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**

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<tr>
<th>Acronym</th>
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<tr>
<td>AACP</td>
<td>American Association of Colleges of Pharmacy</td>
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<td>AAPS</td>
<td>American Association of Pharmaceutical Scientists</td>
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<td>AAPT</td>
<td>American Association of Pharmacy Technicians</td>
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<td>ACA</td>
<td>American College of Apothecaries</td>
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<td>ACCME</td>
<td>Accreditation Council for Continuing Medical Education</td>
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<td>ACCP</td>
<td>American College of Clinical Pharmacy</td>
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<td>ACE</td>
<td>Advisory Committee on Examinations (NABP)</td>
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<td>American Dental Association</td>
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<td>ADC</td>
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<td>ADS</td>
<td>automated dispensing system</td>
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<td>AFDO</td>
<td>Association of Food &amp; Drug Officials</td>
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<tr>
<td>AFPE</td>
<td>American Foundation for Pharmaceutical Education</td>
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<td>AIHP</td>
<td>American Institute of the History of Pharmacy</td>
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<td>Academy of Managed Care Pharmacy</td>
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<td>APEC</td>
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<td>advanced pharmacy practice experience</td>
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<td>United States Pharmacopeia / United States Pharmacopeial Convention</td>
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<td>WHPA</td>
<td>World Health Professions Alliance</td>
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</table>
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:

AGENDA

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)

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

Regular Meeting & Administrative Hearing

Wednesday, May 10, 2017 at 10:00 a.m.
Wednesday, May 10, 2017 at 3:00 p.m.
Thursday, May 11, 2017 at 8:30 a.m.

Location:
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
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<td>2.</td>
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<td>3.</td>
<td>Quorum Call</td>
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<td>4.</td>
<td>Call for Additional Agenda Items &amp;</td>
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<td>Adoption of Agenda</td>
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<td>5.</td>
<td>Consideration of Minutes from Previous Meetings</td>
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<td>6.</td>
<td>Report on Action Items</td>
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<td>7.</td>
<td>Confirmation of Acts</td>
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<td>8.</td>
<td>Opportunity for Public Comment</td>
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<td>*</td>
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<td>9.</td>
<td>Special Orders of the Day</td>
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<td>A. Finance</td>
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<td>B. Application Review</td>
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<td>C. Reciprocity</td>
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<td>D. Violations</td>
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**Thursday, January 26, 2017**

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<td>E.</td>
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<td>F.</td>
<td>Adjourn</td>
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A regular meeting of the Louisiana Board of Pharmacy was held on Wednesday, May 10, 2017 in the Boardroom of the Board’s office, located at 3388 Brentwood Drive in Baton Rouge, Louisiana. The meeting was held pursuant to public notice, each member received notice, and public notice was properly posted.

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

2. Invocation & Pledge
Mr. Aron called upon Mr. Brian Bond, and he delivered the invocation. Mr. Don Resweber then led the group in the Pledge of Allegiance.

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

Members Present:
- Mr. Carl W. Aron
- Mr. Brian A. Bond
- Mr. Allen W. Cassidy, Jr.
- Mr. Richard Mannino
- Mr. Marty R. McKay
- Ms. Chris B. Melancon
- Ms. Diane G. Milano
- Mr. Blake P. Pitre
- Mr. T. Morris Rabb
- Mr. Don L. Resweber
- Mr. Douglas E. Robichaux
- Mr. Richard A. Soileau
- Dr. Raymond J. Strong
- Mr. Rhonny K. Valentine

Members Absent:
- Ms. Jacqueline L. Hall
- Mr. Richard M. Indovina, Jr.
- Mr. Ronald E. Moore

Staff Present:
- Mr. Malcolm J. Broussard, Executive Director
- Mr. Carlos M. Finalet, III, General Counsel
- Mr. M. Joseph Fontenot, Assistant Executive Director
- Mr. Benjamin S. Whaley, Chief Compliance Officer

Guests:
- Mr. Jonathon Shuler – Wal-Mart Pharmacies
- Ms. Michele Fuselier – La. Pharmacists Association
- Mr. Ben J. Sims – Brookshire Grocery Co. Pharmacies
- Dr. Andrea Gisclair – LSU Veterinary Teaching Hospital Pharmacy
Mr. Bond certified 14 of the 17 members were present, constituting a quorum for the conduct of official business.

4. **Call for Additional Agenda Items & Adoption of Agenda**
Mr. Aron asked if there were any additional agenda items but none were requested. With no further requests for amendment, and with no objection, the Board adopted the posted agenda dated April 26, 2017. Mr. Aron then requested authority from the Board to reorder the agenda as necessary for the purpose of accommodating certain guests and/or reports. There were no objections to that request.

5. **Consideration of Minutes**
Mr. Aron reminded the members they had received the draft minutes from the Regular Board Meeting on January 25, 2017, the Administrative Hearing on January 25-26, 2017, and the Special Board Meeting on March 14, 2017, all of which were held in Baton Rouge, Louisiana. With no objections, he waived the reading of the draft minutes. With no requests for amendment or any objection to their approval, Mr. Aron declared the minutes were approved as presented. Mr. Bond reminded the members to sign the Minute Book.

6. **Report on Action Items**
Mr. Aron called on Mr. Broussard for the report. Mr. Broussard directed the members to a copy of the report in their meeting binder. There were no questions from the members.

7. **Confirmation of Acts**
Pursuant to Mr. Aron’s declaration that the officers, committees, and executive director had attended to the business of the Board since their last meeting in accordance with policies and procedures previously approved by the Board, Mr. Rabb moved, **Resolved**, that the actions taken and decisions made by the Board officers, Board committees, and Executive Director in the general conduct and transactions of Board business since January 26, 2017 are approved, adopted, and ratified by the entire Board.

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

8. **Opportunity for Public Comment**
Mr. Aron reminded the members and guests the Open Meetings Law requires all public bodies to provide an opportunity for public comment at all meetings and for each agenda item upon which a vote is to be taken. He solicited general comments on non-agenda items from the guests present, and one guest requested the opportunity to ask a question.

Mr. Peter Prevot identified himself as a commentator during the March 2 public
hearing relative to the proposed rule on marijuana pharmacy. He noted that regulatory project was not listed on the published agenda for that day and asked the status of the project. Mr. Broussard replied with detailed information including the next steps and timeline. Mr. Prevot indicated that information answered his questions.

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

9. Special Orders of the Day
Mr. Aron noted there were no special orders for that day.

10. Committee Reports
   A. Finance Committee
      Mr. Aron called upon Mr. Pitre for the committee report. Mr. Pitre directed the members to the interim report for the current fiscal year, reviewed the highlights, and indicated the report was presented for information only and required no action by the Board. There were no questions from the members.
      Finally, he expressed his appreciation to the other committee members for their ongoing efforts.

   B. Application Review Committee
      Mr. Aron called upon Mr. Soileau for the committee report. Mr. Soileau reported the committee had met the previous day to consider one referral from staff. Following their interview and deliberation, the committee authorized the issuance of the pharmacy technician candidate registration without restriction; therefore, no action was required by the Board.
      Finally, Mr. Soileau expressed his appreciation to the other members of the committee for their ongoing efforts.

   C. Reciprocity Committee
      In the absence of Ms. Hall, Mr. Aron called upon Mr. Valentine for the committee report. He reported the staff had evaluated 79 applications for pharmacist licensure by reciprocity since the last Board meeting and that none of them contained information that warranted a committee level review. In conformance with policies and procedures previously approved by the Board, the staff approved the applications and issued the credentials.
      He reported the committee had met earlier that morning to consider two referrals from staff. On behalf of the committee, Mr. Valentine then moved to approve pharmacist licensure without restriction for Messay Alem Addis (reciprocating from VA) and Robert Brent Clevenger (reciprocating from NC). The motion was adopted after a unanimous vote in the affirmative.
      Finally, he closed the report with appreciation to the other committee members for their ongoing efforts.
D. Violations Committee

Mr. Aron called upon Mr. Bond for the committee report. Mr. Bond reported the committee held preliminary hearings on March 8-9, 2017 to consider their posted agenda which included 20 cases: 7 pharmacists, 3 pharmacy technicians, 2 pharmacy technician candidates, 7 pharmacy permits, and one applicant for a pharmacy permit. Prior to the meeting, the committee authorized continuances for 5 of the respondents. After interviews and deliberations, the committee took no action on 3 of the respondents and issued a non-disciplinary letter of noncompliance to one respondent. They continued one of the cases pending the results of a medical evaluation. One of the respondents voluntarily surrendered their credential in lieu of an appearance before the committee. The committee offered proposed voluntary consent agreements to the remaining 9 respondents. Mr. Bond then presented the following proposals to the members for their consideration.

Walgreen Louisiana Co., Inc. d/b/a Walgreen Pharmacy No. 15067 [Metairie, LA] (PHY.006406) Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed a fine of $5,000 plus administrative and investigative costs.

Alvin Watts, III d/b/a Doc-Your-Dose Pharmacy [Grosse Tete, LA] (PHY.005969) Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board revoked the permit.

Alvin Watts, III (PST.018168) Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board revoked the license; and further, issued a lifetime prohibition on the ownership of any pharmacy licensed by the Board; and further, assessed a fine of $45,000 plus administrative and investigative costs.

Reeves Apothecary, Inc. d/b/a New Arcadia Drug Store [Arcadia, LA] (PHY.000814) Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed a fine of $1,000 plus administrative and investigative costs.

Jesse Eugene Reeves, III (PST.010221) Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed a fine of $1,000 plus administrative costs.

Matthew Ian Johnson (CPT.013661) Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a
unanimous vote in the affirmative. The Board assessed a fine of $250 plus administrative costs.

**Ricky Lamar Zeigler (PST.017855)** Mr. Bond moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective January 30, 2017.

**Executive Pharmacy, LLC d/b/a Executive Pharmacy [Sunrise, FL] (PHY.007214)** Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed a fine of $20,000 plus administrative and investigative costs.

**Trinity Medical Pharmacy, LLC d/b/a Trinity Medical Pharmacy [New Port Richey, FL] (PHY.007182)** Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board assessed a fine of $10,000 plus administrative and investigative costs.

**Clemencia Ann Henry (CPT.011507)** Mr. Bond moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $250 plus administrative costs.

Mr. Bond reported the committee will meet on June 14-15, 2017 to consider that docket, which was still under development.

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

**E. Impairment Committee**

Mr. Aron called upon Mr. Rabb for the committee report. Mr. Rabb reported the committee met the previous day to consider 15 referrals from the staff. Following their interviews of the applicants and subsequent deliberations, the committee took no formal action for one of the respondents, directed one respondent to submit to a medical evaluation, and deferred further action for three respondents pending additional review. Mr. Rabb then presented the following files to the members for their consideration.

**Eric Christopher Ament (PST.020768)** Mr. Rabb moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective March 31, 2017.
Kevin Trenouth Kellow (PST.019095) Mr. Rabb moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board granted the respondent’s request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, then placed the license on probation for five years effective May 10, 2017, subject to certain terms enumerated in the consent agreement.

Ricky Thomas Guidry (PST.013683) Mr. Rabb moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board granted the respondent’s request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of ten years and stayed the execution of the suspension, then placed the license on probation for ten years effective May 10, 2017, subject to certain terms enumerated in the consent agreement.

Timothy Keith Freeman (PST.020918) Mr. Rabb moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board granted the respondent’s request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, then placed the license on probation for five years effective May 10, 2017, subject to certain terms enumerated in the consent agreement.

Justin Matthew Scalfano (PST.018787) Mr. Rabb moved to decline the respondent’s request for early termination of the previously-imposed probationary period which was scheduled to conclude on August 17, 2021, and in the alternative, to modify the previously-imposed probationary terms. The motion was adopted after a unanimous vote in the affirmative. The Board removed Article 2-e from his May 2016 Probation Board order which had restricted him from accepting an appointment as the pharmacist-in-charge at a pharmacy.

Andrea Katherine Bourque (PST.019587) Mr. Rabb moved to approve the respondent’s request for modification of previously-imposed probationary terms. The motion was adopted after a unanimous vote in the affirmative. The Board removed Article 2-e from her February 2016 Probation Board Order which had restricted her from accepting an appointment as the pharmacist-in-charge at a pharmacy.

Matthew Marston Lane (PST.018065) Mr. Rabb moved to approve the respondent’s request for modification of previously-imposed probationary terms. The motion was adopted after a unanimous vote in the affirmative. The Board removed Article 2-e from his February 2015 Probation Board
Order which had restricted him from accepting an appointment as the pharmacist-in-charge at a pharmacy.

**Doddi Vidrine Alexander (PST.016007)** Mr. Rabb moved to approve the respondent’s request for modification of previously-imposed probationary terms. The motion was adopted after a unanimous vote in the affirmative. The Board removed Articles 2-e and 2-f from her May 2015 Probation Board Order, of which the former had restricted her from accepting an appointment as the pharmacist-in-charge at a pharmacy and the latter had required her practice to be supervised by another pharmacist at all times.

**Victor James Whitacre (CPT.013240)** Mr. Rabb moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board suspended the certificate for five years and stayed the execution of the suspension, then placed the certificate on probation for five years effective May 10, 2017, subject to certain terms enumerated in the consent agreement.

**Rebecca Thrasher Ricks (CPT.001817)** Mr. Rabb moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board suspended the certificate for one year and stayed the execution of the suspension, then placed the certificate on probation for one year effective May 10, 2017, subject to certain terms enumerated in the consent agreement.

Mr. Rabb reported the committee had performed its annual review of the Board’s *Roster of Approved Addictionists*. The members determined it appropriate to remove one of the providers on the roster and also add several new providers to the roster. Mr. Rabb then moved,

**Resolved**, to approve the May 10, 2017 edition of the Board’s *Roster of Approved Addictionists* for the remainder of Fiscal Year 2016-2017 as well as Fiscal Year 2017-2018.

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

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

**F. Reinstatement Committee**

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

**Michel Darlene Rush (CPT.003241)** Ms. Melancon moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board granted respondent’s request for reinstatement of the previously lapsed certificate, contingent upon the
successful completion of certain requirements identified in the consent agreement.

**Janna Eve Husser (CPT.004466)** Ms. Melancon moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board granted respondent’s request for reinstatement of the previously lapsed certificate, contingent upon the successful completion of certain requirements identified in the consent agreement.

**Christine Adele Ackal (PST.015539)** Ms. Melancon moved to approve the respondent’s request for early termination of the previously-imposed probationary period which was scheduled to conclude on January 30, 2019. The motion was adopted after a unanimous vote in the affirmative. The Board removed all probationary terms and restored the license to active and unrestricted status.

**Ackal’s Community Pharmacy, Inc. d/b/a Ackal’s Community Pharmacy [Youngsville, LA] (PHY.005948)** Ms. Melancon moved to approve the respondent’s request for early termination of the previously-imposed probationary period which was scheduled to conclude on January 30, 2019. The motion was adopted after a unanimous vote in the affirmative. The Board removed all probationary terms and restored the permit to active and unrestricted status.

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

**G. Tripartite Committee**

Mr. Aron called upon Mr. Moore for the committee report. Mr. Moore noted the committee had not met since March 2016 and therefore no report was available.

**H. Regulation Revision Committee**

Mr. Aron called on Mr. McKay for the committee report. Mr. McKay noted the committee had not met since the last Board meeting. He noted the Board had approved several regulatory projects for promulgation and that activity was described in the Report on Action Items presented earlier that day.

**I. Executive Committee**

Mr. Aron reported the committee had met the previous day to consider the items on their posted agenda. In particular, the committee performed their annual review of the policy and procedure manuals, the approved pharmacy educational institutions, as well as preliminary preparations for the annual financial audit. The committee developed several recommendations for the Board’s consideration. Mr. Aron requested Mr. Rabb to offer those motions
Resolved, to approve the proposed revision of Policy No. LPM.II.A – Authorized Drivers in the Board’s Loss Prevention Manual.

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

Resolved, to renew the approval of the updated Loss Prevention Manual for Fiscal Year 2017-2018.

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

Resolved, to approve the proposed new Policy No. PPM.I.A.22 ~ Transfer of Prescription Information Between Pharmacies for the Board’s Policy & Procedure Manual.

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

Resolved, to renew the approval of the updated Policy & Procedure Manual for Fiscal Year 2017-2018.

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

Resolved, to renew the approval of the updated Roster of Accredited Colleges & Schools of Pharmacy for Fiscal Year 2017-2018.

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

Resolved, to renew the approval of the updated Roster of Accredited Pharmacy Technician Training Programs for Fiscal Year 2017-2018.

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

Resolved, to approve the Management’s Representation Letter for the 2017 Audit by the Office of the Legislative Auditor; and further, to authorize the President and Executive Director to execute that document on our behalf.

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

Finally, Mr. Aron closed his report with appreciation for the other committee members and their work the previous day.

11. Staff Reports

J. Report of Assistant Executive Director

Mr. Aron called upon Mr. Fontenot for his report. Mr. Fontenot directed the members to the quarterly report for the Prescription Monitoring Program, reviewing transaction data, registration counts, and search data. He then reviewed his efforts to establish interstate sharing relationships with several
states, including Alabama, Florida, and Georgia.

Mr. Fontenot then directed the members to the new requests for exemption from the PMP reporting requirements. Mr. Rabb moved, Resolved, to authorize the issuance of PMP reporting waivers to:

- PHY.007260-NR – Absolute Veterinary Compounding Pharmacy (TX);
- PHY.007356-NR – American Service & Product (IL);
- PHY.007189-NR – Bluegrass Pharmacy of Lexington (KY);
- PHY.006432-NR – BriovaRx of Texas (TX);
- PHY.007329-NR – Heartland Veterinary Pharmacy (NE);
- PHY.006868-NR – IV Solutions of Lubbock (TX);
- PHY.007425-NR – Medication Management Program (OH);
- PHY.007063-NR – MedImpact Direct (AZ);
- PHY.007467-NR – NuFactor (CA);
- PHY.007464-SAT – Ochsner Cancer Center – Baton Rouge Infusion Pharmacy (LA);
- PHY.007263-SAT – Ochsner Health Center – Summa Infusion Pharmacy (LA);
- PHY.000835-HOS – Ochsner Foundation Hospital Pharmacy (LA);
- PHY.007380-SAT – Ochsner Infusion Center (LA);
- PHY.006730-HOS – Ochsner Medical Center – Baptist Pharmacy (LA);
- PHY.006820-NR – Onco360 (NY);
- PHY.007443-NR – Optime Care, Inc. (MO);
- PHY.007451-NR – Pharmaceutical Specialties Express (GA);
- PHY.005865-NR – Triad Isotopes, Inc. (AL);
- PHY.006672-NR – Triad Isotopes, Inc. (MS);
- PHY.006610-NR – Truax Patient Services (MN);
- PHY.007466-NR – U of A Medication Management Center #2 (AZ);
- PHY.007405-NR – US Healthlink, LLC (FL); and
- PHY.005693-HOS – Vermilion Behavioral Health Systems (LA)

once they have executed the standard consent agreement for that purpose.

The motion was adopted after a unanimous vote in the affirmative. Finally, Mr. Fontenot indicated completion of his report.

At this point, Mr. Aron declared a luncheon recess. It was noted the members recessed at 11:45 a.m. and reconvened at 12:55 p.m. Mr. Aron re-ordered the agenda to consider Item 12 on the published agenda.

12. Request to Extend Authority for Pilot Project at LSU Veterinary Teaching Hospital Pharmacy

Mr. Aron recognized Mr. James German, Operations Manager at LSU Veterinary Teaching Hospital. Mr. German introduced his colleagues, Ms. Andrea Gisclair and Mr. Colin Mitchell. Mr. German presented an addendum to the policy originally approved by
the Board in May 2016 which would add certain specifically-named individuals to the list of persons authorized to enter the pharmacy after hours in accordance with the facility’s policies and procedures. Following a short discussion, Mr. Rabb moved, **Resolved**, to approve the March 14, 2017 version of the *Pharmacy After-Hours Access Policy Addendum*, to provide interim authority for the Board staff and the facility staff to make necessary adjustments to the list of specifically named individuals as needed by the facility, and to extend the authority for the pilot project at LSU Veterinary Teaching Hospital Pharmacy through June 30, 2018.

The motion was adopted after a unanimous vote in the affirmative. The LSU representatives extended their appreciation to the Board for its favorable consideration of their request.

Mr. Aron then re-ordered the agenda to return to the staff reports.

11. **Staff Reports**

   **K. Report of General Counsel**

   Mr. Aron called upon Mr. Finalet for his report. Mr. Finalet then presented the following files to the members for their consideration.

   **Nadia Deolinda Archambault (PST.020942)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

   **Steven David Webb (PST.019070)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

   **Madhavi Padigala (PST.020460)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

   **Shamina Olia Antenucci (PST.018120)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

   **Avery Carlton Huff (PST.020002)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

   **Harold D. Ross (PST.020478)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous
vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

**Custom Meds, Inc. d/b/a Custom Meds [Inverness, FL] (PHY.006141)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $5,000 plus administrative costs.

**National Pharmaceutical Network, Inc. d/b/a EntrustRx [Memphis, TN] (PHY.006764)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $5,000 plus administrative costs.

**Robin Rashauon Vidal (PST.018051)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

**Brigit Marino Schexnayder (PST.014791)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

**Jason S. Kim (PST.020110)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

**Picton Timothy Evans (PST.020532)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

**Kroger Specialty Pharmacy, Inc. d/b/a Kroger Specialty Pharmacy MS [Vicksburg, MS] (PHY.005747)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Warning; and further, assessed a fine of $5,000 plus administrative costs.

**Parrish Wendell Posey, Jr. (PTC.023548)** Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board revoked the registration effective March 28, 2017; and further, prohibited the acceptance of any future application for the reinstatement of the registration or for any other credential issued by the Board.
Michelle Eileen Ulrich-Goebel (PST.021401) Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $1,000 plus administrative costs.

Drug Depot, Inc. d/b/a APS Pharmacy [Palm Harbor, FL] (PHY.006689) Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Reprimand; and further, assessed a fine of $20,000 plus administrative costs.

Marian Respiratory Care, Inc. d/b/a Marian Respiratory Care [Daphne, AL] (PHY.006762) Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board suspended the permit for one year plus seven months plus twenty-one days and stayed the execution of the suspension, then placed the permit on probation for one year plus seven months plus twenty-one days effective May 10, 2017, to run concurrently with the probationary period imposed on its Alabama permit by the Alabama Board of Pharmacy, subject to certain terms enumerated in the consent agreement; and further, assessed administrative costs.

Cammie Michelle Seago (CPT.013255) Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board revoked the certificate effective April 27, 2017; and further, prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Crysoncare Pharmacy, Inc. d/b/a Crysoncare Pharmacy [Spring, TX] (PHY.007441) Mr. McKay moved to approve the proposed voluntary consent agreement. The motion was adopted after a unanimous vote in the affirmative. The Board issued a Letter of Warning; and further, assessed a fine of $10,000 plus administrative costs.

DeLynn Eubanks (PST.015490) Mr. McKay moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective February 23, 2017.

Jason Van Johnson (PTC.024586) Mr. McKay moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the registration for an indefinite period of time, effective February 24, 2017.
Mykia Shavon Hemphill (CPT.013040) Mr. McKay moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the certificate for an indefinite period of time, effective March 17, 2017.

Francis Renee Vercher (CPT.013765) Ms. Melancon moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the certificate for an indefinite period of time, effective March 22, 2017.

Wilkinson Family Pharmacy, LLC d/b/a Wilkinson Family Pharmacy [Chalmette, LA] (PHY.006645 & CDS.042758) Mr. McKay moved to accept the voluntary surrender of the credentials. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrenders, resulting in the active suspension of the permit and CDS license for an indefinite period of time, effective April 24, 2017.

Keith Daniel Wilkinson (PST.017070) Mr. McKay moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective April 24, 2017.

James Edward Helou (PST.019129) Mr. McKay moved to accept the voluntary surrender of the credential. The motion was adopted after a unanimous vote in the affirmative. The Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective May 4, 2017.

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

At this point, Mr. Aron declared a brief recess. It was noted the members recessed at 1:30 p.m. and then reconvened at 1:40 p.m.

L. Report of Executive Director
   Mr. Aron called upon Mr. Broussard for the report. Mr. Broussard directed the members to his report in the meeting binder. He reviewed the following topics:
   • Meeting Activity
   • Reports
     Census Reports – Credentials & Compliance Divisions
     Production Reports – Credentials Division
     Exceptions Report
   • Examinations
Mr. Rabb requested an update concerning one of the legislative proposals approved by the Board, more particularly the proposal relative to pharmacy benefit managers (PBMs). Mr. Broussard reminded the members of the proposal which requested the legislative staff draft language that would authorize the Board to license and regulate PBMs with respect to their pharmacy practice activities such as drug formulary restrictions, prior authorization policies and procedures, other policies and procedures which restrict patient access to medications, as well as patient freedom of choice to select their pharmacy provider. He reported he submitted the legislative proposal to the legislative staff at the House Health & Welfare Committee. He also reported a board member had informed him another organization would secure a legislative sponsor, relieving the Board of that task. Mr. Aron reported a legislator had contacted him the previous day looking for the PBM legislation, which had not yet been filed. The legislator also informed Mr. Aron that a request for an opinion from the Office of the Attorney General had apparently been filed, seeking clarification whether the pharmacy practice act already contains sufficient authority for the Board to license and regulate PBMs. Mr. Aron noted Mr. Justin Johnson, a representative for the Louisiana Independent Pharmacies Association (LIPA) was in the audience. Mr. Johnson confirmed a request for that opinion had been submitted.

Mr. Aron reviewed SB 75, which proposes to centralize all the administrative hearing proceedings for all the healthcare licensing boards in the Div. of Administrative Law, as well as HB 436, relative to drug price transparency and SB 59, relative to marketing of prescription drugs to practitioners. He asked if any members had any information about HB 488, which seeks to amend all the Board’s powers and duties; to date, it had not received any committee hearing.

Mr. Rabb asked about the upcoming NABP Annual Meeting in Orlando, noting the candidates for the various open positions on the NABP Executive Committee, as
well as the proposed resolutions. The members reviewed the candidates as well as the proposed resolutions.

Mr. Soileau asked about the NABP District 6 meetings and whether there would be an option to meet with any other districts. Mr. Broussard reviewed the options relative to meeting with other districts.

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

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

14. Recess
Having completed the tasks itemized on the posted agenda, with no further business pending before the Board, and without objection, Mr. Aron recessed the meeting at 2:20 p.m.

* * * * *

An Administrative Hearing was convened on Wednesday, May 10, 2017 in the Boardroom of the Board’s office, located at 3388 Brentwood Drive in Baton Rouge, Louisiana. The hearing was held pursuant to public notice, each member received notice, each respondent received notice (unless specifically stated otherwise in the official transcript), and public notice was properly posted.

A. Call to Order
Mr. Aron called the hearing to order at 3:00 p.m.

B. Quorum Call
Mr. Aron called upon Secretary Bond and he called the roll. After doing so, he certified Ms. Hall, Mr. Indovina, Ms. Melancon, Mr. Moore, Mr. Rabb, and Mr. Valentine were absent; however, the remaining 11 members were present, constituting a quorum for the conduct of official business.

C. Call for Additional Agenda Items & Adoption of Agenda
Mr. Aron asked if there were any additional agenda items, and none were requested. With no objection, the Board adopted the posted agenda, dated April 26, 2017. He then requested authority to re-order the agenda as may become necessary, and there was no objection to that request.

D. Opportunity for Public Comment
Mr. Aron reminded the members and guests the Open Meetings Law requires all public bodies to provide an opportunity for public comment at all meetings and prior to the vote on each agenda item. He solicited comments from the guests, but none were offered.
Appearances
Mr. Aron indicated he would serve as the Hearing Officer, Mr. Carlos Finalet as the Prosecuting Attorney, Ms. Susan Erckle as the Official Recorder, and Mr. Malcolm Broussard as the Hearing Clerk. Without objection, Mr. Aron waived the reading of the posted agenda and instead directed the insertion thereof into these minutes. The posted agenda is re-created here.

A G E N D A
NOTE: This agenda is tentative until 24 hours in advance of the meeting, at which time the most recent revision becomes official.
Revised 04-26-2017

A. Call to Order
B. Quorum Call
C. Call for Additional Agenda Items & Adoption of Agenda
D. Opportunity for Public Comment
E. Formal Hearings

01. CPT.011432 – Chandrika Te’Nea Woods Case No. 16-0202
02. CPT.009209 – Candace Cecile Navarra Case No. 16-0212

At the conclusion of the cases docketed above, the Board will recess; they will reconvene the following day at 8:30 a.m., in the Board office, to consider the following agenda:

A. Call to Order
B. Invocation & Pledge of Allegiance
C. Quorum Call
D. Opportunity for Public Comment
E. Formal Hearings (continued)

03. PTC.021994 – Kristen Je’Nay Williams Case No. 15-0350
04. PHY.007309 – Reliable Pharmacy, LLC d/b/a Reliable Pharmacy [Marco Island, FL] Case No. 16-0272

F. Adjourn

E. Formal Hearings

Chandrika Te’Nea Woods (CPT.011432) Mr. Finalet appeared for the Board and noted the absence of the respondent or counsel. After verifying the absence of the respondent, Mr. Aron ruled the hearing would proceed as scheduled in the form of a default proceeding. Mr. Finalet presented an opening statement, no witnesses, and seven exhibits. He then presented a closing statement and offered proposed findings of fact, conclusions of law, and board order, following
which he tendered the matter to the hearing panel for its consideration. Mr. Pitre moved to enter into executive session for the purpose of deliberating the disciplinary matter and discussing the respondent’s professional competency. The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered executive session at 3:10 p.m. and then reconvened in open session at 3:20 p.m. Mr. Aron reported no decision was made during the executive session.

Mr. Resweber moved,  
Resolved, that the hearing panel, having heard the testimony and considered the evidence, accept the Findings of Fact as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record. The motion was adopted after a unanimous vote in the affirmative. Mr. Resweber then moved,

Resolved, that the hearing panel accept the Conclusions of Law as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record. The motion was adopted after a unanimous vote in the affirmative. Mr. Resweber then moved,

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

It is ordered, adjudged, and decreed that Louisiana Pharmacy Technician Certificate No. 11432, held by Chandrika Te'Nea Woods, shall be and is hereby suspended for an indefinite period of time, effective on the entry of this order, and further, the respondent shall pay the following assessments:
(1) A fine of $250;
(2) The administrative hearing fee of $250; and
(3) The investigative and hearing costs, including the costs of the prosecuting attorney, and the official recorder; and

It is further ordered the acceptance of any future application for the reinstatement of this certificate, or any application for any other credential issued by the Board, shall be conditioned upon the satisfaction of the following terms:
(1) Respondent shall have paid all assessments levied herein; and
(2) Respondent shall have no pending legal or disciplinary actions against her in any jurisdiction.

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

Candace Cecile Navarra (CPT.009209) Mr. Finalet appeared for the Board and noted the absence of the respondent or counsel. After verifying the absence of the respondent, Mr. Aron ruled the hearing would proceed as scheduled in the
form of a default proceeding. Mr. Finalet presented an opening statement, no witnesses, and six exhibits. He then presented a closing statement and offered proposed findings of fact, conclusions of law, and board order, following which he tendered the matter to the hearing panel for its consideration. Mr. Cassidy moved to enter into executive session for the purpose of deliberating the disciplinary matter and discussing the respondent's professional competency. The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered executive session at 3:35 p.m. and then reconvened in open session at 3:45 p.m. Mr. Aron reported no decision was made during the executive session.

Ms. Milano moved,

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

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

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

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

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

It is ordered, adjudged, and decreed that Louisiana Pharmacy Technician Certificate No. 9209, held by Candace Cecile Navarra, shall be and is hereby suspended for an indefinite period of time, effective on the entry of this order, and further, the respondent shall pay the following assessments:

1. A fine of $500;
2. The administrative hearing fee of $250; and
3. The investigative and hearing costs, including the costs of the prosecuting attorney, and the official recorder; and

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

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

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

Mr. Finalet indicated completion of the cases scheduled for that day. Mr. Aron expressed his appreciation to Ms. Erckle for her recording services that day.

Having completed the tasks itemized on the posted agenda, with no further business pending before the Board, and without objection, Mr. Aron recessed the hearing at 3:50 p.m.

