequency Distribution of Scaled Scores

Based on First-Time Candidates N = 2

Scaled Score Range	Frequency	Cumulative Percent of the Upper Limit of the Interval
[0,4]	0	0%
[5,9]	0	0%
[10,14]	0	0%
[15,19]	0	0%
[20,24]	0	0%
[25,29]	0	0%
[30,34]	0	0%
[35,39]	0	0%
[40,44]	0	0%
[45,49]	0	0%
[50,54]	1	50%
[55,59]	0	50%
[60,64]	0	50%
[65,69]	0	50%
[70,74]	0	50%
[75,79]	0	50%
[80,84]	0	50%
[85,89]	0	50%
[90,94]	1	100%
[95,99]	0	100%
[100,104]	0	100%
[105,109]	0	100%
[110,114]	0	100%
[115,119]	0	100%
[120,124]	0	100%
[125,129]	0	100%
[130,134]	0	100%
[135,139]	0	100%
[140,144]	0	100%
[145,150]	0	100%

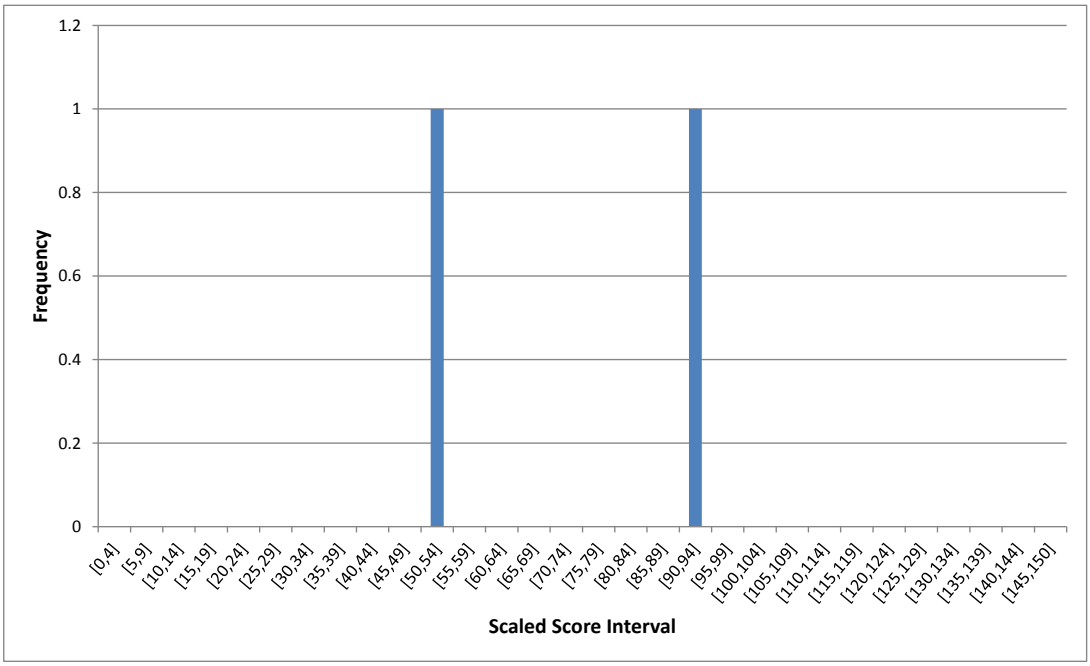
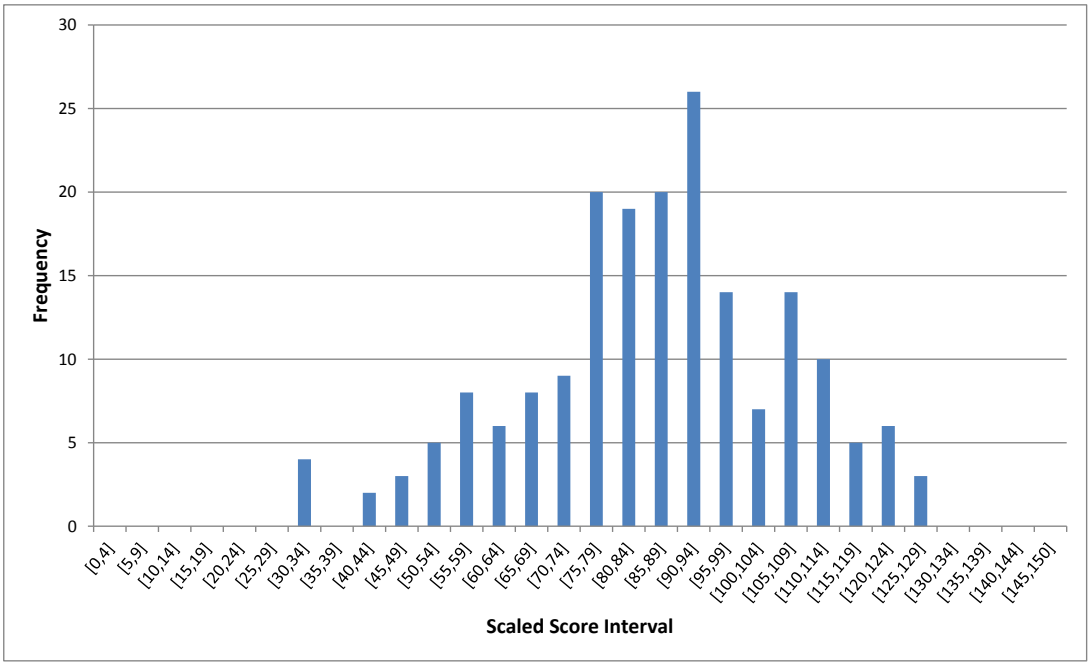


Table 6 & Graph 2 National Frequency Distribution of Scaled Scores

Based on First-Time Candidates from ACPE-Accredited Programs N = 189

Scaled Score Range	Frequency	Cumulative Percent of the Upper Limit of the Interval
[0,4]	0	0%
[5,9]	0	0%
[10,14]	0	0%
[15,19]	0	0%
[20,24]	0	0%
[25,29]	0	0%
[30,34]	4	2%
[35,39]	0	2%
[40,44]	2	3%
[45,49]	3	5%
[50,54]	5	7%
[55,59]	8	12%
[60,64]	6	15%
[65,69]	8	19%
[70,74]	9	24%
[75,79]	20	34%
[80,84]	19	44%
[85,89]	20	55%
[90,94]	26	69%
[95,99]	14	76%
[100,104]	7	80%
[105,109]	14	87%
[110,114]	10	93%
[115,119]	5	95%
[120,124]	6	98%
[125,129]	3	100%
[130,134]	0	100%
[135,139]	0	100%
[140,144]	0	100%
[145,150]	0	100%



North American Pharmacist Licensure Examination (NAPLEX)

University of Louisiana at Monroe

	2000			*2001*			*2002*			*2003*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
TOTAL CANDIDATE GROUP												
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
FIRST-TIME CANDIDATE GROUP												
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

	2004			*2005*			*2006*			*2007*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
TOTAL CANDIDATE GROUP												
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
FIRST-TIME CANDIDATE GROUP												
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

	2008			*2009*			*2010*			*2011*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
TOTAL CANDIDATE GROUP												
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
FIRST-TIME CANDIDATE GROUP												
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)

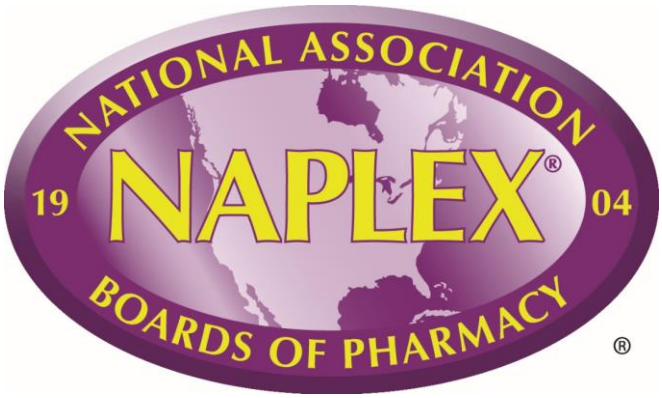
University of Louisiana at Monroe

	2012			*2013*			*2014*			*2015*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
												S+O/N+D
TOTAL CANDIDATE GROUP												
No. of Candidates	6	80	17	3	40	7	1	68	11	4	79	9 / 3
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	83.89/89.67
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	85.60/73.62
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	88.25/73.84
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	77.78/100
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	76.00/46.15
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	77.64/46.27
FIRST-TIME CANDIDATE GROUP												
No. of Candidates	2	80	9	3	38	4	1	68	3	1	78	5 / 0
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	83.60 / 0
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	86.50 / 0
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	91.24 / 0
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	80.00 / 0
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	75.00 / 0
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	81.88 / 0

North American Pharmacist Licensure Examination (NAPLEX)

University of Louisiana at Monroe

	2016			***2017***			***2018***			***2019***		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
TOTAL CANDIDATE GROUP												
No. of Candidates	4	94	18	11								
Mean Scaled Score - School	60.25	87.35	83.76	87.45								
Mean Scaled Score - State	66.88	89.27	77.06	80.50								
Mean Scaled Score - National	74.52	84.81	81.48	79.33								
School Pass Rate:	0.00	76.6	77.78	81.82								
State Pass Rate:	22.22	77.61	54.72	70.59								
National Pass Rate:	48.80	85.71	65.32	62.73								
					ACPE probation eff. 06-24-2017							
FIRST-TIME CANDIDATE GROUP												
No. of Candidates	1	91	4	2								
Mean Scaled Score - School	31.00	87.62	79.67	72.50								
Mean Scaled Score - State	47.33	89.71	71.05	87.50								
Mean Scaled Score - National	78.95	95.9	83.02	86.04								
School Pass Rate:	0.00	76.92	50.00	50.00								
State Pass Rate:	0.00	78.07	38.10	75.00								
National Pass Rate:	57.75	87.78	65.64	76.19								



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

Xavier University of Louisiana

Test Window: January 1, 2017 - April 30, 2017

This NAPLEX score report consists of two levels of scores: aggregated school scores and individual candidate scores. Beginning November 1, 2015, individual (unidentified) scores are reported in the NAPLEX Roster excel file. Summary information is provided separately for first-time examinees from ACPE-accredited schools/colleges and for all examinees, regardless of repeater status and/or the educational institution.

Tables 1 and 2 contain school, state, and national pass rate information as well as total score means and area score means for each of the two main NAPLEX content domains:

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Area 2 - Safe and Accurate Preparation, Compounding, Dispensing and Administration of Medications and Provision of Healthcare Products (33%)

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
School	1	100.00%	111.00	-	13.00	-	14.00	-
State	4	75.00%	87.50	27.91	11.75	1.50	12.25	2.06
National	189	76.19%	86.04	20.21	11.87	1.38	11.85	1.55

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
School	25	64.00%	77.68	18.99	11.36	1.15	11.36	1.47
State	34	70.59%	80.50	16.75	11.44	1.05	11.50	1.31
National	1277	62.73%	79.33	18.29	11.38	1.26	11.61	1.55

Table 3 contains information on the range of scaled scores achieved by FT ACPE (First-Time, ACPE-Accredited) candidates as well as the pool of all candidates. It also shows the boundaries of the Scaled Score Range.

Table 3 Total Scaled Score Min/Max

	Min	Max
FT ACPE	22	132
All Candidates	22	132
Scaled Score Range	0	150

Interpretation and Uses of Candidate Scores

At the candidate level, two sets of scores are produced: an overall, composite score and area scores. Only overall scores are used to make pass/fail decisions. Area scores are intended to provide insight into performances in each of the content area domains independent of one another.

There are a total of two area scores, one per main competency area. Area scores are 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 two content areas.

Table 4 shows the mean area scores for candidates scoring within the designated ranges of NAPLEX total scores. Data in this table includes outcomes from all candidates testing between January 1, 2016 and December 31, 2016.

Comparison Information

Total Scaled Score Range	*AREA 1*	*AREA 2*
0 - 24	8	7
25 - 49	9	9
50 - 74	11	11
75 - 99	12	12
100 - 124	13	13
125 - 150	15	15

The following tables and graphs 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 5 & Graph 1 School Frequency Distribution of Scaled Scores

Based on First-Time Candidates N = 1

Scaled Score Range	Frequency	Cumulative Percent of the Upper Limit of the Interval
[0,4]	0	0%
[5,9]	0	0%
[10,14]	0	0%
[15,19]	0	0%
[20,24]	0	0%
[25,29]	0	0%
[30,34]	0	0%
[35,39]	0	0%
[40,44]	0	0%
[45,49]	0	0%
[50,54]	0	0%
[55,59]	0	0%
[60,64]	0	0%
[65,69]	0	0%
[70,74]	0	0%
[75,79]	0	0%
[80,84]	0	0%
[85,89]	0	0%
[90,94]	0	0%
[95,99]	0	0%
[100,104]	0	0%
[105,109]	0	0%
[110,114]	1	100%
[115,119]	0	100%
[120,124]	0	100%
[125,129]	0	100%
[130,134]	0	100%
[135,139]	0	100%
[140,144]	0	100%
[145,150]	0	100%

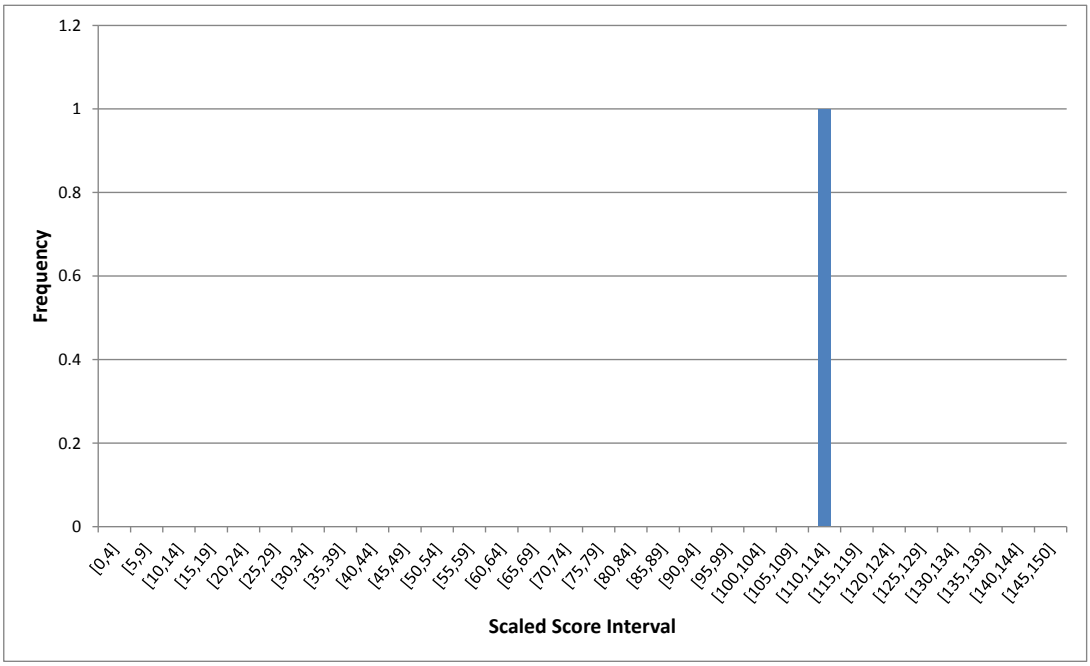
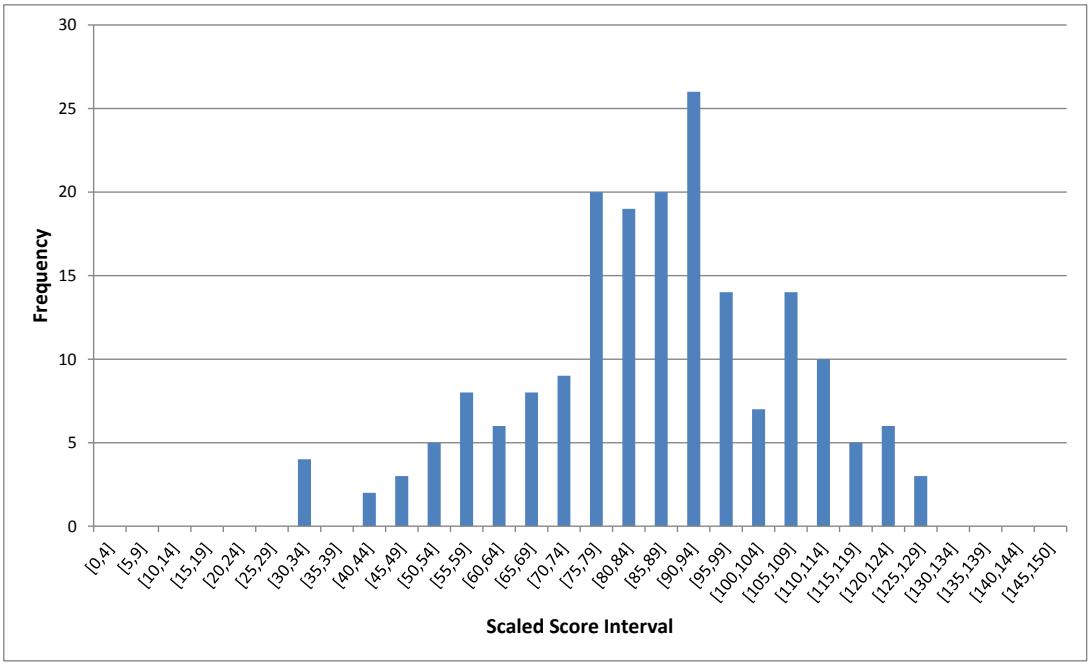


Table 6 & Graph 2 National Frequency Distribution of Scaled Scores

Based on First-Time Candidates from ACPE-Accredited Programs N = 189

Scaled Score Range	Frequency	Cumulative Percent of the Upper Limit of the Interval
[0,4]	0	0%
[5,9]	0	0%
[10,14]	0	0%
[15,19]	0	0%
[20,24]	0	0%
[25,29]	0	0%
[30,34]	4	2%
[35,39]	0	2%
[40,44]	2	3%
[45,49]	3	5%
[50,54]	5	7%
[55,59]	8	12%
[60,64]	6	15%
[65,69]	8	19%
[70,74]	9	24%
[75,79]	20	34%
[80,84]	19	44%
[85,89]	20	55%
[90,94]	26	69%
[95,99]	14	76%
[100,104]	7	80%
[105,109]	14	87%
[110,114]	10	93%
[115,119]	5	95%
[120,124]	6	98%
[125,129]	3	100%
[130,134]	0	100%
[135,139]	0	100%
[140,144]	0	100%
[145,150]	0	100%



North American Pharmacist Licensure Examination (NAPLEX)

Xavier College of Pharmacy

	2000			*2001*			*2002*			*2003*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
TOTAL CANDIDATE GROUP												
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
FIRST-TIME CANDIDATE GROUP												
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

	2004			*2005*			*2006*			*2007*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
TOTAL CANDIDATE GROUP												
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
FIRST-TIME CANDIDATE GROUP												
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

	2008			*2009*			*2010*			*2011*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
TOTAL CANDIDATE GROUP												
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
FIRST-TIME CANDIDATE GROUP												
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

	2012			*2013*			*2014*			*2015*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
												S+O/N+D
TOTAL CANDIDATE GROUP												
No. of Candidates	13	120	21	10	136	43	18	138	27	15	141	22 / 9
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	86.73/59.78
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	85.60/73.62
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	88.25/73.84
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	86.36/22.22
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	76.00/46.15
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	77.64/46.27
FIRST-TIME CANDIDATE GROUP												
No. of Candidates	3	111	12	1	131	29	3	131	18	4	137	10 / 1
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	89.60/27.00
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	86.50/73.67
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	91.24/81.00
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	80.00 / 0
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	75.00/33.33
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	81.88/58.74

North American Pharmacist Licensure Examination (NAPLEX)

Xavier College of Pharmacy

	2016			*2017*			*2018*			*2019*		
	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec	Jan - Apr	May - Aug	Sept - Dec
TOTAL CANDIDATE GROUP												
No. of Candidates	16	123	43	25								
Mean Scaled Score - School	61.87	89.84	75.2	77.68								
Mean Scaled Score - State	66.88	89.27	77.06	80.50								
Mean Scaled Score - National	74.52	94.81	81.48	79.33								
School Pass Rate:	25.00	78.05	51.16	64.00								
State Pass Rate:	22.22	77.61	54.72	70.59								
National Pass Rate:	48.80	85.71	65.32	62.73								
FIRST-TIME CANDIDATE GROUP												
No. of Candidates	4	114	22	1								
Mean Scaled Score - School	63.67	91.1	74.81	111.00								
Mean Scaled Score - State	47.33	89.71	81.05	87.50								
Mean Scaled Score - National	78.95	95.9	83.02	86.04								
School Pass Rate:	25.00	80.7	50.00	100.00								
State Pass Rate:	0.00	78.07	38.10	75.00								
National Pass Rate:	57.75	87.78	65.64	76.19								

Louisiana Board of Pharmacy

Pharmacy Technician Certification Board (PTCB) Examination

National Data	1995-1999 Data	3/25/2000	7/22/2000	11/18/2000	3/10/2001	7/14/2001	11/10/2001	3/16/2002	7/27/2002	11/16/2002
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%
Louisiana Data										
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%

National Data	2000-2002 Data	3/29/2003	7/26/2003	11/15/2003	3/20/2004	7/17/2004	11/13/2004	3/19/2005	7/23/2005	11/19/2005
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%
Louisiana Data										
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

National Data	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
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%
Louisiana Data										
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%

National Data	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
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%
Louisiana Data										
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

National Data	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
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%
Louisiana Data										
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%

National Data	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 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%
Louisiana Data								
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

National Data	2000-2013 Data	1/1/2014 to 6/30/2014	7/1/2014 to 12/31/2014	2000-2014 Data	1/1/2015 to 06/30/2015	7/1/2015 to 12/31/2015
No. of Candidates Attempting	628,957	26,423	27,085	682,465	22,197	36,167
No. of Candidates Passing	470,680	15,233	15,125	501,038	13,280	21,643
Passing Score	650	650	650	650	650	650
Average Score						
Pass Rate	74.8%	57.7%	55.8%	73.4%	59.8%	59.8%
Louisiana Data						
No. of Candidates Attempting	11,002	630	568	12,200	480	632
No. of Candidates Passing	7,451	287	265	8,003	255	304
Average Score						
Pass Rate	67.7%	45.6%	46.7%	65.6%	53.1%	48.1%

National Data	2000-2015 Data	1/1/2016 to 12/31/2016	2000-2016 Data	1/1/2017 to 6/30/2017	7/1/20147 to 12/31/2017
No. of Candidates Attempting	740,829	53,277	794,106		
No. of Candidates Passing	535,961	30,835	566,796		
Passing Score	650	650			
Average Score					
Pass Rate	72.3%	57.8%	71.4%		
Louisiana Data					
No. of Candidates Attempting	13,314	1,329	14,643	595	
No. of Candidates Passing	8,562	592	9,154	271	
Average Score					
Pass Rate	64.3%	44.5%	62.5%	45.5%	

Final Rule

Department of Health
Board of Pharmacy

Marijuana Pharmacy (LAC 46:LIII.Chapter 24)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy has adopted a new subchapter of rules, more specifically, *Chapter 24 ~ Limited Service Providers, Subchapter E. Marijuana Pharmacy*. The rule was prepared in response to Act 261 of the 2015 Legislature and Act 96 of the 2016 Legislature, and it establishes standards for the packaging and labeling of marijuana products as well as the dispensing of such products in pharmacies licensed by the Board.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 24. Limited Service Providers

Subchapter E. Marijuana Pharmacy

§2440. Preamble; Warning; Consultation Suggested

A. Pursuant to Act 261 of the Regular Session of the 2015 Louisiana Legislature as well as the subsequent amendment found in Act 96 of the Regular Session of the 2016 Louisiana Legislature, the Board of Pharmacy was directed to:
   1. Develop an annual, nontransferable specialty license for a pharmacy to dispense recommended marijuana for therapeutic use, to limit the number of such licenses to a maximum of 10, and to adopt rules regarding the geographical locations of dispensing pharmacies in the state; and
   2. Adopt rules relating to the dispensing of recommended marijuana for therapeutic use, with such rules to include, at a minimum, the following:
      a. Standards, procedures, and protocols for the effective use of recommended marijuana for therapeutic use as authorized by state law and related rules;
      b. Standards, procedures, and protocols for the dispensing and tracking of recommended therapeutic marijuana;
      c. Procedures and protocols to provide that no recommended therapeutic marijuana may be dispensed from, produced from, obtained from, sold to, or transferred to a location outside of this state;
      d. Standards, procedures, and protocols for determining the amount of usable recommended therapeutic marijuana that is necessary to constitute an adequate supply to ensure uninterrupted availability for a period of one month, including amount for topical treatments;
      e. Standards, procedures, and protocols to ensure all recommended therapeutic marijuana dispensed is consistently pharmaceutical grade;
      f. Standards and procedures for the revocation, suspension, and nonrenewal of licenses;
      g. Other licensing, renewal, and operational standards deemed necessary by the Board of Pharmacy;
      h. Standards and procedures for testing recommended therapeutic marijuana samples for levels of tetrahydrocannabinols (THC) or other testing parameters deemed appropriate by the Board of Pharmacy;
      i. Standards for the protection of health, safety, and security for dispensers of recommended therapeutic marijuana;
      j. Standards for the licensure of dispensers of recommended therapeutic marijuana; and
      k. Standards for financial capacity to operate a marijuana pharmacy.

B. Marijuana is classified as a Schedule I controlled substance by the U.S. Department of Justice, Drug Enforcement Administration.
   1. As provided by the federal Controlled Substances Act, the procurement, possession, prescribing, distribution, dispensing, or administering of any Schedule I controlled substance, including marijuana, is a violation of federal law.
   2. Neither Louisiana law nor this Part can preempt federal law. Therefore, the provisions of this Subchapter notwithstanding, persons engaged in the activities described herein remain subject to the full force of federal law enforcement, including arrest and prosecution of criminal charges, the assessment of civil fines and forfeitures, as well as administrative consequences such as forfeiture of federal controlled substance registrations and exclusion from Medicare and other federal payer programs.

C. For the foregoing reasons, pharmacists and other persons credentialed by the board may wish to consult with their own legal counsel as well as any health care facility, private or governmental payor with which they are affiliated, professional liability insurers, and financial institutions with which they maintain depository relationships before engaging in the activities described herein.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017)

§2441. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

Administer – the direct application of marijuana to the body of a qualifying patient by ingestion or any other means.

Advertisement – all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana.

Agent – an authorized person who acts on behalf of or at the direction of another person. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

Approved Safe – a safe which conforms to or exceeds all of the following standards:

a. Shall have the following specifications or the equivalent:
   i. 30 man-minutes against surreptitious entry;
   ii. 10 man-minutes against forced entry;
   iii. 20 man-hours against lock manipulation; and
   iv. 20 man-hours against radiological techniques;
b. If it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way it cannot be readily removed; and
c. Is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve.

Approved Vault:

a. A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or
b. A vault constructed after September 1, 1971:
   i. The walls, floors, and ceilings of which are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;
   ii. The door and frame unit of which vault shall conform to the following specifications or the equivalent:
      (a) 30 man-minutes against surreptitious entry;
      (b) 10 man-minutes against forced entry;
      (c) 20 man-hours against lock manipulation; and
      (d) 20 man-hours against radiological techniques;
   iii. Which vault, if operations require it to remain open for frequent access, is equipped with a "day gate" which is self-closing and self-locking or the equivalent, for use during the hours of operation in which the vault door is open;
   iv. The walls or perimeter of which are equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve, and if necessary, alarm buttons at strategic points of entry to the perimeter area of the vault;
   v. The door of which shall be equipped with one or more contact switches; and
   vi. Which vault has one of the following:
      (a) Complete electrical lacing of the walls, floor and ceiling;
      (b) Sensitive ultrasonic equipment within the vault;
      (c) Sensitive sound accumulator system; or
      (d) Such other device designed to detect illegal entry as may be approved by the board.

Board – the Louisiana Board of Pharmacy.

CFR – the Code of Federal Regulations.

Deliver or *Delivery* – the actual, constructive or attempted transfer from one person to another of marijuana, whether or not there is an agency relationship.

Financial Interest – any actual, or a future right to, ownership or investment, either directly or indirectly, through business, investment or immediate family. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by such person do not exceed 5 per cent of the total number of shares issued by the corporation.
Immediate Family – R.S. 42:1102, i.e., his children and the spouses of his children, his brothers and their spouses, his sisters and their spouses, his parents, his spouse, and the parents of his spouse.
LDAF – the Louisiana Department of Agriculture and Forestry.
LDH – the Louisiana Department of Health.
Louisiana Medical Marijuana Tracking System (LMMTS) – the required seed-to-sale tracking system that tracks medical marijuana from either the seed or immature plant stage until the product is sold to a pharmacy or is destroyed.
Marijuana – all parts of plants of the genus *Cannabis*, whether growing or not, the seeds thereof, the resin extracted from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin, but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.
Marijuana Pharmacy – that area within a facility where marijuana is stored, dispensed, and sold. If a facility does not offer any products or services other than marijuana and/or related supplies, the entire facility is a marijuana pharmacy for the purposes of this Subchapter.
Marijuana Pharmacy Owner – any person with an ownership interest in a marijuana pharmacy, except the term does not include a person with an investment interest through a publicly-held company provided the interest held by such person does not exceed 5 per cent of the total ownership or interest rights in such pharmacy and such person does not participate directly or indirectly in the control, management, or operation of the pharmacy.
Marijuana Product – any product containing marijuana, including raw materials, that requires no further processing and that is packaged for sale to pharmacies, qualifying patients and primary caregivers.
Owner's Managing Officer – the person designated by the organization owning the pharmacy to be responsible to the board for the proper operation of the pharmacy in compliance with all applicable laws and regulations.
Pharmaceutical Grade Marijuana – marijuana or marijuana products that are not adulterated and are:

a. Processed, packaged and labeled according to the United States Food & Drug Administration's "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements" as found in 21 CFR 111 or its successor;
b. Labeled with the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis, and a pesticide chemical residue analysis which have been completed on a batch basis by a laboratory; and
c. Where each step of the production, cultivating, trimming, curing, manufacturing, processing, and packaging method has been documented by using standard operation procedures approved by the Commissioner of the Department of Agriculture and Forestry.

Pharmacist – an individual currently licensed by the board to engage in the practice of pharmacy.
Pharmacy Technician – an individual who assists in the practice of pharmacy under the direct and immediate supervision of a licensed pharmacist and is currently certified to do so by the board.
Physician – an individual currently licensed by the state Board of Medical Examiners to engage in the practice of medicine.
Prescription Monitoring Program (PMP) – the electronic prescription drug monitoring program established by La. R.S. 40:1001 *et seq*.
Producer – a person licensed by the Department of Agriculture and Forestry to cultivate marijuana for therapeutic use.
Production or *Produce* – the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, compounding, conversion or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of marijuana by a patient or caregiver for the patient's use.

Production Facility – a secure facility where the production of marijuana occurs and that is operated by a person to whom the Department of Agriculture and Forestry has issued a producer license.
Sale – any form of delivery, which includes barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor, agent, servant, or employee.
Usable Marijuana – the dried leaves and flowers of the marijuana plant, and any mixtures or preparations of such leaves and flowers, that are appropriate for the therapeutic use of marijuana, but does not include the seeds, stalks, and roots of the marijuana plan.

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§2443. Marijuana Products

A. Exclusive Source.
   1. The exclusive source of marijuana products shall be the producer licensed for that activity by the Department of Agriculture and Forestry (LDAF).
   2. That producer shall prepare pharmaceutical grade marijuana products for distribution to the marijuana pharmacies licensed by the board.
   3. Marijuana products from any other source shall be deemed misbranded and/or adulterated and shall not be distributed to any marijuana pharmacy, nor may such misbranded and/or adulterated products be dispensed by any marijuana pharmacy.

B. Laboratory Testing.
   1. Prior to manufacturing any marijuana product, the producer shall segregate all harvested marijuana into homogenized batches.
   2. A producer shall make available each such batch at the production facility for testing by a laboratory approved by LDAF. The laboratory employee shall select a random sample from each batch.
      a. Medical marijuana concentrate shall not be used to produce any form of product until it has passed all analysis limits for:
         i. Active ingredient analysis for characterization of potency;
         ii. Pesticide active ingredients, including but not limited to, the most recent list of targeted pesticides published by LDAF;
         iii. Residual solvents;
         iv. Heavy metals; and
         v. Mycotoxins.
      b. Product shall not be released for delivery to a pharmacy for sale or consumption until it has passed all analysis limits for:
         i. Microbiological contaminants;
         ii. Active ingredient analysis for accuracy of potency; and
         iii. Homogeneity.
      c. LDAF personnel may select a random sample at any point in the process for the purpose of analysis for anything the LDAF deems necessary.
      d. Samples shall be secured in a manner approved by LDAF at all times when not in immediate use for the analyses being conducted.
   3. From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a pharmacy until the laboratory provides the results from its tests and analyses, the producer shall segregate and withhold from use the entire batch with the exception of the samples removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a pharmacy prior to the time the laboratory has completed its testing and analysis and provided those results, in written or electronic form, to the producer or the producer's designated employee.
   4. Testing Specifications
      a. With respect to the microbiological test, a marijuana sample shall be deemed to have passed if it satisfies the recommended microbial and fungal limits for cannabis products as follows:
         i. Total yeast and mold: < 10,000 colony-forming units per gram (CFU/g); and
         ii. E. coli (pathogenic strains) and Salmonella *spp*: < 1 CFU/g.
      b. With respect to the mycotoxins test, a marijuana sample shall be deemed to have passed if it meets the following standards:

i. Aflatoxin b1 < 20 parts per billion (ppb);
ii. Aflatoxin b2 < 20 ppb;
iii. Aflatoxin g1 < 20 ppb;
iv. Aflatoxin g2 < 20 ppb; and
v. Ochratoxin < 20 ppb.

c. With respect to the heavy metals test, a marijuana sample shall be deemed to have passed if it meets the following standards:
   i. Arsenic < 10 parts per million (ppm);
   ii. Cadmium < 4.1 ppm;
   iii. Lead < 10 ppm; and
   iv. Mercury < 2 ppm

d. With respect to the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the United States Environmental Protection Agency's "Tolerances and Exemptions for Pesticide Chemical Residues in Food", as found in 40 CFR 180 or its successor.

e. With respect to the residual solvent test, a marijuana sample shall be deemed to have passed if the following solvents are below the listed limits:
   i. Butanes < 800 ppm;
   ii. Heptanes < 500 ppm;
   iii. Benzene < 1 ppm;
   iv. Toluene < 1 ppm;
   v. Hexanes < 10 ppm;
   vi. Total Xylenes < 1 ppm; and
   vii. Ethanol < 5,000 ppm.

f. With respect to the test for homogeneity, a marijuana sample shall be deemed to have failed if 10 percent of the sample contains more than 20 percent of the total active ingredient.

g. Every sample shall undergo an active ingredient analysis or potency analysis.
   i. For medical marijuana concentrate samples, the potency test is to establish the presence of active ingredients and their concentrations for accurate calculations of amounts needed for the production of products. The analysis must identify the following substances:
      (a) THC (tetrahydrocannabinol);
      (b) THCA (tetrahydrocannabinolic acid);
      (c) CBD (cannabidiol); and
      (d) CBDA (cannabidiolic acid).
   ii. For product samples, the potency test is to establish the active ingredient composition for verification of labeling to ensure accurate dosing. The maximum variance permitted is 15 percent from the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligrams THC.

5. Procedures for Sample Failures

a. In the event a medical marijuana concentrate sample fails testing for pesticides, heavy metals or mycotoxin, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.

b. In the event a medical marijuana concentrate sample fails residual solvent testing, then, with prior approval of LDAF, the product may be subjected to an appropriate remedy, e.g., vacuum drying, reformulated and tested again. The reformulation must pass all required tests for a medical marijuana concentrate in duplicate before it can be released for use in products. If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF. A batch of medical marijuana concentrate can only be reformulated once and only to remedy excessive residual solvents.

c. In the event a product fails the microbiological testing, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.

d. In the event a product fails the potency or homogeneity testing, then, with prior approval of LDAF, the product can be re-sized and tested again. The reformulated product shall be tested again in duplicate and pass all required tests before it can be released for sale or consumption. If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF.

6. In the event of any test failure, the laboratory shall transmit to LDAF an electronic copy of such test result at the same time it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results including all relevant chromatograms and quality control documentation for at least five years and make them available to LDAF at its request.
7. The laboratory shall dispose of any remaining medical marijuana concentrate or product samples no sooner than 60 days following the completion of any testing, in compliance with the disposal rules promulgated by LDAF.
8. A producer shall provide the laboratory test results to the marijuana pharmacy for each batch of marijuana used in a product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and physicians who recommended such marijuana products dispensed to their patients.

C. Product Dosage Forms.
1. The producer shall limit their production of pharmaceutical grade marijuana products to the following dosage forms:
   a. Oils, extracts, tinctures, or sprays;
   b. Solid oral dosage forms, e.g., capsules or pills;
   c. Liquid oral dosage forms, e.g., solutions or suspensions;
   d. Gelatin-based chewables;
   e. Topical applications, oils or lotions;
   f. Transdermal patches; or
   g. Suppositories.
2. No marijuana product shall:
   a. Include alcoholic liquor, dietary supplements, or any drug, except for pharmaceutical grade marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than 0.5 percent of alcohol by volume, or ethanol-based tinctures;
   b. Be manufactured or sold as a beverage;
   c. Be manufactured or sold in a form or with a design that:
      i. Is obscene or indecent;
      ii. May encourage the use of marijuana for recreational purposes;
      iii. May encourage the use of marijuana for a condition other than a debilitating medical condition; or
      iv. Is customarily associated with persons under the age of 18 years; or
   d. Have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved by the Commissioner of LDAF.
3. Any marijuana product not in compliance with the provisions of this Paragraph shall be deemed adulterated.

D. Packaging and Labeling Requirements.
1. Packaging.
   a. The producer shall ensure every product intended for dispensing to a patient is placed within a child-resistant, light-resistant, tamper-evident container prior to sale or transport to the pharmacy.
      i. A package shall be deemed child-resistant if it satisfies the standard for 'special packaging' as set forth in the United States Consumer Product Safety Commission's "Poison Prevention Packaging" as found in 16 CFR 1700.1(b)(4) or its successor.
      ii. A package shall be deemed light-resistant if it satisfies the standard set forth in "Chapter 671 – Containers: Performance Testing" of the *United States Pharmacopeia* (USP).
      iii. A package shall be deemed tamper-evident if it clearly indicates prior access to the container.
   b. Any product containing pharmaceutical grade marijuana or its principal psychoactive constituent tetrahydrocannabinol (THC) shall be packaged so that one dose contains no more than 10 milligrams of THC.
   c. If it is not intended for the entire product to be used at a single time, the packaging must be re-sealable in a manner that maintains its child-resistant property for multiple openings. Single doses may be placed in a package with other single doses; however, the total amount of active THC contained within the larger packaging shall not exceed 100 milligrams.
   d. No single container shall contain more than a one month supply of marijuana.
   e. Packaging selected by the producer shall be subject to the following restrictions.
      i. Shall not specifically target individuals under the age of 18 years;

ii. Shall not bear any resemblance to a trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;
iii. Shall not use the words “candy” or “candies”;
iv. Shall not use a cartoon, color scheme, image, graphic or feature that might make the package attractive to children; and
v. Shall not use a seal, flag, crest, coat of arms or other insignia that could reasonably lead any person to believe the product has been endorsed, manufactured by, or used by any state, parish, municipality, or any agent thereof.

2. Labeling.
   a. Each product shall be labeled by the producer prior to its sale to the marijuana pharmacy. Each label shall be securely affixed to the package and shall include, at a minimum:
      i. The batch or lot number assigned by the producer to the marijuana plant(s) from which the marijuana used in the product was harvested;
      ii. A complete list of solvents, chemicals, and pesticides used in the creation of any marijuana concentrate;
      iii. A complete list of all ingredients used to manufacture the product, which may include a list of any potential allergens contained within, or used in the manufacture of, a product;
      iv. The potency of the THC and CBD in the product, expressed in milligrams for each cannabinoid;
      v. The net weight, using a standard of measure compatible with the LMMTS, of the product prior to its placement in the shipping container;
      vi. A product expiration date, upon which the product will no longer be fit for use. Once a label with an expiration date has been affixed to a product, the producer shall not alter that date or affix a new label with a later date; and
      vii. A statement the product has been tested for contaminants, that there were no adverse findings, and the date of such testing.
   b. The labeling text on any marijuana product shall not make any false or misleading statements regarding health or physical benefits to the consumer. Further, each label shall include all of the following statements:
      i. “Contains Marijuana. For Medical Use Only. KEEP OUT OF THE REACH OF CHILDREN.”
      ii. “Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug.”
      iii. “There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning to become pregnant.”
      iv. A statement that it is illegal for any person to possess or consume the contents of the package other than the patient for whom it was recommended.
   c. The labeling text required by this Section shall be no smaller than 1/16 of an inch, shall be printed in English, and must be unobstructed and conspicuous.
   d. The producer may utilize a package insert which is enclosed or attached to the product container to provide the information required in this Section. If the producer elects to use such supplementary labeling, the label affixed to the outer surface of the product container shall contain the following information, at a minimum
      i. the batch or lot number referenced at Clause D.2.a.i of this Section;
      ii. the potency of the THC and CBD referenced at Clause D.2.a.iv of this Section;
      iii. the net weight referenced at Clause D.2.a.v of this Section;
      iv. the expiration date referenced at Clause D.2.a.vi of this Section; and
      v. the caution statement referenced at Clause D.2.b.i of this Section.

E. Distribution of Marijuana Products to Marijuana Pharmacies.
   1. The producer shall maintain complete inventory records in the Louisiana Medical Marijuana Tracking System (LMMTS), as required and delineated in rules promulgated by LDAF.
   2. The producer shall maintain comprehensive records in LMMTS of all marijuana products distributed to the marijuana pharmacies, whether by transport and delivery to the pharmacy or by transfer to the agent of the pharmacy at the production facility.
   3. In the event the producer delivers the products to the pharmacy, such activities must be in compliance with the rules for that activity promulgated by LDAF.
   4. In the event the pharmacy elects to send an agent to the production facility to retrieve products ordered by the pharmacy, the personnel at the production facility shall verify the identity and credentials of the pharmacy’s agent before releasing the products to the agent.

a. The producer shall provide a copy of the transport manifest generated by LMMTS, which shall contain the following information:
   i. The name and address of the producer selling the product;
   ii. The name and address of the pharmacy purchasing the product;
   iii. The name and quantity (by weight or unit) of marijuana products included in the delivery;
   iv. The date of transport and time of departure from the production facility;
   v. The make, model, and license plate number of the delivery vehicle;
   vi. The date and time of arrival at the pharmacy; and
   vii. The name and signature of the pharmacy's agent.
b. The pharmacy's agent shall compare the transport manifest to the products transferred to his possession, and when correct, shall return a signed copy of the manifest to the producer before departing from the production facility.
c. The pharmacy's agent shall place the products in a locked, safe, and secure storage compartment that is part of the motor vehicle, or in the alternative, in a locked storage container that has a separate key or combination pad, and further, the product shall not visible or recognizable from outside the vehicle, and further, the vehicle shall not bear the name of the pharmacy or any markings to indicate the vehicle contains marijuana
d. The pharmacy's agent shall maintain physical control of the vehicle at all times during the transport, and shall not leave the vehicle unattended at any time.
e. The pharmacy's agent shall have access to a secure form of communication with the pharmacy as well as the ability to contact law enforcement through the 911 emergency system.
f. Upon arrival at the pharmacy, the pharmacy's agent shall deliver the product to a pharmacist for verification of receipt; the pharmacist shall time, date, and sign the delivery manifest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017).

§2445. Marijuana Pharmacy Permit

A. The board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit.
B. The dispensing of marijuana for therapeutic purposes shall be limited to those pharmacies holding a marijuana pharmacy permit issued by the board, and only when that permit is in active or restricted status.
C. When issued to a successful applicant, the permit will authorize the operation of a marijuana pharmacy in compliance with the provisions of this Subchapter.
D. When the permit is issued, it shall be valid only for the owner and the specific location noted on the application and recorded on the permit.
E. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event the ownership of the organization that acquired the permit changes by 50 percent or more, then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy permit owner continuing to operate a marijuana pharmacy after its ownership has changed by 50 percent or more without obtaining a new marijuana pharmacy permit shall be deemed guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221.
F. Although a change of ownership of less than 50 percent shall not require a new pharmacy permit, any proposed change of ownership shall require prior notice to the board, and further, approval by the board.
G. The board shall not have more than 10 active marijuana pharmacy permits at any given time. To facilitate compliance with that legislative restriction, the board recognizes the nine regions previously declared by the Department of Health, to wit:
   1. *Metropolitan*, composed of the parishes of Jefferson, Orleans, Plaquemines, and St. Bernard;
   2. *Capitol*, composed of the parishes of Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, West Baton Rouge, and West Feliciana;
   3. *Teche*, composed of the parishes of Assumption, Lafourche, St. Charles, St. James, St. John, St. Mary, and Terrebonne;
   4. *Acadian*, composed of the parishes of Acadia, Evangeline, Iberia, Lafayette, St. Landry, St. Martin, and Vermilion;
   5. *Southwest*, composed of the parishes of Allen, Beauregard, Calcasieu, Cameron, and Jefferson Davis;

6. *Central*, composed of the parishes of Avoyelles, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon, and Winn;
7. *Northwest*, composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster;
8. *Northeast*, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, and West Carroll; and
9. *Southeast*, composed of the parishes of Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington.

H. To achieve an equitable distribution of the marijuana pharmacy permits across the state, the board shall reserve one marijuana pharmacy permit for each of the nine regions identified above. In the event the board is convinced of the need for a second permit in one region, it may issue that permit following the procedures identified in this Subchapter. Further expansion will require a legislative amendment of the original restriction.

I. When the board is prepared to receive and process applications for and issue marijuana pharmacy permits, it shall publish on its internet web site, and in such other places as the board deems appropriate, a notice to that effect. Such notice shall include, but not be limited to:
1. The maximum number of permits to be awarded;
2. Information on how to obtain an application;
3. The deadline for receipt of applications;
4. Acceptable methods for submitting an application;
5. The preferred locations, if any, for the marijuana pharmacy permits; and
6. The criteria that shall be considered in awarding the marijuana pharmacy permits.

J. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and award marijuana pharmacy permits on a competitive basis based on the criteria set out in the notice for applications. In the event the board determines there are an insufficient number of qualified applicants to award all of the marijuana pharmacy permits the board has determined are desirable, the board may republish, in accordance with this Section, a notice of open applications for marijuana pharmacy permits.

K. The board shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.

L. The board shall have the right to cancel a notice of open applications prior to the award of a marijuana pharmacy permit.

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HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1543 (August 2017).

§2447. Licensing Procedures

A. Application for Initial Issuance of Permit
1. The board shall develop an application form suitable for the marijuana pharmacy permit. The board may revise that application form on its own initiative in order to collect the information it deems necessary to properly evaluate an applicant.
2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
3. The applicant shall fully disclose the ownership of the entity that will own the permit as well as any additional holding companies that may exist, such that any natural person with any ownership interest shall be fully identified.
4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
   a. Within the two-year period preceding the date of the application, the person or any member of the person's immediate family served as a member of the board or its staff.
5. The applicant shall provide a complete street address reflecting the location at which the applicant proposes to operate the marijuana pharmacy.
6. The applicant shall provide the following information and records in the application process:
   a. A detailed description of any other services or products to be offered by the marijuana pharmacy;
   b. Details regarding the applicant's plans to maintain adequate control against the diversion, theft, or loss of marijuana;

c. Documents or information sufficient to establish the applicant is authorized to conduct business in Louisiana and that all applicable state and local building, fire and zoning requirements, and local ordinances will be met;
d. Text and graphic materials showing the exterior appearance of the proposed marijuana pharmacy and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;
e. A blueprint of the proposed marijuana pharmacy which shall, at a minimum, show and identify:
    i. The square footage of the area which will constitute the prescription department;
    ii. The square footage of the overall marijuana pharmacy;
    iii. The square footage and location of areas used as storerooms or stockrooms;
    iv. The size of the counter that will be used for the dispensing and sale of marijuana;
    v. The location of the marijuana pharmacy sink and refrigerator, if any;
    vi. The location of all approved safes and vaults that will be used to store marijuana;
    vii. The location of the toilet facilities;
    viii. The location of the break room and location of lockers for personal belongings;
    ix. The location and size of the patient counseling area(s);
    x. The location(s) where any other products or services will be offered; and
    xi. The location of all areas that may contain marijuana showing the location of walls, partitions, counters, and all areas of ingress and egress.
f. Such other documents and information reasonably required by the board to determine the applicant's suitability for permitting or to protect the public's health and safety.

7. The owner's managing officer and the pharmacist-in-charge shall be fully identified within the application and they both shall sign and date the application form.
8. The applicant shall direct the following persons to submit to the criminal history record check process used by the board, at the applicant's expense:
    a. The owner's managing officer;
    b. The pharmacist-in-charge; and
    c. Any person holding any share of ownership in the entity; provided however that any person not holding any share of ownership but holding a corporate officer position in the entity may be required to submit to the criminal history record check.
9. The requirement for a criminal history record check may be waived by the board in the event the person has already completed that process for the board within the two-year period prior to the date of the application.
10. The applicant shall supplement the application form with sufficient documentation of the applicant's financial capacity to properly operate a marijuana pharmacy, including but not limited to, evidence of his escrow account, letter of credit, or surety bond of at least $100,000 in a financial institution headquartered in Louisiana.
    a. The pharmacy's $100,000 escrow account, letter of credit, or surety bond shall be payable to the board in the event the board determines after a due process hearing that the pharmacy has failed to timely and successfully complete the construction of the pharmacy or to operate such pharmacy in compliance with the provisions of this Subchapter.
    b. The board shall permit the pharmacy's escrow account, letter of credit, or surety bond to be reduced by $25,000 upon the successful achievement of each of the following milestones:
        i. A determination by the board that the pharmacy is fully operational and able to commence and has begun dispensing of marijuana as provided in this Subchapter;
        ii. A determination by the board that the pharmacy remained operational and without substantial interruption and without any violation of law or regulation for a one year period; and
        iii. A determination by the board that the pharmacy remained operational and without substantial interruption and without any violation of law or regulation for a second one year period.
        iv. The pharmacy shall maintain the escrow account, letter of credit, or surety bond for a minimum of $25,000 for the remainder of its operation.
    c. In the event a pharmacy voluntarily chooses not to renew the pharmacy permit and follows proper closure procedures, the board shall extinguish the obligations under the escrow account, letter of credit, or surety bond at the end of the permit's term.
11. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and

provide corrected information in a timely manner so as not to disrupt the application processing or permit selection process.

12. The board may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a marijuana pharmacy. The board may verify the information and assess the applicant's character and fitness by, among other actions:
    a. Contacting the applicant by telephone, electronic mail, mail, or such other means as is reasonable under the circumstances;
    b. Conducting one or more on-site visits of the location for the proposed marijuana pharmacy, or other pharmacies associated with the applicant or any of the applicant's owners;
    c. Conducting background checks or contacting references of the applicant, its managing officer, any of the corporate officers, or any shareholder, as well as the pharmacist-in-charge;
    d. Contacting state regulators in any other states where the applicant, the applicant's owners or corporate officers, or its pharmacist-in-charge are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; or
    e. Requiring a personal meeting with the owner's managing officer and the pharmacist-in-charge and the submission of additional information or documents.
13. The application shall be accompanied by payment of the permit fees and administrative hearing fee authorized by R.S. 37:1184 and 40:1013.
14. When the staff has determined an entity's application package is complete, the application shall be referred to the board's Application Review Committee, and further, the applicant shall be properly notified at least 30 days prior to the committee's hearing during which their application will be considered.
15. During the hearing held by the board's Application Review Committee, the members shall consider, but are not limited to, the following criteria when evaluating an application for a marijuana pharmacy permit:
    a. The character and fitness of the owner's managing officer, the pharmacist-in-charge, any of the owners and any other person who may have control or influence over the operation of the proposed marijuana pharmacy;
    b. The location for the proposed marijuana pharmacy including, but not limited to:
        i. Its proximity to previously approved marijuana pharmacies or locations of proposed marijuana pharmacies with pending applications;
        ii. Whether the patient population in the area proposed by the marijuana pharmacy permit applicant justifies the need for a marijuana pharmacy, or an additional marijuana pharmacy, in that area;
        iii. Whether the proximity of the proposed marijuana pharmacy will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment; or
        iv. Whether the number of marijuana pharmacies in the locality is such that the granting of a permit is detrimental to the public interest. In reaching a conclusion in this respect, the board may consider the population of, the number of like permits and number of all - permits existent in, the particular municipality and the immediate neighborhood concerned, the effect that a new permit may have on such town or neighborhood or on like permits existent in such municipality or neighborhood.
    c. The applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana;
    d. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of marijuana; and
    e. The extent to which the applicant or any of the applicant's owners have a financial interest in any other permittee, licensee, registrant, or other applicant currently or previously credentialed by the board; and
    f. Any other reason provided by any federal law or rule or state law or rule that is not inconsistent with R.S. 40:1046 or 40:1047 or this Subchapter.
16. Following their evaluation of the applications for a marijuana pharmacy permit, the committee shall develop a recommendation for presentation to the board at the board's next meeting. The board may accept the committee's recommendation, select an alternative applicant, reject all of the applicants, or return all the applicants to the committee for their reconsideration.

17. The board may disqualify any applicant who:
    a. Submits an incomplete, false, inaccurate, or misleading application;
    b. Fails to submit an application by the published deadline; or
    c. Fails to pay all applicable fees.
18. The decision of the board to award or not to award a marijuana pharmacy permit to an applicant shall be final.
19. Upon the approval of an application, the board shall issue the marijuana pharmacy permit and state controlled dangerous substance license to the applicant.
20. If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation of such pharmacy within 310 days of being notified of the marijuana pharmacy permit award, the board may, in the board's discretion, rescind such marijuana pharmacy permit, unless such delay was caused by force majeure. A marijuana pharmacy shall be deemed to have commenced operation if the pharmacy is capable of operating in accordance with the applicant's approved application. In the event a marijuana pharmacy permit is rescinded pursuant to this Subsection, the board shall award a marijuana pharmacy permit by selecting among the qualified applicants who applied for the marijuana pharmacy permit that was rescinded. If no other qualified applicant applied for such marijuana pharmacy permit or satisfied the criteria for awarding a permit, the board shall publish, in accordance with this Section, a notice of open applications for marijuana pharmacy permits.

B. Application for Renewal of Permit
    1. All marijuana pharmacy permits expire at midnight on December 31 of every year, regardless of the date of its initial issuance.
    2. The owner's managing officer and pharmacist-in-charge of the marijuana pharmacy permit shall complete, sign and date a permit renewal application form supplied by the board, and further, shall include all information requested on the form and attach the pharmacy permit renewal fee and state controlled dangerous substance license renewal fee authorized in R.S. 37:1184 and the prescription monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application package to the board office prior to the expiration date of the pharmacy permit.
    3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
    4. In the event the pharmacy does not submit a properly completed renewal application form and fee to the board prior to the expiration of the permit, the permit shall be rendered null and void. A marijuana pharmacy shall not operate with an expired permit. Evidence it has done so will provide sufficient basis for the board to discipline the permit for violation of R.S. 37:1241(12).
    5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is received in the board office no later 30 thirty days after the expiration date of the permit may be processed by the board staff, provided the appropriate delinquent fee authorized in R.S. 37:1184 is included with the application.
    6. A marijuana pharmacy permit not renewed by 30 days after the expiration date shall be automatically terminated by the board.
    7. An application for the reinstatement of a terminated marijuana pharmacy permit shall be referred to the board's Reinstatement Committee for its consideration.

C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits
    1. The applicant shall complete an application form for this specific purpose supplied by the board; the application shall require the inclusion of the annual renewal fee, the delinquent fee, the administrative hearing fee, and the reinstatement fees authorized in R.S. 37:1184 and the program fee authorized in R.S. 40:1013.
    2. An application for the reinstatement of a marijuana pharmacy permit previously terminated, suspended or revoked by the board may only be approved following a preliminary hearing to determine whether the reinstatement of the permit is in the public's best interest.

D. Maintenance of Marijuana Pharmacy Permit
    1. A marijuana pharmacy permit is valid only for the entity or person to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the business location recorded thereon.
    2. A duplicate or replacement permit shall be issued upon the written request of the licensee and payment of the fee authorized in R.S. 37:1184. A duplicate or replacement license shall not serve or be used as an additional or second license.

