REVISED MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

June 13, 2018
3:00 p.m.

Notice is hereby given that the Missouri Board of Pharmacy will be meeting at 3:00 p.m. on June 13, 2018 via conference call. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 MO Blvd., Jefferson City, Missouri at 3:00 p.m. on June 13, 2018.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes pursuant to Section 610.021(1), (5), (7), (13) and (14) and section 324.001.8, RSMo. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.
REVISED MEETING NOTICE
Missouri Board of Pharmacy
CONFERENCE CALL

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

June 13, 2018
3:00 p.m.

OPEN SESSION AGENDA

1. Call to Order: Christian Tadrus, PharmD, President

2. Roll Call

3. Approval of Minutes
   a. November 2017
   b. January 10 -11, 2018

4. 20 CSR 2220-6.050 (Immunization by Protocol) Final Order

5. 20 CSR 2220-2.200 (Sterile Compounding- Emergency Rule)

6. 2018 Budget/Legislation Update

7. The Board may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (5), (7), (13) and (14) and under Section 324.001.8, and .9 RSMo. The Board will return to open session at the conclusion of discussion on closed session items.

8. Adjournment
3. **Approval of Minutes**
   a. November 15, 2017
   b. January 10-11, 2018
The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. The regular meeting was called to order by Vice-President Douglas Lang at approximately 3:03 p.m. on November 15, 2017. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Christian Tadrus, PharmD, President
Douglas Lang, R.Ph., Vice-President
Pamela Marshall, R.Ph., Member
Anita Parran, Public Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Jennifer Luebbert, Administrative Coordinator
Sarah Decker, Compliance Coordinator

**Others Present**
Curtis Thompson, General Counsel

VICE-PRESIDENT DOUGLAS LANG CALLED THE MEETING TO ORDER AT 3:03 P.M. AND ROLL CALL WAS TAKEN.

#A1 20 CSR 2220-6.040 (Administration by Medical Prescription Order)

**ITEMS ENCLOSED:**
- Proposed Amendment
- VAERS Information for Healthcare Providers
- VAERS Table of Reportable Events Following Vaccinations

**DISCUSSION:**
Christian Tadrus commented federal law requires some adverse reactions to be reported but not all and questioned if the rule should be more stringent than federal law. Pamela Marshall added the Board may increase awareness if the federal requirement is referenced in the rule. Douglas Lang suggested the Board also look at the adverse event reporting in the immunization by protocol rule. Tom Glenski suggested 20 CSR 2220-2.040 and 20 CSR 2220-2.050 should mimic each other. Board discussion held. **A motion was made by Pamela Marshall, seconded by Anita Parran, to remove the adverse event reporting requirement from both 20 CSR 2220-6.040 (Administration by Medical Prescription Order) and 20 CSR 2220-6.050 Administration of Vaccines Per Protocol. Motion passed 3:0:0:2 with roll call vote as follows:**

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Missouri Board of Pharmacy
Open Minutes
November 15, 2017
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#A2 Executive Director Updates

- General Office Updates
- 2018 Bd. Meeting Dates
- Rule Review Update

**DISCUSSION:** Kimberly Grinston reported contracts for 2018 Board Meeting dates are still pending. Pamela Marshall asked if meetings should be held in other locations throughout the state. Board discussion held; Board consensus to research meeting in Springfield, Missouri in August 2018.

Kimberly Grinston reported that the Missouri Pharmacy Association (MPA) is sponsoring a naloxone training session at their regional meeting on December 13, 2017, in conjunction with the Missouri Department of Mental Health; The Department of Mental Health has asked for Board support/participation. The MPA program will begin at 6 p.m.; Board inspectors will present a compliance/diversion program at the same location immediately prior to the MPA/DMH program.

A motion was made by Pamela Marshall, seconded by Anita Parran, to approve 2.5 hours of Continuing Education for the Board compliance program on December 13, 2017. Motion passed 3:0:0:2 with roll call vote as follows:

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<tr>
<th>Name</th>
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<th>Yes</th>
<th>Absent</th>
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<tbody>
<tr>
<td>Barbara Bilek</td>
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<td>Douglas Lang</td>
<td>Pamela Marshall</td>
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<td>Anita Parran</td>
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CHRISTIAN TADRUS ASSUMED CHAIR OF THE MEETING AT 3:20 p.m.
#A3 St. Louis College of Pharmacy Preceptor List

**DISCUSSION:** Tom Glenski recommended approval of all sites and preceptors listed. A motion was made by Douglas Lang seconded by Pamela Marshall, to approve the St. Louis College of Pharmacy preceptor list. Motion passed 3:0:0:2 with roll call vote as follows:

Anita Parran – yes  Christina Lindsay – absent

#A4. Special Sites/Preceptors

- a) Annette Island Service Unit Pharmacy
- b) Cellatrix LLC
- c) Centers for Medicare & Medicaid Services, Region VII
- d) CVS Regional Office
- e) Goppert Trinity Family Care Clinic
- f) Luke AFB
- g) Meritas Health Internal Medicine Clinic
- h) Peking Union
- i) Shaare Zedek Medical Center
- j) UMKC School of Pharmacy @ MU Columbia
- k) University of Missouri Physicians Fairview
- l) University of Missouri Physicians Woodrail
- m) VA Northern California
- n) CVS Field Management Office

**DISCUSSION:** Tom Glenski recommended approval of all special sites and non-pharmacist preceptors listed. Douglas Lang asked if the CVS Regional offices are affiliated with a school of pharmacy; Tom Glenski stated the Board’s current rule does not require pharmacy school affiliation. Douglas Lang asked to review special site school affiliation in the future to ensure adequate supervision. A motion was made by Pamela Marshall, seconded by Anita Parran, to approve the included special sites and preceptors for 500 hours. Motion passed 3:0:0:2 with roll call vote as follows:

Anita Parran – yes  Christina Lindsay – absent

#A5 Missouri Hospital Association (MHA)

**DISCUSSION:** Kimberly Grinston reported the Missouri Hospital Association (MHA) has asked for Board review of potential statutory or rule language that would allow remote technician supervision and technician final product verification (tech-check-tech) in Class-B pharmacies and DHSS regulated hospital pharmacies. Tom Glenski stated MHA’s expressed goal is to expand technician duties only for Class B pharmacies where drugs are administered onsite such as offsite infusion clinics. Board discussion held; Board members expressed concerns regarding the broad scope of the draft language is and enacting varying standards for pharmacy technician practice based on practice setting. Douglas Lang also expressed concerns with treating Class-B
Missouri Board of Pharmacy

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Pharmacies differently based on their pharmacy activity; Kimberly Grinston noted the proposed draft would essentially create a sub-class of Class-B pharmacies.

Christian Tadrus suggested any legislative/regulatory proposal regarding pharmacy technician activities should be evidence-based and questioned if additional research is appropriate. Kimberly Grinston and Tom Glenski indicated MHA may proceed with legislation without the Board’s input and suggested the Board provide any guidance or suggestions to MHA prior to the start of the legislative session. Douglas Lang questioned the legality of allowing Missouri pharmacists with a medication therapy services certificate to modify controlled substances. Mrs. Grinston reported she consulted with Scott Collier with the DEA who indicated federal law may not allow controlled substance modifications unless pharmacists have prescriptive authority. Board consensus to support expanded prescriptive authority; Further Board consensus to discuss potential legal implications with general counsel prior to finalizing a recommendation.

MOTION TO CLOSE 3:49 P.M.
At 3:49 p.m., Pamela Marshall made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 3:0:0:2 with roll call vote as follows:

Anita Parran – yes  Christina Lindsay – absent

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on November 15, 2017, at approximately 5:04 P.M.

#A5. Missouri Hospital Association (MHA)

DISCUSSION: Further Board discussion held after consultation with legal counsel in closed session. A motion was made by Douglas Lang, seconded by Pamela Marshall, to have staff draft a letter to communicate the Board’s concerns regarding establishing disparate pharmacy technician practice standards and outlining areas where further discussion is needed. It was further moved to offer MHA an opportunity to discuss its proposal during the Board’s December 13, 2017 conference call. Motion passed 3:0:0:2 with roll call vote as follows:

Anita Parran – yes  Christina Lindsay – absent

MOTION TO ADJOURN 5:07 P.M.
At approximately 5:07 p.m., a motion was made by Pamela Marshall, seconded by Douglas Lang, to adjourn the November 15, 2017 meeting. Motion passed 3:0:0:2 with roll call vote as follows:

Anita Parran – yes  Missouri Board of Pharmacy
Christina Lindsay – absent  Open Minutes
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Anita Parran – yes   Christina Lindsay – absent

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christian Tadrus at approximately 8:06 a.m. on January 10, 2018. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Christian Tadrus, PharmD, President
Douglas R. Lang, R.Ph., Vice-President
Barbara Bilek, PharmD, Member
Christina Lindsay, PharmD, Member
Pamela Marshall, R.Ph., Member
Anita Parran, Public Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Bennie Dean, Inspector
Sarah Decker, Compliance Coordinator
Jennifer Luebbert, Administrative Coordinator
Andi Miller, Inspector
Scott Spencer, Inspector
Dan Vandersand, Inspector
Elaina Wolzak, Inspector
Barbara Wood, Inspector

**Others Present**
Curtis Thompson, Legal Counsel

PRESIDENT CHRISTIAN TADRUS CALLED THE MEETING TO ORDER AT 8:06 A.M. AND ROLL CALL WAS TAKEN.