*    *    *    *    *

The Administrative Hearing was re-convened on Thursday, May 11, 2017 in the Boardroom of the Board’s office, located at 3388 Brentwood Drive in Baton Rouge, Louisiana. The hearing was held pursuant to public notice, each member received notice, each respondent received notice (unless specifically stated otherwise in the official transcript), and public notice was properly posted.

A.   Call to Order
Mr. Aron called the hearing to order at 8:40 a.m.

B.   Invocation & Pledge of Allegiance
Mr. Aron called upon Mr. Bond, and he delivered the invocation. Mr. Cassidy then led the members in the Pledge of Allegiance.

C.   Quorum Call
Mr. Aron called upon the Secretary, Mr. Bond, to call the roll to establish a quorum. Mr. Bond certified that Ms. Hall, Mr. Indovina, Ms. Melancon, Mr. Moore, and Mr. Valentine were absent; however, the remaining 12 members were present, constituting a quorum for the conduct of Board business.

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

*    Appearances
Mr. Aron indicated he would abstain from both cases scheduled that day due to his prior knowledge, and he appointed Mr. Marty McKay to serve as the Hearing Officer. Ms. Celia R. Cangelosi served as the Prosecuting Attorney, Ms. Susan Erckle as the Official Recorder, and Mr. Malcolm Broussard as the Hearing Clerk.
E. Formal Hearings (continued)

Mr. McKay, without objection, re-ordered the sequence of the posted agenda and requested Ms. Cangelosi to proceed when she was ready.

Kristen Je’Nay Williams (PTC.021994) Ms. Cangelosi appeared for the Board and noted the absence of the respondent but the presence of respondent’s counsel, Mr. Kris Perret. Mr. Perret indicated the reason for the absence of the respondent was a last-minute change in the date of a previously-scheduled test in her university course. Respondent attempted to re-schedule that proctored final examination but was unable to do so. Mr. Perret suggested the Board and the respondent would benefit from her presence, and he requested a continuance. Ms. Cangelosi noted the case had received multiple prior continuances; however, the credential was no longer active and the respondent was not actively practicing. Mr. McKay granted the continuance but cautioned counsel it would be the last continuance granted.

Reliable Pharmacy, LLC d/b/a Reliable Pharmacy [Marco Island, FL] (PHY.007309) Ms. Cangelosi appeared for the Board and noted the absence of the respondent or counsel. After verifying the absence of the respondent, Mr. McKay ruled the hearing would proceed as scheduled in the form of a default proceeding. Ms. Cangelosi presented an opening statement, one witness, and five exhibits. She then presented a closing statement and offered proposed findings of fact, conclusions of law, and board order, following which she tendered the matter to the hearing panel for its consideration. Mr. Pitre moved to enter into executive session for the purpose of deliberating the disciplinary matter and discussing the respondent’s professional competency. The motion was adopted after a unanimous roll call vote in the affirmative.

It was noted the hearing panel entered into executive session at 9:05 a.m. and then reconvened in open session at 9:20 a.m. Mr. McKay reported no decision was made during the executive session.

Mr. Cassidy moved,

Resolved, that the hearing panel, having heard the testimony and considered the evidence, accept the Findings of Fact as proposed by the Prosecuting Attorney, modify them by amending Item 2 to correct the dates of departure and notice, Item 8 to reflect the absence of the respondent, and Item 9 to reflect the absence of respondent’s counsel, to adopt the amended findings as our own, and then enter them into the hearing record.

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

Resolved, that the hearing panel accept the Conclusions of Law as proposed by the Prosecuting Attorney, adopt them as our own, and then enter them into the hearing record.
The motion was adopted after a unanimous vote in the affirmative. Mr. Cassidy then moved, 

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

It is ordered, adjudged, and decreed that Louisiana Pharmacy Permit No. 7309, held by Reliable Pharmacy, LLC *d/b/a* Reliable Pharmacy, shall be and is hereby suspended for an indefinite period of time, effective on the entry of this order, and further, the respondent shall pay the following assessments:

1. A fine of $5,000;
2. The administrative hearing fee of $250; and
3. The investigative and hearing costs, including the costs of the prosecuting attorney and the official recorder; and

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

1. Respondent shall have paid all assessments levied herein; and
2. Respondent shall have no pending legal or disciplinary actions against the firm in any jurisdiction.

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

Ms. Cangelosi indicated completion of the cases scheduled for that day. Mr. McKay expressed his appreciation to Ms. Cangelosi for her prosecutorial services and to Ms. Erckle for her recording services that day.

**F. Adjourn**

Having completed the tasks itemized on the posted agenda, with no further business pending before the Board, and without objection, Mr. McKay adjourned the hearing at 9:25 a.m.

Respectfully submitted,

______________________________
Brian A. Bond
Secretary
Report on Action Items
Agenda Item 6: Report on Action Items

During your May 4, 2016 Board meeting, you approved two regulatory proposals for promulgation. In particular:

- You approved Regulatory Proposal 2016-B ~ Internship Requirements (Draft #5) for promulgation upon the instruction of the President. We prepared the required impact statements and negotiated those to the satisfaction of the Legislative Fiscal Officer. On April 10, 2017, we submitted the Notice of Intent to the Joint Legislative Oversight Committee on Health & Welfare and to the Louisiana Register. We distributed an electronic Notice of Rulemaking Activity the same day. The Notice of Intent was published in the April 20, 2017 edition of the Louisiana Register, and as advertised in the notice, we conducted a public hearing on May 30 to receive comments and testimony. You will evaluate those comments and testimony later today.

- You approved Regulatory Proposal 2016-D ~ Equivalent Drug Product Interchange (Draft #1) for promulgation upon the instruction of the President. We prepared the required impact statements and negotiated those to the satisfaction of the Legislative Fiscal Officer. On April 10, 2017, we submitted the Notice of Intent to the Joint Legislative Oversight Committee on Health & Welfare and to the Louisiana Register. We distributed an electronic Notice of Rulemaking Activity the same. The Notice of Intent was published in the April 20, 2017 edition of the Louisiana Register, and as advertised in the notice, we conducted a public hearing on May 30 to receive comments and testimony. You will evaluate those comments and testimony later today.

During your March 14, 2017 Board meeting, you approved several items. In particular:

- With respect to Regulatory Project 2015-9 ~ Pharmacy Technicians, you reviewed the comments and testimony submitted during the March 1 public hearing, following which you approved four sets of proposed revisions to the original proposed rule. The Legislative Fiscal Office opined your proposed revisions impacted the previously-approved Fiscal & Economic Impact Statement, so we negotiated a revised statement to their satisfaction. We then published the proposed revisions and revised impact statement as a Potpourri Notice in the May 20, 2017 edition of the Louisiana Register. As indicated in that notice, we conducted a second public hearing on June 26 to receive comments and testimony on the proposed revisions. You will evaluate those comments and testimony later today.

- With respect to Regulatory Project 2016-6 ~ Marijuana Pharmacy, you reviewed the comments and testimony submitted during the March 2 public hearing, following which you approved sixteen sets of proposed revisions to the original proposed rule. The Legislative Fiscal Office opined that while your proposed revisions were substantial, they did not affect the original Fiscal & Economic Impact Statement. We then published the proposed revisions as a Potpourri Notice in the May 20, 2017 edition of the Louisiana Register. As indicated in that notice, we conducted a second public hearing on June 26 to receive comments and testimony on the proposed revisions. We received one comment requesting a reversal of the revision relative to edible dosage forms. Board President Aron noted since the revision of that portion of the rule was made at the request of the legislative sponsor, the Board would not make the reversal requested by the commentator. We submitted the required comprehensive report to the Joint Legislative Oversight Committee on Health & Welfare. With no intervention by the legislature, we then submitted the Final Rule for publication in the August 20, 2017 edition of the Louisiana Register. The rule became effective on the date of publication.

Respectfully submitted,
Malcolm J Broussard
Executive Director
Finance Committee
Finance Committee

Final Report for Fiscal Year 2016-2017

August 23, 2017

Blake P. Pitre
Chair
Louisiana Board of Pharmacy
Finance Committee

Final Report for Fiscal Year 2016-2017

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# Louisiana Board of Pharmacy

## FY 2016-2017

### Statement of Net Position

<table>
<thead>
<tr>
<th></th>
<th>FY 15-16 Q4 06/30/2016</th>
<th>FY 16-17 Q4 06/30/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Current Assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Cash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Operations</td>
<td></td>
<td></td>
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<tr>
<td>Whitney Bank</td>
<td>160,674</td>
<td>160,985.43</td>
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<td>Iberia Bank</td>
<td>977,494</td>
<td>648,018.98</td>
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<td>Hurricane Relief Fund - Whitney Bank</td>
<td>83,305</td>
<td>83,389.04</td>
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<td>Reserve Funds</td>
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<td>General Account</td>
<td>1,250,999</td>
<td>1,235,544.47</td>
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<tr>
<td>OPEB Account</td>
<td>1,113,112</td>
<td>1,198,137.48</td>
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<tr>
<td>Pension Account</td>
<td>992,198</td>
<td>1,760,670.05</td>
</tr>
<tr>
<td>* Total Cash</td>
<td>4,577,782</td>
<td>5,086,745.45</td>
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<tr>
<td>* Prepaid Expenses</td>
<td>29,900</td>
<td>6,600.00</td>
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<tr>
<td>* Accounts Receivable</td>
<td>330</td>
<td>14,593.74</td>
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<tr>
<td><strong>Total Current Assets</strong></td>
<td>4,608,012</td>
<td>5,107,939.19</td>
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<tr>
<td>&gt; Fixed Assets</td>
<td></td>
<td></td>
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<tr>
<td>Land: Lot 5-A, Towne Center Business Park</td>
<td>709,080</td>
<td>709,079.90</td>
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<tr>
<td>Land: Lot 1-A-2, Leonard Place Subdivision</td>
<td>295,860</td>
<td>295,860.00</td>
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<tr>
<td>Office Building - 3388 Brentwood Drive</td>
<td>1,057,861</td>
<td>1,057,861.29</td>
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<td>Office Equipment</td>
<td>222,949</td>
<td>224,348.23</td>
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<td>Furniture</td>
<td>156,785</td>
<td>157,808.58</td>
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<tr>
<td>Software: Licensure &amp; Website</td>
<td>408,560</td>
<td>408,560.00</td>
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<tr>
<td>Accumulated Depreciation</td>
<td>(826,997)</td>
<td>(887,718.31)</td>
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<tr>
<td><strong>Total Fixed Assets</strong></td>
<td>2,024,098</td>
<td>1,965,799.69</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>6,632,110</td>
<td>7,073,738.88</td>
</tr>
</tbody>
</table>

### DEFERRED OUTFLOWS OF RESOURCES

**TOTAL ASSETS & DEFERRED OUTFLOWS**

- **7,231,092**
- **8,289,497.88**

### LIABILITIES

<table>
<thead>
<tr>
<th></th>
<th>FY 15-16</th>
<th>FY 16-17</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; Current Liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accrued salaries and benefits</td>
<td>27,169</td>
<td>41,249.33</td>
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<td>Unemployment taxes payable</td>
<td>69</td>
<td>73.35</td>
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<tr>
<td>State taxes withheld</td>
<td>4,820</td>
<td>3,772.92</td>
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<tr>
<td>Deferred compensation withheld</td>
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<td>50.00</td>
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<td>Accounts payable</td>
<td>5,097</td>
<td>4,975.76</td>
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<td>Compensated absences (ST)</td>
<td>43,997</td>
<td>56,822.31</td>
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<td>PES fee payable</td>
<td>0</td>
<td>400.00</td>
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<td><strong>Total Current Liabilities</strong></td>
<td>81,152</td>
<td>107,343.67</td>
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<tr>
<td>Liabilities (cont.)</td>
<td>FY 15-16 Q4 06/30/2016</td>
<td>FY 16-17 Q4 06/30/2017</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Long Term Liabilities</td>
<td></td>
<td></td>
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<tr>
<td>Compensated absences (LT)</td>
<td>76,420</td>
<td>64,263.96</td>
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<td>Other Post Employment Benefits (OPEB) Payable</td>
<td>1,172,029</td>
<td>1,209,508.00</td>
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<td>Net Pension Liability</td>
<td>4,545,653</td>
<td>5,336,594.00</td>
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<td>Total Long Term Liabilities</td>
<td>5,794,102</td>
<td>6,610,365.96</td>
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<td><strong>Total Liabilities</strong></td>
<td>5,875,254</td>
<td>6,717,709.63</td>
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**Deferred Inflows of Resources**

<table>
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<tr>
<th>FY 15-16 Q4 06/30/2016</th>
<th>FY 16-17 Q4 06/30/2017</th>
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<tbody>
<tr>
<td>61,980</td>
<td>78,386.00</td>
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**Equity**

<table>
<thead>
<tr>
<th>FY 15-16 Q4 06/30/2016</th>
<th>FY 16-17 Q4 06/30/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,293,858</td>
<td>1,493,402.25</td>
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</table>

**Total Liabilities, Deferred Inflows, & Equity**

<table>
<thead>
<tr>
<th>FY 15-16 Q4 06/30/2016</th>
<th>FY 16-17 Q4 06/30/2017</th>
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<tbody>
<tr>
<td>7,231,092</td>
<td>8,289,497.88</td>
</tr>
<tr>
<td>Account</td>
<td>FY 16-17 6/30/2017</td>
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<tr>
<td>----------------------------------------------</td>
<td>---------------------</td>
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<tr>
<td>Balance of Equity at Beginning of Year</td>
<td>1,293,857.73</td>
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<tr>
<td>Net Income</td>
<td>199,544.52</td>
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<td>Balance of Equity at End of Year</td>
<td>1,493,402.25</td>
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Components of Equity:

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<tr>
<th>Description</th>
<th>Amount</th>
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<tr>
<td>Fund Balance at End of Prior Year</td>
<td>(881,161.96)</td>
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<td>Fund Balance - designated</td>
<td>209,220.00</td>
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<td>Invested in Fixed Assets</td>
<td>1,965,799.69</td>
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<td></td>
<td>1,293,857.73</td>
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Louisiana Board of Pharmacy
FY 2016-2017
Statement of Revenue, Expenses, and Budget Performance

<table>
<thead>
<tr>
<th>Revenue</th>
<th>FY 15-16 Q4 06/30/2016</th>
<th>FY 16-17 Q4 06/30/2017</th>
<th>Budget (A#1)</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Licenses &amp; Permits</td>
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<tr>
<td>Pharmacist Renewals</td>
<td>811,750</td>
<td>831,200.00</td>
<td>815,000.00</td>
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<td>New Pharmacist Licensing Fee</td>
<td>183,600</td>
<td>178,800.00</td>
<td>185,000.00</td>
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<td>Technician Renewals</td>
<td>334,150</td>
<td>339,350.00</td>
<td>335,000.00</td>
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<td>Technician Candidate Registrations</td>
<td>36,000</td>
<td>42,975.00</td>
<td>35,000.00</td>
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<td>Lapsed Credential Fees</td>
<td>46,400</td>
<td>28,400.00</td>
<td>30,000.00</td>
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<td>Student Registrations</td>
<td>2,890</td>
<td>3,030.00</td>
<td>3,000.00</td>
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<td>Permits - Pharmacies</td>
<td>301,175</td>
<td>281,325.00</td>
<td>300,000.00</td>
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<td>Permits - CDS</td>
<td>466,580</td>
<td>472,545.00</td>
<td>465,000.00</td>
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<td>Permits - Emergency Drug Kits</td>
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<td>12,025.00</td>
<td>12,000.00</td>
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<td>Permits - Automated Medication Systems</td>
<td>20,100</td>
<td>19,950.00</td>
<td>20,000.00</td>
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<td>Permits - Durable Medical Equipment</td>
<td>84,275</td>
<td>86,700.00</td>
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<td>Examinations</td>
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<td>Reciprocity</td>
<td>54,000</td>
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<td>55,000.00</td>
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<td>63,500</td>
<td>54,800.00</td>
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<tr>
<td>Penalties</td>
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<tr>
<td>Licenses and Certificates</td>
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<td>13,400.00</td>
<td>12,000.00</td>
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<tr>
<td>Permits</td>
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<td>Administrative Fees</td>
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<td>Documents: Copies and Certification Fees</td>
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<td>Duplicate Credentials</td>
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<td>Original Certificates</td>
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<td>425.00</td>
<td>500.00</td>
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<td>Handling &amp; Mailing Fees</td>
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<td>Sale of Goods &amp; Services</td>
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<td>Official Lists of Licensees</td>
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<td>USCPSC Inspection Fee</td>
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<td>2,400.00</td>
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<td>Investigative Costs</td>
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<td>Miscellaneous</td>
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<td>1,000.00</td>
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TOTAL REVENUE 3,473,372 3,228,078.78 3,309,500.00 30
# Louisiana Board of Pharmacy
## FY 2016-2017
### Statement of Revenue, Expenses, and Budget Performance

<table>
<thead>
<tr>
<th>Expenses</th>
<th>FY 15-16 Q4 06/30/2016</th>
<th>FY 16-17 Q4 06/30/2017</th>
<th>Budget (A#1)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operations</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Equipment Rentals</td>
<td>15,218</td>
<td>15,169.70</td>
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<td>Equipment Maintenance</td>
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<td>2,793.92</td>
<td>3,000.00</td>
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<td>Telephone</td>
<td>19,029</td>
<td>16,410.53</td>
<td>20,000.00</td>
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<td>Printing</td>
<td>23,951</td>
<td>26,962.56</td>
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<td>Postage</td>
<td>56,467</td>
<td>50,033.28</td>
<td>50,000.00</td>
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<td>Civil Service Assessment</td>
<td>6,323</td>
<td>5,805.00</td>
<td>6,500.00</td>
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<td>Office Insurance (ORM)</td>
<td>8,931</td>
<td>10,595.00</td>
<td>9,000.00</td>
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<td>Dues &amp; Subscriptions</td>
<td>5,832</td>
<td>11,871.81</td>
<td>7,500.00</td>
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<td>Office Supply Expenses</td>
<td>19,008</td>
<td>21,596.15</td>
<td>21,000.00</td>
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<td>Financial Service Charges</td>
<td>50,755</td>
<td>59,196.40</td>
<td>50,000.00</td>
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<td>Depreciation of Fixed Assets</td>
<td>64,639</td>
<td>60,720.98</td>
<td>64,000.00</td>
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<td>608.55</td>
<td>1,000.00</td>
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<td>Utilities</td>
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<td>9,402.63</td>
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<td>Miscellaneous</td>
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<td>Interest Payments on Building Loan</td>
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<td><strong>Acquisitions</strong></td>
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<td>4,543.62</td>
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<td><strong>Personal Services</strong></td>
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<td></td>
</tr>
<tr>
<td>Salaries</td>
<td>1,257,374</td>
<td>1,337,023.83</td>
<td>1,582,000.00</td>
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<td>Payroll Taxes (FICA + FUTA)</td>
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<td>22,260.29</td>
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<td>Retirement Contributions</td>
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<td>663,901.70</td>
<td>594,000.00</td>
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</tr>
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<td>Health Insurance (SEGBP)</td>
<td>139,728</td>
<td>158,756.68</td>
<td>175,000.00</td>
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<td>Other Post Employment Benefits (OPEB)</td>
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<td>37,479.00</td>
<td>100,000.00</td>
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<tr>
<td>Board Member Per Diem</td>
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<td>29,175.00</td>
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<tr>
<td><strong>Professional Services</strong></td>
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<td></td>
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<td>Accounting</td>
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<td>24,315.10</td>
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<td>Legal</td>
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<td>Property Management</td>
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<td>28,130.25</td>
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<td>Temp. Labor</td>
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<td>Prescription Monitoring Program</td>
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<td>82,400.00</td>
<td>90,000.00</td>
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<td><strong>Staff Expenses</strong></td>
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<tr>
<td>ED - Travel</td>
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<td>4,838.79</td>
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<td>GC - Travel</td>
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<td>8,595.85</td>
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<td>AED - Travel</td>
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<td>5,782.27</td>
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<tr>
<td>CO - Travel</td>
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<tr>
<td>CO - Rental Cars &amp; Fuel</td>
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<td>16,438.45</td>
<td>17,500.00</td>
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<td>CO - Education</td>
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<td>6,001.16</td>
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<td>House Staff - Travel</td>
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<tr>
<td>Mileage</td>
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<td>19,092.87</td>
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<td><strong>Board Expenses</strong></td>
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<tr>
<td>Meeting Expenses</td>
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<td>16,543.17</td>
<td>15,000.00</td>
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<td>Committee Expenses</td>
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<td>3,853.40</td>
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<td>Conventions</td>
<td>17,742</td>
<td>22,563.37</td>
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<td>Mileage</td>
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<td>15,568.71</td>
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<td>President's Expenses</td>
<td>9,063</td>
<td>6,282.79</td>
<td>8,000.00</td>
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</tr>
<tr>
<td><strong>TOTAL EXPENSES</strong></td>
<td>2,582,629</td>
<td>2,992,207.25</td>
<td>3,309,500.00</td>
<td>70</td>
</tr>
</tbody>
</table>
## Louisiana Board of Pharmacy

**FY 2016-2017**

### Statement of Fund Balance Changes

<table>
<thead>
<tr>
<th></th>
<th>FY 15-16 Q4 06/30/2016</th>
<th>FY 16-17 Q4 06/30/2017</th>
<th>Budget (A#1)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Income Statement</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Revenue</strong></td>
<td>3,473,372</td>
<td>3,228,078.78</td>
<td>3,309,500.00</td>
<td>71</td>
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<tr>
<td><strong>Total Expenses</strong></td>
<td>2,582,629</td>
<td>2,992,207.25</td>
<td>3,309,500.00</td>
<td>72</td>
</tr>
<tr>
<td><strong>Net Ordinary Income</strong></td>
<td>890,743</td>
<td>235,871.53</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td><strong>Other Income &amp; Expenses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Investment</strong></td>
<td>39,318</td>
<td>(36,327.01)</td>
<td>0.00</td>
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<tr>
<td><strong>Net Income</strong></td>
<td>930,061</td>
<td>199,544.52</td>
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</tr>
</tbody>
</table>

| **Fund Balance**     |                         |                        |              |       |
| **Beginning Fund Balance** | 363,796                | 1,293,857.73           | 1,293,857.00 |       |
| **Total Income**     | 3,512,690               | 3,191,751.77           | 3,309,500.00 |       |
| **Total Expenses**   | 2,582,629               | 2,992,207.25           | 3,309,500.00 |       |
| **Ending Fund Balance** | 1,293,857              | 1,493,402.25           | 1,293,857.00 |       |
| **Reservations of Fund Balance** | 772,000              | 1,750,000.00           | 1,750,000.00 |       |
| **Unreserved Fund Balance** | 521,857               | (256,597.75)           | (456,143.00) |       |

**Notes on Reservation of Fund Balance**

<table>
<thead>
<tr>
<th>Description</th>
<th>FY 15-16 Q4 06/30/2016</th>
<th>FY 16-17 Q4 06/30/2017</th>
<th>FY 16-17 Q4 06/30/2017</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Pension Liability</td>
<td>0</td>
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<td>1,000,000.00</td>
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<td>Other Post Employment Benefits</td>
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<td>500,000.00</td>
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<tr>
<td>Continuing Payroll Obligations</td>
<td>150,000</td>
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<td>150,000.00</td>
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<tr>
<td>Land &amp; Building Maintenance</td>
<td>50,000</td>
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<td>100,000.00</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
<td>772,000</td>
<td>1,750,000.00</td>
<td>1,750,000.00</td>
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</table>
Louisiana Board of Pharmacy  
Statement of Cash Flows  
For the Year Ended June 30, 2017

<table>
<thead>
<tr>
<th>Cash flows from operating activities</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash received from licensees</td>
<td>3,213,815.04</td>
</tr>
<tr>
<td>Cash payments to suppliers for goods and services</td>
<td>(545,114.38)</td>
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<tr>
<td>Cash payments to employees for services</td>
<td>(2,120,987.72)</td>
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<tr>
<td><strong>Net cash provided by operating activities</strong></td>
<td><strong>547,712.94</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cash flows from capital and related financing activities</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase of capital assets</td>
<td>(2,422.99)</td>
</tr>
<tr>
<td><strong>Net cash used by capital and related financing activities</strong></td>
<td><strong>(2,422.99)</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Cash flows from investing activities</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase of securities</td>
<td>(873,225.86)</td>
</tr>
<tr>
<td>Interest income</td>
<td>52,196.34</td>
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<tr>
<td><strong>Net cash provided (used) by investing activities</strong></td>
<td><strong>(821,029.52)</strong></td>
</tr>
</tbody>
</table>

Net decrease in cash and cash equivalents  
(275,739.57)

Cash and cash equivalents, beginning of period  
1,225,893.94

Cash and cash equivalents, end of period  
950,154.37

Reconciliation of operating income to net cash provided by operating activities

<table>
<thead>
<tr>
<th>Cash flows from operating activities</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating income</td>
<td>235,871.53</td>
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</table>

<table>
<thead>
<tr>
<th>Adjustments to reconcile operating income to net cash provided by operating activities</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>Depreciation</td>
<td>60,720.98</td>
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<tr>
<td>Changes in current assets and liabilities</td>
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<tr>
<td>Increase in accounts receivable</td>
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<td>Decrease in prepaid expenses</td>
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<tr>
<td>Increase in deferred outflows related to pensions</td>
<td>(616,777.00)</td>
</tr>
<tr>
<td>Increase in accounts payable and PES fee payable</td>
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<tr>
<td>Increase in salaries and benefits payable</td>
<td>14,080.07</td>
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<tr>
<td>Decrease in payroll tax liability</td>
<td>(992.86)</td>
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<tr>
<td>Increase in compensated absences</td>
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<tr>
<td>Increase in net pension liability</td>
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<tr>
<td>Increase in OPEB payable</td>
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<td>Increase in deferred inflows related to pensions</td>
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<tr>
<td><strong>Total adjustments</strong></td>
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Net cash provided by operating activities  
547,712.94
# Louisiana Board of Pharmacy  
**FY 2016-2017**  
**Budget Variance Notes**

<table>
<thead>
<tr>
<th>Notes</th>
<th>Account No.</th>
<th>Account Name</th>
<th>% Variance</th>
<th>Comment</th>
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<tbody>
<tr>
<td>1</td>
<td>4201</td>
<td>Pharmacist Renewals</td>
<td>1.90</td>
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</tr>
<tr>
<td>2</td>
<td>4206</td>
<td>New Pharmacist Licensing Fee</td>
<td>(3.40)</td>
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</tr>
<tr>
<td>3</td>
<td>4204</td>
<td>Technician Renewals</td>
<td>1.30</td>
<td>Underestimated by 90 applicants</td>
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<td>4</td>
<td>4208</td>
<td>Tech Candidate Registrations</td>
<td>22.80</td>
<td>Underestimated by 319 applicants</td>
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<td>5</td>
<td>4205</td>
<td>Lapsed Credential Fees</td>
<td>(5.30)</td>
<td>Overestimated reinstatement applications</td>
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<td>6</td>
<td>4350</td>
<td>Student Registrations</td>
<td>1.00</td>
<td>Overestimated by 3 applicants</td>
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<td>7</td>
<td>4301</td>
<td>Permits - Pharmacies</td>
<td>(6.20)</td>
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<td>8</td>
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<td>Permits - CDS</td>
<td>1.60</td>
<td>Underestimated growth and renewals</td>
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<td>9</td>
<td>4303</td>
<td>Permits - EDK</td>
<td>0.20</td>
<td>Underestimated by 1 permit</td>
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<tr>
<td>10</td>
<td>4304</td>
<td>Permits - AMS</td>
<td>(0.25)</td>
<td>Overestimated by 1 permit</td>
</tr>
<tr>
<td>11</td>
<td>4306</td>
<td>Permits - DME</td>
<td>2.00</td>
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</tr>
<tr>
<td>12</td>
<td>4153</td>
<td>Exams - Reciprocity</td>
<td>(7.50)</td>
<td>Overestimated by 27 applicants</td>
</tr>
<tr>
<td>13</td>
<td>4152</td>
<td>Exams - Technicians</td>
<td>(8.70)</td>
<td>Underestimated by 52 applicants</td>
</tr>
<tr>
<td>14</td>
<td>4252</td>
<td>Penalties - Licenses</td>
<td>11.70</td>
<td>Underestimated reinstatements</td>
</tr>
<tr>
<td>15</td>
<td>4251</td>
<td>Penalties - Permits</td>
<td>1.90</td>
<td>Underestimated reinstatements</td>
</tr>
<tr>
<td>16</td>
<td>4460+62</td>
<td>Documents: Copies + Certified</td>
<td>(10.20)</td>
<td>Overestimated demand</td>
</tr>
<tr>
<td>17</td>
<td>4452</td>
<td>Duplicate credentials</td>
<td>(11.60)</td>
<td>Overestimated demand</td>
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<tr>
<td>18</td>
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<td>Pharmacist Silver Certificates</td>
<td>0.00</td>
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<tr>
<td>19</td>
<td>4459</td>
<td>Pharmacist Original Certificates</td>
<td>(16.00)</td>
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<tr>
<td>20</td>
<td>4454</td>
<td>NSF Fees</td>
<td>(15.00)</td>
<td>Overestimated incidence</td>
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<tr>
<td>21</td>
<td>4463</td>
<td>Handling &amp; Mailing Fees</td>
<td>(15.50)</td>
<td>Overestimated demand</td>
</tr>
<tr>
<td>22</td>
<td>4402</td>
<td>Law Books</td>
<td>(91.50)</td>
<td>Overestimated demand for supplements</td>
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<tr>
<td>23</td>
<td>4461</td>
<td>Lists of Licensees</td>
<td>51.30</td>
<td>Underestimated demand by 43 requests</td>
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<tr>
<td>24</td>
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<td>Inspection Fees</td>
<td>20.00</td>
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<td>25</td>
<td>4102</td>
<td>Administrative Hearing Fees</td>
<td>(4.80)</td>
<td>Overestimated caseload by 4 cases</td>
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<tr>
<td>26</td>
<td>4501</td>
<td>Fines</td>
<td>(29.40)</td>
<td>Overestimated amount of sanctions</td>
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<tr>
<td>27</td>
<td>4502</td>
<td>Investigative Costs</td>
<td>(50.90)</td>
<td>Overestimated cost recoveries</td>
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<td>28</td>
<td>4660</td>
<td>PMP Assessments</td>
<td>1.80</td>
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<tr>
<td>29</td>
<td>4455</td>
<td>Miscellaneous</td>
<td>404.80</td>
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<tr>
<td>30</td>
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<td>Total Revenue</td>
<td>2.5%</td>
<td>under budget</td>
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**Total Revenue:** 2.5% under budget
# Louisiana Board of Pharmacy
## FY 2016-2017
### Budget Variance Notes