3. Prior to any person affiliating with a marijuana pharmacy, including any change in the ownership of the permit, such person shall comply with the credentialing requirements of the board. No person shall commence their affiliation with a marijuana pharmacy until approved by the board.
4. Prior to making any change in the marijuana pharmacy's name or trade name, the owner of the permit shall notify the board and request approval of the contemplated name or trade name. The board shall reasonably accommodate such requests, unless there is cause not to do so, e.g., duplicative or misleading names. The marijuana pharmacy shall not change its name or trade name until approved by the board.
5. Prior to any modification, remodeling, expansion, reduction, other physical, non-cosmetic alteration of the marijuana pharmacy, the owner of the permit shall notify the board and request approval of the contemplated change(s). The board shall reasonably accommodate such request, unless there is cause not to do so, e.g., inconsistent with operating requirements. The marijuana pharmacy shall not make such changes until approved by the board.
6. Prior to any change in the location of a marijuana pharmacy, the owner of the permit shall submit an application form for that purpose supplied by the board and pay the appropriate fee authorized in R.S. 37:1184. The board may require an inspection of the new location prior to the issuance of the permit for the new location. No marijuana pharmacy shall commence operation in a new location until approved by the board.
7. The owner of the pharmacy permit shall notify the board no later than 10 days following a change in the pharmacist-in-charge for the marijuana pharmacy permit.
8. The owner of the pharmacy permit shall notify the board no later than 10 days following a change in the owner's managing officer for the marijuana pharmacy permit.
9. In the event a marijuana pharmacy contemplates permanent closure, the pharmacist-in-charge shall notify the board in accordance with the rules governing the permanent closure of a pharmacy as described in Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1544 (August 2017).

§2449. Marijuana Pharmacy Personnel; Therapeutic Marijuana Designation

A. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.
B. The owner's managing officer and all persons holding a professional credential from the board shall first obtain a Therapeutic Marijuana (TM) designation from the board before affiliating with a marijuana pharmacy.
C. The board may issue a TM designation to a person who has filed the application for that designation supplied by the board and has completed a criminal background check for the board within the two-year period prior to the date of the application for the TM designation, and that person:
   1. Has been listed as an owner's managing officer on an application for a marijuana pharmacy permit, or on a request to become a replacement owner's managing officer for an existing marijuana pharmacy permit; or
   2. Holds one of the following professional credentials issued by the board (pharmacist, pharmacy intern, or certified pharmacy technician) and further, that professional credential was issued by the board at least two years prior to the date of the application for the TM designation, is in active status and has not been disciplined by the board within the two-year period prior to the date of the application for the TM designation.
D. The board may restrict, suspend, or revoke a TM designation for cause, but only pursuant to the Administrative Procedure Act.
E. No pharmacist, pharmacy intern, or certified pharmacy technician may practice within a marijuana pharmacy in the absence of an active professional credential, an active TM designation, as well as access privileges to the state prescription monitoring program. A pharmacist may elect to not allow a pharmacy intern or pharmacy technician to function as his delegate with respect to access privileges to the state prescription monitoring program, but the pharmacist shall have such access. A pharmacy technician candidate shall not practice in a marijuana pharmacy.
F. A pharmacist shall first acquire a Pharmacist-in-Charge (PIC) privilege, as described in §1105 of this Part, and the TM designation, as described in this Section, before accepting an appointment as the PIC of a marijuana pharmacy.
   1. The PIC of the marijuana pharmacy shall comply with the requirements of §1105 of this Part.

2. The PIC shall be responsible for notice to the board of all pharmacists, pharmacy interns, and pharmacy technicians practicing at the marijuana pharmacy. The PIC shall cause such notice to be received in the board office in written form (mail, fax, or electronic mail) no later than 10 days after the arrival or departure of the pharmacist, pharmacy intern, or pharmacy technician.

G. The PIC shall insure and document the initial and continuing competency of the entire professional staff to provide the pharmacy care services rendered at the marijuana pharmacy. At a minimum, the PIC shall provide access to education and training in the following domains:
   1. Policies and procedures of the pharmacy, especially those relating to the tasks and functions that employee is expected to perform;
   2. Professional conduct, ethics, and patient confidentiality; and
   3. Developments in the therapeutic use of marijuana.

   Further, the PIC shall document such education and training, provide such records to the board when requested, and retain such records for at least two years after the employee disassociates with the pharmacy.

H. The PIC shall comply with the professional supervision rules and ratios found in Chapter 7 (pharmacy interns) and Chapter 9 (pharmacy technicians) of this Part.

I. In addition to the scope of practice limitations found in Chapter 9 of this Part, pharmacy technicians practicing in a marijuana pharmacy shall not:
   1. Consult with a patient or the patient's caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or regarding any medical information contained in a patient medication record;
   2. Consult with the physician who issued the recommendation/prescription/order for marijuana to the patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;
   3. Interpret the patient's clinical data or provide medical advice;
   4. Perform professional consultations with physicians, nurses, or other health care professionals or their authorized agents; or
   5. Determine whether a different brand or formulation of marijuana should be dispensed for the marijuana product or formulation recommended/prescribed/ordered by the physician or requested by the patient or his caregiver.

AUHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1546 (August 2017).

§2451. Operation of Marijuana Pharmacy

A. No person may operate a marijuana pharmacy without a marijuana pharmacy permit issued by the board, and further, that permit shall be in active or restricted status. A pharmacist shall be on duty at all times during the regular open hours of the marijuana pharmacy.

B. A marijuana pharmacy shall not dispense marijuana from, obtain marijuana from, or transfer marijuana to, a location outside of the state of Louisiana.

C. A marijuana pharmacy shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:
   1. It may acquire marijuana from an authorized producer pursuant to the provisions of R.S. 40:1046; and
   2. It may dispense and sell marijuana to a patient with a recommendation/prescription/order for such marijuana or the patient's caregiver.

D. No person at a marijuana pharmacy shall provide marijuana samples.

E. A marijuana pharmacy shall sell marijuana products only in a secure and light-resistant container. Nothing herein shall preclude a pharmacist from compounding a marijuana product appropriate for his patient.

F. Only a pharmacist may dispense marijuana, and only a pharmacist, pharmacy intern, or pharmacy technician may sell marijuana to patients and caregivers. A pharmacy intern or pharmacy technician may assist, under the direct supervision of a pharmacist, in the dispensing of marijuana.

G. A marijuana pharmacy shall place all products sold to the patient or caregiver in an opaque package that shall not indicate the contents of the package, the originating facility or in any other way cause another person to believe that the package may contain marijuana.

H. A marijuana pharmacy shall not permit any person to enter the prescription department unless that person's responsibilities necessitate access to the department and then for only as long as necessary to perform the person's job duties.

I. While inside the pharmacy, all pharmacy employees shall wear name tags or similar forms of identification that clearly identify them to the public, including their position at the pharmacy.

J. A marijuana pharmacy shall be open for qualifying patients and primary caregivers to purchase marijuana products for a minimum of 10 hours per week.

1. A marijuana pharmacy that closes during its normal hours of operation shall implement procedures to notify patients and caregivers of when the marijuana pharmacy will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs.
2. In the event the pharmacist on duty leaves the prescription department, the prescription department shall comply with the provisions of §1109 (temporary absence) or §1111 (closure) of this Part.

K. A marijuana pharmacy shall provide information to patients and caregivers regarding the possession and use of marijuana. Such informational material shall include information related to:

1. Limitations on the right to possess and use marijuana pursuant to R.S. 40:1046;
2. Safe techniques for proper use of marijuana and paraphernalia;
3. Alternative methods and forms of consumption by which one can use marijuana;
4. Signs and symptoms of substance abuse; and
5. Opportunities to participate in substance abuse programs.

L. The marijuana pharmacy shall establish, implement and adhere to a written alcohol-free, drug-free and smoke-free work place policy, which shall be available to the board upon request.

M. The receipt of all deliveries from producers shall be carried out under the direct supervision of a pharmacist who shall be present to accept the delivery. Upon delivery, the marijuana shall immediately be placed in an approved safe or approved vault within the pharmacy where marijuana is stored.

N. No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications, durable medical equipment (DME), and other retail products from the same premises but outside the prescription department.

O. No marijuana shall be administered on the premises of a marijuana pharmacy, except during patient counseling, education or training.

P. No person associated with a marijuana pharmacy shall enter into any agreement with a physician or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the marijuana pharmacy at which the patient or caregiver will purchase marijuana.

Q. No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a marijuana pharmacy, except that a caregiver may deliver marijuana to the caregiver's patient.

R. No marijuana shall be sold when the marijuana pharmacy is closed and not open for business.

S. Board representatives, local law enforcement or other federal, state or local government officials may enter any area of a marijuana pharmacy if necessary to perform their governmental duties.

T. Right of inspection. The board, or its agent, representative, or designee, is authorized:

1. To enter a marijuana pharmacy at any time during its hours of operation, or any other place, including a vehicle, wherein marijuana is held, dispensed, sold, or otherwise disposed of;
2. To inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein, including records, files, financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls and facilities; and
3. To inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished material.

U. Inspection of records. Every person required to prepare, obtain or keep records, logs, reports or other documents, and every person in charge, or having custody, of such documents shall maintain such documents in an auditable format for no less than two years. Upon request, such person shall make such documents immediately available for inspection and copying by the board or its authorized representative. In complying with this Section, no person shall use a foreign language or codes or symbols to designate marijuana types or persons in the keeping of any required document.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1547 (August 2017).

§2453. Security Requirements for Marijuana Pharmacies

A. A marijuana pharmacy shall:

1. Store all marijuana in an approved safe or vault, as defined in this Subchapter, and in such a manner as to prevent diversion, theft, or loss;
2. Maintain all marijuana in a secure area or location accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;
3. Not permit any person less than 18 years of age to enter the prescription department, with the exception of patients being counseled by the pharmacist;
4. Keep all approved safes and vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana;
5. Keep all locks and security equipment in good working order;
6. Not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;
7. Not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees;
8. Keep the pharmacy securely locked and protected from entry by unauthorized employees;
9. Keep the outside perimeter of the pharmacy premises well-lit; and
10. Post a sign at all entry ways into any area of the pharmacy containing marijuana, including a room with an approved safe or vault, which sign shall be a minimum of twelve inches in height and twelve inches in width which shall state: "Do Not Enter – Limited Access Area – Access Limited to Authorized Employees Only" in lettering no smaller than one-half inch in height.

B. All pharmacies shall have an adequate security system to prevent and detect diversion, theft or loss of marijuana utilizing commercial grade equipment, which shall include at a minimum:
1. A perimeter alarm;
2. Motion detector;
3. Video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The pharmacy shall direct cameras at all approved safes and vaults, dispensing areas, marijuana sales areas and any other area where marijuana is being stored or handled. At entry and exit points, the pharmacy shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the pharmacy.
4. 24-hour recordings from all video cameras, which the pharmacy shall make available for immediate viewing by the board or its authorized representative upon request and shall retain for at least thirty days. If a pharmacy is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the pharmacy shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmacy that it is not necessary to retain the recording.
   a. All video recordings shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that ban be played on a standard computer operating system. A pharmacy shall erase all recordings prior to disposal or sale of the pharmacy.
5. Duress alarm, which for purposes of this Subsection means a silent security alarm system signal generated by the entry of a designated code in into an arming station in order to signal that the alarm user is being forced to turn off the system.
6. Panic alarm, which for purposes of this Subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;
7. Holdup alarm, which for purposes of this Subsection means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;
8. Automatic voice dialer, which for purposes of this Subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;
9. A failure notification system that provides an audible, text or visual notification of any failure in

the surveillance system. The failure notification system shall provide an alert to the pharmacy within five minutes of the failure, either by telephone, email, or text message;

10. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);
11. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and
12. The ability to remain operational during a power outage.

C. A pharmacy shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations.
   1. A pharmacy shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.
   2. A pharmacy shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, and the board's authorized representative.
   3. A pharmacy shall make available to the board upon request a current list of authorized employees and service employees that have access to the surveillance room.

D. A pharmacy shall keep all security equipment in good working order and shall test such equipment no less than two times per year.

E. When a pharmacy presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to, or actual, diversion, theft or loss, the board may require additional safeguards, including but not limited to, a supervised watchman service.

F. Any marijuana not stored in compliance with this Section, or stored at a location other than that for which the pharmacy permit was issued, shall be subject to embargo or seizure by the board.

G. In the event any marijuana pharmacy permit is revoked, suspended, or not renewed, the pharmacy shall dispose of its entire stock of marijuana in accordance with the disposal provisions in this Subchapter.

H. If a pharmacy has provided other safeguards which can be regarded in total as an adequate substitute for some element of protection required of the pharmacy, such added protection may be taken into account by the board in evaluating overall required security measures.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017).

§2455. Reportable Security Events

A. Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana, or of any loss or unauthorized alternation of records related to marijuana or patients, a pharmacy shall immediately notify:
   1. Appropriate law enforcement authorities; and
   2. The board.

B. A pharmacy shall provide the written notice to the board by way of a signed statement which details the circumstances of the event, including an accurate inventory of the quantity and brand names of the marijuana diverted, stolen, lost, destroyed, or damaged, along with confirmation that the local law enforcement authorities were notified. A pharmacy shall make such notice no later than 24 hours after discovery of the event.

C. A pharmacy shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:
   1. An alarm activation or other event that requires response by public safety personnel;
   2. A breach of security;
   3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and
   4. Corrective measures taken, if any.

D. A pharmacy shall maintain and shall make available all documentation related to an occurrence that is reportable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017).

§2457. Standards of Practice

A. Environmental Standards

1. The prescription department shall be of sufficient size commensurate with the nature and scope of practice. The space occupied by the prescription department shall be restricted to authorized personnel only, as determined by the pharmacist-in-charge, and shall not be accessible to the general public.
2. The prescription department shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.
3. The prescription department shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with approved sewage disposal.
4. All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained at temperatures which will ensure the integrity of drugs during their storage and prior to their dispensing as stipulated by the *United States Pharmacopeia* and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board.
5. The prescription department shall be secured by one or more physical barriers with suitable locks and a monitored alarm system capable of detecting unauthorized entry, and further, complies with security requirements identified elsewhere in this Subchapter.
6. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.

B. Minimum Staffing Requirements
1. There shall be at least one pharmacist on duty at all times the pharmacy is open for business.
2. Every pharmacist practicing in the pharmacy shall possess a Louisiana pharmacist license in active status, a Therapeutic Marijuana designation, and access privileges to the state prescription monitoring program.
3. A pharmacy intern may assist the pharmacist in the prescription department, but only when in possession of a Louisiana pharmacy intern registration in active status as well as a Therapeutic Marijuana designation. The supervising pharmacist may establish a delegate credential for the pharmacy intern in the state prescription monitoring program.
4. A pharmacy technician may assist the pharmacist in the prescription department, but only when in possession of a Louisiana pharmacy technician certificate in active status as well as a Therapeutic Marijuana designation. The supervising pharmacist may establish a delegate credential for the pharmacy technician in the state prescription monitoring program.
5. No pharmacy technician candidate may practice in a marijuana pharmacy.
6. Additional clerical personnel may also be present at the pharmacy.

C. Operational Standards
1. The marijuana pharmacy shall comply with the provisions of Chapters 11, 25, 27, 29, and 31 of this Part except when this Subchapter grants exceptions or imposes more stringent requirements.
2. In the event the marijuana pharmacy intends to close permanently, the pharmacist-in-charge (PIC) shall comply with the pharmacy closure procedures described in Chapter 11 of this Part, and further, the owner of the pharmacy permit shall not prevent or interfere with the PIC's performance of those tasks.
   a. In addition to the other closure requirements, the closing pharmacy shall include in its notice to the board and to the public the identification of the destination pharmacy where the closing pharmacy's prescription records will be transferred. That destination pharmacy shall be the marijuana pharmacy nearest the closing pharmacy, unless otherwise approved by the board.

D. Recordkeeping Requirements
1. Prescription/recommendation/order (hereinafter, "request") for Marijuana
   a. Authorization for Emergency Dispensing.
      An emergency situation exists when administration of the marijuana product is necessary for immediate treatment, an appropriate alternate treatment is not available, and the recommending physician cannot reasonably provide a written recommendation. In the case of an emergency situation, a pharmacist may dispense a marijuana product upon receiving oral authorization directly from a recommending physician, provided that:
      i. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written recommendation signed by the recommending physician);
      ii. the oral authorization shall be immediately reduced to written form by the pharmacist and shall contain, at a minimum, the following information:
         (a) Full name and address of the patient;
         (b) Drug product name, strength, and dosage form;
         (c) Quantity of product recommended;

(d) Directions for use;
(e) Name, address, telephone number, and CDS license number of the recommending physician; and
(f) Name of the pharmacist receiving the oral authorization.

iii. if the recommending physician is not known to the pharmacist, he shall make a reasonable effort to determine that the oral authorization came from a physician authorized to recommend marijuana products in Louisiana, which may include a callback to the physician using his telephone number as listed in the telephone directory or other good faith efforts to insure his identity; and

iv. within seven days after authorizing an emergency oral recommendation, the physician shall cause a written recommendation for the emergency quantity authorized to be delivered to the dispensing pharmacist. The recommendation shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral authorization. The written recommendation may be delivered to the pharmacist in person or by mail, but if delivered by mail, it shall be postmarked within the seven day period. Upon receipt, the dispensing pharmacist shall attach this recommendation to the oral emergency authorization which had earlier been reduced to written form. The pharmacist shall notify the board if the recommending physician fails to deliver a written recommendation to him within the required time; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written recommendation from the recommending physician.

b. In the event the pharmacy receives a request in written form by facsimile, the pharmacy may begin the preparation of the product to be dispensed, but the pharmacist shall not dispense the product until the original form of the request is delivered to him in the pharmacy and he has compared it to the product prepared for dispensing.

c. The written request shall bear the manual signature of the recommending physician. No other form of signature shall be valid, including (but not limited to) stamps, computer generated signatures, or signatures of anyone other than the recommending physician.

d. A request generated, signed, and transmitted in electronic format which is compliant with the standards for electronic prescribing of controlled substances identified in 21 CFR 1311 (or its successor) shall be construed as a validly formatted request.

2. When the pharmacy receives a request for marijuana from a recommending physician in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging system in compliance with §1123 of this Part.

3. Request forms (and electronic images thereof) shall be retained on the pharmacy's premises for at least two years after the date of dispensing, and further, shall be readily retrievable upon request by the board.

4. Inventory of Marijuana Product

a. The pharmacist-in-charge shall develop and maintain a perpetual inventory of all marijuana products acquired, held, dispensed, and disposed by the pharmacy.

b. The pharmacy shall access the LMMTS and enter all inventory-related transactions in that system.

c. In the event the pharmacist-in-charge designates an agent to retrieve new marijuana product inventory from the production facility, the pharmacist shall verify the agent is at least 21 years of age and is eligible to drive on public roadways.

d. The pharmacist-in-charge shall conduct an annual inventory of all marijuana products in the possession of the pharmacy on any date which is within one year of the previous annual inventory, and further, shall conduct additional inventory counts on the following occasions:

i. arrival of a new pharmacist-in-charge;
ii. discovery of any significant loss, disappearance, or theft of marijuana product;
iii. departure of a pharmacist-in-charge; and
iv. permanent closure of the pharmacy.

e. Inventory records shall be retained on the pharmacy's premises for at least two years after the most recent entry.

5. The pharmacy shall develop and maintain sufficient records to fully reveal the business transactions related to marijuana products, including their procurement and sale, for the current tax year as well as the two immediately preceding tax years, all of which shall be made available to the board upon request.

6. The board may require any pharmacy or its owners to furnish such information as the board considers necessary for the proper administration of R.S. 40:1046, and may require a financial audit of the business of any marijuana pharmacy, and the expense thereof shall be paid by the marijuana pharmacy.

E. Professional Practice Standards

1. Prior to dispensing any marijuana product to a patient, the pharmacist shall review that patient's records in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending physician.
2. Labeling of Marijuana Product Dispensed
   a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required by the LDAF, and further, the pharmacy dispensing label shall not overlay or obscure the producer label in any way.
   b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:
      i. Name and address of the pharmacy dispensing the product;
      ii. Telephone number or other contact information of the pharmacy dispensing the product;
      iii. Name of the recommending physician;
      iv. Name of the patient;
      v. Date the product was dispensed;
      vi. Prescription number, which shall be a unique identifier for that specific transaction;
      vii. Name of the marijuana product, including any concentration, strength, or other identifiers of the marijuana product;
      viii. Quantity of marijuana dispensed;
      ix. Directions for use of the product as included in the recommending physician's request;
      x. Expiration date of the product, which shall not exceed the expiration date determined by the producer of the product; and
      xi. Other information selected by the dispensing pharmacist to inform the patient as to the best use of the product for the intended purpose.
3. The pharmacist shall perform prospective drug utilization review and shall counsel every patient receiving marijuana product every time it is dispensed, in compliance with the rules on drug utilization review and patient counseling in Chapter 5 of this Part.
4. Reporting transactions to state prescription monitoring program. The pharmacy shall comply with the reporting requirements as found in Chapter 29 of this Part.
5. Disposal of Marijuana Product.
   a. A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is determined to be misbranded, adulterated, expired, deteriorated, undesired, excess, unauthorized, or unfit for dispensing; however, once accepted by the pharmacy, no marijuana product may be returned to any producer.
   b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the product shall be removed from active dispensing stock and quarantined in the pharmacy pending its disposal, and further, the removal from active dispensing stock shall be recorded in the LMMTS.
   c. The pharmacist-in-charge shall render the waste unusable by grinding and incorporating the waste with other ground materials so the resulting mixture is at least 50% non-marijuana waste by volume. Material used to grind with the waste may include:
      i. Yard waste;
      ii. Paper waste;
      iii. Cardboard waste;
      iv. Plastic waste; or
      vi. Soil or sand
   d. Waste shall be rendered unusable prior to leaving the pharmacy. Waste rendered unusable shall be disposed of by delivery to an approved solid waste facility for final disposition.
      i. Examples of acceptable permitted solid waste facilities include:
         (a) Compost; anaerobic digester;
         (b) Landfill, incinerator; or
         (c) Waste-to-energy facility.
   e. The pharmacist-in-charge shall prepare a record of each disposal, and that record shall contain, at a minimum, the following information:
      i. Brand name and other specific identifiers of the marijuana product disposed;
      ii. Quantity of product disposed;

iii. Manner of disposal; and
iv. Signatures of the pharmacist-in-charge disposing the product plus at least one witness who is either a credentialed staff member of that pharmacy or an agent of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017).

§2459. Advertising

A. The marijuana pharmacy shall not advertise through any public medium, including but not limited to newspapers, billboards, television, radio, internet, social media, or any other means designed to market its products to the general public.
B. The marijuana pharmacy may market its products through direct mail, brochures, or other means to Louisiana-licensed physicians, but only when such advertising is directed solely to the practitioner and is not available to the general public.
C. Any advertisement permitted in Paragraph B of this Section shall not:
   1. Make any deceptive, false, or misleading assertions or statements regarding any product; or
   2. Assert that its products are safe because they are regulated by LDAF or the board. The pharmacy may advertise that its products have been tested by an approve laboratory, but shall not assert that its products are safe because they are tested by an approved laboratory.
D. The marijuana pharmacy may attach a maximum of two separate signs to the exterior of the building which identify the business by its business or trade name, provided that neither sign exceeds the size limit of sixteen hundred square inches.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1552 (August 2017).

Rules

RULE

Department of Agriculture and Forestry
Office of Agricultural and Environmental Sciences

Medical Marijuana (LAC 7:XLIX.Chapters 1-31)

In accordance with the Administrative Procedure Act, R.S. 49:950 et seq., the Department of Agriculture and Forestry ("department"), has adopted LAC 7:XLIX.Chapters 1-31 regarding the growing and production of medical marijuana. The rules are adopted pursuant to R.S. 40:1046. Chapter 1 of the rules sets forth definitions used in the medical marijuana rules. Chapter 3 sets for the department's authority to adopt the rules and addresses administrative matters, such as rules of construction for the regulations. Chapter 5 addresses the license issued by the department to the grower and permits issued by the department to employees of the licensee. Chapter 5 includes rules regarding the form, content and information required in applications. Chapter 5 also addresses suitability standards, the ownership and transferability of the license and requires permits for employees. Chapter 7 addresses fees charged by the department to the licensee. Chapter 9 addresses compliance by the licensee and permitees and inspections by the department. Chapter 9 further sets forth a procedure for the licensee to request waivers from certain rules in emergency situations. Chapter 11 requires the licensee to establish internal controls for the production facility and sets forth the areas that must be covered by the internal controls. Chapter 13 sets forth record keeping and reporting requirements for the licensee and requires the licensee to submit an annual report to the department. The department, in turn, is required by law to submit an annual report to the legislature. Chapter 15 governs the production facility, including requiring certain areas of the facility be restricted. Chapter 15 also addresses the use of pesticides on medical marijuana plants. Chapter 17 addresses surveillance and security requirements that the licensee must follow at the production facility. Chapter 19 requires the licensee to use a tracking system for inventory. Chapter 21 addresses quality control of the medical marijuana products produced by the licensee and requires the licensee to conduct quality assurance tests. Chapter 23 sets forth the requirements for laboratory testing, including which tests must be run. Chapter 23 sets forth requirements on the licensee and its employees when transporting medical marijuana or medical marijuana infused products to laboratories, pharmacies or research facilities. Chapter 27 sets forth sanitation requirements for the production facility and provides rules for the disposal of waste. Chapter 29 addresses labeling of medical marijuana or medical marijuana infused products and also addresses advertising by the licensee. Finally, Chapter 31 sets forth the procedures for the department to take enforcement action against the licensee.

Title 7
AGRICULTURE AND ANIMALS
Part XLIX. Medical Marijuana
Chapter 1. General Provisions
§101. Definitions

A. The provisions of the Act, R.S. 40:1046 and 1047, relating to definitions, words and terms are hereby incorporated by reference and made a part hereof and will therefore apply and govern the interpretation of these rules, unless the context otherwise requires or unless specifically redefined in a particular Section. Any word or term not defined in these rules shall have the same meaning ascribed to it in the Act. Any word not defined by the Act or these regulations shall be construed in accordance with its plain and ordinary meaning.

B. The following words and terms shall have the following meanings.

Act—R.S. 40:1046 et seq.

Applicant—any person or legal entity who has submitted an application or bid to the department for a license, permit, registration, contract, certificate or other finding of suitability or approval, or renewal thereof, authorized by the Act or rule.

Applicant Records—those records which contain information and data pertaining to an applicant's criminal record, background, and financial records, furnished to or obtained by the department from any source incidental to an investigation for licensing or permitting, findings of suitability, registration, the continuing obligation to maintain suitability, or other approval.

Application—the documentation, forms and schedules prescribed by the department upon which an applicant seeks a license, permit, registration, contract, certificate or other finding of suitability or approval, or renewal thereof, authorized by the Act or rule. Application also includes questionnaires, information, disclosure statements, financial statements, affidavits, and all documents incorporated in, attached to, or submitted by an applicant or requested by the department.

Architectural Plans and Specifications or *Architectural Plans* or *Plans* or *Specifications*—all of the plans, drawings, and specifications for the construction, furnishing, and equipping of the facility including, but not limited to, detailed specifications and illustrative drawings or models depicting the proposed size, layout and configuration of the production facility, including electrical and plumbing systems, engineering, structure, and aesthetic interior and exterior design as are prepared by one or more licensed professional architects and engineers.

Background Investigation—all efforts, whether prior to or subsequent to the filing of an application, designed to discover information about an applicant, affiliate, licensee, permittee, registrant, or other person required to be found suitable and includes, without time limitations, any

additional or deferred efforts to fully develop the understanding of information which was provided or should have been provided or obtained during the application process.

Batch—the established segregation of a group of plants at the time of planting for the control of quantity, traceability and/or strain. A batch number will be assigned a specific unit or finite set of marijuana plants, therapeutic marijuana or therapeutic chemicals identifiable by a unique number or other unique designation, every portion or package of which is uniform,within recognized characteristics or tolerances for factors specific to the production stage. This unique identification follows each specific unit or finite set throughout growing, production, laboratory testing and product packaging and labelling.

Business Entity or *Legal Entity*—a natural person, a corporation, limited liability company, partnership, joint stock association, sole proprietorship, joint venture, business association, cooperative association, professional corporation, including the Louisiana State University Agricultural Center and the Southern University Agricultural Center, or any other legal entity or organization through which business is conducted.

Consent to Administrative Supervision—a confidential legal agreement signed by the department and an individual, business, or other entity through which the violator agrees to pay for correction of violations, take the required corrective actions, or refrain from an activity while under the department's supervision.

Department—the Louisiana Department of Agriculture and Forestry.

Department Agent—any employee of the department designated by the commissioner of agriculture and forestry.

Economic Interest—any interest in a license from which a person receives or is entitled to receive, by agreement or otherwise, a profit, gain, thing of value, loss, credit, security interest, ownership interest or other benefit. Economic interest includes voting shares of stock or otherwise exercising control of the day-to-day operations through a management agreement or similar contract. Economic interest does not include a debt unless upon review of the instrument, contract, or other evidence of indebtedness, the department determines a finding of suitability is required based upon the economic relationship with the licensee.

Employee Permit—the permit issued by the department authorizing a person to work for the licensee.

Financial Interest—any actual or future right to ownership, investment, or compensation arrangement with another person, either directly or indirectly, through business, investment, spouse, parent or child, in the licensee. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a national securities exchange or over-the-counter market in the United States, provided the investment securities held by the person and the person's spouse, parent or child, in the aggregate, do not exceed one percent ownership in the licensee.

Financial Statements or *Financial Records*—both summaries of financial matters of any sort and any source documents or records from which summaries are or may be derived. Those statements and the information contained therein which relate to balance sheets, profit and loss statements, mortgages, debt instruments, ledgers, journals, invoices, and any other document bearing on the financial status of an entity, whether historical or current.

Geographic Location—a single location in the control of a licensee, which by definition is the premises, that has contiguous boundaries and is located within a parish in Louisiana.

Internal Controls—internal procedures and administration and accounting controls designed by the licensee for the purpose of exercising control over the licensee's operations as approved by the department.

License—the authorization by the department to produce medical marijuana and medical marijuana-infused product in accordance with the Act.

Licensed Dispensary Pharmacy or *Marijuana Pharmacy*—a pharmacy licensed by the Louisiana Board of Pharmacy to dispense medical marijuana-infused product.

Licensee—a person or legal entity holding the specialty license issued by the department authorizing the holder, directly or through a producer, to operate a medical marijuana production facility.

Louisiana Medical Marijuana Tracking System (LMMTS)—the required seed-to-sale tracking system that tracks medical marijuana from either the seed or immature plant stage until the product is sold to a marijuana pharmacy or is destroyed.

LMMTS Tracking System User—a licensee or its representative or authorized employees who is granted LMMTS user account access for the purpose of conducting inventory tracking functions in the LMMTS, who has been successfully trained by LMMTS trained administrator(s) in the proper and lawful use of LMMTS, and who has completed any additional training required by the department.

LMMTS Trained Administrator—a licensee or authorized employee who has attended and successfully completed LMMTS training and who has completed any additional training required by the department.

Medical Marijuana—substances which are identified as including any parts of the plant *Cannabis sativa*, and all derivatives or subspecies of all strains of cannabis, whether growing or not, the seeds thereof; the resin extracted from any part of such plant; and any compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin, including tetrahydrocannabinol (THC), Cannabidiol (CBD) and all other naturally occurring cannabinol derivatives, whether produced directly or indirectly by extraction. This term shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of such plant which is incapable of germination.

Medical Marijuana Concentrate—a product derived from medical marijuana that is produced by extracting cannabinoids from the plant through the use of propylene glycol, glycerin, butter, olive oil or other typical cooking fats; water, ice or dry ice; or butane, propane, CO_2, ethanol

or isopropanol. The use of any other solvent as is expressly prohibited unless and until it is approved by the department.

Medical Marijuana-Infused Product or *Product*—a product infused with medical marijuana that is intended for use or consumption other than by smoking, including but not limited to edible products, ointments, and tinctures.

Medical Marijuana Waste—medical marijuana or medical marijuana-infused product that is not usable or cannot be processed.

Monitoring—the continuous and uninterrupted video surveillance of cultivation activities and oversight for potential suspicious actions. The department or law enforcement agencies designated by the department shall have the ability to access the licensee's monitoring system in real-time via a secure web-based portal.

Permit—authorization issued from the department to a natural person to work for, or on behalf of, the licensee.

Permittee—a principle officer or board member of the licensee or producer, or a person employed in the operation or supervision of the licensee's operation, including any individual whose employment duties directly relate to the growing, cultivating, harvesting, processing, weighing, packing, transportation and selling of product.

Permittee Identification Card—a document approved by the department that identifies a person as a production facility permittee.

Person—any individual, partnership, association, organization, corporation or any other legal entity.

Premises—land, together with all buildings, improvements, and personal property located thereon, wherein medical marijuana or product is produced.

Produce or *Production*—the growing, compounding, conversion, processing or manufacturing of medical marijuana and medical marijuana-infused product, by extraction from substances of natural origin including any packaging or repackaging of the products or the labeling or relabeling of these products or their containers.

Producer—the licensee or a person or legal entity under contract, memorandum of understanding, or cooperative endeavor agreement with the licensee for services to grow or produce medical marijuana and medical marijuana-infused product.

Production Facility—a permanent, secured space designed and located in one geographic location, operated solely for the production of medical marijuana and product by the licensee to perform necessary activities to provide licensed pharmacies with usable product.

Production Facility Agent-In-Charge or *Agent-In-Charge*—the production facility permittee who has been designated by the licensee to have control and management over the day to day operations of the production facility. The licensee may designate more than one agent-in-charge to cover varying operational work shifts, but may only have one per work shift as approved by the department.

Records—all books, records, writings, accounts, letters and letter books, maps, drawings, photographs, cards, tapes, recordings, memoranda, and papers, and all copies, duplicates, photographs, or other reproductions thereof, or any other documentary materials, regardless of physical form or characteristics, including information contained in electronic data processing equipment, having been used, being in use, or prepared, possessed, or retained for use in the conduct, transaction, or performance of any business, transaction, work, duty, or function which was conducted, transacted, or performed by or under the authority of a license or permit issued by the department.

Restricted Access Area—a building, room or other area in the production facility where medical marijuana is grown, cultivated, harvested, stored, weighed, packaged, sold or processed for sale to a licensed marijuana pharmacy.

Subcontractor—a person under contract, memorandum of understanding, cooperative endeavor agreement, or any other agreement, with the producer or licensee for any service other than services to grow or produce medical marijuana and medical marijuana-infused products.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1251 (July 2017).

Chapter 3. Administrative Procedures and Authority

§301. Policy

A. It is the declared policy of the department that production of medical marijuana in Louisiana be strictly regulated and controlled through administrative rules to protect the public welfare of the inhabitants of the state of Louisiana.

B. Marijuana is classified as a schedule I controlled substance by the U.S. Department of Justice, Drug Enforcement Administration.

1. As provided by the federal Controlled Substances Act, the procurement, possession, prescribing, distribution, dispensing, or administering of any schedule I controlled substance, including marijuana, is a violation of federal law.

2. Neither Louisiana law nor these rules can preempt federal law. Therefore, the provisions of this chapter notwithstanding, persons engaged in the activities described herein remain subject to the full force of federal law enforcement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1253 (July 2017).

§303. Construction of Regulations and Administrative Matters

A. Nothing contained in these regulations shall be so construed as to conflict with any provision of the Act, any other applicable statute. If any regulation is held invalid by a final order of a court of competent jurisdiction at the state or federal level, such provision shall be deemed severed and the court's finding shall not be construed to invalidate any other regulation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1253 (July 2017).

§305. Louisiana State University Agricultural Center and/or Southern University Agricultural Center is Licensee

A. These regulations, subject to any rights in the Act, intend for the term licensee to apply to Louisiana State University Agricultural Center, Southern University

Agricultural Center, either separately or jointly, if the universities exercise the right of first refusal granted under the Act.

1. If the universities do not exercise their rights of first refusal, the term licensee shall apply to the recipient of the license awarded pursuant to R.S. 40:1046.

B. In either case, the licensee is authorized to enter into agreements with producers or subordinate contractors; however, the licensee shall be the responsible party for compliance with all obligations under the Act and rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1253 (July 2017).

Chapter 5. License and Permits

§501. Procedure for Issuing the License

A. The department shall issue the license pursuant to the Act.

B. *Louisiana Revised Statute* 40:1046 entitles the Louisiana State University Agricultural Center and the Southern University Agricultural Center to the right of first refusal to be licensed as the production facility. This entitlement carries a presumption of suitability and accordingly, the following Sections of this Chapter pertaining to licensing shall not apply to the Louisiana State University Agricultural Center and the Southern University Agricultural Center: §§505, 507, 509, 513.A, 515.A, 517, 519.A.3, 521, 701.A. The presumption of suitability does not apply to any producer or subcontractor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1254 (July 2017).

§503. General Authority of the Department

A. The department shall have the authority to call forth any person who, in their opinion, has the ability to exercise significant influence over an applicant or licensee, and such person shall be subject to all suitability requirements. The department may require any person who furnishes goods or services, by contract or any other type of agreement, to the licensee, producer or subcontractor to undergo a suitability determination.

B. In the event a person is found unsuitable, then the applicant or licensee shall have no association or connection with such person.

C. The department may grant variances in writing from certain licensing requirements for Louisiana State University Agricultural Center and Southern University Agricultural Center.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1254 (July 2017).

§505. Applications in General

A. The license and any permit issued by the department is deemed to be a revocable privilege, and no person or legal entity holding such a license or permit is deemed to have acquired any vested rights therein.

B. An applicant for a license or permit authorized by the Act or rule is seeking the granting of a privilege, and the burden of proving qualification and suitability to receive the license or permit is at all times on the applicant.

C. The securing of the license, permit or approval required under the Act or these rules is a prerequisite for conducting, operating, or performing any activity regulated by the Act or these rules. Each applicant must file a complete application as prescribed by the department.

D. The filing of an application under the Act or these rules constitutes a request for a decision upon the applicant's general suitability, character, integrity, and ability to participate or engage in or be associated with the licensee or permittee. By filing an application, the applicant specifically consents to the making of such a decision by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1254 (July 2017).

§507. Investigations; Scope

A. The department shall investigate all applications for the license or permit or other matters requiring department approval. The department may investigate, without limitation, the background of the applicant, the suitability of the applicant, the suitability of the applicant's finances, the applicant's business integrity, the suitability of the proposed premises for the facility, the suitability of a person with an ownership or economic interest in the applicant for a license of 5 percent or more, and the suitability of any person who in the opinion of the department has the ability to exercise significant influence over the activities of an applicant for a license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1254 (July 2017).

§509. Ownership of License and Permits

A. The license and all permits issued by the department as provided in the Act or by rule, are and shall remain the property of the department at all times.

B. The license shall be issued in the name of the licensee. One license will be issued even though multiple individuals may file or be required to file applications related thereto.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1254 (July 2017).

§511. Transfer of License or Permits

A. The license and all permits are not transferable or assignable. If the status of the licensee or permittee should change such that the person no longer needs or is entitled to the license or permit, then the license or permit shall be cancelled and any tangible item which evidences such a license or permit shall be surrendered to the department within five days of the change of status.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1254 (July 2017).

§513. Eligibility Suitability Standards

A. Eligibility. No person shall be eligible to apply for the license unless he meets all of the following requirements:

1. is in compliance with all requirements provided by the Act; and

2. is properly registered and in good standing with the Louisiana Secretary of State and Department of Revenue.

B. Suitability. No person shall be eligible to obtain a license, permit, or contract related to the production of medical marijuana, or to obtain any other approval pursuant to the provisions of the Act, or these rules unless the applicant has demonstrated by clear and convincing evidence to the department, where applicable, that he is suitable. Suitable means the person has filed the suitability documents required by the department and is:

1. a person of good character, honesty, and integrity;

2. a person whose prior activities, criminal record, if any, reputation, habits, and associations do not pose a threat to the public interest of this state or to the effective regulation and control of the production of medical marijuana or product or enhance the dangers of unsuitable, unfair, or illegal practices, methods, and activities in the production of medical marijuana or product or carrying on of the business and financial arrangements incidental thereto;

3. capable of and likely to conduct the activities for which the applicant, licensee, permittee, is licensed, permitted, or approved pursuant to the provisions of the Act or these rules; and

4. not disqualified pursuant to the provisions of Subsection B of this Section.

C. The department, where applicable, shall not grant a license or permit, or issue any other approval pursuant to the provisions of the Act or these rules to any person who is disqualified on the basis of the following criteria:

1. the conviction or a plea of guilty or nolo contendere by the applicant or any person required to be suitable under the provisions of the Act or these rules for any of the following:

a. any offense punishable by imprisonment of more than one year;

b. theft or attempted theft, illegal possession of stolen things, or any offense or attempt involving the misappropriation of property or funds;

c. any offense involving fraud or attempted fraud, false statements or declarations;

d. a crime of violence as defined in R.S.14:2(B); and

e. any offense involving schedule I narcotics;

2. there is a current prosecution or pending charge against the person in any jurisdiction for any offense listed in Paragraph 1 of this Subsection; and

3. the failure to provide information and documentation to reveal any fact material to a suitability determination, or the supplying of information which is untrue or misleading as to a material fact pertaining to the suitability criteria.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1255 (July 2017).

§515. Suitability Determination

A. An applicant and officers, directors, and any person having a 5 percent or more economic interest in the licensee shall be required to submit to an investigation to determine suitability.

B. All subcontractors shall meet suitability standards set forth in §513 of this Chapter and may be required to submit to an investigation to determine suitability.

C. Any person, who in the opinion of the department, has the ability to exercise significant influence over the activities of an applicant for license or licensee shall be required to submit to an investigation to determine suitability.

D. All costs associated with conducting an investigation for suitability shall be borne by the applicant, licensee, or permittee or the person who is the subject of the investigation.

E. Failure to submit to a suitability determination as required by this Section may constitute grounds for delaying consideration of the application or for denial of the application.

F. Appeals. Any finding of suitability may be appealed to the commissioner by the person who was found unsuitable by seeking an adjudicatory hearing to have said decision reconsidered in accordance with chapter 13 of title 49 of the *Louisiana Revised Statutes*, provided said appellant files with the commissioner a written notice of appeal within 30 days of the date of the decision regarding suitability to the affected party.

1. The commissioner shall appoint a hearing officer to preside over a hearing to determine whether to uphold the suitability determination. The hearing shall be conducted in accordance with the provisions of the Administrative Procedure Act.

2. Notice of the hearing date shall be sent by the hearing officer to the department and the affected party at least 30 days prior to the hearing. Notice shall be sent by certified mail, return receipt requested.

3. The presiding hearing officer shall prepare a written determination, which shall contain, at a minimum, the record of the hearing, including all submissions and the decision regarding the appeal of the suitability determination. The hearing officer shall render his decision within 30 days after the hearing is conducted.

4. All appeals from any decision of the hearing officer shall be filed in accordance with chapter 13 of title 49 of the *Louisiana Revised Statutes*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1255 (July 2017).

§517. Form of Application

A. An application for a license, permit, or finding of suitability shall be filed by way of forms prescribed by and obtained from the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1255 (July 2017).

§519. Information Required from an Applicant for a License

A. An application for the license shall contain the following information including but not limited to:

1. information required by the Act;

2. one copy of detailed plans of design of the facility, including the projected use of each area;

3. an estimated timetable for the proposed financing arrangements through completion of construction;

4. the construction schedule proposed for completion of the production facility including therein projected dates for completion of construction and commencement of operations and indicating whether the construction contract includes a performance bond;

5. explanation and identification of the source or sources of funds for the construction of the facility;

6. description of the production facility size;

7. a detailed plan of surveillance and surveillance equipment to be installed;

8. proposed hours of operation;

9. the proposed management plan, management personnel by function and organizational chart by position; and

10. a list of positions, including job descriptions, which the applicant anticipates employing in the production facility operation.

B. An applicant for the license shall provide a copy of proposed internal controls which shall include:

1. accounting and financial controls including procedures to be utilized in counting, banking, storage and handling of cash;

2. job descriptions and the systems of personnel and chain-of-command, establishing a diversity of responsibility among employees engaged in production facility operations and identifying primary and secondary supervisor positions for areas of responsibility, which areas shall not be so extensive as to be impractical for an individual to monitor;

3. procedures for the inventory control and tracking, security, storage, and recordation of inventory; and

4. procedures and security standards for total operation of the production facility.

C. In addition, the department may require an applicant to provide such other information and details as it needs to discharge its duties properly.

D. Failure to comply with the provisions of this Section may constitute grounds for delaying consideration or for denial of the application.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1256 (July 2017).

§521. Fingerprinting

A. An initial application for a license, permit, or finding of suitability is not complete unless all persons required by the department to be fingerprinted have submitted to fingerprinting at the direction of the department.

B. Failure to submit to fingerprinting may constitute grounds for delaying consideration of the application or for denial of the application.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1256 (July 2017).

§523. Employee Permits Required

A. A person employed in the operation or supervision of the licensee's operation including any individual whose employment duties require or authorize access to the premises on a regular basis, or a principle officer or board member of the licensee, shall be permitted by the department annually. A permit is valid for one year from the date of issuance.

B. No person employed in a capacity which requires an employee permit may begin his employment until a valid permit is issued to him by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1256 (July 2017).

§525. Display of Identification Badge

A. Every person required to be permitted shall be issued a permittee identification badge, which shall be on his person and displayed at all times when on the production facility premises or when transporting product.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1256 (July 2017).

§527. Permit Renewal Applications

A. Applications for renewal of permits shall be made in such a manner and by way of forms prescribed by the department and shall contain all information requested by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1256 (July 2017).

Chapter 7. Fees

§701. Fees

A. The license fee of $100,000 shall be payable to the department upon issuance of the license and annually thereafter.

B. The fee for a permit shall be $100 annually.

C. A fee in an amount not to exceed 7 percent of gross sales shall be paid quarterly to the department.

D. All fees collected by the department pursuant to this Section shall be collected from the licensee and shall be used to fund expenses relating to the regulation and control of the medical marijuana program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1256 (July 2017).

Chapter 9. Compliance and Inspections

§901. Applicability and Resources

A. This Chapter is applicable to inspections relative to compliance with the Act and the rules. The department is empowered to employ such personnel as may be necessary for such inspections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1256 (July 2017).

§903. Conduct

A. General provisions:

1. all licensees, producers, subcontractors and permittees shall comply with all applicable federal, state, and local laws and regulations. For purposes of this Chapter, applicable federal law shall not mean the growing, sale, possession, or distribution of medical marijuana; and

2. all notifications to the department required by this Section shall be in writing.

B. Unsuitable conduct:

1. a licensee, producer, subcontractor or permittee shall not engage in unsuitable conduct or practices and shall not employ or have a business association with any person, natural or juridical, that engages in unsuitable conduct or practices; and

2. for purposes of this Section, unsuitable conduct or practices shall include, but not be limited to, the following:

a. employment of, in a managerial or other significant capacity as determined by the department, business association with, or participation in any enterprise or business with a person disqualified pursuant to Section 513 of Chapter 5 of these rules or declared unsuitable by the department;

b. failure to provide information or documentation of any material fact or information to the department;

c. misrepresentation of any material fact or information to the department;

d. engaging in, furtherance of, or profit from any illegal activity or practice, or any violation of these rules or the Act;

e. obstructing or impeding the lawful activities of the department; or

f. persistent or repeated failure to pay amounts due or to be remitted to the state;

3. the licensee, producer, subcontractor or permittee shall not engage in, participate in, facilitate, or assist another person in any violation of these rules or the Act; or

4. any person required to be found suitable or approved or permitted by the department pursuant to this Part, shall have a continuing duty to notify the department of his arrest, summons, citation or charge for any criminal offense or violation that would deem him unsuitable in accordance with these rules. The notification required by this Paragraph shall be made within 15 calendar days of the arrest, summons, citation, charge, fact, event, occurrence, matter or action.

C. Responsibility for the employment and maintenance of suitable methods of operation rests with the licensee. Willful or persistent use or toleration of methods of operation deemed unsuitable is cause for administrative action.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1257 (July 2017).

§905. Compliance with Laws

A. Acceptance of a license or permit or renewal thereof constitutes an agreement on the part of the licensee or permittee to be bound by all of the applicable provisions of the Act and the regulations. It is the responsibility of the licensee or permittee to keep informed of the content of all such laws, and ignorance thereof shall not excuse violations. Violation of any applicable provision of the Act or the rules by a licensee or its agent, or permitte, employee or representative, is contrary to the public health, safety, morals, good order and general welfare of the inhabitants of the state of Louisiana and constitutes cause for administrative action.

B. In the event the licensee subcontracts services in the production of medical marijuana or product, the producer‘s acts or omissions shall be considered the acts or omissions of the licensee. All obligations, duties, and responsibilities imposed on the licensee by these regulations shall be the obligations, duties and responsibilities of the producer. The licensee retains ultimate liability and responsibility for the obligations imposed on the licensee under the Act and these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1257 (July 2017).

§907. Inspections and Observations

A. The department and its representatives shall have complete, immediate and unrestricted access to the production facility at any and all times without notice or demand to the licensee, permittee or any other person, to enter and:

1. inspect the entire production facility and its ancillary facilities, including all restricted areas;

2. observe production activities; or

3. observe the transportation of product.

B. A licensee shall, upon request, immediately make available for inspection by the department all papers, documents, books and records used in the licensed operations.

C. Such inspections and observations may or may not be made known to the licensee.

D. All requests for access to the production facility and production of records and documents in connection with any inspection shall be granted in accordance with the provisions of the Act and these regulations.

E. In conducting an inspection, the department is empowered to:

1. inspect and examine the entire production facility wherein production activities are conducted or proposed to be conducted, wherein inventory, equipment or supplies are maintained, and wherein all papers, books, records, documents and electronically stored media are maintained;

2. summarily seize and remove product, inventory, supplies, and equipment from such premises for the purpose of examination and inspection;

3. have access to inspect, examine, photocopy and, if necessary seize all papers, books, records, documents, information and electronically stored media of an applicant,

licensee, or permittee pertaining to the licensed operation or activity, on all premises where such information is maintained;

4. review all papers, books, records, and documents pertaining to the licensed operation; and

5. conduct audits to determine compliance with all laws, rules and operations authorized by the Act under the department's jurisdiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1257 (July 2017).

§909. Production Facility Agent-In-Charge

A. The licensee shall designate one or more permittees as production facility agent-in-charge. A production facility agent-in-charge shall be on the production facility premises at all times during hours of operation and shall have authority to immediately act in any matter or concern of the department. A description of the duties and responsibilities of the production facility agent-in-charge shall be included in the written system of internal controls.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1258 (July 2017).

§911. Waivers and Authorizations

A. All requests to the department for waivers, approvals, or authorizations, except matters concerning emergency situations, shall be submitted in writing no less than 30 days prior to the licensee's planned implementation date, unless a shorter time is approved by the department.

B. No waiver, approval, or authorization is valid until such time as the licensee receives written authorization from the department.

C. The department, in its sole discretion, may determine what constitutes an emergency situation. Such determinations will be made on a case-by-case basis.

D. A licensee shall adhere to all the requirements and provisions of the authorization. Violation of the terms of a written authorization may be cause for administrative action.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1258 (July 2017).

Chapter 11. Internal Controls

§1101. Internal Control for Production Facility

A. The licensee shall establish administrative and accounting procedures for the purpose of exercising effective control over the internal fiscal affairs. The procedures must be designed to reasonably ensure that:

1. assets are safeguarded;

2. financial records are accurate and reliable;

3. transactions are performed only in accordance with management's general or specific authorization;

4. transactions are recorded adequately to permit proper reporting of sales and maintain accountability for inventory and assets;

5. access to assets is permitted only in accordance with management's specific authorization; and

6. functions, duties, and responsibilities are appropriately segregated and performed in accordance with sound practices by competent, qualified personnel.

B. The licensee shall describe, in such manner as the department may approve or require, its administrative and accounting procedures in detail in a written system of internal control. The licensee shall submit for approval a copy of its written system to the department. Each written system shall include:

1. an organizational chart depicting segregation of functions and responsibilities;

2. a description of the duties and responsibilities of each position shown on the organizational chart;

3. a detailed, narrative description of the administrative, accounting, and operational procedures designed to satisfy the requirements of Subsection A. This description shall address operational and management practices, including but not limited to:

a. record keeping;

b. security measures to deter and prevent theft of medical marijuana and product;

c. authorized entrance into areas containing medical marijuana or product;

d. types and quantities of medical marijuana or products that are produced at the manufacturing facility;

e. methods of planting, harvesting, drying, batching, and storage of medical marijuana;

f. estimated quantity of all crop inputs used in production;

g. estimated quantity of waste material to be generated;

h. disposal methods for all waste materials;

i. inventory storage procedures;

j. employee training methods for the specific phases of production;

k. biosecurity measures used in production and manufacturing;

l. strategies for reconciling discrepancies in plant material, medical marijuana or product;

m. sampling strategy and quality testing for labeling purposes;

n. medical marijuana and product packaging and labeling procedures;

o. procedures for the mandatory and voluntary recall of medical marijuana and product;

p. plans for responding to a security breach at a production facility, or while medical marijuana or product is in transit to another approved facility;

q. business continuity plan;

r. procedures and records relating to all transport activities; and

s. other information requested by the department;

4. a written statement signed by the licensee's chief financial officer and either the licensee's chief executive officer or a licensed owner attesting that the system satisfies the requirements of this Section; and

5. such other items as the department may require.

C. The system of internal control procedures shall meet, at a minimum, the requirements set forth in the Act and administrative rules. If the department determines that the administrative or accounting procedures or its written system

does not meet the standards, the department shall so notify the licensee in writing. Within 30 days after receiving the notification, the licensee shall amend its procedures and written system accordingly, and shall submit a copy of the written system as amended and a description of any other remedial measures taken.

D. The licensee shall promptly report any amendments to the its system of internal control procedures. The report must include either a copy of the written system of internal control procedures as amended or a copy of each amended page of the written system of internal control procedures, and a written description of the amendments signed by the licensee's chief financial officer. The department may also request the licensee to submit a copy of the written system of internal control procedures at any time.

E. The licensee shall comply with ~~its~~ the written system of internal control procedures submitted pursuant to Subsection B as it relates to compliance with the requirements set forth in these regulations. Failure to comply is an unsuitable method of operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1258 (July 2017).

§1103. Application Control

A. The licensee shall establish application control procedures for the purpose of exercising effective control over the management information systems to include the LMMTS, and to provide for a stable operation of the IT environment. The licensee shall comply with the system of application control as it relates to compliance with the requirements set forth in these regulations. The application procedures shall include a business continuity plan, an organizational chart depicting segregation of functions and responsibilities, and a description of the duties and responsibilities of each position shown on the organizational chart.

B. The procedures must be designed to reasonably ensure that:

1. information is safeguarded and logically secured through the use of passwords, biometrics, or other means as approved by the department;

2. electronic records are accurate and reliable;

3. controls assure the accuracy of the data input, the integrity of the processing performed, and the verification and distribution of the output generated by the system. Examples of these controls include:

a. proper authorization prior to data input, for example, passwords;

b. use of parameters or reasonableness checks; and

c. use of control totals on reports and comparison of them to amounts input;

4. transactions are performed only in accordance with control procedures; and

5. transactions are recorded adequately to permit proper reporting of data, and to maintain accountability for processing tracking, inventory, sales, and assets.

C. Data server equipment and system storage shall be housed in a secured environment equipped with a non-water based fire suppression system, redundant power supply and UPS battery backup, redundant HVAC system, and protected by surveillance and security alarm systems. Only authorized personnel shall have physical access to the computer software and hardware.

D. Backup and recovery:

1. the licensee shall perform a backup to the system data daily. Backup and recovery procedures shall be written and distributed to all applicable personnel. These policies shall include information and procedures, which includes, at a minimum, a description of the system and system manual(s) that ensure the timely restoration of data in order to resume operations after a hardware or software failure;

2. the licensee shall maintain copies of system-generated edit reports, exception reports and transaction logs for a minimum of five years; and

3. the licensee shall maintain either printed or electronic copies of system-generated edit reports, exception reports, and transaction logs.

E. Access to software and hardware:

1. the licensee shall establish security groups based on job requirements and access level of employees. This information shall be maintained by the licensee and include the employee's name, position, identification number, and the date authorization is granted. These files shall be updated as employees or the functions they perform change;

2. the licensee shall print and review the computer security access report monthly. Discrepancies shall be investigated, documented, and maintained for five years;

3. only authorized personnel shall have physical access to the computer software and hardware;

4. all changes to the system and the name of the individual who made the change shall be documented; and

5. reports and other output generated by the system shall be available and distributed to authorized personnel only.

F. Computer records:

1. at a minimum, the licensee shall generate, review, document this review, and maintain reports on a daily basis for the respective system(s) utilized in its operation.

G. The licensee may not implement application control procedures that do not satisfy the requirements set forth in these regulations unless the department approves otherwise in writing. If the department determines that the licensee's application control procedures do not comply with the requirements of the Act or administrative rules, the department shall so notify the licensee in writing. Within 30 days after receiving the notification, the licensee shall amend its application controls, and shall submit a copy of the amended application controls and a description of any other remedial measures taken.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1259 (July 2017).

Chapter 13. Reporting and Record Keeping

§1301. Reporting and Record Keeping

A. The licensee shall keep and maintain all of the true, accurate, complete, legible and current books upon the licensed premises for a five-year period and made available for inspection if requested by the department. Electronic records may be maintained in other locations if access to the records is available on computers located at the production facility or other location approved by the department.

B. The licensee shall conduct a complete system data backup to an off-site location a minimum of once a month. For purposes of this Section, the licensee shall submit the name, location, and security controls of the off-site storage facility to the department.