**MOTION TO CLOSE**
At 8:07 a.m., Pamela Marshall made a motion, seconded by Barbara Bilek, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 by roll call vote as follows:
PUBLIC ATTENDEES LEFT THE MEETING ROOM AT APPROXIMATELY 8:07 A.M.

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on January 10, 2018, at approximately 9:02 A.M.

#A3. Agenda Additions/Corrections

DISCUSSION: Kimberly Grinston reported open minutes were added to the addendum.

#A4. 2020 Rule Review

- Rule Review Calendar
- 20 CSR 2220-5.010 (Drug Distributor Advisory Committee)
- 20 CSR 2220-5.020 (Drug Distributor Licensing Requirements)
- 20 CSR 2220-5.025 (Termination of Business as a Drug Distributor)
- 20 CSR 2220-5.030 (Definitions and Standards for Drug Wholesale and Pharmacy Distributors)
- 20 CSR 2220-5.040 (Drug Distributor Inspection Exemptions)
- 20 CSR 2220-5.050 (Out-of-State Distributor License/Registration Requirements)
- 20 CSR 2220-5.060 (Controlled Substance Reporting)
- 20 CSR 2220-5.070 (Standards of Operation for Medical Gas Distributors)

DISCUSSION: The following comments were received and actions taken by the Board:

- 20 CSR 2220-5.020 (Drug Distributor Licensing Requirements): Bert McClary reported the Hospital Advisory Committee (HAC) has concerns with distribution and dispensing from healthcare sites that are not part of the hospital's licensed premises. Mr. McClary stated the HAC has been working on an automated distribution rule draft but noted revisions may be needed to also accommodate automated dispensing needs. HAC comments will be forwarded to the Board once completed.
- Sam Leveritt suggested the Board delay revising 20 CSR 2220-5 pending additional guidance/rules from the FDA.
- Douglas Lang provided a handout of proposed revisions. Kimberly Grinston advised any changes would need to be reviewed by the Drug Distributor Advisory Committee. Board consensus to forward Chapter 5 to the Drug Distributor Advisory Committee for comments/suggestions.

A full transcript of the 2020 rule review discussion is available in the Board’s offices.

#A5. Draft Rule Amendments

- 20 CSR 2220-2.010 Pharmacy Standards of Operation
DISCUSSION: The following Board/public discussion was held:

- Public attendee Ryan Butler (Genoa Health Care) asked the Board to amend the rules to allow remote technician non-dispensing functions such as gathering or collecting patient data. Mr. Butler further suggested the Board revise the rules to accommodate other emerging remote technician functions. President Tadrus provided a historical overview of the Board’s recent consideration of technician training/remote activities.

- **20 CSR 2220-2.010 (Pharmacy Standards of Operation):** Board discussion held on requiring humidity monitoring equipment; Douglas Lang suggested humidity monitoring should be required to ensure the integrity of the drug supply. Barbara Bilek indicated not all drugs have humidity requirements and questioned how mandatory humidity monitoring would affect licensees in different practice settings. Public Attendee Samuel Leveritt suggested pharmacies should not be treated as drug distributors and noted humidity monitoring may be more appropriate in distributorships since these facilities may not have personnel regularly onsite.

  A motion was made by Barbara Bilek to require drug storage within appropriate humidity requirements without mandatory humidity monitoring equipment; The motion died for lack of a second. Further Board discussion held. **A motion was made by Christina Lindsay, and seconded by Pamela Marshall, to amend the rule to provide drugs must be stored within appropriate humidity requirements. Motion passed 5:0:0:0 by roll call vote as follows:**

  Anita Parran – yes  Christina Lindsay – yes

  Further Discussion: Public attendee Samuel Leveritt suggested the identification badge requirement should not apply to nuclear pharmacies because these facilities are not open to the public and personnel are generally donning multiple layers of garb. Mr. Leveritt further indicated some of the proposed reference sources do not exist for nuclear pharmacy. Board discussion held; Board consensus to clarify the badge requirement for pharmacies not open to the public in the Pharmacy Practice Guide.

  Additional Board discussion held; Board consensus to amend section (13) to grant the Board discretion to limit rule exemptions to a designated time period. Further consensus to review a revised rule draft at a future meeting.