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<th>Notes</th>
<th>Acct. No.</th>
<th>Account Name</th>
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<tbody>
<tr>
<td>31</td>
<td>5321</td>
<td>Equipment Rentals</td>
<td>10.80</td>
<td>Timing issue on office equipment leases</td>
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<td>32</td>
<td>5330</td>
<td>Equipment Maintenance</td>
<td>6.90</td>
<td>Overestimated need for some + timing issue</td>
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<tr>
<td>33</td>
<td>5370</td>
<td>Telephone</td>
<td>17.90</td>
<td>Overestimated utilization</td>
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<tr>
<td>34</td>
<td>5305</td>
<td>Printing</td>
<td>(7.90)</td>
<td>Underestimated demand</td>
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<tr>
<td>35</td>
<td>5300</td>
<td>Postage</td>
<td>(0.07)</td>
<td>Close estimate</td>
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<tr>
<td>36</td>
<td>5125</td>
<td>Civil Service Assessment</td>
<td>10.70</td>
<td>Annual fee, based in part on size of staff</td>
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<td>37</td>
<td>5230</td>
<td>Office Insurance (ORM)</td>
<td>(17.70)</td>
<td>Annual fee, based in part on size of staff</td>
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<tr>
<td>38</td>
<td>5190</td>
<td>Dues &amp; Subscriptions</td>
<td>(58.30)</td>
<td>Underestimated renewal demands</td>
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<tr>
<td>39</td>
<td>5280</td>
<td>Office Supply Expenses</td>
<td>(2.80)</td>
<td>Underestimated demand</td>
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<tr>
<td>40</td>
<td>5381</td>
<td>Financial Service Charges</td>
<td>(18.30)</td>
<td>Underestimated use of online renewals</td>
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<td>41</td>
<td>5180</td>
<td>Depreciation</td>
<td>5.10</td>
<td>Overestimated depreciation schedule</td>
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<td>42</td>
<td>5260</td>
<td>Office Meetings</td>
<td>39.10</td>
<td>Overestimated demand</td>
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<tr>
<td>43</td>
<td>5390</td>
<td>Utilities</td>
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<td>44</td>
<td>5115</td>
<td>Acquisitions</td>
<td>81.80</td>
<td>Deliberate deferrals</td>
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<td>45</td>
<td>5350</td>
<td>Salaries</td>
<td>15.50</td>
<td>Staff turnovers</td>
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<td>46</td>
<td>5290</td>
<td>Payroll Taxes (FICA + FUTA)</td>
<td>30.40</td>
<td>Staff turnovers + less temporary staff</td>
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<td>47</td>
<td>5340</td>
<td>Retirement Contributions</td>
<td>(11.80)</td>
<td>Premium increased by state</td>
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<tr>
<td>48</td>
<td>5220</td>
<td>Health Insurance (SEGBP)</td>
<td>9.30</td>
<td>Plan premium changes + plan choice change</td>
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<td>49</td>
<td>2400</td>
<td>OPEB</td>
<td>(62.50)</td>
<td>Premium decreased by state</td>
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<td>50</td>
<td>5152</td>
<td>Board Member Per Diem</td>
<td>2.80</td>
<td>Overestimated meeting activity</td>
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<tr>
<td>51</td>
<td>5110</td>
<td>Accounting Services</td>
<td>18.90</td>
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<td>52</td>
<td>5250</td>
<td>Legal Services</td>
<td>(154.00)</td>
<td>Unanticipated litigation</td>
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<td>53</td>
<td>5295</td>
<td>Information Systems</td>
<td>9.50</td>
<td>Delayed planned upgrade</td>
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<td>54</td>
<td>5297</td>
<td>Property Management</td>
<td>29.70</td>
<td>Deferred roof and A/C replacement</td>
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<td>55</td>
<td>5296</td>
<td>Temporary Labor</td>
<td>71.10</td>
<td>Less robust labor pool in high school</td>
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<tr>
<td>56</td>
<td>5600</td>
<td>Prescription Monitoring Program</td>
<td>8.40</td>
<td>Delayed additional enhancements</td>
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<td>57</td>
<td>5361</td>
<td>Staff Travel - Executive Director</td>
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<tr>
<td>58</td>
<td>5365</td>
<td>Staff Travel - General Counsel</td>
<td>14.00</td>
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<tr>
<td>59</td>
<td>5373</td>
<td>Staff Travel - Asst Exec Dir</td>
<td>42.70</td>
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<tr>
<td>60</td>
<td>5363</td>
<td>Staff Travel - Compliance Officers</td>
<td>27.50</td>
<td>Overestimated demand</td>
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<tr>
<td>61</td>
<td>5371-72</td>
<td>Staff Travel - Rental Cars &amp; Fuel</td>
<td>6.10</td>
<td>Overestimated demand</td>
</tr>
<tr>
<td>62</td>
<td>5368</td>
<td>Staff Educ - Compliance Officers</td>
<td>64.70</td>
<td>Limited to USP-797 inspection training</td>
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<tr>
<td>63</td>
<td></td>
<td>Staff - Office staff travel</td>
<td>*</td>
<td>House staff educational seminars</td>
</tr>
<tr>
<td>64</td>
<td>62+64+67</td>
<td>Mileage - entire staff</td>
<td>4.50</td>
<td>Overestimated travel demands</td>
</tr>
<tr>
<td>65</td>
<td>5153</td>
<td>Board - Meeting Expenses</td>
<td>(10.30)</td>
<td>Underestimated meeting travel</td>
</tr>
<tr>
<td>66</td>
<td>5155</td>
<td>Board - Committee Expenses</td>
<td>51.80</td>
<td>Overestimated meeting travel</td>
</tr>
<tr>
<td>67</td>
<td>5154</td>
<td>Board - Convention Expenses</td>
<td>(12.80)</td>
<td>Underestimated conference travel</td>
</tr>
<tr>
<td>68</td>
<td>5151</td>
<td>Board - Mileage</td>
<td>8.40</td>
<td>Overestimated meeting travel</td>
</tr>
<tr>
<td>69</td>
<td>86+87+88</td>
<td>Board - President's Expenses</td>
<td>21.50</td>
<td>Overestimated meeting travel</td>
</tr>
<tr>
<td>70</td>
<td></td>
<td>Total Expenses</td>
<td></td>
<td>9.6% under budget</td>
</tr>
</tbody>
</table>

### Summary

- **Total Revenue**: 7.1% decrease from FY 16 revenue
- **Total Expenses**: 16% increase from FY expenses
- **Investments**: 52,198 income + 88,525 loss in value
- **Net Income/Loss**: 78.5% decrease from FY 16 net income
Louisiana Board of Pharmacy
FY 2016-2017
Schedule A - Hurricane Katrina/Rita Pharmacy Relief Fund

Statement of Assets, Liabilities & Equity

<table>
<thead>
<tr>
<th></th>
<th>FY 15-16</th>
<th>FY 16-17</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td>Q4 06/30/2016</td>
<td>Q4 06/30/2017</td>
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<tr>
<td>Current Assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hancock Bank - Checking Account</td>
<td>83,305</td>
<td>83,389</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>83,305</td>
<td>83,389</td>
</tr>
<tr>
<td><strong>LIABILITIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Liabilities</td>
<td>0</td>
<td>0</td>
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<tr>
<td><strong>EQUITY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retained Earnings</td>
<td>83,221</td>
<td>83,305</td>
</tr>
<tr>
<td>Net Income</td>
<td>84</td>
<td>84</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES &amp; EQUITY</strong></td>
<td>83,305</td>
<td>83,389</td>
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</tbody>
</table>

Statement of Receipts & Disbursements

<table>
<thead>
<tr>
<th></th>
<th>FY 15-16</th>
<th>FY 16-17</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RECEIPTS</strong></td>
<td>Q4 06/30/2016</td>
<td>Q4 06/30/2017</td>
</tr>
<tr>
<td>FEMA - Funds for payment of claims</td>
<td>8,920,812</td>
<td>8,920,812</td>
</tr>
<tr>
<td>FEMA - Administrative allowance</td>
<td>81,103</td>
<td>81,103</td>
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<tr>
<td>Pharmacies - reversal of claims</td>
<td>430,138</td>
<td>430,138</td>
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<tr>
<td>Interest income</td>
<td>22,230</td>
<td>22,314</td>
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<tr>
<td><strong>TOTAL RECEIPTS</strong></td>
<td>9,454,283</td>
<td>9,454,367</td>
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<table>
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<tr>
<th></th>
<th>FY 15-16</th>
<th>FY 16-17</th>
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<tbody>
<tr>
<td><strong>DISBURSEMENTS</strong></td>
<td>Q4 06/30/2016</td>
<td>Q4 06/30/2017</td>
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<tr>
<td>Claims paid to pharmacies</td>
<td>8,920,812</td>
<td>8,920,812</td>
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<tr>
<td>Reversed claim funds returned</td>
<td>430,138</td>
<td>430,138</td>
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<tr>
<td>Reversed administrative allowance returned</td>
<td>7,338</td>
<td>7,338</td>
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<tr>
<td>Interest earned on reversed admin. allowance returned</td>
<td>12,690</td>
<td>12,690</td>
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<tr>
<td><strong>TOTAL DISBURSEMENTS</strong></td>
<td>9,370,978</td>
<td>9,370,978</td>
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</table>

**FUND BALANCE**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>83,305</td>
</tr>
<tr>
<td></td>
<td>83,389</td>
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</tbody>
</table>

Note: These funds are held in an account separate and apart from the Board's operating funds. Further, all recordkeeping is kept separate from the Board's general fund records. At the conclusion of the audit exposure period, any funds remaining will be transferred to the Board's operating account.
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/17/2015</td>
<td>Original Budget - Finance Committee Approval</td>
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<tr>
<td>11/18/2015</td>
<td>Original Budget - Board Approval</td>
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<tr>
<td>8/9/2016</td>
<td>Budget Amendment #1 - Finance Committee Approval</td>
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<tr>
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<td>Budget Amendment #1 - Board Approval</td>
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<tr>
<td></td>
<td>Budget Amendment #2 - Finance Committee Approval</td>
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<td>Budget Amendment #2 - Board Approval</td>
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<td></td>
<td>Acceptance of Final Report</td>
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## Holdings by Investor

### LA Board of Pharmacy

**Acct Name:** Louisiana Board of Pharmacy  
**Acct No:** H5E049797  
**Acct Type:** Non-Profit Organization

<table>
<thead>
<tr>
<th>Asset Name</th>
<th>Ticker</th>
<th>Investment Objective</th>
<th>Mgt. Name</th>
<th>Quantity</th>
<th>Price ($)</th>
<th>Value ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BROKERAGE MONEY MARKET</td>
<td></td>
<td>CASH</td>
<td>BROKERAGE MONEY MARKET</td>
<td>17,344.53</td>
<td>1.00</td>
<td>17,344.53</td>
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<tr>
<td>CASH</td>
<td></td>
<td>CASH</td>
<td>BROKERAGE MONEY MARKET</td>
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<td>1,178.13</td>
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<tr>
<td>UNITED STATES TREAS NTS NOTE 1.625000%</td>
<td>TSRYS44944</td>
<td>NON-CLASSIFIED</td>
<td></td>
<td>145,000.00</td>
<td>1.00</td>
<td>145,255.20</td>
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<tr>
<td>06/30/2020</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>US TREAS INFLAT PROT</td>
<td>912826NM8</td>
<td>LONG-TERM BOND</td>
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<td>25,000.00</td>
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<tr>
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<td>593,000.00</td>
<td>0.99</td>
<td>591,534.36</td>
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</table>

**Account Total**  
$1,235,527.11

**Investor Total**  
$1,235,527.11
# Holdings by Investor

**LA Board of Pharmacy**

**Acct Name:** OPEB Reserve account  
**Acct No:** H5E077160  
**Acct Type:** Non-Profit Organization

<table>
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<tr>
<th>Asset Name</th>
<th>Ticker</th>
<th>Investment Objective</th>
<th>Mgt. Name</th>
<th>Quantity</th>
<th>Price ($)</th>
<th>Value ($)</th>
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</thead>
<tbody>
<tr>
<td>BROKERAGE MONEY MARKET</td>
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<td>UNITED STATES TREAS NTS 1.250% 12/31/18 B/EDTD 12/31/16</td>
<td>TSRYS44 943</td>
<td>NON-CLASSIFIED</td>
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<td>99,000.00</td>
<td>1.00</td>
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<tr>
<td>UNITED STATES TREAS NTS NOTE 1.62500% 06/30/2020</td>
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<td>61,129.67</td>
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<td>728,000.00</td>
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<td>240,474.48</td>
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**Account Total** $1,197,865.54  
**Investor Total** $1,197,865.54
# Holdings by Investor

**LA Board of Pharmacy**

**Acct Name:** Pension Reserve account  
**Acct No:** H5E102679  
**Acct Type:** Non-Profit Organization

<table>
<thead>
<tr>
<th>Asset Name</th>
<th>Ticker</th>
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<th>Mgt. Name</th>
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<th>Value ($)</th>
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</thead>
<tbody>
<tr>
<td>BROKERAGE MONEY MARKET</td>
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<td>CASH</td>
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<td>29,061.65</td>
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<tr>
<td>1.62500% 06/30/2020</td>
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Finance Committee

Proposed Budget Amendment No. 1
Fiscal Year 2017-2018

August 23, 2017

Blake P. Pitre
Chair
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<td>5151+5288</td>
<td>Mileage - Members &amp; President</td>
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<td>5286+87</td>
<td>President's Expenses</td>
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<td><strong>TOTAL EXPENSES</strong></td>
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<td><strong>3,160,000.00</strong></td>
<td><strong>3,560,000.00</strong></td>
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## Louisiana Board of Pharmacy
### FY 2017-2018 Budget

### Summary

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<tr>
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<th>FY 17-18 Original</th>
<th>FY 17-18 BA-1</th>
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<tr>
<td>Total Expenses</td>
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<td>Investments</td>
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<td>Reserve Account - Deposit/Withdrawal</td>
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<td>Net Income</td>
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### FY 16-17 Actual FY 17-18 Budget FY 17-18 BA-1

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<td>Beginning Fund Balance</td>
<td>1,293,857.73</td>
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<td>Unreserved Fund Balance</td>
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<td>Total</td>
<td>1,750,000.00</td>
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Louisiana Board of Pharmacy  
FY 2017-2018 Budget

Notes

Revenue
1. Using historical data, estimate 600 new pharmacists @ $300 each.
2. Using historical data, estimate 330 reciprocity applicants @ $150 each.
3. Using historical data, estimate 8,300 pharmacists renewing @ $100 each.
4. Using historical data, estimate 1,600 tech candidate applicants @ $25 each.
5. Using historical data, estimate 550 tech applicants @ $100 each.
6. Using historical data, estimate 1,990 permits renewing @ $125 each + 275 new @ $150 ea.
7. Using historical data.
8. Using historical data.
9. Using historical data, estimate 84 orders @ $75 each.
10. Using historical data, estimate 100 orders @ $150 each.
11. Using historical data.
12. Using historical data.
14. Using historical data, estimate 20,800 assessments @ $25 each.

Expenses
15. Using historical data.
17. Using historical data, including additional printing for regulatory projects.
18. Using historical data, including additional postage for 2018 member elections.
19. Using historical data + enhanced information system network security subscription.
20. Using historical data.
22. Using historical data.
25. Using historical data.
26. For planned rotations of office computers, equipment, and furniture.
27. Includes 2% statewide general pay increase scheduled for 01-01-2018.
28. Includes additional student labor in lieu of additional permanent staff.
29. Calculated value: 2% of salaries + temp labor.
30. Calculated value: 12% of salaries.
31. Calculated value: 37.9% of salaries.
32. Using historical data, reflecting agency assessment.
33. Using historical data.
34. Using historical data, including increased medical evaluations.
35. Using historical data, including special project for auto-registration of prescribers.
36. Using historical data, including renovation project (see data worksheet).
37. Using historical data.
38. Using historical data.
39. Using historical data.
40. Using historical data, including an extra board meeting.
41. Using historical data.
42. Reflects 12% increase over original budget and 18% increase over FY 16-17 actual.
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## Louisiana Board of Pharmacy
### FY 2017-2018
#### Budget Amendment No. 1 Proposal

**Data Worksheet**

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<th>Operations</th>
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<tr>
<td></td>
<td>Copier #2</td>
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<tr>
<td></td>
<td>Postage + folder</td>
<td>605/month</td>
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<tr>
<td>5370</td>
<td>Telephone System</td>
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<td>AT&amp;T charges</td>
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<td>State OTM charges</td>
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<td>5125</td>
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**Acquisitions**

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<tr>
<td>5105</td>
<td>Acquisitions</td>
<td>Planned rotations of computers, printers, software, and furniture</td>
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**Personal Services**

5350 Salaries  
Includes 2% general state pay increase  
1,480,000

5340 Retirement  
FY 16-17 Rate – 37.2%  
FY 17-18 Rate – 37.9%  
568,500

5220 Health Insurance (SEGBP)  
includes current staff as well as retirees and widows; current experience is 12% of salaries.  
178,000

**Professional Services**

5295 Information Systems  
Iron Data Maintenance  
70,000

➢ PMP Auto Registration Report  
06,500

Essential Solutions (support)  
45,000

Medical assessments  
10,000

5297 Property Management  
393,500

Security  
295/month  
03,540

Interior Maintenance  
250/month  
03,000

Groundskeeping + Pest  
460/month  
05,520

➢ Project re Termite Prevention  
01,500

Trash & Recycling  
160/month  
01,920

General Maintenance  
165/month  
02,000

HVAC Maintenance  
620/quarter  
02,500

19,980

Cooperative Endeavor Agreement (CEA) with Office of Facility Planning & Control (FPC) in La. Division of Administration (DOA)  
373,500

• Building Exterior  
➢ Roof replacement  
➢ Stucco repair or replacement as needed  
➢ Pressure wash building and parking lot  
➢ Re-stripe parking lot and relocate blue zone  
➢ Column repair and pain  
➢ Paint trim, metal rails, 2 employee doors  
➢ Replace exterior slate at main entrance  
➢ Replace HVAC for northwest quadrant of building  
➢ Replace exterior fabric awning with metal awning  
➢ Replace fencing around HVAC units in parking lot

• Building Interior  
➢ Renovate 4 restrooms (flooring, fixtures, cabinets, toilets, sinks, partitions, electrical, ventilation)  
➢ Replace brick paver flooring  
➢ Steam clean carpet  
➢ Paint doors, trim, molding, ceiling in lobby  
➢ Replace electrical lighting fixtures
Contract awarded after public bid process in 2013; successful bidder (Optimum Technology) was acquired by current vendor (Appriss).
Bid price was $378,000 over 5 years:

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<tr>
<td>FY 16-17</td>
<td>73,200</td>
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<tr>
<td>FY 17-18</td>
<td>73,200</td>
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</table>

Special Project for FY 17-18:
- Automatic Enrollment for Prescribers 20,000

Must return to public bid process prior to Nov. 18.

Special Project for FY 18-19:
- Enhanced Analytics Reporting Package TBD
Application Review Committee
Reciprocity Committee

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.
Violations Committee
Impairment Committee

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.
Roster of Approved Addictionists

Richard P. Amar, MD
Talbott Recovery Center
5448 Yorktowne Drive
Atlanta, GA 30349
Telephone (844) 225-3097
La. License No. 049558
Issued: 12-08-2000 Expires: 04-30-2019
Status: Active and unrestricted
Certification: ABPN No. 2041
Issued: 10-12-2010 Expires: 10-12-2020

Roy D. Ary, Jr., MD
BioBehavioral Medicine, Inc.
4933 Wabash Street
Metairie, LA 70001
Telephone (504) 780-2766
La. License No. MD.09977R
Issued: 07-29-1993 Expires: 08-31-2017
Status: Active and unrestricted
Certification: ABAM No. 000870
Issued: 03-12-2009 Expires: 12-31-2019

Navjyot S. Bedi, MD
Talbott Recovery Center
5448 Yorktowne Drive
Atlanta, GA 30349
Telephone (844) 225-3097
Ga. License No. 055658
Issued: 12-03-2004 Expires: 04-30-2019
Status: Active and unrestricted
Certification: ABAM No. 002509
Issued: 05-02-2009 Expires: 12-31-2019

Joan E. Brunson, MD
Edgefield Recovery Center
10631 Hwy. 71 North
Cheneyville, LA 71325
Telephone (888) 327-2673
La. License No. MD.017125
Issued: 06-16-1983 Expires: 09-30-2017
Status: Active and unrestricted (D)
Certification: ABAM No. 000999
Issued: 03-12-2008 Expires: 12-31-2018

José Calderón-Abbo, MD
The Mind-Body Center of Louisiana
3439 Magazine Street
New Orleans, LA 70115
Telephone (504) 891-8808
La. License No. MD.14816R
Issued: 10-22-2002 Expires: 01-31-2018
Status: Active and unrestricted
Certification: ABAM No. 000881
Issued: 03-12-2009 Expires: 03-12-2019

Louis Cataldie, MD
3535 Brentwood Drive
Baton Rouge, LA 70806
Telephone (225)
La. License No. MD.012613
Issued: 06-13-1974 Expires: 08-31-2017
Status: Active and unrestricted (D)
Certification: ABAM No. 003000
Issued: 05-02-2009 Expires: 05-02-2019

John R. Colaluca, DO
Palmetto Recovery Center
86 Palmetto Road
Rayville, LA 71269
Telephone (318) 728-2970
La. License No. DO.021805
Issued: 07-01-1993 Expires: 09-30-2017
Status: Active and unrestricted (D)
Certification: ABAM No. 000886
Issued: 03-12-2009 Expires: 03-12-2019

Revised: 08-22-2017
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<tbody>
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<td>J. David Hammond, Jr., MD</td>
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<td>86 Palmetto Road</td>
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<tr>
<td>Rayville, LA 71269</td>
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<td>Telephone (318) 728-2970</td>
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<tr>
<td>Dean A. Hickman, MD</td>
<td>La. License No. MD.020992</td>
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<td>Oksana V. Kershteyn, MD</td>
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<td>Telephone (844) 225-3097</td>
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<tr>
<td>Edward C. LaFleur, MD</td>
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<td>111 Liberty Avenue</td>
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<tr>
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<tr>
<td>Scott D. Mayers, MD</td>
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<td>Telephone (888) 991-2237</td>
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<tr>
<td>Jay L. Piland, Sr., MD</td>
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<tr>
<td>Alphonse K. Roy, III, MD</td>
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<td>Telephone (504) 780-2766</td>
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<td>Kelly A. Scheinberg, MD</td>
<td>Ga. License No. 067608</td>
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<td>Telephone (844) 225-3097</td>
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Revised: 08-22-2017
Ronald V. Taravella, MD  
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Status: Active and unrestricted (D)  
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Issued: 06-30-1994 (Issues prior to 1998 do not expire)

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Certification: ABPN No. 002346  
Issued: 09-29-2014 Expires: 09-29-2024

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Certification: ABAM No. 000853  
Issued: 03-12-2009 Expires: 12-31-2019
Reinstatement Committee
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.
Regulation Revision Committee
MEMORANDUM

To: Board Members

From: Malcolm Broussard

Date: August 23, 2017

Re: Regulatory Project 2015-9 ~ Pharmacy Technicians

Project Timeline

11-30-2015 > Board adopted Emergency Rule #1 for the purpose of delaying the implementation date in the current rule (§905.A.3.b) from January 1, 2016 to January 1, 2017; the current rule requires applicants for the pharmacy technician certificate submitting their applications to document their successful completion of a nationally-accredited and board-approved pharmacy technician training program.

> Board directed the Regulation Revision Committee to revise the current rule to shift the requirement of national accreditation of the training program FROM qualification for the technician certificate TO qualification for the technician candidate registration; and further, to update the CE requirements to include CPE Monitor; and further, to update the scope of practice for technicians by removing the compounding restriction.

03-24-2016 Re-issued original Emergency Rule #2.

05-04-2016 Board approved Regulatory Proposal 2015-J (Draft #4) for promulgation.

07-22-2016 Re-issued original Emergency Rule #3.

11-17-2016 Board adopted Revised Emergency Rule #4 for the purpose of further delaying the implementation date, from January 1, 2017 to January 1, 2018.

01-09-2017 Initiated Regulatory Project 2015-9; submitted Notice of Intent to Joint Legislative Oversight Committee.

01-20-2017 Notice of Intent published in Louisiana Register.

03-01-2017 Public hearing to receive comments and testimony on proposed rule.

03-14-2017 Special Board Meeting to consider comments and testimony; approved rule changes in 4 topics.
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<tr>
<td>03-15-2017</td>
<td>Re-issued <em>Revised Emergency Rule #5</em>.</td>
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<tr>
<td>05-20-2017</td>
<td>Proposed rule changes published as <em>Potpourri Notice</em> in <em>Louisiana Register</em>.</td>
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<tr>
<td>06-26-2017</td>
<td>Public hearing to receive comments and testimony on proposed rule changes.</td>
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<tr>
<td>07-10-2017</td>
<td>Re-issued <em>Revised Emergency Rule #6</em>.</td>
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<tr>
<td>08-23-2017</td>
<td>Board meeting to consider comments and testimony on proposed rule changes.</td>
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<tr>
<td>11-06-2017</td>
<td>Scheduled to re-issue <em>Revised Emergency Rule #7</em>.</td>
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Louisiana Administrative Code
Title 46 – Professional and Occupational Standards
Part LIII: Pharmacists

Chapter 9. Pharmacy Technicians

§901. Definitions

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

1. CPE Monitor – a collaborative service from the National Association of Boards of Pharmacy (NABP) and the Accreditation Council for Pharmacy Education (ACPE) that provides an electronic system for pharmacists and pharmacy technicians to record and track their completed CPE activities.

2. Pharmacy Technician Candidate – an individual not yet certified as a pharmacy technician by the board who is registered by the board, training to become a pharmacy technician, who assists in the practice of pharmacy under the direct and immediate supervision of a Louisiana-licensed pharmacist.
   a. an individual who possesses a valid registration and is working under the supervision of a pharmacist for the purpose of obtaining practical experience for certification as a pharmacy technician by the board; or
   b. an individual who possesses a valid registration and is awaiting examination.

3. Structured Training Program – Repealed a pharmacy technician training program that is currently nationally-accredited and has been approved by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2485 (November 2004), effective January 1, 2005, amended LR 39:1777 (July 2013), amended LR

§903. Pharmacy Technician Candidates

A. Registration

1. All pharmacy technician candidates shall obtain a registration from the board prior to performing any professional functions in a pharmacy; failure to do so may result in disciplinary action by the board.

2. Qualifications
   a. All pharmacy technician candidates shall register with the board, failure to do so may result in disciplinary action by the board.
   b. a. The candidate applicant shall be at least 18 years of age, as evidenced by a valid and legible copy of a birth certificate or other appropriate credential.
      b. The candidate applicant shall be of good moral character and non-impaired.
   c. The candidate shall be a graduate from a high school approved by a state department of education, or shall possess an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential.
   d. The applicant shall satisfy one of the following eligibility criteria:
      i. Proof of enrollment in a nationally-accredited and board-approved pharmacy technician training program; or
      ii. Proof of successful completion of the board-approved technician certification examination, and further, proof of successful completion of a high school approved by a state department of education or an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential; or
      iii. Proof of credentialing as a pharmacy technician by another state board of pharmacy as well as evidence of practice as a pharmacy technician for at least one year in that state, and further, proof of successful completion of the board-approved technician certification examination.
e. d. Exceptions:
   i. A pharmacist or pharmacist intern whose board credential has been denied, suspended, revoked, or restricted for disciplinary reasons by any board of pharmacy shall not be a pharmacy technician candidate or pharmacy technician.
   ii. A pharmacist or pharmacist intern who board credential is lapsed shall not be a pharmacy technician candidate or pharmacy technician until such lapsed credential is recalled through non-disciplinary board action.

3. Issuance and Maintenance
   a – b …
   c. The registration shall expire 18 24 months after the date of issuance, and it shall not be renewable.
   d – e …

B. Training Programs
1. All training programs approved by the board shall maintain their national accreditation.
2. The training program shall notify the board when a pharmacy technician candidate is no longer satisfactorily progressing in the program. Evidence of a program’s failure to comply with this rule shall constitute sufficient basis for the withdrawal of the board’s approval for the program.
3. The training program shall provide an appropriate credential to the pharmacy technician candidate who has successfully completed the program, provided, however, that such credential shall not be formatted in such a manner to lead anyone to believe that credential resembles a document providing legal authority to practice as a pharmacy technician.

B. C. Practical Experience
1. The candidate shall possess a registration prior to performing any permitted professional function or earning any practical experience in a pharmacy.
2. The candidate’s registration shall be conspicuously displayed in the prescription department.
3. The candidate shall wear appropriate attire and be properly identified as to name and candidate status while on duty in the prescription department.
4. A candidate shall not work in a permitted site that is on probation with the board, or with a pharmacist who is on probation with the board.
5. The candidate’s registration shall evidence his authority to earn a minimum of 600 hours of practical experience in a pharmacy, under the supervision of a pharmacist, in satisfaction of the requirements for pharmacy technician certification.
   a. In the event the registration was issued to an applicant enrolled in a nationally-accredited and board-approved training program, the candidate shall earn the amount of experience prescribed by the curriculum of that program; or
   b. In the event the registration was issued to an applicant by any other method, the candidate shall earn at least 600 hours of practical experience in a pharmacy in Louisiana, provided however, that a candidate may receive board credit for a maximum of 50 hours per week.
6. A candidate may receive board credit for a maximum of 50 hours per week.
7. Hours of practical experience earned by a candidate shall expire one two years after the expiration date of the registration.

C. D. Examination
1. A board-approved technician examination shall consist of integrated pharmacy subject matter and any other disciplines the board may deem appropriate in order to permit the candidate to demonstrate his competency. The candidate shall achieve a passing score, as determined by the board.
2. Re-examination
   a. Following the first or second unsuccessful attempt of an examination, the candidate may be permitted to retake that examination.
   b. Following the third unsuccessful attempt of an examination, the candidate shall wait one year after the date of the last examination to retake that examination. If the candidate fails to wait the prescribed one year period, the board may delay any future certification until that one year period has elapsed.
§905. Pharmacy Technician Certificate

A. Qualifications

3. An applicant shall demonstrate one of the following educational competencies:
   a. shall be a graduate from a high school approved by a state department of education, or shall possess an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential; and
   b. For those applicants submitting applications on or after January 1, 2016, the applicant shall demonstrate successful completion of a nationally-accredited and board-approved pharmacy technician training program, as evidenced by a valid and legible copy of the appropriate credential from that program.
      a. In the event the applicant obtained their technician candidate registration on the basis of their enrollment in a nationally-accredited and board-approved pharmacy technician training program, the applicant shall demonstrate successful completion of that training program, or in the alternative, another nationally-accredited and board-approved pharmacy technician training program.
      b. In the event the applicant obtained their technician candidate registration by any other method, the applicant shall demonstrate the acquisition of at least 600 hours of practical experience under the supervision of a pharmacist, using a form supplied by the board.

4. An applicant shall demonstrate evidence of at least 600 hours of practical experience under the supervision of a pharmacist, using a form supplied by the board.

§907. Scope of Practice

C. Pharmacy technicians shall not:

3. compound high-risk sterile preparations, as defined by the United States Pharmacopeia (USP), or its successor;
4. counsel patients.
§909. Continuing Education

A. …

B. Certified pharmacy technicians shall maintain copies of their individual records of personal CPE activities at their primary practice site for at least 2 years with CPE Monitor and shall authorize the board’s access to their file by recording their Louisiana pharmacy technician certificate number within that file, and shall present them a copy of their CPE Monitor transcript when requested by the board.

C – D.3 …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

MEMORANDUM

To: Board Members & Staff
From: Malcolm Broussard
Date: March 15, 2017
Re: Proposed Revisions to Pharmacy Technician Notice of Intent

The following proposed revisions to the Pharmacy Technician Notice of Intent were approved by the board during their March 14, 2017 meeting. These proposed revisions will be published as a Potpourri Notice in the Louisiana Register, and a second public hearing will be held on June 26, 2017 to solicit comments and testimony of these proposed revisions.

1. §903.A.2.c.ii and iii
   To allow for the possibility of more than one board-approved technician certification examination, by changing ‘the’ to ‘a’.

2. §903.A.3.d
   To add new language to clarify that termination of enrollment in a training program removes the eligibility for a candidate to retain their registration (if the registration was issued pursuant to such enrollment) and provide a mechanism for the re-issuance of the registration upon re-enrollment in a training program.

3. §903.B.2
   To change the requirement for training programs to notify the board when candidates are ‘no longer satisfactorily progressing’ to ‘no longer enrolled due to any reason other than graduation.’

4. §903.C.4.a
   To allow candidates enrolled in a nationally-accredited training program to acquire some of their hours of practical experience in a consultant pharmacy practice that does not hold a pharmacy permit.
NOTICE IS HEREBY GIVEN that a Public Hearing has been ordered and called for 9:00 a.m. on Monday, June 26, 2017 at the Board office, for the purpose to wit:

AGENDA

1. Call to Order
2. Appearances
3. Potpourri Notices
   A. Regulatory Project 2015-9 ~ Pharmacy Technicians
   B. Regulatory Project 2016-6 ~ Marijuana Pharmacy
4. Opportunity for Public Comment
5. Adjourn
# Louisiana Board of Pharmacy
3388 Brentwood Drive  
Baton Rouge, LA 70809-1700  
www.pharmacy.la.gov

**Public Hearing**  
**Monday, June 26, 2017**

## Guest Register

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<tr>
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<tr>
<td>M. Allam Baheth</td>
<td>Baheth R&amp;D Labs</td>
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<td>Richard Perry</td>
<td>Baheth R&amp;D Labs</td>
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<td>Joel Fruge</td>
<td>Brown &amp; Brown INSURANCE</td>
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<td>Kiana London</td>
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<td>Paul R. Reynolds</td>
<td>MTC, Director</td>
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<td>Randy P. Gros</td>
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<td>Hossee M.</td>
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<tr>
<td>Lindsey McDonald</td>
<td>National Healthcare Association</td>
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<tr>
<td>Jesse McCormick</td>
<td>Capitol Partners</td>
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Summary of Testimony & Public Comments  
re  
Regulatory Project 2015-9 ~ Pharmacy Technicians  
at  
June 26, 2017 Public Hearing

1. June 23, 2017 letter Mary Staples, for NACDS  
Revisited their previous comment from the first public hearing on the requirement for pharmacy technician training programs to maintain national accreditation as well as board approval. Requested again the proposed rule be revised to require one or the other, but not both. The language for this requirement is found in the definition of training program in §901, as well as in §903.A.2.c.i, §903.B.1, and §905.A.3.a.