C. The licensee shall have a written contingency plan in the event of a system failure or other event resulting in the loss of system data. The plan shall address backup and recovery procedures and shall be sufficiently detailed to ensure the timely restoration of data in order to resume operations after a hardware or software failure or other event that results in the loss of data.

D. The licensee is responsible for keeping and maintaining all of the production facility's records that clearly reflect all financial transactions and the financial condition of the business. The following records shall be kept and maintained on the licensed premises for a five-year period and shall be made available for inspection if requested by the department:

1. purchase invoices, bills of lading, manifests, sales records, copies of bills of sale and any supporting documents, including the items and/or services purchased, from whom the items were purchased, and the date of purchase;

2. bank statements and cancelled checks for all accounts relating to the production facility;

3. accounting and tax records related to the production facility and each producer backer;

4. records of all financial transactions related to the production facility, including contracts and/or agreements for services performed or received that relate to the production facility;

5. all permittee records, including training, education, discipline, etc.;

6. soil amendment, fertilizers, pesticides, or other crop production aids applied to the growing medium or plants or used in the process of growing medical marijuana;

7. production records, including:

a. planting, harvest and curing, weighing, destruction of medical marijuana, creating batches of products, and packaging and labeling; and

b. disposal of medical marijuana, products and waste materials associated with production;

8. records of each batch of medical marijuana concentrate or products made, including, at a minimum, the usable medical marijuana or trim, leaves, and other plant matter used (including the total weight of the base product used), any solvents or other compounds utilized, and the product type and the total weight of the end product produced;

9. transportation records;

10. inventory records;

11. records of all samples sent to an independent testing lab and/or the department's lab and the quality assurance test results;

12. all samples provided to anyone or any entity for any purpose; and

13. records of any theft, loss or other unaccountability of any medical marijuana seedlings, clones, plants, trim or other plant material, extracts, products, or other items containing medical marijuana.

E. The records required by this section shall include the following:

1. the amount of plants being grown at the production facility on a daily basis;

2. the quantity and form of medical marijuana and product maintained at the production facility on a daily basis;

3. the date of each sale, transporting or disposing of any product;

4. the name, address and registration number of the marijuana pharmacy to which the product was sold;

5. the item number, product name (description), and quantity of products registered by the department and sold or otherwise distributed to the marijuana pharmacy;

6. the name of the marijuana pharmacy and the marijuana pharmacy employee who took custody of the product;

7. the price charged and the amount received for the products from the marijuana pharmacy;

8. name of production facility employee(s) transporting the product; and

9. if the distribution was for a purpose other than sale, the reason for the distribution.

F. A record of all approved products that have been distributed shall be filed electronically with the department, utilizing a transmission format acceptable to the department, not later than 24 hours after the product was transported to a marijuana pharmacy or disposed of by the production facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1259 (July 2017).

§1303. Annual Report

A. The licensee shall prepare an annual report detailing all of the following:

1. the amount of gross medical marijuana and product produced by the licensee during each calendar year;

2. the details of all production costs including but not limited to seed, fertilizer, labor, advisory services, construction, and irrigation;

3. the details of any items or services for which the licensee subcontracted and the costs of each subcontractor directly or indirectly working for the contractor;

4. the amount of products produced resulting from the medical marijuana grown;

5. the amounts paid each year to the licensee related to the licensee's production of medical marijuana and product; and

6. the amount of medical marijuana and product distributed to each pharmacy licensed to dispense medical marijuana in this state during each calendar year.

B. The report shall cover the previous calendar year and be received by the department no later than January 15.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1260 (July 2017).

Chapter 15. Production Facility

§1501. Production Facility and Areas

A. The production facility shall be compartmentalized based on function, and access shall be restricted between areas or compartments. The licensee shall develop, establish, maintain and comply with its written system of internal controls approved by the department regarding best practices for the secure and proper production of medical marijuana or products. These practices shall include, but not be limited to, policies and procedures that:

1. restrict movement between production areas or compartments;

2. ensure that only those personnel necessary for a production function have access to that area or compartment of the production facility;

3. require pocket-less clothing for all production facility employees working in an area containing medical marijuana or products;

4. document the chain of custody of all medical marijuana or products;

5. require the storage of all medical marijuana or products in the process of production, manufacture, distribution, transfer, or analysis in such a manner as to prevent diversion, theft or loss;

6. make all medical marijuana or products accessible only to the minimum number of specifically authorized employees essential for efficient operation;

7. require the return of all medical marijuana or products to their designated, secure locations immediately after completion of the process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the licensee shall securely lock the medical marijuana or products, or tanks, vessels, bins, or bulk containers containing any such materials inside a processing area or compartment that affords adequate security;

8. address mandatory and voluntary recalls of medical marijuana or products in a manner that adequately deals with recalls due to any action initiated at the request of the department and any voluntary action by the licensee to remove defective or potentially defective products from the market, or any action undertaken to promote public health and safety by replacing existing medical marijuana or products with improved products or packaging; and

9. prepare for, protect against, and handle any crises that affect the security or operation of the production facility in the event of fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

B. Each production area or compartment within a production facility shall:

1. develop, establish, maintain and comply with policies and procedures contained in the written system of internal controls for each production area, as approved by the department;

2. be maintained free of debris and kept clean and orderly;

3. be kept free from infestation by insects, rodents, birds or vermin of any kind, including the use of adequate screening or other protection against the entry of pests;

4. implement and maintain biosecurity measures at all times;

5. allow access on all sides of each medical marijuana plant group to allow for unobstructed movement of personnel and materials, for plant observation and for inventory of each plant group;

6. maintain production and storage areas, including areas where equipment or utensils are cleaned, with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions for the production of medical marijuana or products;

7. prevent the growth of undesirable microorganisms that can occur on medical marijuana plants by holding the plants in a manner that prevents such growth;

8. move medical marijuana or products that are outdated, damaged, deteriorated, misbranded or adulterated, or whose containers or packaging have been opened or breached, into a separate storage room, in a quarantined area, until the medical marijuana or products are destroyed pursuant to Chapter 27;

9. ensure that the oldest stock of medical marijuana or products is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

10. not produce any products other than medical marijuana or products;

11. maintain a record of all crop inputs for at least five years at the production facility. The record shall include the following (see Section 1507 for additional requirements for the use of pesticides):

a. the date of crop input application;

b. the name and title of the individual making the application;

c. the product that was applied;

d. the section, including the square footage, that received the application (by group designation or number);

e. the amount of product that was applied; and

f. a copy of the label of the product applied;

12. hold and store toxic cleaning compounds, sanitizing agents, solvents used in the production of any products, and pesticide chemicals in a manner that protects against contamination of medical marijuana or products, and in a manner that is in accordance with any applicable local, State or federal law, rule, regulation or ordinance;

13. ensure that the water supply to the production areas or compartments is sufficient for the operations intended and is derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable and adequate supply of water to meet the production facility's needs (see Chapter 27); and

14. ensure that plumbing complies with all applicable plumbing codes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1261 (July 2017).

§1503. Age Restrictions

A. No persons under the age of 21 shall:

1. enter any restricted area of the facility; or

2. be licensed or permitted by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1261 (July 2017).

§1505. Restricted Areas

A. Only permittees as provided in these rules, or in the internal controls may enter restricted areas except as otherwise provided herein. The licensee shall implement procedures to ensure compliance with this Section.

B. All non-permitted employees and visitors shall be accompanied by an authorized permittee.

C. All access to the production area of the facility, any area where product is located, and the vault shall be documented on a log maintained by the licensee. The logs shall contain entries with the following information:

1. the identity of each person entering the restricted area;
2. for non-permitted employees and visitors authorized by the department, the reason each person entered the restricted area;
3. the date and time each person enters and exits the restricted area;
4. a description of any unusual events occurring in the restricted area; and
5. such other information required in the internal controls.

D. The logs shall be made available to the department upon request.

E. Only transparent trash bags shall be utilized in restricted areas.

F. All authorized persons working in any restricted area when product is present shall wear clothing without any pockets or other compartments, unless otherwise authorized by the department.

G. Employees shall not bring purses, handbags, briefcases, bags or any other similar item into the restricted area.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1262 (July 2017).

§1507. Pesticide Usage on Medical Marijuana Plants

A. Only pesticides approved by the department may be applied by the licensee to the medical marijuana plant. The department's approved pesticide list shall be published in the Potpourri section of the *Louisiana Register* and on the department's website. Updates to the approved list shall be posted in the same manner.

B. All pesticide products shall be registered with the department, including those products classified by the United States Environmental Protection Agency as 25(b) “minimum risk” products.

C. No application of pesticides shall be made after the budding/flowering of the cannabis plant.

D. All permittees applying pesticides shall adhere fully to product label requirements and shall employ all personal protective equipment prescribed by the label.

E. A record of all pesticide applications shall be maintained at the production facility for at least five years and shall be made available to the department. The application record shall include the following information:

1. owner/operator name, address, and license number;
2. certified applicator, name, address and certification number;
3. product/brand name;
4. LDAF product registration number (if applicable);
5. application date;
6. crop/type of application;
7. location of application;
8. size of area treated acres, square feet, or minutes of spraying;
9. rate of application;
10. total amount of pesticide product (concentrate) applied; and
11. applicator name (working under the supervision of a certified applicator).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1262 (July 2017).

Chapter 17. Surveillance and Security

§1701. Required Surveillance Equipment

A. The licensee shall install a surveillance system on the entire premises of the production facility which meets or exceeds specifications established by the department and provide access to the department at all times.

B. Cameras, as approved by the department, shall monitor in detail, from various vantage points, the following:

1. the entire premises to include all areas within and outside the production facility excluding restrooms and private offices where product is not located;
2. the movement of medical marijuana and product on the premises;
3. the entrance and exits to the production facility;
4. inside of the vault area and restricted areas; and
5. such other areas as designated by the department.

C. All cameras shall be equipped with lenses of sufficient magnification to allow the operator to clearly distinguish product identifiers and ID tags.

D. All date and time generators shall be based on a synchronized, central or master clock, recorded and visible on any monitor when recorded.

E. The surveillance system and power wiring shall be tamper resistant.

F. The system shall be supplemented with a back-up gas or diesel generator power source which is automatically engaged in case of a power outage and capable of returning to full power within 7 to 10 seconds.

G. The system shall have an additional uninterrupted power supply system so that time and date generators remain active and accurate.

H. Video switchers shall be capable of both manual and automatic sequential switching for the appropriate cameras.

I. Recorders, as approved by the department, shall be capable of producing high quality first generation pictures and recording with high speed scanning and flicker-less playback capabilities in real time, or other medium approved by the department. Such recorders must possess time and date insertion capabilities for recording what is being viewed by any camera in the system.

J. The system shall have audio capability in certain areas as required by the department.

K. The production facility shall have adequate lighting in all areas where camera coverage is required. The lighting shall be of sufficient intensity to produce clear recording and still picture production, and correct color correction where color camera recording is required. The video must demonstrate a clear picture, in existing light under normal operating conditions.

L. Adequate back-up replacement equipment shall be maintained on the premises to ensure prompt replacement in the event of failure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1262 (July 2017).

§1703. Surveillance System Plans

A. The licensee shall submit to the department for approval a surveillance system plan prior to the commencement of operations. The surveillance system plan shall include a floor plan indicating the placement of all surveillance equipment and a detailed description of the surveillance system and its equipment. The plan shall also include a detailed description of the configuration of the monitoring equipment. The plan may include other information that evidences compliance with this Subsection by the licensee including, but not limited to, a configuration detailing the location of all production equipment.

B. Any changes to the surveillance system shall require prior approval by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1263 (July 2017).

§1705. Surveillance Personnel Employment Provisions

A. The licensee shall designate at a minimum one permittee responsible in the use, monitoring, and administration of the surveillance system. This employee is prohibited from having duties in the production process.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1263 (July 2017).

§1707. Storage and Retrieval

A. All video recordings shall be retained for at least 30 days, unless otherwise provided for in these rules or required by the department.

B. Any video recording of illegal or suspected illegal activity shall, upon completion of the recording, be duplicated and the copy shall be preserved until the department notifies the licensee otherwise.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1263 (July 2017).

§1709. Security Plan Requirements

A. The licensee shall submit to the department a security plan prior to commencement of operations to include, at a minimum, the following:

1. a detailed description of all security solutions for the production facility and transportation of product to and from the facility to be implemented by the licensee;

2. security training requirements and procedures; and

3. other information required by the department that evidences compliance with the Act and these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1263 (July 2017).

§1711. Security Alarm System

A. The licensee shall install and maintain in good working order a professionally installed and monitored security alarm system as approved by the department. This system shall provide intrusion and fire detection for all buildings and areas within the premises. The alarm system shall be able to operate in the event of a power outage.

B. The security system shall be able to summon law enforcement personnel during, or as a result of, an alarm condition. The security system must be equipped with the following components or features:

1. motion detectors;
2. a duress alarm
3. a panic alarm;
4. a holdup alarm;
5. an automatic voice dialer; and
6. a failure alert system that provides an audio, text, or visual notification of any failure in the alarm system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1263 (July 2017).

§1713. Security of Premises and Production Facility

A. The licensee shall:

1. erect fencing or other barriers as approved by the department of adequate type and height to prevent unauthorized persons from entering the premises. Ingress and egress to the premises shall be controlled by use of a gate or other approved device;

2. install locks or locking mechanisms of adequate type to securely lock and protect the premises and production facility from unauthorized entry at all times. The licensee shall safeguard all keys, combinations, passwords, and other security sensitive measures in a manner that prevents accessibility from unauthorized persons;

3. install exterior lighting sufficient to illuminate all areas of the premises to facilitate surveillance and deter unauthorized activity;

4. load the medical marijuana or product for transportation to dispensaries in a locked, secured area within the perimeter protected by fence or other approved barrier. This area shall be considered a restricted area obscured from public view; and

5. post a sign at all entryways into the premises and production facility which shall be a minimum of 12 inches in height and 12 inches in width which shall state: "DO NOT ENTER—RESTRICTED ACCESS AREA—ACCESS LIMITED TO AUTHORIZED PERSONNEL ONLY", or other wording approved by the department. The lettering shall be no smaller than one-half inch in height.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1263 (July 2017).

§1715. Security Log/Notification/Reports

A. The licensee shall maintain a security log of all visitors to the production facility and unusual incidents. Each incident without regard to materiality shall be entered in the log containing, at a minimum, the following information:

1. the assignment number;
2. the date;
3. the time;
4. the description of the incident;
5. the person involved in the incident; and
6. the permittee assigned.

B. The security logs required by this Section shall be retained and stored by month and year.

C. The licensee or its employees shall provide immediate notification to the department of knowledge of any theft of medical marijuana or product, or violation of the Act, or these rules.

D. The licensee shall compile a written report to be promptly filed with the department on any incident in which the licensee has knowledge of, or reasonable suspicion that a violation of the Act, these rules, or its system of internal controls has occurred.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1264 (July 2017).

Chapter 19. Inventory

§1901. Medical Marijuana Inventory; Inventory Tracking System Required

A. The licensee shall provide a reliable and ongoing supply of medical marijuana as required by R.S. 40:1046(C)(2)(D).

B. The licensee shall establish inventory controls and procedures for conducting inventory reviews and comprehensive inventories of plant material, medical marijuana, and product to prevent and detect any diversion, theft, or loss in a timely manner.

C. The licensee shall maintain a record of its inventory of all medical marijuana waste, product waste, and plant material waste for disposal.

D. The licensee shall be required to use the LMMTS as the primary inventory tracking system of record. The system and all use thereof shall conform to the requirements set forth in Section 1903 and Chapter 19.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1264 (July 2017).

§1903. General Inventory Tracking System Use

A. All inventory tracking activities by the licensee shall be tracked through use of the LMMTS. The licensee shall reconcile all on-premises and in-transit medical marijuana and product inventories each day in the LMMTS at the close of business.

B. Common weights and measures:

1. the licensee shall utilize a standard of measurement that is supported by the LMMTS to track all medical marijuana and product;

2. a scale used to weigh such product prior to entry into the LMMTS shall be tested and approved in accordance with R.S 3:4601 et seq.

C. LMMTS administrator and user accounts, security and record:

1. the licensee is accountable for all actions permittees take while logged into the LMMTS or otherwise conducting medical marijuana or product inventory tracking activities; and

2. Each individual user is also accountable for all of his or her actions while logged into the LMMTS or otherwise conducting medical marijuana or product inventory tracking activities, and must maintain compliance with all relevant laws and rules.

D. Secondary software systems allowed:

1. nothing in this rule prohibits the licensee from using separate software applications to collect information to be used by the business including secondary inventory tracking or point of sale systems; and

2. a licensee shall ensure that all relevant LMMTS data is accurately transferred to and from the LMMTS for the purpose of reconciliations with any secondary systems.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1264 (July 2017).

§1905. Inventory Tracking System Access

A. The licensee shall have at least one individual permittee who is a LMMTS administrator. The licensee may also designate additional permittees to obtain LMMTS administrator accounts in accordance with internal controls.

B. In order to obtain a LMMTS administrator account, a person must attend and successfully complete all required LMMTS training. The department may also require additional ongoing, continuing education for an individual to retain his or her LMMTS administrator account.

C. The licensee may designate permittees who hold a valid employee permit as a LMMTS User. The licensee shall ensure that all permittees who are granted LMMTS user account access for the purposes of conducting inventory tracking functions in the system are trained by LMMTS administrators in the proper and lawful use of LMMTS.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1264 (July 2017).

§1907. ID Tags Required

A. The licensee shall be responsible to ensure its inventories are properly tagged where the LMMTS requires ID tag use. The licensee must ensure it has an adequate supply of ID tags to properly identify medical marijuana and product as required by the LMMTS.

B. The licensee is responsible for the cost of all ID tags and any associated fees as approved by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1264 (July 2017).

§1909. Conduct While Using Inventory Tracking System

A. The licensee and its designated LMMTS administrators and LMMTS users shall enter data into the LMMTS that fully and transparently accounts for all inventory tracking activities. Both the licensee and the permittees using the LMMTS are responsible for the accuracy of all information entered into the LMMTS. Any misstatements or omissions may be considered a violation of these rules.

B. Individuals entering data into the LMMTS shall only use that individual's LMMTS account.

C. If at any time the licensee loses access to the LMMTS for any reason, the licensee shall keep and maintain comprehensive records detailing all medical marijuana and medical marijuana-infused product tracking inventory activities that were conducted during the loss of access. See Section 1301, Reporting and Record Keeping. Once access is restored, all medical marijuana and product inventory tracking activities that occurred during the loss of access shall be entered into the LMMTS. The licensee must document when access to the system was lost and when it was restored.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1265 (July 2017).

§1911. System Notifications

A. The licensee shall monitor all compliance notifications from the LMMTS. The licensee shall resolve the issues detailed in the compliance notification in a timely fashion. Compliance notifications shall not be dismissed in the LMMTS until the licensee resolves the compliance issues detailed in the notification.

B. The licensee shall take appropriate action in response to informational notifications received through the LMMTS, including but not limited to notifications related to ID billing, enforcement alerts, and other pertinent information.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1265 (July 2017).

Chapter 21. Quality Control/Assurance Program

§2101. Quality Control

A. The licensee shall develop and implement a written quality assurance program for determining necessary storage conditions and shelf life for both medical marijuana concentrates and products subject to the following:

1. the quality assurance program shall include procedures to be followed if the mandated testing described in Chapter 23 indicates contamination or non-homogenous products;

2. any area within the production facility where medical marijuana will be produced into an edible form shall comply with the Louisiana State Food, Drug & Cosmetic Law.

3. no products requiring refrigeration or hot-holding shall be manufactured at a production facility for sale or distribution to a marijuana pharmacy due to the potential for food-borne illness.

B. The licensee shall develop and follow written procedures determining storage conditions and establishing shelf life for each product type such that:

1. samples are collected in a manner that provides analytically sound and representative samples;

2. sample size and test intervals are based on statistical criteria for each attribute examined to ensure valid stability estimates;

3. samples are labeled with the unique batch identifier;

4. samples are tested at a minimum for both potency and microbiological contamination against the limits set forth in Chapter 23;

5. storage conditions do not involve refrigeration, heating, or specialized ventilation systems;

6. the same container-closure system in which the product is dispensed at point of sale is used during the shelf life testing; and

7. the documentation supporting required storage conditions and shelf life determinations are retained for at least five years.

C. The licensee shall develop and follow written procedures for responding to mandated testing results indicating contamination of any kind including:

1. documenting the destruction of the contaminated medical marijuana or product as described in Chapter 27;

2. determining the source of the contamination;

3. documentation of the elimination of the source of contamination; and

4. retention of all documents involved in the incident for at least five years.

D. The licensee shall bear any and all costs incurred in determining the shelf life, the storage conditions and the activities necessary to respond to findings of contamination or non-homogeneity.

E. If shelf life studies have not been completed, the licensee may assign a tentative expiration date based on any available stability information. The licensee shall concurrently conduct shelf life studies to determine the actual product expiration date.

F. After the licensee verifies the tentative expiration date, or determines the appropriate expiration date, the licensee shall include that expiration date on each batch of product.

G. Shelf life testing shall be repeated if the production facility's process or the product's chemical composition is changed.

H. The licensee shall retain a reserve sample that represents each batch of medical marijuana and store it under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the product is dispensed, or in one that has similar characteristics. The reserve sample must consist of at least twice the quantity necessary to perform all the required tests.

I. The licensee shall retain the reserve for at least one year following the batch's expiration date. At the end of this time or later, the reserve shall be destroyed following the procedures set forth in Chapter 27.

J. If the department deems that public health may be at risk, the department may require the licensee to release any

reserve sample to be tested at any time for any analysis it deems necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1265 (July 2017).

Chapter 23. Laboratory Approval and Testing

§2301. Laboratory Approval

A. No laboratory shall handle, test or analyze medical marijuana or product unless approved by the department in accordance with this Section. A list of approved laboratories will be made available by the department on its website.

B. No laboratory shall be approved to handle, test or analyze medical marijuana or product unless the laboratory:

1. is accredited to International Organization for Standards (ISO) 17025 standards by a private laboratory accrediting organization for the analyses being conducted. Additionally, the laboratory must provide the department with a copy of the most recent inspection report granting accreditation and every inspection report thereafter. Failure to maintain accreditation to the ISO 17025 will result in the revocation of the department's approval for medical marijuana or product testing;

2. is independent from all other persons involved in the medical marijuana industry in Louisiana, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial, management or other interest in a licensed marijuana pharmacy, licensee, production facility, certifying physician or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase or use of medical marijuana or product;

3. employs, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification;

4. maintains a written and documented system to evaluate and document the laboratory's and each employee's competency in performing authorized required tests. Prior to independently analyzing samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls);

5. submits to an on-site facility review by the department or its designated agent prior to the granting of departmental approval. The production facility will continue to be subject to inspection at any time subsequent to approval; and

6. accepts the requirement that laboratories utilize the department's approved computerized inventory tracking system (LMMTS) to post results of sample analyses for review by the department and licensee. The laboratory is responsible for any costs associated with their access to the computerized inventory tracking system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1266 (July 2017).

§2303. Laboratory Testing

A. Each batch of medical marijuana concentrate and product shall be made available by the licensee for an employee of an approved laboratory or otherwise independent sample collector to select a random and representative sample of sufficient volume to conduct required analyses, which shall be tested by an approved laboratory.

1. Medical marijuana concentrate shall not be used to produce any form of product until it has passed all analysis limits for:

a. active ingredient analysis for characterization of potency;

b. pesticide active ingredients, including but not limited to, the most recent list of targeted pesticides published by the department;

c. residual solvents;

d. heavy metals; and

e. mycotoxins.

2. product shall not be released for delivery to a marijuana pharmacy for sale or consumption until it has passed all analysis limits for:

a. microbiological contaminants;

b. active ingredient analysis for accuracy of potency; and

c. homogeneity.

B. The department may select a random sample at any point in the process for the purpose of analysis for anything the department deems necessary.

C. Samples shall be secured in a manner approved by the department at all times when not in immediate use for the analyses being conducted.

D. Testing Specifications and Limits

1. Every sample shall undergo a microbiological test. For purposes of the microbiological test, a sample shall be deemed to have passed if it satisfies the recommended microbial and fungal limits for cannabis products in colony forming units per gram (CFU/g) as follows:

a. total yeast and mold: <10,000 CFU/g; and

b. E. coli (pathogenic strains) and Salmonella spp. <1 CFU/g.

2. Every sample shall undergo a mycotoxin test. For purposes of the mycotoxin test, a sample shall be deemed to have passed if it meets the following standards:

a. aflatoxin B1: <20 ppb;

b. aflatoxin B2: <20 ppb;

c. aflatoxin G1: <20 ppb;

d. aflatoxin G2: <20 ppb; and

e. ochratoxin: <20 ppb.

3. Every sample shall undergo a pesticide chemical residue test. For purposes of the pesticide chemical residue test, a sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in subpart C of USEPA's regulations for tolerances and exemptions for pesticide chemical residues in food [40 CFR 180 (2014)];

4. Every sample shall undergo a residue solvent test. For purposes of the residue solvent test, a sample shall be deemed to have passed if the following solvents are below the limits listed below:

a. butanes: <800 ppm;
b. heptanes: <500 ppm;
c. benzene: <1 ppm;
d. toluene: <1 ppm;
e. hexanes: <10 ppm;
f. total xylenes: <1 ppm; and
g. ethanol: <5,000 ppm.

5. Every sample shall undergo a heavy metal test. For the purpose of the heavy metal test, a sample shall be deemed to have passed if it meets the following standards:

a. arsenic: <10ppm;
b. cadmium: <4.1ppm;
c. lead: <10ppm; and
d. mercury:<2.0ppm.

6. Every sample shall undergo an active ingredient analysis or potency analysis. For medical marijuana concentrate samples, the potency test is to establish the presence of active ingredients and their concentrations for accurate calculations of amounts needed for the production of products. For product samples, the potency test is to establish the active ingredient composition for verification of labeling to ensure accurate dosing:

a. requires analysis of the following actives:
i. THC (tetrahydrocannabinol);
ii. THCA tetrahydrocannabinol acid;
iii. CBD cannabidiol; and
iv. CBDA cannadidiolic acid.

b. for product analysis, a variance of no more than plus or minus fifteen percent is allowed from the labeled amount of active ingredient. Thus a product labeled as containing 10 milligrams THC must contain no less than 8.50 milligrams THC and no more than 11.50 milligrams THC.

7. Every sample shall undergo a homogeneity test. A product will be considered not homogenous if ten percent of the product contains more than twenty percent of the total active ingredient.

E. If a medical marijuana concentrate sample fails testing for pesticides, heavy metals or mycotoxin, the entire batch from which the sample was taken shall be disposed of in accordance with Chapter 27.

F. If a medical marijuana concentrate sample fails residual solvents testing, then, with prior approval of the department, the product may be subjected to an appropriate remedy (ex. vacuum drying) , reformulated and tested again. The reformulation must pass all required tests for a medical marijuana concentrate in duplicate before it can be released for use in products. If either duplicate fails any test, the entire batch shall be disposed of in accordance with Chapter 27. A batch of medical marijuana concentrate can only be reformulated once and only to remedy excessive residual solvents.

G. If a product fails the microbiological testing the entire batch from which the sample was taken shall be disposed of in accordance with Chapter 27.

H. If a product fails the potency or homogeneity testing then, with prior approval of the department, the product can be re-sized and tested again. The re-formulated product shall be tested again in duplicate and pass all required tests before it can be released for sale or consumption. If either duplicate fails any test, the entire batch shall be disposed of in accordance with Chapter 27.

I. The laboratory shall enter the results of any tests performed pursuant to this Section into LMMTS within 24 hours of completion of each test. The laboratory shall file with the department and licensee an electronic copy of each laboratory test result for any sample that does not pass a test. In addition, the laboratory shall maintain the laboratory test results including all relevant chromatograms and quality control documentation for at least five years and make them available at the department's request.

J. The laboratory shall dispose of any remaining medical marijuana or product samples no sooner than 60 days following the completion of any testing. Disposal will be performed in accordance with Chapter 27.

K. The licensee shall provide to the marijuana pharmacy the laboratory test results for each batch of product purchased.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1266 (July 2017).

Chapter 25. Transportation

§2501. Transportation

A. The licensee or its authorized permittee shall only be allowed to transport medical marijuana or product to the following locations:

1. from its production facility to dispensaries;
2. from its production facility to a laboratory for testing or research; and
3. when a specific non-routine transport request from the licensee is approved in writing by the department.

B. The licensee or its authorized permittee shall:

1. have a valid Louisiana driver's license and be insured above the legal requirements in Louisiana; and
2. be capable of securing (locking) medical marijuana and product items during transportation.

C. Prior to transporting medical marijuana or product, a licensee shall generate a transport manifest, utilizing LMMTS, that accompanies every transport of medical marijuana or product. Such manifests shall contain the following information:

1. the name, contact information of a licensee authorized representative, licensed premises address, and the authorized permittee transporting the medical marijuana or product;
2. the name, contact information, and premises address of the marijuana pharmacy or laboratory receiving the delivery;
3. medical marijuana or product name and quantities (by weight or unit) of each item contained in each transport, along with the requisite unique identification number for every item;
4. the date of transport and time of departure;
5. arrival date and estimated time of arrival;
6. delivery vehicle make and model and license plate number; and
7. name and signature of the authorized permittee accompanying the transport.

D. Only the licensee or its authorized permittee may transport medical marijuana or product from the production facility to multiple dispensaries in a single trip in the event that each transport manifest correctly reflects specific inventory in transit.

E. Transport manifests shall be available for viewing through LMMTS, to the marijuana pharmacy, laboratory for testing, and the department before the close of business the day prior to transport.

F. The licensee or its authorized employees shall provide a copy of the transport manifest to law enforcement if requested to do so while in transit.

G. An authorized employee of the marijuana pharmacy or approved laboratory for testing shall verify that the medical marijuana or product are received as listed in the transport manifest by:

1. verifying and documenting the type and quantity of the transported medical marijuana or product against the transport manifest; and

2. returning a copy of the signed transport manifest to the production facility.

H. A receiving marijuana pharmacy or approved laboratory for testing shall separately document any differences between the quantity specified in the transport manifest and the quantities received. Such documentation shall be made in LMMTS and in any relevant business records.

I. The licensee shall ensure that all medical marijuana, plant material, or product transported on public roadways is:

1. only transported in a locked, safe and secure storage compartment that is part of the motor vehicle transporting the medical marijuana or product, or in a locked storage container that has a separate key or combination pad;

2. transported so it is not visible or recognizable from outside the vehicle; and

3. transported in a vehicle that does not bear any markings to indicate that the vehicle contains medical marijuana or bears the name or logo of the licensee.

J. Authorized permittees who are transporting medical marijuana or product on public roadways shall:

1. travel directly to the marijuana pharmacy or laboratory testing facility; and

2. document refueling and all other stops in transit, including:

a. the reason for the stop;

b. the duration of the stop;

c. the location of the stop; and

d. all activities of employees exiting the vehicle.

K. Every authorized permittee shall have access to a secure form of communication with the licensee and the ability to contact law enforcement through the 911 emergency systems at all times that the motor vehicle contains medical marijuana or product. If an emergency requires stopping the vehicle, the employee shall report the emergency immediately to law enforcement through the 911 emergency systems and the licensee, which shall immediately notify the department. The employee shall also complete an incident report form provided by the department.

L. The licensee shall ensure that all delivery times and routes are randomized.

M. Under no circumstance shall any person other than a designated permittee have actual physical control of the motor vehicle that is transporting the medical marijuana or product.

N. The licensee shall staff all transport motor vehicles with a minimum of two employees. At least one employee must remain with the motor vehicle at all times that the motor vehicle contains medical marijuana or product.

O. A permittee shall carry his permittee identification card at all times when transporting or delivering medical marijuana or product and, upon request, produce the identification card to the department or to a law enforcement officer acting in the course of official duties.

P. The licensee shall ensure that a vehicle containing medical marijuana or product in transit is not left unattended.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1267 (July 2017).

Chapter 27. Sanitation and Disposal

§2701. Production Facility Sanitation

A. The production facility shall be designed, constructed and operated in such a manner that:

1. all buildings, fixtures and other facilities are maintained in a sanitary condition;

2. floors, walls and ceilings are adequately cleaned;

3. litter and waste are properly removed and all waste disposal operating systems are maintained in such a manner that they do not constitute a source of contamination;

4. rubbish is disposed of so as to minimize the development of odor and minimize the potential for waste becoming an attractant, harborage or breeding place for pests;

5. all activities and operations involved in the receiving, inspecting, transporting, segregating, preparing, production, packaging and storing of medical marijuana or products shall be conducted in accordance with adequate sanitation principles;

6. all contact surfaces, including utensils and equipment used for the preparation of medical marijuana or products, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be designed and shall be of such material and workmanship as to be adequately cleanable, and shall be properly maintained;

7. only sanitizing agents registered with the department pursuant to the Act shall be used in the production facility, and they shall be used in accordance with labeled instructions;

8. the licensee shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and in good repair; and

9. hand-washing facilities shall be adequate and conveniently located in the production facility, and furnished with running water at a suitable temperature. They must provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices.

B. Permittees and authorized visitors to the production facility shall follow hygienic practices while present at the facility, including but not limited to the following:

1. maintaining adequate personal cleanliness;

2. washing hands thoroughly in adequate hand-washing areas before starting work and at any other time when hands may have become soiled or contaminated; and

3. permittees and authorized visitors who, by medical examination or supervisory observation, are shown to have,

or appear to have, an illness, open lesion, including boils, sores or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with medical marijuana or products, shall be excluded from any operations that may be expected to result in microbial contamination until the condition is corrected.

C. Prior to commencing operation, the production facility in its entirety will be inspected by State Fire Marshall, Department of Health, and any other entity required by law.

D. The authorized health inspectors may at any time enter any building, room, enclosure, or premises occupied or used, or suspected of being occupied or used, in production facility activities for the purpose of inspecting the premises and all utensils, fixtures, furniture, and machinery used in the production facility

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1268 (July 2017).

§2703. Potable Water Supply

A. Potable water supply lines shall not be connected to process water lines, chemical lines or equipment, unless proper backflow protection is installed.

B. Water service lines that connect a production facility to a public water supply shall include either a reduced pressure principle backflow preventer or a fixed proper air gap, in accordance with the Part XIV (Plumbing) of the *Sanitary Code*, state of Louisiana.

C. Water service lines that connect a production facility to a potable water supply other than a community public water supply shall include either a reduced pressure principle backflow preventer or a fixed proper air gap, in accordance with the Part XIV (Plumbing) of the *Sanitary Code*, state of Louisiana

D. Installation, maintenance and inspection of backflow prevention devices shall be carried out in accordance with the requirements of Part XIV (Plumbing) of the *Sanitary Code*, state of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1269 (July 2017).

§2705. Disposal of Waste

A. Disposal of waste rendered unusable shall follow the methods set forth in this section. For the purpose of this Section "waste" shall include:

1. plant material waste;
2. medical marijuana waste; and
3. product waste.

B. The licensee shall dispose of any waste as provided for in this section, and maintain a written record of disposal that includes:

1. the date returned;
2. the quantity returned; and
3. the type and batch number returned.

C. Waste must be stored, secured, locked and managed in accordance with these rules and as submitted and approved in the licensee's written system of internal controls.

D. The licensee shall provide the department, through the LMMTS, a minimum of seven days notice prior to rendering the product unusable and disposing of the product.

E. The allowable method to render waste unusable is by grinding and incorporating the waste with other ground materials so the resulting mixture is at least 50 percent non-medical marijuana waste by volume. Other methods to render waste unusable must be approved by the department before implementation. Material used to grind with the waste may include:

1. food waste;
2. yard waste;
3. vegetable-based grease or oils;
4. paper waste;
5. cardboard waste;
6. plastic waste;
7. soil; or
8. other wastes approved by the department (e.g., non-recyclable plastic, broken glass, leather, agricultural material, biodegradable products, paper, clean wood, fruits, vegetables, and plant matter).

F. Waste shall be rendered unusable prior to leaving a production facility. Waste rendered unusable following the methods described in this Section shall be disposed of by delivery to an approved solid waste facility for final disposition. Examples of acceptable permitted solid waste facilities include:

1. compost, anaerobic digester;
2. landfill, incinerator, or other facility with approval of the jurisdictional health department; or
3. a waste-to-energy facility

G. Inventory Tracking Requirements

1. In addition to all other tracking requirements set forth in these rules, the licensee shall utilize the LMMTS to ensure its post-harvest waste materials are identified, weighed and tracked while on the licensed premises until disposed of.

2. All waste shall be weighed, recorded and entered into LMMTS prior to mixing and disposal. Verification of this event shall be performed by a supervisor and conducted in an area with video surveillance.

3. All waste shall be weighed before leaving the production facility. A scale used to weigh waste prior to entry into the LMMTS shall be tested and approved in accordance with R.S. 3:4601 et seq.

4. The licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of waste.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1269 (July 2017).

Chapter 29. Labeling

§2901. Labeling Requirements

A. Each product shall be labeled by the licensee prior to sale to a marijuana pharmacy. Each label shall be securely affixed to the package and shall include:

1. the batch number(s) assigned by the licensee to the marijuana plant(s) from which the medical marijuana used in the product was harvested;

2. a complete list of solvents, chemicals and pesticides used in the creation of any medical marijuana concentrate;

3. a complete list of all ingredients used to manufacture the product, which may include a list of any potential allergens contained within, or used in the manufacture of a product;

4. the potency of the THC and CBD in the product, expressed in milligrams for each cannabinoid;

5. the net weight, using a standard of measure compatible with the LMMTS, of the product prior to its placement in the shipping container;

6. a product expiration date, upon which the product will no longer be fit for consumption, or a use-by date, upon which the product will no longer be optimally fresh. Once a label with a use-by or expiration date has been affixed to a product, the licensee shall not alter that date or affix a new label with a later use-by or expiration date; and

7. a statement that the product has been tested for contaminants, that there were no adverse findings, and the date of testing.

B. Labeling text on any product may not make any false or misleading statements regarding health or physical benefits to the consumer. Each label must include the following statements:

1. "Contains Medical Marijuana. For Medical Use Only. KEEP OUT OF THE REACH OF CHILDREN.";

2. "There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant.";

3. a statement that it is illegal for any person to possess or consume the contents of the package other than the qualifying patient.

C. Labeling text required by this section to be placed on any product may be no smaller than 1/16 of an inch, must be printed in English and must be unobstructed and conspicuous.

D. The following information is permissible on a label:

1. the product's compatibility with dietary restrictions; and

2. a nutritional fact panel.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1269 (July 2017).

§2903. Packaging Requirements

A. The licensee shall ensure that every product being sent to a marijuana pharmacy for sale to a qualified patient is placed within a child resistant, light resistant, tamper proof container prior to sale or transport to the marijuana pharmacy.

B. If it is not intended for the entire product to be used at a single time, the packaging must be resealable in a manner that maintains its child resistant effectiveness for multiple openings.

C. A product may not be placed in packaging that specifically targets individuals under the age of 21. Any packaging must not:

1. bear any resemblance to a trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;

2. use the word "candy" or "candies";

3. use a cartoon, color scheme, image, graphic or feature that might make the package attractive to children; or

4. use a seal, flag, crest, coat of arms or other insignia that could reasonably lead any person to believe that the product has been endorsed, manufactured, or used by any state, parish, municipality or any agent thereof.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1270 (July 2017).

§2905. Product Dosage Identification

A. Each product shall be marked, stamped or emprinted with the dosage, as approved by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1270 (July 2017).

§2907. Advertising

A. The licensee shall not advertise through any public medium, including but not limited to newspapers, television, radio, internet, or any other means designated to market its products to the general public. The licensee may market its products directly to the licensed dispensaries and to physicians through direct mail, brochures or other means directed solely to the licensed dispensaries and/or physicians and not available to the general public.

B. Any advertisement permitted by Subsection A shall not:

1. make any deceptive, false, or misleading assertions or statements regarding any product; or

2. assert that its products are safe because they are regulated by the department. The licensee may state in advertisements that its products have been tested by an approved laboratory, but shall not assert that its products are safe because they are tested by an approved laboratory.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1270 (July 2017).

Chapter 31. Enforcement

§3101. Enforcement

A. Whenever the department has any reason to believe that a violation of the Act or this Part or of any rule or regulation adopted pursuant to this Part has occurred, the department may present the alleged violations to a hearing officer for a determination.

B. The department may impose civil penalties and/or suspend, revoke or place on probation any permitee or licensee for the commission of a violation of the Act or of these rules. Civil penalties may be assessed, probation may be imposed, and permits and licenses may be suspended or revoked only upon a ruling of the hearing officer based on an adjudicatory hearing held in accordance with the Administrative Procedure Act.

1. The department shall appoint a hearing officer to preside over all hearings.

2. The department shall notify the alleged violator of the hearing, by personal service or certified mail, at least 30 days prior to the date the hearing is held.

3. The notice shall contain the following information:

a. a statement of the alleged violation;

b. the specific section of the Act or these rules and regulations alleged to have been violated;

c. the date, time, and place where the hearing will be held;

d. a statement of the rights which will be afforded to the licensee or permittee at the hearing; and

e. a statement as to the possible penalties which may be imposed upon a finding by the hearing officer at the hearing that the alleged violator committed the alleged violation.

4. The alleged violator shall have the right to representation by legal counsel and the right to examine and cross-examine witnesses as in civil cases. The alleged violator shall have the right to compel the attendance of witnesses and the production of evidence upon depositing with the department the fees required for issuing subpoenas and subpoenas duces tecum in civil cases.

C. Any person who violates any provision of the Act or this Part or any rule or regulation adopted pursuant thereto or any provision of a stop order, shall be subject to a civil penalty of not more than $50,000 for each act of violation and for each day of violation. Each day on which a violation occurs shall be a separate offense.

D. The department may summarily suspend the licensee or a permit without a hearing, simultaneously with the institution of proceedings for a hearing, if the department finds that the public safety or welfare immediately requires this action. In the event that the department summarily suspends a licensee or a permit, a hearing shall be held within 30 days after the suspension has occurred. The suspended party may seek a continuance of the hearing, during which the suspension shall remain in effect. The proceeding shall be concluded without reasonable delay. If the department does not hold a hearing within 30 days after the date of the suspension, and the licensee or permitee has not requested a continuance, the license or permit shall be automatically reinstated.

E. The department may require an individual permitee or the licensee against whom disciplinary action has been taken by the department to pay the reasonable costs incurred by the department for the hearing or proceedings, including its legal fees, court reporter, investigators, witness fees, and any such costs and fees incurred by the department. These costs and fees shall be paid no later than 30 days after the decision of the hearing officer becomes final. No license or permit shall be renewed or reinstated until such costs have been paid.

F. The department may institute civil proceedings in the Nineteenth District Court to enforce the rulings of the hearing officer. The department may institute civil proceedings seeking injunctive relief to restrain and prevent violations of the provisions of this Part or of the rules and regulations adopted under the provisions of this Part in the Nineteenth District Court.

G. As to every matter on which a hearing is held, the presiding hearing officer shall prepare a written findings of fact and conclusions of law, which shall contain, at a minimum, the record of the hearing, including all submissions, his finding of the facts that are pertinent to the decision, his conclusions of applicable law related to the decision, and his decision. The submission shall be in writing, shall be provided to all involved applicants, and shall be a public record, except for any submitted materials which are confidential pursuant to law.

H. The hearing officer shall render his decision within 30 days after the hearing is conducted.

I. All appeals from any decision of the hearing officer shall be filed in accordance with chapter 13 of title 49 of the *Louisiana Revised Statutes*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of Agricultural and Environmental Sciences, LR 43:1270 (July 2017).

Mike Strain, DVM
Commissioner

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Louisiana Board of Pharmacy

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M E M O R A N D U M

To: Board Members & Staff

From: Malcolm Broussard

Date: August 23, 2017

Re: Resolutions from 2017 NABP Annual Meeting

Delegates at the 113th Annual Meeting of the National Association of Boards of Pharmacy considered ten resolutions; they approved seven and rejected three. The resolutions adopted are summarized here, and their full text follows:

- No. 113-1-17: Best Practices for Veterinary Compounding
- No. 113-2-17: Definition of a Patient-Pharmacist Relationship
- No. 113-3-17: Experiential Learning for Non-US Pharmacists and Students
- No. 113-4-17: Task Force on Long-Term Care Pharmacy Rules
- No. 113-5-17: Adjudication of Concurrent Disciplinary Actions
- No. 113-6-17: Uniform Unit-of-Use Packaging Standards
- No. 113-7-17: Recognition Resolution

No. 113-1-17: Best Practices for Veterinary Compounding

WHEREAS, the compounding of medications for human use is regulated by the state boards of pharmacy through statutes, regulations, and applicable standards such as United States Pharmacopeia Chapters and the Food and Drug Administration (FDA), where applicable; and

WHEREAS, pharmacists who oversee or are engaged in the compounding of human products are required to demonstrate competence and engage in continuing education; and

WHEREAS, the scope and regulation of the compounding of animal products differ from the compounding of medications for human use and administration; and

WHEREAS, the Drug Quality Security Act and accompanying guidance documents issued by FDA do not include regulatory guidance for the compounding of animal products;

THEREFORE BE IT RESOLVED that NABP commission a task force of stakeholders, which may include FDA, to develop model regulations for the compounding of animal products.

Note: The NABP Executive Committee established the Task Force on Best Practices for Veterinary Compounding, and NABP President Jeanne Waggener appointed nine members and four alternates to the task force. The task force met on August 14-15, 2017 to begin their deliberations.

No. 113-2-17: Definition of a Patient-Pharmacist Relationship

WHEREAS, a patient-physician relationship is generally formed when a physician agrees to assume care for a patient. Once the physician consensually enters into a relationship with a patient in any of these ways, a legal obligation is established in which the physician owes a duty to that patient to continue to treat or properly terminate the relationship; and

WHEREAS, when a patient-physician relationship is established, the physician has an ethical and legal duty to continue care and not to abandon the patient; and

WHEREAS, the pharmacist's role in their patients' health care is rapidly expanding due to the pharmacist's expertise, accessibility, and the shortage of primary care providers; and

WHEREAS, the pharmacist's role continues to change and evolve as a patient care advocate, prescriber, disease treatment manager, protector, and educator; the patient should be informed as to how the pharmacist will honor and legally act in response to the patient's health care matters; and

WHEREAS, other health care professional relationships have definitions, which provide patients with an understanding of the trust, ethical, and patient-centric behaviors required of other health care professionals; and

WHEREAS, the definition of a patient-pharmacist relationship has never been adopted;

THEREFORE BE IT RESOLVED that NABP convene a task force that includes appropriate stakeholders to examine this issue and recommend amending, if necessary, the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy to include a definition of a patient-pharmacist relationship.

Note: The NABP Executive Committee established the Task Force on the Definition of a Patient-Pharmacist Relationship, and NABP President Jeanne Waggener appointed fifteen members and five alternates to the task force. The task force is scheduled to meet on September 18-19, 2017 to begin their deliberations.

No. 113-3-17: Experiential Learning for Non-US Pharmacists and Students

WHEREAS, there is an increasing interest in global exchange programs that provide practitioners and pharmacy students opportunities to learn about pharmacy services in the United States and other countries; and

WHEREAS, international students coming to US schools and colleges of pharmacy and practice sites may encounter significant restrictions in their ability to engage in practice-based clinical learning activities due to regulatory and institutional constraints; and

WHEREAS, state boards of pharmacy can play a key role in optimizing the learning experience of such students by requiring that students must always be under the supervision of licensed pharmacists;

THEREFORE BE IT RESOLVED that NABP collaborate with stakeholders to examine mechanisms that would allow exchange students and practitioners to participate in clinical learning activities in the US.

No. 113-4-117: Task Force on Long-Term Care Pharmacy Rules

WHEREAS, there is an increase in the practice of long-term care pharmacy due to the aging of the United States population; and

WHEREAS, some state pharmacy laws and regulations have not evolved with this growing practice, including but not limited to the areas of definitions, therapeutic interchange, automation, emergency kits, consultant pharmacists, chart order transmission, delivery, drug take-back, drug destruction, transfer of chart orders, immediate need dose provision, prepackaging, repackaging, and on-call or remote services;

THEREFORE BE IT RESOLVED that NABP convene a task force that includes appropriate stakeholders to study long-term care pharmacy rules and to review and amend, if necessary, the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy accordingly.

Note: The NABP Executive Committee established the Task Force on Long-Term Care Pharmacy Rules, and NABP President Jeanne Waggener appointed nine members and four alternates to the task force. The task force met on August 15-16, 2017 to begin their deliberations.

No. 113-5-17: Adjudication of Concurrent Disciplinary Actions

WHEREAS, the authority of state boards of pharmacy to enforce concurrent sister-state disciplinary actions can be an effective mechanism for regulating multi-state practices; and

WHEREAS, the potential for concurrent sister-state disciplinary actions may impact the initiating state board of pharmacy to fully adjudicate a matter;

THEREFORE BE IT RESOLVED that NABP encourage state boards of pharmacy that are reviewing another board's imposition of a disciplinary action to consider forgoing sister-state disciplinary action absent direct patient impact or harm in their own states; and

BE IT FURTHER RESOLVED that NABP collaborate with state boards of pharmacy to provide guidance on defining and enforcing qualifying concurrent sister-state disciplinary actions, particularly those that involve direct patient impact or harm in states other than the initiating board.

No. 113-6-17: Uniform Unit-of-Use Packaging Standards

WHEREAS, some community pharmacies are repackaging medication in unit-of-use containers in order to safely and securely manage patient care in long-term care facilities, group homes, and assisted living facilities, as well as by individual patient request; and

WHEREAS, state rules for community pharmacy may not adequately address unit-of-use packaging; and

WHEREAS, inconsistencies exist surrounding the sanitary packaging, safe labeling, and identification of unit-of-use containers;

THEREFORE BE IT RESOLVED that NABP review existing unit-of-use packaging standards and revise the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, if necessary, to assist in establishing consistency for packaging unit-of-use containers.

No. 113-7-17: Recognition Resolution

WHEREAS, the individuals listed here have made significant contributions to NABP, the protection of the public health, and the practice of pharmacy:

Allan L. Brinkhaus (LA)
Jacqueline M. Carson (VA)
Thomas Dickson (MN)
John A. Foust (OK)
John O. LeTard (LA)
Kendall M. Lynch (TN)
Pauline Montgomery (PA)
David Work (NC)
Sister Margaret Wright (IL)

WHEREAS, NABP and its member boards are saddened by the death of these individuals;

THEREFORE BE IT RESOLVED that NABP and its members formally acknowledge the leadership and contributions made by these individuals; and

BE IT FURTHER RESOLVED that NABP and the boards of pharmacy extend their sincere sympathies to the family and friends of these members.

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION
REPORT OF PROCEEDINGS – June 21-24, 2017

I. Public Interest Panel Review of Professional Degree Programs

The ACPE Public Interest Panel met on June 14, 2017, to discuss the professional degree programs scheduled for review by the ACPE Board of Directors during its June 21-24, 2017, meeting. Evaluation team reports and other materials associated with the evaluation of the professional degree programs were duly considered, and a report of the Panel's discussion was prepared and presented to the ACPE Board at its June 21-24, 2017, meeting. The Board considered the comments and recommendations of the Panel. Panel members who attended the meeting of the Public Interest Panel were: Dana Thomas and William Michael Youngblood.

II. Accreditation Actions for Professional Degree Programs, taken at the ACPE Board of Directors Meeting, June 21-24, 2017

A list of accredited professional degree programs of colleges and schools of pharmacy, which designates the respective preaccreditation and accreditation status of the programs and the academic year for the next currently scheduled evaluation, is posted on the ACPE web site at www.acpe-accredit.org.

Accreditation Actions

On the basis of self-studies, on-site evaluations, communications received from the institutions, ongoing annual review of North American Pharmacist Licensure Examination (NAPLEX) passing rates, entry class size, and attrition and on-time graduation rates, as well as the comments of the Public Interest Panel, the Board of Directors determined the accreditation status of the following professional programs, along with preaccreditation and accreditation terms and conditions.

In order to be eligible for initial or continuing accreditation, the Doctor of Pharmacy program must be part of an independent College or School of Pharmacy or a College or School of Pharmacy within a University, which is regularly incorporated and is a legally empowered postsecondary educational institution. The institution housing the College or School, or the independent College or School, must be accredited by a regional accreditation agency recognized by the U.S. Department of Education or another agency acceptable to the Accreditation Council for Pharmacy Education (ACPE). Accreditation standards call for a College or School of Pharmacy as an organizational unit and the administrative structure of the College or School of Pharmacy must provide for a Dean, who serves as the chief administrative and academic officer. Evaluation for purposes of preaccreditation and initial or continued accreditation requires an invitation by the chief executive officer, or designate, of the institution.

An action to "affirm" implies that a previously established accreditation term has been confirmed. An action to "continue" implies that the accreditation date has been extended. The customary review cycle for established accredited programs had been six years but it was extended to eight years as programs were reviewed beginning with Board actions at the January 2012 meeting and beyond.

The customary review cycle for new programs achieving initial accreditation status is two years. The dates indicated in parentheses for each College or School are the academic year of the most recent determination of accreditation status and the academic year of the next scheduled determination of accreditation status, and thus define the present accreditation term for the Doctor of Pharmacy program. An (*) following these dates indicate a shortened accreditation term.

The accreditation actions are as follows:

For Purposes of Considering Continued Accreditation Status

Lake Erie College of Osteopathic Medicine School of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

Medical University of South Carolina College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

Northeast Ohio Medical University College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

Palm Beach Atlantic University Lloyd L. Gregory School of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2018-2019)*
Standards found to be Partially Compliant: Standards No. 10, 24, 25

Samford University McWhorter School of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

South Carolina College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2018-2019)
(Term through graduation of final cohort)

Sullivan University College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

University of Findlay College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

University of Hawaii at Hilo Daniel K. Inouye College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

University of Houston College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2018-2019)*
Standards found to be Partially Compliant: Standards No. 12, 25

University of Puerto Rico Medical Sciences Campus School of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

University of South Carolina College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

University of Texas at Austin College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2024-2025)

Accredited with Probation Status:

Hampton University School of Pharmacy
Doctor of Pharmacy Program has been placed on Accredited with Probation status (appealable) with a focused on-site evaluation in the fall 2017. Standards cited in this probationary action: *Standards No. 10 and 17* (2014-2015) (2022-2023)

MCPHS University School of Pharmacy – Boston
Doctor of Pharmacy Program has been placed on Accredited with Probation status (appealable) with a focused on-site evaluation in spring 2018. Standards cited in this probationary action: *Standards No. 18, 21, 24 and 25* (2015-2016) (2017-2018)

Touro College of Pharmacy New York
Doctor of Pharmacy Program has been placed on Accredited with Probation status (appealable) and has been invited to meet with the ACPE Board in January 2018. Standards cited in this probationary action: *Standards No. 8, 9, 10, 12, 15, 17, 19, 24 and 25* (2014-2015) (2017-2018)

University of Louisiana at Monroe College of Health and Pharmaceutical Sciences School of Pharmacy
Doctor of Pharmacy Program has been placed on Accredited with Probation status (appealable) with a focused on-site evaluation in spring 2018. Standards cited in this probationary action: *Standards No. 8, 11, 18 and 23* (2013-2014) (2021-2022)

For Purposes of Considering: Continued Candidate Status

Chapman University School of Pharmacy
Doctor of Pharmacy Program: Candidate status continued. (2016-2017) (2017-2018)

Keck Graduate Institute School of Pharmacy
Doctor of Pharmacy Program: Candidate status continued. (2016-2017) (2017-2018)

West Coast University School of Pharmacy
Doctor of Pharmacy Program: Candidate status continued. (2016-2017) (2017-2018)

For Purposes of Considering: Advancement from Candidate Status to Accredited Status

University of North Texas System College of Pharmacy
Doctor of Pharmacy Program: Advanced to Accredited status. (2016-2017) (2018-2019)

For Purposes of Considering: Advancement from Precandidate Status to Candidate Status

High Point University Fred Wilson School of Pharmacy
Doctor of Pharmacy Program: Advanced to Candidate status. (2016-2017) (2018-2019)

Larkin University College of Pharmacy
Doctor of Pharmacy Program: Advanced to Candidate status. (2016-2017) (2018-2019)

Marshall B. Ketchum University College of Pharmacy
Doctor of Pharmacy Program: Precandidate status continued. (2016-2017) (2017-2018)
Standard found to be Less than Expected for Developing Program: Standard No. 21 (Focused on-site evaluation spring 2018)

For Purposes of Considering: Application for Precandidate Status

Medical College of Wisconsin School of Pharmacy
Doctor of Pharmacy Program: Advanced to Precandidate status. (2016-2017) (2017-2018)

University of Texas El Paso School of Pharmacy
Doctor of Pharmacy Program: Advanced to Precandidate status. (2016-2017) (2017-2018)

New School Applications: For Purposes of Considering: Authorization of On-site Evaluations

Stony Brook University School of Pharmacy and Pharmaceutical Sciences
A comprehensive on-site evaluation was not authorized; the program was advised to revise the application and resubmit for the Board's consideration at its January 2018 meeting.

William Carey University School of Pharmacy
A comprehensive on-site evaluation was not authorized; the program was advised to revise the application and resubmit for the Board's consideration at its January 2018 meeting.