2. Testimony from Lyndsey McDonald on behalf of National Healthcareer Association (NHA)  
Indicated NHA is the provider of the Examination for the Certification of Pharmacy Technicians (ExCPT). Noted the proposed revision of §903.A.2.c.ii, which would allow for the approval of more than one pharmacy technician certification, and requested information on the procedures NHA should follow to secure the Board’s approval of their ExCPT test. Offered no specific recommendations for revision.
June 23, 2017

Mr. Malcolm J. Broussard  
Executive Director  
Louisiana Board of Pharmacy  
3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700

RE: Proposed Regulation for Pharmacy Technicians

Dear Mr. Broussard:

On behalf of our members operating in the state of Louisiana, the National Association of Chain Drug Stores (NACDS) appreciates the Louisiana Board of Pharmacy (Board) for accepting our changes regarding the notice requirement by training programs in the proposed regulation 46-LIII-9 (Proposed Regulation). However, we have an ongoing concern which we urge you to seriously consider.

To optimize the delivery of high quality and timely patient care, NACDS supports a practice environment that utilizes and promotes well-qualified pharmacy technicians as essential members of the pharmacy care team. NACDS believes that a choice in exam is vital to this goal. The certification should reflect the needs of the employer so that the technician can perform the necessary duties. If an exam is certified by the National Commission for Certifying Agencies, it should be an accepted certification in Louisiana. As such, we urge you to make the following changes in the Proposed Regulation to allow a choice in certification exams.

Section 901: Definition of “Training Programs”

   *Training Program* – a pharmacy technician training program that is currently nationally-accredited and or has been approved by the board.

This language appears throughout the regulation and we recommend the following revisions to ensure uniformity:

Section 903(A)(2)(c)(i): Proof of enrollment in a nationally-accredited and or board-approved pharmacy technician training program;

Section 903(B)(1): All accredited training programs approved by the board shall maintain their national accreditation.

Section 905(A)(3)(a): In the event the applicant obtained their technician candidate registration on the basis of their enrollment in a nationally-accredited and or board-approved pharmacy technician training program, the applicant shall demonstrate successful completion of that training program, or in the alternative, another nationally-accredited and or board-approved pharmacy technician training program.
In conclusion, we applaud the Legislature for sharing our concerns as stated in House Resolution 162 and Senate Resolution 146 which urge the Board to recognize more than one pharmacy technician certification exam. We look forward to working with the Board to develop policy to recognize the value of pharmacy technicians. Please do not hesitate to contact me with any questions or concerns at mstaples@nacds.org or 817-442-1155.

Sincerely,

Mary Staples

cc: Chairman, Senator Fred Mills, Jr.
Chairman, Representative Frank Hoffmann
Nick Cahanin, The Picard Group
Bud Courson, Courson Nickel
A RESOLUTION

To urge and request the Louisiana Board of Pharmacy to recognize more than one accredited pharmacy technician certification program prior to adopting final rules pursuant to its administrative rulemaking initiative entitled "Regulatory Project 2015-19 - Pharmacy Technicians".

WHEREAS, pharmacists are highly educated healthcare professionals who provide convenient, high-quality healthcare services, including medication management therapy, immunizations, long-acting injectable medications, disease management, point-of-care testing, and patient assessments and screenings to a great number of patients; and

WHEREAS, Louisiana pharmacists work in partnership with other healthcare entities and providers to improve patient outcomes and public health in this state; and

WHEREAS, in an effort to improve patient care, Louisiana pharmacists and pharmacy owners support a practice environment that utilizes and promotes well-qualified pharmacy technicians as essential members of the pharmacy care team; and

WHEREAS, certified pharmacy technicians in Louisiana are paraprofessionals who work exclusively under the direct supervision of a licensed pharmacist and assist pharmacists in preparing and dispensing prescription medications, administrative duties, and performing pharmacy care services; and

WHEREAS, the Louisiana Board of Pharmacy requires a certified pharmacy technician to complete six hundred hours of board-approved training and pass a nationally accredited certification examination; and

WHEREAS, because no single training and certification method meets the needs of all pharmacy technicians or community pharmacies, pharmacists and pharmacy owners support multiple pathways for certified pharmacy technicians so that those technicians may
complete a certification program that is best suited for the work they will perform in their unique practice setting, whether that setting is a hospital, a community-based provider, a long-term care facility, a nuclear pharmacy, or other pharmacy location; and

WHEREAS, the National Commission for Certifying Agencies is a nationally recognized third party agency that accredits certification programs which are able to meet and comply with its standards, and has accredited more than one pharmacy technician certification exam; and

WHEREAS, though the Louisiana Board of Pharmacy has the authority to approve multiple nationally accredited certification programs, the board has chosen to recognize only one such program, resulting in a statewide monopoly for the sole company that administers the only board-approved examination; and

WHEREAS, without competition, monopolistic pricing could cause financial difficulty, obstacles to practice, and undue strain for professionals who provide vital healthcare services.

THEREFORE, BE IT RESOLVED that the House of Representatives of the Legislature of Louisiana does hereby urge and request the Louisiana Board of Pharmacy to expand upon its exclusive agreement with the Pharmacy Technician Certification Board, and to change its definition of "approved certification examination" in order to recognize more than one pharmacy technician certification program accredited by the National Commission for Certifying Agencies prior to adopting final rules pursuant to the administrative rulemaking effort that the board has entitled "Regulatory Project 2015-19 - Pharmacy Technicians".

BE IT FURTHER RESOLVED that a copy of this Resolution be transmitted to the chairperson and the executive director of the Louisiana Board of Pharmacy.

SPEAKER OF THE HOUSE OF REPRESENTATIVES
A RESOLUTION

To urge and request the Louisiana Board of Pharmacy to consider alternative training and certification options for pharmacy technicians.

WHEREAS, pharmacists provide convenient healthcare services, including medication management therapy, immunizations, long-acting injectable medications, disease management, point-of-care testing, and patient assessments and screenings to a great number of patients each day; and

WHEREAS, Louisiana pharmacists work in partnership with other healthcare entities and providers to improve patient outcomes and public health in this state; and

WHEREAS, in an effort to improve patient care, Louisiana pharmacists and pharmacy owners support a practice environment that utilizes and promotes pharmacy technicians as essential members of the pharmacy care team; and

WHEREAS, certified pharmacy technicians in Louisiana work under the direct supervision of a licensed pharmacist and assist pharmacists in preparing and dispensing prescription medications, administrative duties, and performing pharmacy care services; and

WHEREAS, the Louisiana Board of Pharmacy requires a certified pharmacy technician to complete six hundred hours of board-approved training and pass a nationally accredited certification examination; and

WHEREAS, although there are multiple nationally accredited training and certification programs available, the Louisiana Board of Pharmacy has elected to recognize only one such program; and

WHEREAS, because no single training and certification method meets the needs of all pharmacy technicians or community pharmacies, pharmacists and pharmacy owners support alternative options for pharmacy technicians so that those technicians may complete a certification program that is best suited for the work they will perform in their unique practice setting; and
WHEREAS, the National Commission for Certifying Agencies is a nationally recognized entity that accredits certification programs that are able to meet and comply with its standards, and has accredited more than one pharmacy technician certification exam; and

WHEREAS, the Louisiana Board of Pharmacy should consider whether those training and certification programs made available by the National Commission for Certifying Agencies or any other accreditation entity may be appropriate options for pharmacy technicians.

THEREFORE, BE IT RESOLVED that the Senate of the Legislature of Louisiana does hereby urge and request the Louisiana Board of Pharmacy to consider alternative training and certification options for pharmacy technicians prior to adopting final rules pursuant the Administrative Procedure Act regarding the board's rulemaking effort entitled "Regulatory Project 2015-19 - Pharmacy Technicians”.

BE IT FURTHER RESOLVED that a copy of this Resolution be transmitted to the executive director of the Louisiana Board of Pharmacy.

______________________________
PRESIDENT OF THE SENATE
TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
FROM: Carmen A. Catizone, Executive Director/Secretary  
DATE: August 10, 2017  
RE: National Healthcareer Association (NHA) ExCPT Program

Some states may be aware of a discussion between representatives of NHA’s ExCPT / CPhT certification program and NABP. The discussion is focused on NABP conducting an assessment of the ExCPT exam similar to the assessment conducted of the Pharmacy Technician Certification Board and its examination (PTCE). We are hopeful that an agreement will be reached on the process to be utilized and the psychometric experts who will be engaged to conduct the assessment so that results can be communicated to the states. The timeline under consideration proposes a late fall / early winter conclusion of the assessment.

If you have any questions or require additional information, please do not hesitate to contact me at ExecOffice@nabp.pharmacy.

cc: Lyndsey McDonald, National Healthcareer Association
Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 9. Pharmacy Technicians

§901. Definitions

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

... CPE Monitor – a collaborative service from the National Association of Boards of Pharmacy (NABP) and the Accreditation Council for Pharmacy Education (ACPE) that provides an electronic system for pharmacists and pharmacy technicians to record and track their completed CPE activities.

... Pharmacy Technician Candidate – an individual, registered by the board, training to become a pharmacy technician, who assists in the practice of pharmacy under the direct and immediate supervision of a Louisiana-licensed pharmacist.

Training Program – a pharmacy technician training program that is currently nationally-accredited and has been approved by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2485 (November 2004), effective January 1, 2005, amended LR 39:1777 (July 2013), amended LR 43:

§903. Pharmacy Technician Candidates

A. Registration

1. All pharmacy technician candidates shall obtain a registration from the board prior to performing any professional functions in a pharmacy; failure to do so may result in disciplinary action by the board.

2. Qualifications

a. The applicant shall be at least 18 years of age, as evidenced by a valid and legible copy of a birth certificate or other appropriate credential.

b. The applicant shall be of good moral character and non-impaired.

c. The applicant shall satisfy one of the following eligibility criteria:

i. Proof of enrollment in a nationally-accredited and board-approved pharmacy technician training program; or

ii. Proof of successful completion of a board-approved technician certification examination, and further, proof of successful completion of a high school approved by a state department of education or an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential; or

iii. Proof of credentialing as a pharmacy technician by another state board of pharmacy as well as evidence of practice as a pharmacy technician for at least one year in that state, and further, proof of successful completion of a board-approved technician certification examination.

d. Exceptions

i. A pharmacist or pharmacist intern whose board credential has been denied, suspended, revoked, or restricted for disciplinary reasons by any board of pharmacy shall not be a pharmacy technician candidate or pharmacy technician.

ii. A pharmacist or pharmacist intern whose board credential is lapsed shall not be a pharmacy technician candidate or pharmacy technician until such lapsed credential is recalled through non-disciplinary board action.

3. Issuance and Maintenance

a. - b. ...

c. The registration shall expire 24 months after the date of issuance, and it shall not be renewable.
d. Termination of Enrollment; Status of Registration
   i. In the event the candidate is no longer enrolled in a nationally-accredited and board-approved pharmacy technician training program for any reason other than graduation, the candidate no longer meets the eligibility criteria to possess the registration, and the candidate shall relinquish the registration to the board, giving notice of their last day of enrollment in the program.
   ii. In the event a candidate fails to relinquish their registration when required to do so, or when notified by the board office of that requirement, the board staff shall inactivate the registration and refer the matter to the board for its consideration of disciplinary action against the candidate.
   iii. In the event the candidate should re-enroll in the original program or a different program, and gives proof of that enrollment to the board, the board may re-issue the registration with the original expiration date preserved.
   iv. In its discretion, the board may grant an exception to the original expiration date upon request by the candidate demonstrating unusual circumstances.
   e. A pharmacy technician candidate shall notify the board, in writing, no later than 10 days following a change of mailing address. The written notice shall include the candidate’s name, registration number, and old and new addresses.
   f. A pharmacy technician candidate shall notify the board, in writing, no later than 10 days following a change in location(s) of employment. The written notice shall include the candidate’s name, registration number, and name, address, and permit numbers for old and new employers.

B. Training Programs
   1. All training programs approved by the board shall maintain their national accreditation.
   2. The training program shall notify the board when a pharmacy technician candidate is no longer enrolled in the program. Evidence of a program’s failure to comply with this rule shall constitute sufficient basis for the withdrawal of the board’s approval for the program.
   3. The training program shall provide an appropriate credential to the pharmacy technician candidate who has successfully completed the program, provided, however, that such credential shall not be formatted in such a manner to lead anyone to believe that credential resembles a document providing legal authority to practice as a pharmacy technician.

C. Practical Experience
   1. The candidate shall possess a registration prior to performing any permitted professional function or earning any practical experience in a pharmacy.
   2. The candidate shall wear appropriate attire and be properly identified as to name and candidate status while on duty in the prescription department.
   3. A candidate shall not work in a permitted site that is on probation with the board, or with a pharmacist who is on probation with the board.
   4. The candidate’s registration shall evidence his authority to earn practical experience in a pharmacy, under the supervision of a pharmacist, in satisfaction of the requirements for pharmacy technician certification.
      a. In the event the registration was issued to an applicant enrolled in a nationally-accredited and board-approved training program, the candidate shall earn the amount of experience prescribed by the curriculum of that program, which may include hours earned in a consultant pharmacy practice which does not hold a pharmacy permit; or
      b. In the event the registration was issued to an applicant by any other method, the candidate shall earn at least 600 hours of practical experience in a pharmacy in Louisiana, provided however, that a candidate may receive board credit for a maximum of 50 hours per week.
   5. Hours of practical experience earned by a candidate shall expire two years after the expiration date of the registration.

D. Examination
   1. A board-approved technician examination shall consist of integrated pharmacy subject matter and any other disciplines the board may deem appropriate in order to permit the candidate to demonstrate his competency. The candidate shall achieve a passing score, as determined by the board.
   2. Re-examination
      a. Following the first or second unsuccessful attempt of an examination, the candidate may be permitted to retake that examination.
      b. Following the third unsuccessful attempt of an examination, the candidate shall wait
one year after the date of the last examination to retake that examination. If the candidate fails to wait the prescribed one year period, the board may delay any future certification until that one year period has elapsed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.


§905. Pharmacy Technician Certificate

A. Qualifications

1 – 2 …

3. An applicant shall demonstrate one of the following educational competencies:

a. In the event the applicant obtained their technician candidate registration on the basis of their enrollment in a nationally-accredited and board-approved pharmacy technician training program, the applicant shall demonstrate successful completion of that training program, or in the alternative, another nationally-accredited and board-approved pharmacy technician training program.

b. In the event the applicant obtained their technician candidate registration by any other method, the applicant shall demonstrate the acquisition of at least 600 hours of practical experience under the supervision of a pharmacist, using a form supplied by the board.

4. An applicant shall demonstrate successful completion of a board-approved technician examination, as evidenced by a valid and legible copy of the appropriate credential.

B. Issuance and Maintenance

1. Upon receipt of a properly completed application, copies of valid and legible credentials, the appropriate fee, and any other documentation required by the board, and following verification that all requirements have been satisfied, the board may issue a pharmacy technician certificate to the applicant for the current renewal period.

2 – 6 …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.


§907. Scope of Practice

A – B.5 …

C. Pharmacy technicians shall not:

1 – 2 …

3. counsel patients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2486 (November 2004), effective January 1, 2005, amended LR 32:1049 (June 2006), amended LR 43:

§909. Continuing Education

A. …

B. Certified pharmacy technicians shall maintain copies of their individual records of personal CPE activities with CPE Monitor and shall authorize the board’s access to their file by recording their Louisiana pharmacy technician certificate number within that file, and shall present a copy of their CPE Monitor transcript when requested by the board.

C – D.3 …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.
NOTICE IS HEREBY GIVEN that a Public Hearing has been ordered and called for 9:00 a.m. on Tuesday, May 30, 2017 at the Board office, for the purpose to wit:

AGENDA

1. Call to Order

2. Appearances

3. Notices of Intent
   A. Regulatory Project 2017-1 ~ Internship Requirements
   B. Regulatory Project 2017-2 ~ Equivalent Drug Product Interchange

4. Opportunity for Public Comment

5. Adjourn
§703. Registration
A. All pharmacy interns shall meet the following requirements for registration:
   1. All pharmacy interns shall register with the board. The failure to register may result in disciplinary action by the board.
      a. The applicant shall submit to the board office a properly completed application no later than the end of the first semester of the first academic year at a board-approved college of pharmacy.
      b. The board may issue an Intern Registration to the applicant, upon receipt of a properly completed application, appropriate fee, and any other documentation required by the board office.
      c. The Intern Registration shall expire one year after the certification of graduation from a board-approved college of pharmacy.
         (1) Intern registrations issued to foreign pharmacy graduates shall expire two years after the date of issue.
      d. The Intern Registration shall be conspicuously displayed at the preceptor site.
      e. The board shall reserve the right to recall or refuse to issue any Intern Registration for cause.
   2. A pharmacy intern shall wear appropriate attire and be properly identified with his name and intern status while on duty at the preceptor site.
   3. A pharmacy intern shall notify the board in writing within ten days of a change of address. This notice shall include the pharmacy intern’s name, registration number, and old and new addresses.
   4. A pharmacy intern shall notify the board in writing within ten days of a change in location(s) of employment. This notice shall include the pharmacy intern’s name and registration number, the name and address of old and new employment, and the permit numbers of those pharmacies involved.
   5. The pharmacy intern shall be non-impaired.
      a. The pharmacy intern is subject to confidential random drug screen testing and/or evaluations.
      b. A positive drug screen may be self evident as proof of improper drug use. For the purposes of this chapter, a missed screen, a screen submitted beyond the mandated period, and/or any screen submitted indicating the sample provided is diluted, substituted, or in any way adulterated is considered to be a positive drug screen.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

§705. Practical Professional Experience
A. All applicants for licensure by examination shall earn practical professional experience in the practice of pharmacy concurrent with attending or after graduation from a board-approved college of pharmacy.
B. The practical experience 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 making of reports as required under federal and state law.
   1. The practical experience earned shall have been under the supervision of a pharmacist, or in the alternative, a licensed practitioner.
2. A pharmacy intern shall not practice in a permitted pharmacy site that is on probation with the board. A pharmacy intern shall not practice under the supervision of a pharmacist or other licensed practitioner whose license is on probation with the board or their primary professional licensing agency.

C. Practical Professional Experience Hours. To qualify for pharmacist licensure, an intern shall supply evidence of the acquisition of at least 1,500 hours of practical professional experience, of which at least 1,500 hours of which shall be practical experience as described in Subsection B above.

1. The board shall award 1,000 hours credit to an intern for his successful completion of a professional experience curriculum at a board-approved college of pharmacy. The dean of the board-approved college of pharmacy shall certify the completion of this requirement in the manner prescribed by the board office.

2. The intern shall earn at least 500 hours of practical experience in a permitted pharmacy site under the supervision of a pharmacist with no less than two years of experience as a licensed pharmacist. Further, neither the pharmacist’s license nor the pharmacy’s permit may be on probation with the board at the time the practical experience is earned.

3. In the event an applicant for pharmacist licensure by examination is unable to document the acquisition of 1,740 hours of professional experience through the successful completion of a professional experience curriculum at a board-approved college of pharmacy by means of an attestation from the dean of that college, then the applicant shall demonstrate the acquisition of at least 1,740 hours of pre-licensure practical experience in a licensed pharmacy, subject to the following limitations:
   a. The pharmacy permit shall not have been on probation or otherwise restricted during the time the hours were earned.
   b. The license of the pharmacist supervising the intern and signing the affidavit shall have been issued no less than two years before supervising the intern, and further, shall not have been on probation or otherwise restricted during the time the hours were earned.

4. Practical experience hours that are submitted to the board for credit consideration (other than those attested to by the dean of the college of pharmacy for the successful completion of a professional experience curriculum at a board-approved college of pharmacy) shall be listed on an affidavit form supplied by the board office, and signed by the supervising pharmacist and pharmacy intern.
   a. A pharmacy intern may receive credit for a maximum of 50 hours per week.
   b. A separate affidavit shall be required from each permitted pharmacy site.
   c. No credit shall be awarded for hours earned within the professional experience curriculum of a board-approved college of pharmacy, nor for hours earned outside the professional experience curriculum but at the same time and location as hours earned for that professional experience curriculum.

5. Certification of Hours To and From Another Jurisdiction.
   a. Interns enrolled in a board-approved college of pharmacy in Louisiana who earn hours of practical professional experience in another jurisdiction, as well as interns enrolled in a board-approved college of pharmacy in another jurisdiction who earn hours of practical professional experience in another jurisdiction, may transfer those hours to Louisiana under the following conditions:
      i. The hours of practical experience shall be listed on an affidavit form supplied by the Louisiana Board of Pharmacy, signed by the preceptor supervising pharmacist and the intern, and submitted to the Louisiana Board of Pharmacy for consideration of credit; and
      ii. The board of pharmacy in the jurisdiction where the hours were earned shall certify those hours to the Louisiana Board of Pharmacy.
      iii. The Louisiana Board of Pharmacy may grant credit for all hours that comply with the Louisiana Board of Pharmacy’s requirements as delineated in this section.
   b. Upon written request by the pharmacy intern, the Louisiana Board of Pharmacy may certify practical professional experience hours earned in Louisiana to a board of pharmacy in another jurisdiction.

6. Credited hours of practical experience shall expire on two years after the expiration date of the Intern Registration and shall no longer be valid for licensure purposes.
AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

Louisiana Board of Pharmacy  
3388 Brentwood Drive  
Baton Rouge, LA 70809-1700  
www.pharmacy.la.gov

Public Hearing  
Tuesday, May 30, 2017

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<td>Stephanie Anders</td>
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1. May 30, 2017 letter and testimony from Dr. Stephanie Anders, Ochsner Health System

Expressed concern for difficulties PGY-2 residents have in obtaining pharmacist licensure which is required for them to participate and complete their residency training. In particular, she cited the current requirement for one year of post-licensure experience to qualify for licensure by reciprocity. Offered examples of laws, rules, exemptions and exceptions available at other state boards of pharmacy.

Did not request any specific changes in the proposed rule.
May 30, 2017

Malcolm Broussard  
Executive Director  
Louisiana Board of Pharmacy  
5533 Brentwood Drive  
Baton Rouge, Louisiana 70809

RE: Regulatory Project 2017-1, Internship Requirements

Dear Malcolm Broussard:

As program directors of the three Post-Graduate Year 2 (PGY-2) training programs in the state of Louisiana, we applaud the Board's effort to address the obstacles in licensure attainment by pharmacists who participate in PGY2 training programs in the state. However, Regulatory Project 2017-1 (Internship Requirements) will not solve this issue for these pharmacists.

We would like to highlight why it is important that the state support these training programs. First, the number of PGY-2 residency training programs in this state lags significantly behind the number in 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. Lastly, residents trained here are more likely to stay in the state and practice.

There are many obstacles that we have encountered in obtaining timely licensure for PGY2 residents whose primary license is out of state. Most PGY1 residents become licensed as Registered Pharmacists in July - September. Under the current law, these residents are not eligible to apply for reciprocity (Licensure Transfer) until July-September of the following year. Because of this, PGY2 residents would likely not be licensed (by reciprocity) until August - 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. This 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.
There are only five states in the country that have a requirement for one year of licensure in another state in order to be eligible for reciprocity. These states are New York, Colorado, Tennessee, Oregon, and Louisiana. Three of these states make exceptions for pharmacists participating in approved residency training programs. New York treats pharmacists in training programs as "Score Transfer Candidates", disregarding the 90 day rule for score transfer of the original NAPLEX results. Colorado allows pharmacists in residency training programs to be exempt from licensure in Colorado, as long as they are licensed in another state. In Oregon, pharmacy residents are given an exception to the one year rule for licensure.

Please consider a rule change to address the difficulty in licensure for pharmacists seeking PGY2 residency training in our state. Potential options may include amending the rule regarding the one year licensure requirement to be eligible for reciprocity or the generation of a Graduate Intern license that may allow pharmacists in training programs to begin their programs prior to receiving their Pharmacist License in Louisiana. Proposed rule changes would apply to a very small number of pharmacists each year (generally less than three) and would be more consistent with the regulations regarding reciprocation for residents in the rest of the country.

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
Dr. Anders,

Thank you for taking the time to participate in the May 30 public hearing on the proposed rule, and for submitting comments on the proposed rule for the Board’s consideration. As I prepare a summary of comments for the Board’s consideration, I wanted to ensure I properly characterize your comments. I did not see any recommendations for changes to any specific portion of the proposed rule.

I did take note of your recommendation for a change in the one year licensure requirement for reciprocity. That is not a rule; it is part of the licensing law. That change must be made by the legislature. I also took note of your recommendation for a Graduate Intern license that would allow participation in residency programs prior to pharmacist licensure. The Board’s current rule for pharmacy interns contains a definition of that term, and that definition includes an individual participating in a residency. For your convenience, I have reproduced that definition here from the Board’s rules.

§701. Definition
A. A pharmacy intern is an individual who is not yet licensed as a pharmacist in any jurisdiction, and is:
   1. engaged in the practice of pharmacy while under the direct and immediate supervision of a pharmacist for the purpose of obtaining practical experience for licensure as a pharmacist, and is satisfactorily progressing in a board-approved college of pharmacy; or
   2. a graduate of a board-approved college of pharmacy awaiting examination for licensure; or
   3. a graduate who has established educational equivalency through a program approved by the board; or
   4. an individual participating in a residency or fellowship.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

For now, I would like to obtain clarification of your comment as to whether you have any recommendations for specific changes to the proposed rule, a copy of which I have attached to this message.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
USA ~ GMT-6
Telephone +1.225.925.6481
See attached.

Thank you for your time. Please contact me with questions or concerns.

Stephanie Anders, Pharm.D., BCPS
Clinical Specialist, Abdominal Transplant
Residency Program Director, PGY2 Solid Organ Transplant
Ochsner Medical Center, New Orleans
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 postgraduate 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
Chapter 7. Pharmacy Interns

§703. Registration
A. All pharmacy interns shall meet the following requirements for registration:
   1. All pharmacy interns shall register with the board. The failure to register may result in
disciplinary action by the board.
      a. The applicant shall submit to the board office a properly completed application no
         later than the end of the first semester of the first academic year at a board-
         approved college of pharmacy.
      b. The board may issue an Intern Registration to the applicant, upon receipt of a
         properly completed application, appropriate fee, and any other documentation
         required by the board office.
      c. The Intern Registration shall expire one year after the certification of graduation
         from a board-approved college of pharmacy.
         i. Intern registrations issued to foreign pharmacy graduates shall expire two years
            after the date of issue.
      d. The board shall reserve the right to recall or refuse to issue any Intern Registration
         for cause.
   2. A pharmacy intern shall wear appropriate attire and be properly identified with his name and
      intern status while on duty at the preceptor site.
   3. A pharmacy intern shall notify the board in writing within ten days of a change of address.
      This notice shall include the pharmacy intern’s name, registration number, and old and new
      addresses.
   4. A pharmacy intern shall notify the board in writing within ten days of a change in location(s)
      of employment. This notice shall include the pharmacy intern’s name and registration
      number, the name and address of old and new employment, and the permit numbers of those
      pharmacies involved.
   5. The pharmacy intern shall be non-impaired.
      a. The pharmacy intern is subject to confidential random drug screen testing and/or
         evaluations.
      b. A positive drug screen may be self evident as proof of improper drug use. For the
         purposes of this chapter, a missed screen, a screen submitted beyond the mandated
         period, and/or any screen submitted indicating the sample provided is diluted,
         substituted, or in any way adulterated is considered to be a positive drug screen.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
(October 1988), effective January 1, 1989, amended LR 26:2285 (October 2000), amended LR 29:2086 (October
2003), effective January 1, 2004, amended LR

§705. Professional Experience
A. All applicants for licensure by examination shall earn professional experience in the practice of
   pharmacy concurrent with attending or after graduation from a board-approved college of pharmacy.
B. The practical experience 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 making of reports as required under federal and state law.

1. The practical experience earned shall have been under the supervision of a pharmacist, or in the alternative, a licensed practitioner.

2. A pharmacy intern shall not practice in a permitted pharmacy site that is on probation with the board. A pharmacy intern shall not practice under the supervision of a pharmacist or other licensed practitioner whose license is on probation with their primary professional licensing agency.

C. Professional Experience Hours. To qualify for pharmacist licensure, an intern shall supply evidence of the acquisition of at least 1,740 hours of professional experience, of which at least 1,500 hours of which shall be practical experience as described in Subsection B above.

1. The board shall award 1,740 hours credit to an intern for his successful completion of a professional experience curriculum at a board-approved college of pharmacy. The dean of the board-approved college of pharmacy shall certify the completion of this requirement in the manner prescribed by the board office.

2. In the event an applicant for pharmacist licensure by examination is unable to document the acquisition of 1,740 hours of professional experience through the successful completion of a professional experience curriculum at a board-approved college of pharmacy by means of an attestation from the dean of that college, then the applicant shall demonstrate the acquisition of at least 1,740 hours of pre-licensure practical experience in a licensed pharmacy, subject to the following limitations:
   a. The pharmacy permit shall not have been on probation or otherwise restricted during the time the hours were earned.
   b. The license of the pharmacist supervising the intern and signing the affidavit shall have been issued no less than two years before supervising the intern, and further, shall not have been on probation or otherwise restricted during the time the hours were earned.

3. Practical experience hours that are submitted to the board for credit consideration (other than those attested to by the dean of the college of pharmacy for the successful completion of a professional experience curriculum at a board-approved college of pharmacy) shall be listed on an affidavit form supplied by the board office, and signed by the supervising pharmacist and pharmacy intern.
   a. A pharmacy intern may receive credit for a maximum of 50 hours per week.
   b. A separate affidavit shall be required from each permitted pharmacy site.
   c. No credit shall be awarded for hours earned within the professional experience curriculum of a board-approved college of pharmacy, nor for hours earned outside the professional experience curriculum but at the same time and location as hours earned for that professional experience curriculum.

4. Certification of Hours To and From Another Jurisdiction.
   a. Interns enrolled in a board-approved college of pharmacy in Louisiana who earn hours of professional experience in another jurisdiction, as well as interns enrolled in a board-approved college of pharmacy in another jurisdiction who earn hours of professional experience in another jurisdiction, may transfer those hours to Louisiana under the following conditions:
      i. The hours of practical experience shall be listed on an affidavit form supplied by the Louisiana Board of Pharmacy, signed by the supervising pharmacist and the intern, and submitted to the Louisiana Board of Pharmacy for consideration of credit; and
      ii. The board of pharmacy in the jurisdiction where the hours were earned shall certify those hours to the Louisiana Board of Pharmacy.
      iii. The Louisiana Board of Pharmacy may grant credit for all hours that comply with the Louisiana Board of Pharmacy’s requirements as delineated in this section.
   b. Upon written request by the pharmacy intern, the Louisiana Board of Pharmacy may certify professional experience hours earned in Louisiana to a board of pharmacy in another jurisdiction.

5. Credited hours of experience shall expire two years after the expiration date of the Intern Registration and shall no longer be valid for licensure purposes.
AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

NOTICE IS HEREBY GIVEN that a Public Hearing has been ordered and called for 9:00 a.m. on Tuesday, May 30, 2017 at the Board office, for the purpose to wit:

A G E N D A

1. Call to Order
2. Appearances
3. Notices of Intent
   A. Regulatory Project 2017-1 ~ Internship Requirements
   B. Regulatory Project 2017-2 ~ Equivalent Drug Product Interchange
4. Opportunity for Public Comment
5. Adjourn
§2511. Prescriptions


2. The pharmacist shall not select an equivalent drug product when the prescriber handwrites a mark in the check box labeled “Dispense as Written,” or “DAW”, or both, and personally handwrites his signature on a printed single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.

b. In the event an authorized prescriber has indicated that an equivalent drug product interchange is prohibited by handwriting a mark in the check box labeled “Dispense as Written”, or “DAW”, or both, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient’s desire for an equivalent drug product interchange.

c. For prescriptions reimbursable by Medicaid or Medicare, the authorized prescriber may only prohibit equivalent drug product interchange by handwriting the words “brand necessary” or “brand medically necessary” on the face of the prescription order or on a sheet attached to the prescription order.

D. Oral Prescriptions.

1. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, a pharmacist may enter the prescription information directly into the pharmacy’s dispensing information system. In the event a pharmacy intern or pharmacy technician transcribes such a prescription, the supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.

2. The pharmacist shall not select an equivalent drug product when the authorized prescriber or his agent has verbally indicated a specific brand name drug or product is ordered.

3. The pharmacist may select an equivalent drug product if the authorized prescriber or his agent has given his approval to the equivalent drug product interchange. The patient shall be informed of, and consent to, the proposed cost saving interchange.

E. Electronic Prescriptions.

1. The prescription shall clearly indicate the authorized prescriber’s name, licensure designation, address, telephone number, and if for a controlled substance, the DEA registration number.

2. The pharmacist shall not select an equivalent drug product when the prescriber indicates “Dispense as Written,” “DAW,” or “Brand Medically Necessary” and transmits his electronic signature. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.

F. Exclusion. The provisions of this Section shall not apply to medical orders written for patients in facilities licensed by the Department of Health and Hospitals or its successor.
§2517. Prescription Dispensing

A – A.6 …

B. Equivalent Drug Product Interchange

1. The pharmacist shall not select an equivalent drug product when the prescriber prohibits interchange by any one of the following methods:

   a. On a prescription generated in written form, the prescriber shall handwrite a mark in a check box labeled “Dispense as Written”, or the abbreviation “DAW”, or both, and shall manually sign the prescription form.

      i. For prescriptions reimbursable by the state Medicaid program, the prescriber shall handwrite the words “Brand Necessary” or “Brand Medically Necessary” on the prescription form or on a sheet of paper attached to the prescription form.

   b. On a prescription generated in oral or verbal form, the prescriber (or the prescriber’s agent) shall indicate a specific brand name drug or product is ordered by the practitioner, and the pharmacist shall note such information on the file copy of the prescription.

   c. On a prescription generated in electronic form, the prescriber shall indicate “Dispense as Written”, “DAW”, or “Brand Medically Necessary.”

2. Where the prescriber has indicated that an equivalent drug product interchange is prohibited, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient’s desire for an equivalent drug product interchange.

3. In the event the prescriber has not prohibited equivalent drug product interchange in the manner described above, the pharmacist may select an equivalent drug product for dispensing, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.

4. When the pharmacist selects a biological product rated as interchangeable for the product ordered by the prescriber, the dispensing pharmacist (or his designee) shall communicate to the prescriber – by any means, but no later than five business days following the dispensing date – the specific product dispensed to the patient, including the name of the product and the manufacturer. However, no such communication to the prescriber is required when:

   a. The prescriber prohibited interchange in the manner described above;

   b. There is no product rated as interchangeable or therapeutically equivalent; or

   c. The product dispensed is a refill not changed from the product dispensed on the prior filling of the prescription.

B. C. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

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

Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
www.pharmacy.la.gov

Public Hearing
Tuesday, May 30, 2017

Guest Register

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Summary of Testimony & Public Comments
re
Regulatory Project 2017-2 ~ Equivalent Drug Product Interchange
at
May 30, 2017 Public Hearing

1. May 25 and June 22, 2017 letters from Ms. Mary Staples, on behalf of NACDS
Requested changing the required communication when the pharmacist dispenses certain interchangeable biological products from “by any means” to certain specified methods of communication identified in their letter. In addition, requested deletion of the current rule’s requirement for patient consent when the pharmacist performs a generic interchange.
May 25, 2017

Mr. Malcolm J. Broussard, R.Ph.
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700

RE: Proposed Regulation for Equivalent Drug Product Interchange

Dear Mr. Broussard:

On behalf of our members that operate in the state of Louisiana, the National Association of Chain Drug Stores (NACDS) is writing to convey concerns with proposed changes to the Louisiana Administrative Code Section 46: LIII 2517, regarding requirements for equivalent drug product interchange.

Section 2517 (Prescription Dispensing) of the proposed changes would require a dispensing pharmacist to communicate to the prescriber within five days if the pharmacist dispenses a drug rated as interchangeable for the product ordered by the prescriber. The language further suggests that this communication can be made by making an entry in an interoperable electronic medical records system, using electronic prescribing technology, a pharmacy benefits management system, or using a pharmacy record that is electronically accessible by the prescriber. Further, if such methods are not available, then they should be contacted by facsimile, telephone, electronic transmission, or other prevailing means, and shall be filed in the patients’ medical record.

As written, NACDS and its members believe that the proposed language is more restrictive than the current standing laws for the notification of interchangeable biosimilar products. As such, we believe that the above language should be rejected and existing language should be maintained to align with the Sections R.S. 37:1164 and R.S. 37:1226.1 of the Louisiana Pharmacy Practice Act. We believe that such language not only recognizes the importance of informing the physician of when an interchangeable product is dispensed, but also allows for such notices to be made by any means if the prescriber is notified. As written, the proposed language indirectly suggests the use of one-to-one communication, which could prove to be problematic when such systems are either not available or not functioning properly.

We thank you for the opportunity to comment on this important Regulation. Please do not hesitate to contact me with any questions or concerns at mstaples@nacds.org or 817-442-1155.

Sincerely,

Mary Staples

NACDS Regional Office
1560 East Southlake Boulevard, Suite 230 • Southlake, TX 76092 • 817.442.1155 • www.NACDS.org
Ms. Staples,

Since I do not know the source of the document you provided, I have attached a reprint of the proposed rule as it appeared in the April 20, 2017 edition of the Louisiana Register. The language in the proposed rule indicates the communication may occur “by any means.” The proposed rule does not contain the specific methods identified in your document. So that I can properly characterize your comments for the Board’s consideration, is it your recommendation the Board should revise the proposed rule to change “by any means” to specify the methods contained in your document?

Thanks,
Malcolm

Malcolm J Broussard  
Executive Director  
Louisiana Board of Pharmacy  
3388 Brentwood Drive  
Baton Rouge, LA 70809-1700  
USA ~ GMT-6  
Telephone +1.225.925.6481  
Telecopier +1.225.923.5669  
mbroussard@pharmacy.la.gov

Sure.

On April 20, 2017 the Department of Health/Board of Pharmacy published a proposed rule regarding Equivalent Drug Products (Attached). In that publication at the bottom of page 5, there is recommended language insert to Section 2517(4) that would require a dispensing pharmacist to communicate to the prescriber within five
days if the pharmacist dispenses a drug rated as interchangeable for the product ordered by the prescriber. The language further suggests that this communication can be made by making an entry in an interoperable electronic medical records system, using electronic prescribing technology, a pharmacy benefits management system, or using a pharmacy record that is electronically accessible by the prescriber. Further, if such methods are not available, then they should be contacted by facsimile, telephone, electronic transmission, or other prevailing means, and shall be filed in the patients’ medical record.

Our comments are specific to that recommended revision and the language in that insert box as stated above and in the letter.

--------- Forwarded message ---------
From: "Malcolm J. Broussard" <mbroussard@pharmacy.la.gov>
Date: Jun 13, 2017 10:46 AM
Subject: FW: NACS Comments on Proposed Regulation for Equivalent Drug Product Interchange
To: Mary Staples <mstaples@NACDS.org>
Cc: Nicholas Cahanin <ncahanin@thepicardgroup.com>, Nic Walts <nwalts@thepicardgroup.com>, Bud @ Courson Nickel, Jim Nickel <jimnickel@me.com>

Ms. Staples,

As I review your letter and compare it to the proposed rule, I am a little confused. Can you identify specifically which portion of the proposed rule gave rise to your comment?

Thanks,
Malcolm

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Please accept these comments for the record.

Mary

Mary Staples
Regional Director, State Government Affairs
mstaples@nacds.org
P: (817) 442-1155
F: (817) 442-1140
C: (817) 308-2103

National Association of Chain Drug Stores (NACDS)
1560 E. Southlake Blvd., Suite 230, Southlake, Texas 76092

www.nacds.org
www.facebook.com/NACDS.org
www.twitter.com/@NACDS
NOTICE OF INTENT

Department of Health
Board of Pharmacy
Equivalent Drug Product Interchange
(LAC 46:LIII.2511 and 2517)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend § 2511 and § 2517 of its rules. The amended rules will implement Act 391 of the 2015 Legislature, which amended the statutory definition of the term 'equivalent drug product' and imposed certain communication requirements on pharmacists dispensing certain interchangeable biological products.

Malcolm J. Broussard  
Executive Director  
1704#039

Evan Brasseaux  
Staff Director  
Legislative Fiscal Office

Public Hearing

A public hearing on this proposed rule is scheduled for Tuesday, May 30, 2017 at 9 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12 noon that same day.

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Equivalent Drug Product Interchange

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

Other than the publication fee associated with the proposed rule changes, which are estimated to cost the Board of Pharmacy $2,000, it is not anticipated that state or local governmental units will incur any other costs or savings. The proposed rule codifies Act 391 of the 2015 Regular Legislative Session and revises the definition of equivalent drug product.
drug products and imposes communication requirements on pharmacists dispensing certain interchangeable biological products.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule change will not affect state or local government revenue collections.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule imposes certain communication requirements on pharmacists dispensing certain interchangeable biological products within five days of dispensing the product, but permits that communication to the prescriber to be accomplished by any means. Therefore, the cost of the communication is anticipated to be minimal.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will have no effect on competition or employment as it only adds a reporting requirement if certain interchangeable biological products are dispensed.

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency Rule.

1. The effect on the stability of the family. The proposed Rule will have no effect on the stability of the family.

2. The effect on the authority and rights of parents regarding the education and supervision of their children. The proposed Rule will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The effect on the functioning of the family. The proposed Rule will have no effect on the functioning of the family.

4. The effect on family earnings and family budget. The proposed Rule will have no effect on family earnings or family budget.

5. The effect on the behavior and personal responsibility of children. The proposed Rule will have no effect on the behavior and personal responsibility of children.

6. The ability of the family or a local government to perform the function as contained in the proposed Rule. The proposed Rule will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed Rule.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The effect on household income, assets, and financial security. The proposed Rule will have no effect on household income, assets, or financial security.

2. The effect on early childhood development and preschool through postsecondary education development. The proposed Rule will have no effect on early childhood development or preschool through postsecondary education development.

3. The effect on employment and workforce development. The proposed Rule will have no effect on employment or workforce development.

4. The effect on taxes and tax credits. The proposed Rule will have no effect on taxes or tax credits.
5. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. The proposed Rule will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

**Provider Impact Statement**

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities.

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. The proposed Rule will have no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

2. The total direct and indirect effect on the cost to the provider to provide the same level of service. The proposed Rule will have no effect on the total direct and indirect costs to the provider to provide the same level of service.

3. The overall effect on the ability of the provider to provide the same level of service. The proposed Rule will have no effect on the ability of the provider to provide the same level of service.

**Small Business Analysis**

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses.

1. The establishment of less stringent compliance or reporting requirements for small businesses. The proposed Rule requires the dispensing pharmacist to communicate certain information to a prescriber within five days, but allows that communication to be completed in any manner; there are no reporting requirements in the proposed Rule.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses. The five day deadline for the required communication was imposed in the enabling legislation; therefore, the rule cannot allow for a less stringent schedule.

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no reporting requirements in the proposed Rule.

4. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed Rule. There are no design or operational standards required in the proposed Rule.

5. The exemption of small businesses from all or any part of the requirements contained in the proposed Rule. There are no exemptions for small businesses.

**Public Comments**

Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule.

Malcolm J. Broussard
Executive Director

**Title 46**

**PROFESSIONAL AND OCCUPATIONAL STANDARDS**
Part LIII. Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

Subchapter B. Prescriptions

§ 2511. Prescriptions

A. - C.6. ...

D. Oral Prescriptions

1. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, a pharmacist may enter the prescription information directly into the pharmacy's dispensing information system. In the event a pharmacy intern or pharmacy technician transcribes such a prescription, the supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.

E. Electronic Prescriptions

1. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the DEA registration number.

F. Exclusion. The provisions of this Section shall not apply to medical orders written for patients in facilities licensed by the Department of Health or its successor.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), amended LR 29:2102 (October 2003), effective January 1, 2004, amended LR 41:98 (January 2015), amended LR 41:2147 (October 2015), amended by the Department of Health, Board of Pharmacy, LR 43:

§ 2517. Prescription Dispensing

A. - A.6. ...

B. Equivalent Drug Product Interchange

1. The pharmacist shall not select an equivalent drug product when the prescriber prohibits interchange by any one of the following methods:

a. On a prescription generated in written form, the prescriber shall handwrite a mark in a check box labeled "Dispense as Written ", or the abbreviation " DAW ", or both, and shall manually sign the prescription form.

i. For prescriptions reimbursable by the state Medicaid program, the prescriber shall handwrite the words " Brand Necessary " or " Brand Medically Necessary " on the prescription form or on a sheet of paper attached to the prescription form.

b. On a prescription generated in oral or verbal form, the prescriber (or the prescriber's agent) shall indicate a specific brand name drug or product is ordered by the practitioner, and the pharmacist shall note such information on the file copy of the prescription.

c. On a prescription generated in electronic form, the prescriber shall indicate " Dispense as Written ", " DAW ", or " Brand Medically Necessary."

2. Where the prescriber has indicated that an equivalent drug product interchange is prohibited, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient’s desire for an equivalent drug product interchange.
3. In the event the prescriber has not prohibited equivalent drug product interchange in the manner described above, the pharmacist may select an equivalent drug product for dispensing, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.

4. When the pharmacist selects a biological product rated as interchangeable for the product ordered by the prescriber, the dispensing pharmacist (or his designee) shall communicate to the prescriber by any means, but no later than five business days following the dispensing date, the specific product dispensed to the patient, including the name of the product and the manufacturer. However, no such communication to the prescriber is required when:

   a. the prescriber prohibited interchange in the manner described above;

   b. there is no product rated as interchangeable or therapeutically equivalent; or

   c. the product dispensed is a refill not changed from the product dispensed on the prior filling of the prescription.

C. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 43:

Recommended revision:
4. When the pharmacist selects a biological product rated as interchangeable for the product ordered by the prescriber, the dispensing pharmacist (or his designee) shall communicate to the prescriber. The communication required under this subsection shall be made as follows:

   a. By making an entry in an interoperable electronic medical records system, through the use of electronic prescribing technology, pharmacy benefits management system, or through the use of a pharmacy record, that is electronically accessible by the prescriber.

   b. If the methods described in the subdivision (a) are not available, then by facsimile, telephone, electronic transmission, or other prevailing means, and shall be filed in the patients medical record.

   c. Entry into an electronic records system as described in this subsection (a) is presumed to provide communication requirement in subsection (4). This communication shall take place no later than five business days following the dispensing date, the specific product dispensed to the patient, including the name of the product and the manufacturer. However, no such communication to the prescriber is required when:

   a. the prescriber prohibited interchange in the manner described above;

   b. there is no product rated as interchangeable or therapeutically equivalent; or

   c. the product dispensed is a refill not changed from the product dispensed on the prior filling of the prescription.

Is it necessary to have consent from the patient to substitute? Seems like an unnecessary burden. All prescriptions should be subject to generic substitution as allowed by law without the requirement of notifying and getting consent from the patient. This also means that the prescription must be run through the system before a cost savings proposal can be given to the patient. Again, this is unnecessary and burdensome to the pharmacy and the patient.
2015 Regular Session

HOUSE BILL NO. 319

BY REPRESENTATIVE SIMON

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

DRUGS/PRESCRIPTION: Provides relative to the dispensing of interchangeable biological products.

AN ACT

To amend and reenact R.S. 37:1164(16) and 1241(A)(17) and to enact R.S. 37:1164(58) and (59), 1185, and 1226.1, relative to interchangeable biological products; to provide for definitions; to provide for licensure penalties; to require certain information to be sent to a prescriber; to require the posting of certain information on the Louisiana Board of Pharmacy's web page; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1164(16) and 1241(A)(17) are hereby amended and reenacted and R.S. 37:1164(58) and (59), 1185, and 1226.1 are hereby enacted to read as follows:

§1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

* * *

(16) "Equivalent drug product" means either of the following:

(a) A drug product that has been rated as a pharmaceutical equivalent by the federal food and drug administration United States Food and Drug Administration (FDA) and has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendial or other applicable standards such as strength, quality, purity, and identity, but which may differ in characteristics such as shape, scoring, configuration, packaging, excipients including colors, flavors, preservatives, and expiration time.

CODING: Words in struck through type are deletions from existing law; words underscored are additions.
(b) An interchangeable biological product.

§1185. Interchangeable biological products; list maintained on Louisiana Board of Pharmacy's web page

The board shall maintain on its public web page a link to the current list, if available, of biological products determined by the United States Food and Drug Administration to be interchangeable.

§1226.1. Communication to the prescriber

A. No later than five business days following the dispensing of a biological product, the dispensing pharmacist or his designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer.

B.(1) The dispensing pharmacist or his designee shall convey the communication required by Subsection A of this Section by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber.

(2) If the required communication cannot be conveyed pursuant to a method listed in Paragraph (1) of this Subsection, the dispensing pharmacist or his designee
shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means.

C. No communication shall be required if there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed, or if the prescription is a refill not changed from the product dispensed on the prior filling of the prescription.

§1241. Refusal, restriction, suspension, or revocation of license

A. The board may, after due notice and hearing, assess a fine not to exceed the sum of five thousand dollars for each offense, refuse to license, register, certify, or permit any applicant, refuse to renew the license or permit of any person, or may revoke, summarily suspend, suspend, place on probation, reprimand, issue a warning against the person who was issued the license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy upon proof that the person:

(17)(a) Has knowingly selected an equivalent drug or interchangeable biological product if the practitioner or authorized prescriber instructs otherwise by either of the following:

(1) On a written prescription drug order, handwriting a mark in a check-off box labeled "Dispense as Written", or the abbreviation "DAW", or both, and personally handwriting his signature on a printed-single-signature line. A written prescription drug order shall indicate the practitioner's or authorized prescriber's name, licensure designation, and practice affiliation, if any.

(ii) On an oral prescription, verbally indicating that a specific brand-name drug or biological product is ordered by the practitioner or authorized prescriber or his agent. The pharmacist shall note such information on the file copy of the prescription.
(b) The patient shall be informed of, and consent to, the equivalent drug or interchangeable biological product interchange when the practitioner or authorized prescriber permits the equivalent drug or interchangeable biological product interchange.

(c) In order to comply with 42 CFR 447.331, for prescriptions reimbursable by Medicaid, the practitioner or authorized prescriber may prohibit equivalent drug or interchangeable biological product interchange only by handwriting the words "brand medically necessary" or "brand necessary" directly on the written prescription drug order or on a sheet attached to the prescription. Recipients of Medicaid prescription benefits demonstrate implied consent by their participation in the program, provided the practitioner or authorized prescriber has not prohibited equivalent drug or interchangeable biological product interchange in the manner specified in Subparagraph (a) of this Paragraph.

*          *          *

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 319 Original 2015 Regular Session Simon

Abstract: Prohibits the dispensing of an interchangeable biological product if the prescription requires the named product and requires notification to the prescriber when an interchangeable biological product is dispensed.

Proposed law defines "biological product", "equivalent drug product", and "interchangeable".

Proposed law requires the La. Board of Pharmacy to maintain on its public web page a link to the current list, if available, of biological products determined by the U.S. Food and Drug Administration (FDA) to be interchangeable.

Present law prohibits a pharmacist from knowingly dispensing an equivalent drug product if the prescriber instructs otherwise on the written prescription drug order or by verbally indicating the instruction for an oral prescription.

Proposed law retains present law and adds a prohibition against dispensing an interchangeable biological product if the prescriber instructs otherwise.

Present law requires the patient to consent to the equivalent drug if substitution is permitted by the prescriber.

CODING: Words in struck through type are deletions from existing law; words underscored are additions.
Proposed law retains present law and adds the requirement that the patient consent to the interchangeable biological product if substitution is permitted by the prescriber.

Proposed law requires the dispensing pharmacist or his designee to communicate to the prescriber the specific biological product provided to the patient, including the name of the product and the manufacturer, no later than five days following the dispensing of a biological product unless there is no interchangeable biological product approved by the FDA for the product prescribed or a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(Amends R.S. 37:1164(16) and 1241(A)(17); Adds R.S. 37:1164(58) and (59), 1185, and 1226.1)
AN ACT

To amend and reenact R.S. 37:1164(16) and to enact R.S. 37:1164(58) and 1226.1, relative to interchangeable biological products; to provide for definitions; to provide for licensure penalties; to require certain information to be sent to a prescriber; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1164(16) is hereby amended and reenacted and R.S. 37:1164(58) and 1226.1 are hereby enacted to read as follows:

§1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

* * *

(16) "Equivalent drug product" means either of the following:

(a) A drug product that has been rated as a pharmaceutical equivalent by the federal food and drug administration United States Food and Drug Administration (FDA) and has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendial or other applicable standards such as strength, quality, purity, and identity, but which may differ in characteristics such as shape, scoring, configuration, packaging, excipients including colors, flavors, preservatives, and expiration time.
(b) A biological product that is either one of the following:

(1) Deemed by the United States Food and Drug Administration as meeting the standard set forth in 42 U.S.C. 262(k)(4) and rated as interchangeable in the *Lists of Licensed Biologic Products with Reference Product Exclusivity and Biosimilarity and Interchangeability Evaluations*, sometimes referred to as the "Purple Book", or its successors.

(2) Rated therapeutically equivalent by the United States Food and Drug Administration as set forth in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, sometimes referred to as the "Orange Book", or its successors.

* * *

(58) "Biological product" has the meaning assigned by Section 351 of the Public Health Service Act, 42 U.S.C. 262.

* * *

§1226.1. Communication to the prescriber

A. No later than five business days following the dispensing of a biological product, the dispensing pharmacist or his designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer.

B. The required communication included in Subsection A may be done by any means.

C. No communication shall be required if there is no interchangeable or therapeutically equivalent biological product approved by the United States Food and Drug Administration for the product prescribed, or if the prescription is a refill not changed from the product dispensed on the prior filling of the prescription.

D. Nothing in this Section shall create a cause of action against the prescriber and the dispensing pharmacist or his designee for a communication as required pursuant to this Section.

CODING: Words in struck through type are deletions from existing law; words underscored are additions.
E. No communication shall be required pursuant to this Section if the prescriber indicates "dispense as written".

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: ____________________

CODING: Words in struck through type are deletions from existing law; words underscored are additions.
Executive Committee

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.
Final Legislative Brief

2017-0609 @ 1800

Regular Session of the 2017 Louisiana Legislature
Convened 2017-0410 @ 1200 – Adjourned 2017-0608 @ 1800

Last Items Reviewed

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<tr>
<th>HB</th>
<th>692</th>
<th>HR</th>
<th>246</th>
<th>HCR</th>
<th>121</th>
<th>HSR</th>
<th>2</th>
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<td>SB</td>
<td>257</td>
<td>SR</td>
<td>225</td>
<td>SCR</td>
<td>125</td>
<td>SSR</td>
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<td>SCSR</td>
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Total = 1,670

Items on Watch List = 41

House of Representatives

Bills

HB 185  Armes  Health & Welfare
Establishes the Louisiana Military Medics and Corpsmen Pilot Program.
05-26-2017  Signed by Governor as Act 1; effective 08-01-2017.

This law adds a new Chapter 59-A in Title 37 – Professions & Occupations under the jurisdiction of the La. Dept. of Veterans Affairs to establish the Louisiana Military Medics & Corpsmen Pilot Program. That department is authorized to collaborate with the healthcare licensing boards to construct the capability for military medics and corpsmen to practice under the supervision of a physician or podiatrist. When appropriate, the licensing boards are authorized to promulgate rules to facilitate such activities. The pilot program is scheduled to sunset on 12-31-2020.

HB 192  Moreno  Health & Welfare
Provides for limitations on the prescribing of opioids.
06-12-2017  Signed by Governor as Act 82; effective 08-01-2017.

This law amends §978 – Prescriptions in the Controlled Substance Law by adding two new Paragraphs.

- Paragraph G imposes a prescribing limit for certain controlled substances [For adults in outpatient settings with acute conditions, no more than a seven-day supply on a first-time opioid prescription; for minors in any setting, no more than a seven-day supply on any opioid prescription] and requires consultation with parents or guardians before issuing opioid prescription for minors. This paragraph also permits the prescriber to exceed the seven-day limit when professional judgment warrants, and requires that judgment to be documented in the medical record with a notation that a nonopioid alternative was not appropriate to address the medical condition. The seven-day limit is also waived for the treatment of chronic pain, pain associated with a cancer diagnosis or palliative care. Further, this limit shall not apply to medications designed for the treatment of substance abuse or opioid dependence.

- Paragraph H requires the practitioner issuing any prescription for an opioid to do 2 things prior to issuing the prescription: (1) Consult with the patient regarding the quantity to be prescribed and the patient's option to partially fill the prescription, and (2) Inform the patient of the risks associated with the opioid prescribed. This paragraph also authorizes the dispensing pharmacist...
to partially fill the prescription and to issue the remaining amount of the prescription as authorized by federal and state pharmacy laws and rules. The dispensing pharmacist dispensing a partial fill of an opioid prescription shall report the actual amount dispensed to the state prescription monitoring program. If the interoperable electronic health record is accessible to the pharmacist, the pharmacist or his designee shall make a notation of the partial fill within seven days.

HB 209  Coussan  Health & Welfare
Establishes a licensure exemption for dental hygiene students.
06-16-2017  Signed by Governor as Act 296; effective 08-01-2017.

This law amends the Dental Practice Act to exempt dental hygiene students, but not residents, from the licensure requirements.

HB 210  Coussan  Health & Welfare
Provides for the licensure of retired volunteer dentists.

This law amends the Dental Practice Act to provide a limited type of license to retired volunteer dentists and places limitation on their liability when rendering gratuitous patient care.

HB 225  Pearson  Administration of Criminal Justice
Adds certain substances to the Uniform Controlled Dangerous Substances Law.
06-12-2017  Signed by Governor as Act 100; effective 08-01-2017.

This law amends the Controlled Substance Law for two purposes: (1) to harmonize the federal and state schedules for new commercial products scheduled by the DEA and to add new substances to Schedule I, and (2) to insert provisions to accommodate the anticipated approval of a cannabidiol drug product in early 2018. The law amends the definition of marijuana to exempt cannabidiol when contained in a drug product approved by the federal FDA, and further, adds a specific cannabidiol product to Schedule V.

HB 250  Pylant  Health & Welfare
Authorizes local needle exchange programs.
06-03-2017  Signed by Governor as Act 40; effective 06-03-2017.

This law amends the Controlled Substances Law to permit local jurisdictions (town, city, or parish) to establish local needle exchange programs.

HB 305  R. Johnson  Health & Welfare
Provides for the regulation of the practice of physical therapy.
06-16-2017  Signed by Governor as Act 300; effective 08-01-2017.

This law amends the Physical Therapy Act to establish licensing requirements for graduates of physical therapy education programs located outside the USA as well as for graduates of military-based physical therapy education.

HB 306  R. Johnson  Health & Welfare
Provides relative to pharmacy reimbursement by managed care organizations.
06-16-2017  Signed by Governor as Act 301; effective 10-01-2017.

This law amends the Medicaid Managed Care Prescription Drug Benefit Law, to provide that pharmacy reimbursements by managed care organizations shall not be less than the legacy Medicaid rate.

HB 436  Talbot  Health & Welfare
Requires drug manufacturers to provide information regarding prescription drug prices.
06-14-2017  Signed by Governor as Act 220; effective 08-01-2017.

This law adds a new Part VII to Title 40, titled Pharmaceutical Cost Transparency. Subpart A defines the terms “prescription drug” and “prescription drug marketing.” Subpart B requires each drug manufacturer or marketer who engages in prescription drug marketing to a prescriber, his designee, or any member of
his staff in the state to provide the current wholesale acquisition cost for FDA approved drugs to the Board of Pharmacy no later than the first day of January, April, July, and October of each calendar year.

**HB 490  Leger  Health & Welfare**
Creates the Advisory Council on Heroin and Opioid Prevention & Education.  
06-12-2017  Signed by Governor as Act 88; effective 08-01-2017.

This law establishes the Advisory Council on Heroin and Opioid Prevention and Education within the Drug Policy Board, an agency housed within the Office of the Governor. The law identifies the 13 members of the advisory council and charges the council with the development of an Interagency Heroin and Opioid Coordination Plan. The Secretary of the Dept. of Health is identified as the chair. All of the organizations represented on the council shall fund their own representative. The council shall meet at least quarterly. The law requires the inclusion of at least three components in the Coordination Plan: (1) parish-level data on opioid overdoses and the dispensing of overdose-reversal medication; (2) progress of current initiatives in the state relating to the heroin and opioid epidemic; and (3) specific impacts to agencies addressing education, treatment including the use of medication-assisted treatment, prevention, overdose, and recovery. The law specifically charges the council to coordinate and maintain parish-level data on the usage of overdose-reversal medication. The law also identifies 19 specific organizations with whom the council may engage and solicit input, recommendations and guidance pertaining to heroin and opioid prevention and education, including the Board of Pharmacy.

**HB 519  Emerson  Commerce**
Modifies the Provisional Licenses for Ex-Offenders Act to create the Licenses for Ex-Offenders Act.  

This law amends the existing law to delete the term ‘provisional’ from the license type. That law requires licensing agencies to issue licenses to ex-offenders that otherwise qualify for those licenses, the criminal conviction notwithstanding. A number of licensing agencies are exempted from that section of law, including the Board of Pharmacy. The law also imposes a requirement for all licensing agencies to compile data on how many licenses are issued to applicants with criminal convictions and how many are denied, and to file an annual report with the House Commerce Committee by February 1 of each year.

**Resolutions**

**HR 162  Hoffman**
Urges and requests the La. Board of Pharmacy to recognize more than one accredited pharmacy technician certification program.  
06-01-2017  Sent to Secretary of State.

With respect to Regulatory Project 2015-9 ~ Pharmacy Technicians, this resolution requests the Board to change its definition of “approved certification examination” in order to recognize more than one pharmacy technician certification program accredited by the National Commission for Certifying Agencies prior to adopting its Final Rule.

**HR 181  Talbot**
Urges and requests the La. Dept. of Health to study the desirability and feasibility of adopting state policy to provide for review of prescription drug prices in the medical assistance program.  
06-08-2017  Sent to Secretary of State.

This resolution cites a recent policy adopted by the State of New York authorizing, when total Medicaid drug expenditures are projected to exceed the state’s annual growth limitation, the referral of prescription drugs to a drug utilization review board for a recommendation as to whether a target supplemental Medicaid rebate should be paid to the state by the manufacturer of the drug and the target amount of the rebate. The resolution requests evaluation of the policies in New York, Ohio, and Texas and the use of a similar policy in Louisiana; and further, directs the submission of a written report, with proposed legislation as appropriate, at least 60 days prior to the opening of the 2018 Regular Session.
HR 189 Hoffmann
Urges and requests certain universities to pursue opportunities for research on the safety and clinical efficacy of therapeutic marijuana,
06-08-2017 Sent to Secretary of State.

This resolution requests LSU Health Sciences Centers in New Orleans and Shreveport, Pennington Biomedical Research Center, and the LSU and Southern University Agricultural Centers to pursue opportunities for basic research, applied research, and clinical trials to evaluate safety and clinical efficacy of marijuana for therapeutic use. The resolution urges relevant state boards, including the Board of Pharmacy, to collaborate in the efforts to pursue research opportunities.

Concurrent Resolutions

HCR 51 Jackson Health & Welfare
Authorizes and directs the La. Dept. of Health to issue rules requiring reporting of immunization information.
06-08-2017 Sent to Secretary of State.

This concurrent resolution urges and requests the Dept. of Health to promulgate rules that would require all physicians, nurses, and other healthcare providers including pharmacies, that administer immunizations to adults and children report those immunizations to the LINKS system operated by the Dept. of Health.

HCR 75 M. White Health & Welfare
Requests the Dept. of Health take all necessary steps to bring attention to the need to eliminate pain as the fifth vital sign and a determinate of quality patient care.
06-05-2017 Sent to Secretary of State.