Focused On-site Evaluation Visits
Focused on-site evaluation visits are authorized when the Board is desirous of additional on-site monitoring to evaluate various programmatic issues. An action to "affirm" implies that a previously established accreditation term has been confirmed. An action to "continue" implies that the accreditation date has been extended, usually to reestablish the customary eight-year cycle.

Howard University College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2020-2021)

Roosevelt University College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2019-2020)
Standard previously found Partially Compliant: Standard No. 8 (June 2016)

Rosalind Franklin University of Medicine and Science College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2020-2021)

South College School of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2020-2021)

Touro College of Pharmacy New York
(See **Accredited with Probation Status** above)

University of Maryland Eastern Shore School of Pharmacy and Health Professions
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2018-2019)

University of Missouri-Kansas City School of Pharmacy
Doctor of Pharmacy Program: Accredited status affirmed. (2016-2017) (2023-2024)

University of South Florida School of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2020-2021)

Western New England University College of Pharmacy
Doctor of Pharmacy Program: Accredited status continued. (2016-2017) (2020-2021)

Monitoring During the Accreditation Period

Interim Reports and/or Annual Monitoring Parameters for the Doctor of Pharmacy programs of the following colleges/schools were reviewed.

Interim Report Reviews

Belmont University College of Pharmacy
Binghamton University School of Pharmacy and Pharmaceutical Sciences
California Northstate University College of Pharmacy
Chicago State University College of Pharmacy
Florida Agricultural & Mechanical University College of Pharmacy and Pharmaceutical Sciences
(Focused on-site evaluation in fall 2017)
Hampton University School of Pharmacy
(See **Accredited with Probation Status** above)
Husson University School of Pharmacy
MCPHS University School of Pharmacy – Boston
(See **Accredited with Probation Status** above)
Midwestern University College of Pharmacy - Glendale
Northeastern University Bouvé College of Health Sciences School of Pharmacy
Notre Dame of Maryland University School of Pharmacy
Ohio Northern University College of Pharmacy
Standard No. 12: Non-Compliant
Pacific University School of Pharmacy
Regis University School of Pharmacy
Shenandoah University Bernard J. Dunn School of Pharmacy
South University School of Pharmacy
St. Louis College of Pharmacy
Texas A & M University Health Science Center Irma Lerma Rangel College of Pharmacy
Texas Southern University College of Pharmacy and Health Sciences
Touro University – California College of Pharmacy
University of Colorado Anschutz Medical Campus Skaggs School of Pharmacy and Pharmaceutical Sciences
University of Iowa College of Pharmacy
University of Louisiana at Monroe College of Health and Pharmaceutical Sciences School of Pharmacy
(See **Accredited with Probation Status** above)
University of Maryland School of Pharmacy
University of Minnesota College of Pharmacy
University of Nebraska Medical Center College of Pharmacy
University of New England College of Pharmacy
University of Pittsburgh School of Pharmacy
University of Saint Joseph School of Pharmacy
University of Toledo College of Pharmacy and Pharmaceutical Sciences

Annual Monitoring Reviews

Appalachian College of Pharmacy
Butler University College of Pharmacy and Health Sciences
California Health Sciences University College of Pharmacy
Chicago State University College of Pharmacy
Concordia University School of Pharmacy
Fairleigh Dickinson University School of Pharmacy
Florida Agricultural & Mechanical University College of Pharmacy and Pharmaceutical Sciences
Hampton University School of Pharmacy
Howard University College of Pharmacy
Husson University School of Pharmacy
(Meet with ACPE Board January 2018 to address progression concerns)
Lipscomb University College of Pharmacy and Health Sciences

Loma Linda School of Pharmacy
Manchester University College of Pharmacy, Natural and Health Sciences
Marshall University School of Pharmacy
MCPHS University School of Pharmacy - Boston
MCPHS University School of Pharmacy - Worcester
Northeast Ohio Medical University College of Pharmacy
Notre Dame of Maryland University School of Pharmacy
Ohio Northern University College of Pharmacy
Philadelphia College of Osteopathic Medicine School of Pharmacy
Presbyterian College School of Pharmacy
Regis University School of Pharmacy
Rosalind Franklin University of Medicine and Science College of Pharmacy
Samford University McWhorter School of Pharmacy
Shenandoah University Bernard J. Dunn School of Pharmacy
South College School of Pharmacy
South University School of Pharmacy
St. John Fisher College Wegmans School of Pharmacy
St. John's University College of Pharmacy and Health Sciences
Texas Southern University College of Pharmacy and Health Sciences
Union University School of Pharmacy
University of Charleston School of Pharmacy
University of California, San Diego Skaggs School of Pharmacy & Pharmaceutical Sciences
University of Mississippi School of Pharmacy
University of New England College of Pharmacy
University of South Florida College of Pharmacy
University of Toledo College of Pharmacy and Pharmaceutical Sciences
University of Wyoming School of Pharmacy
(Meet with ACPE Board in January 2018 to address progression concerns)

Review of Programs with Substantive Change and other requests

Albany College of Pharmacy and Health Sciences School of Pharmacy and Pharmaceutical Sciences
Appalachian College of Pharmacy
Auburn University Harrison School of Pharmacy
Campbell University College of Pharmacy and Health Sciences
Cedarville University School of Pharmacy
Chapman University School of Pharmacy
Creighton University School of Pharmacy and Health Professions
Duquesne University School of Pharmacy
D'Youville College School of Pharmacy
East Tennessee State University Bill Gatton College of Pharmacy
Ferris State University College of Pharmacy
Florida Agricultural & Mechanical University College of Pharmacy and Pharmaceutical Sciences
(Focused on-site evaluation fall 2017)
Harding University College of Pharmacy
Howard University College of Pharmacy
Larkin University College of Pharmacy
Long Island University Arnold and Marie Schwartz College of Pharmacy and Health Sciences
Manchester University College of Pharmacy, Natural and Health Sciences
Medical University of South Carolina College of Pharmacy
Mercer University College of Pharmacy
Midwestern University Chicago College of Pharmacy
(Focused on-site evaluation spring 2019 for pathway expansion)
Northeast Ohio Medical University College of Pharmacy
Northeastern University Bouvé College of Health Sciences School of Pharmacy

Philadelphia College of Osteopathic Medicine School of Pharmacy
Presbyterian College School of Pharmacy
Purdue University College of Pharmacy
Regis University School of Pharmacy (Follow-up report)
Rosalind Franklin University of Medicine and Science College of Pharmacy
Roseman University of Health Sciences College of Pharmacy
South College School of Pharmacy
South Dakota State University College of Pharmacy and Allied Health Professions
St. John Fisher College Wegmans School of Pharmacy
Sullivan University College of Pharmacy
Texas Tech University Health Science Center School of Pharmacy
Touro College of Pharmacy New York
Union University School of Pharmacy
University of Houston College of Pharmacy
University of Illinois at Chicago College of Pharmacy
University of Louisiana at Monroe College of Health and Pharmaceutical Sciences School of Pharmacy
(See **Accredited with Probation Status** above)
University of Maryland Eastern Shore School of Pharmacy and Health Professions
University of Missouri-Kansas City School of Pharmacy
University of New England College of Pharmacy
University of North Texas System College of Pharmacy
University of Puerto Rico Medical Sciences Campus School of Pharmacy
University of South Carolina College of Pharmacy
University of Tennessee Health Science Center College of Pharmacy
University of Texas at Tyler Ben and Maytee Fisch College of Pharmacy
University of the Sciences Philadelphia College of Pharmacy
University of Washington School of Pharmacy
Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences
West Coast University School of Pharmacy
West Virginia University School of Pharmacy
Wilkes University Nesbitt School of Pharmacy

Review of Complaints

Seventeen complaints, each from a student, faculty member, or dean from one of thirteen accredited Doctor of Pharmacy programs, were received during the spring 2017 cycle. Following the Board's review of each complaint, fifteen are closed and two remain open pending the results of ACPE's investigation.

III. Accreditation Actions for Providers of Continuing Pharmacy Education

ACPE Board of Directors accepted the report of the ACPE Continuing Pharmacy Education Commission at the June 2017 meeting.

	Session	Board Action		
1.	Accreditation of New Applications Organizations seeking ACPE-accredited provider status are asked to submit an Application for Initial Accreditation. This application asks questions regarding the applicant's experience relative to areas addressed by ACPE's standards for continuing pharmacy education. Initial terms of accreditation are usually for a short term with a First Review in 1 year and a Second Review in 2 years.			
	Applicant Organization	**Provider Type**	**State**	**Term**
1.	Elsevier Office of Continuing Medical Education	Publisher	PA	2 Year

2.	Louisiana Independent Pharmacies Association	State or Local Associations	LA	2 Year
3.	The Ohio State University College of Pharmacy	College or School	OH	2 Year
4.	UnitedHealth Group Center for Clinician Advancement	Other	FL	2 Year

	Session		Board Action	
2.	Submission of First Review by Applicants Accredited in Spring 2016 (Action would include Comprehensive Review in 5 years or Second Review Spring 2018)			
	First Review S2017 (Accredited in S2016)	**Provider Type**	**State**	**Second Review**
1.	California Northstate University	College or School	CA	Spring 2018
2.	Missouri Pharmacy Association	State or Local Associations	MO	Spring 2018
3.	Swedish Medical Center	Hospitals; Health Care Network	WA	Spring 2018
4.	Western Schools	Educational Company	MA	Comprehensive Review Spring 2022

	Session			Board Action	
3.	Submission of Second Review by Applicants Accredited in Spring 2015 (Action would include Comprehensive Review in 4 years from now or Spring 2021)				
	Second Review S2017 (Accredited in S2015)	**Provider Type**	**State**	**Interim Report**	**Comprehensive Review**
1.	American Association of Colleges of Pharmacy	National Associations	VA		Spring 2021
2.	Escola de Pós-graduação em Saúde e Gestão	National Associations	Portugal	Spring 2018	Spring 2021
3.	Orlando Health, Inc.	Hospitals; Health Care Network	FL		Spring 2021
4.	St. John Fisher College Wegmans School of Pharmacy	College or School	NY	Spring 2018	Spring 2021

	Session			Board Action	
4.	Consideration for Continued Accreditation on the Basis of Comprehensive Reviews. The submitted Self-Assessment Report undergoes a CPE Commissioner review, an internal (ACPE staff) review, an external (Field reviewer) review, a review of all records including correspondence, Activity Description Forms (ADFs), complaints (if any) and third party comments. The Comprehensive Review for Continued Accreditation provides the basis for the Council's action to continue the provider's term of accreditation. The standard term of accreditation is six years.				
	Organization Name	**Provider Type**	**State**	**Interim Report**	**Comprehensive Review**
1.	Alpha Zeta Omega National Pharmaceutical Fraternity Philadelphia Alumni Chapter	State or Local Associations	PA	Spring 2019	Spring 2023
2.	Banner Health	Hospitals; Health	AZ	Spring 2018	Spring 2023

		Care Network			
3.	CVS Health	Other	IL	Spring 2018	Spring 2023
4.	Educational Review Systems	Educational Company	FL	Spring 2018	Spring 2023
5.	GNYHA Services, Inc.	Other	NY		Spring 2023
6.	Korean American Pharmacists Association of U.S.A	National Associations	CA	Spring 2019	Spring 2023
7.	Louisiana Pharmacists Association	State or Local Associations	LA	Spring 2018	Spring 2023
8.	Marshfield Clinic Health Systems, Inc.	Other	WI		Spring 2023
9.	National Comprehensive Cancer Network	National Associations	PA	Spring 2018	Spring 2023
10.	New Jersey Society of Health-System Pharmacists	State or Local Associations	NJ		Spring 2023
11.	Nova Southeastern University College of Pharmacy	College or School	FL	Spring 2018	Spring 2023
12.	Omnicare, Inc.	Hospitals; Health Care Network	OH	Spring 2018	Spring 2023
13.	Pediatric Pharmacy Advocacy Group	Other	TN	Spring 2018	Spring 2023
14.	Pharmacists Society of the State of New York	State or Local Associations	NY	Spring 2018	Spring 2023
15.	Phoenix VA Health Care System	Government Agencies	AZ	Spring 2018	Spring 2023
16.	Samford University McWhorter School of Pharmacy	College or School	AL	Spring 2018	Spring 2023
17.	St. Jude Children's Research Hospital Pharmaceutical Department MS150	Hospitals; Health Care Network	TN	Spring 2018	Spring 2023
18.	TRINU Corporation	Educational Company	TX		Spring 2023
19.	University of New England College of Pharmacy	College or School	ME	Spring 2018	Spring 2023
20.	University of Utah College of Pharmacy	College or School	UT	Spring 2018	Spring 2023

	Session		**Board Action**	
5.	Consideration for Continued Accreditation on the Basis of Comprehensive Reviews that resulted in shortened terms.			
	Organization Name	**Provider Type**	**State**	**Progress Report**
1.	Biomedical Learning Institute	Educational Company	TX	Fall 2017
2.	Nesbitt School of Pharmacy at Wilkes University	College or School	PA	Spring 2018
3.	University Learning Systems, Inc.	Educational Company	NY	Spring 2018

	Session	Board Action
6.	Consideration for Continued Accreditation on the Basis of Progress Reports Providers who have a shortened term of accreditation of 1 year are asked to submit a Progress Report. A Progress Report addresses only those issues that remain of concern following the previous Comprehensive Review or Interim Report. However, because the provider has been given a shortened term of accreditation, the Progress Report, like the Comprehensive Review, serves as the basis for the Council to act to continue recognition as an accredited provider.	

	Organization Name	Provider Type	State	Interim Report	Comprehensive Review
1.	Allegheny General Hospital Department of Pharmacy Services	Hospitals; Health Care Network	PA	Spring 2018	Spring 2022
2.	University of Toledo College of Pharmacy	College or School	OH	Spring 2018	Spring 2022
3.	Utah Society of Health-System Pharmacists	State or Local Associations	UT	Spring 2018	Spring 2022

	Session	Board Action
7.	Consideration for Continued Accreditation on the Basis of Progress Reports resulting in shortened term on probation. Providers who have a shortened term of accreditation of 1 year are asked to submit a Progress Report. A Progress Report addresses only those issues that remain of concern following the previous Comprehensive Review or Interim Report. However, because the provider has been given a shortened term of accreditation, the Progress Report, like the Comprehensive Review, serves as the basis for the Council to act to continue recognition as an accredited provider. [*Probation]	

	Organization Name	Provider Type	State	Progress Report
1.	Utah Pharmacists Association*	State or Local Associations	UT	Fall 2017
2.	VCU School of Pharmacy, Office of Continuing Education*	College or School	VA	Extension to Fall 2017

	Session	Board Action
8.	Consideration for Continued Accreditation on the Basis of Interim Reports Providers with a standard term of accreditation of 6 years are asked to submit an Interim Report, usually in one or two years. The Interim Report serves as an update on specific issues that were identified in the provider's Comprehensive Review. Action required to affirm status and terms and to determine additional reporting as needed or to modify previously established terms and determine new reporting requirements.	

	Accredited Provider	Provider Type	State	Interim Report	Comprehensive Review
1.	Annenberg Center for Health Sciences at Eisenhower	Educational Company	CA	Spring 2018	Spring 2021
2.	Arizona Pharmacy Association	State or Local Associations	AZ		Spring 2019
3.	Arnold and Marie Schwartz College of Pharmacy and Health Sciences of Long Island University	College or School	NY		Spring 2022

4.	Atlanta Academy of Institutional Pharmacists	State or Local Associations	GA		Fall 2018
5.	Auburn University Harrison School of Pharmacy	College or School	AL	Spring 2018	Spring 2020
6.	Centers for Disease Control and Prevention	Government Agencies	GA		Spring 2022
7.	Children's Health	Hospitals; Health Care Network	TX		Spring 2021
8.	Colegio de Farmaceuticos de Puerto Rico	State or Local Associations	Puerto Rico		Spring 2019
9.	Georgia Society of Health-System Pharmacists, Inc.	State or Local Associations	FL	Spring 2018	Spring 2022
10.	Kaiser Foundation Health Plan of Colorado Department of Pharmacy	Hospitals; Health Care Network	CO		Spring 2022
11.	Lahey Hospital & Medical Center	Hospitals; Health Care Network	MA		Spring 2022
12.	National Pharmaceutical Association, Inc.	National Associations	NC		Spring 2019
13.	National Pharmacy Technician Association (NPTA)	National Associations	TX	Spring 2018	Fall 2021
14.	New York Presbyterian Hospital Department of Pharmacy	Hospitals; Health Care Network	NY	Spring 2018	Fall 2021
15.	Ohio Northern University College of Pharmacy	College or School	OH		Spring 2020
16.	Ohio Pharmacists Foundation, Inc.	State or Local Associations	OH		Spring 2021
17.	PDA	State or Local Associations	MD	Spring 2018	Spring 2021
18.	Texas Society of Health-System Pharmacists, The	State or Local Associations	TX		Spring 2021
19.	The Education Unit at ICON	Educational Company	MD	Spring 2018	Spring 2021
20.	University of Southern California School of Pharmacy	College or School	CA		Spring 2022
21.	Washington State University College of Pharmacy	College or School	WA		Spring 2021
22.	West Virginia University School of Pharmacy	College or School	WV	Spring 2018	Spring 2021
23.	W-F Professional Associates, Inc.	Educational Company	IL	Spring 2018	Spring 2022

	Session			
9.	Voluntary Withdrawal of Accreditation Status			
	Organization Name	**Provider Type**	**State**	**Effective Date**
1.	University of Findlay	College or School	OH	July 1, 2017
2.	Wingate University School of Pharmacy	College or School	NC	June 30, 2017

IV. Accreditation Actions for Joint Accreditation for Interprofessional Continuing Education™

Sixteen organizations are presented for review this cycle. The decisions will be presented when each of the three boards from the Accreditation Council for Pharmacy Education (ACPE), American Nurses Credentialing Center (ANCC) and the Accreditation Council for Continuing Medical Education (ACCME) convene.

V. Certification Actions for Professional Degree Programs based outside the United States of America and its Territories:

Certification Actions

On the basis of self-studies, on-site evaluations, communications received from the institutions, as well as the comments and recommendations of the ACPE International Commission, the Board of Directors determined the Certification status of the following professional degree programs, along with Certification terms and conditions.

In order to be eligible for initial or continued Certification, the professional degree program in pharmacy must be part of an independent school of pharmacy or a school of pharmacy within a university. The school or university must be a postsecondary educational institution that is regularly incorporated, legally empowered, and authorized to award such a degree in accordance with national and/or regional laws and regulations. The institutional environment or setting for the professional degree program must be equivalent to a university and include a mission that encompasses professional education, scholarship, research, and service. The school of pharmacy must have graduated at least one class of students from the professional degree program in pharmacy for which Certification is being applied. Evaluation for purposes of initial or continued Certification by ACPE requires an invitation by the chief executive officer or designate of the institution.

To apply for Certification, a school must submit an application, a self-study report of the program, and any additional materials specified by ACPE. After receipt of the application, self-study report, and other required materials, a preliminary review of the application is carried out to confirm eligibility for Certification and evaluate the application. The findings and conclusions from the review are presented to the International Commission, which in turn makes a recommendation to the Board regarding authorization of an on-site evaluation. If the Board authorizes an on-site evaluation, it is scheduled in accord with standard evaluation and operational procedures.

The customary review cycle (period between comprehensive on-site evaluation visits) for established certified programs is six years. The customary term for programs granted initial Certification is two years. The customary term for programs granted Provisional Certification is

two years. The dates indicated in parentheses for each college or school are the academic year[1] of the most recent determination[2] of Certification status and/or Certification term and the academic year of the next scheduled determination of Certification status and/or term, and thus define the present Certification term for the professional degree program.

The Certification actions are as follows:

For Purposes of Considering Authorizing an On-Site Evaluation Visit

There were no pending applications for certification to be considered by the Board for authorization of an on-site evaluation visit.

For Purposes of Considering Granting of Initial Certification Status

There were no pending applications for certification to be considered by the Board for granting of initial certification status.

For Purposes of Considering Continued Certification

There were no programs to be considered by the Board for continued Certification.

Monitoring During the Certification Period

The interim reports for the programs of the following schools were reviewed. If additional on-site monitoring has been requested through a focused on-site evaluation, it is so indicated.

Al Ain University of Science and Technology College of Pharmacy, United Arab Emirates
Bachelor of Science in Pharmacy (2016-17; 2020-21); (a focused visit is scheduled for fall 2018)

University of Jordan School of Pharmacy, Hashemite Kingdom of Jordan

Bachelor of Science in Pharmacy Program (2015-16; 2017-18)
Doctor of Pharmacy Program (2015-16; 2017-18)

Review of Programs with Substantive Change and Other Requests

Substantive change notifications from the following schools were received (action noted in parentheses):

Jagadguru Sri Shivarathreeswara (JSS) University College of Pharmacy, Republic of India (change noted; request update in April 2018 interim report)

King Saud University College of Pharmacy, Kingdom of Saudi Arabia (change noted; review at January 2018 meeting)

Approval of Changes to Policies and Procedures

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[1] For consistency, Certification cycles and academic years are named in accordance with the standard terminology used by ACPE for accreditation and Certification activities and reporting. Academic years run from July 1 to June 30.
[2] Determination includes granting of Certification status, a change of Certification status, a continuation of Certification status (new term), and other changes of a Certification term (e.g., shortening); it does not include affirmation of an existing Certification status and term.

There were no changes to the Certification Policies and Procedures to be considered.

Approval of Changes to Certification Quality Criteria

There were no changes to the Certification Policies and Procedures to be considered.

VIII. Accreditation Actions for Pharmacy Technician Education and Training Programs, in collaboration with the American Society of Health-System Pharmacists (ASHP)

The Accreditation Actions for Pharmacy Technician Education and Training Programs recommended by the Pharmacy Technician Accreditation Commission at their May 8-10, 2017 and approved by both the ACPE and ASHP boards of directors during their June meetings will be distributed in the near future by ASHP in their publication: The Pharmacy Technician Education and Training TABLET. Copies will be sent by ACPE to the U.S. state boards of pharmacy.

IX. Opportunity for Comment

Professional Programs of Colleges and Schools of Pharmacy Scheduled for On-Site Evaluations, Academic Year 2017-2018

The programs of the colleges and schools of pharmacy listed below are to be considered for accreditation during the upcoming academic year (2017-2018). On-site evaluations have been scheduled for fall or spring terms, as noted. Opportunity is hereby given for the submission of written third-party comments concerning qualifications for preaccreditation or accreditation. Copies of the ACPE Accreditation Manual are available, upon request, by writing to ACPE, 135 South LaSalle Street, Suite 4100, Chicago, Illinois 60603, or through the ACPE website (www.acpe-accredit.org). Written third-party comments must be received in the ACPE office not later than September 1, 2017 for fall 2017 or November 1, 2017 for spring 2018. The procedure for considering third-party comments received by the deadlines noted above should provide treatment in a way that is fair and equitable to all parties, including opportunity for response by the colleges and schools of pharmacy prior to ACPE's accreditation action.

Fall 2017

Chicago State University College of Pharmacy
Florida Agricultural & Mechanical University College of Pharmacy and Pharmaceutical Sciences
Hampton University School of Pharmacy
Harding University College of Pharmacy
Ohio State University College of Pharmacy
Thomas Jefferson University School of Pharmacy
University of Southern California School of Pharmacy
University of the Sciences Philadelphia College of Pharmacy

Spring 2018

Belmont University College of Pharmacy
Binghamton University School of Pharmacy and Pharmaceutical Sciences
California Health Sciences University College of Pharmacy
Campbell University College of Pharmacy and Health Sciences
Cedarville University School of Pharmacy
Fairleigh Dickinson University School of Pharmacy
Ferris State University College of Pharmacy
Husson University School of Pharmacy
Lipscomb University College of Pharmacy and Health Sciences
Manchester University College of Pharmacy
Marshall Ketchum University College of Pharmacy
Marshall University School of Pharmacy
MCPHS University School of Pharmacy Boston
Medical College of Wisconsin School of Pharmacy

Palm Beach Atlantic University Lloyd L. Gregory School of Pharmacy
Presbyterian College School of Pharmacy
Touro New York College of Pharmacy
Union University School of Pharmacy
University of Louisiana at Monroe College of Health and Pharmaceutical Sciences School of Pharmacy
University of Texas at El Paso School of Pharmacy
University of Texas at Tyler Ben and Maytee Fisch College of Pharmacy

Providers of Continuing Pharmacy Education Scheduled for Review for Purposes of Continued Accreditation, Year 2017-2018

The providers of continuing pharmacy education listed below are to be considered for continued accreditation during 2017-2018. Opportunity is hereby given for the submission of written third-party comments concerning qualifications for accreditation. Copies of the ACPE *Standards for Continuing Pharmacy Education* and the *Policies and Procedure Manual: A Guide for ACPE-accredited Providers,* are available, upon request, by writing to ACPE, 135 South LaSalle Street, Suite 4100, Chicago, Illinois 60603, or through the ACPE website (www.acpe-accredit.org). Written third-party comments must be received in the Council office not later than September 1, 2017, for fall 2017, and not later than November 1, 2017, for spring 2017. The procedure for considering third-party comments received by the deadlines noted above should provide for treatment in a way that is fair and equitable to all parties, including opportunity for response by the provider prior to ACPE's accreditation action.

Fall 2017

American College of Apothecaries, Inc.
Aurora Health Care, Department of Pharmacy Services
Austin Community College Pharmacy Technician Program
Drug Experts Inc.
Humana, Inc.
Independent Pharmacy Alliance, Inc.
Indiana Pharmacists Alliance
Massachusetts General Hospital Department of Pharmacy GRB 005
Northeast Kentucky Area Health Education Center
Oregon State University
PCMA
Quest Educational Services, Inc.
SolutionSight, Incorporated
South University School of Pharmacy
University of Maryland School of Pharmacy
University of the Incarnate Word, Feik School of Pharmacy
Virginia Society of Health-System Pharmacists

Spring 2018

Accredo Health Incorporated
Albany College of Pharmacy and Health Sciences
American Academy of Clinical Toxicology, Inc.
BioMed General
Brookdale Hospital Medical Center Department of Pharmacy Services
Fisher BioServices, Inc.
Florida A&M University College of Pharmacy and Pharmaceutical Sciences
Froedtert Hospital
Grady Health System Pharmacy
Howard University College of Pharmacy
JPS Health Network

Louisiana Society of Health-System Pharmacists
MediCom WorldWide, Inc.
North Dakota State University College of Health Professions School of Pharmacy
Postgraduate Healthcare Education, LLC
Pro CE, Inc.
Roseman University of Health Sciences
Saint Thomas West Hospital
Sharp HealthCare
Skaggs School of Pharmacy at the University of Montana
StrategicHealthSolutions, LLC
TG Medical Education, LLC
UAB Hospital Department of Pharmacy
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences
University of Connecticut School of Pharmacy
University of North Texas Health Science Center
USF Health
VA Employee Education System

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ACPE was founded in 1932 as the American Council on Pharmaceutical Education.

SPRING 2017

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

UPDATE

ACPE Elects New Officers and Appoints Committee Liaisons

Timothy L. Tucker, John Clay Kirtley, and **Anthony Provenzano** have been elected as members of the ACPE Executive Committee for the 2017–2018 term of office. Elections were held during the ACPE Board of Directors Meeting, January 19–21, 2017, in Chicago, Illinois.

Executive Committee pictured from left to right: Anthony Provenzano, PharmD; Timothy L. Tucker, PharmD; John Clay Kirtley, PharmD

Timothy L. Tucker, PharmD, was elected as President of ACPE. Dr. Tucker is the Owner of City Drug Company in Huntingdon, Tennessee and a practicing community-based pharmacist. Previously, he served as former president and speaker of the House of Delegates for the American Pharmacists Association (APhA) and is also a past national president of Phi Lambda Sigma. Dr. Tucker was appointed to the ACPE Board by APhA. He has previously served as ACPE Vice –President, Secretary/Treasurer and as the ACPE Board Liaison to the International Services Program Commission

John Clay Kirtley, PharmD, was elected as Vice-President of ACPE. Dr. Kirtley is the Executive Director of the Arkansas State Board of Pharmacy. Currently, he serves on the Arkansas State and Public School Life and Health Insurance Board. The National Association of Boards of Pharmacy (NABP) appointed Dr. Kirtley to the ACPE Board. He has previously served as ACPE Secretary/Treasurer and as ACPE Board Liaison to the Continuing Pharmacy Education Commission.

Anthony Provenzano, PharmD, was elected as Secretary/Treasurer of ACPE. Dr. Provenzano is the Vice President of Pharmacy Compliance and Government Affairs for The Albertsons Companies. He has served on numerous pharmacy association advisory panels and currently serves on two colleges of pharmacy dean's advisory boards. APhA appointed Dr. Provenzano to the ACPE Board. He has previously served as ACPE Secretary/Treasurer and as ACPE Board Liaison to the Continuing Pharmacy Education Commission and the Pharmacy Technician Accreditation Commission.

ACPE would like to thank **Michael A. Moné, BPharm, JD,** for his tireless work over the past five years as a member of the ACPE Executive Committee, having served as Secretary/Treasurer for three years, Vice-President and President.

continued on page 2

Please provide us your feedback on the ACPE Update!

Click here to complete a short survey.

Assuring and Advancing Quality in Pharmacy Education

continued from page 1

ACPE Commission Liaisons pictured from left to right: Martha Rumore, PharmD, JD, MS, LLM, FAPhA; LuGina Mendez-Harper, PharmD; Michael A. Moné, BPharm, JD

ACPE has also announced the appointment of three new Commission Liaisons for the 2017–2018 term. They include:

LuGina Mendez-Harper, PharmD, was elected as the Continuing Pharmacy Education (CPE) Commission Liaison. She is the Director of Professional Practices at Prime Therapeutics where she manages activities related to pharmacy regulatory issues. She was appointed to the ACPE Board by NABP.

Martha Rumore, PharmD, JD, MS, LLM, FAPhA, was elected as the International Commission (IC) Liaison. She is an Associate Professor at Touro College of Pharmacy, an Adjunct Professor at the Touro College Jacob D. Fuchsberg Law Center, and Of Counsel at Sorell, Lenna & Schmidt, LLP. Dr. Rumore is a Fellow and former Trustee of APhA. She was appointed to the ACPE Board by APhA.

Michael A. Moné, BPharm, JD, was elected as the Pharmacy Technician Accreditation Commission (PTAC) Liaison. He is the Vice President, Associate General Counsel-Regulatory for Cardinal Health. Mr. Moné has held leadership roles within many industry associations, including APhA, NABP, US Pharmacopeia, and the Florida Pharmacy Association. He was appointed to the ACPE Board by NABP.

"ACPE would like to recognize the service of **Lori Duke, PharmD,** the 2015–2016 CPE Commissioner, **Victoria F. Roche, PharmD,** the 2015–2016 International Commissioner and **Anthony Provenzano, PharmD,** the 2015-2016 Pharmacy Technician Accreditation Commissioner," expressed Peter H. Vlasses, PharmD, DSc (Hon), FCCP, Executive Director of ACPE. "The dedication and guidance provided by these leaders helps ACPE stay true to its mission of assuring and advancing excellence in education for the profession of pharmacy." ■

Pictured above is ACPE's Board of Directors. Back row from left to right: Martha Rumore, PharmD, JD, MS, LLM, FAPhA; Anthony Provenzano, PharmD; John Clay Kirtley, PharmD; Timothy L. Tucker, PharmD; Michael A. Moné, BPharm, JD. Front row from left to right: Lori Duke, PharmD; LuGina Mendez-Harper, PharmD; Marie A. Chisholm-Burms, PharmD, MPH, MBA, FCCP, FASHP; Sharon Hahs, PhD; Victoria Roche, PhD.

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PETER H. VLASSES
PharmD, DSc (Hon), FCCP,
ACPE Executive Director

Readers,

Included elsewhere in this issue of ACPE Update is an article about the Pharmacy Technician Stakeholder Consensus Conference (PTSCC) held February 14–16, 2017. My colleague and co-editor of the ACPE Update, Patti Manolakis, PharmD, served as a workshop facilitator at the conference. Based on our discussions, during and after the conference, I asked her to share her feelings in place of my column.

It's Time!

"The heritage of our past is the seed that brings forth the harvest for our future."

These words, engraved on the main entrance stairs of the National Archives building, provide wisdom as our profession wrestles with addressing the growing public health and patient safety demands of defining and equipping a solid workforce of pharmacy technicians. This workforce is required to provide a strong foundation for pharmacists to provide care to patients in our nation.

What can we learn by looking to the heritage of our past?

Patient safety, quality, and advancing technology have long been drivers of improvements in health care education, training, and credentialing for members of the health care team. When ACPE was founded in 1932, pharmacy and health care looked very different, and passage of the U.S. Food Drug and Cosmetic Act was still six years away. Change is not easy. Sometimes it is forced by tragedies, such as the laws around drug safety and efficacy. Other times, change is proactively implemented to enable progress, such as the advancement of entry-level education for pharmacists to the doctor of pharmacy degree in the 1990s. Those of us in practice then, remember it was not an easy time for the profession, with a period of division, fear, and uncertainty among many. Although heated and tumultuous, the challenges were temporary, and student pharmacists modeled the leadership that encouraged the profession to embrace this change and enable growth and advancement.

Change is not easy. Sometimes it is forced by tragedies… Other times, change is proactively implemented to enable progress, such as the advancement of entry-level education for pharmacists to the doctor of pharmacy degree in the 1990s.

History suggests that we should honestly assess the extent to which quality is assured throughout the present system of pharmacy technician education, accreditation, practice, certification, and monitoring as it has evolved and how well pharmacy practice is positioned to grow forward. Are we positioned to provide care within our patient-centered health care system that is focused to enable high quality care, grounded in evidence-based medicine, integrated through the use of informatics and technology, and delivered by teams of health care providers working together? As we deliberate the advantages, disadvantages, barriers, and benefits of defining and aligning the assurance and expectations for baseline educational and practice competence of pharmacy technicians, we find that the landscape is similar to 27 years ago, when change in entry-level pharmacy education was necessary.

Medications and related technology have advanced health care and life expectancy tremendously, and they have lessened the impact of many diseases and conditions that once killed individuals in childhood and early adulthood. Every individual that has a hand in prescribing, procuring, preparing, distributing, and administering medications must possess and demonstrate a defined set of knowledge and skills. These knowledge and skills provide a baseline for their role in the medication use process and help ensure the quality of care and prevent patient harm. As a pharmacist in practice, I had to know that the physician writing the prescription had a foundation for diagnosing and treating the patient's condition, and I still used my professional knowledge and judgment to ensure accuracy and safety. Likewise, before we can delegate tasks of pharmacy practice to another, we need to know and trust that the individual engaging in every part of the prescription fill process is equipped, alert to similarities and differences in medications, instructions, and appropriate preparation — whether reconstituting an antibiotic, pulling the bottle from the shelf, or entering the prescription into the computer. Delegation requires confidence and trust.

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One father has broadly shared the painful story of the loss of his 2-year-old daughter who had overcome her battle with cancer; however, on her last infusion, she was mistakenly given a hypertonic solution that tragically and painfully ended her life. The IV was prepared in error by a pharmacy technician and not caught by the supervising pharmacist. There are examples of harmful and fatal medication errors occurring in pharmacy practice in every setting when incorrect drugs are mistakenly dispensed, when instructions are erroneously labeled, or other errors are made. We know that no human is perfect, so we must rely on baseline safeguards for education and demonstrated competency of all who engage in health care in our society.

Education and Credentialing of Others Within Health Care

Many different individuals are part of the delivery of quality health care in the U.S. Beyond physicians, pharmacists, nurses, physician assistants, dentists, and nurse practitioners are many others who engage in and enable the care of patients, including dieticians, laboratory technicians, medical assistants, dental hygienists, optometrists, and support staff, among others. Public assurance of the education and skills of all individuals practicing and contributing to health care is vital. Most of these professions have clearly defined entry-level education requirements, as well as registration, certification and/or licensure, and ongoing requirements to maintain competency. Outside of health care, professionals such as hair stylists and barbers are required to complete minimum education and obtain and maintain a license to perform the tasks that are part of their everyday work. Why would we continue to allow a lower, variable standard to persist for pharmacy technicians, who are integral to pharmacy practice and engage directly in the processing and preparation of prescription medications for patients?

During the recent *Pharmacy Technician Stakeholder Consensus Conference* (PTSCC), participants explored variability among state practice laws, certification and education, licensure, and registration requirements for pharmacy technicians. Accreditation of pharmacy technician education programs has been available for well over 30 years, in part to help assure a level of quality and consistency and reduce variability across education programs. However, there is wide variability among unaccredited programs and requirements by states and other entities for program accreditation. Conference attendees discussed issues around the tremendous variation in education programs — some of which do not effectively prepare individuals to obtain pharmacy technician certification. Students who are not assured of the quality of their educational program may be left with the educational debt and without an ability to pursue their chosen path in health care. With ASHP, ACPE has specifically engaged through the joint formation of the Pharmacy Technician Accreditation Council (PTAC). PTAC advises both the ASHP and ACPE boards of directors prior to their decisions on the accreditation pharmacy technician education programs.

The time has come for the profession of pharmacy to unite and ensure that entry-level pharmacy technician practice is clearly defined.

The time has come for the profession of pharmacy to unite and ensure that entry-level pharmacy technician practice is clearly defined. Pharmacy technicians, and all who rely on them, should have confidence in the quality of education programs and a clear path to certification and accountability for their contributions to pharmacy practice and patient care within their states. As pharmacists advance their direct patient care roles, and as practices ultimately receive more compensation for care in medication use, pharmacists must be confident in the baseline, entry-level foundational knowledge and skills of the technicians who help support their practice. Patients and society must be assured that every person who has a hand in preparing and providing medications has the baseline knowledge and skills to do so, is credentialed, and is regulated and monitored as necessary—and certainly not less than the hard-working professional who cuts their hair.

The PTSCC provided a great step forward, finding important common ground within dozens of specific statements. Let's continue to come together and work to remove barriers that prevent our profession from implementing what we know is needed to support and enhance the role of pharmacy technicians. History tells us that these advancements are necessary to ensure quality in pharmacy practice teams in all settings, in the medication use process, and to support pharmacists' provision of high quality care to patients as a core member of the health care team. ■

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PharmD Program Accreditation

ACPE Staff Participates in Council for Higher Education Accreditation (CHEA) 2017 Annual Conference

The Council for Higher Education Accreditation (CHEA) held its Annual Conference, *Quality Assurance and Accreditation: Moving into the Future,* in Washington, DC, from January 30 – February 1, 2017. ACPE's Assistant Executive Director and Director of Professional Degree Program Accreditation, **J. Gregory Boyer,** served as a panelist discussing the value programmatic accreditation brings to institutions.

The following individuals served alongside J. Gregory Boyer on the panel:

- **Joseph Vibert (Moderator),** Executive Director, Association of Specialized and Professional Accreditors (ASPA)
- **Crystal Calarusse,** Chief Accreditation Officer, Network of Schools of Public Policy, Affairs, and Administration, Commission of Peer Review and Accreditation
- **Barry Eckert,** Dean, School of Health Professions, Long Island University
- **Earl Seaver,** Principal Partner, Academy Solutions

Pictured above: Attendees of the Council for Higher Education Accreditation (CHEA) Annual Conference in Washington, DC, January 30 – February 1, 2017.

Accreditation Statistics

135 Colleges and Schools with Accreditation Status
125 Colleges and Schools with Accreditation Status
7 Colleges and Schools with Candidate status
3 Colleges and Schools with Precandidate status

Program Evaluator Training Resumes

After a brief hiatus triggered by the implementation of Standards 2016, the first workshop to train site team members for college and school accreditation site visit evaluations was held on February 16–17, 2017. A full class of 35 faculty members from colleges and schools of pharmacy and one practitioner was held in Chicago. After a brief didactic learning session, the workshop employed active learning components that simulated discussions of a typical site visit. All participants, organized into teams, were involved in role-playing activities that varied from a program's curriculum committee to a group of diverse pharmacy students. Using an actual self-study helped solidify understanding of the exercises and learning.

The next scheduled workshop for fall 2017 is booked to capacity; however, an individual can be added to the notification list. Participation as a program evaluator requires five or more years of academic/practice experience, submission of a curriculum vitae, and a letter of recommendation from the dean. Individuals who meet these criteria and are interested in being considered for this training, please email **Lauren Donnelly** (ldonnelly@acpe-accredit.org) to be notified of future workshops.

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Continuing Education Provider Accreditation

CPE Commission Announces New Chair, Vice Chair and Member

ACPE has appointed **Dennis Brierton, PharmD, BCPS, FASHP,** Director for Clinical Pharmacy Services at Aurora Health Care in Milwaukee, Wisconsin, as the 2017 Chair of the CPE Commission. **Aaron Reich, PharmD,** President of TRINU Healthcare has been named as Vice Chair of the Commission. ACPE would also like to extend their gratitude to **Tian Merren Owens, MS, PharmD,** Director of Continuing Pharmacy Education for the Florida Pharmacy Association, for her service as the 2016 Chair of the CPE Commission.

Joe Fontenot, RPh, Assistant Executive Director, Louisiana State Board of Pharmacy has been appointed as a new Commission member, with a term extending through December 2019. ACPE would like to thank and congratulate outgoing member **Kevin Mitchell, RPh,** for his dedicated service and hard work in achieving the objectives of the CPE Commission. ■

Accreditation Statistics

353 Continuing Education Providers with Accreditation Status

4 Continuing Education Providers have Inactive Status

3 Continuing Education Providers have Probation Status

CPE Commission Meets with Canadian Council on Continuing Education in Pharmacy

On November 16, 2016, the Canadian Council on Continuing Education in Pharmacy (CCCEP) Board and the ACPE CPE Commission convened for two days in Chicago, Illinois, during ACPE's fall commission meeting. Led by **Dimitra Travlos,** ACPE Director of the Continuing Pharmacy Education Provider Accreditation and Art Whetstone, CCCEP Executive Director, the meeting consisted of discussions and presentations regarding international collaboration in accreditation. Dimitra Travlos gave an overview of ACPE and its processes. **Jennifer Baumgartner,** ACPE Assistant Director of the Continuing Pharmacy Education Provider Accreditation Program provided an overview of the Continuing Professional Development (CPD) program and its mission. **Mike Rouse,** ACPE Assistant Executive Director, Professional Affairs and Director, International Services, shared his experience in the international arena and attempt

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Members of the Canadian Council on Continuing Education in Pharmacy (CCCEP) Board and the ACPE CPE Commission met to discuss international collaboration in accreditation.

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to push CPD abroad and into a working global CE framework. Art Whetstone gave a comprehensive overview of CCCEP and its processes and history. The meeting was then divided into five working groups, with each group comprised of a mix of ACPE and CCCEP members assigned to brainstorm on a specific question and report back. Once the break-out sessions were concluded, next steps were discussed, with interest from both ACPE and CCCEP members to further conversations and communication between the two organizations. ■

Update on Joint Accreditation for Interprofessional Continuing Education™

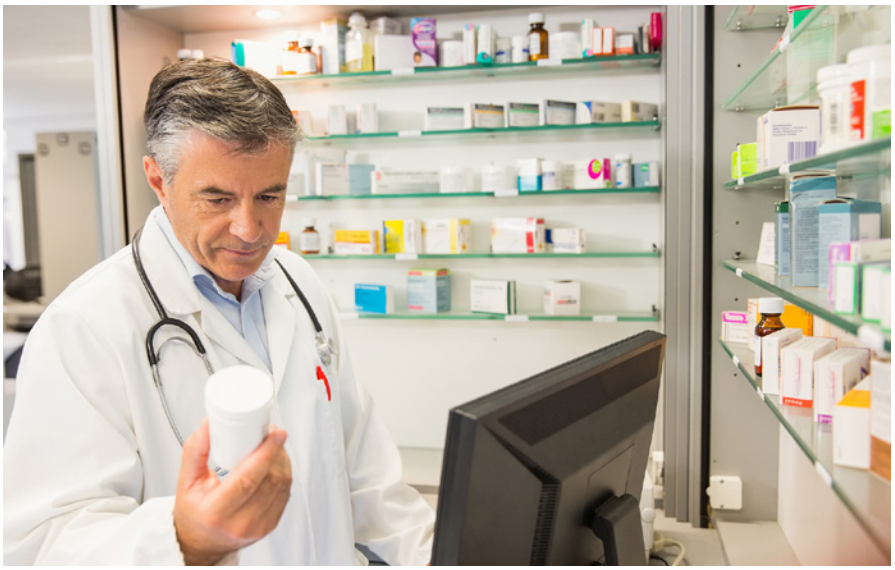
Providers Receive Accreditation

At the ACPE Board of Directors Meeting in January, five continuing education providers received Joint Accreditation status with a 6-year term, and three providers received Joint Accreditation status with a 4-year term. The American Nurses Credentialing Center (ANCC) and the Accreditation Council for Continuing Medical Education (ACCME), the partnering organizations that collectively award the distinction of Joint Accreditation, have also ratified these decisions. A complete list of all 42 Jointly Accredited providers can be accessed at www.jointaccreditation.org/accredited-providers. If you have any questions regarding Joint Accreditation, please contact **Anna Treudt,** CE and Joint Accreditation Coordinator, at info@jointaccreditation.org.

JOINT ACCREDITATION™
INTERPROFESSIONAL CONTINUING EDUCATION

Upcoming Joint Accreditation Educational Opportunities

The Joint Accreditation Leadership Summit: Research and the Continuum of Health Professions Education is scheduled for June 9, 2017, 8:00 AM–4:00 PM CST at the ACCME office: 401 North Michigan Avenue, Suite 1850, Chicago, Illinois 60611. The program is geared toward Jointly Accredited Providers or organizations in the process of applying for Joint Accreditation. *Getting Started in Joint Accreditation* is scheduled for September 19, 2017, and is applicable to organizations interested in applying for Joint Accreditation. Additional program details will be published on www.jointaccreditation.org as they become available. ■



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International Services Program

International Commission Convenes

The International Commission (IC) Meeting took place November 20–22, 2016, in Chicago, Illinois. Commissioners and staff were in attendance. Additionally, **Yousif Abdu Asiri,** Commissioner-elect, and **LuGina Mendez-Harper, Martha Rumore,** and **Sharon Hahs,** ACPE's newest Board Members, attended the meeting for orientation purposes. The IC made recommendations to the ACPE Board regarding Qassim University's application for initial Certification, Al Ain University of Science and Technology's Two-Year Post-Certification Focused Visit, and King Saud University's Interim Report. A variety of other topics were discussed at the meeting, including renewing and advancing the strategic partnerships and memorandums of understanding (MOUs) with various organizations around the world and ISP's strategic plan. Additionally, **Michael Diamond** was invited to present, "Health is Everybody's Business" and "Pharmacists are at the Heart of Health." Mr. Diamond is a Professional Lecturer at DePaul University School of Public Service and lectures at Northwestern University on global health, management of civil society organizations, and the reduction of health disparities.

International Commission members pictured left to right: Magaly Rodriguez de Bittner, PharmD, BCPS, FAPhA; Indra K. Reddy, PhD, MS; Bhojraj Suresh, PhD; Anthony K. Wutoh, PhD, RPh; Janet P. Engle, PharmD, PhD (Hon), FAPhA, FNAP; and Yousif Abdu Asiri, MS, PhD

Certification Status

9 Pharmacy Degree Programs outside the USA with Certification Status

ISP 2nd Annual Report

ACPE's International Services Program (ISP) published its second Annual Report, which provides an overview of ISP activities from February 1, 2016, to January 31, 2017. The report includes the following:

- Visual representations of ISP activities via two electronic maps
- Vision and Mission
- Leadership team
- ACPE Certified Pharmacy Programs
- On-site evaluation visits
- Collaborations
- Communications
- List of presentations, conferences and workshops members of the ISP Staff/IC/ISPAG attended over the last year

The complete annual report can be found here.

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Global Conference on Pharmacy and Pharmaceutical Sciences Education in Nanjing, China

The International Pharmaceutical Federation (FIP) organized the Global Conference on Pharmacy and Pharmaceutical Sciences Education. It was held November 7–8, 2016, in Nanjing, China. The objective of the conference was to join pharmacy leaders from various countries to implement a distinctive global vision with specific goals to improve pharmacy education and the pharmacy workforce. ACPE's Executive Director, **Peter Vlasses,** and **Mike Rouse,** Assistant Executive Director, Professional Affairs and Director, International Services, attended. Mr. Rouse conducted a workshop at the conference on quality assurance of pharmacy education. To learn more about the conference, click here.

Pictured above: Workshop facilitators and presenters at the Global Conference on Pharmacy & Pharmaceutical Sciences Education with FIP's President Carmen Peña.

Pictured below (left to right): Mike Rouse, Pete Vlasses and Richard Ye (University of Macau) at Nanjing Conference.

Nanjing China

Global Conference on Pharmacy & Pharmaceutical Sciences Education

7-8 November 2016

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International Commission Announces New Officers

The International Commission has announced newly elected officers. **Yousif Abdu Asiri** was named the new International Commissioner; **Anthony K. Wutoh** was elected as Chair of the International Commission; **Bhojraj Suresh** and **Magaly Rodriguez de Bittner** were elected as International Commission's Vice-Chair and Chair Elect for 2017–18 and 2018–19 respectively, and **Martha Rumore** was elected as the ACPE Board Liaison to the International Commission.

Yousif Abdu Asiri, PhD, MS, is Vice Rector for Planning and Development, Professor of Clinical Pharmacy at King Saud University College of Pharmacy in Riyadh, Kingdom of Saudi Arabia. Currently, he serves as a member of the Saudi Food and Drug Authority's Board of Directors. Dr. Asiri's three-year term as International Commissioner began February 1, 2017.

Anthony K. Wutoh, PhD, RPh, is Provost and Chief Academic Officer at Howard University in Washington, DC. He has led and participated in international programs with various organizations, including the United States Agency for International Development (USAID), Centers for Disease Control (CDC), and the President's Emergency Plan for AIDS Relief (PEPFAR). Dr. Wutoh will serve as Chair of the International Commission from February 1, 2017 to January 31, 2018.

Bhojraj Suresh, PhD, is Vice-Chancellor of JSS University College of Pharmacy, Mysuru, Republic of India. He pioneered the promotion of the Pharmacy Practice concept in India, introduced a postgraduate program in Pharmacy Practice and PharmD programs in India, and continues to uplift this facet of the pharmacy profession by working with other global leaders. Dr. Suresh will serve as Vice-Chair/Chair Elect of the International Commission from February 1, 2017 to January 31, 2018.

Magaly Rodriguez de Bittner, PharmD, BCPS, FAPhA, is Associate Dean for Clinical Services and Practice Transformation at the University of Maryland School of Pharmacy in Baltimore, Maryland. She is a member of the International Pharmaceutical Federation (FIP) Academic Pharmacy Section and currently serves as a member of the FIP Advisory Committee on Pharmacy Education. Dr. Rodriguez de Bittner will serve as Vice-Chair/Chair Elect of the International Commission from February 1, 2018 to January 31, 2019.

Martha M. Rumore, PharmD, JD, MS, LLM, FAPHA, is Associate Professor at Touro College of Pharmacy, an Adjunct Professor at Touro College Jacob D. Fuchsberg Law Center, and Of Counsel at Sorell, Lenna & Schmidt, LLP in New York. She is a pharmacist and attorney admitted to the NY, NJ, and DC bars. Dr. Rumore will serve as the ACPE Board Liaison to the International Commission from February 1, 2017 to January 31, 2018.

ACPE would like to recognize the tremendous contributions of **Azza M. Agha, MSc, PhD,** during her service to the International Commission from 2012–2017. ■

A session of the SMART Project in Egypt.

SMART Project in Egypt and Kuwait

Mike Rouse, Assistant Executive Director, Professional Affairs and Director, International Services, and **Arijana Meštrović,** ISPAG member, have initiated their work with the Life Sciences Academy (Kuwait) and Children's Cancer Hospital Foundation 57357 (Egypt). Rouse and Meštrović travelled to Egypt and Kuwait in February to provide workshops and training for both organizations. ■

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Pharmacy Technician Education Accreditation Collaboration

ACPE Leadership Jointly Convenes National Pharmacy Technician Stakeholder Consensus Conference

Almost 100 leaders from across the continuum of pharmacy and pharmacy technician practice and public representatives gathered in-person for the *Pharmacy Technician Stakeholder Consensus Conference* on February 14–16, 2017, in Irving, Texas. The PTSCC sponsored by the Pharmacy Technician Certification Board (PTCB) was planned and conducted jointly by ACPE, PTCB, and the American Society of Health-System Pharmacists. Hundreds of additional stakeholders joined the plenary sessions via webinar over the three-day meeting. Discussions were centered on building a road map that supports the evolution and advancement of pharmacy technicians. The aim of the conference was to explore consensus on the following:

PHARMACY TECHNICIAN
Stakeholder Consensus Conference

Peter Vlasses addresses participants at the Pharmacy Technician Stakeholder Consensus Conference

Participants at the Conference partake in discussion. Pictured from left to right: Scott Meyers, Executive Vice President, Illinois Council of Health-System Pharmacists and Malcolm Broussard, Executive Director, Louisiana Board of Pharmacy.

- The necessity of public confidence in pharmacy's process for ensuring the competency of pharmacy technicians.
- An optimal level of basic ("generalist") knowledge, skills, and abilities that pharmacy technicians should have regardless of practice site.
- An optimal definition of entry-level ("generalist") pharmacy technician practice with respect to (a) legally recognized scope of practice; (b) educational requirements; (c) training requirements; (d) certification requirements; and (e) state board of pharmacy registration or licensure.
- The desirability and feasibility of developing a process for recognizing competencies of pharmacy technicians beyond entry-level practice.
- The desirability and feasibility of minimizing variability among the states in the definition and regulation of pharmacy technicians.
- The entities that potentially could take responsibility for any changes in pharmacy's process for ensuring the competency of pharmacy technicians.

Nationally recognized speakers and panelists provided insights on how the contributions of technicians in pharmacy practice can be recognized, the way in which the pharmacy technician workforce is currently being utilized, what might be the optimal requirements for pharmacy technicians in entry-level practice, the opportunities related to advanced technician practice, and models for moving forward on pharmacy technician issues.

On-site participants also engaged through in-depth workgroup sessions and developed statements regarding the development of uniform national standards related to the competencies/credentials of entry-level pharmacy technicians, opportunities to support and develop pharmacy technicians in advanced practice, and the importance of working to achieve a higher level of state-to-state consistency in the regulation of pharmacy technicians' scope of practice, education, training, certification, and licensure or registration. Conference participants engaged in a process of seeking consensus on the key findings and recommendations by providing feedback on each specific recommendation and finding. Detailed proceedings of the meeting outcomes will be submitted for publication. ■

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ACPE and ASHP Boards Approve Changes to PTAC

The ACPE and ASHP Boards of Directors recently approved the following changes to the Pharmacy Technician Accreditation Commission. **John Smith** was reappointed as Chair, and **Donna Wall** was appointed as Vice Chair. **Michael Diamond** was reappointed as a public member, and **Mario Gomez** was newly appointed to the Commission.

- **John Smith, EdD,** is Director of Secondary Programs and Alternative Education for East San Gabriel Valley Regional Occupational Program and Technical Center. He has more than 25 years of leadership experience in Secondary and Post-Secondary Education. Dr. Smith currently serves as an ASHP accreditation surveyor of pharmacy technician training programs. He has held several leadership positions for the California Society of Health-System Pharmacists.
- **Donna Wall, PharmD,** is Clinical Pharmacist at Indiana University Hospital in Indianapolis, Indiana. Previously, she worked as a PGY1 Residency Director and Pharmacy and Therapeutics Secretary and Drug Information Director at Indiana University Hospital, as well as an Adjunct Associate Professor of Clinical Pharmacy at Purdue and Butler Universities. She is currently a member of Indiana's Board of Pharmacy. Dr. Wall served as the Vice President of ACPE's Board of Directors and was President of the National Association of Boards of Pharmacy Board.
- **Michael Diamond, MA,** is President of World Resources Chicago where his primary focus is to improve health outcomes in resource challenged communities. He worked with global health, refugee, rehabilitation, and social and economic development programs in over 100 countries. Mr. Diamond is also a Professional Lecturer at DePaul University School of Public Service and lectures on global health, management of civil society organizations, and the reduction of health disparities at Northwestern University. Previously, he served on ACPE's Public Interest Panel.
- **Mario Gomez, CPhT,** is Program Director and Clinical Liaison for the San Jacinto Community College District and serves as an ASHP co-surveyor for PTAC Accreditation. He conducts site surveys, oversees student placement, and maintains affiliate documentation as a Clinical Liaison for the pharmacy technician department. Mr. Gomez earned a BS in Biological/Physical Science from the University of Houston and an Associate of Science from the University of South Carolina.

ACPE and ASHP would like to thank **Jan Keresztes, PharmD,** outgoing member, for her contributions to PTAC.