This concurrent resolution urges and requests the Dept. of Health to take all necessary steps to bring attention to the need to eliminate the use of pain as the fifth vital sign and a determinant of quality patient care, and to increase prescriber education and awareness on assessing, identifying, and treating the symptom of pain with the goal of reducing the use of opioids to treat patient-reported pain when alternative forms of pain management would be sufficient.

HCR 104 R. Edmonds Labor & Industrial Relations
Requests the La. Workforce Commission and the La. Dept. of Veterans Affairs to study employment practices and professional licensing requirements to benefit veterans in the workforce.
06-08-2017 Sent to Secretary of State.

This concurrent resolution urges and requests the Workforce Commission and the Dept. of Veterans Affairs to study employment practices and policies as well as various professional licensing requirements, certification requirements, and training programs to benefit veterans in the workforce, to consult with 46 named boards and commission, including the Board of Pharmacy, and to submit a written report to the House & Senate Committees on Labor & Industrial Relations no later than February 15, 2018.

Senate

Bills

SB 035 Colomb Judiciary-C
Provides exemptions from arrest and prosecution to persons lawfully in possession of medical marijuana.

This law amends Controlled Substance Law, more specifically §966 which details the criminal penalties for possession of marijuana. This new law amends the subsection on immunity from prosecution passed in the 2016 Legislature, to limit that immunity for those in possession of marijuana products to those products prescribed by a physician licensed by the La. State Board of Medical Examiners. The new law extends the immunity from prosecution to the following: (1) any pharmacy licensed by the Board of
Pharmacy to dispense marijuana, and any employee, board member, director, or agent thereof; (2) any licensee or its subcontractor licensed by the Dept. of Agriculture & Forestry to produce marijuana, and any employee, board member, director, or agent thereof; (3) any laboratory that tests marijuana produced in the statewide medical marijuana program, and any employee, board member, director, or agent thereof; and (4) any person conducting with marijuana as the licensee or in partnership with the licensee, and any employee, board member, director, or agent thereof.

SB 055  Mills  Health & Welfare
Provides relative to prescribers of controlled dangerous substances.  
06-12-2017  Signed by Governor as Act 76;  
Section 1 (all but CE) effective 06-12-2017;  
Section 2 (CE) effective 01-18-2018.

This law amends the Controlled Substances Law, for three purposes:

• With respect to §973 relative to licensing requirements, to update the original 1972 law. That original law required licensing for those persons manufacturing, distributing or dispensing controlled substances. The current span of the medication use process now includes persons conducting research, as well as procuring, possessing, and prescribing controlled substances. This law adds those persons to the licensing requirement, and the new law now conforms to current practice at the state and federal levels. In addition, a new paragraph was added to require the Board of Pharmacy to automatically issue access privileges to the state prescription monitoring program (PMP) upon the initial issuance or renewal of the CDS license for those practitioners with prescriptive authority for controlled substances, excluding veterinarians.

• With respect to §978 relative to prescriptions, the law amends the current requirement for a prescriber of an initial prescription for a Schedule II medication for the treatment of non-cancer-related chronic or intractable pain to access the PMP prior to issuing such a prescription. The new law requires the prescriber or his delegate to access the PMP and review the patient’s record prior to issuing the initial prescription of any opioid medication, and in the event the therapy extends beyond 90 days, then to review those records at least every 90 days; however, the requirement shall not apply when: (1) the drug is prescribed or administered to a hospice patient or any patient diagnosed with a terminal illness; (2) the drug is prescribed or administered for the treatment of cancer-related chronic or intractable pain; (3) the drug is ordered or administered for a patient being treated in a hospital; (4) when the PMP is inaccessible or not functioning properly, with such occurrences noted in the patient’s chart and the program reviewed when accessibility is restored; (5) no more than a single seven-day supply is prescribed or administered to a patient. The law specifically tasks the licensing board of the prescribing practitioner with enforcement of this provision, to promulgate rules to enforce this requirement, and to treat a practitioner’s failure to comply with this requirement as a complaint against the practitioner.

• The law enacts a new section, §978.3, to establish continuing education (CE) requirements for prescribers of controlled substances. Licensing boards of prescribing practitioners shall promulgate rules for CE and require compliance with this rule as a prerequisite for license renewal. In particular, the law requires three hours of CE relative to drug diversion training, best practice prescribing of controlled substances, appropriate treatment of addiction, and any other matter relative to controlled substances deemed appropriate by the board. The law allows a prescribing practitioner to claim an exemption from the CE requirement upon his certification he has not prescribed, administered, or dispensed a controlled substance during the applicable reporting period; the law requires the licensing board to verify the attestation by accessing the prescriber’s PMP records. The law requires the board to withhold the license renewal for an individual who fails to comply with this provision. The law requires the licensing board to retain annual compliance documentation that shall be reported to the House & Senate Committees on Health & Welfare to demonstrate aggregate prescriber compliance. Finally, the law specifies the CE earned in compliance with this law shall be acquired on or after August 1, 2017, and shall be considered part of the total CE requirement and not an additional requirement.

SB 059  Mills  Health & Welfare
Provides relative to prescription drug price information.  
06-14-2017  Signed by Governor as Act 236; effective 06-14-2017.

This law adds a new Part to the Louisiana Pharmacy Practice Act, entitled Disclosure of Prescription Drug
Price Information. The law requires the Board to publish a website for prescribers containing drug price information arranged by therapeutic category, including product name, whether it is a branded or generic item, its strength, per-unit wholesale acquisition cost, and any disclaimers deemed appropriate by the Board. The law authorizes the Board to enter into contracts to administer this law and requires the Board to actively seek grant funds from private entities. Within ten months of receipt of grant funds adequate to develop, implement, operate, and maintain the website, the Board shall make the website available to prescribers.

SB 070  Donahue   Judiciary-C
Makes misbranding or adulteration of drugs under certain circumstances a felony.
06-12-2017  Signed by Governor as Act 108; effective 08-01-2017.

This law adds a new §971.3 to the Controlled Substance Law, to establish criminal penalties for the misbranding or adulteration of any drug with the intent to mislead or defraud, with a maximum prison sentence of five years, with or without hard labor, a maximum fine of ten thousand dollars, or both.

SB 096  Johns    Health & Welfare
Provides relative to the prescription monitoring program.
06-14-2017  Signed by Governor as Act 241; effective 06-14-2017.

This law updates the Controlled Substance Law, more particularly the Prescription Monitoring Program (PMP) Law to include new provisions in the recently-updated National Model PMP Law, as well as recommendations from the Louisiana Commission on Preventing Opioid Abuse:
- Defines ‘audit trail information’, extends the same level of protection from discovery as applicable to prescription transaction information, but permits disclosure to named entities for use in active investigations;
- Establishes new categories of person authorized to access PMP records, including medical examiners, licensed substance abuse addiction counselor in a state-licensed substance abuse program, probation or parole officer, and judicially supervised specialty courts within criminal justice system authorized by the La. Supreme Court;
- Revises the current authority for persons to access their own information to add parents, legal guardians, legal healthcare agents, executor of will, and court-appointed succession representative of an estate;
- Added protection for board and advisory council from civil liability, administrative action, or other legal relief for certain actions, e.g., failure to possess prescription information not reported to the board and release of PMP information that was factually incorrect. Also added protection from same types of actions for dispensers for reporting of PMP information to the Board. Further, added protection for prescriber, dispenser, or other authorized entities in proper possession of PMP or audit trail information;
- Deleted certain educational requirements required on implementation of the program in 2008; and
- Amended the unlawful acts section to add a provision that a dispenser who fails to correct or amend prescription data after notification from the Board shall be subject to disciplinary action by the Board; further, the current language subjecting a person authorized to access PMP information who knowingly discloses that information in violation of the PMP law to both administrative and criminal penalties was amended to include knowingly accessing such information in violation of the PMP law shall also be subject to administrative and criminal penalties.

SB 220  Alario   Judiciary-C
Provides relative to adopting a felony class system.

This law made significant changes to the crime laws as well as the criminal penalty sections of the Controlled Substance Law.
**Resolutions**

**SR 146**  Mills  Health & Welfare
Requests the Louisiana Board of Pharmacy to consider alternative training and certification options for pharmacy technicians.  
06-05-2017  Sent to Secretary of State.

*This resolution requests the Board to consider alternative training and certification options for pharmacy technicians prior to adopting final rules for Regulatory Project 2015-9 ~ Pharmacy Technicians.*

**SR 197**  Martiny
Urges and requests certain state universities and research entities to pursue opportunities for research on the safety and clinical efficacy of therapeutic marijuana.  
06-06-2017  Sent to Secretary of State.

*This resolution requests LSU Health Sciences Centers in New Orleans and Shreveport, Pennington Biomedical Research Center, and the LSU and Southern University Agricultural Centers to pursue opportunities for basic research, applied research, and clinical trials to evaluate safety and clinical efficacy of marijuana for therapeutic use. Resolution urges relevant state boards, including Board of Pharmacy, to collaborate in the efforts to pursue research opportunities.*

**Concurrent Resolutions**

**SCR 21**  Mizell  Health & Welfare
Requests Louisiana medical schools, prescriber licensing boards, and prescriber trade associations to take all necessary steps to eliminate pain as the fifth vital sign and to increase prescriber education and awareness in assessing, identifying, and treating the symptom of pain.  
06-05-2017  Sent to the Secretary of State.

*This concurrent resolution urges and requests the Dept. of Health to take all necessary steps to bring attention to the need to eliminate the use of pain as the fifth vital sign and a determinant of quality patient care, and to increase prescriber education and awareness on assessing, identifying, and treating the symptom of pain with the goal of reducing the use of opioids to treat patient-reported pain when alternative forms of pain management would be sufficient.*

**SCR 48**  Milkovich  Senate & Governmental Affairs
Requires state agencies to include on their website information regarding any properties rented by the agency.  
06-08-2017  Sent to Secretary of State.

*This concurrent resolution urges and requests the Div. of Administration to request each state agency to publish information on its website as to whether the agency leases nonpublic buildings for its operation, and if so, to publish and update certain information (location, dimensions, ownership, lease payments, and amount of underutilized space) about those leases.*
MEMORANDUM

To: Executive Committee

From: Malcolm Broussard

Date: August 22, 2017

Re: Proposal to improve compliance and enforcement policies and procedures

With the development of core modules of the Universal Inspection Form by NABP, through a collaborative process with over 40 state boards of pharmacy, we now have an opportunity to improve our compliance and enforcement policies and procedures. In particular, the core modules of the Universal Inspection Form are:

- Basic pharmacy inspection;
- Compounding of nonsterile preparations, based on USP Chapter <795>; and
- Compounding of sterile preparations, based on USP Chapter <797>.

Additional modules under development include nuclear pharmacy and other special pharmacy practices.

Using the inspection forms, I have developed blueprint documents for the three modules itemized above. These blueprint documents contain the numbered standards itemized on the inspection forms. The blueprints for the compounding practices are based on nationally developed criteria derived from the USP standards; therefore, unless Louisiana intends to vary from certain USP standards, there is no need to modify those blueprint documents. The blueprint for the basic pharmacy inspection contains room for additional standards specific to Louisiana.

When the Board has approved the blueprint documents, I propose the following actions:

1. Develop a resource page on the Board’s website for pharmacies. Some existing resources could be linked, e.g., forms and applications, guidance documents, etc. In addition, we can place links to the blueprint documents. Pharmacies will then know the standards by which they will be inspected.
2. Map the blueprint standards to specific federal and state laws and rules. This should assist the compliance officer preparing an investigative report serving as the basis for board action.
3. Construct a matrix describing ranges of sanctions (including field and administrative corrections as well as board actions) for noncompliance with blueprint standards, including aggravating and mitigating factors. This should include authority for staff-initiated consent agreements for minor or routine compliance issues.
4. Prepare committee policies and procedures for Board approval.
5. Analyze inspection reports to collect information on which standards elicit most frequent noncompliant inspections. Report that information to the Board and to the licensees.
# Blueprint for Inspection of Pharmacies

**Pharmacy Practice Profile**

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**General Operations and Licensure**

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**Personnel**

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### Pharmacy Practice Profile

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<tr>
<td>01.00</td>
<td>Name, location, contact information, and key personnel</td>
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<tr>
<td>02.00</td>
<td>Is the PIC (or pharmacy manager/director) present for the inspection?</td>
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<tr>
<td>03.00</td>
<td>Are there any other businesses located at this address?</td>
</tr>
<tr>
<td>04.00</td>
<td>Does the pharmacy have any other websites?</td>
</tr>
<tr>
<td>05.00</td>
<td>Do any other websites link to the pharmacy website (such as a provider or other affiliate)?</td>
</tr>
<tr>
<td>06.00</td>
<td>Does the pharmacy allow patients to enter/update profile and medical information through the website?</td>
</tr>
<tr>
<td>07.00</td>
<td>Are patients able to order or refill prescriptions through the website?</td>
</tr>
<tr>
<td>08.00</td>
<td>Are photographs allowed during the inspection (no PHI)?</td>
</tr>
<tr>
<td>09.00</td>
<td>List of additional personnel interviewed as part of the inspection.</td>
</tr>
<tr>
<td>10.00</td>
<td>List of personnel present at the time of the inspection.</td>
</tr>
<tr>
<td>11.00</td>
<td>Business licensure information for Louisiana and Federal (La. Board of Pharmacy, CDS, La. Board of Drug &amp; Device Distributors, DEA, FDA, etc.)</td>
</tr>
<tr>
<td>12.00</td>
<td>Type(s) of practice; Facility Size; Volume of Dispensing &amp; Distribution; Staffing Summary; Interstate Activity.</td>
</tr>
<tr>
<td>13.00</td>
<td>If the pharmacy mails or delivers filled prescriptions (patient-specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient?</td>
</tr>
<tr>
<td>14.00</td>
<td>Does the pharmacy provide prescription products to a provider or facility for 'office use' (not pursuant to a prescription received prior to delivery, not patient-specific, and not labeled with the patient name)?</td>
</tr>
<tr>
<td>15.00</td>
<td>Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributor (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?</td>
</tr>
<tr>
<td>15.01</td>
<td>If so, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? Indicate actual percentage and whether percentage is based on a number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.</td>
</tr>
</tbody>
</table>
15.02 If so, is the percentage of products distributed at wholesale to providers or facilities in other states less than 5%? Indicate actual percentage and whether percentage is based on a number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.

[Additional Louisiana standards]

**General Operations and Licensure**

16.00 Are pharmacy licenses, permits, and registrations posted in customers’ view and current?

17.00 Is the most recent board of pharmacy inspection report available for review?

18.00 Were any repeat deficiencies noted?

19.00 Has this pharmacy been inspected by any other state for which it holds a license? Any noted deficiencies?

20.00 Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed?

21.00 Has this pharmacy been inspected as part of the NABP Verified Pharmacy Program?

22.00 Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed?

23.00 Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc.)?

24.00 Has the pharmacy been inspected by the DEA?

25.00 Has the pharmacy been inspected by the FDA?

26.00 Does the pharmacy hold any accreditations or certifications?

27.00 Has the pharmacy held any accreditations or certifications in the past that have been rescinded or suspended?

28.00 Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc.?

29.00 Does the pharmacy maintain all required records, including but not limited
to prescription files and invoices on site?

29.01  Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period?

29.02  Are electronic prescriptions (e-scripts but not fax) kept on site for the entire retention period?

29.03  Are all dispensing records (refills, verifications, DUR overrides) kept on-site for the entire retention period?

[Additional Louisiana standards]

Personnel

30.00  Are all pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician candidate credentials issued by the board current?

31.00  Is there a process for periodic verification of credential validity?

32.00  Are pharmacists providing patient services that require additional training or certification appropriately trained and certified?

33.00  Does the pharmacy maintain the proper staffing ratios for pharmacy interns, pharmacy technicians, and pharmacy technician candidates?

[Additional Louisiana standards]

Facility and Security

34.00  Does the pharmacy have a working security/alarm system in place that is in compliance with the laws and regulations of the resident state?

35.00  Are Schedule II controlled substances secured in a locked cabinet or safe?

36.00  Are there contingency plans in the event the pharmacy cannot be secured?

37.00  Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume?

38.00  Does the pharmacy have a private area for patient counseling and providing patient services?

39.00  Is temperature in the drug storage area monitored?
39.01 Is the temperature in the drug storage area within the USP range for controlled room temperature (20°-25°C or 68°-72°F)?

40.00 Are the refrigerator and freezer restricted to drug products only (no food)?

41.00 The pharmacy has a process for how the refrigerator temperature is monitored for excursions 24/7.

41.01 Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46°F)?

42.00 The pharmacy has a process for how the freezer temperature is monitored for excursions 24/7.

42.01 Is the temperature in the freezer within the USP range (-25° to -10°C or -13° to 14°F)?

43.00 Are there contingency plans in the event of power outage or refrigerator/freezer failure?

44.00 Are there contingency plans in the event of heating or air conditioning failure?

45.00 Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?

46.00 Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc.)?

[Additional Louisiana standards]

Product Receipt and Inventory

47.00 Does the pharmacy restrict ordering to only approved wholesale distributors or manufacturers?

47.01 If the pharmacy is not restricted to vendors approved by the corporate office, or the pharmacy can purchase from other sources, are the other sources verified? If so, how?

47.02 Are all products received from authorized trading partners?

47.03 Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement) is received at the same time or before the product is received?

47.04 Does the pharmacy have a procedure to verify product (suspect or
illegitimate) including quarantine of product and reporting?

48.00 Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? If so, who has power of attorney to sign the forms?

49.00 Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances?

50.00 Is the receipt of Schedule II orders documented appropriately? Does the DEA-222 form indicate quantity received and date on each line of product received? Does the CSOS record indicate verification of receipt and staff performing verification?

51.00 Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?

52.00 Are all orders received when the pharmacy is open?

53.00 Does the pharmacy purchase any compounded preparations from other entities for dispensing to patients?

54.00 Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft?

54.01 Are incidents of diversion or resignation/termination of personnel for cause appropriately reported?

55.00 Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?

56.00 Is the Schedule II perpetual inventory log reconciled regularly?

57.00 Is the most recent complete controlled substance inventory available for review?

57.01 Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc.)?

58.00 Does the pharmacy stock and sell OTC pseudoephedrine (an/or ephedrine) products?

58.01 Are these products mailed, sent, or delivered into other states?

59.00 Does the pharmacy stock and sell other OTC restricted products for which identification is required and a log kept of the sale?

59.01 Are these products mailed, sent, or delivered into other states?
60.00 Are outdated, damaged, or recalled products segregated? How often does the pharmacy check for out-of-date products? Does it include OTC products?

60.01 If the pharmacy destroys products on site, are appropriate records kept of the destruction?

60.02 Does the pharmacy use a reverse distributor?

60.03 Does the pharmacy have a hazardous waste handling and collection system? How does the pharmacy handle empty bottles of chemotherapy medications or warfarin or hazardous drug compounding waste?

61.00 Does the pharmacy repackage bulk containers of prescription medications into smaller containers for ease of use? What expiration date is used on the repacked container?

62.00 Does the pharmacy prepackage bulk containers of prescription medications into unit-of-use quantities? What expiration date is used on the prepacked container?

63.00 Does the pharmacy return to stock prescription drugs that were filled but never picked up?

[Additional Louisiana standards]

Prescription Processing

64.00 Patient Profile: Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver?

64.01 If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law?

65.00 Prescription: Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders?

65.01 Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent?

65.02 Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship?

65.03 Does the pharmacy have electronic prescription capability?
66.00  **Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information?  

67.00  **DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product?  

67.01  Does the DUR include:  
- Drug-drug interaction (prescription and OTC);  
- Drug-allergy interaction;  
- Therapeutic duplication;  
- Under- or over-utilization (including clinical abuse/misuse);  
- Disease state or condition contraindication;  
- Incorrect dosage or duration of therapy; and  
- Gender or age-related contraindications.  

67.02  Does the pharmacy staff obtain additional information to use in the DUR process?  

67.03  Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?  

67.04  Does the pharmacy report appropriate data to the state PMP, in this state and the other states in which the pharmacy is licensed?  

67.05  Does the pharmacy access state PMP data for specific patients?  

67.06  Are DUR overrides/bypasses documented? Indicate if documented via a password/biometric override or by computer logs.  

67.07  Is the DUR process performed electronically by the computer system?  

67.08  If the DUR is manual, is there a system to document:  
- How manual DUR is performed;  
- Specific issues that were identified; and  
- Pharmacist that considered the identified issues and gage the order to proceed.  

67.09  If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR?  

68.00  Are filled prescriptions verified for accuracy prior to dispensing?  

69.00  Are filled prescriptions appropriately labeled?  

70.00  **Confidentiality:** Is access to the pharmacy computer system limited to
appropriate personnel?

70.01 Does the pharmacy appropriately destroy PHI including labeled prescription vials?

71.00 Mail/Delivery: If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?

72.00 Off-Site Processes: Are any portions of the prescription processing (in the questions below) performed at a different location?

72.01 Is patient information (demographics and contact information) and profile information (allergies, disease states, etc.) entered into the computer at another location?

72.02 Are prescriptions received by another location (including written, telephone, fax, electronic)?

72.03 Is prescription information entered into the computer system at another location?

72.04 Is the accuracy of the prescription information entered into the computer verified at another location?

72.05 Is any part of the DUR process (including assessing and acting on DUR alerts and warnings) performed at another location?

72.06 Are any prescriptions dispensed or sold from this facility filled at another location?

72.07 If any of the above functions are performed at another location, is the other location under common ownership?

72.08 If any of the above functions are performed at another location, is that location in a different state than this facility?

72.09 If any of the above functions are performed at another location, are there policies and procedures for the function that include maintaining records of the person(s) performing the function and accountability?

72.10 Is the other pharmacy and any personnel at another location licensed in this state?

73.00 Off-Site Inventory: Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, emergency medical services, ambulances, correctional facilities, etc.)?
73.01 Do the emergency kits contain any compounded sterile preparations?

74.00 **Off-Site Devices:** Does the pharmacy maintain any automated medication dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc.?

74.01 If so, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy?

74.02 Do the automated dispensing devices contain any compounded sterile preparations?

[Additional Louisiana standards]

**Patient Counseling and Communication**

75.00 Does the pharmacy provide counseling for all new prescriptions picked up at the pharmacy (proactively, no ‘offer’)?

75.01 Is an ‘offer’ to counsel made for all new prescriptions picked up at the pharmacy?

76.00 Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no ‘offer’)?

76.01 Is an ‘offer’ to counsel made for all refilled prescriptions picked up at the pharmacy?

77.00 Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no ‘offer’)?

77.01 Is an ‘offer’ to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist?

78.00 Is patient counseling provided for delivered prescriptions? How?

79.00 Is patient counseling provided for mailed prescriptions? How?

80.00 Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc.)? How?

81.00 Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDs, antidepressants, etc)? How?
82.00 Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Identify the programs and confirm procedures in place.

83.00 Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? How?

84.00 Do patients have 24-hour access to a pharmacist? How?

85.00 Are processes in place to handle a drug recall?

86.00 Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?

86.01 Does the take-back program include controlled substances?

86.02 Does the pharmacy have a modified DEA registration (Authorized Collector) for controlled substances take-back?

[Additional Louisiana standards]

Quality Assurance / Quality Improvement Program

87.00 Is there a documented continuous quality improvement (CQI) program for the purpose of detecting, documenting, assessing, and preventing quality-related events (QREs)?

87.01 Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form.

87.02 “Quality Related Event” (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication, including (but not limited to):

1. A variation from the prescriber’s prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions;

2. A failure to identify and manage over-utilization or under-utilization, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of treatment, drug-allergy interactions, or clinical abuse/misuse;

3. Packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient’s drug therapy.
87.03  There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes.

88.00  Documentation of QREs starts as soon as possible, but no more than three days after determining their occurrence.

88.01  Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.

88.02  Documentation includes documenting the type of QRE details and how/who discovered the QRE.

88.03  Documentation includes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting workflow at the time.

88.04  Documentation includes steps taken to remediate, including communications with the patient and the provider, and if the medication was ingested, and disposition of the patient.

89.00  QRE data collected is analyzed to assess causes and any contributing factors (root cause)? Who performs that analysis and often is the analysis performed?

89.01  The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.

89.02  For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of the patients.

90.00  Quality Meetings are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

90.01  The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.

90.02  Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.

91.00  Reporting: Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization.
91.01 Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?

91.02 Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc.) are documented and reported to the manufacturer or distributor.

92.00 Quality Self-Audits are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.

93.00 Customer Surveys are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying each patient. Each pharmacy should use the results of its customer survey to evaluate its own performance at a particular time and over a period of time.

94.00 Patient Complaints are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.

[Additional Louisiana standards]
Blueprint for Inspection of Pharmacies Compounding Nonsterile Preparations

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Finished Preparation Release Checks and Tests 73.00 – 82.00 Page 13

Patient Counseling and Communication 83.00 – 86.00 Page 14
SIMPLE
Making a preparation that has a *United States Pharmacopeia (USP)* compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include *Captopril Oral Solution*, *Indomethacin Topical Gel*, and *Potassium Bromide Oral Solution, Veterinary*.

MODERATE
Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. Examples include *Morphine Sulfate Suppositories*, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.

COMPLEX
Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.

[Abstracted from *2016 USP Compounding Compendium*, current with USP-39/NF-34 through First Supplement]
General Operations Information

01.00 Does the pharmacy dispense nonsterile compounded preparations pursuant to a prescription?

01.01 Are patient profiles complete and DUR performed for each prescription?

01.02 Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?

01.03 Are nonsterile compounded prescriptions picked up at the pharmacy?

01.04 Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?

01.05 Are nonsterile compounded prescriptions delivered to practitioner for administration to the patient in the office, clinic, or facility?

02.00 Does the pharmacy distribute nonsterile compounded preparations?

02.01 Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?

02.02 Does the pharmacy distribute nonsterile compounded preparation to hospitals, clinics, or surgery centers?

02.03 Does the pharmacy have a sales force that distributes samples containing active ingredients?

03.00 Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?

03.01 If so, does the pharmacy have central fill contracts or agreements with these pharmacies for patient-specific preparations?

04.00 Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)?

05.00 Does the pharmacy compound topical (creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)?

06.00 Does the pharmacy compound vitamin or nutritional supplements?

07.00 Does the pharmacy compound investigational drugs?
08.00  Does the pharmacy make a copy of an approved commercial product?

08.01  Products are verified as not available via FDA list and/or the manufacturer and documented.

08.02  FDA list and manufacturer information is monitored, and when item is taken off the list or becomes available, any remaining stock is quarantined for destruction and not dispensed or distributed.

09.00  Does the pharmacy perform compounding identified as *simple*? If so, indicate percentage of total compounding activity designated as such.

1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUDs).

2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.

10.00  Does the pharmacy perform compounding identified as *moderate*? If so, indicate percentage of total compounding activity designated as such.

1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units.

2. Making a preparation for which stability data for that specific formula is not available.

11.00  Does the pharmacy perform compounding identified as *complex*? If so, indicate percentage of total compounding activity designated as such.

1. Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.

12.00  Does the pharmacy perform compounding with *hazardous drugs*? If so, indicate percentage of total compounding activity designated as such.

12.01  Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?

12.02  Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, hazardous drug compounding waste.

12.03  Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of
hazardous products such as chemotherapy medications?

13.00 Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?

14.00 Does the pharmacy compound using any controlled substances? If so, indicate percentage of total compounding activity designated as such.

15.00 **APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?

15.01 Does the pharmacy purchase APIs directly from the manufacturer?

15.02 Does the pharmacy verify that the manufacture of the API is an FDA-registered facility? How?

15.03 Does the pharmacy use active ingredients that are not from an FDA-registered facility?

15.04 Does the pharmacy computer track on-hand quantities of APIs used for compounding?

16.00 Does the pharmacy perform any testing in-house (not sent to an outside lab)?

17.00 Does the pharmacy send samples to an outside lab to perform testing?

18.00 **Quality Assurance/Quality Improvement:** Does the pharmacy’s continuous quality improvement program include nonsterile compounding measures?

- Quality Related Events (QREs) related to the preparation of compounded products;
- Personnel testing and validation;
- Equipment calibration, testing, and validation;
- End product testing, such as potency, particulates, consistency, etc.; and
- Patient or prescriber reports or complaints regarding nonsterile compounded preparations.

18.01 Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?

18.02 Does the recall system include communication with both the patient and the prescriber regarding the affected nonsterile compounded preparation?

18.03 Are QREs involving nonsterile compounded preparations or all pharmacy recall campaigns reported to the Board of Pharmacy?
Component Selection and Use

19.00  All bulk drug substances (APIs) used are:
(1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or
(2) A component of an FDA-approved human drug product; or
(3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation. [Note: must comply with (1) or (2) above until the FDA list is issued]

19.01  Certificates of Analysis (COAs) obtained for all bulk APIs used for compounding.

19.02  USP- or NF-grade substances used, if available.

19.03  If compendial quality components are not available, chemically pure, analytical reagent grade or ACS [American Chemical Society]-certified components are used and are determined to be free from impurities.

19.04  APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate “for research purposes only”, “not for drug use”, or are handwritten labels from other pharmacies.

19.05  If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding.

19.06  All substances and components have a complete label including a batch control or lot number, and an expiration date.

19.07  For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three years for ingredients used for nonsterile compounding and does not exceed one year for ingredients used for sterile compounding. The pharmacy may perform purity and quality testing to further extend their expiration date.

19.08  All APIs and components received without an expiration date are labeled with the date they were received.

19.09  If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically, the lesser of one year or the actual expiration date from the original container). Product may be tested to extend the expiration date, but may not exceed the original package expiration date.
19.10 Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances (including hormones) are segregated.

19.11 Components from foreign sources that are derived from ruminant animals (cow, sheep, goat) have documentation that the component is in compliance with federal laws governing processing, use, and importation – that the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist.

20.00 Where water is an ingredient, purified or distilled water is used.

21.00 Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.

22.00 No preparations are made or ingredients used that appear on the FDA’s list of drug products withdrawn or removed from the market for safety reasons. The facility has a copy of the list or other way to determine.

23.00 When manufactured products are used for compounding, all the other excipients in the product (in addition to the active ingredient) are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.

24.00 For animal compounding, the compounding meets the same standards as compounding for human patients.

24.01 The pharmacist is knowledgeable or has references regarding the individual species’ limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.

24.02 It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.

24.03 The pharmacist is familiar with or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.

24.04 The facility has a list of drugs and components not allowed when compounding for food-producing animals.

24.05 The pharmacist is familiar with or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs).
Beyond Use Dating (BUD)

25.00 BUDs are assigned from the day of preparation.

26.00 BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six months.

27.00 BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).

28.00 BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations are not later than 30 days.

29.00 BUDs are assigned based on dispensing in tight, light-resistant contains/overpacks.

30.00 Extended BUDs are supported by testing data.

Environment

31.00 The nonsterile compounding area is a controlled environment and separate from the general pharmacy.

32.00 There is sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.

33.00 Only one preparation is compounded at a time.

34.00 Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.

35.00 The compounding area is well-lit.

36.00 The pharmacy performs hazardous nonsterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI; however, CAI may not be used for hazardous drugs that may volatilize. {USP Chapter <800> will change hazardous drug compounding requirements.}

36.01 Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.

36.02 Hood prefilters are checked and replaced regularly. {Recommended}

36.03 If the hoods or isolators are not located in a closed, controlled room
environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.

37.00 Appropriate protective attire (gowns, gloves, masks, etc.) is available including appropriate personal protective equipment (PPE) for hazardous drug compounding if hazardous drugs are used.

38.00 There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.

39.00 There is adequate space to wash equipment and utensils including access to water for rinsing.  *(Purified water is recommended, but not required.)*

40.00 The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.

41.00 *Temperature* in the compounding area is maintained to provide controlled room temperature storage of 20° to 25°C (68° to 77°F), or more restrictive if warranted by specific drug product storage requirements.

41.01 Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.

41.02 Excursion action plan is in place, including evaluating excursion effects on drug product integrity.

41.03 Temperature monitoring is also performed in drug storage areas, if separate from the compounding areas.

42.00 *Humidity* in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a ‘dry place’, humidity is not to exceed 40%. Generally recommended range is 35-60%.

42.01 Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.

42.02 Excursion action plan in place including evaluating excursion effects on drug product integrity.

42.03 Humidity monitoring is also performed in drug storage areas, if separate from the compounding areas.

43.00 The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.
44.00  All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.

45.00  All components and packaging containers and closures are properly rotated to use oldest first.

46.00  Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel (OSHA regulations and NIOSH Alerts).