Accreditation and Certification Statistics

271 Pharmacy Technician Education Programs are in the accreditation process which includes accredited programs and programs in candidate status

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ACPE Staff Highlight

Dimitra V. Travlos, PharmD

Assistant Executive Director and Director, Continuing Pharmacy Education Provider Accreditation

Dr. Travlos provides leadership and oversight over all ACPE activities and services in the area of continuing pharmacy education and accreditation. Her responsibilities include administration of evaluative processes in continuing pharmacy education, provision of staff support, and consultative guidance on activities and issues relating to continuing education providers, provision of educational support for the ACPE standards, and support for a quality assurance process of continuing pharmacy education. She also is responsible for the Joint Accreditation for Interprofessional Continuing Education™ pathway, a collaboration with the Accreditation Council for Continuing Medical Education (ACCME) and American Nurses Credentialing Center (ANCC). Prior to joining ACPE, Dr. Travlos was an Associate Professor in the Division of Pharmacy Practice at St. Louis College of Pharmacy. Dr. Travlos received her PharmD degree from the University of Illinois at Chicago College of Pharmacy. Dr. Travlos lives with her husband and two sons in Glenview. Her husband, Jerry, is a Chicago Public School Principal for a K-8 school. Her son, John, is a high school sophomore and plays football and basketball; Anthony is an 8th grader who enjoys playing football, basketball, and baseball.

Upcoming ACPE Activities

June Board Meeting
June 21-24, 2017, Chicago, Illinois

ACPE CPE Modified Administrator Workshop and CPD in Pharmacy Education: Engagement in Self-Directed Lifelong Learning
July 15, 2017
AACP Annual Meeting, Nashville Tennessee

Professional Degree Program – Self-Study Workshop #1
August 5–6, 2017, Chicago, Illinois

Professional Degree Program – Self-Study Workshop #2
August 21–22, 2017, Chicago, Illinois

September Evaluator Site Training Workshop
September 25–26, 2017, Chicago, Illinois

November International Commission Meeting
November 13–14, 2017, Chicago, Illinois

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M E M O R A N D U M

To: Members & Staff

From: Malcolm Broussard

Date: August 23, 2017

Re: Comprehensive Addiction & Recovery Act of 2016 (CARA)
S. 524 → Public Law 114-198

The U.S. Congress passed this legislation and it was signed into law on July 22, 2016. This legislation addressed a number of issues related to addiction and recovery, including an amendment of the Controlled Substances Act (CSA) to permit the partial filling of prescriptions for Schedule II medications beyond the limited exceptions present in the DEA's current rules.

The DEA has not yet amended its rules for controlled substances to permit the partial filling described in this law. Further, the Board has not amended its rules on the same topic. However, Act 82 of the 2017 Louisiana Legislature specifically referenced this section of the amended CSA to authorize such partial fills of Schedule II prescriptions.

The relevant portion of CARA is reproduced here:

§702. Partial fills of Schedule II controlled substances.

(a) In general. Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

"(f) Partial Fills of Schedule II Controlled Substances.

(1) Partial Fills. A prescription for a controlled substance in Schedule II may be partially filled if:

(A) it is not prohibited by state law;

(B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and state law;

(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(2) Remaining portions:

(A) In general, except as provided in Subparagraph (B), remaining portions of a partially filled prescription for a

controlled substance in Schedule II:

(i) may be filled; and

(ii) shall be filled not later than 30 days after the date on which the prescription is written.

(B) Emergency situations. In emergency situations, as described in Subsection (a), the remaining portions of a partially filled prescription for a controlled substance in Schedule II:

(i) may be filled; and

(ii) shall be filled not later than 72 hours after the prescription is issued.

(3) Currently lawful partial fills.
Notwithstanding Paragraph (1) or (2), in any circumstance in which, as of the day before the date of enactment of this Subsection, a prescription for a controlled substance in Schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled.

(b) Rule of Construction. Nothing in this Section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in Schedule III, IV, or V of Section 202(c) of the Controlled Substance Act (21 U.S.C. 812(c)) to be partially filled.

Advancing Team-Based Care Through Collaborative Practice Agreements

A Resource and Implementation Guide for Adding Pharmacists to the Care Team

Dear Pharmacists and Collaborating Prescribers:

Nearly one in every three deaths in the United States is caused by cardiovascular disease (CVD).[1] Sixty percent of preventable heart disease and stroke deaths happen to people under age 65.[2] With the burden of chronic disease in the US increasing, we need new ways to empower patients and improve care. Pharmacists have long been identified as an underutilized public health resource.[3] Pharmacists are well positioned to help fill the chronic disease management gap and can make a difference when they are actively engaged as part of a team-based care approach.

Collaborative practice agreements increase the efficiencies of team-based care and formalize practice relationships between pharmacists and collaborating prescribers. For this reason, the **National Alliance of State Pharmacy Associations (NASPA), American Pharmacists Association (APhA), American Medical Association (AMA), the American Association of Nurse Practitioners (AANP),** the **Network for Public Health Law – Eastern Region, and University of Maryland Francis King Carey School of Law** have collaborated with the **Centers for Disease Control and Prevention, Division for Heart Disease and Stroke Prevention,** to develop this guide, **Advancing Team-Based Care through Collaborative Practice Agreements.**

The guide is a resource for pharmacists to use in developing and executing collaborative practice agreements in the spirit of advancing team-based care. It provides a customizable template that can be used as a starting point to developing a collaborative practice agreement.

The collaborating organizations recognize the value of pharmacists as a necessary member of the patient care team and endorse use of this guide to form collaborative practice agreements. Together, we can work to improve the quality of patient care, better prevent and treat chronic disease and improve population health.

National Alliance of State Pharmacy Associations (NASPA)

American Pharmacists Association (APhA)

American Medical Association (AMA)

American Association of Nurse Practitioners (AANP)

Network for Public Health Law – Eastern Region

University of Maryland Francis King Carey School of Law

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1 Centers for Disease Control and Prevention. National Statistics Report: Deaths: Final Data for 2014. 2016(June);65(4). Chamblee, GA: CDC, U.S. Department of Health and Human Services; 2016. Accessed December 19, 2016.
2 Centers for Disease Control and Prevention. Vital Signs: Preventable Deaths from Heart Disease & Stroke. Accessed December 19, 2016.
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Executive Summary

Rationale

Chronic diseases are the leading causes of death and disability in the United States, accounting for seven of every ten deaths in this country. In 2014, one in every three deaths was due to cardiovascular disease (CVD). One in three U.S. adults has high blood pressure, and almost half of these individuals do not have this condition under control. Team-based care results in personalized, timely, and empowered patient care—and it facilitates communication and coordination among team members. The evidence is strong that when pharmacists are members of the health care team, outcomes related to preventing or managing chronic disease (e.g., blood pressure, blood glucose, cholesterol, obesity, smoking cessation) and medication adherence improve. The purpose of this guide is to empower community pharmacists and collaborating prescribers to initiate collaborative practice agreements (CPAs) focused on caring for patients with chronic diseases, including CVD.

Collaborative Practice Agreements

CPAs create a formal practice relationship between a pharmacist and a prescriber, who is most often a physician, although a growing number of states are allowing for CPAs between pharmacists and other health professionals, such as nurse practitioners. The agreement specifies what functions (in addition to the pharmacist's typical scope of practice) can be delegated to the pharmacist by the collaborating prescriber. The terms used and the functions provided under a CPA vary from state to state based on the pharmacist's and prescriber's scope of practice and the state's collaborative practice laws. Most often, the functions delegated to pharmacists by prescribers include initiating, modifying, or discontinuing medication therapy. Ordering and interpreting laboratory tests may also be included if those services are not already authorized in the pharmacist's regular scope of practice.

CPAs Support Team-Based Care

CPAs are built upon a foundation of trust between pharmacists and prescribers and serve as a useful mechanism for increasing efficiencies of team-based care. When designed correctly, CPAs are beneficial to the collaborative delivery of care through delegation by the physician or other prescriber of specific patient care services to pharmacists. This delegation can expand available services to patients and increase coordination of care. For example, the use of CPAs can decrease the number of requests to authorize refills, modify prescriptions, initiate therapeutic interchanges (in which the pharmacist can substitute another drug for the medication prescribed), and order and interpret laboratory tests, while keeping the prescriber apprised of the pharmacist's actions through established communication mechanisms. This allows each member of the health care team to complement the skills and knowledge of the other members and more effectively facilitate patient care, resulting in improved patient outcomes.

Scope of Service and Requirements

Many pharmacists' services do not require a CPA. For example, assessing medication therapy for drug-related problems, performing hypertension and cholesterol screenings, and educating patients are already within pharmacists' regular scope of practice. A CPA is not required for pharmacists or practitioners to collaborate in providing care. The only requirement is cooperation toward achieving a common goal—providing optimal patient care. While it is important to have shared goals,

clear roles, effective communication, and measurable processes and outcomes, the degree of trust within the relationship is often the deciding factor for turning collaborative relationships into contractual CPAs.

Building trust is often a progressive process. For example, a collaborative relationship may begin with a pharmacist dispensing a prescriber's prescription, followed by an exchange of medication information. This advances to a prescriber accepting a pharmacist's recommendations for medication therapy, and then to a prescriber delegating disease management responsibilities and granting authority for medication therapy management to a pharmacist under a formal CPA. Trustworthiness, role specification, and professional interactions are three critical factors to establishing trust within a collaborative relationship.

Components of a CPA and Applicable Laws

Pharmacists interested in pursuing CPAs with prescribers should seek to understand the laws on CPAs within their state, identify prescribers with whom a relationship already exists or build a relationship with prescribers with mutual interests, and consider offering basic services (e.g., refill authorizations, therapeutic interchange) as an initial step. Seeking to identify and understand the prescriber's unmet needs and demonstrating competency as it relates to the prescriber's patient population and the services provided will help to facilitate the uptake of a CPA. Finally, pharmacists can anticipate prescribers' concerns related to delegating authority for care and be prepared to respond to those concerns in an effective manner.

Steps to Implementation

A CPA template and sample language for each component are included in this resource guide. The implementation of a CPA involves a series of steps that depend on state laws and pharmacist-prescriber preferences. The implementation steps may include registering the CPA with the board of pharmacy or some other governing body, developing data sharing and business associate agreements, obtaining a pharmacist National Provider Identifier number, and identifying a business model that sustains the agreed-upon scope of services.

CPAs offer a unique opportunity for pharmacists to collaborate with prescribers in the treatment and management of chronic conditions, including CVD and hypertension. This guide offers resources to develop and implement a CPA between pharmacists and prescribers for the purpose of advancing public health and improving patient outcomes, quality and process measures, efficacy, and patient and provider satisfaction.

A formal CPA can have many components including the following:

Scope of Agreement

- Parties to the agreement
- Patient inclusion criteria
- Patient care functions authorized

Legal Components

- Authority and purpose
- Liability insurance
- Informed consent of the patient
- Review of the agreement and maximum period of validity
- Rescindment or alteration of agreement
- Signatures of the parties to the agreement

Administrative Components

- Training and education
- Documentation
- Communication
- Quality assurance (or quality measurement)
- Retention of records

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Overview

Impact of Chronic Disease

Chronic diseases are the leading causes of death and disability in the United States, accounting for seven of every ten deaths.[1] In 2012, 117 million Americans (about half of the adult population) had at least one chronic illness.[2] An estimated 25% of U.S. adults with chronic conditions have one or more limitations in daily activities.[2] In 2014, one in every three deaths was due to cardiovascular disease (CVD).[3,4]

Hypertension, hyperlipidemia, and smoking are key risk factors for CVD, and 47% of Americans have at least one of these three risk factors.[5] One in three U.S. adults has high blood pressure, and almost half of these individuals do not have this condition under control.[5] Another 11.5 million of these adults are neither aware of their hypertension nor taking antihypertensive medications.[3,5] In addition, only one third of people with high cholesterol have adequate control of their hyperlipidemia, and 17% of U.S. adults smoke cigarettes.[6,7,8] Improved control of the risk factors for CVD requires an expanded effort from health care systems and health care professionals in the health system, including pharmacists.[6]

Value of Pharmacists' Patient Care Services

Interventions to manage and control hypertension and other risk factors for CVD can focus on removing health care professional- and patient-related barriers.[9,10,11] A team-based model organizes care around patient needs and commonly involves systems that support clinical decision making through collaborations between health care professionals or between these professionals and their patients. There is strong evidence that when pharmacists are part of the health care team, outcomes related to preventing or managing chronic diseases (e.g., blood pressure, blood glucose, cholesterol, obesity, smoking cessation) and adherence to medication improve.[12,13] Team-based care results in personalized, timely, and empowered patient care and facilitates communication and coordination among team members.

In 1981, the American Public Health Association declared that pharmacists were an underutilized resource in promoting public health. Since then, several public health needs—such as public access to immunizations—have been addressed by community pharmacists. One of the reasons that pharmacists can address emerging public health needs is that they are among the most accessible health care professionals in the United States. Notably, an estimated 86% of the U.S. population lives within 5 miles of a community pharmacy.[14] While examples of pharmacists practicing in team-based environments exist, there remains an opportunity to increase and accelerate the inclusion of pharmacists as part of the patient care team.

In 2011, the chief pharmacist officer of the U.S. Public Health Service authored a report, titled *Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice*, to the U.S. surgeon general.[15] This report highlighted the efficacy of pharmacists in advanced practice roles and advocated for intensified utilization of pharmacists in alleviating our nation's imminent primary care provider crisis. The findings of the report were promptly endorsed and supported by the 18th surgeon general, Vice Admiral Dr. Regina Benjamin, who recommended that health leadership and policy makers optimize the pharmacist's role.[16] Vice Admiral Benjamin recommended that this be done through implementation of collaborative practice models; recognition of pharmacists as providers, clinicians, and essential members of the health care team; and exploration of additional compensation models to support pharmacists in these expanded roles.

Advancing Pharmacists in Team-Based Care

The Centers for Disease Control and Prevention (CDC) recognizes the role of pharmacists in team-based care for chronic disease management. The CDC Division for Heart Disease and Stroke Prevention has created resources to encourage pharmacists and prescribers (physicians and others who prescribe drugs) to work collaboratively and formalize those relationships through collaborative practice agreements (CPAs), when possible. These resources include:

- A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. This resource provides examples of how pharmacists can work within the four public health domains (i.e., environmental approaches, health systems, community-clinical linkages, and epidemiology and surveillance) to have a positive effect on patient health outcomes.[17]
- How Pharmacists Can Improve Our Nation's Health. This resource (a CDC Public Health Grand Rounds presentation) provides examples of the roles that pharmacists can play in team-based care.[18]
- Collaborative Practice Agreements and Pharmacists' Patient Care Services. This resource provides an overview of CPAs.[19]
- Collaborative Drug Therapy Management: Case Studies of Three Community-Based Models of Care.[20] This resource illustrates how CPAs have been successfully implemented in three pharmacy practice settings.

Purpose and Development Process

The purpose of this resource guide is to empower community pharmacists and collaborating prescribers to initiate CPAs that are focused on caring for patients with chronic diseases. CVD and its risk factors are used as an example throughout the resource guide. The primary audience is pharmacists practicing in states where existing regulations permit them to engage in CPAs for the monitoring and management of chronic disease.

The information contained in this resource guide was collected in these four ways: (1) reviewing existing literature and resources; (2) analyzing laws and regulations on collaborative practice; (3) reviewing examples of CPAs currently in use; and (4) holding roundtable meetings with pharmacists, physicians, public health professionals, academicians, and payer representatives in five states (i.e., Kentucky, Minnesota, Tennessee, Washington, and Wisconsin).

CPA-related Terminology

Other terms for a CPA include:

- Collaborative pharmacy practice agreement.
- Collaborative care agreement.
- Consult agreement.
- Physician-pharmacist agreement.
- Standing order or protocol.
- Delegation of authority by physician.

Terms used to describe the services provided under a CPA include:

- Collaborative drug therapy management.
- Drug therapy management.
- Pharmaceutical care.
- Medication therapy services.
- Collaborative pharmacy practice.[22]

About Collaborative Practice Agreements

Definition of a CPA

CPAs create a formal practice relationship between a pharmacist and a prescriber. The agreement specifies what functions—in addition to the pharmacist's typical scope of practice—are delegated to the pharmacist by the collaborating prescriber. The collaborating prescriber is most often a physician, but a growing number of states are allowing for CPAs between pharmacists and nurse practitioners or other nonphysicians. This resource guide uses the term "prescriber" to reference the collaborating provider who is delegating patient care services to the pharmacist under the CPA.

The functions provided under the agreement vary from state to state based on the pharmacist's scope of practice and the state's collaborative practice laws.[21]

Most often, CPAs are used in the context of authorizing pharmacists to initiate, modify, or discontinue medication therapy. Functions performed under a CPA may also include ordering and interpreting laboratory tests if those services are not already authorized in the pharmacist's scope of practice.

Using CPAs to Facilitate Team-Based Patient Care[22]

When trust has been established, CPAs are a useful way to increase the efficiency of team-based care. When designed correctly, CPAs benefit the collaborative delivery of care by delegating specific patient care services to pharmacists. This delegation can expand available services to patients and increase the efficiency and coordination of care. For example, CPAs can decrease the number of phone calls required to authorize refills or modify prescriptions, thus allowing each member of the health care team to complement the skills and knowledge of the other member(s) and more effectively facilitate patient care, resulting in improved patient outcomes.

Terminology

This resource guide uses the term "collaborative practice agreement," "collaborative agreement," or "CPA" to describe a practice relationship in which a prescriber delegates selected patient care services to a pharmacist. The terminology used to describe this authority varies among states as do the terms used to describe the services provided under a CPA.

States Permitting CPAs

As of May 2016, 48 states permit some type of pharmacist-prescriber collaborative practice authority. However, some of these states' laws and regulations may not support the implementation of a CPA. For example, in Alabama and Delaware, prescribers cannot delegate authority to pharmacists via a CPA, and in Florida and Oklahoma, pharmacists are restricted to providing only limited services under a CPA.

State laws for CPAs vary widely; the key variables in these laws are below. Thus, the terms of the written CPA will need to be customized to the laws and regulations of a given state.

Finding the Applicable State Laws and Regulations

Before entering into a CPA, pharmacists and prescribers may benefit by reviewing their state's current laws and regulations pertaining to CPAs. Appendix A contains CPA laws for each state (as of December 31, 2015). State boards of pharmacy and medicine and state pharmacy and medical associations can serve as points of contact for the most up-to-date information on CPA authority. To obtain access to a specific state's current pharmacy laws and regulations, visit the National Association of Boards of Pharmacy website.

Pharmacy Services Under CPAs

A variety of pharmacist-provided services can be performed under a CPA. CVD-related services are used as examples below to illustrate how pharmacists may define pharmacy services within a CPA. Because of variations in state laws, some of the services may be permitted under a pharmacist's regular scope of practice in some states but represent an expansion of practice in others.

Authorization of refills. In this service, the prescriber authorizes the pharmacist to extend refills based on the pharmacist's assessment (e.g., using the pharmacists' patient care process) of the patient. For example, under the terms of a CPA, a pharmacist may be permitted to extend refills of a patient's medications for treating chronic hypertension and hypercholesterolemia, thereby removing delays in therapy and administrative barriers and potentially increasing medication adherence. Without a CPA, in most states, pharmacists would need to contact the prescriber to obtain authorization for a refill.

Variables in State CPA Laws and Regulations

CPA Participants
- Number of pharmacists.
- Number of prescribers.
- Number of patients.
- Types of prescribers.
- Relationship between patient and prescriber.
- Pharmacist-to-prescriber ratio.

Authorized Functions
- Modify medication therapy.
- Initiate medication therapy.
- Discontinue medication therapy.
- Conduct physical assessment.
- Order laboratory studies.
- Interpret laboratory studies.
- Perform laboratory tests.

Requirements and Restrictions
- Continuing education.
- Qualifications of pharmacist.
- Liability insurance.
- Disease state of patient.
- Practice setting.
- Medications to be managed.
- Involvement of patient.
- Agreements approved or reported, and to which entity.
- Length of time that agreement is valid.
- Documentation.
- Communications.
- Review by physician.

Therapeutic interchange. Here the prescriber authorizes the pharmacist, under a CPA, to substitute another drug in the same drug class (e.g., angiotensin-converting enzyme inhibitors to treat hypertension) for the medication originally prescribed. This usually happens because of the variability in a particular health plan's formulary of accepted drugs. The pharmacist's clinical knowledge of medications informs his or her choice of medication within a particular class of drugs.

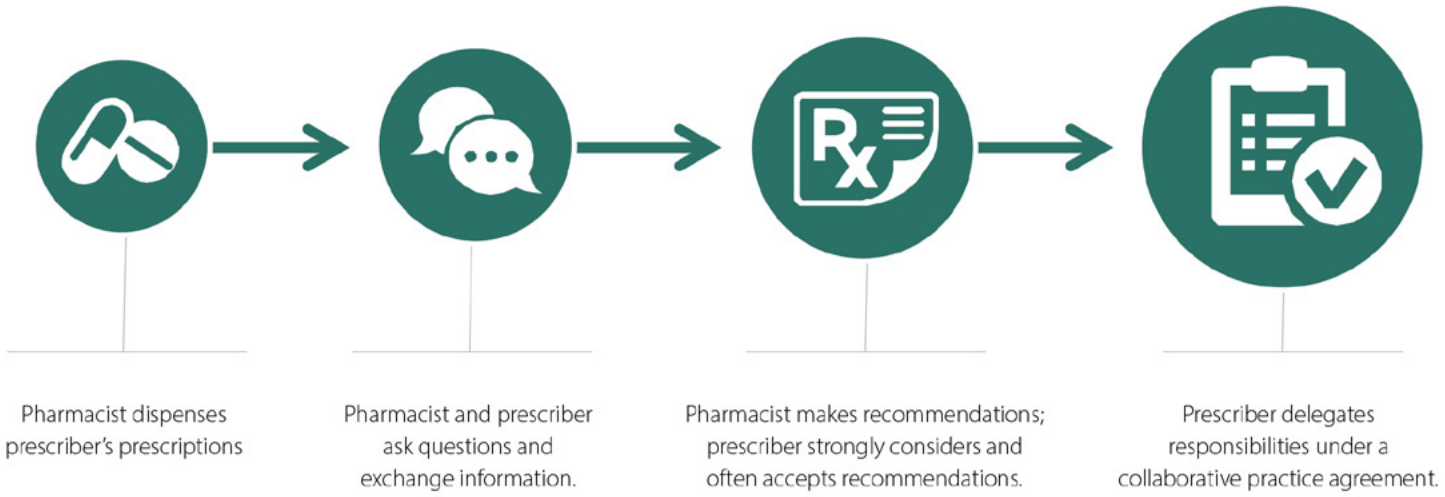
Hypertension management. In this service, the prescriber authorizes the pharmacist to initiate, modify, or discontinue medications. For example, under the terms of a CPA, a pharmacist may be permitted to add therapies if the patient's hypertension is uncontrolled, adjust doses of medication, or discontinue medications that are not working or cause side effects. The medications or medication classes that pharmacists are permitted to initiate, modify, or discontinue may be indicated in the agreement. Without the CPA, the pharmacist would have to assess the patient and make a recommendation to the prescriber. The prescriber would then have to act on the recommendation in order for the pharmacist to make a change in therapy. The CPA leverages the pharmacist's medication and health-related expertise to extend the care of the prescriber's patients while coordinating care with the prescriber.

Ordering laboratory tests.
Here the CPA may authorize the pharmacist to order and interpret laboratory tests that are essential for effectively monitoring medications or the status of chronic conditions. For example, as part of a hypertension CPA, the pharmacist could order urine and blood analyses to test for electrolyte levels, fluid balance, and kidney function.

Note that some pharmacists' CVD-related services, such as assessing medication therapy for medication-related problems, performing hypertension and cholesterol screenings, and educating the patient, are within pharmacists' regular scope of practice.

State Scope of Practice & CPAs
The patient care functions that pharmacists are authorized to perform with and without a CPA are highly variable from state to state. A function that a pharmacist can perform only if authorized under a CPA in one state may be a function that a pharmacist can perform autonomously in another state. This resource guide's primary focus is on developing a CPA to facilitate those patient care functions required by state law to be delegated to the pharmacist through a written CPA. However, it is important to note that pharmacists and other health care professionals may still choose to formalize their collaboration with an agreement—to outline communications, documentation, and other pertinent subjects—even if the activities the parties agree to collaborate on can be performed autonomously by the pharmacist pursuant to the state pharmacy practice act. Pharmacists should consult with the state board of pharmacy or a licensed attorney when there is a question regarding whether an agreement must comply with a given state's CPA laws.

Figure 1: Level of Professional Interaction Reflects Degree of Trust Between the Pharmacist and the Prescriber



Collaborative Care as a Basis for CPAs

The World Health Organization has stated that "Collaborative care in health care occurs when multiple health providers from different professional backgrounds provide comprehensive services by working with patients, their families, care providers, and communities to deliver the highest quality of care across settings."[23] Thus, a CPA is not required for practitioners to collaborate in providing care. The only requirement is cooperation toward achieving a common goal—providing optimal patient care. As part of collaboration, it is important to have shared goals, clear roles, effective communication, and measurable processes and outcomes. The degree of trust within the relationship is often the deciding factor for collaborative relationships becoming contractual CPAs.[24] Figure 1 illustrates the relationship between greater trust within a collaborative relationship and a higher degree of professional interactions.

Developing the Relationship and Building Trust

Once an initial relationship is established, the collaborating providers can work together to develop mutual trust. Three factors that may be important to the development of a working clinical relationship are trustworthiness, role specification, and professional interactions.[24,25,26,27,28,29]

Trustworthiness. The development of trust requires time and the demonstration of competence.[29] Physicians may be more trusting when they know the amount of training, experience, and credentials that the pharmacist has.[24,25,26,27,28,29] Pharmacists may recognize this tendency and be open to sharing this information about themselves.

Patients also benefit from developing trust with the members of their care team. One way to accomplish

this is for the prescriber and pharmacist to meet with the patient together. If a joint appointment is not possible, the prescriber can advise the patient of the benefits from seeing the pharmacist. Regardless, the expectation is that trust will be built gradually among pharmacists, providers, and patients.

Role specification. Defining which activities will be performed by pharmacists and which by the prescriber enables both parties to have shared expectations about how they will collaborate. When first establishing a collaborative relationship, health care professionals may choose to begin with focusing on basic services until trust can be established. As both health care professionals work together to understand each other's skills and competence, trust will grow, and more complex services can be introduced.[30] Many pharmacists have reported that as prescribers experience pharmacists' skills firsthand, the prescribers begin to offer ideas for more collaboration.

Professional interactions. Direct interactions between pharmacists, prescribers, and their patients are essential to growing trust and collaboration. Effective communication is key to building professional interactions and demonstrating trustworthiness. When pharmacists and physicians start their collaborative relationship, frequent in-person communication may be ideal.[25] For example, pharmacists may consider practicing in the prescriber's office for a specific time frame (e.g., a half day each week for 2 months) to learn the prescriber's approach to patient care and style of communication. When building the relationship, pharmacists can consider providing an example of the type of communication the prescriber can expect to receive after patient visits. This may serve as a conversation starter when developing the CPA.[25] Communication between providers can be initiated by either party; communication could include, for example, sharing relevant patient information, discussing drug-related problems, or requesting a pharmacist consultation. Increasing professional interactions leads to increased collaboration.[28]

Formalizing Collaborative Relationships Through CPAs

Once pharmacists and prescribers have established collaborative relationships built upon trust, they may choose to enter into a formalized CPA to facilitate the pharmacist's ability to care for the prescriber's patients in accordance with mutually established role specifications. In the beginning of the collaborative relationship, the pharmacist will likely initiate the conversation about the CPA; he or she should be prepared to make the case for the value of formalizing the relationship. Pharmacists should be aware that the collaborating prescriber would be increasing his or her own liability by entering into a CPA, and so it will be important to let the prescriber ask questions, voice concerns, and help to shape the scope of the CPA. When first establishing a formal collaborative arrangement, pharmacists and prescribers may choose to begin with focusing on basic services such as authorization for refills or therapeutic interchange.

Identifying Partners

Finding and approaching a potential collaborator without having a prior relationship with that person can seem daunting. One approach is for pharmacists to work with prescribers they already know. This familiarity might come from collaborating on initiatives, such as the delivery of immunizations, or through mutual involvement in community organizations or local coalitions.[25] In addition, pharmacists can approach prescribers in their community with whom they do not have a prior relationship but where common goals exist.

Pharmacists' ability to improve metrics of quality—both clinical and financial—can also create opportunities for collaboration. Hospitals are increasingly under pressure to reduce readmissions, and the services of pharmacists can help here. Pharmacists can meet with the medical director and pharmacy director from local hospitals to explore collaboration on transitions of care from the hospital to an outpatient/office or clinic setting. Clinics and physicians' offices, as well as hospitals, are held to quality measurements that pharmacists' services can often improve. Other potential collaborators include state and local public health agencies, accountable care organizations, and patient-centered medical homes. It can be helpful for pharmacists to understand the metrics for which potential collaborators are responsible and then think of ways to help them improve those scores.

When identifying providers for new collaborative relationships, pharmacists may consider those provisions in state CPA laws that limit which prescribers can enter into CPAs with pharmacists. In all states, pharmacists may partner with physicians in their community to deliver collaborative care. Additionally, in states where nurse practitioners and physician assistants can enter into CPAs with pharmacists, these prescribers may be familiar candidates for collaboration because they were previously required to have CPAs with physicians in order to prescribe. Table 1 in Appendix A describes state laws and regulations, including those governing which prescribers can authorize a CPA.

Initiating the Relationship

Pharmacists seeking to start a collaborative model of care delivery may benefit from taking the first step in initiating the relationship.[25,26] To initiate discussions, a face-to-face meeting should be held with the prospective collaborating prescriber. The meeting can be scheduled in advance by the pharmacist, and might take place over lunch or dinner and include other staff members whose buy-in may be important.[25]

During the initial meeting with a prospective collaborator, the pharmacist should be prepared to articulate specific goals and benefits of collaboration and discuss how the collaboration can lead to enhanced patient care. He or she should consider focusing on unmet patient needs in the prescriber's practice and in the community. Where are there gaps that the pharmacist could fill? If the pharmacist has worked with other prescribers in the past, using examples of how that collaboration worked can spark conversation. For example, a pharmacist can use the first collaborating prescriber as a reference for future potential collaborations. If this is a new endeavor, one place to start is for the pharmacist to assist with improving medication adherence for patients in the prescriber's practice. Improving medication adherence is a service that pharmacists can provide without a CPA. In brief, it is a way to engage in offering a basic service with the intent to demonstrate success, build trust, and work collaboratively before a CPA is started. In a study reported in 2011, physicians' belief that collaboration with pharmacists could result in increased patient adherence to medication regimens was a predictor of a positive attitude toward collaboration.[27] Regardless, pharmacists should expect that prescribers, especially those who have not previously worked in collaborative relationships, might have many questions. It is important to consider each of the questions set forth on the next page titled "Anticipating the Concerns of Prescribers" before meeting with a prescriber and to have a well-formulated response to each one.

Garnering the support of prescribers for entering into a CPA might require various approaches and timelines. Once the partners agree to formalize their collaboration, creating the legal agreement may require consideration of the components included in state CPA laws (Appendix A). Figure 2 presents a sample CPA and sample language that may be customized by pharmacists and prescribers using their specific state laws to create a CPA.

Anticipating the Concerns of Prescribers

1. **What is the pharmacist's training, and what credentials does the pharmacist have?**
   Pharmacists can educate the prescriber on the pharmacist's training and focus on the skills and credentials of the particular pharmacist(s) who would be working in the practice.

2. **What has been the pharmacist's experience in delivering various patient care services?**
   Pharmacists can explain how their experience aligns with the needs of the patient population cared for by the prescriber and elaborate on how that experience can benefit the patient and improve outcomes.

3. **What is the pharmacist's scope of practice in the state?**
   Pharmacists can educate the prescriber about which patient care functions pharmacists can perform pursuant to the state's pharmacy practice act as well as the functions that can be authorized in a CPA. Providing specific examples can be very helpful.

4. **How will the pharmacist communicate with the prescriber?**
   Pharmacists can discuss the prescriber's preferred method of communication and review opportunities for using health information technology to facilitate the exchange of information. In addition, they should provide examples of how pharmacists communicate (using health information technology and other means) with prescribers in collaborative care models.

5. **Will the prescriber incur additional liability?**
   In a collaborative care relationship that is not governed by a CPA, the prescriber is not likely to incur additional liability for any actions of the pharmacist. This is because the prescriber must approve any recommendations made by the pharmacist before medication therapy is initiated or modified. In this scenario, the risk may be lower because care is likely to be better coordinated in a collaborative care relationship. When using a CPA, pharmacists should discuss terms of liability—which can be clearly described in the CPA—to mitigate risk and any concerns of either party to the agreement.

6. **What costs will be incurred by the prescriber in collaborating with the pharmacist?**
   The prescriber is likely to bring up issues of cost and reimbursement. Costs may vary depending on where the pharmacist will practice (e.g., within the physician's office or remotely). Pharmacists should be prepared to discuss needs for resources and payment. During this discussion, it may be important to include the value that pharmacists can bring to the practice. Appendix B provides general information about payment for pharmacy services.[28]

1 in 3 adults

has high blood pressure

1 in every 3 deaths

was from cardiovascular disease

Adapting a Template CPA for a Hypertension and Cardiovascular Disease Service*

This section provides examples of language that can be used to draft a CPA. Figure 2, the sample CPA, demonstrates how the language options presented in the following call-out boxes can be applied to create a customized CPA. (Note that Figure 2 uses Virginia's provisions as an example and thus would not meet the requirements in all states.)

The language in the call-out boxes was adapted from CPAs that are currently in use and from feedback received at the roundtable meetings. This language is provided solely for educational purposes and is only for use as an example. Pharmacists may benefit from consulting legal counsel when drafting a CPA based on the laws and regulations in the jurisdiction where the CPA will be implemented. To get a better understanding of state laws and regulations—as of December 2015— those drafting a CPA should refer to the tables in Appendix A and be sure to check the current laws and regulations.

Not every state addresses every component that appears in these tables. The word "silent" indicates that the state has not addressed that particular issue in its laws and regulations. In these cases, pharmacists and prescribers should work within their scope of practice, use their judgment while developing a CPA, and keep the best interests of the patient in mind.

*Disclaimer: The information contained in this document does not constitute legal advice. Use of any provision herein should be contemplated only in conjunction with advice from legal counsel. The CPA language in the text boxes below was provided by attorneys at the University of Maryland Francis King Carey School of Law as example CPA language for educational purposes only and is adapted from CPA language from multiple states. Provisions may need to be modified, supplemented, or replaced to ensure appropriate citation of or compliance with relevant laws, to accurately reflect the intent of the parties to a particular agreement, or to otherwise address the needs or requirements of a specific jurisdiction.

Figure 2: Sample Collaborative Practice Agreement for Hypertension/Cardiovascular Disease (Continued on next page)

COLLABORATVE PRACTICE AGREEMENT

for authorization of therapy continuation and therapeutic interchange

A. AUTHORITY AND PURPOSE

I, Dr. Susan Patel and Jessica Johnson authorize the pharmacist(s) named herein, who hold an active license to practice from the Commonwealth of Virginia, to manage and/or treat patients pursuant to the parameters outlined in this agreement. This authority follows the laws and regulations of the Commonwealth of Virginia. The purpose of this agreement is to facilitate consistent access to medications for the collaborating providers' mutual patients.

B. PARTIES TO THE AGREEMENT

The following providers agree to the parameters outlined in this agreement:

Pharmacists:	Prescribers:
James Lee, PharmD	Susan Patel, MD
Alexa Garcia, PharmD	Jessica Johnson, ANP

C. PATIENTS

Patients whose therapy may be managed pursuant to this agreement include those who are currently receiving hypertension or dyslipidemia therapy prescribed by a prescriber listed in Section B of this agreement.

D. PATIENT CARE FUNCTIONS AUTHORIZED

Pharmacist(s) included in Section B of this agreement will have the authority to manage and/or treat patients in accordance with this section.

In managing and/or treating patients, the pharmacist(s) may authorize continuation of drug therapy and modification of drug therapy to a therapeutic alternative medication (defined as a medication in the same class with an equivalent dose), if appropriate, based on current literature and clinical judgment.

D.1. Dyslipidemia[1]

The pharmacist(s) will evaluate dyslipidemia as outlined by 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults and other nationally recognized standards of care as supported by current literature. Pharmacist(s) will have authority to authorize continuation of therapy or therapeutic interchange for the treatment of lipids which may include, but are not limited to the following classes: HMG-CoA reductase inhibitors (statins), bile-acid sequestrants, cholesterol absorption inhibitors, fibrates, omega-3 fatty acids, niacin.

D.2. Hypertension[2]

The pharmacist(s) will evaluate hypertension therapy as outlined in 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report from the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) and other nationally recognized standards of care as supported by current literature. Pharmacist(s) will have authority to authorize continuation of therapy or therapeutic interchange for the treatment of hypertension which may include, but are not limited to the following classes: beta-blockers, calcium channel blockers, ACE inhibitors, angiotensin II receptor blockers, direct renin inhibitors, diuretics, alpha-blockers, α_1- centrally active agents.

E. TRAINING/EDUCATION

All parties to this agreement are expected to maintain up-to-date competencies and knowledge of current guidelines for disease states covered under this agreement.

F. LIABILITY INSURANCE

All parties to this agreement shall maintain at least $1,000,000 (per occurrence) of professional liability insurance during the term of the agreement which specifically covers drug therapy.

G. PATIENT INFORMED CONSENT

The pharmacist shall obtain written informed consent from the patient upon first meeting with the patient. A record of provision of care by a pharmacist shall be maintained in the patient's pharmacy record, which is available to the pharmacist.

SAMPLE

Figure 2: Sample Collaborative Practice Agreement for Hypertension/Cardiovascular Disease (Continued from previous page)

H. DOCUMENTATION
The pharmacist(s) shall document each continuation or modification of therapy authorization in the patient's pharmacy record.

I. COMMUNICATION
The pharmacists shall provide the patient's original prescriber with notification in the form of fax or secure email when their patient's therapy is continued or therapeutically interchanged pursuant to this agreement. In this notification, the pharmacists will include any relevant information that was collected from the patient such as current blood pressure, adherence issues, or any socioeconomic challenges identified.
The pharmacist shall report any new patient complaints and/or deterioration in the patient's condition to the patient's primary care provider and/or other provider immediately after learning of the new condition or as soon as possible thereafter.

J. QUALITY ASSURANCE
Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high quality patient care. Annual evaluation of pharmacist(s) may include clinical outcomes, number of patients treated, and satisfaction surveys of patients and providers as appropriate.

K. AGREEMENT REVIEW AND DURATION
This agreement shall be valid for a period not to exceed two years from the effective date. However, it may be reviewed and revised at any time at the request of any signatories.

L. RECORD RETENTION
Each signatory to this agreement shall keep a signed copy, written or electronic, of this agreement on file at their primary place of practice. Record of each therapeutic interchange made for a specific patient shall be maintained in the patient's pharmacy record.

M. RESCINDMENT OR ALTERATION OF AGREEMENT
A signatory may rescind from this agreement or a patient may withdraw from treatment under this agreement at any time. The prescriber(s) may override this agreement whenever he or she deems such action necessary or appropriate for a specific patient without affecting the agreement relative to other patients.

N. REFERENCES

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O. AGREEMENT SIGNATURES
This agreement includes patients under the care of the practitioner(s) and extends for a period of two (2) years from this date unless rescinded earlier in writing.

Signatures:

[Prescriber name and credentials]	**[Prescriber Signature]**	**License #**	**Date**
[Prescriber name and credentials]	**[Prescriber Signature]**	**License #**	**Date**
[Pharmacist name and credentials]	**[Pharmacist Signature]**	**License #**	**Date**
[Pharmacist name and credentials]	**[Pharmacist Signature]**	**License #**	**Date**

SAMPLE

A. Authority and Purpose

This section is not required by law to be included in a CPA but may help the collaborating providers establish their vision for the purpose of the agreement.

AUTHORITY AND PURPOSE:

I, [INSERT PRESCRIBER NAMES], authorize the pharmacist(s) named herein, who hold an active license to practice issued by [STATE NAME], to manage and/or treat patients pursuant to the parameters outlined in this agreement. This authority follows the laws and regulations of [STATE NAME]. The purpose of this agreement is to facilitate consistent access to medications for the collaborating providers' mutual patients.

-OR-

PURPOSE:

In order to enhance collaborative patient care and optimize medication-related outcomes, patient care services will be provided by the pharmacists listed in Section B of this agreement in collaboration with the prescribers listed in Section B of this agreement. Services will include those listed in Section D of this agreement. The pharmacists will deliver these services in a manner consistent with the parameters outlined in this collaborative practice agreement and in compliance with the protocols included in the appendices to this agreement.

B. Parties to the Agreement

Both the pharmacists and the prescribers who are participating in the CPA are identified in this section. In some states, a medical director may be authorized to sign onto an agreement on behalf of the providers within a given practice. In this case, each practitioner may or may not have to individually sign the agreement, depending on state laws and regulations. Which prescribers may authorize a CPA and how many pharmacists and prescribers may be on an agreement varies from state to state.

See Table 1 in Appendix A for more information on the authority and restrictions in a particular state.

PARTIES TO THE AGREEMENT:

The following parties agree to the parameters outlined in this agreement:

Pharmacists:	Prescribers:

C. Patients

In this section, either the specific patient(s) or the defined population of patients that will receive care can be specified. Some state laws restrict eligibility to only those patients who are actively being treated by the collaborating provider. Others specify that each patient who will receive care under the parameters of the agreement be listed in the agreement. Still others may even require that the agreement be specific to a single patient and disease state. Drafters of a CPA should see Table 1 in Appendix A for more information on their state.

PATIENTS [PRESCRIBER'S PATIENT PANEL]:

Patients whose therapy may be managed pursuant to this agreement include those who are currently receiving hypertension or dyslipidemia therapy prescribed by one of the prescribers listed in Section B of this agreement.

-OR-

PATIENTS [SPECIFIC LIST OF PATIENTS]:

The pharmacists listed in Section B of this agreement are authorized to provide care to the following patients, pursuant to this agreement:

-OR-

PATIENTS [SPECIFIC TO A SINGLE PATIENT]:

Pursuant to this agreement, the pharmacist(s) listed in Section B of this agreement are authorized to provide care, in the manner outlined in this agreement, to [INSERT PATIENT], a patient of [AUTHORIZING PRESCRIBER].

D. Patient Care Functions Authorized

Role specification allows for mutual understanding of each provider's role in care delivery. As trust develops and the collaborative relationship grows, providers can become interdependent, and their roles can evolve over time.[27,29] Setting expectations for each provider's role can help all parties to feel more comfortable with moving forward. Note that it may be helpful to set expectations for when the initial role specification will be assessed and adjusted. Setting such expectations allows for open communication and continual process improvement.

All CPAs define the scope of the patient care functions that pharmacists are authorized to provide pursuant to the agreement. In the sample agreement, pharmacists are authorized to continue prescription therapy for a medication that does not have refills remaining and make a therapeutic substitution for medications in the same drug class as that prescribed.

Not all states require that a treatment protocol be used as part of a CPA. For example, in Michigan and Wisconsin, physicians can delegate any patient care service to a pharmacist, and the pharmacist's authority does not require the use of a treatment protocol. Even in states where such a protocol is required, providing general guidance, such as referring to evidence-based guidelines, may be appropriate.

Additionally, some states require that the CPA specify which drugs the pharmacist may initiate and/or modify. If this is required, the list of drugs could be included in the "Patient Care Functions Authorized" or in an appendix to the agreement.

It may also be useful to include language covering the instances when the pharmacist refers the patient back to the prescriber. This language would discuss issues outside the scope of the agreement.

Those interested in drafting a CPA should look at Table 2 in Appendix A for more information on what patient care functions can be authorized under such an agreement.

PATIENT CARE FUNCTIONS AUTHORIZED:
Pharmacist(s) included in Section B of this agreement will have the authority to manage and/or treat patients in accordance with this section. In managing and/or treating patients, the pharmacist(s) may [INSERT PATIENT CARE FUNCTIONS AUTHORIZED, SUCH AS INITIATE, MODIFY, OR DISCONTINUE DRUG THERAPY], if appropriate, based on current literature and clinical judgment. The pharmacist(s) will refer the patient back to her/his prescriber for issues that are outside the scope of this agreement. [DEPENDING ON STATE LAW, IT MAY BE NECESSARY TO LIST THE DRUGS, DRUG CLASSES, AND/OR TREATMENT PROTOCOLS AS WELL. THESE ELEMENTS COULD BE INCLUDED IN AN APPENDIX TO THE AGREEMENT.]

E. Training/Education

Some states require that specific education and/or training be completed before a pharmacist is allowed to enter into a CPA. In other states, the education and training that is appropriate for each situation should be determined by the collaborating prescribers. In the example CPA in Figure 2, Virginia does not require any specific education or training. Thus, the collaborating prescribers wrote the agreement so that the responsibility rested with each provider to ensure that he or she actively maintained his or her clinical competencies. Those interested in developing a CPA should see Table 3 in Appendix A for the requirements in their state.

TRAINING/EDUCATION:
All parties to this agreement are expected to maintain up-to-date competencies and knowledge of current guidelines for disease states covered under this agreement.

F. Liability Insurance

State laws/regulations in some states require that providers maintain professional liability insurance in order to participate in a CPA. Regardless of whether it is required by law, health care professionals may want to maintain

liability insurance and may consider including that as a requirement in the CPA. Those interested in developing a CPA should see Table 3 in Appendix A for the requirements in their state.

LIABILITY INSURANCE:
All parties to this agreement shall maintain at least $1,000,000 (per occurrence) of professional liability insurance during the term of the agreement, which specifically covers drug therapy.

G. Informed Consent of the Patient

Although obtaining a written informed consent from the patient is not required in all states, it is beneficial for patients to have an understanding of how their care is delivered. Even in states where a specific form of patient consent is not mandated, health care professionals can discuss whether it needs to be obtained at the first meeting with the patient and the procedure that will be used. Those interested in creating a CPA should see Table 3 in Appendix A for the requirements in their state.

INFORMED CONSENT OF THE PATIENT [WRITTEN CONSENT REQUIRED]:
The pharmacist shall obtain written informed consent from the patient upon first meeting with that patient. A record of provision of care by a pharmacist shall be maintained in the patient's pharmacy record, which is available to the pharmacist.
-OR-
INFORMED CONSENT OF THE PATIENT [WRITTEN CONSENT NOT REQUIRED]:
At the start of care provided by the pharmacist, each new patient will be provided with an explanation of the collaborative relationship between the pharmacist and the collaborating prescriber. Patients will be informed of their right to opt out of care.

H. Documentation

Several states have specific laws and regulations pertaining to the documentation of care delivered under a CPA (see Table 3 in Appendix A for more information). Regardless of whether it is required by law, thorough documentation of clinical activities is considered standard practice. Clinical documentation is a relatively new concept for the community pharmacy setting, however, especially beyond formal medication therapy management services. Documentation can be performed using electronic software systems or in a paper chart, although some states require that services provided pursuant to a CPA be documented in an electronic health record. It is sometimes required that the collaborating prescriber and pharmacist both have access to the patients' medical records. Documentation can be done in the traditional subjective, objective, assessment, plan (SOAP note) method or using forms that are more tailored to the specific service(s) the pharmacist is providing.[31]

It can be beneficial to include specifications on documentation and the maintenance of records in the CPA. Some states may require it and even have a minimum duration for retaining records.[32] Table 3 in Appendix A lists state requirements for documentation and the maintenance of records associated with CPAs. Because provisions related to documentation are often complex, those interested in a CPA should refer to the actual legal language in their state to be sure that they are in compliance with the requirements.

DOCUMENTATION [SIMPLE]:
The pharmacist(s) shall document each continuation or modification of an authorization for therapy in the patient's pharmacy record.
-OR-
DOCUMENTATION [NO SHARED ACCESS TO AN ELECTRONIC RECORD]:
The pharmacist will complete a progress note for each patient encounter. For each visit, the pharmacist will record subjective/objective information, the assessment, and the plan. Following each visit, the pharmacist will communicate (e.g., fax) the visit note to the referring provider.
-OR-
DOCUMENTATION [SHARED ACCESS TO AN ELECTRONIC RECORD]:
The pharmacist shall document each scheduled visit with the patient in the patient's medical record. The documentation contained in the medical record shall include medical and medication history, assessment, recommendations, monitoring, educational interventions, and documentation of decisions made, including medications initiated, modified, or discontinued.
-OR-
DOCUMENTATION [SHARED ACCESS TO AN ELECTRONIC RECORD; PRESCRIBER REVIEW REQUIRED]:
The pharmacist shall document each scheduled visit with the patient in the patient's medical record. The documentation contained in the medical record shall include medical and medication history, assessment, recommendations, monitoring, educational interventions, and documentation of decisions made, including medications initiated, modified, or discontinued. The collaborating prescriber will review and cosign all notes in the patient chart and provide feedback to the pharmacist on a regular basis.

I. Communication

As discussed earlier, communication among providers can be helpful for building trust, and it is essential for providing high-quality care. Without efficient and consistent communications, care can become fragmented, duplicative, ineffective, or even harmful.[24] Communication can occur through a variety of media, such as mutually accessed patient records, telephonic and live conversations, email, and text messages or instant messaging.[24] Expectations for the methods used, their frequency, and the timing of communications can be discussed among providers and, when appropriate, outlined in the CPA. When initiating work under a CPA, there may need to be more collaboration on individual clinical decisions and, therefore, more regular communications. Once both parties are comfortable with the care plan and each other's communication needs, the communication procedures outlined in the CPA could be reexamined.

Some states do have specific requirements for communications between providers (see Table 3 in Appendix A and relevant state laws and regulations, as these provisions can be complex).

COMMUNICATION:
The pharmacist shall provide the patient's original prescriber with notification in the form of a fax or secure email when her/his patient's therapy is continued or there is a therapeutic interchange pursuant to this agreement. In this notification, the pharmacist will include any relevant information that was collected from the patient, such as current blood pressure, adherence issues, or any socioeconomic challenges identified.

The pharmacist shall report any new patient complaints and/or deterioration in the patient's condition to the patient's primary care provider and/or other provider/prescriber immediately after learning of the new condition or as soon as possible thereafter.

J. Quality Assurance [and/or Quality Measurement]

Although a specific plan for quality assurance is not required in most states, it may be best to implement a program for continuous quality improvement.

A few states specifically require that a section on quality assurance be included in the CPA (see Table 3 in Appendix A).

Additionally, practitioners may consider collecting and analyzing data related to outcomes. This information can be used to assess the effectiveness of interactions, to market services in the future, and to demonstrate value to payers, patients, and potential collaborating prescribers. It may be helpful to consider a variety of outcome measures, including those that are economic (e.g., reduction in overall health costs), clinical (e.g., adherence measures, reduction in blood pressure), and personal (e.g., patient satisfaction, quality of life). More information about quality measurements related to pharmacy and to health care in general can be found on the Pharmacy Quality Alliance website and the Agency for Healthcare Research and Quality website.

QUALITY ASSURANCE [MORE GENERAL LANGUAGE]:

Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high-quality patient care. Annual evaluation of pharmacist(s) may include clinical outcomes, number of patients treated, and surveys of patient and provider satisfaction, as appropriate.

-OR-

QUALITY ASSURANCE [MORE SPECIFIC LANGUAGE]:

Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high-quality patient care. For each visit with the patient, parties to this agreement will collect and share information, including the patient's blood pressure, recent hospital admissions, and days missed from work or school. Outcomes will be analyzed and discussed among the parties to the agreement at least once per year.

K. Review of the Agreement and Maximum Period of Validity

About half of the states have set a maximum length of time that agreements are valid — typically 1 to 2 years. Even in those states where it is not required, the parties to the agreement may find it beneficial to discuss and agree upon a period for review and renewal of the agreement.

Those interested in creating a CPA should review Table 3 in Appendix A for their state's requirements.

REVIEW OF THE AGREEMENT AND MAXIMUM PERIOD OF VALIDITY:

This agreement shall be valid for a period not to exceed 2 years from the effective date. However, it may be reviewed and revised at any time at the request of any signatories.

L. Retention of Records

Some states have provisions regarding how long and in what manner patient records should be maintained (see Table 3 in Appendix A). In addition to any state requirements, pharmacists should know that if any insurer contracts are in place, these contracts may include separate requirements for maintenance of records. Record retention methods should be compliant with federal laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA), state laws and regulations, and any payer contracts in place.

RETENTION OF RECORDS:

Each signatory to this agreement shall keep a signed copy, written or electronic, of this agreement on file at his/her primary place of practice. A record of each therapeutic interchange made for a specific patient shall be maintained in the patient's pharmacy record.

M. Rescindment or Amendment of Agreement

It may be beneficial to have a method for providers to withdraw their participation in the agreement and a procedure for altering the terms of that agreement.

RESCINDMENT OR AMENDMENT OF AGREEMENT:

A signatory may rescind this agreement or a patient may withdraw from treatment under this agreement at any time. Prescribers may override this agreement whenever they deem such action necessary or appropriate for a specific patient without affecting the agreement relative to other patients.

N. References

If any clinical guidelines are referred to within the text of the agreement, it may be advisable to include the sources so that providers can quickly reference them and ensure that the most up-to-date resources are being used.

O. Signatures of the Parties to the Agreement

The providers or designees of organizations (e.g., medical directors) who are listed as parties to the agreement must sign the agreement in this section. Note that there are some states that also require the patient(s) to sign the agreement. Because this requirement can make implementation of the agreement challenging in the community setting, providers may want to work together to create a procedure that allows for compliance with this requirement.

The parties should see Table 3 in Appendix A for their state's requirements regarding patient signatures on the CPA.

Facilitating the Use of CPAs: Other Considerations

While writing the agreement is the key step for entering into a CPA, other logistical steps may be considered. The list below outlines several of these steps, although there may be others, depending on the circumstances.

Registering With State Agencies

Some states require registration with the board of pharmacy or a similar body for the pharmacist to qualify for participation in a CPA. Others require that the CPA be submitted to or approved by such a body. Those interested in developing a CPA should see Table 3 in Appendix A for their state's requirements.

Data Sharing and Business Associate's Agreements

Per HIPAA, protected health information can be shared with a health care provider for treatment of an individual patient. Covered entities include health plans, health care clearinghouses, and certain health care providers.[33]

According to the U.S. Department of Health & Human Services, "The Privacy Rule does not require you to obtain a signed consent form before sharing information for treatment purposes. Health care providers can freely share information for treatment purposes without a signed patient authorization."[34] However, if patient health information is used by or is accessible to an organization that is not a covered entity, such as legal counsel or a firm of certified public accountants, a business associate agreement may already be in place. Sample business associate agreements are available from the U.S. Department of Health & Human Services.[35]

Sustainability of Pharmacists' Patient Care Services

The focus of this resource guide is to help pharmacists establish CPAs to facilitate the treatment and management of chronic conditions. For any services to be incorporated into a pharmacist's practice, it also can be beneficial to have a viable business model in place, regardless of whether there is a CPA. Appendix B of this resource guide provides an introduction to the topic as well as recommendations for other resources that are available.

Pharmacist's National Provider Identifier Number

If the pharmacist is the provider listed on a prescription, his or her National Provider Identifier (NPI) number may need to be updated to reflect the appropriate taxonomy code. Pharmacists should consult Appendix C for information on why and how to update their NPI number.

Conclusion

CPAs offer a unique opportunity for pharmacists and prescribers to collaborate in a formal way. Such collaboration increases the efficiency of team-based care in the treatment and management of chronic conditions, including CVD and hypertension. This resource guide provides pharmacists with information and resources to empower them to initiate CPAs with collaborating prescribers. Although the target audience is community pharmacists, CPAs can be used in all pharmacy practice settings, such as long-term care facilities, primary care offices or clinics, specialty clinics, and general and specialty hospitals. Each of these practice settings has its own nuances, challenges, and opportunities.

CVD and hypertension were used in this resource guide as examples of disease states that can be managed using a CPA, but the concepts presented here can be applied to many other chronic conditions, treatments for acute illness, and preventive health measures as well.

No two collaborative relationships look exactly the same, and the development process will vary.[28] The information in this resource guide is intended to provide ideas and spur innovation, but it is not intended to be rigid steps in a process. Pharmacists attempting to initiate collaborative relationships should have patience and be flexible. Both the collaborative relationship and the CPA are likely to change over time. By keeping patients and a continuous improvement in their outcomes the central goal of therapy, it is clear that collaborative care delivery, facilitated by CPAs, can result in improved health, efficiency, and patient and provider satisfaction.[28]

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Appendix A: Collaborative Practice Agreement Authority Tables

Table 1: Participants

State	Site restrictions	Pharmacist qualifications	Multiple or single pharmacist(s)	Which prescribers (MD, NP, PA?)	Multiple or single prescriber(s)?	Multiple or single patient(s)?	Prescriber–Patient Relationship defined?
AK	Silent	Yes - H	Multiple	All prescribers	Multiple	Multiple - T	Silent
AL	CPAs not allowed under state law.						
AZ	Silent	Silent	Single	Physician + NP	Single	Single	Yes - LL
AR	Silent	Silent	Single	All prescribers - U	Single	Single - HH	Silent
CA	Silent	Yes - I	Single	All prescribers - V	Single	Single	Yes - MM
CO	Yes - A	Yes - I	Multiple	Physician + NP	Multiple	Multiple	Yes - NN
CT	Silent	Yes - J	Multiple	Physician	Multiple	Single - II	Yes - OO
DC	Silent – E3	Silent – E3	Single – E3	Physician, others – E3, F3	Single	Silent – E3	Silent – E3
DE	CPAs not allowed under state law.						
FL	Silent	Silent	Multiple	Physician	Single	Single	Yes - PP
GA	Silent	Yes - K	Single	Physician	Single	Multiple - T, JJ	Yes - QQ
HI	Silent	Silent	Multiple	Physician	Single	Single	Yes - RR
ID	Silent	Silent	Multiple	All prescribers	Multiple	Multiple	Silent
IL	Silent	Silent	Multiple	Physician	Single	Multiple	Silent
IN	Yes - A	Yes - L	Multiple	Physician, others - W	Multiple	Multiple	Yes - RR
IA	Yes - A	Yes - M	Multiple - S	Physician	Multiple	Single	Yes - MM
KS	Silent	Silent	Multiple	Physician	Multiple	Single	Yes - SS
KY	Silent	Silent	Multiple - T	All prescribers - X	Multiple	Multiple - T	Yes - TT
LA	Yes - B	Yes - N	Single	Physician	Single	Single	Yes - UU
ME	No - C	Yes - I	Multiple	All prescribers - Y	Single	Multiple - T	Yes - QQ
MD	Silent	Yes - I	Multiple - GG	Physician, others - Z	Multiple - GG	Single	Yes - VV
MA	Yes - A	Yes - J, O	Single	Physician - C3	Single	Single	Yes - WW
MI	Silent	Silent	Multiple	Physician	Single	Silent	Silent
MN	Silent	Silent	Multiple	Physician, others - AA	Multiple	Silent	Silent
MS	Silent	Yes - I	Multiple	All prescribers - BB	Multiple	Single - KK	Silent
MO	Yes - A, B	Yes - I	Multiple	Physician	Multiple	Single	Yes - QQ
MT	Yes - B	Silent	Multiple	Medical practitioner - CC	Multiple	Silent	Silent
NE	Silent	Silent	Single	Medical practitioner	Single	Silent	Silent
NV	No - D	Silent	Single	All prescribers	Single	Single	Silent
NH	Yes - E	Yes - J, O, P	Single	All prescribers	Single	Single	Yes - OO
NJ	Silent	Yes - I	Multiple - T	Physician	Multiple - T	Single	Yes - MM
NM	Silent	Yes - I	Multiple	Physician	Multiple	Multiple	Silent
NY	Yes - F	Yes - I	Single	Physician	Single	Single	Yes - MM
NC	Silent	Yes - I	Single - A3	Physician - DD, A3	Single	Single	Yes - XX
ND	Silent	Yes - M	Multiple - S, B3	Physician + NP - A3	Multiple - S	Silent	Silent
OH	Silent	Yes - D3	Multiple	Physician	Multiple	Multiple	Yes - SS
OK	Silent	Silent	Silent	Physicians	Silent	Silent	Silent
OR	Silent	Yes - Q	Multiple - S	Physician - EE	Multiple - S	Single	Silent
PA	Silent	Silent	Single	Physician	Single	Multiple	Yes - TT
RI	No - C	Yes - I	Single	All prescribers	Multiple	Single	Silent
SC	Silent	Silent	Silent	All prescribers	Multiple	Silent	Silent
SD	Silent	Silent	Silent	All prescribers	Single	Silent	Silent
TN	Silent	Silent	Multiple	All prescribers - C3	Multiple	Multiple	Silent
TX	Yes - E	Yes - R	Single	Physician	Single	Single	Yes - YY
UT	Silent	Silent	Multiple	All prescribers	Multiple	Multiple	Silent

State	Site restrictions	Pharmacist qualifications	Multiple or single pharmacist(s)	Which prescribers (MD, NP, PA?)	Multiple or single prescriber(s)?	Multiple or single patient(s)?	Prescriber–Patient Relationship defined?
VT	Silent	Silent	Single	All prescribers	Multiple	Multiple	Silent
VA	Yes - G	Silent	Multiple - S	All prescribers - FF	Multiple	Multiple - ZZ	Yes - TT, ZZ
WA	Silent	Silent	Multiple	All prescribers	Single	Multiple	Silent
WV	Yes - A	Yes - I	Multiple	Physician	Multiple	Single	Silent
WI	Silent	Silent	Multiple	Physician	Multiple	Silent	Silent
WY	Silent	Silent	Multiple	All prescribers	Multiple	Single	Yes - TT, XX

Key for Table 1: Participants

A	Allowed in most or all settings but with different rules for some
B	Physician must be nearby the collaborating pharmacist - see law/regulations for more details
C	Site must be specifically identified in the agreement
D	Nearly all locations allowed
E	Not allowed in community pharmacy settings
F	Limited to teaching hospitals
G	If multiple pharmacists are included in an agreement, all must be at a single physical location where patients receive services
H	Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol
I	Complicated requirements - see state law/regulations for details
J	Nearly all pharmacists would qualify - see state law/regulations for details
K	Application to board of pharmacy, additional continuing education, and a fee required - see state law/regulations for details
L	Physician responsible for ensuring pharmacist is properly trained to administer the protocol
M	Nearly all pharmacists would qualify, extra requirements for non-PharmD
N	Must register with the board and renew annually
O	Additional logistical requirements - see law/regulations for details
P	Must register with the board
Q	As specified in the agreement
R	Additional continuing education required
S	All must work within the same practice
T	All must be listed on the agreement
U	Practitioner authorized to prescribe drugs and responsible for the delegation of disease state management
V	Patient's treating prescriber
W	Physician, nurse practitioner, physician assistant
X	Medical/osteopathic physicians, dentists, chiropodists, veterinarians, optometrists when administering or prescribing pharmaceutical agents, advanced practice registered nurses, physician assistants when administering or prescribing pharmaceutical agents, and other health care professionals who are residents of and actively practicing in a state other than Kentucky and who are licensed and have prescriptive authority under the professional licensing laws of another state
Y	Any individual who is licensed, registered, or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice
Z	Licensed physician, licensed podiatrist, or certified advanced practice nurse with prescriptive authority
AA	Dentist, optometrists, physicians, podiatrists, veterinarians, nurse practitioners, physician assistants
BB	Physician, dentist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs
CC	Any person licensed by the state of Montana to engage in the practice of medicine, dentistry, osteopathy, podiatry, optometry, or a nursing specialty
DD	Must be approved by the board - see law/regulations for details
EE	Physician or group of physicians
FF	Any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in §32.1-276.3 (Virginia Law), provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working as part of a patient care team as defined in § 54.1-2900 (Virginia Law), involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners
GG	One plus a designated alternate
HH	A standard protocol may be used, or the attending practitioner may develop a disease state management protocol for the individual patient
II	Multiple patients under one agreement; protocol is patient specific
JJ	Multiple but each patient's diagnoses and current medication list must be listed in agreement
KK	Single in community setting, multiple in institutional setting
LL	Collaborating prescriber must be acting as a primary care provider
MM	Individual patient's treating prescriber
NN	All physicians who are actively involved in the management of the relevant conditions shall be parties to the agreement
OO	Physician-patient relationship narrowly defined - see law/regulations for details
PP	Individualized assessment
QQ	Patient specific information must be included in the protocol/agreement - see laws/regulations for details
RR	Agreement must be related to the condition(s) for which the patient has been seen by the collaborating prescriber/physician
SS	Established "physician-patient relationship"
TT	Referral from collaborating prescriber required
UU	Patient/ drug/disease or condition specific order set prepared by the physician must be based on a face-to-face visit with the patient
VV	Directly involved in patient care
WW	Referral required, must include a diagnosis from the supervising physician
XX	Diagnosis and initial drug therapy must be prescribed
YY	The delegation must follow a diagnosis, initial patient assessment, and drug therapy order by the physician. The physician must have an established a physician-patient relationship with each patient who is provided drug therapy management by a delegated pharmacist. Physician-patient relationship must be maintained.
ZZ	Pharmacist may only implement drug therapy post diagnosis by the prescriber
A3	Limited to one physician to three pharmacists
B3	A pharmacist may have an agreement with one or more physicians, the number of which may be limited by the board based on individual circumstances
C3	Pharmacies can't hire physicians to maintain CPAs
D3	Training and experience related to the particular diagnosis for which drug therapy is prescribed
E3	For immunization or vaccination written protocols: multiple pharmacists may participate, pharmacists must be board certified and meet continuing education requirements; a written immunization or vaccination protocol may apply to individual or groups of patients; some setting limitations apply; patient informed consent required. Board of pharmacy and board of medicine are required to issue regulations jointly governing the implementation and use of CPAs between a pharmacist and physician; however, as of 11/2016, no new rules have been promulgated.
F3	Additional licensed health practitioners with independent prescriptive authority may participate in CPAs if authorized by rule (none authorized as of 11/2016)

Table 2: Functions Authorized

State	Modify Existing Therapy	Initiate New Therapy	Perform a Physical Assessment	Order Laboratory Tests	Interpret Laboratory Tests	Perform Laboratory Tests
AK	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
AL	CPAs not allowed under state law.					
AZ	Yes - W, AA	Yes - A, W, AA	Silent	Yes	Silent	Silent
AR	Yes - V, AA	Yes - A, V, AA	Silent	Silent	Silent	Silent
CA	Yes - Z	Yes - A, Z	Yes	Yes	Yes	Silent
CO	Yes - A, V, AA	Yes - A, M, V, AA	Yes - G	Yes - I, M	Yes - I, M	Silent
CT	Yes - B, W, AA	Yes - W, AA	Silent	Yes	Silent	Silent
DC	Yes - DD	Yes - DD	Silent	Silent	Silent	Silent
DE	CPAs not allowed under state law.					
FL	No	No - GG	Silent	Yes	Yes	Silent
GA	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
HI	Yes	Yes	Yes - H	Yes	Silent	Silent
ID	Yes - AA	Yes - AA	Yes - I	Silent	Silent	Yes
IL	Yes - A	Yes - A	Silent	Yes - I	Yes - I	Silent
IN	Yes	Yes	Silent	Silent	Silent	Silent
IA	Yes - BB	Yes - BB	Yes	Yes	Yes	Yes
KS	Silent	Silent	Silent	Silent	Silent	Silent
KY	Yes - AA	Yes - AA	Silent	Yes	Silent	Silent
LA	Yes - C, W, CC	No	Yes	Yes	Yes - P	Silent
ME	Yes - D, V, AA	Yes - D, V, AA	Yes	Yes	Yes - P, Q	Silent
MD	Yes - A, V, AA	Silent	Yes - J	Yes - I	Yes, I	Silent
MA	Yes - X, FF	Yes - X, FF	Yes - G	Yes - N	Yes - P	Silent
MI	Yes	Yes	Silent	Silent	Silent	Silent
MN	Yes	Yes	Silent	Silent	Silent	Yes
MS	Yes - AA	Yes - AA	Silent	Yes	Silent	Silent
MO	Yes - E, W, CC	Yes - E, W, CC	Yes	Yes	Yes	Yes
MT	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
NE	Yes - W	Yes - W	Silent	Silent	Silent	Silent
NV	Yes - AA	Yes - AA	Yes - K	Yes	Yes	Silent
NH	Yes - W, AA	Yes - W, AA	Silent	Yes	Silent	Silent
NJ	Yes - W, AA	No	Silent	Yes	Yes - Q	Yes
NM	Yes - W, AA	Yes - W, AA	Silent	Yes - I	Yes	Silent
NY	Yes - F, W, AA	No - F	Yes - I	Yes	Yes - R	Silent
NC	Yes - U, AA	Yes - U, AA	Silent	Yes - I	Silent	Silent
ND	Yes - BB	Yes - BB	Silent	Silent	Silent	Silent
OH	Yes - W	Yes - W	Silent	Yes	Yes - P	Silent
OK	No	No - EE	Silent	Silent	Silent	Silent
OR	Yes - W, AA	Yes - W, AA	Silent	Yes - I	Yes - I	Silent
PA	Yes - AA	No	Yes	Yes	Silent	Yes
RI	Yes - W, AA	No	Yes - G	Yes	Yes - R	Yes
SC	Yes - DD	Yes - DD	Silent	Silent	Silent	Silent
SD	Yes	Yes	Silent	Silent	Silent	Silent
TN	Yes	Yes	Yes	No	Silent	Silent
TX	Yes - W, AA	Yes - A, W, AA	Yes - H	Yes	Silent	Silent
UT	Yes	Yes	Yes - G	Yes	Yes - S	Silent

State	Modify Existing Therapy	Initiate New Therapy	Perform a Physical Assessment	Order Laboratory Tests	Interpret Laboratory Tests	Perform Laboratory Tests
VT	Yes - W, AA	Yes - W, AA	Yes	Yes - I	Yes - I	Silent
VA	Yes - Y, AA	Yes - Y, AA	Silent	Yes	Silent	Silent
WA	Yes - W, AA	Yes - A, W, AA	Yes - G	Yes	Yes - R	Silent
WV	Yes - CC	No	Yes - L	Yes - O	Yes - T	Yes
WI	Yes	Yes	Silent	Silent	Silent	Silent
WY	Yes - W, AA	Yes - A, W, AA	Yes	Yes	Silent	Yes

Key for Table 2: Functions Authorized

A	Drugs limited to those in the protocol
B	Notify physician within 24 hours if therapy is discontinued
C	Therapeutic substitution not allowed without the physicians explicit consent
D	First 3 months limited to monitoring
E	State specific rules regarding initiation and modification of a prescription - refer to state laws/regulations for details
F	Therapeutic substitution allowed but not initiation of new therapy
G	Obtaining and checking vital signs
H	Ordering or performing routine drug therapy–related patient assessment procedures
I	As specified in the agreement/protocol
J	Other patient care management measures related to monitoring or improving the outcomes of drug or device therapy
K	Examinations
L	The protocol may authorize the pharmacist to check only these findings: vital signs, oximetry, or peak flows that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred to the patient's physician for follow-up. Pharmacists shall not conduct any physical examination of the patient other than taking vital signs.
M	Protocol requirements outlined in the regulations are very prescriptive - see Colorado regulations before initiating a CPA
N	Under the supervision of, or in direct consultation with, a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation shall not include a diagnostic component
O	Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician
P	Evaluate but not to be used for diagnosis
Q	In direct consultation with the physician
R	Evaluate
S	Ordering and evaluating the results of laboratory tests directly applicable to the drug therapy, when performed in accordance with approved protocols applicable to the practice setting
T	Laboratories utilized by the pharmacist may be in a pharmacy or pharmacy center. All laboratory results obtained are to be sent to the physician within 48 hours, except that any severely abnormal or critical values shall be sent by the pharmacist to the physician immediately.
U	Agreement is disease specific
V	Disease states limited to those defined in agreement for each individual patient
W	Disease states limited to those specified in protocol or agreement
X	Disease states limited to those specified in the protocol or agreement; restrictions for community pharmacists only
Y	Diseases states limited to those with a defined standard of care required or the protocol must be approved by the board of pharmacy
Z	Restricted to conditions for which the patient has first been seen by a physician
AA	Medications limited to those specified in agreement or protocol
BB	Does not include CIIs
CC	Does not include any controlled substances
DD	Medications limited to those specified in the therapeutic plan
EE	Limited to administering immunizations and therapeutic injections
FF	Restrictions for community pharmacists only
GG	Therapy initiation is limited to a defined list of drugs but does not require a collaborative agreement

Table 3: Requirements

State	Additional continuing education requirements	Requirement for liability insurance?	Documentation and/or notification requirements	Patient involvement in agreement – signature or opt out?	Must agreements be sent to or approved by a state agency?	Length of time agreement is valid defined?
AK	Silent	Silent	Yes - I, O, AA	Silent	Yes - WW	Yes - ZZ
AL	CPAs not allowed under state law.					
AZ	Silent	Silent	Yes - Z	Silent	Silent	Silent
AR	Silent	Silent	Yes - O, P, Q, Z	Silent	Yes - UU	Yes - YY
CA	Silent	Silent	Yes - R, S	Silent	Silent	Silent
CO	Silent	Yes - L	Yes - T, U, Y	Yes - QQ	Yes - UU	Yes - YY
CT	No - A	Silent	Yes - V, W, X	Silent	Yes - UU	Silent
DC	Silent - E3	Silent	Yes - E3	Silent - E3	Silent - E3	Silent - E3
DE	CPAs not allowed under state law.					
FL	Silent	Silent	Yes - BB, Z	Silent	Silent	Silent
GA	Yes - B	Silent	Yes - H, Z, CC	Yes - RR	Silent	Yes - ZZ
HI	Silent	Silent	Yes - R	Silent	Silent	Silent
ID	Silent	Silent	Yes - S, Z	Silent	Yes - UU	Yes - YY
IL	Silent	Silent	Silent	Silent	Silent	Silent
IN	Silent	Silent	Yes - S, DD	Silent	Silent	Yes - YY
IA	Silent	Silent	Yes - I	Yes - SS	Yes - UU	Yes - ZZ
KS	Silent	Silent	Silent	Silent	Silent	Silent
KY	Silent	Silent	Yes - H, EE	Yes - SS	Yes - UU	Silent
LA	Silent	Silent	Yes - H	Yes - SS	Yes - UU	Yes - YY
ME	Yes - C	Yes - M	Yes	Silent	Yes - VV	Yes - I
MD	Silent - D3	Silent - D3	Yes – H, D3	Yes – SS, D3	Yes – VV, D3	Yes – YY, D3
MA	Yes - D	Yes - L	Yes - H	Yes - TT	Yes - UU	Yes - ZZ
MI	Silent	Silent	Silent	Silent	Silent	Silent
MN	Silent	Silent	Yes - FF	Silent	Silent	Silent
MS	Yes - E	Silent	Yes - I	Yes - RR	Yes - WW	Yes - YY
MO	Yes - F	Silent	Yes - H	Silent	Yes - VV	Yes - YY
MT	Silent	Silent	Yes - I, Y	Yes - SS	Yes - VV	Yes - YY
NE	Silent	Silent	Silent	Silent	Yes - VV	Yes - YY
NV	Silent	Silent	Yes - Z, GG	Silent	Yes - WW	Silent
NH	Yes - G	Yes - L	Yes - I, HH	Yes - SS	Yes - UU	Yes - ZZ
NJ	Yes - H	Silent	Yes - I, Y	Yes - TT	Yes - UU	Yes - YY
NM	Yes - H	Silent	Yes - I	Silent	Yes - VV	Yes - ZZ
NY	Silent	Silent	Yes - I, II	Yes - SS	Silent	Silent
NC	Yes - H	Silent	Yes - NN	Yes - RR	Yes - UU	Silent
ND	Silent	Silent	Yes - JJ, E3	Silent	Yes - WW	Yes - A3
OH	Silent	Silent	Yes - B3, F3	Yes - SS	Yes - UU	Yes - ZZ
OK	Silent	Silent	Silent	Silent	Yes - UU	Silent
OR	Yes - I	Silent	Yes - I	Silent	Yes - UU	Yes - ZZ
PA	Silent	Yes - L	Yes - I, KK, C3	Yes - RR	Yes - VV	Yes - ZZ
RI	Yes - J	Yes - M	Yes - I	Yes - TT	Yes - VV	Yes - ZZ
SC	Silent	Silent	Silent	Silent	Silent	Silent
SD	Silent	Silent	Silent	Silent	Yes - WW	Silent
TN	Silent	Silent	Yes - S, KK	Silent	Check	Yes - ZZ
TX	Yes - K	Silent	Yes - I, X, LL	Silent	Yes - VV	Yes - YY
UT	Silent	Silent	Silent	Silent	Silent	Silent
VT	Silent	Silent	Yes - OO	Silent	Silent	Yes - YY

State	Additional continuing education requirements	Requirement for liability insurance?	Documentation and/or notification requirements	Patient involvement in agreement – signature or opt out?	Must agreements be sent to or approved by a state agency?	Length of time agreement is valid defined?
VA	Silent	Silent	Yes - I	Yes - TT	Yes - XX	Silent
WA	Silent	Silent	Yes - I	Silent	Yes - VV	Yes - ZZ
WV	Silent	Yes - N	Yes - I, V, W, MM, PP	Yes - TT	Yes - WW	Yes - ZZ
WI	Silent	Silent	Silent	Silent	Silent	Silent
WY	Silent	Silent	Yes - I, O	Yes - SS	Yes - WW	Yes - YY

Key for Table 3: Requirements

A	Continuing education is mentioned in CPA language but the requirements are the same as for licensure
B	Annual completion of 0.3 CEUs regarding modification of drug therapy
C	Fifteen hours per year: 2 hours in drug administration, 5 hours in the areas of practice covered by agreement
D	Five additional contact hours of continuing education that addresses areas of practice generally related to collaborative practice agreements
E	Biennial basis: obtain recertification in each disease state by completing a continuing education program consisting of not less than 6 hours focusing on nationally recognized updates
F	Biennial recertification required (6 hours of continuing education in medication therapy management)
G	Complete at least 5 contact hours or 0.5 CEUs of board-approved continuing education each year; such continuing education shall address the area or areas of practice generally related to the collaborative pharmacy practice agreement or agreements
H	Complicated requirements - see law/regulations for details
I	As specified in the agreement
J	Five hours of continuing education each year that must be in the practice area covered by the agreement; documentation must be maintained and available for inspection at the practice site
K	Six hours of continuing education related to drug therapy
L	At least $1,000,000 of professional liability insurance
M	Agreement must include proof that liability insurance is maintained by all parties to the agreement
N	Personally have or have employer coverage of at least $1,000,000 of professional liability insurance coverage
O	Documentation/patient records maintained for 2 years
P	Documentation recorded within a reasonable time of each intervention
Q	Documentation may be on the patient medication record, patient medical chart, or in a separate logbook
R	Written notification to patient's treating prescriber or entry into electronic patient record shared by the prescriber of any drug initiation within 24 hours
S	Medical records of the patient must be available to both the patient's treating prescriber and the pharmacist
T	Notification to the physician within 24 hours of modification of therapy
U	Physician must review and document acceptance or rejection of the drug therapy modification within 72 hours
V	All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record
W	The pharmacist shall report at least every 30 days to the physician regarding the patient's drug therapy management
X	Protocol must include a plan for periodic review, feedback, and quality assurance
Y	Records maintained for 7 years
Z	Physician notification/review as specified in agreement
AA	Physician review of pharmacist's decisions at least every 3 months
BB	Transferrable patient record for orders and progress notes
CC	Patient records maintained for 10 years after protocol is terminated
DD	Document in patient record immediately after making a change to drug therapy
EE	Records maintained for 5 years
FF	Document change of therapy in medical record or report to patient's provider
GG	Specific requirements for protocols developed for use in care transitions - see laws/regulations for details
HH	All agreements must include provisions for documentation of any initiation, modification, or discontinuation of a patient's medications in the patient's permanent medical record; community pharmacists must maintain a written record of the individual patient referral and the patients' written informed consent
II	Must immediately enter into the patient record any change or changes made to the patient's drug therapy and notify the physician (and the patient's other physicians)
JJ	The practitioner and the pharmacist must have access to the patient's appropriate medical records; the care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the practitioner
KK	Document as soon as possible, no longer than 72 hours after a change is made, as specified in the agreement
LL	The delegating physician must receive, as appropriate, a periodic status report on each patient, including any problem or complication encountered as defined in the protocol. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book.
MM	Notify the treating physician of any discontinuation of drug therapy
NN	Agreement must include a plan and schedule for weekly quality control, review and countersignature of all orders written by the CPP in a face-to-face conference between the physician and CPP
OO	Annual quality assurance review by the collaborating practitioner
PP	All evaluation notes shall be in the physician's patient's chart within 1 week of the evaluation and drug management change
QQ	Patients must be informed of their right to refuse care under the agreement; patient's signature on the institution's general consent may be used
RR	Patient notification required
SS	Written consent required
TT	Informed consent required
UU	Maintained and available upon request
VV	Copy of agreement must be submitted to the relevant board(s)
WW	Agreement must be reported to and approved by the relevant board(s)
XX	Protocol only needs to be approved for conditions for which there is no accepted standard of care
YY	Agreement can only be valid for up to 1 year
ZZ	Agreement can only be valid for up to 2 years
A3	Agreement can only be valid for up to 4 years
B3	Records maintained for 3 years
C3	Records maintained in an electronic medical record
D3	Extensive requirements regarding components of the agreement - see regulations for details
E3	Pharmacist must notify the prescriber within 24 hours of initiating or modifying therapy; CPA may clarify some situations where notice within 72 hours is acceptable
F3	Communication must occur between providers on a regular basis - see laws/regulations for details

Appendix B: Sustainability of Pharmacists' Services Delivered Under Collaborative Practice Agreements

Sustainable business models are needed to support pharmacists' patient care services, including those services delivered under collaborative practice agreements (CPAs). While CPAs can be very helpful in providing expanded authority for pharmacists to provide care to patients, a viable business model is critical for supporting the time commitment of the pharmacist and the expertise that he or she brings as part of a health care team. CPAs can improve access to care as well as facilitate efficiencies in the delivery of coordinated team-based care and sufficient payment to sustain pharmacists' services over the long term.

If revenue sources are already available for the services that pharmacists will be delivering under a CPA, then development of the CPA may focus on the operational aspects of the agreement. If revenue sources are not available, the negotiation phase of the CPA can also include discussions about the business model for compensating the pharmacist. Focus areas to consider include potential sources of direct payment and the value-added benefits that the pharmacist can provide. This appendix covers three key areas: potential payment sources for pharmacists' services, development of a value proposition, and monitoring the return on investment.

Potential Payment Sources

The health care system is undergoing significant changes in payment models for health care. The long-standing fee-for-service (FFS) model is shifting toward value-based models that pay for services provided by health care providers based on the value of those services in meeting quality measures, improving outcomes, and containing costs. In addition, bundled payments to organizations to cover the medical management of a patient population are becoming more common. Many payment models are currently a mix of FFS and value-based incentives.

Traditional FFS Payment Opportunities for Pharmacists

- FFS is currently the predominant compensation mechanism for health care providers in the United States. Under this model, health care providers are reimbursed for the number and array of clinical services they provide, typically through the use of specific billing codes that correspond to the level and type of services provided.[1] Commercial, public, and private insurers, along with pharmacy benefits managers and managed care organizations, all have potential to be payers for pharmacists' services. FFS payment opportunities for pharmacists' patient care services have been sporadic to date, however. As of 2016, many payers view pharmacists as being eligible for compensation only for dispensing medications, not for the provision of collaborative patient care services.[2]

Among the list of services below that pharmacists can currently provide, direct payment opportunities are available only for medication therapy management (MTM) and, in some cases, training in diabetes self-management. The other listed services are Medicare Part B services, where physicians or other qualified providers bill for the pharmacist's service under specific billing requirements:

- MTM.
- Training in diabetes self-management.
- A service incident to physician services in a physician-based practice or hospital outpatient clinic.
- Transitional care management as part of a team-based bundled payment.
- Chronic care management.
- Annual wellness visit.[1]

Potential payers for pharmacists' patient care services include those described below:

- **Centers for Medicare & Medicaid Services (CMS) Part B**—Pharmacists' services are not currently recognized for payment through Medicare Part B (where outpatient health care professionals' services are covered). Under specific circumstances, physicians and qualified nonphysician practitioners (NPPs) can utilize their National Provider Identifier number to bill for pharmacists' services performed under the direct or general supervision of the physician or NPP (depending on the service). This process is often referred to as "incident to" billing, and the setting is either a physician-based practice or a hospital outpatient clinic.
    - Because specific requirements for this type of billing must be met, and the requirements vary by the service, it is extremely important to consult applicable resources. Pharmacists must be in an employed, contracted, or leased arrangement in order for the physician to bill for the pharmacist's services.[1]
    - For services requiring direct supervision, the physician or NPP must be present in the office suite or in the building and immediately available to the pharmacist. In contrast, under general supervision, the physician provides overall direction and control, but the physician's presence is not required. Community pharmacists under the general supervision of the physician or NPP could perform Medicare services with a general supervision requirement (e.g., chronic care management, transitional care management) in the pharmacy.
- **CMS Medicare Part D**—CMS contracts with Part D Prescription Drug Plans (PDPs) to provide MTM services for eligible beneficiaries. PDPs can then contract with pharmacies or pharmacists to provide MTM services. MTM service opportunities are variable but, where present, could be a revenue source to support the pharmacist working under a CPA with a prescriber. Pharmacists would bill directly for any MTM services provided to the patient.
- **State Medicaid programs**—Some state Medicaid programs provide payment to pharmacists for various services, which can include medication management, chronic condition management, and wellness services. There also may be opportunities in some state Medicaid programs for physicians to bill for pharmacists' services under an "incident to" arrangement. Pharmacists should check with state boards of pharmacy or state pharmacy associations to learn about available opportunities in a given state.

- **Commercial health plans and self-insured employers**—Commercial health plans may cover pharmacists' services delivered in an "incident to" arrangement with a prescriber. It will be helpful for pharmacists to become familiar with the requirements for specific plans because commercial health plans often follow CMS's guidelines but may have their own requirements. In addition, some commercial health plans are involved in pilot programs to pay pharmacists directly for certain services, such as diabetes management. Many state pharmacy associations are working to address payment barriers for pharmacists' services. For example, the state of Washington recently implemented a law that requires commercial health plans in that state to cover pharmacists' services if the service is within the pharmacist's scope of practice and that same service is covered for other health care practitioners. Self-insured employers are another potential source of payment for services such as the management of chronic conditions and wellness services. Pharmacists interested in these opportunities may benefit from networking to learn about available programs.

Funding Opportunities in New Models for Delivering Care

In new care delivery models, such as accountable care organizations and patient-centered medical homes, various health care practitioners are compensated for delivering quality, affordable, and coordinated care to patients under new payment models. In these models, the focus is on "pay for value" instead of the "pay for volume" approach in FFS. Pharmacists may be able to contract directly with an organization for specific services or integrate directly into the organization as salaried employees. This will depend on the nature of the care provided and the interest of the collaborating providers or insurers.[2]

New care delivery models may include a mix of FFS payment, incentive payments for meeting quality metrics and cost targets, and payments for managing and coordinating the care of populations of patients. The incentive payments may be provided through payments for nontraditional services, higher rates for contracted services, lump sum payments, additional per-member per-month payments, shared savings when expected expenditures are below actual costs, or other pay-for-performance incentives.[2]

Payment models are not mutually exclusive. For example, a pharmacist may be contracted by a medical group to provide patient care services 3 days per week. Each time the pharmacist conducts services that are currently paid under the fee-for-service model, the medical group bills the insurer to recover reimbursement for the provided service. If the pharmacist improves the outcomes of patients who are part of an integrated care model, the medical group will earn an incentive payment. The reimbursement received by the medical group may be used to offset the cost of the pharmacist or may be shared with the pharmacist as a bonus payment, depending on the terms of the contract.

Pharmacists who plan to seek payment within integrated care models will benefit from being prepared to document, monitor, and improve specific quality measures that drive incentive payments. Because many care delivery organizations receive capitated payments to cover a patient population, there is a greater focus on keeping the population healthy and achieving better health outcomes. Pharmacists may want to focus on understanding the organization's relevant quality measures and how pharmacists' services can improve specific metrics and increase savings.

Assessing Payer Mix

If the source of payment for pharmacists' services will come from the physician's practice, it will be helpful to understand the types of payers (the payer mix) in the practice in order to build a business model. For example, in a practice that has a payer mix of 60% Medicare, 30% commercial health plans, and 10% Medicaid, a pharmacist working in the practice might want to collaborate with the physician to deliver annual wellness visits (incident to physician services) and chronic care management services to the practice's Medicare beneficiaries. A pharmacist might collaborate to deliver chronic care management services and transitional care management while assisting the practice with meeting selected quality metrics. Payment opportunities available through Medicaid or commercial health plans could be considered as well. The pharmacist's contributions to meeting quality metrics could be covered through incentive payments.

Formulating the Value Proposition[3,4,5]

With an understanding of potential payment sources, pharmacists can begin building the business case for collaborating with physicians to deliver services under a CPA. The value proposition is composed of the most persuasive reasons why a physician should consider entering into a business agreement with the pharmacist to deliver services under a CPA. Value propositions can also be developed for approaching payers directly for coverage of pharmacists' services. Potential elements of the value proposition include the following:

- Specific patient care services that the pharmacist can provide.
- Unique benefits that the pharmacist can bring to the practice, such as assistance with meeting quality metrics, providing drug information, and assistance with meeting evidence-based guidelines.
- Revenue opportunities and potential ROI as well as other factors that help to justify the business case for making the decision.

The value proposition is often summarized in an executive summary of one or two pages that creates a compelling case to be used during negotiations. A pro forma that projects anticipated revenues for specific services over a specified timeline is a helpful addition to the executive summary.

Monitoring the Return on Investment (ROI)

A physician practice that is contemplating paying for the services of a pharmacist may be interested in the ROI, which is the ratio of the gains (revenue and other benefits) to the total costs of the collaborative services. An ROI greater than 1 indicates that the investment is beneficial, and the higher the ROI above 1, the better the investment.

ROI = Gains (revenues and other benefits)/Costs

Costs may include payment to the pharmacist, the physical space used by the pharmacist, health information technology, and staff to support the pharmacist. Gains, which can be more difficult to quantify, can include direct revenues from pharmacists' services, cost savings to the practice, and indirect benefits such as physician efficiencies, patient and physician satisfaction, and meeting quality metrics. Published studies, previously collected data, and case studies can be used to help estimate these components to provide the overall "gains" in the ROI calculation. Pharmacists can anticipate that it may take time to reach a positive ROI, and tracking mechanisms should be in place to track the ROI over time.

Appendix B: References

1. U.S. Department of Health & Human Services. Health information privacy: business associate contracts website. https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html. Accessed September 1, 2016.

2. Carrier E, Dowling MK, Pham HH. Care coordination agreements: barriers, facilitators, and lessons learned. *Am J Manag Care*. 2012;18(11):e398-e404.

3. Schumock GT, Butler MG, Meek PD, et al. Evidence of the economic benefit of clinical pharmacy services: 1996-2000. *Pharmacotherapy*. 2003;23(1):113-132.

4. Academy of Managed Care Pharmacy. Practice Advisory on Collaborative Drug Therapy Management. Alexandria, VA: Academy of Managed Care Pharmacy; 2012. http://www.amcp.org/workarea/downloadasset.aspx?id=14710. Accessed November 21, 2016.

5. Adams AJ, Klepser M, Klepser D. Physician-pharmacist collaborative practice agreements: a strategy to improve adherence to evidence-based guidelines. *Evidence-Based Med Public Health*. 2015;1:e923.

Appendix C: Updating a National Provider Identifier Number

If the pharmacist will be the signatory on prescriptions that are initiated or modified under a collaborative practice agreement, it may be beneficial for him or her to obtain an updated National Provider Identifier (NPI). The updated NPI number will indicate to pharmacy benefit managers that the pharmacist has an expanded scope of practice that may include authority to write prescriptions. Although updating the NPI number will not ensure coverage of prescriptions written with that NPI number, it may increase the likelihood that the pharmacy benefit manager identifies the pharmacist as a valid prescriber. Having an NPI is also important for billing.

The instructions below outline how to update an existing NPI number. If the pharmacist is applying for an NPI for the first time, he or she should follow the instructions found on the NPI website (https://nppes.cms.hhs.gov/NPPES/), taking note of the instructions below to select the correct provider taxonomy.

Step 1: Pharmacists should log into their NPI account at https://nppes.cms.hhs.gov/NPPES/. Note: Because passwords expire every 60 days, the pharmacist may need to go through the "lost password" process available on this page.

Step 2: Select view/modify NPI data.

Step 3: *Most important step*. Update taxonomy. The pharmacist can add multiple taxonomies and should choose the taxonomy code for the primary taxonomy that most appropriately fits his or her position. Pharmacists in the community setting who are participating in medication initiation and/or modification should consider the pharmacist clinician (PhC)/clinical pharmacy specialist as their primary taxonomy. Note: More information about the provider taxonomies is available at http://www.wpc-edi.com/reference/.

Step 4: Update other information (e.g., password, profile, mailing address, practice location).

Step 5: Complete the certification statement.

Step 6: Submit and log off.

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
CDC

Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

Request for Approval
of
Life Safety Training Program

(EMS Safety Services, Inc.)

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.*

EMS SAFETY
Teaching skills for life

Phone: (800) 215-9555 Fax: (949) 388-2776 Email: info@emssafety.com

Dear Louisiana Board of Pharmacy,

EMS Safety Services, Inc. is seeking approval of our CPR, AED and First Aid training curriculum, specifically our Basic Life Support, in hopes our certifications will be recognized by the Louisiana Board of Pharmacy.

EMS Safety is committed to providing the best in quality education for the healthcare provider, childcare provider, caregiver and general public. Our programs have been reviewed, approved or meet the guidelines for more than 200 federal, state and local organizations; private agencies; and regulatory bodies. To view a complete listing of our approvals, please visit http://www.emssafetyservices.com/training-programs/approvals/.

We provide emergency response instructors with compliant, cost-effective training programs at the Community Rescuer and Professional Rescuer levels. Our curriculum includes CPR and AED for adults, children and infants; First Aid; Bloodborne Pathogens Awareness; and Emergency Oxygen Administration.

I have attached information regarding our company and an overview of our BLS program. Thank you for your time and consideration. I look forward to speaking with you soon.

Warm Regards,

Krysten Winstead

Krysten Winstead
Regulatory Affairs Coordinator
(949) 325-9676
Kwinstead@emssafety.com

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EMS SAFETY
Teaching skills for life

Phone: (800) 215-9555 Fax: (949) 388-2776 Email: info@emssafety.com

May 15, 2017

To Whom It May Concern,

EMS Safety Services, Inc. is a nationally recognized training company in business since 1993. We provide emergency response instructors with compliant, cost-effective training programs at the Community Rescuer and Professional Rescuer levels. Our curriculum includes CPR and AED for adults, children and infants; First Aid; Bloodborne Pathogens Awareness; and Emergency Oxygen Administration. We also offer programs tailored for childcare providers and caregivers. Our programs have been reviewed, approved or meet the guidelines for more than 200 federal, state and local organizations; private agencies; and regulatory bodies.

Emergency care procedures are based on recommendations from the 2015 ILCOR International Consensus on CPR and ECC Science with Treatment Recommendations, as published by the American Heart Association and the International First Aid Science Advisory Board. Other resources include the National Highway and Traffic Safety Administration (NHTSA-DOT) First Responder Curriculum, National EMS Standards, and standards set forth by Federal OSHA.

Additionally, Dr. Samuel Stratton, medical director for the Orange County Health Care Agency's Emergency Medical Services division, chairs our Advisory Committee. Dr. Stratton serves as our medical director and is a practicing emergency room physician. This committee, comprised of professional rescuers, instructors and healthcare providers, ensures the accuracy of the information and the effectiveness of the instructional design.

EMS Safety also provides an array of products for businesses, emergency responders and individual instructors. We have multiple federal and state government contracts and are a corporate supplier. We provide competitive pricing on everything designed for responding to emergencies and for teaching first responders. These products include training manikins, AEDs, AED trainers, first aid supplies and disaster kits.

There are over 5,000 EMS Safety Instructors across the country who certify over 300,000 lay and professional rescuers each year. We are focused on customer service, cost-effective compliance and easy-to-use quality materials and products.

Thank you for inquiring about EMS Safety's products and services. Please contact me any time for more information.

Warm Regards,

Paul Lepore
Operations Director

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Phone: (800) 215-9555 Fax: (949) 388-2776 Email: info@emssafety.com

August, 2016

RE: EMS Safety Medical Direction and Equivalency

To Whom It May Concern:

The purpose of this letter is to inform you of my role as the physician Medical Director for EMS Safety Services. As Medical Director, I have reviewed and approved EMS Safety's emergency care training programs including CPR, First Aid, AED, Bloodborne Pathogens, and Emergency Oxygen Administration.

EMS Safety's emergency care procedures are based on guidelines from the 2015 ILCOR International Consensus on CPR and ECC Science with Treatment Recommendations and the ILCOR First Aid Task Force, as published by the American Heart Association. The courses are instructor-mediated and use video, lecture and hands-on practice to improve long term retention of critical skills. Skills proficiency is required for certification.

The CPR programs are consistent with the current standards of the American Heart Association for CPR, the use of an AED, rescue breathing, and foreign body airway obstruction as they pertain to the lay provider, healthcare provider and professional rescuer.

The First Aid programs are consistent with the programs offered by the American Red Cross.

EMS Safety lay provider and healthcare/professional rescuer programs also conform to the standards set forth by the Commission on Accreditation for Pre-Hospital Continuing Education, state EMS agencies, Federal OSHA, the National Highway Traffic Safety Administration, the Joint Commission and the United States Coast Guard.

I can be reached at approvals@emssafety.com if you have any questions.

Sincerely,

Dr. Samuel Stratton, MD
Medical Director
EMS Safety Services, Inc.

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EMS SAFETY
Teaching skills for life

Phone: (800) 215-9555 Fax: (949) 388-2776 Email: info@emssafety.com

Overview and Capabilities Statement

Company: EMS Safety Services, Inc.

Established: 1993

Mission: Teaching Skills for Life

Core Competency: CPR, AED and First Aid Training

- Nationally recognized, evidence-based guidelines
- Skills practice, written testing and skills testing required
- Instructor and student training
- Professional and workplace levels

Key Contacts:

- President and CEO: Marian Lepore, marian@emssafety.com
- Operations Director: Paul Lepore, PLepore@emssafety.com
- Programs and Product Manager: Geoff Albrecht, galbrecht@emssafety.com
- Sales Manager: Sarah Hudson, shudson@emssafety.com

Core Programs:

Program Title	Intended Audience	Duration
CPR & AED for Professional Rescuers	EMS Responders, Healthcare Providers	6 Hours
CPR, AED & First Aid for Community Rescuers	Community, Workplace, School	8 Hours
CPR & First Aid for Childcare Providers	Childcare Providers, Teachers, Coaches	8 Hours
CPR, AED & First Aid for Caregivers	Seniors, Caregivers, Skilled Nursing	8 Hours
Emergency Oxygen Administration	EMS Responder	1 Hour
Bloodborne Pathogens Awareness	Std: 1910.1030	1 Hour

Sample Approval List:

Below is a very small sample of EMS Safety program approvals. For a complete list of EMS Safety program approvals, please visit http://www.emssafetyservices.com/training-programs/approvals/.

- Commission on Accreditation for Pre-Hospital Continuing Education (CAPCE, formerly known as CECBEMS)
- United States Coast Guard
- State EMS Agencies (CA, DE, FL, IL, KY, ME, NY, OH, PA, TX, and more)
- American General Dentistry/PACE
- Mine Safety and Health Administration (MSHA)

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Requirements to Complete EMS Safety Instructor Course

Below, you will find a summary of the requirements and qualifications our instructors must meet in order to instruct EMS Safety CPR, AED and First Aid courses.

Evaluation of Instructor Competency

Instructor candidates complete a 16 hour in-classroom instructor course that includes:

Instructor Requirements

EMS Safety Instructor Manual (Instructor Manual, Admin, pages 15-16)

Instructor Progress Pack

- Assigned 5-minute skills lecture with instructor trainer and peer review.
- Assigned 10-minute skills demonstration and lecture with instructor trainer and peer review. Assigned volunteer makes deliberate errors, and instructor uses techniques to correct mistakes.
- Serve as peer evaluators for other instructor candidates in the course for the above topics.
- Candidate Skill Check – Adult CPR (Instructor Progress Pack, Form 3)
- Candidate Skill Check – Infant CPR (Instructor Progress Pack, Form 4)
- Written examination – 60 questions with a minimum passing score of 80%
- Instructor written exam answer sheet (Instructor Progress Pack, Form 5)
- Instructor recommendation sheet (Instructor Progress Pack, Form 6)
- Course evaluation form (Instructor Progress Pack, Form 7)

Instructor Course Outline and Objectives

Instructor Candidates are tested on basic CORE skills found below. Skill Sheets can also be found in the back of the Instructor Manual under Master Documents.

- Skills Summary sheet (V1)
- Skill Sheet 1 – Glove Removal (Outline and Objectives, Page 3)
- Skill Sheet 2 – Adult CPR and AED Use (Outline and Objectives, Page 4)
- Skill Sheet 3 – Child and Infant CPR (Outline and Objectives, Page 5)
- Skill Sheet 4 – Assessment (Outline and Objectives, Page 6)
- Skill Sheet 5 – Bleeding Control and Bandaging (Outline and Objectives, Page 7)
- Skill Sheet 6 – Adult & Child Choking Care (Outline and Objectives, Page 8)
- Skill Sheet 7 – Infant Choking Care (Outline and Objectives, Page 9)
- Skill Sheet 8 – Epinephrine Auto-Injector (Outline and Objectives, Page 10)

Methods of Instructor Monitoring

- Full time EMS Safety employee assigned to monitor quality and develop instructors
- Random student sampling through course rosters
- Easy access for students to reach out to EMS Safety (toll free number)
- Recertification exam every 2 years
- When guidelines change, instructors must complete webinar and exam
- Quality assurance investigations as needed

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About EMS Safety

EMS Safety Services, Inc. is a nationally recognized CPR, AED and First Aid training company in business since 1993. We provide emergency response instructors with compliant, cost-effective training programs at the Community Rescuer and Professional Rescuer levels. Our programs have been reviewed, approved or meet the guidelines for more than 200 federal, state and local organizations; private agencies; and regulatory bodies.

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Outline & Objectives

Course Outline

Day 1	Day 2
Intro & Overview	Course Admin, Instructor Resources
About EMS Safety	Basic First Aid Mini-Course
CPR/AED Mini-Course	Assessment & Feedback of Student Skills
Mini-Topic & Skills Presentation Selections	Activity: Spotting the Error
Lunch*	**Lunch***
Adult Learning	Mini-Topic Lecture/Skills Presentations
Leading the Class	Activity: Candidate Skill Checks
Mini-topic Lectures	Conclusion & Written Exam
Optional Practice	Final feedback and Sign-off

Learning Objectives

1. Understand the importance of accurate, thorough and effective provider courses.
2. Learn the origins of CPR, AED and first aid guidelines.
3. Understand how programs are approved and meet standards.
4. Identify certification levels and the target audiences for each.
5. Know the requirements for certification of your students.
6. Identify how adults learn and retain knowledge.
7. Learn to effectively demonstrate and evaluate students' skills.
8. Identify effective lecture and feedback techniques, and ways to improve.
9. Learn how to use instructor resources and training materials.
10. Understand pre- and post-course procedures, recordkeeping, and required paperwork.
11. Learn how to purchase workbooks, certification cards and Instructor supplies.
12. Successfully demonstrate knowledge and skills through written and skills testing.

* Lunch scheduling is flexible, the Instructor Trainer will determine when and how long lunch is depending on the course's needs, size and capabilities.

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Skill Sheet 1: **Glove Removal**

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Student Name:		Test Date:	

Instructions: Check off actions as they are performed correctly and in sequence. If not performed correctly, provide feedback and retest the student from the beginning of the scenario. **Student should be wearing exam gloves to start the scenario.**

Read this Statement: This is a skill test. I cannot coach you. After hearing the scenario, take the actions you feel are best. Continue until you are told to stop.

Scenario: You have assisted in a first aid emergency. It's time to remove your contaminated gloves. Remove the gloves without touching the outside of them.

STEPS	RESCUER ACTIONS	Test 1	Test 2
CONTAMINATED GLOVE REMOVAL			
1st Glove	Pinch the base of 1 glove and gently peel it off; hold in gloved hand	☐	☐
2nd Glove	Slip ungloved fingers under base of glove; slowly peel glove back	☐	☐
Finish	End with gloves inside out, one inside the other	☐	☐
Say or simulate	Dispose of gloves properly and wash hands	☐	☐
Stop the test after all actions are observed.		NOT READY ☐	PASS ☐

Glove removal skill training is required for both CPR and First Aid certification.

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Instructor Initials:		Instructor #:	

Skill Sheet 2: **Adult CPR and AED Use**

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Student Name:		Test Date:	

Instructions: Check off actions as they are performed correctly and in sequence. If errors are observed during the first cycle of CPR, stop the test. Make corrections and retest the student from the beginning of the scenario.

Read this Statement: This is a skill test. I cannot coach you. After hearing the scenario, take the actions you feel are best. Continue cycles of CPR until you are told to stop.

Scenario: You are at a high school football game when you see an adult man clutch his chest. He appears unsteady and is assisted to the ground. He stops moving. You have gloves and a CPR barrier with you. There is an AED nearby and bystanders are present.

STEPS	RESCUER ACTIONS	Test 1	Test 2
CHECK SCENE			
Quickly check the scene	Determine scene is safe	☐	☐
Put on PPE	Put on gloves or say, "Gloves are on"	☐	☐
CHECK & CALL			
Check response	Tap shoulder, shout "Are you ok?"	☐	☐
Call for help	Send bystander to call 911 and get AED	☐	☐
Check breathing	Scan face and chest for 5-10 seconds	☐	☐
GIVE 30 CHEST COMPRESSIONS			
Location	Center of chest, 2 hands between nipples	☐	☐
Push hard	Minimum 23 out of 30 compressions are at least 2" deep	☐	☐
Push fast	Give 30 compressions in 15-18 seconds	☐	☐
Do not lean on chest	Allow full chest rise between compressions	☐	☐
OPEN AIRWAY & GIVE 2 BREATHS			
Open airway	Tilt head back and lift chin	☐	☐
Give breaths	Pinch nose or use CPR mask and give 2 breaths	☐	☐
	Just enough air to see the chest rise	☐	☐
Minimize interruptions to compressions	Less than 10 seconds to give 2 breaths & resume compressions	☐	☐
USE AN AED* After 2 CPR cycles, an AED is brought to the scene.			
Place the AED and turn it on	Place near victim's head; turn on AED	☐	☐
2-Rescuer Option: Rescuer 1 provides CPR; Rescuer 2 uses AED			
Place the AED and turn it on	Place near victim's head; turn on AED	☐	☐
Apply pads	Right upper chest, left lower chest	☐	☐
Minimize interruptions to compressions	*2 rescuers only: Apply pads without stopping CPR*	☐	☐
Stop CPR when prompted	*2 rescuers only: Say, "Stop CPR" to CPR provider*	☐	☐
Clear victim before shocking	Say, "Clear!" and look to see if victim is clear	☐	☐
Deliver shock	Press shock button when victim is clear	☐	☐
Immediately resume CPR	Start compressions after it is safe to touch victim	☐	☐
Stop the test after all actions are observed.		**NOT READY** ☐	**PASS** ☐

**AED skill testing is required for AED certification, an optional topic in CPR courses.*

Instructor Initials:		Instructor #:	

Skill Sheet 3: **Child and Infant CPR**

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Student Name:		Test Date:	

Instructions: Check off actions as they are performed correctly and in sequence. If errors are observed during the first cycle of CPR, stop the test. Make corrections and retest the student from the beginning of the scenario.

Read this Statement: This is a skill test. I cannot coach you. After hearing the scenario, take the actions you feel are best. Continue cycles of CPR until you are told to stop.

Child CPR Scenario: You are at the community pool when you hear someone yelling for help. You see a young boy lifted from the pool and laid on the deck. His face appears blue and he is not moving. You have gloves and a CPR barrier with you. There is an AED in the clubhouse. No lifeguard is on duty.

Infant CPR Scenario: You are babysitting your 8-month-old nephew. You check on him shortly after putting him down for a nap, and notice he is twisted up in the blankets. He does not appear to be moving or breathing. Your friend is downstairs, and you have gloves and a CPR barrier. There is not an AED in the home.

STEPS	RESCUER ACTIONS	Child		Infant	
		Test 1	Test 2	Test 1	Test 2
CHECK SCENE					
Quickly check the scene	Determine scene is safe	☐	☐	☐	☐
Put on PPE	Put on gloves or say, "Gloves are on"	☐	☐	☐	☐
CHECK & CALL					
Check response	**Child:** Tap shoulder, shout, "Are you ok?"	☐	☐	☐	☐
	Infant: Flick soles of feet, shout				
Call for help	**Child:** Send bystander to call 911 and get AED	☐	☐	☐	☐
	Infant: Yell for help. Send bystander to call 911				
Check breathing	Scan face and chest for 5-10 seconds	☐	☐	☐	☐
GIVE 30 CHEST COMPRESSIONS					
Location	**Child:** Center of chest, 1 or 2 hands between nipples	☐	☐	☐	☐
	Infant: Center of chest, 2 fingers just below nipple line				
Push hard	**Child:** 23 out of 30 compressions are about 2"	☐	☐	☐	☐
	Infant: 23 out of 30 compressions are about 1.5"				
Push fast	Complete 30 compressions in 15-18 seconds	☐	☐	☐	☐
Do not lean on chest	Allow full chest rise between compressions	☐	☐	☐	☐
OPEN AIRWAY & GIVE 2 BREATHS					
Open airway	**Child:** Tilt head back and lift chin	☐	☐	☐	☐
	Infant: Tilt head back and lift chin to a neutral position	☐	☐	☐	☐
Give breaths	**Child:** Pinch nose or use CPR mask & give 2 breaths	☐	☐	☐	☐
	Infant: Give 2 breaths over mouth and nose				
	Just enough air to see the chest rise	☐	☐	☐	☐
Minimize interruptions to compressions	Less than 10 seconds to give 2 breaths & resume compressions	☐	☐	☐	☐
Stop the test after all actions are observed.		NOT READY ☐ PASS ☐			

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Instructor Initials:		Instructor #:	

Skill Sheet 4: **Adult & Child Choking Care**

EMS SAFETY
Teaching skills for life

Student Name:		Test Date:	

Instructions: Check off actions as they are performed correctly and in sequence. If not performed correctly, provide feedback and retest the student from the beginning of the scenario. **Use a manikin or trainer vest as the victim.**

Read this Statement: This is a skill test. I cannot coach you. After hearing the scenario, take the actions you feel are best. Continue until you are told to stop.

Scenario: You are at a restaurant when you witness an adult at the next table clutch his throat and stand up. His face looks panicked and is turning red. He appears unable to speak.

STEPS	RESCUER ACTIONS	Test 1	Test 2
ADULT OR CHILD CHOKING CARE			
Quickly check scene	Determine scene is safe	☐	☐
Recognize choking	Ask person, "Are you choking?"	☐	☐
Abdominal thrusts	From behind, reach under person's arms and locate navel with finger	☐	☐
	Make fist with other hand and place thumb-side in, just above navel	☐	☐
	Grasp fist with free hand	☐	☐
	Give continuous abdominal thrusts, quick and forceful, inward and upward	☐	☐
Stop the test after all actions are observed.		NOT READY ☐	PASS ☐

Choking care skills training is required for both CPR and First Aid certification.

Instructor Initials:		Instructor #:	

Skill Sheet 5: **Infant Choking Care**

EMS SAFETY
Teaching skills for life

Student Name:		Test Date:	

Instructions: Check off actions as they are performed correctly and in sequence. If not performed correctly, provide feedback and retest the student from the beginning of the scenario. **Use an infant manikin as the victim.**

Read this Statement: This is a skill test. I cannot coach you. After hearing the scenario, take the actions you feel are best. Continue until you are told to stop.

Scenario: You're at a picnic when you hear a woman scream, 'My baby is choking, someone help!" You see an infant on the blanket with several small toys close by. The infant's face is bright red, and his eyes are bulging.

STEPS	RESCUER ACTIONS	Test 1	Test 2
INFANT CHOKING CARE			
Quickly check scene	Determine scene is safe	☐	☐
Recognize choking	Observe infant to confirm severe choking	☐	☐
5 Back blows	Sit or kneel down & hold infant face-down on forearm, with head lower than body	☐	☐
	Support the infant's head	☐	☐
	Slap forcefully 5 times with the heel of the hand between the shoulder blades	☐	☐
5 Chest thrusts	Hold infant face-up on forearm, with head lower than the body	☐	☐
	Support the infant's head	☐	☐
	Place 2 fingers in the center of the chest just below the nipple line	☐	☐
	Provide 5 chest thrusts quickly and forcefully downward	☐	☐
Complete at least 2 cycles. Stop the test after all actions are observed.		NOT READY ☐	PASS ☐

Infant Choking Care training is required only for Infant CPR certification.

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Instructor Initials:		Instructor #:	

Skill Sheet 6: **Assessment**

EMS SAFETY
Teaching skills for life

Student Name:		Test Date:	

Instructions: Check off actions as they are performed correctly and in sequence. If not performed correctly, provide feedback and retest the student from the beginning of the scenario. **Use a volunteer or full-body manikin as the victim.**

Read this Statement: This is a skill test. I cannot coach you. After hearing the scenario, take the actions you feel are best.

Scenario: You are at a construction site when you see a man slip and fall off the bed of a pickup truck. After the fall, he is not moving or attempting to get up. You have gloves with you, and there are bystanders close by with access to a phone, first aid kit and AED.

STEPS	RESCUER ACTIONS	Test 1	Test 2
CHECK SCENE			
Quickly check the scene	Determine scene is safe **Instructor Prompt:** "Scene is safe"	☐	☐
Put on PPE	Put on gloves or say, "Gloves are on"	☐	☐
CHECK PERSON			
Check response	Tap shoulder, shout "Are you ok?" **Instructor Prompt:** "No response"	☐	☐
Call for help	Send bystander to call 911 and get the AED	☐	☐
Check breathing	Scan face & chest for 5-10 seconds **Instructor Prompt:** "Normal Breathing"	☐	☐
Check for severe bleeding	Look quickly for severe bleeding **Instructor Prompt:** "Bleeding heavily from forearm"	☐	☐
	Apply direct pressure to control bleeding	☐	☐
Check head-to-toe	Look from head-to-toe for signs of injury	☐	☐
CHECK AGAIN			
Recheck scene	Determine the scene is still safe **Instructor Prompt:** "Scene is still safe"	☐	☐
Recheck breathing	Scan face & chest for 5-10 seconds **Instructor Prompt:** "Normal breathing"	☐	☐
Recheck if severe bleeding is controlled	Check bandage for blood soaking through	☐	☐
Stop the test after all actions are observed.		**NOT READY** ☐	**PASS** ☐

Instructor Initials:		Instructor #:	

Skill Sheet 7: **Bleeding Control and Bandaging**

EMS SAFETY
Teaching skills for life

Student Name:		Test Date:	

Instructions: Check off actions as they are performed correctly and in sequence. If not performed correctly, provide feedback and retest the student from the beginning of the scenario. **Use a volunteer as the victim.**

Read this Statement: This is a skill test. I cannot coach you. After hearing the scenario, take the actions you feel are best.