47.00  Trash is disposed of in a safe, sanitary, and timely manner including hazardous waste.

48.00  Environmental testing is performed to detect contamination by drug residue in the pharmacy area or areas served by the same ventilation system.  {Recommendation: drug residue may cause cross contamination to other products or expose staff.  Not required but is recommended if compounding with hazardous materials or known allergens such as penicillin, not using a hood, or the compounding room is not segregated.}

Training

49.00  All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs, including teratogenicity, carcinogenicity, and reproductive issues.

50.00  There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and are not allowed to compound or supervise compounding until training is successfully completed.

51.00  There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.

52.00  There is documentation that training includes the operation of any equipment that may be used when preparing compounded products; documentation includes operation and troubleshooting.

53.00  There is documentation available showing employees performing nonsterile compounding are evaluated at least annually (including hazardous drug handling).

54.00  If the pharmacy uses relief personnel from outside agencies to perform
nonsterile compounding there is documentation that training is verified.

**Compounding Equipment**

**55.00** Appropriate equipment and utensils are available, clean, and in good working order. Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.

**56.00** Scales, balances, or other equipment used for measurement is validated and calibrated at least annually. If scales are not validated and sealed by a state or local weights and measures agency, describe procedure used.

**57.00** Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function. Hood filters are checked regularly and replaced when necessary.

**58.00** All equipment is cleaned promptly after each use. Equipment and utensils washing using potable water with a soap or detergent, and rinsed.

*{Recommendation: rinse with purified water.}*

**59.00** The pharmacy uses separate equipment and utensils to compounding allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross contamination or exposure.

**Documentation**

**60.00** The pharmacy creates a *Master Formulation Record* the first time before compounding a new preparation.

**60.01** Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.

**60.02** The *Master Formulation Record* contains:
1. Official or assigned name, strength, and dosage form;
2. All necessary calculations;
3. Description of all ingredients and their quantities;
4. Compatibility and stability information including references (when available);
5. Equipment used for the preparation;
6. Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors);
7. Container used and packaging requirements;
8. Assigned BUD information;
9. Labeling information, including the name of and quantity or concentration of each active ingredient;
10. Description of the finished preparation;
11. Storage requirements; and
12. Quality control procedures and expected results (e.g., dose measurement of capsule in the dose calibrator).

61.00 The pharmacy creates a **Compounding Record** for each compound prepared.

61.01 The **Compounding Record** includes:
1. Official or assigned name, strength, and dosage of the preparation;
2. Master Formulation Record reference;
3. Sources, lot numbers, and expiration dates of all components;
4. Total quantity or number of dosage units compounded;
5. Person compounding the preparation;
6. Person performing the quality control procedures;
7. Person who approved the preparation;
8. Date of compounding;
9. Assigned internal identification number or prescription number;
10. Description of the final preparation;
11. Assigned BUD;
12. Duplicate label;
13. Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.); and
14. Documentation of any quality control issues, and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate.

**Compounding Procedures**

62.00 The **Master Formulation Record** and the **Compounding Record** has been reviewed by the compounder to ensure it is error free.

63.00 Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit physical inspection of the components.

64.00 The containers and closures selected meet USP standards (from container supplier).

65.00 Container selection determined by physical and chemical properties of the preparation.

66.00 Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.

67.00 Personnel don appropriate protective garb when compounding includes hazardous compounding.
68.00    Routine compounding procedures for batch preparation completed and verified according to written procedures, including: calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly.

69.00    Procedures for in-process checks followed. These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution, and component usage. {Recommendation: compounding accuracy checked by a person other than the compounder.}

70.00    If there are any deviations from the master formulation record, these deviations are recorded.

71.00    There is a plan for cleaning, e.g., after each preparation, daily tasks, monthly tasks, etc.

72.00    Personnel are appropriately garbed for protection when cleaning.

72.01    Compounding employees are using appropriate techniques.

Finished Preparation Release Checks and Tests

73.00    The finished preparation is observed to appear as expected in the Master Formulation Record and documented.

74.00    As appropriate, the final completed preparation is assessed for weight, mixing, clarity, color, consistency, pH, and strength, and is documented.

75.00    There are established written processes that describe test or examinations conducted on the compounded preparation e.g., degree of weight variation in capsules.

76.00    Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.

76.01    If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient.

76.02    If products are being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.
There are appropriate control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations, e.g., validation of equipment and personnel performance documentation.

Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, and indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.

Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch preparations in stock are all within their BUD (not outdated).

Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.

Preparations are stored properly prior to dispensing based upon conditions upon which BUD was assigned.

Preparations are examined immediately after preparation and again immediately prior to dispensing for any signs of instability.

Patient Counseling and Communication

Patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications.

The required printed drug information materials (drug information sheets, patient package inserts, MedGuides, etc.) are provided for the compounded preparations.

Patients are instructed on the signs of product instability or contamination (as appropriate) and how to report any changes in the physical characteristics of the preparation to the pharmacy.

Product recalls include documentation that both the patient and the physician/prescriber of the potentially contaminated compounded preparation are notified of the potential risk.
Blueprint for Inspection of Pharmacies Compounding Sterile Preparations

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Introduction

United States Pharmacopeia (USP)

Chapter <797> Pharmaceutical Compounding - Sterile

The objective of USP Chapter <797> is to describe conditions and practices to prevent harm, including death, to patients that could result from:
- Microbial contamination (nonsterility);
- Excessive bacterial endotoxins;
- Variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles or 10% for nonofficial articles;
- Unintended chemical and physical contaminants; and
- Ingredients of inappropriate quality in compounded sterile preparations (CSPs).

Despite the extensive attention in the chapter to the provision, maintenance, and evaluation of air quality, the avoidance of direct or physical contact contamination is paramount. It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 areas.

To achieve the above five conditions and practices, the chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in the chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described therein. The standards in the chapter do not pertain to the clinical administration of CSPs in patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in the chapter: low-risk level, medium-risk level, high-risk level, and immediate use.

The standards in the chapter are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physician practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians. These terms recognize that most sterile compounding is performed by or under the supervision of pharmacists in pharmacies and also that the chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of the chapter, CSPs include any of the following:
1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous, bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.
2. Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers’ approved labeling (product package inserts) or prepared differently than published in such labeling. [Note: The FDA states that “Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product’s manufacturer and other manufacturer directions consistent with that labeling.” However, the FDA-approved labeling (product package insert) rarely describes environmental quality (e.g., ISO Class air designation, exposure durations to non_ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration). Beyond-use exposure and storage dates or times for sterile products that have been either opened or prepared for administration are not specified in all package inserts for all sterile products. Furthermore, when such durations are specified, they may refer to chemical stability and not necessarily to microbiological purity or safety.]

ISO Classification of Particulate Matter in Room Air
(limits are in particles of 0.5 microns and larger per cubic meter [ISO] and cubic feet [FS 209E]*

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Microbial Contamination Risk Levels of Compounded Sterile Preparations

Low Risk Level
Preparations compounded under all of the following conditions are at a low risk of contamination:

1. The compounded sterile preparations (CSPs) are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.
2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.
3. Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other
sterile products, and containers for storage and dispensing.

4. For a low risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature, for not more than 14 days at a cold temperature, and for 45 days in solid frozen state.

Examples of Low Risk Compounding
1. Single-volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampuls should be passed through a sterile filter to remove any particles.
2. Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including infusion or diluents solution to compound admixtures and nutritional solutions.

Examples of Medium Risk Compounding
When CSPs are compounded aseptically under Low Risk conditions and one or more of the following conditions exist, such CSPs are at a medium risk of contamination:
1. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.
2. The compounding process includes complex aseptic manipulations other than the single-volume transfer.
3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing.
4. For a medium risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state.

Examples of Medium Risk Compounding
1. Compounding of total parenteral nutrition fluids using manual or automated devices during which there are multiple injection, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to the final sterile container.
2. Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed.
3. Transfer of volumes from multiple ampuls or vials into one or more final sterile containers.

Examples of High Risk Compounding
When CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated:
1. Nonsterile ingredients, including manufactured products not intended for sterile
routes of administration (e.g., oral), are incorporated or a nonsterile device is employed before sterilization.

2. Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:
   - Sterile contents of commercially manufactured products;
   - CSPs that lack effective antimicrobial preservatives; and
   - Sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

3. Compounding personnel are improperly garbed and gloved.

4. Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.

5. It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

**Examples of High Risk Compounding**

1. Dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized.

2. Exposing the sterile ingredients and components used to prepare and package CSPs to room air quality worse than ISO Class 5 for more than 1 hour.

3. Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed.

4. Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

**Immediate Use**

The immediate use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low Risk Level subjects the patient to additional risk due to delays in therapy. Immediate use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium risk level and high risk level CPSs shall not be prepared as immediate use CSPs.

Immediate use CSPs are exempt from the requirements described for Low Risk Level only when all of the following criteria are met:

1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers’ original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate use CSPs because they are hazardous drugs.

2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
3. During preparation, aseptic technique is followed and, if not immediately administered, the CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
4. Administration begins not later than 1 hour following the start of the preparation of the CSP.
5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.
6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

Compounding in worse than ISO Class 5 conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.

[Abstracted from 2016 USP Compounding Compendium, current with USP-39/NF-34 through First Supplement]
General Operations Information

001.00 Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?

001.01 Are patient profiles complete and DUR performed for each prescription?

001.02 Are sterile compounded prescriptions picked up at the pharmacy?

001.03 Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities?

001.04 Are sterile compounded prescriptions delivered/mailed to the practitioner for administration to the patient in the office, clinic, or facility?

002.00 Does the pharmacy **distribute** sterile compounded preparations?

002.01 Does the pharmacy distribute sterile compounded preparations to practitioners for office use?

002.02 Does the pharmacy distribute sterile compounded preparation to hospitals, clinics, or surgery centers?

002.03 Is the pharmacy registered with the FDA as an Outsourcing Facility?

002.04 Does the pharmacy have a sales force that distributes samples containing active ingredients?

003.00 Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?

003.01 If so, does the pharmacy have central fill contracts or agreements with these pharmacies for patient-specific preparations?

004.00 Which of the following sterile compounds are prepared?

004.01 Allergen extracts

004.02 Parenteral solutions

004.03 Parenteral suspensions

004.04 Preservative-free parenterals

004.05 Ophthalmic preparations
004.06 Oral or nasal inhalation preparations (not topical sprays)
004.07 Baths and soaks for live organs and tissues
004.08 Irrigations for wounds and body cavities
004.09 Any other sterile preparations (implants, pellets, etc.)

005.00 Does the pharmacy compound investigational drugs?

006.00 Does the pharmacy make a copy of an approved commercial product?
    006.01 Products are verified as appearing on the Drug Shortage List in effect under 506(E) of the Federal Act at the time of compounding, distribution, and dispensing.
    006.02 The Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing.
    006.03 If the essential copy is not on the Drug Shortage List, the compounded preparation produces a clinical difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner.

007.00 Does the pharmacy perform low-risk compounding?
    007.01 Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)?

008.00 Does the pharmacy perform medium-risk compounding?
    008.01 Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)?

009.00 Does the pharmacy perform high-risk compounding?
    009.01 Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)?

010.00 Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?
    010.01 Are BUDs assigned to include the full length of time during which the CSP will be administered or present in the reservoir of the
pump?

011.00 Does the pharmacy perform compounding for immediate use?

012.00 Does the pharmacy perform compounding with hazardous drugs?

012.01 Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?

012.02 Are hazardous drugs segregated and stored in a room that is negative pressure (at least 0.01" water column) to adjacent areas and with at least 12 ACPH?

012.03 Is hazardous drug waste quarantined in a designated area and disposed of in compliance with local, state, and federal regulations?

013.00 Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?

014.00 Does the pharmacy perform compounding using blood products (or other biological materials), such as wound care, autologous eye drops, etc?

015.00 Does the pharmacy compound using any federally controlled substances I-V?

016.00 Does the pharmacy make any sterile or nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?

016.01 Does the pharmacy purchase APIs directly from the manufacturer?

016.02 Does the pharmacy verify that the source of the API is an FDA-registered facility?

016.03 Does the pharmacy use active ingredients that are not from an FDA-registered facility?

017.00 Does the pharmacy have a lyophilizer?

017.01 Where is the lyophilizer located?

017.02 Note the products lyophilized and the volume or percent of products per week produced using the lyophilizer.

017.03 Is the lyophilizer part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures?
018.00 Does the pharmacy perform any testing in-house (not sent to an outside lab)?

019.00 Does the pharmacy send samples to an outside lab to perform testing?

020.00 Quality Assurance/Quality Improvement: Does the pharmacy’s continuous quality improvement program include sterile compounding measures?

020.01 Nonviable environmental monitoring and testing

020.02 Viable environmental testing

020.03 Personnel testing and validation

020.04 Equipment calibration, testing and validation

020.05 Sterilization method and testing

020.06 End product testing (e.g.: potency, particulates, sterility, endotoxin, etc.)

020.07 Patient or prescriber reports or complaints regarding CSPs

020.08 Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?

020.09 Does the recall system include communication with both the patient and the prescriber regarding the potentially contaminated CSP administered and the potential risks?

020.10 Are quality-related events involving CSPs that may have been contaminated or are recalled reported to the Board of Pharmacy?

020.11 Are all incidents (CFUs [colony-forming units] detected by any personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc.) remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future?

Component Selection and Use

021.00 All bulk drug substances (APIs) used are:

(1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or

(2) A component of an FDA-approved human drug product; or

(3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation. [Note: must comply with (1)
or (2) above until the FDA list is issued]

021.01 Certificates of Analysis (COAs) obtained for all bulk APIs used for compounding.

021.02 USP- or NF-grade substances used, if available.

021.03 If compendia quality components are not available, chemically pure, analytical reagent grade or ACS [American Chemical Society]-certified components are used and are determined to be free from impurities.

021.04 APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate “for research purposes only”, “not for drug use”, or are handwritten labels from other pharmacies.

021.05 If compounding for humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding.

021.06 All substances and components have a complete label including a batch control or lot number, and an expiration date.

021.07 For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one year, and is supported with data and/or testing.

021.08 All APIs are labeled with the date they were received.

021.09 If the pharmacy repackages the APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration date from the original container). Product may be tested to extend the expiration date, but may not exceed the original package expiration.

021.10 Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated.

021.11 Components from foreign sources that are derived from ruminant animals (cow, sheep, goat) have documentation that the component is in compliance with federal laws governing processing, use, and importation – that the animals were free from disease, and that they were born, raised, and slaughtered in locations where spongiform encephalopathy and scrapie are not known to exist.
022.00 No preparations are made or ingredients used that appear on the FDA’s list of drug products withdrawn or removed from the market for safety reasons. The facility should have a copy of the list or other way to determine.

023.00 No preparations are compounded that present demonstrable difficulties for compounding as identified by the FDA.

024.00 When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.

025.00 For animal compounding, does the compounding meet the same standards as compounding for human patients?

025.01 The pharmacist is knowledgeable or has references regarding the individual species’ limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.

025.02 It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.

025.03 The pharmacist is familiar with or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.

025.04 The facility has a list of drugs and components not allowed when compounding for food-producing animals.

025.05 The pharmacist is familiar with or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs).

026.00 If the pharmacy compounds stock solutions or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding.

026.01 The stock solutions are assigned a BUD based on the USP <797> high-risk compound BUD, or there is documentation of stability or testing to support an extended BUD.

026.02 Sterility testing is performed on stock solutions.

026.03 Endotoxin testing is performed after sterilization on stock solutions to be used for parenteral preparations.

026.04 Once punctured, the stock solution is discarded after 6 hours if kept
Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements.

Environment

If the facility performs both sterile and nonsterile compounding, the areas are separate and distinct.

If the facility performs compounding using blood products (or other biological material), this compounding area is separate and distinct from the general compounding areas.

Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?

Entry into the sterile compounding area is limited to task-critical employees [limited to only the pharmacist(s) and other trained and authorized pharmacy personnel].

The ante-room has a line of demarcation or other separation of the dirty to clean side.

Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.

Carts used in the clean room/buffer room are kept on the clean side of the line of demarcation.

All surfaces of the sterile compounding area carts, shelves, stools, chairs and other items resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low-particulate generating.

Walls are painted with epoxy-based paint or other impermeable surface, and are seamless or have sealed seams where panels meet and corners with no cracks.

The ceiling tiles are composed of a vinyl surface, with the tiles caulked and sealed, and the seams where the walls meet the ceiling are caulked and sealed.

The floor is overlaid with wide sheet flooring and seamless or with heat-welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall.

The clean room or ante-room does not have dust-collecting overhangs,
such as ceiling utility pipes or ledges, and sprinkler heads are flush with the ceiling.

036.00 The exposed surfaces of the light fixtures are smooth, mounted flush, and sealed.

037.00 A sink with hot and cold running water, and an eyewash station, are located on the clean side of the line of demarcation in the ante-room that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands.

037.01 The sink and the soap-dispensers are hand-free. \textit{(Recommended)}

038.00 Hand drying is accomplished with non-linting paper towels or an electronic or HEPA-filtered hand dryer.

038.01 If using a hand dryer, particle count and smoke testing is performed when the dryer is in use (while someone is actively using the dryer to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed [not applicable if only using towels].

039.00 There is no sink or drain in the clean room/buffer room.

040.00 All air ducts controlling air flow into the sterile compounding clean room/buffer room and ante-room are equipped with HEPA filters that maintains the clean room in an ISO Class 7 environment.

041.00 Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the ante-room and clean room.

042.00 If there is particle generating equipment in the clean room or ante-room (such as computers and printers), the equipment is located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while the equipment was in use.

043.00 If there is particle generating equipment in the clean room or ante-room (such as computers and printers), the equipment is located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while the equipment was in use, and appliances are also part of the viable surface sampling program.

044.00 Beverages including drinking water, chewing gum, candy or food items are prohibited from the clean room/buffer room or the ante-room.

045.00 If compounding occurs using nonsterile ingredients, products, components, or devices (e.g., compounding with nonsterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to
sterilize the finished product.

045.01 Pre-sterilization procedures for high-risk CSPs (such as weighing and mixing) are performed in no worse than ISO Class 8 environment. \{Recommended\}

046.00 Completely enclosed ante-room and clean room (with a door) are equipped with monitors or gauges to measure differential pressure.

046.01 Ante-room is at least 0.02” water column positive pressure to general pharmacy areas.

046.02 Clean room/buffer room is at least 0.02” water column positive pressure to the ante-room.

046.03 Hazardous compounding room and storage area is at least 0.01” water column negative pressure to ISO Class 7 ante-room.

046.04 Pressures are read and recorded each shift, or a minimum of once daily, or in the alternative, are continuously recorded.

046.05 There is a plan in place to detect and react to pressure differentials outside limits.

047.00 If the cleanroom and anteroom are not fully enclosed (open or with plastic strips – no door that closes), the air flow is measured across the openings.

047.01 The air flow is at least 40 feet per minute across the entire opening.

047.02 Airflow is read and recorded each shift (minimum of once daily) or continuously.

047.03 Plan in place to detect and react to airflow measurements outside of limits

047.04 This area is used only for low- and medium-risk compounding. (High-risk not allowed.)

048.00 The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.

048.01 Temperature in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77°F), or more restrictive if warranted by specific drug product storage requirements. Recommended temperature range for performing sterile compounding while garbed is between 64-72°F (18-22°C).

048.02 Temperature monitoring in place to detect any excursions
(24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.

048.03 Temperature monitoring is also performed in drug storage area (if separate from the compounding area).

048.04 Temperature in the refrigerator or cooler is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F).

048.05 Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.

048.06 Temperature in the freezer is maintained to provide controlled frozen temperature of -10° to -25°C (-13° to 14°F).

048.07 Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.

048.08 Action plan in place for temperature excursions including evaluating excursion effects on drug product integrity.

049.00 Humidity in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a “dry place”, humidity is not to exceed 40%. Generally recommended range is 35-60% for performing sterile compounding.

049.01 Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.

049.02 Excursion action plan in place including evaluating excursion effects on drug product integrity.

049.03 Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).

050.00 Blowers on ISO-5 primary engineering controls are operated continuously during compounding activity, including during interruptions of less than eight hours.

051.00 When the ISO-5 laminar air LAFW blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purpose of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces.

052.00 The doors into the anteroom from the general pharmacy area and from
the anteroom into the clean room are prevented from both being open at the same time (by interlocking, training of personnel, or signage).

053.00 The inside and outside doors of a pass-through are prevented from both being open at the same time (by interlocking, training of personnel, or signage).

053.01 Pass-throughs are located between outside areas and the anteroom, or between the anteroom and the buffer room (and NOT between the outside areas directly into the buffer room) {Recommended}

054.00 The immediate area around the doorway or pass-through into the anteroom from the general area is free of particle-generating materials (such as corrugated cardboard, etc.) and is located in an area that limits particles (not next to an outside door or window, etc.) to limit potential contamination from being brought in through the entry. {Recommended}

055.00 For BSC or LAFW that is NOT located in an ISO-7 clean/buffer room, the BSC or LAFW has been certified to maintain ISO-5 during compounding activities.

055.01 Used only for low-risk compounded preparations with a 12-hour or less BUD assigned.

055.02 All garbing requirements adhered to.

055.03 Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.

055.04 Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas.

055.05 The sink is separated from the immediate area of the ISO-5 workbench (not adjacent) and an eyewash station.

056.00 For CAI/CACI that is NOT located in an ISO-7 clean/buffer room, the CAI/CACI has been certified to maintain ISO-5 under dynamic conditions including transferring of ingredients, components, and devices, and during preparation of compounded sterile preparations.

056.01 The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse then ISO-7 environments.

056.02 The CAI or CACI is located in an area that is maintained under
sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.

056.03 There is a sink in the compounding area, not directly adjacent to the CAI or CACI, that enables pharmacy personnel to wash hands and an eyewash station.

056.04 For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is located in a physically separated area that maintains a negative pressure of 0.01” water column pressure to adjacent areas and a minimum of 12 air changes per hour (ACPH).

Cleaning and Disinfection

057.00 Are all personnel performing cleaning appropriately garbed?

058.00 Is the sterile compounding area equipped with appropriate non-shedding cleaning equipment and supplies?

059.00 If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area and are buckets inverted to prevent moisture accumulation?

060.00 Are reusable tools appropriately labeled to prevent them from being used inappropriately, e.g., a mop used for the floors cannot also be used for the ceilings and walls?

061.00 Are there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use and is the preparation of cleaning supplies documented?

062.00 Are cleaning and sanitizing agents appropriately labeled including expiration dates?

063.00 Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?

064.00 Is the ISO-5 primary engineering control cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?

065.00 Does the cleaning of the ISO-5 primary engineering control include cleaning with sterile water and sanitizing with sterile 70% isopropyl alcohol using a non-linting wipe?

066.00 Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?
067.00 Does daily cleaning include the floors starting from the clean room and working outwards?

068.00 If fatigue mats are used, are they cleaned daily and let dry on both sides?

069.00 Is a tacky mat used and if so, is there a procedure in place regarding replacement?

070.00 Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls thoroughly cleaned monthly? This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.

071.00 Is enough time allocated for cleaning activities?

Training

072.00 There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, hazardous drug handling, and aseptic technique. Compounding personnel includes persons performing, supervising, and verifying compounding activities.

072.01 All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed.

072.02 All personnel that supervise compounding and/or perform verifications of other’s compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed.

073.00 All personnel of reproductive capacity who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs.

074.00 There is documentation that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning, and disinfection.

075.00 There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile preparations.

076.00 If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified.

077.00 There is documentation that all compounding personnel (including those
supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs.

078.00 There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs.

079.00 There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests.

080.00 There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedures and gloved fingertip sampling test.

081.00 There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products.

082.00 The media fill testing procedures include:
- Media selection (including obtaining COAs or growth promotion certificates from suppliers);
- Fill volume;
- Incubation time and temperature (30-35°C for a minimum of 7 days then 20-25°C for 7 days);
- Inspection of filled units;
- Documentation;
- Interpretation of results (including identifying microbes down to genus level); and
- Action levels set with the corrective actions required.

083.00 High-Risk Sterile Compounding: There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six months.

084.00 High-Risk Sterile Compounding: There is documentation that a media fill test procedure is performed for each compounding employee at least every six months for individuals that prepare high-risk level products.

085.00 Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.

085.01 Gloved fingertip tests or media fill tests that failed have the organisms identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to
There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded.

**Garbing**

086.00 Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.

087.00 Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas.

088.00 Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings, such as earrings, lip or eyebrow piercings, etc. when entering clean/buffer room.

089.00 Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.

090.00 Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe).

091.00 Garbing includes head and facial hair covers and masks. There is a mirror available to check that all hair is covered.

092.00 Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with a non-linting disposable towel or a hand dryer.

093.00 The gown is non-shedding with sleeves that fit snugly around the wrists and enclosed at the neck.

094.00 All bare skin is covered on the arms and legs (no bare ankles, wrists, etc.).

095.00 Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry.

096.00 Upon leaving the sterile preparation compounding area, gowns are taken off and disposed of, or if used for non-hazardous compounding they are left in the anteroom and not reused for longer than one shift.
Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes.

Pharmacists or other personnel do NOT enter the clean room without fully washing and garbing (e.g., not wearing just a mask to check a technician’s work).

**Environmental Monitoring**

The most recent primary engineering control and room certification report is available.

- All ISO Class 7 and 8 SECs (cleanrooms and anterooms) have been certified within the last six months.
- All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last six months.
- Certification is performed at least every six months and whenever a device or room is moved or major work is done to the space.
- Certification is performed to the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is noted on the report.
- If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 standard.
- The PIC is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.

The certification report includes information about the equipment used for performing calibration test including: identification of the equipment used by model, serial number, last calibration date (or when next calibration is due).

The equipment used had not exceeded its calibration date at the time of certification.

The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.
101.01 ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPE with at least 15 ACPH from outside air sources.

101.02 ISO Class 7 anteroom (required if connected to a NIOSH hazardous compounding clean room) is certified as having a minimum of 30 ACPH.

101.03 ISO Class 8 anteroom is certified as having the recommended minimum of 20 ACPH.

101.04 ISO Class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH.

101.05 If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.

102.00 Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the hoods and rooms).

102.01 Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).

102.02 Air pattern analysis was conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs.

102.03 Air pattern analysis was conducted around particle generating equipment while the equipment was in operation to confirm airflow.

103.00 Differential air pressure between rooms was measured.

103.01 The differential pressure measured was at least 0.02” water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed.

103.02 The differential pressure measured was at least 0.01” water column negative from the hazardous cleanroom to the anteroom with the doors closed.

104.00 Displacement airflow between rooms or areas were measured; required for a clean room without a door that closes to the anteroom – may be an open space or may have plastic strips in doorways.

104.01 Displacement airflow (for low and medium-risk non-hazardous
rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom.

105.00 Particle counts of particles 0.5 um and larger were measured under dynamic conditions.

105.01 ISO Class 5 areas and hoods are certified as having less than 3,520 particles per cubic meter of air.

105.02 ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air.

105.03 ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air.

106.00 HEPA filter tests were performed.

106.01 All room HEPA filters were leak tested and if leaks found, they were fixed.

106.02 All hood HEPA filters were leak tested and if leaks found, they were fixed.

107.00 Rooms or hoods with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.

108.00 Viable air and surface sampling tests have been conducted at least every six months.

108.01 Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used.

108.02 Viable air sampling by active impaction using a volumetric air sampling device.

108.03 Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom, and the samples are at least 400 liters in volume. {Recommendation for ISO Class 5 PEC is 1,000 liters.}

108.04 Surface samples performed on all direct compounding areas inside of each ISO-5 PEC, in each room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.
108.05 Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive):

<table>
<thead>
<tr>
<th>Classification</th>
<th>Air Sample</th>
<th>Surface Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5</td>
<td>&gt; 1 CFU/m³</td>
<td>&gt; 3 CFU/plate</td>
</tr>
<tr>
<td>ISO Class 7</td>
<td>&gt; 10 CFU/m³</td>
<td>&gt; 5 CFU/plate</td>
</tr>
<tr>
<td>ISO Class 8</td>
<td>&gt; 100 CFU/m³</td>
<td>&gt; 100 CFU/plate</td>
</tr>
</tbody>
</table>

108.06 CFUs detected by any means (viable air or surface sampling, media fills, gloved fingertip testing, failed sterility tests, etc.) are analyzed to determine the organism down to the genus.

108.07 If the number of CFUs detected exceeds action levels, compounding ceases, immediate remediation and investigation into the cause conducted, and compounding not resumed until subsequent tests are performed successfully.

108.08 If any mold, yeast, coagulase positive staphylococcus, or gram negative rods were detected (whether or not the number of CFUs exceeds action levels), compounding ceases, immediate remediation and investigation into the cause conducted, and compounding not resumed until subsequent tests are performed successfully.

108.09 The testing report indicates growth promotion testing or documentation and sterility quality control testing of the media plates was performed.

108.10 The testing results report includes media lot numbers and expiration dates and a signature of the laboratory analyst and/or reviewer.

109.00 Facilities performing routine air or surface sampling with internal qualified personnel routinely validate sampling procedures.

Compounding Equipment

110.00 Appropriate equipment and utensils are available, clean, and in good working order. Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.

111.00 All environmental monitoring equipment and gauges (differential pressure gauges or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.
112.00 All temperature and humidity monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with equipment manufacturer guidelines. Calibration is documented.

113.00 Scales, balances, or other equipment used for measurement are regularly calibrated, and validated at least annually.

114.00 PEC (hood) prefilters are checked and replaced regularly.  
{Recommended}

115.00 Where Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps), there is a policy and procedure for their use and calibration.

115.01 There is documentation of the ACD tubing being changed or discarded every 24 hours.

115.02 The ACD is used when performing media fill testing.

Compounding Procedures

116.00 Gloves and critical sites are sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA) spray and a non-linting wipe.

117.00 Objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items, e.g., gauze pads.

118.00 Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area.

119.00 Supplies required for the scheduled operations of the shift are prepared and decontaminated by wiping or spraying the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.

120.00 Compounding employees are using appropriate aseptic technique.

121.00 Compounding personnel ascertain that ingredients for compounded sterile preparations are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.
122.00 All rubber stoppers of vials and bottles and the neck of ampoules are sanitized every time with sterile 70% IPA (and a wait of at least ten seconds to dry) prior to the introduction of a needle or spike for the removal of the product.

123.00 Single-dose vials exposed to ISO Class 5 or cleaner air are used within six hours of the initial puncture and any remaining contents discarded; if used in less than ISO Class 5 air, they are used within one hour of the initial puncture and any remaining contents discarded.

124.00 The remaining contents of opened single-dose ampoules are discarded immediately.

125.00 Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer’s specific BUD if less) after the initial entry or puncture and any remaining contents discarded.

126.00 The Compounding Record is complete with the following minimum data elements:
1. Official or assigned name, strength, and dosage of the preparation;
2. Names, lot numbers, and expiration dates of all components;
3. Total quantity or number of units compounded;
4. Person compounding the preparation;
5. Person performing the quality control procedures;
6. Person who approved the preparation;
7. Date of compounding;
8. Assigned internal identification number or prescription number;
9. Assigned BUD and reference if extended beyond USP guidelines;
10. Duplicate label;
11. Sterilization method, if applicable; and
12. Indication of the quality control procedures to perform testing (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation and recall, if applicable.

127.00 Procedure for in-process checks is followed. These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.

128.00 Labels on batch preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.
128.01 Labels on batch single-use containers are clearly marked as “Single Use Only.” {Recommended}

129.00 Labels on patient-specific containers, in addition to standard label requirements, also include identifiers for the persons preparing and performing the final verification, stability or BUD, flow rate (if applicable), and appropriate packaging and labeling of hazardous materials.

129.01 Labels on patient-specific single-use containers are clearly marked as “Single Use Only.” {Recommended}

130.00 Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? If so, list the products including lot and expiration date and obtain photos if possible. Request the product be quarantined.

131.00 Preparations without additional stability testing or supported by data are assigned BUDs within USP <797> guidelines:
   - Low Risk: 48 hrs room – 14 days refrigerated – 45 days frozen;
   - Medium Risk: 30 hrs room – 9 days refrigerated – 45 days frozen;
   - High Risk: 24 hrs room – 3 days refrigerated – 45 days frozen.

132.00 Extended BUDs are assigned and are supported with stability documentation – preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.

133.00 Extended BUDs are assigned and the facility has performed its own stability testing.

134.00 Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use.