Scenario: You are helping a friend move when he cuts his wrist accidentally with a box cutter. The wound is bleeding heavily.

STEPS	RESCUER ACTIONS	Test 1	Test 2
CHECK SCENE			
Quickly check the scene	Determine scene is safe **Instructor Prompt:** "Scene is safe"	☐	☐
Gain consent	Ask for permission to help **Instructor Prompt:** "Your friend gives consent"	☐	☐
Put on PPE	Put on gloves or say, "Gloves are on"	☐	☐
CONTROL BLEEDING			
Apply direct pressure with gauze pads	Press firmly directly over the wound **Instructor Prompt:** "Blood soaks through gauze"	☐	☐
Add dressings	Add additional dressings and continue to apply pressure	☐	☐
	Do not remove any dressings	☐	☐
APPLY BANDAGE			
Wrap with roll gauze or elastic bandage	Start furthest from the heart and wrap upward	☐	☐
Ensure bandage is not too tight	Check for adequate circulation beyond the bandage (can slip a finger under the bandage)	☐	☐
Ensure bleeding is controlled	Check bandage for blood soaking through	☐	☐
Stop the test after all actions are observed.		NOT READY ☐	PASS ☐

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Instructor Initials:		Instructor #:	

Skill Sheet 8: **Epinephrine Auto-Injector**

EMS SAFETY
Teaching skills for life

Student Name:		Test Date:	

Instructions: Check off actions as they are performed correctly and in sequence. If not performed correctly, provide feedback and retest the student from the beginning of the scenario. **For training purposes, students will use an auto-injector trainer on themselves.**

Read this Statement: This is a skill test. I cannot coach you. After hearing the scenario, take the actions you feel are best.

Scenario: You are in the breakroom at work when you hear a coworker complain of exposure to peanuts. Within a few moments the employee's face is swollen around the eyes and lips, he is having difficulty breathing, and you can hear wheezing. The employee asks you to help him use his auto-injector, which is in the next room.

STEPS	RESCUER ACTIONS	Test 1	Test 2
CHECK SCENE			
Quickly check scene	Determine scene is safe	☐	☐
Call for help	Send bystander to call 911	☐	☐
USE AUTO-INJECTOR			
Injection	Injection site: outer thigh between hip and knee	☐	☐
	Do not touch bottom end of auto-injector	☐	☐
	Remove safety cap	☐	☐
	Jab firmly against injection site and hold for 10 seconds	☐	☐
	Rub injection site for 10 seconds	☐	☐
Stop test after all actions are observed.		NOT READY ☐	PASS ☐

Instructor Initials:		Instructor #:	

Instructor Certification Exam

EMS SAFETY

Course Administration

1. EMS Safety Services is:
   a. Approved by the American Heart Association
   b. Approved by the American Red Cross
   c. A new training organization
   d. An organization independent of the American Heart Association or American Red Cross

2. Instructors are to maintain their course records for at least ___ year(s).
   a. 1
   b. 2
   c. 3
   d. 4

3. For certification, students must pass the skills exam with a score of:
   a. 100%
   b. 90%
   c. 80%
   d. N/A, the skills practice and testing is optional.

4. The instructor-to-student ratio for CPR/AED training is 1 Instructor to __ students.
   a. 6
   b. 8
   c. 10
   d. 12

5. CPR Training manikins must be decontaminated _____ .
   a. At least once a month
   b. After 3 classes
   c. After each course
   d. Only if lung bags are not used

6. Course exams, rosters and forms are located_____.
   a. In the back of each Instructor Manual
   b. In the back of each student workbook
   c. In the Instructor Corner at www.emssafety.com/login
   d. a and c

7. Students must receive their certification cards within _____ week(s) of the course.
   a. 1
   b. 2
   c. 3
   d. 4

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8. Course records must be submitted to EMS Safety _____.
    a. Upon request by EMS Safety and when recertifying (2 rosters)
    b. After every course
    c. Monthly
    d. Annually

9. Every student must have access to an original printed EMS Safety student workbook during the course.
    a. True
    b. False

10. The provider certification period for the EMS Safety CPR or Basic First Aid programs is _____.
    a. 1 year
    b. 2 years
    c. 3 years
    d. Up to the Instructor to decide

CPR/AED for Community Rescuers

11. Survival of sudden cardiac arrest is much more likely when early CPR is combined with:
    a. Emergency oxygen
    b. Abdominal compressions
    c. Early defibrillation
    d. Elevation of the feet

12. When there are two rescuers and an AED is available:
    a. One rescuer waits for EMS. The other provides CPR and uses the AED.
    b. One rescuer does CPR. The other reads the AED instruction manual.
    c. One rescuer uses the AED. The other keeps bystanders back.
    d. One rescuer does CPR. The other uses the AED.

13. Which sequence is best for AED use?
    a. Put on pads, turn on AED, resume CPR, deliver shock
    b. Turn on AED, put on pads, deliver shock, resume CPR
    c. Put on pads, resume CPR, turn on AED, deliver shock
    d. Turn on AED, deliver shock, resume CPR, put on pads

14. If no shock is advised by the AED and the victim is not moving, the community rescuer should:
    a. Remove the pads and continue CPR
    b. Leave the pads in place, continue CPR and follow AED prompts
    c. Stop CPR for 2 minutes until the AED analyzes again, then follow AED prompts
    d. Turn off the AED and continue CPR

EMS SAFETY

15. What should you always do just before pushing the shock button?
    a. See if there is a doctor to help
    b. Check for breathing
    c. Ask for permission to help
    d. Make sure no one is touching the victim and yell, "Clear!"

16. For an adult victim who is not breathing, use the AED:
    a. Immediately when it arrives on scene
    b. After 1 minute of CPR
    c. After 2 minutes (5 cycles) of CPR
    d. After 5 minutes of CPR

17. On an **adult**, place AED pads on the:
    a. Right upper chest and left lower chest
    b. Left upper chest and right lower chest
    c. Front and back
    d. Right upper chest and left upper chest

18. You might have to move the AED pad because of:
    a. An implanted device
    b. A tattoo
    c. Water on the chest
    d. None of the above

19. For effective compressions on an **adult**:
    a. Push hard, at least 2 inches.
    b. Push fast, 100-120 compressions per minute.
    c. Minimize interruptions to compressions.
    d. All of the above

20. The rate of chest compressions is at least _____ per minute.
    a. 60
    b. 80
    c. 100
    d. 120

21. Before starting chest compressions, check for breathing by scanning the chest for _____ seconds.
    a. No more than 30
    b. 15 to 20
    c. 10 to 15
    d. 5 to 10

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22. Where should you put your hands to do chest compressions on an adult or child?
    a. Between the nipples
    b. Just below the nipple line
    c. Anywhere on the upper 1/3 of the chest
    d. Just above nipple line

23. The depth of chest compressions for an adult victim is:
    a. About 1 to 2 inches
    b. At least 1½ inches
    c. At least 2 inches
    d. About ½ the depth of the victim's chest

24. What does "avoid leaning" for chest compressions mean?
    a. Bend your elbows as much as possible during chest compressions.
    b. Do not lean on the chest between compressions.
    c. Do not allow the chest to recoil between each compression.
    d. Remove your hands from the chest to get a bouncing action with each compression.

25. Before starting CPR on an adult:
    a. Check for response
    b. Call 911 and get the AED
    c. Check for breathing
    d. All of the above

26. The **most important** part of CPR and the C-A-B sequence is:
    a. Airway management
    b. Rescue breathing
    c. Chest compressions
    d. All of the above

27. If a person is not breathing or only gasping (agonal breaths), give _____ compressions.
    a. 20
    b. 30
    c. 40
    d. 50

28. During rescue breaths:
    a. Watch for chest rise with each breath.
    b. Give just enough air for the chest to start rising.
    c. Don't breathe too hard or too fast.
    d. All of the above

29. If there is more than one rescuer during CPR, switch rescuers every:
    a. 4 minutes
    b. 3 minutes
    c. 2 minutes
    d. 1 minute

30. After completing 30 compressions, it should take no more than ____ seconds to give 2 breaths and resume compressions.
    a. 5
    b. 10
    c. 15
    d. 30

31. For **CPR**, treat a victim like an adult if he or she is:
    a. Age 8 or older and weighs over 55 pounds.
    b. 10 years old
    c. Age 18, when the person is a legal adult
    d. Showing signs of puberty

32. How deep should you compress a child's chest?
    a. About 1 ½ inches
    b. About 2 inches
    c. At least 2 inches
    d. About 3 inches

33. Respiratory arrest can cause cardiac arrest in a child or infant. It may be caused by:
    a. Poisoning
    b. Drowning
    c. Choking
    d. All of the above

34. What are the steps for helping a **conscious** choking infant?
    a. 5 back slaps, 5 chest thrusts
    b. 5 abdominal thrusts, 5 back slaps
    c. Back blows and rescue breaths
    d. Chest thrusts and rescue breaths

35. Use _____ to do chest compressions on an infant.
    a. 2 hands
    b. 1 hand
    c. 2 fingers
    d. 1 or 2 hands

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36. If you are **alone** with a child or infant, do ____ minute(s) of CPR before calling 911.
    a. 1
    b. 2
    c. 3
    d. 4

37. When giving rescue breaths to an **infant** during CPR:
    a. Pinch the nose and seal the mouth with your mouth.
    b. Provide mouth-to-nose rescue breathing.
    c. Cover the mouth and nose with your mouth.
    d. Provide compression-only CPR without rescue breathing.

38. What should you do to protect yourself from bloodborne pathogens (BBP)?
    a. Wear watertight gloves.
    b. Use a CPR barrier for rescue breathing.
    c. Wash your hands after glove removal.
    d. All of the above

39. What are the major symptoms of a heart attack?
    a. Confusion, sweaty skin, restlessness
    b. Slurred speech, uneven smile, weakness in one arm
    c. Chest pain, shortness of breath, sweating a lot
    d. Hot, flushed, dry skin; confusion; extreme thirst

40. What are the major symptoms of a stroke?
    a. Confusion, sweaty skin, restlessness
    b. Slurred speech, uneven smile, weakness in one arm
    c. Chest pain, shortness of breath, sweating a lot
    d. Hot, flushed, dry skin; confusion; extreme thirst

Basic First Aid

41. Get consent to help, then assess the person by doing the following:
    a. Ask questions to help find out what is wrong.
    b. Watch and listen for difficulty breathing.
    c. Look head to toe for injuries, and check for medical alert jewelry.
    d. All of the above

42. What is the **best** way to control bleeding?
    a. Direct pressure
    b. Dabbing with a cloth or gauze
    c. Elevation
    d. Pressure points

43. What should you do if you think someone has a broken leg?
    a. Splint in the position found with a heating pad on the injured area. Wait for EMS.
    b. Keep the person calm and still in the position found until EMS arrives.
    c. Place in the recovery position while waiting for EMS.
    d. Place on a hard, firm, flat surface, and wait for EMS.

44. Always suspect shock if a person:
    a. Is mean, slurs his words, and smells of alcohol
    b. Is bleeding heavily
    c. Stopped exercising from a leg cramp
    d. Stepped on a nail

45. To treat a nosebleed, hold pressure on the bridge of the nose and have the person:
    a. Lean slightly back
    b. Lean slightly forward
    c. Apply a heat pack to the nose
    d. Lie flat on the floor

46. If you suspect a head or neck injury:
    a. Support the head and neck in the position found.
    b. Move the head until the neck is straight.
    c. Always place in the recovery position.
    d. Have the victim sit up

47. A poison can enter the body through eating, drinking, inhaling, absorption through the skin, and _____.
    a. Injection
    b. Intolerance
    c. Imbalance of electrolytes
    d. None of the above

48. What should you do for a person who shows signs of heat stroke?
    a. Stretch and massage cramping muscles.
    b. Have the person put on a hat to protect from the sun.
    c. Help the person walk slowly to cool down.
    d. Rapidly cool the person by immersing (dunking) in water up to the neck.

49. When assessing and emergency scene and possible victim:
    a. Assess the scene for safety.
    b. Assess the person in the position found.
    c. Look for life-threatening conditions first.
    d. All of the above

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50. To treat strains and sprains, use the acronym RICE, which means _____:
    a. Rest, Ice, Compress, Elevate
    b. Run Inside, Call, EMS
    c. Rescue, Incline, Compress, Eliminate pain
    d. Rub, Ice, Crutches, Elevate

51. What is the **most important** thing to do if you think someone is having a heart attack?
    a. Give aspirin and wait to see if it helps.
    b. Help the person lie down.
    c. Call the person's doctor.
    d. Call 911 (activate EMS).

52. What should you do for a person with an object, like a knife, stuck in their leg?
    a. Rinse the wound with water, and apply antibiotic ointment and a sterile dressing.
    b. Quickly remove the object and apply direct pressure to stop the bleeding.
    c. Always cut the object shorter to make it easier to transport the person.
    d. Call 911, control bleeding, and stabilize the object in place.

53. Difficulty breathing may be a sign of:
    a. Heart attack
    b. Asthma attack
    c. Anaphylaxis (severe allergic reaction)
    d. All of the above

54. Signs of anaphylaxis (a severe allergic reaction) may include:
    a. Swollen face, eyes, throat, tongue
    b. Difficulty breathing
    c. Symptoms start quickly
    d. All of the above

55. What is the best way to remove a tick?
    a. Smother it in butter.
    b. Lift it out carefully with tweezers.
    c. Scrape it off with a hard, flat object like a credit card.
    d. Burn it off with a hot match.

56. To flush an eye that has been exposed to a chemical, have the injured eye_____ the unaffected eye.
    a. Higher than
    b. Lower than

57. If a permanent tooth cannot be immediately reinserted, _____, then see a dentist as soon as possible:
    a. Scrub the tooth clean.
    b. Handle the tooth by the crown (biting surface) and place it in whole milk.
    c. Wrap the tooth in sterile gauze.
    d. Protect the tooth by keeping it warm and dry.

58. What should you do if you get a chemical in your eye?
    a. Cover both eyes and wait for EMS.
    b. Flush with water immediately and continue for at least 20 minutes.
    c. Cover the injured eye and drive yourself to the hospital.
    d. None of the above

59. An epinephrine auto-injector is used to treat:
    a. Severe allergic reaction (anaphylaxis)
    b. Mild allergic reaction
    c. Chest pain
    d. Low testosterone

60. What should you do for a diabetic person who acts confused or irritable?
    a. Call the doctor
    b. Give sugar
    c. Assist by giving a shot of insulin
    d. Wait to see if the person improves

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Louisiana Board of Pharmacy

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Request for Approval
of
Alternative Pharmacist Verification Methodology
in
Central Fill System

(Brookshire Grocery Co.)

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.*

BROOKSHIRE GROCERY COMPANY

Central Fill Services

Louisiana Board of Pharmacy

8-23-2017

THE GOAL OF OUR MEETING WITH THE BOARD OF PHARMACY IS….

- Discuss the purpose of BGC's Central Fill System
- Lead you through the process of BGC's Central Fill System
- Gain the Board's affirmation of the Pharmacist Verification process currently in practice in many states in the United States

THE PURPOSE OF CENTRAL FILL FOR BGC

- Improve quality of patient care
  - Medication Therapy Management
  - Increased Immunization Administration
  - Enhanced Patient consultation
  - Medication Adherence Programs
- Improved patient safety through accuracy
  - Replace manual prescription processing with automation
  - Proven processes virtually eliminate errors
- Improve work environment of pharmacists, technicians, and support personnel

BGC CENTRAL FILL

- BGC will operate a central fill facility in Tyler, TX to service its 118 community pharmacies based in 3 states
- Anticipated go-live date is 9-18-17
- System built by McKesson but owned, staffed, and operated by BGC

KEY SYSTEM TECHNOLOGIES AND PROCESSES

The Central Fill system will employ the following technologies and processes:

- Parata Max+ robotics for fully automated tablet/capsule counting
- Semi-Automated unit of use dispensing
- As-dispensed imaging
- Pharmacist exception and audit/quality management
- Product replenishment with pharmacist verification
- Semi-automated product bagging systems
- Automated package sortation systems for store delivery
- Full integration with BGC's retail-level pharmacy management system

SYSTEM LAYOUT

Semi-automated bagging

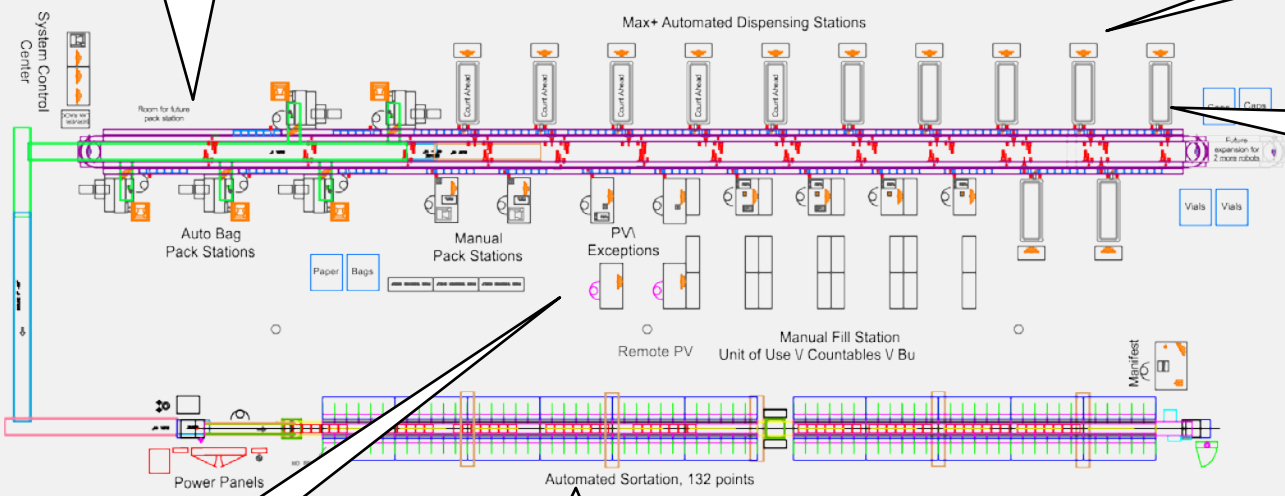
Automated vial labeling

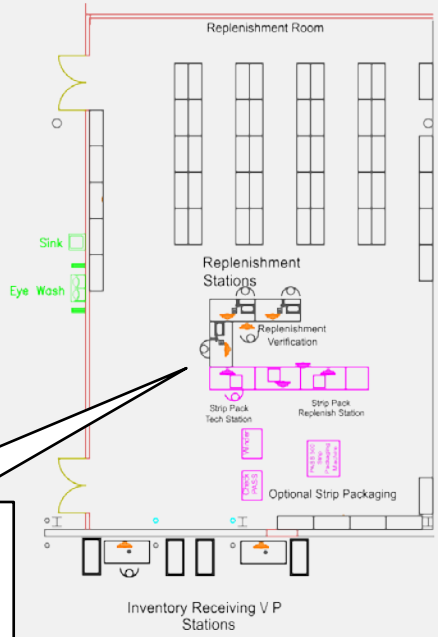
Oral/solid dispensing (Parata robotics & high volume cells)

Manual & bulk dispensing

Store tote sortation

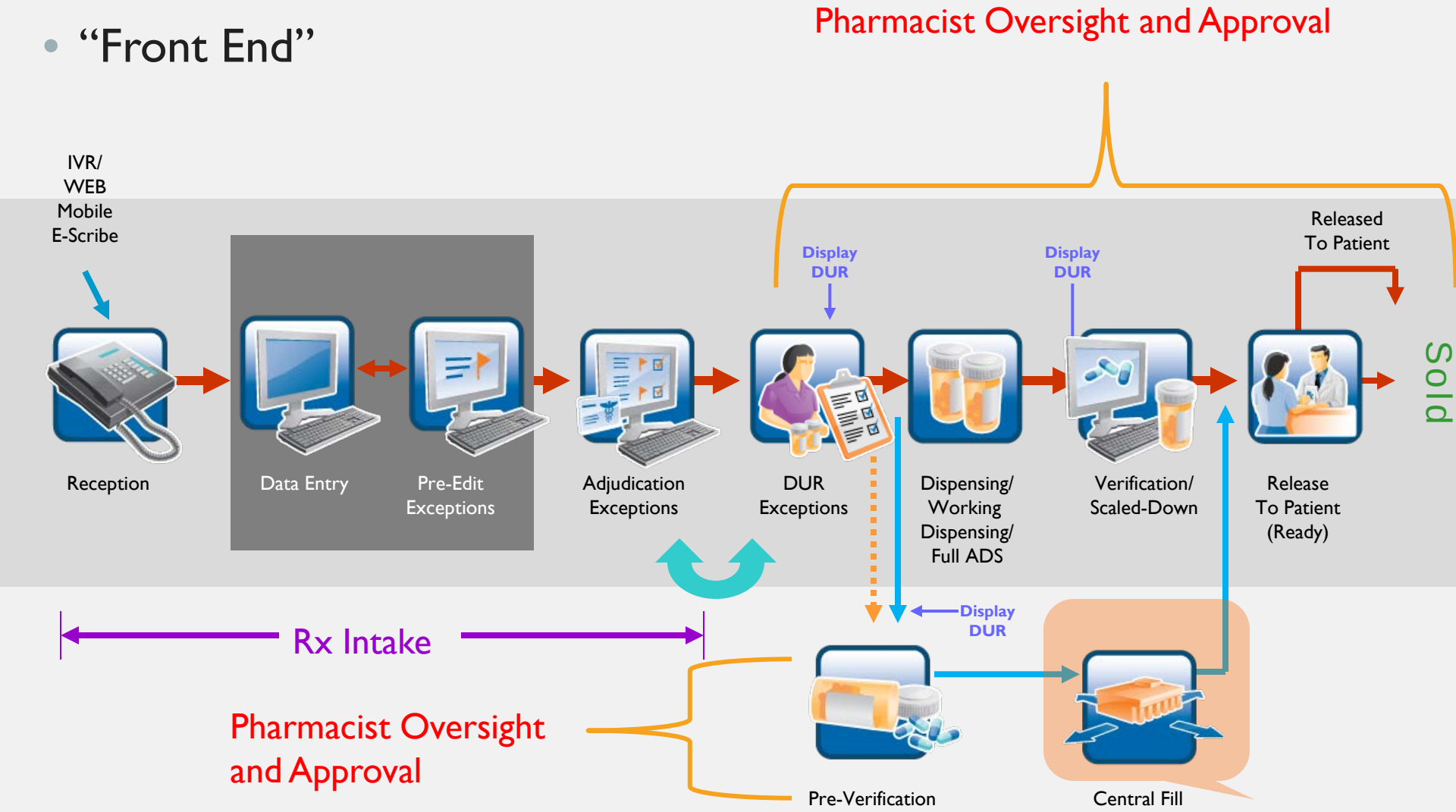
Off-line canister replenishment





COMMUNITY PHARMACY PROCESS

- "Front End"



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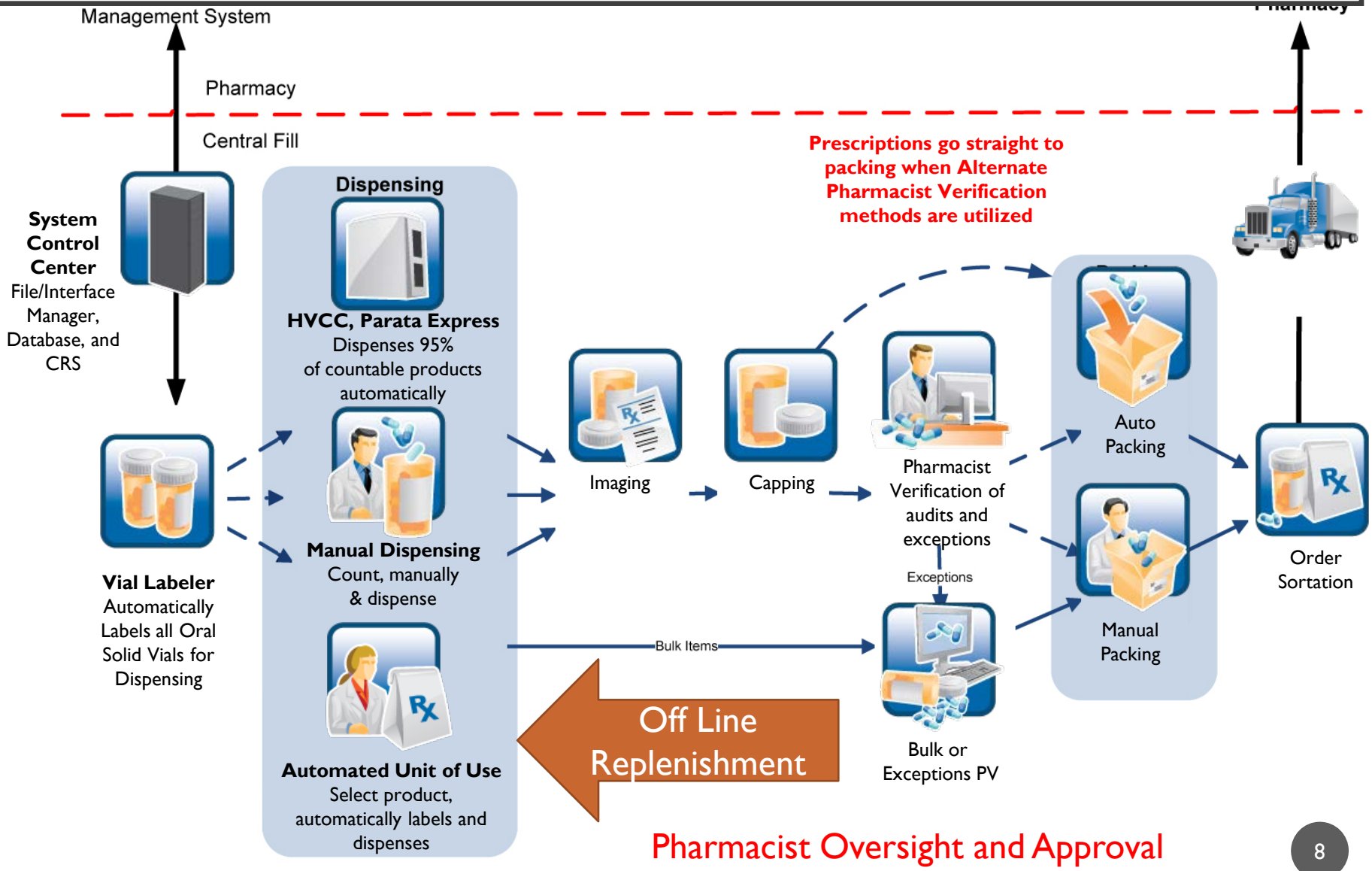
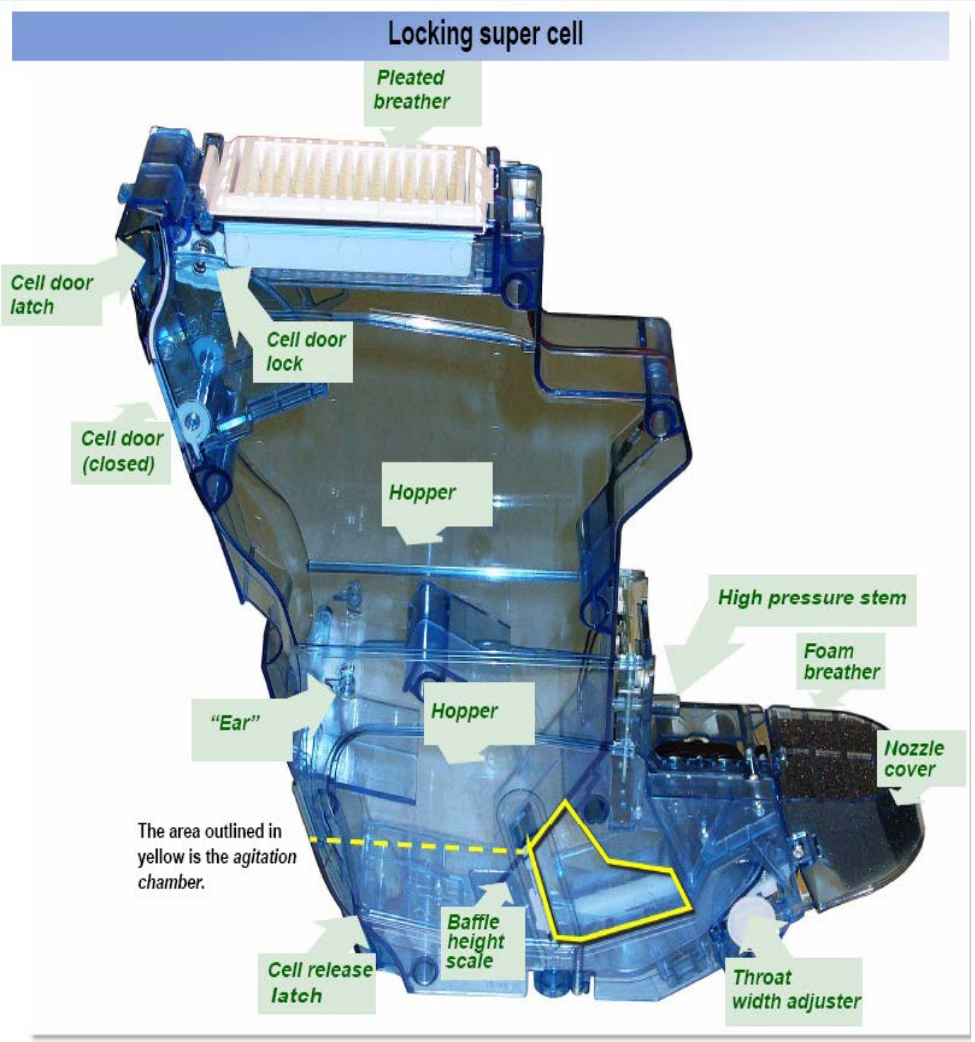
CENTRAL FILL PROCESS FLOW
"BACK END"



PARATA MAX+ ROBOTS

PARATA MAX+ BENEFITS

- 99.99% accurate on pill count (excluding detected miscounts)
- Replenish off-line with pharmacist oversight
- Quality assurance (accuracy of fill, accuracy of count, cross-contamination) is the highest in the industry
- Calibration on site
- All dispensing cells have locking mechanism
- Robotic Intelligence – Robots know when there is a chance of under/overcount and self selects a recount in the system.



AUDIT AND EXCEPTION PRODUCT VERIFICATION

Central Fill Audit Pharmacist Reviews:

1. Picture of product in container vs. reference image
2. Dispense data
3. Any red flags indicating an “exception” or out of tolerance event along with event notes

PACKAGE SORTER SOLUTIONS – AUTOMATED SORTERS

- Sorts all sealed prescription bags into store totes
- Sealed process and audit trails
- Totes delivered to stores and checked into will call bins

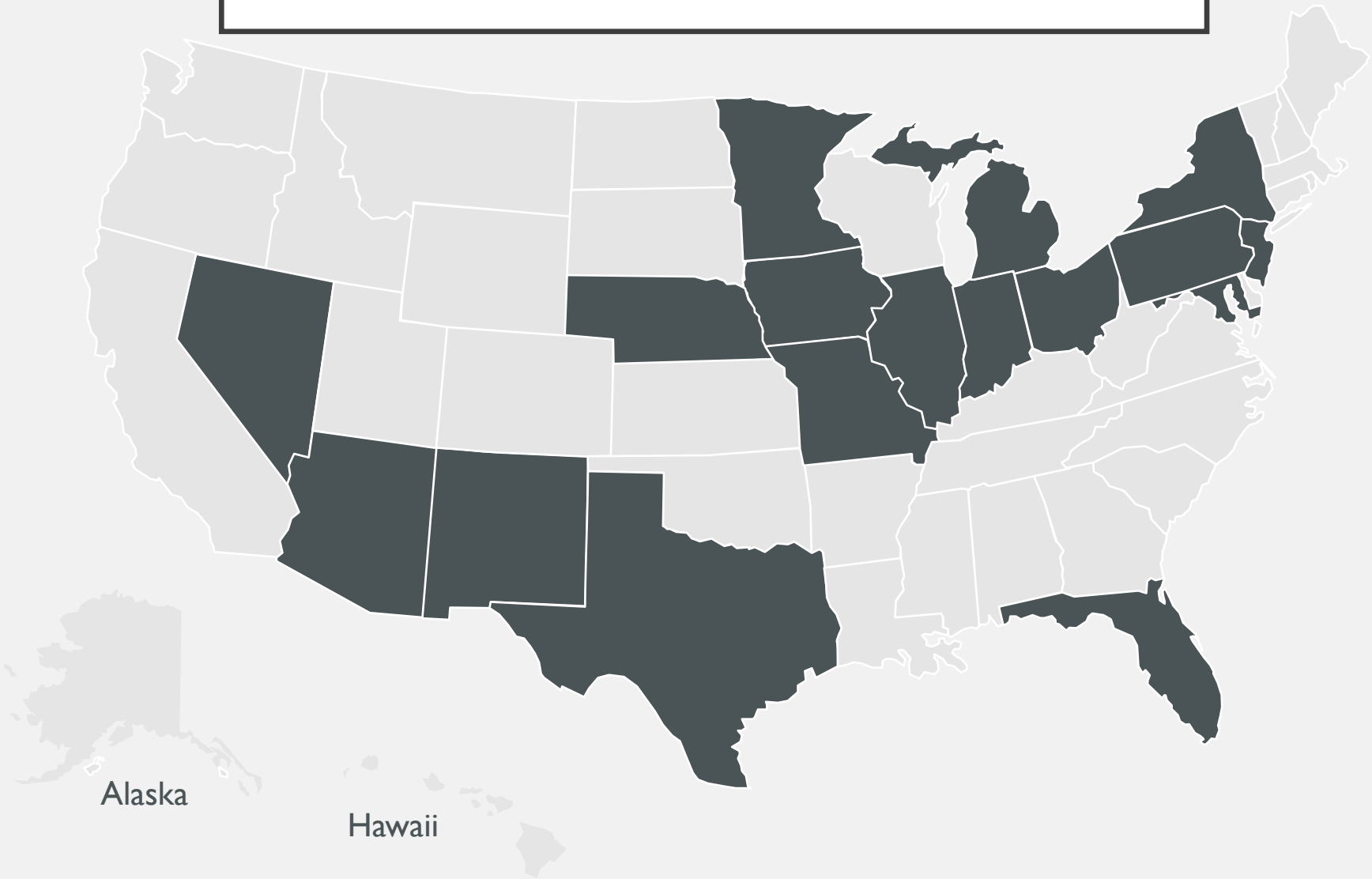
McKesson Proprietary and Confidential - External use is prohibited without permission

PHARMACIST VERIFICATION

THROUGH DIRECT AND IMMEDIATE SUPERVISION OF REPLENISHMENT FOR AUTOMATED DISPENSING DEVICES

- BGC desires to utilize an alternate Pharmacist Verification process to ensure that all prescriptions are processed accurately.
- Process is based on Pharmacist Verification of inventory replenishment (Off-line replenishment) for all prescriptions filled by fully automated processes (no human involvement in dispensing).
- Process is currently utilized by a variety of automated pharmacies including Wegmans, Rite-Aid, Walmart, Meijer, Kroger, Hy-Vee, HEB, Prime-Therapeutics, Express Scripts, Prescription Solutions, Caremark, Kaiser and Novixus with several other retail central fills in selective states.
- Process is prevalent in the industry and an already accepted form of verification in 17 states.

GEOGRAPHIC LAYOUT – U.S.



OFF-LINE REPLENISHMENT AREA WITHIN CENTRAL FILL PHARMACY

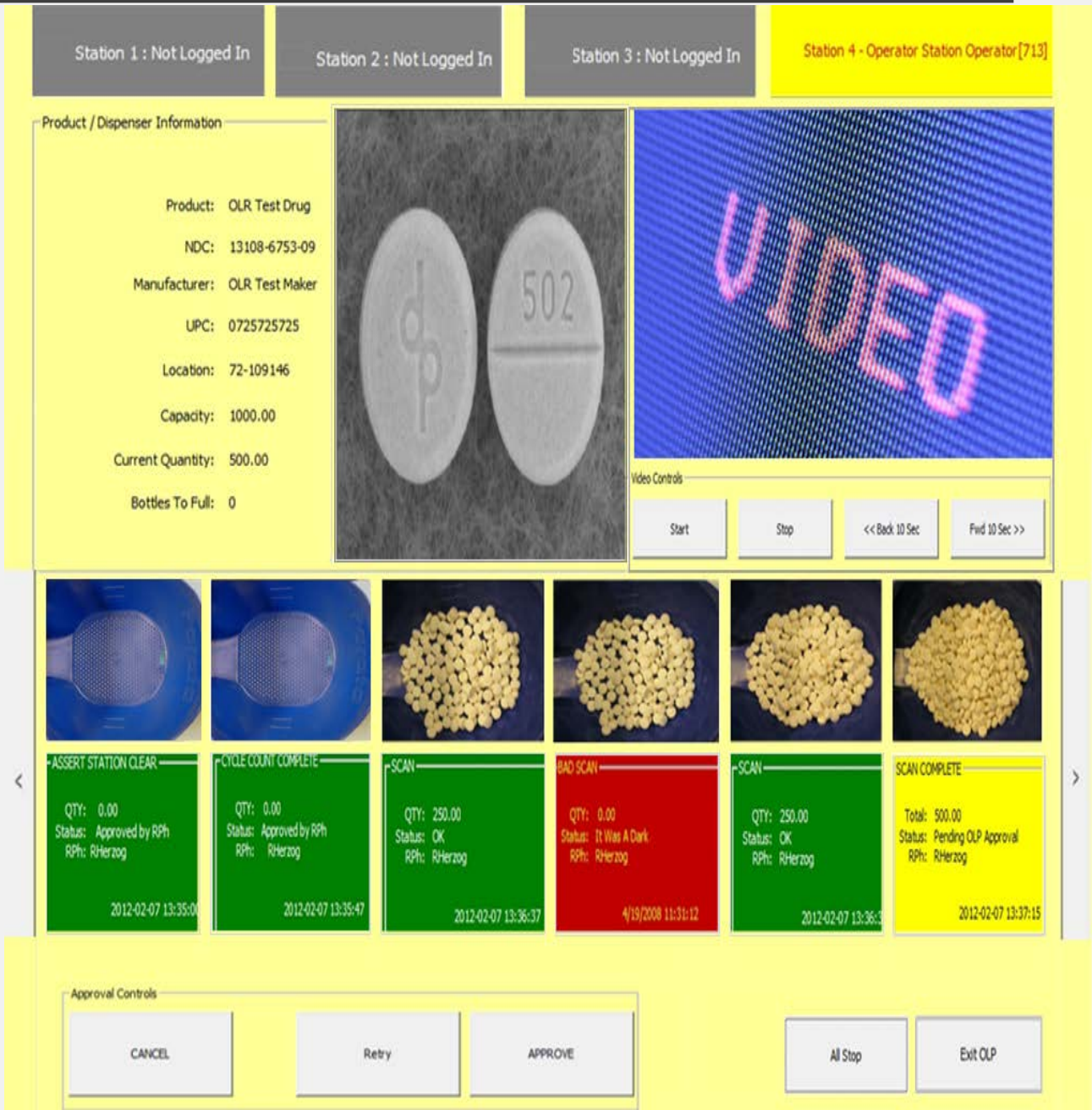
- Dedicated area
- Dedicated personnel
- Replenishment activity away from production line
- Levels of security and inspection configurable
- Direct and immediate Pharmacist supervision with audit trails, data collection, and reporting
- Patent pending process captures digital image of every step in process

OFF-LINE REPLENISHMENT
(PATENT PENDING)

- The replenishment schedule is updated real time
- Immediate and personal supervision by the pharmacist of record
- Allows for a photographed audit trail of all steps in the replenishment process
- Records video of the replenishment process for immediate QA
- Once filled, canisters are locked and cannot be opened without pharmacist authorization

OFF-LINE REPLENISHMENT (PATENT PENDING)

1. Medication location displayed by the system and retrieved by the operator
2. Operator cleans area and requests approval where a picture is taken
3. Once approved to continue, canister is mounted to an automatic counter
4. Canister is then emptied with current contents being counted
5. Authorization to fill is requested and picture is taken
6. Once authorized, operator will scan medication bottle and pour one at a time
7. After each bottle pour, request approval and picture is taken
8. Once authorized, operator will request final approval
9. After final approval, canister is locked



AUDIT TRAILS AND QUALITY ASSURANCE

- Each step of the process is reviewed and approved by a pharmacist.
- Data is collected on each step/approval. Data and photos are stored and can be retrieved for inspection or audits.
- Multiple checks and balances occur along the way to ensure quality and accuracy
- Cells/canisters cannot be replaced without correct security and accuracy barcode scans
- Quality is ensured by QA audits (prescriptions sent to on the line pharmacy verification / exceptions)
  - When new cells/canisters are placed into the counting devices
  - When 50% of the inventory is utilized
  - On all non Automated dispensing products.

CONCLUSIONS AND REQUEST

- BGC embraces Automated Central Fill technology and focus on improved patient care
- Automated Central Fill technology, processes, accuracy, audit trails, quality assurance, and quality control meets or exceeds established standards
- Tablet and capsule counting technology is at least 99.92% accurate (most dispensing is 99.99%). Central Fill mis-fill potential is extremely negligible.
- This established Pharmacist Verification process is well-accepted and utilized throughout the United States. The process and technology ensures all prescriptions will be accurately filled and dispensed.
- BGC requests the Louisiana State Board of Pharmacy approve the use of the Alternative Pharmacist Verification process for use on Central Fill prescriptions dispensed with the system.

ACCURACY VERIFICATION CHECKPOINTS

- RFID
- Bar Code Technology
- Pharmacist oversight of replenishment
- Product image taken
- Robotics intelligence
- Audit pharmacist verification

- Multiple checks ensure accuracy

THANK YOU

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter D. Off-Site Services

§1139. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section, unless the context clearly indicates otherwise.

Centralized Prescription Dispensing – the fulfillment by one permitted pharmacy of a request from another permitted pharmacy to fill or refill a prescription drug order.

On-Site Pharmacy – a permitted pharmacy which utilizes centralized prescription dispensing services from a remote dispenser or remote processing services from a remote processor.

Remote Dispenser – a Louisiana permitted pharmacy which provides centralized prescription dispensing services for another permitted pharmacy in Louisiana.

Remote Processing Services – the processing of a medical order or prescription drug order by one permitted pharmacy on behalf of another permitted pharmacy, including:

a. receipt, interpretation, or clarification of an order;
b. data entry and information transfer;
c. interpretation of clinical data;
d. performance of drug utilization review; and
e. provision of drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation of physical transfer of drugs.

Remote Processor – a Louisiana permitted pharmacy which provides remote processing services for another permitted pharmacy in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007), amended LR 39:313 (February 2013).

§1141. Centralized Prescription Dispensing

A. General Requirements

1. An on-site pharmacy may obtain centralized prescription dispensing services from a remote dispenser provided the pharmacies:
    a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
    b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.
2. All drugs dispensed to a patient that have been dispensed by a remote dispenser shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmacy primary care activities.

B. Policies and Procedures

1. On-site pharmacies and remote dispensers engaging in the acquisition or provision of centralized dispensing services shall maintain a policy and procedure manual for reference by all personnel; it shall be made available for inspection and copying by the board.
2. At a minimum, the manual shall include policies for:
    a. a description of how the parties will comply with federal and state laws and regulations;
    b. the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling process;

c. the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;
d. the maintenance of a mechanism to identify on the prescription label all pharmacies involved in the dispensing of the prescription drug order; and
e. the provision of adequate security to protect the confidentiality and integrity of patient information and to prevent its illegal use or disclosure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007).

…

Chapter 12. Automated Medication Systems

…

§1217. Stocking and Restocking

A. *On-Site Facility System(s).* The stocking and restocking of all medications in the on-site system shall be accomplished by Louisiana licensed pharmacists and/or Louisiana certified pharmacy technicians under the supervision of Louisiana licensed pharmacists. A pharmacist must conduct final checks of work performed by a pharmacy technician. The pharmacy shall have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of the medications to be stocked or restocked in the automated medication systems.

B. *Off-Site Facility System(s).* The stocking and restocking of all medications in the off-site system shall be accomplished by Louisiana licensed pharmacists; however, the certified pharmacy technician may stock or restock an off-site facility system provided a pharmacist is physically present at the off-site facility and supervises and verifies the stocking and/or restocking prior to use. The pharmacy shall have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of the medications to be stocked or restocked in the system.

C. Electronic Product Verification
   1. A bar code verification, electronic verification, or similar verification process may be utilized to assure the correct selection of drugs to be placed into an automated medication system.
   2. The use of a bar code, electronic, or similar verification process shall require an initial quality assurance validation followed by ongoing quality assurance reviews at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.
   3. When a bar code verification, electronic verification, or similar verification process is utilized as specified in the Paragraph, and in the absence of any human intervention in the product selection process, the stocking and restocking functions in systems located either on-site or off-site may be performed by a pharmacy technician without the necessity of direct pharmacist supervision.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000, amended LR 41:1488 (August 2015).

Louisiana Board of Pharmacy

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Request for Revision of Rules for Telepharmacy

(Cardinal Health)

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 24. Limited Service Providers

…

Subchapter C. Telepharmacy Services

…

§2425. Telepharmacy Dispensing Site

A. General Requirements

1. At the time of its opening, there shall be no other pharmacies licensed by the board within ~~20~~ 10 miles (driving distance) of the location of the telepharmacy dispensing site. This mileage restriction does not apply if:
   a. The telepharmacy is located in a hospital or clinic; or
   b. A demonstration of need is presented to the board and a waiver to the mileage restriction is deemed appropriate.

2. – 7. …

B. Licensing Procedure

1. – 5. …

6. In the event a telepharmacy is dispensing more than 200 prescriptions per day based on an average over a calendar year, the telepharmacy site must convert to a community pharmacy prior to the expiration date of the telepharmacy permit. ~~new community pharmacy opens at a location within 20 miles (driving distance) of the telepharmacy dispensing site, then the board shall not renew the telepharmacy dispensing site's pharmacy permit. The board shall notify the central pharmacy supervising the telepharmacy dispensing site of the new pharmacy operating within 20 miles (driving distance) of the telepharmacy dispensing site, and of the requirement for the telepharmacy dispensing site to close permanently on or before the expiration date of the telepharmacy dispensing site's current renewal of its pharmacy permit. The closure shall be accomplished in compliance with the provisions of Section 1133 of the board's rules. In lieu of permanent closure, the telepharmacy dispensing site may elect to apply for and complete the conversion of its permit to a community pharmacy permit prior to the expiration date of the telepharmacy permit.~~

C. – D. …

E. Standards of Practice

1. – 2. …

3. Operational Standards
   a. – c. …
   d. The dispensing of prescriptions shall be construed as completed at the central pharmacy; therefore, the telepharmacy dispensing site shall use the central pharmacy's dispensing information system.

3.e. – 4.d. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2149 (October 2015), amended LR

DRAFT

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Request for Revision of Pharmacist Licensure Requirements for Post-Graduate Year 2 (PGY2) Residents

(Ochsner Health System)

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.*

July 19, 2017

Carl Aron, President, Louisiana Board of Pharmacy
Malcolm Broussard, Executive Director, Louisiana Board of Pharmacy

Louisiana Board of Pharmacy
5533 Brentwood Drive
Baton Rouge, Louisiana 70809

RE: Regulatory Project 2017-1, Internship Requirements

Dear Board Members:

Thank you for your explanation regarding the rule making process for the Board of Pharmacy. With a better understanding of this process, I do not have further comment regarding Regulatory Project 2017-1.

However, there are still significant issues with recruiting pharmacists to enter Post-Graduate Year 2 (PGY-2) pharmacy training programs in Louisiana. The primary deterrent is the process for licensure for these pharmacists.

Supporting PGY-2 pharmacy training programs should be a priority in our state. The number of PGY-2 residency training programs in Louisiana lags significantly behind other states. The American Society of Health Systems Pharmacists (ASHP) supports expansion of these training program. ASHP believes these programs are essential to advancing the profession, as well as, increasing the number of pharmacists practicing with advanced training. Additionally, having these PGY2 training programs in our community attracts pharmacists with PGY2 training to relocate to Louisiana and residents who train here are more likely to stay in the state to practice.

There are significant obstacles in obtaining timely licensure for pharmacists who accept positions in PGY2 pharmacy training programs. For these pharmacists who complete their first year of post-graduate training in other states and have their primary license from other states, they generally have only been licensed 10-11 months when the PGY2 training program is scheduled to start July 1st. Under the current law, these pharmacists are not eligible to apply for reciprocity (Licensure Transfer) until July or August. As a result, these pharmacists may not be licensed (by reciprocity) until as late as October. As program directors, we cannot allow residents to start that late into the training program. As a result, residents who match into our programs from out-of-state are required to obtain a new license by testing which requires residents to retake the NAPLEX and MPJE. This is problematic financially

for the resident and requires that a resident study for these exams during their PGY1 residency training program. This is a significant deterrent in recruiting candidates from out of state. Of note, this is unlikely to affect PGY-1 residents because they are typically new graduates and can obtain a Louisiana Pharmacy Intern License and start their training programs as a Pharmacy Intern until they obtain their license as a Registered Pharmacist.

We are asking that the board consider altering licensure requirements for pharmacists enrolled in PGY-2 training programs in Louisiana. One possible solution would be to expand ***§506. Preferential licensing procedures for military-trained applicants and their spouses*** to include pharmacists in PGY2 training programs. Please consider adding this important matter to the August 23rd Board of Pharmacy agenda. We would be glad to come to the August Board meeting to discuss. Please let us know.

Sincerely,

Stephanie Anders, Pharm.D., BCPS
Residency Program Director, PGY-2 Solid Organ Transplant
Guest Surveyor for Residency Accreditation, ASHP
sanders@ochsner.org

Nicole Fabre'-Lacoste, Pharm.D., BCPS, BCGP
Assistant Director of Pharmacy- Medication Use, Safety and Quality
PGY-1 Pharmacy Residency Director
Residency Program Director, PGY-2 Internal Medicine

Catherine B. Oliver, Pharm.D., BCPS
Assistant Director of Pharmacy- Clinical Services

Deborah Simonson, Pharm.D.
VP, Pharmacy
Residency Program Director, PGY-2 Health Systems Pharmacy Administration

Louisiana Revised Statutes

Title 37 – Professions and Occupations

Chapter 14 – Pharmacy Practice Act

Part III. Licensing, Registration, and Certification of Persons

§1202. Qualifications for licensure by examination

A. To obtain a license to engage in the practice of pharmacy, an applicant for licensure by examination shall:

(1) Be at least twenty-one years of age.

(2) Be of good moral character and temperate habits.

(3) Meet the following educational requirements:

(a) Have graduated and received a professional degree from an approved college of pharmacy.

(b) Have graduated from a foreign college of pharmacy, completed a transcript verification program, taken and passed a college of pharmacy equivalency examination program, and completed a process of communication ability testing as defined by the board in order to assure that the applicant meets the standards necessary to protect public health, safety, and welfare.

(4) Supply proof, substantiated by proper affidavits, of a minimum of one year of service and experience through an internship or other program that has been approved by the board under the supervision of a licensed pharmacist, which service shall be predominantly related to the provision of pharmacy primary care and the dispensing of drugs and medical supplies, the compounding of prescriptions, and the keeping of records and the making of reports as required under state and federal law.

(5) Have submitted to the board an application, in the time frame and form prescribed by the board, by regulation.

(Amended by Act 357 of 2012 Legislature, effective August 1, 2012)

(6) Have paid fees specified by the board for the examination, and issuance of the license, certificate, or registration and any related materials.

(7) Have passed an examination or examinations required by the board.

B. Examinations.

(1) Due notice of all meetings for examination of applicants shall be given to all approved colleges of pharmacy in the state.

(2) The board shall determine the content and subject matter of each examination and approve the site and date of the administration of the examination.

(3) The examination shall be prepared to measure the knowledge of the applicant to engage in the practice of pharmacy. The board may employ, cooperate, and contract with any organization or consultant in the preparation and grading of an examination, but shall retain the sole discretion and responsibility for determining which applicants have passed such an examination.

(4) An applicant who takes and satisfactorily completes any board required examinations shall become licensed within one year of the examination dates or the results of the examinations shall become invalid.

(5) An applicant, who takes any board required examinations and is unsuccessful, may repeat the examinations as administratively defined.

(6) An applicant who takes any board required examinations or any examination or examinations in other jurisdictions and is unsuccessful for the third time shall not thereafter be eligible to take the board examination without satisfying the requirements of the board as administratively defined.

(a) An individual who has taken and failed the examinations more than three times may not practice as a pharmacy intern, as administratively defined.

(b) An individual who has taken and failed for the third time a comparable examination to the board's examination within another jurisdiction shall not be eligible to take the examination of the board without satisfying the requirements of the board as administratively defined.

C. Internship and other training programs.

(1) All applicants for licensure by examination shall obtain practical experience in the practice of pharmacy concurrent with attending or after graduation from an approved college of pharmacy, or both, under such terms and conditions as determined by regulation.

(2) The board shall establish such licensure requirements for pharmacy interns and standards for internship, or any other experiential program necessary to qualify an applicant for the licensure examination, and shall also determine the qualifications of preceptors used in practical experience programs as determined by regulation.

§1203. Qualifications for reciprocity

A. In order for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist by reciprocity in this state, an applicant shall:

(1) Have attained the age of twenty-one years.

(2) Have good moral character and be of temperate habits.

(3) Have possessed at the time of initial licensure as a pharmacist all qualifications necessary to have been eligible for licensure at that time in this state.

(4) Have engaged in the practice of pharmacy for a period of at least one year or have met the internship requirements of this state within the one year period immediately previous to the date of such application.

(5) Have submitted an application in the form prescribed by the board.
(Amended by Act 357 of 2012 Legislature, effective August 1, 202)

(6) Have presented to the board evidence of initial licensure by examination and evidence that such license is in good standing.

(7) Have presented to the board evidence of any disciplinary, criminal, or other adverse action, including arrests, taken against him by another licensing jurisdiction, government agency, law enforcement agency, or court. Such action may serve as grounds for the denial of reciprocity to an applicant.
(*Amended by Act 164 of 2006 Legislature, effective August 15, 2006*)

(8) Have paid the fees specified by the board to defray the expenses of making an investigation of his character, general reputation, and licensure status in the state in which he has resided.

(9) Have passed all examinations required by the board.

B. No applicant shall be eligible for licensure by reciprocity unless the state or jurisdiction in which the applicant was initially licensed as a pharmacist also grants reciprocity to a pharmacist duly licensed by examination in this state, under comparable circumstances and conditions.

C. Upon successful completion of the requirements of Subsections A and B, the board shall license the pharmacist within fourteen working days.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 5. Pharmacists

Subchapter A. Licensure Procedures

§506. Preferential licensing procedures for military-trained applicants and their spouses

A. Preferential licensing procedures are available for certain persons. Eligibility for such procedures are available to the following:
   1. A military-trained applicant is a person who:
      a. Has completed a military program of training, been awarded a military occupational specialty, and performed in that specialty at a level that is substantially equivalent to or exceeds the requirements for pharmacist licensure in this state;
      b. Has engaged in the active practice of pharmacy; and
      c. Has not been disciplined in any jurisdiction for an act that would have constituted grounds for refusal, suspension, or revocation of a license to practice pharmacy in this state at the time the act was committed.
   2. A military spouse is a person who:
      a. Can demonstrate marriage to a person in active duty military service or with commitment to reserve duty, as evidenced by legible copies of marriage license and military orders;
      b. Holds a current and unrestricted license to practice pharmacy in another jurisdiction within the United States or any of its territories that has not been disciplined by the agency issuing that license; and
      c. Can demonstrate competency to practice pharmacy through various methods determined by the board, e.g., evidence of continuing education activity, letters of competency from previous practice manager, remediation examination, or personal interview.

B. Upon receipt of an application for pharmacist licensure by a military-trained applicant or military spouse, the board office shall mark the application for priority processing and preserve that status until the license is issued, or in the alternative, the board gives notice of its intent to deny the application and refuse to issue the license.

C. In the event the military-trained applicant or military spouse intends to practice pharmacy before the issuance of the license, the board may issue a Special Work Permit to that person.
   1. The Special Work Permit shall expire 120 days after the date of issue, and the permit shall not be renewable.
   2. The Special Work Permit shall identify the military-trained applicant or military spouse, and further, shall indicate the authority for that person to practice pharmacy within the State of Louisiana as well as the dates of issue and expiration of the credential.
   3. No military-trained applicant or military spouse may practice pharmacy prior to the receipt of a Special Work Permit or pharmacist license, or with an expired Special Work Permit or pharmacist license.
   4. The Special Work Permit shall not be eligible for reciprocity to any other jurisdiction.