135.00 Filter Sterilization in an ISO Class 5 environment and documentation includes:
   - The 0.2 micron sterile microporous membrane filter used to sterilize compounded sterile preparations is chemically and physically compatible with the compounded sterile preparation; and the filter is intended for human-use applications for sterilizing compounded sterile preparations (labeling does not indicate ‘research only’);
   - That filtering is completed rapidly without filter replacement; and
   - Combination of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration.

136.00 Steam Sterilization documentation includes:
   - The autoclave has been validated for the exposure time and mass of the items to be sterilized;
- Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices;
- Solutions are passed through a 1.2 micron or small filter into the final containers to remove particulates before sterilization;
- Heated filtered air is evenly distributed throughout the chamber with a blower;
- That the compounded sterile preparation will not be adversely affected by the steam and heat; and
- The description of steam sterilization includes conditions and duration for specific compounded sterile preparations.

**137.00 Dry Heat Sterilization** documentation includes:
- Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture;
- Sufficient space is left between materials to allow for air circulation;
- The description of dry heat sterilization includes conditions and duration for specific compounded sterile preparation;
- That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators; and
- The oven is equipped with a system for controlling and recording temperature and exposure period.

**138.00 Depyrogenation by Dry Heat** documentation includes:
- Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes;
- The description of the cycle and duration for specific load items;
- The effectiveness of the cycle is verified using endotoxin challenge vials (EVCs); and
- Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins.

**139.00** Other methods of sterilization are used with documented procedures and validation performed.

**Finished Preparation Release Checks and Tests**

**140.00** Are products checked for particulates or other foreign matter against both a light and a dark colored background?

**141.00** Are there checks for container and closure integrity?

**142.00** Is compounding accuracy documented by verification of steps?

**143.00** Is verification of ingredient identity and quantity verified? Is there a reconciliation of components?
Are labels verified as being correct and is a copy of the label included in the record?

**Sterility Testing** (USP <71>)

145.01 Sterility testing includes both bacterial and fungal testing.

145.02 Sterility testing is performed on all compounded sterile preparations that have extended BUDs.

145.03 Sterility testing is performed for compounded sterile preparations prepared in batches of more than 25 identical containers.

145.04 Sterility testing is performed for compounded sterile preparations exposed longer than 12 hours at 2-8°C or longer than 6 hours at warmer than 8°C before being sterilized.

145.05 The appropriate quantities of units are sterility tested:

- **For parenterals:**
  - For less than 100 units, test 10% or 4 units, whichever is greater;
  - For 100 to 500 units, test 10 units; and
  - For more than 500 units, test 2% or 20 units, whichever is less.

- **For large-volume parenterals:**
  - 2% of the units or 10 containers, whichever is less.

- **For non-parenterals (eye drops, inhalation, etc.):**
  - For less than 200 units, test 5% or 2 containers, whichever is greater;
  - For 200 or more units, test 10 containers; or
  - If the product is packaged in unit doses, use the parenteral testing parameters above.

145.06 For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken.

145.07 If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the practitioner of the patient to whom a potentially contaminated compounded sterile preparation was administered are notified of the potential risk.

**Endotoxin Testing** (USP <85>)

146.01 Is endotoxin testing performed for all high-risk level compounded
sterile preparations for administration by injection prepared in groups of more than 25 single-dose packages, such as ampoules, bags, syringes, vials, etc.?

146.02 High-risk compounded sterile preparations are prepared in multiple dose vials for administration to multiple patients.

146.03 High-risk compounded sterile preparations exposed longer than 12 hours at 2-8°C (25-46°F) or longer than 6 hours at warmer than 8°C (46°F) before they are sterilized.

146.04 For products failing testing, product is quarantined, and an investigation is performed and action taken.

147.00 \textit{Potency Testing} is performed. \textit{[Recommended]}

148.00 View testing records. Products that have failed sterility, endotoxin, purity or potency testing have been quarantined and destroyed, or recalled if dispensed or distributed, and appropriate investigation performed to determine cause and correction or training performed to prevent future occurrence.

\textbf{Patient Counseling and Communication}

149.00 Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?

150.00 Are required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?

151.00 Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?

152.00 Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded sterile preparation was administered are notified of the potential risk.
TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: July 20, 2017
RE: Clarification on Transfer of Unfilled Controlled Substance Prescriptions

A number of states have reported to the National Association of Boards of Pharmacy® (NABP®) some confusion regarding federal regulations and the transfer of unfilled electronic prescriptions for controlled substances. The attached information clarifying this situation was obtained by NABP through our lead role on the Controlled Substances Stakeholder Coalition and excellent working relationship with the Drug Enforcement Administration.

Attachment

cc: NABP Executive Committee
The Controlled Substances Act and its implementing regulations outline what can take place regarding prescriptions for controlled substances. In Title 21, Code of Federal Regulations, Section 1306.25 the DEA made a specific exception so that a DEA registered pharmacy can, once it has filled an original prescription for a controlled substance in Schedules III-V, transfer the original prescription information to another DEA registered pharmacy for the purpose of allowing that second pharmacy to then dispense any remaining valid refills still permitted by law and the prescriber’s authorization. With one exception, such an allowance currently does not exist for the forwarding of an unfilled prescription from one DEA registered retail pharmacy so that it may be filled at another DEA registered retail pharmacy.

Prescriptions can take the form of paper (including fax), call-in, or electronic prescription for controlled substances (EPCS). The DEA has addressed the forwarding of an EPCS prescription. The DEA published information in the preamble of the notice of proposed rulemaking (NPRM) on EPCS, 73 FR 36722, and the preamble of the interim final rule (IFR) on EPCS, 75 FR 16235. Note, because this was in the preamble and not in the EPCS regulations, it represents the DEA’s policy. As posted in the preambles of the NPRM and the IFR, an unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances.

At the start of 2017, the DEA received inquiries from some pharmacists regarding this issue. The DEA was advised that these pharmacists had received notice from their management that they could not forward original unfilled prescriptions for controlled substances as there was no exception in Federal regulation that expressly allowed this activity. The pharmacists were provided with the above information. Although the DEA received several inquiries regarding this issue earlier in the year, these have now ceased.

I hope this helps you and the members of your association.

Loren T. Miller
Associate Section Chief
Liaison and Policy Section
Diversion Control Division
Drug Enforcement Administration
Title: Transfer of Prescription Information
Between Pharmacies

Policy No. I.A.22

Approved: 05-10-2017

1. The Louisiana Pharmacy Practice Act, more specifically at La. R.S. 37:1224.E, authorizes the transfer of prescription information between pharmacies, to wit:

“A prescription may be filled, compounded, and dispensed at the permitted pharmacy which first received the prescription or at any other permitted pharmacy to which the prescription is properly transferred from the originating pharmacy. A prescription may be properly transferred through the transfer of prescription information from one pharmacy to another manually or through an electronic transfer using an electronic file updated on a real-time on-line basis and shared by two or more pharmacies. Electronic transfers of prescriptions shall be permitted regardless of whether or not the pharmacy from which the prescription is transferred is open for business.”

2. The Board’s rules, more specifically LAC 46:LIII.2523 – Transfer of Prescription Information, describes the requirements relative to the transfer of original prescription information between pharmacies for the purpose of refill dispensing, describing procedures for prescriptions for controlled substances as well as prescriptions for non-controlled substances. There are no other rules relative to the transfer of prescriptions which have not yet been dispensed.

3. In response to multiple inquiries from pharmacists across the state, the Board adopted the following opinion pursuant to a unanimous vote in the affirmative of the members present and voting.

The Board interprets its laws and rules such that pharmacies may transfer original prescription information for prescriptions that have not yet been dispensed, subject to the following provisions:

- Prescriptions for medications not listed as a controlled substance may be transferred by a pharmacist, pharmacy intern, or certified pharmacy technician; and further, the person transferring the prescription shall annotate the prescription as to the:
  1. date of its transfer;
  2. name and address of the receiving pharmacy; and
  3. name of the person receiving the prescription.

- Electronic prescriptions which comply with the requirements in 21 CFR 1311 – but not written, faxed, or verbal prescriptions – for medications listed as a controlled substance may be transferred by a pharmacist, subject to the limitation identified in 21 CFR 1311 which prohibits the transfer of electronic prescriptions for controlled substances away from the pharmacy which received that prescription from the prescriber; and further, the pharmacist transferring the prescription shall annotate the prescription as to the:
  1. date of its transfer;
  2. name, address, and DEA registration number of the receiving pharmacy; and
  3. name of the pharmacist receiving the transfer information.
INTERAGENCY COOPERATIVE ENDEAVOR AGREEMENT
between the
DIVISION OF ADMINISTRATION
through the
OFFICE OF FACILITY PLANNING AND CONTROL
and the
LOUISIANA BOARD OF PHARMACY

This INTERAGENCY COOPERATIVE ENDEAVOR AGREEMENT ("Agreement"), is made and entered into this 26th day of July, 2017 in two (2) sets of original by and between the State of Louisiana through the Division of Administration, Office of Facility Planning and Control, represented herein by its Director, and the Louisiana Board of Pharmacy represented herein by their Executive Director, for the public purposes herein declared.

This Agreement outlines the roles of the Louisiana Board of Pharmacy (LBOP) herein referred to as "Agency" and Division of Administration/Facility Planning and Control (DOA/FPC) in the administration of the referenced Project using funds provided by the LBOP for "Renovations to the LA Pharmacy Board Building", 3388 Brentwood Drive, Baton Rouge, Louisiana, East Baton Rouge Parish, and identified as State Project No. 09-B41-17-LBP, Part 01. This Agreement (including any exhibits and schedules hereto) constitutes the entire Agreement among the parties hereto.

WHEREAS, Article VII, Section 14(C) of the Constitution of the State of Louisiana provides that "For a public purpose, the state and its political subdivisions or political corporations may engage in cooperative endeavors with each other, with the United States or its agencies, or with any public or private association, corporation, or individual"; and

WHEREAS, the parties hereto recognize that the Office of Facility Planning and Control (DOA/FPC) is the best agency within the State of Louisiana to administer the bidding/solicitation process and construction of the "Renovations to the LA Pharmacy Board Building" Project; and

WHEREAS, LBOP does own, manage, and control the LA Pharmacy Board Building in Baton Rouge, Louisiana, East Baton Rouge Parish; and

WHEREAS; LBOP wishes to complete exterior and interior renovations to the LA Pharmacy Board Building that consists of, but is not limited to, "exterior stucco and column repairs, roof replacement, HVAC, electrical, painting, flooring, restroom renovations, etc." Project will herein be referred to as "Project" or "the Project"; and

WHEREAS, by this Agreement, the parties wish to establish the terms, conditions and their respective rights and obligations as they relate to the Project; and
NOW, THEREFORE, in consideration of the mutual covenants herein contained, the parties hereto agree as follows:

ARTICLE 1

SCOPE AND RESPONSIBILITIES OF THE PARTIES

1.1 For purposes of identification and record keeping, 09-B41-17-LBP, Part 01 has been designated and shall be affixed to all documents including but not limited to: reports, invoices, letters, memos, emails, contacts and all legal documents related to this project.

1.2 The parties agree to execute any documents necessary to affect the covenants set forth in this Agreement.

1.3 This Project consists of architectural/engineering design and pre-construction preparation of documents for bidding and construction, engineering, bidding, contracting, construction, construction administration and inspection services to design and construct the Project inclusive of Exterior and Interior Renovations to the LA Board of Pharmacy Building.

RESPONSIBILITIES OF LBOP

1.4 LBOP shall be financially responsible for all design, bidding, construction, testing, reimbursables, and miscellaneous associated professional services costs during and throughout construction until completion, acceptance, and one-year warranty closeout is achieved.

1.5 LBOP shall assign an Agency Project Manager as project contact through whom DOA/FPC will coordinate the project and interact as required with DOA/FPC throughout the Project.

1.6 Upon completion and acceptance of the Project, LBOP as the owner of the facility, shall accept all future liabilities, including, but not limited to, all future operation, maintenance, and repairs, associated with the ownership, operation and maintenance of the Project.

RESPONSIBILITIES OF DOA/FPC

1.7 DOA/FPC shall have authority over the entire project with respect to all project management and construction management professional services. The Designer’s and Contractor’s contractual obligations associated with the Project shall be paid by LBOP. Utilizing DOA/FPC “Non-Payable” procedure for contract management, DOA/FPC shall be the contracting party for the design and construction portion of the Project and LBOP shall provide all funding and payments for all DOA/FPC approved invoices for payment legally related to the Project.

1.8 DOA/FPC shall generally provide and administer oversight of the design, bidding/solicitation and construction processes as the Owner’s agent in the same manner that
DOA/FPC manages all Capital Outlay projects. The DOA/FPC basic services will include, but are not limited to: review and approve the design phase submittals and project bid documents, advertise and receive competitive bids, recommend contract award, ongoing review and report on progress of project contractual obligations, review, approval and forwarding of Contractor and Designer pay applications, attend all monthly construction progress meetings along with LBOP Project Manager and the Designer, make monthly or periodic site visits as necessary and consult with LBOP Project Manager when requested or as required by project conditions, and receive and facilitate request for project Acceptance and Closeout.

1.9 DOA/FPC will only be responsible for review and approval of Project Documents, Change Orders, and miscellaneous review for compliance with Chapter 10 of Title 38 (Public Bid Law). The FPC Project Manager (FPC PM) will not act as an agent for LBOP.

1.10 DOA/FPC will receive, review and recommend action (if any) based upon the Designer’s weekly site visit reports as required by the “Instruction to Designers” standards; similarly, FPC PM will receive other documents, including pay applications and manage as provided for in aforementioned “FPC – Instruction to Designers”, and “2006 Edition, Louisiana Capital Improvement Projects Procedure Manual for Design and Construction”.

1.11 DOA/FPC will not be responsible for any direct or incidental damages due to actions or lack of actions by the LBOP. Any claims associated with or actions or lack of actions by LBOP will be the responsibility of LBOP. Further, LBOP shall indemnify and hold DOA/FPC harmless against any and all claims, demands, suits, judgments of any sum of money growing out of, resulting from, or by reason or act of omission of LBOP.

ARTICLE 2

COMPENSATION AND TERMS OF PAYMENT

2.1 LBOP will remit payments due all payees within twenty-one (21) calendar days of receipt of “approved for payment” invoices.

2.2 In recognition of each other’s status as agencies within the executive branch of government of the State of Louisiana, DOA/FPC agrees to provide administrative services in exchange for which DOA/FPC will receive reasonable compensation to cover its costs associated with these services, not to exceed 6% of the total project cost.

2.3 DOA/FPC will not assume, nor will DOA/FPC be responsible for, any damages (direct, incidental, or consequential) due to actions, or lack thereof, including but not limited to, delays by LBOP. LBOP further agrees to defend and hold harmless DOA/FPC against any claims and all related costs from such claims or judgments.

2.4 Electronic transmission may be used at the option of the payee.

ARTICLE 3

TERM
This Agreement shall commence on the date first written above and shall remain in effect until all obligations and payments contained herein have been met.

ARTICLE 4

TERMINATION

4.1 The terms and provision of this Agreement shall be binding upon the parties hereto until the work has been completed, accepted and the warranty period has expired and all Final Payments have been made and accepted; and all obligations and conditions contained herein have been satisfied.

4.2 Notwithstanding the above, this Agreement may be terminated only if all following conditions apply:

1. By mutual written agreement and consent of the parties hereto.

2. In the event that LBOP voluntarily withdraws its support, commitment and financial participation in the Project, LBOP agrees that all remaining and future expenses (including termination expenses, just penalties and interest, legal and remedy fees) will be paid for by LBOP.

3. In the event funding is not provided to LBOP, cannot be provided, or is reduced to such a level that will not allow for the continuation of the Project.

ARTICLE 5

FISCAL FUNDING AND APPROVED CONTINGENTS

This Agreement is contingent upon the appropriation of funds to fulfill the requirements of the Project, verified by written confirmation of that agency and/or the Legislature. If the Legislature fails to appropriate sufficient monies to provide for continuation of the Agreement, or if such appropriation is reduced and such reduction will therefore fail to provide sufficient monies for the continuation of the Agreement; then such reduction shall become cause for remedy by Article 4 “Termination”.

ARTICLE 6

ENTIRE AGREEMENT / MODIFICATIONS

This Agreement, including any attachments that are expressly referred to herein, contains the entire Agreement between the parties and supersedes any and all Agreements or Contracts previously entered into between the parties. No representations are made or relied upon by either
party other than those that are expressly set forth within. Any modification or amendment to this Agreement shall be valid only when it has been reduced to writing and executed by both parties.

ARTICLE 7

CONTROLLING LAW

The validity, interpretation, and performance of this Agreement shall be controlled by and construed in accordance with the laws of the State of Louisiana. The parties submit themselves to the exclusive jurisdiction of the Nineteenth Judicial District Court in and for the Parish of East Baton Rouge, State of Louisiana, for resolution of any disputes arising under this Agreement.

ARTICLE 8

LEGAL COMPLIANCE

The DOA/FPC and LBOP shall comply with all federal, state, and local laws and regulations, including, specifically, but without limitation, the Louisiana Code of Governmental Ethics (R.S42:1101, et seq.), in carrying out the provisions of the Agreement.

ARTICLE 9

PUBLIC LIABILITY / INDEMNIFICATION

LBOP shall indemnify and save harmless DOA/FPC, its officers, agents, employees, contractors and assigns against any and all claims, losses, liabilities, demands, suits, causes of action, damages, and judgments of any sum of money to any party accruing against DOA/FPC, its officers, agents, employees, contractors and assigns, growing out of, resulting from, or by reason of any act or omission of the LBOP, its officers, agents, employees, servants, contractors or assigns while engaged in, upon or about, or in connection with the discharge or performance of the terms of this Agreement or the operation, maintenance and use of the Project.

Nothing herein is intended, nor shall be deemed to create a third party beneficiary to or for any obligation by any party hereto or to authorize any third party person to have any action against any party hereto arising of this Agreement.

ARTICLE 10

SEVERABILITY

If any term, covenant, condition, or provision of this Agreement or the application thereof to any person or circumstances shall, at any time or to any extent, be invalid or unenforceable, the remainder of this Agreement, or the Application of such term, covenant, condition or provision to persons or circumstance other than those as to which it is held invalid or
unenforceable, shall not be affected thereby, and each term, covenant, condition, and provision of this Agreement shall be valid and be enforced to the fullest extent of the law.

ARTICLE 11

CAPTIONS

The captions and headings of the several articles and section of this Agreement are for convenience only and shall not control, affect the meaning of or be taken as an interpretation of any provisions of this Agreement.

ARTICLE 12

GOVERNING DOCUMENT

This Agreement shall govern in the event of any inconsistency between this Agreement and any of the Exhibits attached hereto or any other document or instrument executed or delivered pursuant to this Agreement or in connection with this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement on the day, month and year first written above.

WITNESSES:

Kim Hunter
Lisa Amerigian

STATE OF LOUISIANA
DIVISION OF ADMINISTRATION/
FACILITY PLANNING & CONTROL

By: Mark A. Moses,
Director

WITNESSES:

Sarah Broussard
Joe Fontenot

LOUISIANA BOARD OF PHARMACY

By: Malcolm J. Broussard,
Executive Director
August 23, 2017

Chris Pinell, CPA, CITP, CFE, MBA
Pinell & Martinez, LLC
308 S. Tyler St., Suite 2
Covington, Louisiana 70433

In connection with your audit of our financial statements as of June 30, 2017 and for the year then ended for the purpose of expressing an opinion as to the fair presentation of our financial statements in accordance with accounting principles generally accepted in the United States of America, to assess our system of internal control as a part of your audit, and to review our compliance with applicable laws and regulations, we confirm, to the best of our knowledge and belief, the following representations. These representations are based on the information available to us as of August 23, 2017.

PART I. AGENCY PROFILE

1. Name and address of the organization.

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

2. List the population of the municipality or parish based upon the last official United States Census or most recent official census (municipalities and police juries only). Include the source of the information.

   N/A

3. List names, addresses and telephone numbers of entity officials. Include elected/appointed members of the governing board, chief executive and fiscal officer, and legal counsel.

   Board Members
   Aron, Carl W. 1209 N. 18th St. Monroe, LA 71201 318.323.1232
   Bond, Brian A. PO Box 1154 Jena, LA 71342 318.992.2665
   Cassidy, Allen W. 710 N. Main St. Jennings, LA 70546 337.824.1648
   Hall, Jacqueline L. 5781 Eastover Dr. New Orleans, LA 70128 504.861.5033
   Indovina, Richard M. 1001 Moss Ln. River Ridge, LA 70123 504.473.3180
   Mannino, Richard 113 W. Charles St. Hammond, LA 70401 985.542.8466
   McKay, Marty R. 9049 Hwy. 165 S. Woodworth, LA 71485 318.776.5649
   Melancon, Chris B. 550 Catholique Rd. Carencro, LA 70520 337.257.0400
   Milano, Diane G. 3544 W. Esplanade Ave. Metairie, LA 70002 504.889.2300
   Moore, Ronald E. 13906 Hootsell Ct. Baton Rouge, LA 70816 225.241.2993
4. Period of time covered by this questionnaire.

Fiscal Year 2016-2017 (July 1, 2016 through June 30, 2017)

5. The entity has been organized under the following provisions of the Louisiana Revised Statute(s) (R.S.) and, if applicable, local resolutions/ordinances.


6. Briefly describe the public services provided.

The Board administers the La. Pharmacy Practice Act and the administrative provisions of the La. Uniform Controlled Substances Act through its credentialing and compliance activities. Included within these functions is the administration of the state prescription monitoring program.

The Board’s Credentials Division receives and processes applications for a variety of credentials, including pharmacies, pharmacists, pharmacy interns, pharmacy technicians, pharmacy technician candidates, as well as practitioners and facilities in need of a state controlled dangerous substance license.

The Board’s Compliance Division provides inspection services for all of the pharmacies and other facilities licensed by the Board. Further, the pharmacist compliance officers also conduct investigations of the complaints received by the Board.

The Prescription Monitoring Program office monitors pharmacies to ensure their reporting of all eligible prescription transactions to the program’s database. They assist prescribers and dispensers seeking registration for access privileges to the database. They also assist law enforcement agencies and licensing boards seeking information from the program.

7. Expiration date of current elected/appointed officials’ terms.

Aron, Carl W. 06-30-2020
Bond, Brian A. 06-30-2018
Cassidy, Allen W. 06-30-2022
Hall, Jacqueline L. 06-30-2020
Indovina, Richard M. 06-30-2022
Mannino, Richard 06-30-2022
McKay, Marty R. 06-30-2020
Melancon, Chris B. 06-30-2018
Milano, Diane G. 06-30-2019
LEGAL COMPLIANCE

PART II. PUBLIC BID LAW

8. The provisions of the public bid law, R.S. 38:2211-2296, and, where applicable, the regulations of the Division of Administration, State Purchasing Office have been complied with.
   A. All public works purchases exceeding $150,000 have been publicly bid.
      Yes X No ☐
   B. All material and supply purchases exceeding $30,000 have been publicly bid.
      Yes X No ☐

PART III. CODE OF ETHICS LAW FOR PUBLIC OFFICIALS AND PUBLIC EMPLOYEES

9. It is true that no employees or officials have accepted anything of value, whether in the form of a service, loan, or promise, from anyone which would constitute a violation of R.S. 42:1101-1124.
    Yes X No ☐

10. It is true that no member of the immediate family of any member of the governing authority, or the chief executive of the governmental entity, has been employed by the governmental entity after April 1, 1980, under circumstances that would constitute a violation of R.S. 42:1119.
    Yes X No ☐

PART IV. LAWS AFFECTING BUDGETING

11. We have complied with the budgeting requirements of the Local Government Budget Act (R.S. 39:1301-15), R.S. 39:33, or R.S. 39:1331-1342, as applicable.
   C. Licensing Boards
      The licensing board has complied with the budgetary requirements of R.S. 39:1331-1342.
      Yes X No ☐

PART V. ACCOUNTING, AUDITING, AND FINANCIAL REPORTING LAWS

12. We have maintained our accounting records in such a manner as to provide evidence of legal compliance and the preparation of annual financial statements to comply with R.S. 24:513 and 515 and/or 33:463.
    Yes X No ☐
13. All non-exempt governmental records are available as a public record and have been retained for at least three years, as required by R.S. 44:1, 44:7, 44:31, and 44:36.  
Yes  X  No  ☐

14. We have filed our annual financial statements in accordance with R.S. 24:514, and 33:463 where applicable.  
Yes  X  No  ☐

15. We have had our financial statements audited in a timely manner in accordance with R.S. 24:513.  
Yes  X  No  ☐

16. We have complied with R.S. 24:513(A)(3) regarding disclosure of compensation, reimbursements, benefits, and other payments to the agency head, political subdivision head, or chief executive officer.  
Yes  X  No  ☐

PART VI. MEETINGS

17. We have complied with the provisions of the Open Meetings Law, provided in R.S. 42:11 through 42:28.  
Yes  X  No  ☐

PART VII. ASSET MANAGEMENT LAWS

18. We have maintained records of our fixed assets and movable property, as required by R.S. 24:515 and/or R.S. 39:321-332, as applicable.  
Yes  X  No  ☐

PART VIII. FISCAL AGENCY AND CASH MANAGEMENT LAWS

19. We have complied with the fiscal agency and cash management requirements of R.S. 39:1211-45 and 49:301-327, as applicable.  
Yes  X  No  ☐

PART IX. DEBT RESTRICTION LAWS

20. It is true we have not incurred any long-term indebtedness without the approval of the State Bond Commission, as provided by Article VII, Section 8 of the 1974 Louisiana Constitution; Article VI, Section 33 of the 1974 Louisiana Constitution and R.S. 39:1410.60-1410.65.  
Yes  X  No  ☐

21. We have complied with the debt limitation requirements of state law (R.S. 39:562).  
Yes  X  No  ☐

22. We have complied with the reporting requirements relating to the Fiscal Review Committee of the State Bond Commission (R.S. 39:1410.62).  
Yes  X  No  ☐
PART X.  REVENUE AND EXPENDITURE RESTRICTION LAWS

23. We have restricted the collections and expenditures of revenues to those amounts authorized by Louisiana statutes, tax propositions, and budget ordinances  
   Yes  X  No  ☐

24. It is true we have not advanced wages or salaries to employees or paid bonuses in violation of Article VII, Section 14 of the 1974 Louisiana Constitution; R.S. 14:138; and A.G. Opinion 79-729.  
   Yes  X  No  ☐

25. It is true that no property or things of value have been loaned, pledged, or granted to anyone in violation of Article VII, Section 14 of the 1974 Louisiana Constitution.  
   Yes  X  No  ☐

PART XI. ISSUERS OF MUNICIPAL SECURITIES

26. It is true that we have complied with the requirements of R.S. 39:1438.C  
   Yes  X  No  ☐

PART XII. QUESTIONS FOR SPECIFIC GOVERNMENTAL UNITS

Parish Governments

27. We have adopted a system of road administration that provides as follows:  
   A. Approval of the governing authority of all expenditures, R.S. 48:755(A).  
   B. Development of a capital improvement program on a selective basis, R.S. 48:755.  
      A. Centralized purchasing of equipment and supplies, R.S. 48:755.  
      C. A construction program based on engineering plans and inspections, R.S. 48:755.  
      D. Selective maintenance program, R.S. 48:755.  
      E. Annual certification of compliance to the auditor, R.S. 48:758.  
   Yes [ ]  No [ ]  N/A

School Boards

28. We have complied with the general statutory, constitutional, and regulatory provisions of the Louisiana Department of Education, R.S. 17:51-401.  
   Yes [ ]  No [ ]  N/A

29. We have complied with the regulatory circulars issued by the Louisiana Department of Education that govern the Minimum Foundation Program.  
   Yes [ ]  No [ ]  N/A

30. We have, to the best of our knowledge, accurately compiled the performance measurement data contained in the following schedules and recognize that your agreed upon procedures will be applied to such schedules and performance measurement data:  
   [Note: Parish school boards are required to report as part of their annual financial statements measures of performance. These performance indicators are found in the supplemental schedules.]
Tax Collectors

31. We have complied with the general statutory requirements of R.S. 47.
   Yes [ ]  No [ ]  N/A

Sheriffs

32. We have complied with the state supplemental pay regulations of R.S. 40:1667.7
   Yes [ ]  No [ ]  N/A

33. We have complied with R.S. 33:5535 relating to the feeding and keeping of prisoners.
   Yes [ ]  No [ ]  N/A

District Attorneys

34. We have complied with the regulations of the DCFS that relate to the Title IV-D Program.
   Yes [ ]  No [ ]  N/A

Assessors

35. We have complied with the regulatory requirements found in R.S. Title 47.
   Yes [ ]  No [ ]  N/A

36. We have complied with the regulations of the Louisiana Tax Commission relating to the
    reassessment of property.
   Yes [ ]  No [ ]  N/A

Clerks of Court

37. We have complied with R.S. 13:751-917 and applicable sections of R.S. 11:1501-1562.
   Yes [ ]  No [ ]  N/A

Libraries

38. We have complied with the regulations of the Louisiana State Library.
   Yes [ ]  No [ ]  N/A

Municipalities

39. Minutes are taken at all meetings of the governing authority (R.S. 42:7.1).
   Yes [ ]  No [ ]  N/A
40. Minutes, ordinances, resolutions, budgets, and other official proceedings of the municipalities are published in the official journal (R.S. 43:141-146 and A.G. 86-528).
   Yes [ ] No [ ] N/A

41. All official action taken by the municipality is conducted at public meetings (R.S. 42:11 to 42:28).
   Yes [ ] No [ ] N/A

**Airports**

42. We have submitted our applications for funding airport construction or development to the Department of Transportation and Development as required by R.S. 2:802.
   Yes [ ] No [ ] N/A

43. We have adopted a system of administration that provides for approval by the department for any expenditures of funds appropriated from the Transportation Trust Fund, and no funds have been expended without department approval (R.S. 2:810).
   Yes [ ] No [ ] N/A

44. All project funds have been expended on the project and for no other purpose (R.S. 2:810).
   Yes [ ] No [ ] N/A

45. We have certified to the auditor, on an annual basis, that we have expended project funds in accordance with the standards established by law (R.S. 2:811).
   Yes [ ] No [ ] N/A

**Ports**

46. We have submitted our applications for funding port construction or development to the Department of Transportation and Development as required by R.S. 34:3452.
   Yes [ ] No [ ] N/A

47. We have adopted a system of administration that provides for approval by the department for any expenditures of funds made out of state and local matching funds, and no funds have been expended without departmental approval (R.S. 34:3460).
   Yes [ ] No [ ] N/A

48. All project funds have been expended on the project and for no other purpose (R.S. 34:3460).
   Yes [ ] No [ ] N/A

49. We have established a system of administration the provides for the development of a capital improvement program on a selective basis, centralized purchasing of equipment and supplies, centralized accounting, and the selective maintenance and construction of port facilities based upon engineering plans and inspections (R.S. 34:3460).
   Yes [ ] No [ ] N/A

50. We have certified to the auditor, on an annual basis, that we have expended project funds in accordance with the standards established by law (R.S. 34:3461).
   Yes [ ] No [ ] N/A
Sewerage Districts

51. We have complied with the statutory requirements of R.S. 33:3881-4159.10.
   Yes [ ] No [ ] N/A

Waterworks Districts

52. We have complied with the statutory requirements of R.S. 33:3811-3837.
   Yes [ ] No [ ] N/A

Utility Districts

53. We have complied with the statutory requirements of R.S. 33:4161-4546.21.
   Yes [ ] No [ ] N/A

Drainage and Irrigation Districts

54. We have complied with the statutory requirements of R.S. 38:1601-1707 (Drainage Districts), R.S. 38:1751-1921 (Gravity Drainage Districts), R.S. 38:1991-2048 (Levee and Drainage Districts), or R.S. 38:2101-2123 (Irrigation Districts), as appropriate.
   Yes [ ] No [ ] N/A

Fire Protection Districts

55. We have complied with the statutory requirements of R.S. 40:1491-1509.
   Yes [ ] No [ ] N/A

Other Special Districts

56. We have complied with those specific statutory requirements of state law applicable to our district.
   Yes [ ] No [ ] N/A

The previous responses have been made to the best of our belief and knowledge.

Signature ___________________________ Date 23 August 2017

Title Carl W. Aron, President

Signature ___________________________ Date 23 August 2017

Title Brian A. Bond, Secretary