D. The provisions of this Section shall not apply to a military-trained applicant who has received, or is in the process of receiving, a dishonorable discharge from the military. Further, the provisions of this Section shall not apply to a military spouse whose spouse has received, or is in the process of receiving, a dishonorable discharge from the military.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3650.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:3075 (November 2013).

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Request for Exception to Enforcement of USP Chapter <800> Standards Handling Hazardous Drugs in Healthcare Settings

(Lloyd's Remedies Pharmacy)

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.*

From:	Malcolm J. Broussard
To:	"duplantisent@aol.com"; bpitre@aol.com; Andy Soileu; Ricky Mannino; mmckaypd@bellsouth.net; millsf@legis.la.gov; lebasb@legis.la.gov; johnson@lipanow.org; rickyindovina@gmail.com; acassidy@aol.com; cajunman66@aol.com; Tanner Magee; Beryl Amedee; Diane Milano; Jackie Hall; Raymond Strong; Douglas Robichaux; Morris Rabb; Chris Melancon; Brian Bond; Ron Moore; Carl Aron; Rhonny Valentine; Don Resweber
Bcc:	Carlos M. Finalet; "M Joseph Fontenot (jfontenot@pharmacy.la.gov)"
Subject:	RE: USP 800 Alternatives
Date:	Friday, July 28, 2017 2:29:00 PM

Mr. Duplantis,

Board President Carl Aron has directed the placement of your request on the agenda for the Board's next meeting. Mr. Aron is scheduled to convene that meeting at 9:00 am on Wednesday, August 23, 2017 at the Board's office at 3388 Brentwood Drive in Baton Rouge, LA 70809-1700. In the event you have any materials for the members to review prior to the meeting, we ask that you direct those materials to my attention at the Board office by the close of business on Friday, August 11, 2017. If you have any questions or need any additional information in the interim, please let me know.

Malcolm J Broussard
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From: duplantisent@aol.com [mailto:duplantisent@aol.com]
Sent: Thursday, July 27, 2017 3:48 PM
To: Malcolm J. Broussard; bpitre@aol.com; Andy Soileu; Ricky Mannino; mmckaypd@bellsouth.net; millsf@legis.la.gov; lebasb@legis.la.gov; johnson@lipanow.org; rickyindovina@gmail.com; acassidy@aol.com; cajunman66@aol.com; Tanner Magee; Beryl Amedee; Diane Milano; Jackie Hall; Raymond Strong; Douglas Robichaux; Morris Rabb; Chris Melancon; Brian Bond; Ron Moore; Carl Aron; Rhonny Valentine; Don Resweber
Subject: USP 800 Alternatives

Dear Sir or Madam,

July 31st, 2018 is fast approaching for the enforcement of USPChapter <800>. Since its release in 2016 many pharmacies have grown concerned with the financial burden that will be placed on them to outfit a negative pressure room and all of the appropriate hoods and materials needed, whether the pharmacy participates in sterile or non-sterile compounding with hazardous drugs. There is now a product that incorporates hazardous hormone powders in to a base that will help decrease the risk of negative exposure to employees, while still providing the same level of care to patients. The Hormone Concentrate Program (HCP) provides estrogens, progesterone, and testosterone diluted in a cream base.

USP Chapter <800> mandates that a pharmacy make a list of the hazardous drugs, as defined in the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, dispensed in the pharmacy and assess for risks that may negatively affect employee health. From there, the pharmacy will provide proper mitigation strategies to minimize any exposure. Common routes of exposure include dermal and mucosal absorption, inhalation, injection, eye exposure and ingestion. As stated in Chapter <800>, "gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding…" A containment-primary engineering control (C-PEC; ventilated device) is not required in the event of working with final dosage forms that do not produce particles, aerosols, or gasses.

Biological Hormone Replacement Therapy (BHRT) is a service that many compounding pharmacies provide to their patients,pursuant to a physician's prescription. Many independent pharmacies that participate in non-sterile compounding are concerned for their patient's access to compounded medications if they do not have the funds to invest in a USP <800> compliant room. BHRT can be provided in several different dosage forms, one of the more popular being topical. Estrone, estradiol, estriol, progesterone, and testosterone all appear on the NIOSH list. When working with powders there would be a concern for eye exposure, inhalation and dermal exposure to employees.

There is now a product on the market that provides the hormones listed above as concentrates; meaning the powder is already incorporated in to the base at a predefined percentage. In order to compound the topical product the pharmacist would need to calculate the desired amount of the hormone as provided by the physician. The concentrate would be weighed with appropriate materials and incorporated in to the remaining amount of base to fill the prescription. Using a concentrate would nearly eliminate an exposure through inhalation and eye exposure. This would leave dermal as the primary route of exposure. Sufficient protection would then be provided by the required gown, head, hair, shoe covers and gloves when compounding with the hormone concentrates. I have confirmed with the national and local OSHA offices that if the airborne risk of powders are eliminated then they would have no concerns. They also agreed that there should be no need for providers to do adhere to the nonsterile hazardous component of USP 800 or bare the burdensome cost of facility upgrades and the unnecessary loads of documentation.

I am asking that the United States Pharmacopeia and the State Boards of Pharmacy recognize these hormone concentrates as an appropriate mitigation strategy when preparing for the enforcement of USP <800>. With little to no risk for inhalation exposure there would not be a need to completely outfit a negative pressure room and a C-PEC with appropriate venting as defined by the chapter. These manufactured creams also provide access to extended dating out to 180 days. This could then provide a solution to pharmacies that want to continue providing the best care to their patients while keeping costs down and not affecting the overall business model.

The manufacturer is willing to be added to the Board of Pharmacy's next agenda to give a presentation and share feedback that they are seeing nationally.

Thanks for your consideration,

Errol Duplantis Jr P.D.
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985-872-4547 pharmacy
318-578-1096 cell

Sent from my iPhone

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Subject:	Board Meeting
Date:	Thursday, August 17, 2017 9:53:39 AM
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It has come to my attention that Errol Duplantis is on the agenda at the Louisiana pharmacy board meeting for a USP 800 exception this next Wednesday August 23, 2017. I know he is last on the agenda but hope that he can speak for many of us in compounding pharmacy. I believe he is looking at HUMCO that has some creams available that can then be manipulated. I agree that there should not be any exposure if following USP 795 standards because you are not manipulating powders. I also have heard that Texas does not plan to incorporate USP 800 into their regulations. There may be parts of it looked at but not the unreasonable standards that are in the proposed standards. There has been some studies (finally) utilizing current USP 795 and estradiol powder and these studies show that there was no powder in the room. If there is no powder in the room then there should be no exposure to the pharmacist. Unfortunately this study is recent and has not yet been published. They are working on that. I would be glad to get the person who did this study to give you more information. It has bothered me from the beginning that the people that developed the USP 800 are the ones making the money. We have a nuclear pharmacy and so we understand exposure and working to make that exposure as low as reasonably achievable. USP 800 is an unreasonable standard that I believe was based on people not using USP 795 standards. There is a difference in chemo and estradiol powder. These standards are supposed to apply to everyone (veterinarians, nurses, doctor's offices and pharmacies). If this goes into effect in July 31, 2018 Line Avenue Compounding will no longer service patients that have medications that are on the hazardous drugs list. **This is important for the continuation of care for patients in Louisiana and the unreasonable cost to patients for the board to take some time to really consider looking at USP 800 and making reasonable regulations concerning it.**

Thanks!

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Add the following:

•⟨800⟩ HAZARDOUS DRUGS—HANDLING IN HEALTHCARE SETTINGS

(Chapter to become official July 1, 2018.)

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 that 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:

- A list of HDs
- Facility and 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 and Engineering Controls
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, and Disposal
12. Dispensing Final Dosage Forms
13. Compounding
14. Administering
15. Deactivating, Decontaminating, Cleaning, and Disinfecting
16. Spill Control
17. Documentation and Standard Operating Procedures
18. Medical Surveillance

Glossary
Appendices

Appendix 1: Acronyms
Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas
Appendix 3: Types of Biological Safety Cabinets

References

2. LIST OF HAZARDOUS DRUGS

The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs used in healthcare. An entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. The entity's list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity's list.

The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs. These criteria must be used to identify HDs that enter the market after the most recent version of the NIOSH list, or that the entity handles as an investigational drug. If the information available on a drug is deemed insufficient to make an informed decision, consider the drug hazardous until more information is available.

Box 1: Containment Requirements

- Drugs on the NIOSH list that must follow the requirements in this chapter include:
  - — Any HD API
  - — Any antineoplastic requiring HD manipulation
- Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented include:
  - — Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (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

Some dosage forms of drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (e.g., tablets or capsules—solid, intact medications that are administered to patients without modifying the formulation). However, dust from tablets and capsules may present a risk of exposure by skin contact and/or inhalation. An assessment of risk may be performed for these dosage forms to determine alternative containment strategies and/or work practices. If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in this chapter.

The assessment of risk must, at a minimum, consider the following:

- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least every 12 months and the review documented.

3. TYPES OF EXPOSURE

Routes of unintentional entry of HDs into the body include dermal and mucosal absorption, inhalation, injection, and ingestion (e.g., contaminated foodstuffs, spills, or mouth contact with contaminated hands). Containers of HDs have been shown to be contaminated upon receipt. Both clinical and nonclinical personnel may be exposed to HDs when they handle HDs or touch contaminated surfaces. *Table 1* lists examples of potential routes of exposure based on activity.

Table 1. Examples of Potential Opportunities of Exposure Based on Activity

Activity	Potential Opportunity of Exposure
Receipt	• Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces, or floors
Dispensing	• Counting or repackaging tablets and capsules
Compounding and other manipulations	• Crushing or splitting tablets or opening capsules • Pouring oral or topical liquids from one container to another • Weighing or mixing components • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting HD residue present on PPE or other garments • Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs • Maintenance activities for potentially contaminated equipment and devices
Administration	• Generating aerosols during administration of HDs by various routes (e.g., injection, irrigation, oral, inhalation, or topical application) • Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation) • Priming an IV administration set

Activity	Potential Opportunity of Exposure
Patient-care activities	• Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials
Spills	• Spill generation, management, and disposal
Transport	• Moving HDs within a healthcare setting
Waste	• Collection and disposal of hazardous waste and trace contaminated waste

4. RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS

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 person 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 person must also be responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results.

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 patient-care environment.

Change to read:

5. FACILITIES AND ENGINEERING CONTROLS

HDs must be handled under conditions that promote patient safety, worker safety, and environmental protection. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. 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.

Designated areas must be available for:

- Receipt and unpacking
- Storage of HDs
- Nonsterile HD compounding (if performed by the entity)
- Sterile HD compounding (if performed by the entity)

Certain areas are required to have negative pressure from surrounding areas to contain HDs and minimize risk of exposure. Consideration should be given to uninterrupted power sources (UPS) for the ventilation systems to maintain negative pressure in the event of power loss.

5.1 Receipt

Antineoplastic HDs and all HD APIs must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.

5.2 Storage

HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.

Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.

Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)]. If a refrigerator is placed in a negative pressure buffer room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator should be considered.

5.3 Compounding

Engineering controls are required to protect the preparation from cross-contamination and microbial contamination (if preparation is intended to be sterile) during all phases of the compounding process. Engineering controls for containment are divided into three categories representing primary, secondary, and supplementary levels of control. A containment primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs. The containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed. Supplemental engineering controls [e.g., closed-system drug-transfer device (CSTD)] are adjunct controls to offer additional levels of protection. *Appendix 2* provides examples for designs of HD compounding areas.

Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC. The C-SEC used for sterile and nonsterile compounding must:

- Be externally vented •(ERR 1-Jun-2016)
- Be physically separated (i.e., a different room from other preparation areas)
- Have an appropriate air exchange (e.g., ACPH)
- Have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas

The C-PEC must operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding. If there is any loss of power to the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC must be suspended immediately. If necessary, protect the unit by covering it appropriately per the manufacturer's recommendations. Once the C-PEC can be powered on, decontaminate, clean, and disinfect (if used for sterile compounding) all surfaces and wait the manufacturer-specified recovery time before resuming compounding.

A sink must be available for hand washing. An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. Care must be taken to locate water sources and drains in areas where their presence will not interfere with required ISO classifications. Water sources and drains must be located at least 1 meter away from the C-PEC.

For entities that compound both nonsterile and sterile HDs, the respective C-PECs must be placed in separate rooms, unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process.

5.3.1 NONSTERILE COMPOUNDING

In addition to this chapter, nonsterile compounding must follow standards in *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*. A C-PEC is not required if manipulations are limited to handling of final dosage forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses.

The C-PECs used for manipulation of nonsterile HDs must be either externally vented (preferred) or have redundant–HEPA filters in series. Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A Class II BSC or a compounding aseptic containment isolator (CACI) may also be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC. A C-PEC used only for nonsterile compounding does not require unidirectional airflow because the critical environment does not need to be ISO classified.

The C-PEC must be placed in a C-SEC that has at least 12 ACPH. *Table 2* summarizes the engineering controls required for nonsterile HD compounding.

Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

Table 2. Engineering Controls for Nonsterile HD Compounding

C-PEC	C-SEC Requirements
• Externally vented (preferred) or redundant–HEPA filtered in series • Examples: CVE, Class I or II BSC, CACI	• Externally vented • 12 ACPH • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas

5.3.2 STERILE COMPOUNDING

In addition to this chapter, sterile compounding must follow standards in ⟨797⟩.

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 an ISO 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 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 3* 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 with an ISO Class 7 ante-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 described 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 with an ISO Class 7 ante-room	• Externally vented • Examples: Class II BSC or CACI	• Externally vented • 30 ACPH • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas	As described in ⟨797⟩
Unclassified C-SCA	• Externally vented • Examples: Class II BSC or CACI	• Externally vented • 12 ACPH • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas	As described in ⟨797⟩ for CSPs prepared in a segregated compounding area

ISO Class 7 buffer room with an ISO class 7 ante-room: The C-PEC is placed in an ISO Class 7 buffer room that has fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 30 ACPH.

The buffer room must be externally vented. Because the room through which entry into the HD buffer room (e.g., ante-room or non-HD buffer room) plays an important role in terms of total contamination control, the following is required:

- Minimum of 30 ACPH of HEPA-filtered supply air
- Maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas
- Maintain an air quality of ISO Class 7 or better

An ISO Class 7 ante-room with fixed walls is necessary to provide inward air migration of equal cleanliness classified air into the negative pressure buffer room to contain any airborne HD. A hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the HD buffer room to avoid contamination migration into the negative pressure HD buffer room.

Although not a recommended facility design, if the negative-pressure HD buffer room is entered though the positive-pressure non-HD buffer room, the following is also required:

- A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE
- A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space. The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room. A refrigerator pass-through must not be used. Other methods of containment (such as sealed containers) may be used.

HD CSPs prepared in an ISO Class 7 buffer room with an ISO Class 7 ante-room may use the BUDs described in ⟨797⟩, based on the categories of CSP, sterility testing, and storage temperature.

Containment segregated compounding area (C-SCA): The C-PEC is placed in an unclassified C-SCA that has fixed walls, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas, and a minimum of 12 ACPH. The C-SCA must be externally vented. A hand-washing sink must be placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA.

Only low- and medium-risk HD CSPs may be prepared in a C-SCA. HD CSPs prepared in the C-SCA must not exceed the BUDs described in ⟨797⟩ for CSPs prepared in a segregated compounding area.

5.4 Containment Supplemental Engineering Controls

Containment supplemental engineering controls, such as CSTDs, provide adjunct controls to offer an additional level of protection during compounding or administration. Some CSTDs have been shown to limit the potential of generating aerosols during compounding. However, there is no certainty that all CSTDs will perform adequately. Until a published universal

performance standard for evaluation of CSTD containment is available, users should carefully evaluate the performance claims associated with available CSTDs based on independent, peer-reviewed studies and demonstrated containment reduction.

A CSTD must not be used as a substitute for a C-PEC when compounding. CSTDs should be used when compounding HDs when the dosage form allows. CSTDs must be used when administering antineoplastic HDs when the dosage form allows. CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD.

6. ENVIRONMENTAL QUALITY AND CONTROL

Environmental wipe sampling for HD surface residue should be performed routinely (e.g., initially as a benchmark and at least every 6 months, or more often as needed, to verify containment). Surface wipe sampling should include:

- Interior of the C-PEC and equipment contained in it
- Pass-through chambers
- Surfaces in staging or work areas near the C-PEC
- Areas adjacent to C-PECs (e.g., floors directly under C-PEC, staging, and dispensing area)
- Areas immediately outside the HD buffer room or the C-SCA
- Patient administration areas

There are currently no studies demonstrating the effectiveness of a specific number or size of wipe samples in determining levels of HD contamination. Wipe sampling kits should be verified before use to ensure the method and reagent used have been tested to recover a specific percentage of known marker drugs from various surface types found in the sampled area. There are currently no certifying agencies for vendors of wipe sample kits.

There is currently no standard for acceptable limits for HD surface contamination. Common marker HDs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, fluorouracil, and platinum-containing drugs. An example of measurable contamination would be cyclophosphamide levels >1.00 ng/cm^2, which were shown in some studies to result in uptake of the drug in exposed workers. If any measurable contamination is found, the designated person must identify, document, and contain the cause of contamination. Such action may include reevaluating work practices, re-training personnel, performing thorough deactivation, decontamination, cleaning, and improving engineering controls. Repeat the wipe sampling to validate that the deactivation/decontamination and cleaning steps have been effective.

7. PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) provides worker protection to reduce exposure to HD aerosols and residues. Additional PPE may be required to handle the HDs outside of a C-PEC, such as treating a patient or cleaning a spill. The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in healthcare settings. Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.

Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs. Two pairs of chemotherapy gloves are required for administering antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs. For all other activities, the entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used). The entity must develop SOPs for PPE based on the risk of exposure (see *Types of Exposure*) and activities performed.

Appropriate PPE must be worn when handling HDs including during:

- Receipt
- Storage
- Transport
- Compounding (sterile and nonsterile)
- Administration
- Deactivation/decontamination, cleaning, and disinfecting
- Spill control
- Waste disposal

7.1 Gloves

When chemotherapy gloves are required, they must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor). Chemotherapy gloves should be worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs. Chemotherapy gloves must be powder-free because powder can contaminate the work area and can adsorb and retain HDs. Gloves must be inspected for physical defects before use. Do not use gloves with pin holes or weak spots.

When used for sterile compounding, the outer chemotherapy gloves must be sterile. Chemotherapy gloves should be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated. Hands must be washed with soap and water after removing gloves.

7.2 Gowns

When gowns are required, they must be disposable and shown to resist permeability by HDs. Gowns must be selected based on the HDs handled. Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better

protection than those made of uncoated materials. Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through.

Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials are not appropriate protective outerwear when handling HDs because they permit the permeation of HDs and can hold spilled drugs against the skin, thereby increasing exposure. Clothing may also retain HD residue from contact, and may transfer to other healthcare workers or various surfaces. Washing of non-disposable clothing contaminated with HD residue should only be done according to facility policy as drug residue may be transferred to other clothing. Potentially contaminated clothing must not be taken home under any circumstances.

Gowns must be changed per the manufacturer's information for permeation of the gown. If no permeation information is available for the gowns used, change them every 2–3 hours or immediately after a spill or splash. Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.

7.3 Head, Hair, Shoe, and Sleeve Covers

Head and hair covers (including beard and moustache, if applicable), shoe covers, and sleeve covers provide protection from contact with HD residue. When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC. Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.

Disposable sleeve covers may be used to protect areas of the arm that may come in contact with HDs. Disposable sleeve covers made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials.

7.4 Eye and Face Protection

Many HDs are irritating to the eyes and mucous membranes. Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., administration in the surgical suite, working at or above eye level, or cleaning a spill). A full-facepiece respirator provides eye and face protection. Goggles must be used when eye protection is needed. Eye glasses alone or safety glasses with side shields do not protect the eyes adequately from splashes. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection.

7.5 Respiratory Protection

Personnel who are unpacking HDs that are not contained in plastic should wear an elastomeric half-mask with a multi-gas cartridge and P100-filter until assessment of the packaging integrity can be made to ensure no breakage or spillage occurred during transport. If the type of drug can be better defined, a more targeted cartridge can be used.

Surgical masks do not provide respiratory protection from drug exposure and must not be used when respiratory protection from HD exposure is required. A surgical N95 respirator provides the respiratory protection of an N95 respirator, and like a surgical mask, provides a barrier to splashes, droplets, and sprays around the nose and mouth.

For most activities requiring respiratory protection, a fit-tested NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles. However, N95 respirators offer no protection against gases and vapors and little protection against direct liquid splashes (see the Centers for Disease Control and Prevention's (CDC's) Respirator Trusted-Source Information).

Fit test the respirator and train workers to use respiratory protection. Follow all requirements in the Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134). An appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) should be worn when there is a risk of respiratory exposure to HDs, including when:

- Attending to HD spills larger than what can be contained with a spill kit
- Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
- There is a known or suspected airborne exposure to powders or vapors

7.6 Disposal of Used Personal Protective Equipment

Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC. Chemotherapy gloves and sleeve covers (if used) worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.

8. HAZARD COMMUNICATION PROGRAM

Entities are required to establish policies and procedures that ensure worker safety during all aspects of HD handling. The entity must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

Elements of the hazard communication program plan must include:

- A written plan that describes how the standard will be implemented
- All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings
- Entities must have an SDS for each hazardous chemical they use (29 CFR 1910.1200)
- Entities must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas
- Personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes
- Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

9. PERSONNEL TRAINING

All personnel who handle HDs must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs). Training must occur before the employee independently handles HDs. The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be reassessed at least every 12 months. Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP. All training and competency assessment must be documented.

The training must include at least the following:

- Overview of entity's list of HDs and their risks
- Review of the entity's SOPs related to handling of HDs
- Proper use of PPE
- Proper use of equipment and devices (e.g., engineering controls)
- Response to known or suspected HD exposure
- Spill management
- Proper disposal of HDs and trace-contaminated materials

10. RECEIVING

The entity must establish SOPs for receiving HDs. HDs should be received from the supplier in impervious plastic to segregate them from other drugs and to allow for safety in the receiving and internal transfer process. HDs must be delivered to the HD storage area immediately after unpacking.

PPE, including chemotherapy gloves, must be worn when unpacking HDs (see *Personal Protective Equipment*). A spill kit must be accessible in the receiving area.

The entity must enforce policies that include a tiered approach, starting with visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass). *Table 4* summarizes the steps for receiving and handling of damaged shipping containers.

Table 4. Summary of Requirements for Receiving and Handling Damaged HD Shipping Containers

If the shipping container appears damaged	• Seal container without opening and contact the supplier • If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous" • If the supplier declines return, dispose of as hazardous waste
If a damaged shipping container must be opened	• Seal the container in plastic or an impervious container • Transport it to a C-PEC and place on a plastic-backed preparation mat • Open the package and remove undamaged items • Wipe the outside of the undamaged items with a disposable wipe • Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous" • If the supplier declines return, dispose of as hazardous waste • Deactivate, decontaminate, and clean the C-PEC (see *Deactivating, Decontaminating, Cleaning, and Disinfecting*) and discard the mat and cleaning disposables as hazardous waste

When opening damaged shipping containers, they should preferably be transported to a C-PEC designated for nonsterile compounding. If a C-PEC designated for sterile compounding is the only one available, it must be disinfected after the decontamination, deactivation, and cleaning step before returning to any sterile compounding activity.

Damaged packages or shipping cartons must be considered spills that must be reported to the designated person and managed according to the entity's SOPs. Segregate HDs waiting to be returned to the supplier in a designated negative pressure area. Clean-up must comply with established SOPs.

11. LABELING, PACKAGING, TRANSPORT AND DISPOSAL

The entity must establish SOPs for the labeling, packaging, transport, and disposal of HDs. The SOPs must address prevention of accidental exposures or spills, personnel training on response to exposure, and use of a spill kit. Examples of special exposure-reducing strategies include small-bore connectors (such as Luer Lock) and syringes, syringe caps, CSTDs, the capping of container ports, sealed impervious plastic bags, impact-resistant and/or water-tight containers, and cautionary labeling.

11.1 Labeling

HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during their transport. Personnel must ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.

11.2 Packaging

Personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport. Packaging materials must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. The entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.

11.3 Transport

HDs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations. HDs must be transported in containers that minimize the risk of breakage or leakage. Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination.

When shipping HDs to locations outside the entity, the entity must consult the Transport Information on the SDS. The entity must ensure that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.

11.4 Disposal

All personnel who perform routine custodial waste removal and cleaning activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment to prevent HD contamination. Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations.

12. DISPENSING FINAL DOSAGE FORMS

HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage).

Counting or repackaging of HDs must be done carefully. Clean equipment should be dedicated for use with HDs and should be decontaminated after every use. Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants.

13. COMPOUNDING

Entities and personnel involved in compounding HDs must be compliant with the appropriate USP standards for compounding including ⟨795⟩ and ⟨797⟩. Compounding must be done in proper engineering controls as described in *Compounding*. When compounding HD preparations in a C-PEC, a plastic-backed preparation mat should be placed on the work surface of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use, and should be discarded at the end of the daily compounding activity. Disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs.

Bulk containers of liquid and API HD must be handled carefully to avoid spills. If used, APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder).

14. ADMINISTERING

HDs must be administered safely using protective medical devices and techniques. Examples of protective medical devices include needleless and closed systems. Examples of protective techniques include spiking or priming of IV tubing with a non-HD solution in a C-PEC and crushing tablets in a plastic pouch.

Appropriate PPE must be worn when administering HDs. After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration. Equipment (such as tubing and needles) and packaging materials must be disposed of properly, such as in HD waste containers, after administration.

CSTDs must be used for administration of antineoplastic HDs when the dosage form allows. Techniques and ancillary devices that minimize the risk posed by open systems must be used when administering HDs through certain routes. Administration into certain organs or body cavities (e.g., the bladder, eye, peritoneal cavity, or chest cavity) often requires equipment for which locking connections may not be readily available or possible.

Healthcare personnel should avoid manipulating HDs such as crushing tablets or opening capsules if possible. Liquid formulations are preferred if solid oral dosage forms are not appropriate for the patient. If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, personnel must don appropriate PPE and use a plastic pouch to contain any dust or particles generated.

15. DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING

All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Additionally, sterile compounding areas and devices must be subsequently disinfected.

The entity must establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection. Additionally, cleaning of nonsterile compounding areas must comply with ⟨795⟩ and cleaning of sterile compounding areas must comply with ⟨797⟩. Written procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements.

All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment from contamination. All personnel performing these activities must wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns (see *Personal Protective Equipment*). Additionally, eye protection and face shields must be used if splashing is likely. If warranted by the activity, respiratory protection must be used.

The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials. The products used must be compatible with the surface material. Consult manufacturer or supplier information for compatibility with cleaning agents used. Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading HD residue. All disposable materials must be discarded to meet EPA regulations and the entity's policies. Perform cleaning in areas that are sufficiently ventilated. *Table 5* summarizes the purpose and example agents for each step.

Table 5. Cleaning Steps

Cleaning Step	Purpose	Example Agents
Deactivation	Render compound inert or inactive	As listed in the HD labeling or other agents which may incorporate Environmental Protection Agency (EPA)-registered oxidizers (e.g., peroxide formulations, sodium hypochlorite, etc.)
Decontamination	Remove HD residue	Materials that have been validated to be effective for HD decontamination, or through other materials proven to be effective through testing, which may include alcohol, water, peroxide, or sodium hypochlorite
Cleaning	Remove organic and inorganic material	Germicidal detergent
Disinfection (for sterile manipulations)	Destroy microorganisms	EPA-registered disinfectant and/or sterile alcohol as appropriate for use

15.1 Deactivation

Deactivation renders a compound inert or inactive. Residue from deactivation must be removed by decontaminating the surface.

There is no one proven method for deactivating all compounds. The ultimate goal should be complete surface decontamination. Products that have known deactivation properties (EPA-registered oxidizing agents that are appropriate for the intended use) should be used when possible. Care should be taken when selecting materials for deactivation due to potential adverse effects (hazardous byproducts, respiratory effects, and caustic damage to surfaces). Damage to surfaces is exhibited by corrosion to stainless steel surfaces caused by sodium hypochlorite if left untreated. To prevent corrosion, sodium hypochlorite must be neutralized with sodium thiosulfate or by following with an agent to remove the sodium hypochlorite (e.g., sterile alcohol, sterile water, germicidal detergent, or sporicidal agent).

15.2 Decontamination

Decontamination occurs by inactivating, neutralizing, or physically removing HD residue from non-disposable surfaces and transferring it to absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area being cleaned. When choosing among various products available for decontaminating HDs, consideration should be given to surface compatibility and facility requirements. It is imperative to adhere to manufacturer's use instructions. Because of the growing number of assays available for HDs, additional surface wipe sampling is now possible and should be done to document the effectiveness of any agent used for decontamination of HD residue from work surfaces (see *Environmental Quality and Control*).

The amount of HD contamination introduced into the C-PEC may be reduced by wiping down HD containers. The solution used for wiping HD packaging must not alter the product label. The work surface of the C-PEC must be decontaminated between compounding of different HDs. The C-PEC must be decontaminated at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.

C-PECs may have areas under the work tray where contamination can build up. These areas must be deactivated, decontaminated, and cleaned at least monthly to reduce the contamination level in the C-PEC. Accessing this area may be difficult. Deactivate, decontaminate, and clean as much as possible of the C-PEC surfaces before accessing the area under the work tray. When deactivating, decontaminating, and cleaning the area under the work tray of a C-PEC, the containment airflows are compromised by opening the cabinets. To provide protection to the worker performing this task, respiratory protection may be required.

15.3 Cleaning

Cleaning is a process that results in the removal of contaminants (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergents, surfactants, solvents, and/or other chemicals. Cleaning agents used on compounding equipment should not introduce microbial contamination. No cleaning step may be performed when compounding activities are occurring.

15.4 Disinfection

Disinfection is a process of inhibiting or destroying microorganisms. Before disinfection can be adequately performed, surfaces must be cleaned. Disinfection must be done for areas intended to be sterile, including the sterile compounding areas.

16. SPILL CONTROL

All personnel who may be required to clean up a spill of HDs must receive proper training in spill management and the use of PPE and NIOSH-certified respirators (see *Personal Protective Equipment*). Spills must be contained and cleaned immediately only by qualified personnel with appropriate PPE. Qualified personnel must be available at all times while HDs are being handled. Signs must be available for restricting access to the spill area. Spill kits containing all of the materials needed to clean HD spills must be readily available in all areas where HDs are routinely handled. If HDs are being prepared or administered in a non-routine healthcare area, a spill kit and respirator must be available. All spill materials must be disposed of as hazardous waste.

The circumstances and management of spills must be documented. Personnel who are potentially exposed during the spill or spill clean up or who have direct skin or eye contact with HDs require immediate evaluation. Non-employees exposed to an HD spill should follow entity policy, which may include reporting to the designated emergency service for initial evaluation and completion of an incident report or exposure form.

SOPs must be developed to prevent spills and to direct the clean up of HD spills. SOPs must address the size and scope of the spill and specify who is responsible for spill management and the type of PPE required. The management of the spill (e.g., decontamination, deactivation, and cleaning) may be dependent on the size and type of spill. The SOP must address the location of spill kits and clean-up materials as well as the capacity of the spill kit. Written procedures should address use of appropriate full-facepiece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

17. DOCUMENTATION AND STANDARD OPERATING PROCEDURES

The entity must maintain SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a facility. The SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented. Revisions in forms or records must be made as needed and communicated to all personnel handling HDs.

The SOPs for handling of HDs should include:

- Hazard communication program
- Occupational safety program
- Designation of HD areas
- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs)
- Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal)

- Deactivation, decontamination, cleaning, and disinfection
- Dispensing
- Transport
- Administering
- Environmental monitoring (e.g., wipe sampling)
- Disposal
- Spill control
- Medical surveillance

Personnel who transport, compound, or administer HDs must document their training according to OSHA standards (see OSHA Standard 1910.120 Hazardous Waste Operations and Emergency Response) and other applicable laws and regulations.

18. MEDICAL SURVEILLANCE

Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE. Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program. The general purpose of surveillance is to minimize adverse health effects in personnel potentially exposed to HDs. Medical surveillance programs involve assessment and documentation of symptom complaints, physical findings, and laboratory values (such as a blood count) to determine whether there is a deviation from the expected norms.

Medical surveillance can also be viewed as a secondary prevention tool that may provide a means of early detection if a health problem develops. Tracking personnel through medical surveillance allows the comparison of health variables over time in individual workers, which may facilitate early detection of a change in a laboratory value or health condition. Medical surveillance programs also look for trends in populations of workers. Examining grouped data compared with data from unexposed workers may reveal a small alteration or increase in the frequency of a health effect that would be obscured if individual workers' results alone were considered.

Medical surveillance evaluates the protection afforded by engineering controls, other administrative controls, safe work processes, PPE, and worker education about the hazards of the materials they work with in the course of their duties. The data-gathering elements of a medical surveillance program are used to establish a baseline of workers' health and then to monitor their future health for any changes that may result from exposure to HDs.

Elements of a medical surveillance program should be consistent with the entity's Human Resource policies and should include:

- Development of an organized approach to identify workers who are potentially exposed to HDs on the basis of their job duties
- Use of an entity-based or contracted employee health service to perform the medical surveillance while protecting the confidentiality of the employees' personal medical information
- Initial baseline assessment (pre-placement) of a worker's health status and medical history. Data elements collected include a medical (including reproductive) history and work history to assess exposure to HDs, physical examination, and laboratory testing. Methods used to assess exposure history include a review of:
  - — Records of HDs handled, with quantities and dosage forms
  - — Estimated number of HDs handled per week
  - — Estimates of hours spent handling HDs per week and/or per month
  - — Performance of a physical assessment and laboratory studies linked to target organs of commonly used HDs, such as a baseline complete blood count. Biological monitoring to determine blood or urine levels of specific HDs is not currently recommended in surveillance protocols, but may have a role in the follow-up of acute spills with a specific agent.
- Medical records of surveillance should be maintained according to OSHA regulation concerning access to employee exposure and medical records
- Monitoring workers' health prospectively through periodic surveillance using the elements of data gathering described above (updated health and exposure history, physical assessment, and laboratory measures, if appropriate)
- Monitoring of the data to identify prevention failure leading to health effects; this monitoring may occur in collaboration with the employee health service
- Development of a follow-up plan for workers who have shown health changes suggesting toxicity or who have experienced an acute exposure. This follow-up should include evaluation of current engineering and administrative controls and equipment to ensure that all systems are appropriately and accurately implemented (see *Follow-Up Plan*)
- Completion of an exit examination when a worker's employment at the entity ends, to document the information on the employee's medical, reproductive, and exposure histories. Examination and laboratory evaluation should be guided by the individual's history of exposures and follow the outline of the periodic evaluation

18.1 Follow-Up Plan

The occurrence of exposure-related health changes should prompt immediate re-evaluation of primary preventive measures (e.g., administrative and engineering controls, PPE, and others). In this manner, medical surveillance acts as a check on the effectiveness of controls already in use.

The entity should take the following actions:

- Perform a post-exposure examination tailored to the type of exposure (e.g., spills or needle sticks from syringes containing HDs). An assessment of the extent of exposure should be conducted and included in a confidential database and in an incident report. The physical examination should focus on the involved area as well as other organ systems commonly affected (i.e., the skin and mucous membranes for direct contact or inhalation; the pulmonary system for aerosolized HDs). Treatment and laboratory studies will follow as indicated and be guided by emergency protocols
- Compare performance of controls with recommended standards; conduct environmental sampling when analytical methods are available
- Verify and document that all engineering controls are in proper operating condition
- Verify and document that the worker complied with existing policies. Review policies for the use of PPE and employee compliance with PPE use and policies. Review availability of appropriate PPE (see *Personal Protective Equipment*)
- Develop and document a plan of action that will prevent additional exposure of workers
- Ensure confidential, two-way communication between the worker and the employee health unit(s) regarding notification, discussions about a change in health condition, or detection of an adverse health effect
- Provide and document a follow-up medical survey to demonstrate that the plan implemented is effective
- Ensure that any exposed worker receives confidential notification of any adverse health effect. Offer alternative duty or temporary reassignment
- Provide ongoing medical surveillance of all workers at risk for exposure to HDs to determine whether the plan implemented is effective

GLOSSARY

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.

Ante-room: An ISO Class 7 or cleaner room where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels are performed. The ante-room is the transition room between the unclassified area of the facility and the buffer room.

Assessment of risk: Evaluation of risk to determine alternative containment strategies and/or work practices.

Beyond-use date (BUD): The date or time beyond which a compounded preparation cannot not be used and must be discarded (see ⟨795⟩ and ⟨797⟩). The date or time is determined from the date or time when the preparation was compounded.

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 3* for details.

Buffer room: A type of C-SEC under negative pressure that meets ISO Class 7 or better air quality where the C-PEC that generates and maintains an ISO Class 5 environment 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.

Classified space: An area that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).

Cleaning: The process of removing 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.

Compounding aseptic containment isolator (CACI): A specific type of CAI that is designed for the compounding of sterile HDs. The CACI is designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment with unidirectional airflow for compounding sterile preparations.

Compounding aseptic isolator (CAI): An isolator specifically designed for compounding sterile, non-hazardous pharmaceutical ingredients or preparations. The CAI is designed to maintain an aseptic compounding environment throughout the compounding and material transfer processes.

Compounding personnel: Individuals who participate in the compounding process.

Containment primary engineering control (C-PEC): A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants through the following:

- The full or partial enclosure of a potential contaminant source

- The use of airflow capture velocities to trap and remove airborne contaminants near their point of generation
- The use of air pressure relationships that define the direction of airflow into the cabinet
- The use of HEPA filtration on all potentially contaminated exhaust streams

Containment secondary engineering control (C-SEC): The room with fixed walls in which the C-PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room.
Containment segregated compounding area (C-SCA): A type of C-SEC with nominal requirements for airflow and room pressurization as they pertain to HD compounding.
Containment ventilated enclosure (CVE): A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Deactivation: Treatment of an HD contaminant on surfaces with a chemical, heat, ultraviolet light, or another agent to transform the HD into a less hazardous agent.
Decontamination: Inactivation, neutralization, or removal of HD contaminants on surfaces, usually by chemical means.
Doff: To remove PPE.
Don: To put on PPE.
Disinfection: The process of inhibiting or destroying microorganisms.
Engineering control: Primary, secondary, and supplemental devices designed to eliminate or reduce worker exposure to HDs.
EPA-registered disinfectant: Antimicrobial products registered with the Environmental Protection Agency (EPA) for healthcare use against pathogens specified in the product labeling.
Externally vented: Exhausted to the outside
Final dosage form: Any form of a medication that requires no further manipulation before administration.
Globally Harmonized System of Classification and Labeling of Chemicals (GHS): A system for standardizing and harmonizing the classification and labeling of chemicals.
Goggles: Tight-fitting eye protection that completely covers the eyes, eye sockets, and facial area that immediately surrounds the eyes. Goggles provide protection from impact, dust, and splashes. Some goggles fit over corrective lenses.
Hazardous drug (HD): Any drug identified by at least one of the following criteria:

- Carcinogenicity, teratogenicity, or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low dose in humans or animals
- Genotoxicity or new drugs that mimic existing HDs in structure or toxicity

High-efficiency particulate air (HEPA) filtration: An extended-medium, dry-type filter in a rigid frame, having a minimum particle collection efficiency of 99.97% for particles with a mass median diameter of 0.3 µm when tested at a rated airflow in accordance with MIL STD 282 using IEST Recommended Standard RP-CC001.5.
Negative-pressure room: A room that is maintained at a lower pressure than the adjacent areas; therefore the net flow of air is into the room.
Pass-through: An enclosure with interlocking doors that is positioned between two spaces for the purpose of reducing particulate transfer while moving materials from one space to another. A pass-through serving negative-pressure rooms needs to be equipped with sealed doors.
Personal protective equipment (PPE): Items such as gloves, gowns, respirators, goggles, faceshields, and others that protect individual workers from hazardous physical or chemical exposures.
Positive-pressure room: A room that is maintained at a higher pressure than the adjacent areas; therefore, the net flow of air is out of the room.
Repackaging: The act of removing a product from its original primary container and placing it into another primary container, usually of smaller size.
Safety data sheet (SDS): An informational document that provides written or printed material concerning a hazardous chemical. The SDS is prepared in accordance with the HCS [previously known as a Material Safety Data Sheet (MSDS)].
Spill kit: A container of supplies, warning signage, and related materials used to contain the spill of an HD.
Standard operating procedure (SOP): Written procedures describing operations, testing, sampling, interpretation of results, and corrective actions that relate to the operations that are taking place.
Supplemental engineering control: An adjunct control (e.g., CSTD) that may be used concurrently with primary and secondary engineering controls. Supplemental engineering controls offer additional levels of protection and may facilitate enhanced occupational protection, especially when handling HDs outside of primary and secondary engineering controls (e.g., during administering).
Unclassified space: A space not required to meet any air cleanliness classification based on the International Organization for Standardization (ISO).

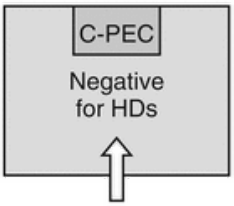
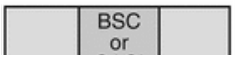
Change to read:

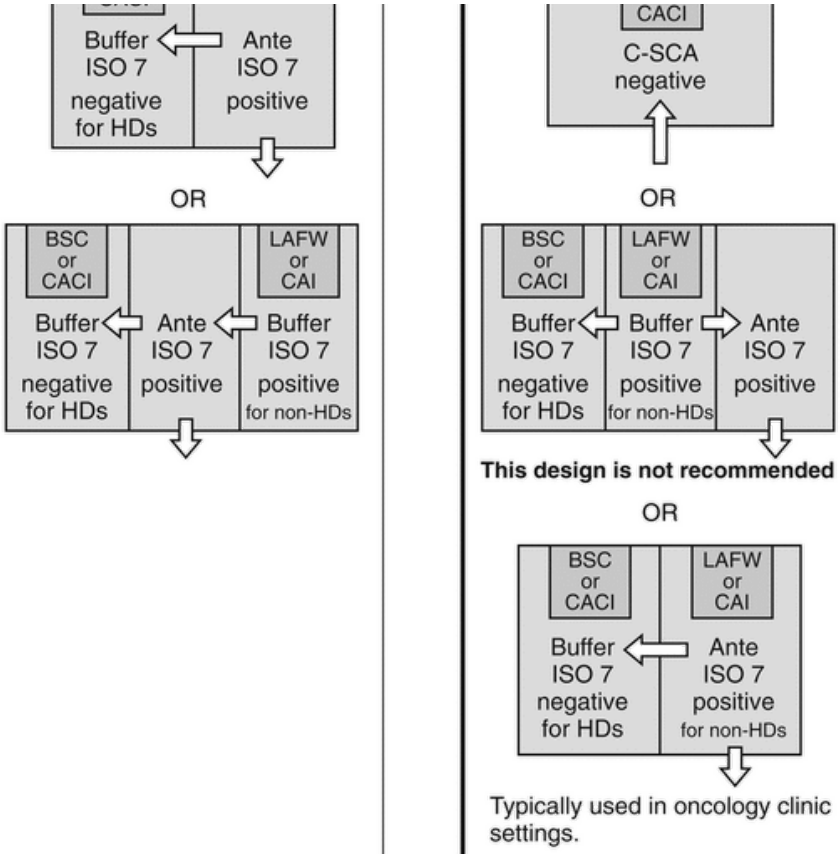
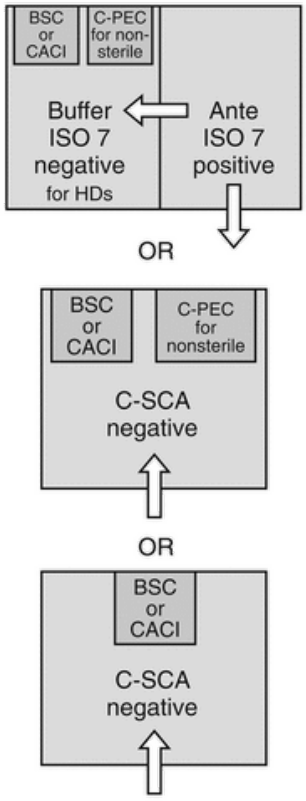
APPENDICES

Appendix 1: Acronyms

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
HCS	Hazard Communication Standard
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
PAPR	Powered air-purified respirator
PPE	Personal protective equipment
SDS	Safety Data Sheet
SOP	Standard operating procedure
ULPA	Ultra-low particulate air
UPS	Uninterrupted power source

Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas[a]

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>

				30 30	for segregated compounding area. If this design is in place, measures must be taken to avoid contamination of the positive-pressure buffer room. Maximum BUD as described in <797>.
Both sterile HD and nonsterile HD compounding	A separate room for sterile and nonsterile compounding is recommended			30 12 12	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. Maximum BUD as described in <797> for segregated compounding area. Maximum BUD as described in <797> for segregated compounding area.

[a] The arrows indicate direction of airflow.

Appendix 3: Types of Biological Safety Cabinets

Class I: A BSC that protects personnel and the environment but does not protect the product/preparation. A minimum velocity of 75 linear feet/minute of unfiltered room air is drawn through the front opening and across the work surface, providing personnel protection. The air is then passed through a HEPA/ULPA (ultra-low particulate air) filter, either into the room or to the outside in the exhaust plenum, providing environmental protection.

Class II: Class II (Types A1, A2, B1, and B2) BSCs are partial barrier systems that rely on the movement of air to provide personnel, environmental, and product/preparation protection. Personnel and product/preparation protection are provided by the combination of inward and downward airflow captured by the front grille of the cabinet. Side-to-side cross-contamination of products/preparations is minimized by the internal downward flow of HEPA/ULPA filtered air moving toward the work surface and then drawn into the front and rear intake grilles. Environmental protection is provided when the cabinet exhaust air is passed through a HEPA/ULPA filter.

Type A1 (formerly, Type A): These Class II BSCs maintain a minimum inflow velocity of 75 feet/minute; have HEPA-filtered, down-flow air that is a portion of the mixed down-flow and inflow air from a common plenum; may exhaust HEPA-filtered air back into the laboratory or to the environment through an exhaust canopy; and may have positive-pressure contaminated ducts and plenums that are not surrounded by negative-pressure plenums. Type A1 BSCs are not suitable for use with volatile toxic chemicals and volatile •radionuclides.• (ERR 1-Oct-2016)

Type A2 (formerly, Type B3): These Class II BSCs maintain a minimum inflow velocity of 100 feet/minute; have HEPA-filtered, down-flow air that is a portion of the mixed down-flow and inflow air from a common exhaust plenum; may exhaust HEPA-filtered air back into the laboratory or to the environment through an exhaust canopy; and have all contaminated ducts and plenums under negative pressure or surrounded by negative-pressure ducts and plenums. If these cabinets are used for minute quantities of volatile toxic chemicals and trace amounts of •radionuclides,• (ERR 1-Oct-2016) they must be exhausted through properly functioning exhaust canopies.

Type B1: These Class II BSCs maintain a minimum inflow velocity of 100 feet/minute; have HEPA-filtered, down-flow air composed largely of uncontaminated, recirculated inflow air; exhaust most of the contaminated down-flow air through a dedicated duct exhausted to the atmosphere after passing it through a HEPA filter; and have all contaminated ducts and plenums under negative pressure or surrounded by negative-pressure ducts and plenums. If these cabinets are used for work involving minute quantities of volatile toxic chemicals and trace amounts of •radionuclides,• (ERR 1-Oct-2016) the work must be done in the directly exhausted portion of the cabinet.

Type B2 (total exhaust): These Class II BSCs maintain a minimum inflow velocity of 100 feet/minute; have HEPA-filtered, down-flow air drawn from the laboratory or the outside; exhaust all inflow and down-flow air to the atmosphere after filtration through a HEPA filter without recirculation inside the cabinet or return to the laboratory; and have all contaminated ducts and plenums under negative pressure or surrounded by directly exhausted negative-pressure ducts and plenums. These cabinets may be used with volatile toxic chemicals and •radionuclides.• (ERR 1-Oct-2016)

Class III: The Class III BSC is designed for work with highly infectious microbiological agents and other hazardous operations. It provides maximum protection for the environment and the worker. It is a gas-tight enclosure with a viewing window that is secured with locks and/or requires the use of tools to open. Both supply and exhaust air are HEPA/ULPA filtered. Exhaust air must pass through two HEPA/ULPA filters in series before discharge to the outdoors.

Change to read:

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●(Official 1-Jul-2018)

Auxiliary Information— Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
General Chapter	Jeanne H. Sun, Pharm.D. Scientific Liaison (301) 230-3361	(CMP2015) Compounding 2015

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Previously Appeared In:

Pharmacopeial Forum: Volume No. 41(2)

Help

Ordering and Customer Support (/help/ordering-customer-support)

Science Support (/help/scientific-support)

FAQs (/frequently-asked-questions)

Technical Support (/help/technical-support)

Hotel Information (/help/hotel-information)

Directions to USP–U.S. (/help/directions-usp)

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FAQs: <800> Hazardous Drugs—Handling in Healthcare Settings

Last Updated: February, 2017

The following are responses provided by members of the USP Compounding Expert Committee. Responses have been provided for informational purposes only, and should not be construed as an official interpretation of USP text or relied on to demonstrate compliance with USP standards or requirements.

General

1. What is a hazardous drug?

2. What is the purpose of this chapter?

3. Who enforces the chapter?

4. Who does the chapter apply to?

5. What settings does the chapter apply to?

6. Does the chapter apply to administration of HDs?

7. What is the status of the General Chapter <800> and when will General Chapter <800> become official?

8. Will there be updates or changes to the chapter?

9. How can I obtain a copy of General Chapter <800>?

10. Have there been any documented/published studies involving harm related to handling of HDs?

Personnel

11. Where does the designated person obtain training? How much training does the designated person need?

Facilities and Engineering Controls

12. Are there requirement for posting signs that HDs are being handled in the facility?

13. Can sterile and nonsterile HDs be stored together?

14. Can refrigerated non-antineoplastic HDs be stored with antineoplastic HDs?

15. Where should the sink be located?

16. Is the C-PEC used for sterile compounding required to be exhausted to the outside or can the C-PEC be recirculated into the negative pressure C-SEC which is exhausted to the outside of the building?

17. Can non-HDs and HDs be compounded in C-PECs located in the same C-SEC?

18. Can a Laminar Airflow Workbench (LAFW) or compounding aseptic isolator (CAI) be used for compounding a non-antineoplastic HD?

19. Can a BSC or CACI used for compounding HDs be used for compounding non-HDs?

20. Are closed-system drug-transfer devices (CSTDs) required for compounding HDs?

21. Is there an evaluation tool one can use for evaluating the performance of the different CSTDs available?

22. How can a CSTD be chemically incompatible with a HD?

23. What is meant by "fixed walls"?

24. Are pressure gauges required to monitor the pressure differential between the C-SEC and the adjacent areas?

Environmental Quality And Control

25. Is environmental wipe sampling required?

26. Why is environmental wipe sampling recommended when there is currently no standard for acceptable limits on HD surface contamination?

27. Does every area where HDs are handled require environmental sampling?

28. What are the acceptable limits for HD surface contamination?

Personal Protective Equipment (PPE)

29. Are the PPE and Engineering Controls specified in Table 5 of the current NIOSH list required?

30. What PPE is required for administering HDs?

31. Are compounders required to remove all PPE when leaving the compounding area?

32. Can gowns be re-worn during the same day if a compounder leaves the HD compounding area?

33. What documentation is required to show that a gown will resist permeability by HDs?

Compounding

34. Is an entity required to have two sets of equipment, one set for compounding HDs and another second set for compounding non-HDs?

General Chapter <800> states that "disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs." This refers to equipment (or parts of equipment) that comes in direct contact with HDs. Equipment that does not come in direct contact with HDs may be shared between HD and non-HD compounding areas provided it is deactivated, decontaminated and cleaned before it is removed from the HD area. Equipment used in HD compounding must be operated in the C-SEC unless it is operated as a closed system (e.g. certain mixers, terminal sterilization using an autoclave or convection oven).

35. During nonsterile compounding with HD APIs, are all steps of the compounding process required to be performed in the C-PEC?

General Chapter <800> states that "bulk containers of liquid and API HD must be handled carefully to avoid spills. If used, APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder)." It is recognized that under some circumstances, it is not possible to perform all steps of the compounding process in the C-PEC (e.g. due to equipment size or function). It is important for the safety of personnel that powdered HDs be weighed and mixed to the wet stage or made into capsules in the C-PEC. Once nonvolatile, non-antineoplastic, powdered HDs are wet, an assessment of risk may be performed to determine alternative containment strategies and/or work practices. The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in healthcare settings including instances where a C-PEC cannot be used.

36. Where should HD APIs be handled prior to sterilization when compounding sterile HDs?

In addition to <800>, sterile compounding must follow standards in <797> which states that presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment. Per <800>, presterilization procedures for high-risk level HD CSPs can occur in the HD ISO Class 7 negative pressure buffer room if the C-PEC used for the nonsterile presterilization procedures is sufficiently effective that the room can continuously maintain ISO 7 classification. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process. Alternatively, an ISO Class 8 or better negative pressure room could be used. An ISO Class 7 negative pressure room would be necessary if it leads directly into the HD ISO 7 negative pressure buffer room.

37. Does the chapter apply if the HD is dissolved in a liquid dosage form and does not become an aerosol or gas?

HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage). Consideration must be given to the aerolization of HDs in liquid formulations.

38. If the HD is a liquid dosage form, may it be compounded in a positive pressure non-HD cleanroom?

No, HD CSPs must be filtered in a BSC or CACI located in an ISO 7 room with negative pressure of 0.01 to 0.03 inches of water and 30 ACPH.

39. Can an assessment of risk be performed on concentrated solutions of HDs (i.e. hormone concentrates)?

No, concentrated solutions of HDs (i.e. hormone concentrates) is an HD API that is further manipulated into a final dosage form and is subject to the containment requirements in <800>. General Chapter <800> defines an API as "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.

40. What kind of materials may be used for the cabinets and counters in the nonsterile compounding room?

The chapter states that cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding but does not limit or define the specific materials that may be used.

Hazard Communication Program

41. Do personnel of reproductive capability include both male and females?

Receiving

42. What PPE is required for receiving HDs?

43. Are suppliers required to ship HDs in impervious plastic?

44. Does the HD return waiting area have to be separate from the regular HD storage area?

45. What container materials are considered impervious?

46. What is the tiered approach for receiving HDs?

Labeling, Packaging, Transport And Disposal

47. What must be on the label for HDs?

48. What kind of packaging containers can be used for packaging HDs?

49. Can HDs be transported in pneumatic tubes, robots, or patient carts?

50. Are personnel involved in waste removal and cleaning required to don PPE?

Medical Surveillance

51. What if the employee wants to keep their medical records private from the employer?

52. What "health variables" should be followed over time for individual workers?

53. In a medical surveillance program, how does an employer obtain data from the unexposed workers for comparison to the exposed workers?

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Olakunle Ekundayo (/our-impact/olakunle-ekundayo)

Sarah Erush (/our-impact/sarah-erush)

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Compounding Standards (/compounding)

Dietary Supplements & Herbal Medicines (/dietary-supplements-herbal-medicines)

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Announcements

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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August 23, 2017

Agenda Item 17: Announcements

Sep. 4	Labor Day – *Board office closed*
Sep. 6	Violations Committee – Informal Conference
Sep. 7	Marijuana Project Team Meeting
Sep. 10-14	FIP World Congress – Seoul, South Korea
Sep. 30	LSHP MidYear Meeting – Shreveport, LA
Oct. 3-4	NABP Executive Officers Forum – Mount Prospect, IL
Oct. 5	.Pharmacy Executive Board Meeting – Mount Prospect, IL
Oct. 8-11	NABP-AACP District 6-7-8 Annual Meeting – San Antonio, TX
Oct. 14-18	NCPA Annual Meeting – Orlando, FL
Oct. 17-20	NASCSA Annual Meeting – San Antonio, TX
Oct. 18	La. Pharmacy Congress
	PMP Advisory Council Meeting
Oct. 22-25	MALTAGON Conference – Charleston, SC
Oct. 29-30	Pharmacy Technician Stakeholder Consensus Conference – Steering Committee Meeting – Washington, DC
Nov. 9	Prescription Drug Abuse Prevention Summit – Hot Springs, AR
Nov. 14	Reinstatement, Impairment, Finance, & Executive Committees
Nov. 15	Reciprocity Committee
	Board Meeting
Nov. 16	Administrative Hearing
Nov. 20-22	Application Review Committee – Marijuana Pharmacy Permits
Nov. 23	Thanksgiving Day – *Board office closed*
Nov. 24	Acadian Day – *Board office closed*
Dec. 2	New Orleans Pharmacy Museum Gala
Dec. 3-7	ASHP MidYear Meeting – Orlando, FL
Dec. 6-7	Violations Committee – Informal Conference
Dec. 25	Christmas Day – *Board office closed*
Jan. 1	New Year's Day – *Board office closed*
Jan. 3-5	Special Board Meeting – Marijuana Pharmacy Permit Selection