- **20 CSR 2220-2.012 (Pharmacy Supervision):** Board discussion held; Board consensus to:
  1. Limit the rule to pharmacies regulated by the Missouri Board of Pharmacy,
  2. Prohibit technicians from receiving therapeutic or blood products in a nuclear pharmacy,
3. Reference drug utilization review on l. 49 of the rule,
4. Prohibit technicians from accepting verbal controlled substance orders, and
5. Amend section (4)(B) to provide technicians may perform listed activities without a pharmacist present “if authorized by a pharmacist and the permit holder.”

Board consensus to review a revised draft at a future Board meeting.

- 20 CSR 2220-2.090 (Pharmacist-In-Charge): Board consensus to review the rule at a future meeting.

A full transcript of the rule review is available in the Board’s office.

**MOTION TO CLOSE**
At approximately 11:19 a.m., Barbara Bilek made a motion, seconded by Pamela Marshall, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (2), (3), (5), (6), (7), (13), (14) and (15), RSMo. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

**RETURN TO OPEN**
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on January 10, 2018, at approximately 1:28 P.M.

#A6. Rules Under Initial Review
- 20 CSR 2220-2.110 (PRN Refills)
- 20 CSR 2220-2.120 (Transfer of Rx Information for Refill)
- 20 CSR 2220-2.130 (Drug Repackaging)
- 20 CSR 2220-2.190 (Patient Counseling)

**DISCUSSION:** The following Board/public discussion was held:

- 20 CSR 2220-2.110 (PRN Refills): Douglas Lang asked staff to ensure the rule correctly refers to “prescriptions” where needed.
- 20 CSR 2220-2.120 (Transfer of Rx Information for Refill): Douglas Lang proposed amending the rule to address controlled substance electronic transfers and to clearly identify requirements for prescription transfers for purposes of initial filling. Christian Tadrus suggested the rule also provide greater flexibility for non-controlled substance transfers.
- 20 CSR 2220-2.130 (Drug Repackaging): No comments/changes.
- 20 CSR 2220-2.190 (Patient Counseling): Board discussion held; Board consensus to revise the rule to:
  1. Address patient counseling for devices and medical equipment,
2. Incorporate recent Class-J Shared Services counseling allowances,
3. Address modern technology and other electronic means of providing patient counseling (e.g., audio, video),
4. Further define what a medication profile should contain,
5. Require compliance with/reference U.S. Food and Drug Administration REMS requirements,
6. Clarify what documentation is required when performing a drug utilization review, including, documentation of prescriber/patient contact, and
7. Ensure all practice settings are being held to the same counseling standards and not treated differently based on delivery model.

Board consensus to revise the rules as suggested and review at a future meeting. A full transcript of the rule discussion is available in the Board’s office.

#A7. FY 17 Annual Report
  - Draft Report

**DISCUSSION:** Kimberley Grinston provided an overview of the Board’s annual report. A motion was made by Douglas Lang, and seconded by Pamela Marshall, to approve the 2017 annual report. Motion passed 5:0:0:0 by roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang- yes
- Pamela Marshall – yes
- Anita Parran – yes
- Christina Lindsay – yes

#A8. 2018 Practice Guide Revision
  - Draft 2018 Practice Guide

**DISCUSSION:** Due to pending rule and statutory changes, Kimberley Grinston proposed delaying publication of the revised Practice Guide until April. Board consensus to hold as advised.

#A9. Red Tape Reduction

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DISCUSSION: The following Board/public discussion was held:

- **20 CSR Chapter 1:** A motion was made by Douglas Lang, and seconded by Pamela Marshall, to approve the proposed revisions to Chapter 1 for filing. Motion passed 5:0:0:0 by roll call vote as follows:
  
  Barbara Bilek – yes  
  Douglas Lang- yes  
  Pamela Marshall – yes  
  Anita Parran – yes  
  Christina Lindsay – yes

- **20 CSR Chapter 2:** The following changes were proposed:
  
  a. 20 CSR 2220-2.110: Amend (1)(C) to provide… “the prescription may not be filled or refilled…”
  
  b. 20 CSR 2220-2.120: Amend section (4) to address the “initial” fill of an original prescription.
  
  c. 20 CSR 2220-2.175: No changes but add as a strategic planning discussion item.
  
  d. 20 CSR 2220-2.600: Board consensus to require annual review of policies and procedures.

A motion was made by Douglas Lang, and seconded by Pamela Marshall, to approve the proposed revisions to Chapter 2 for filing with suggested changes. Motion passed 5:0:0:0 by roll call vote as follows:

  Barbara Bilek – yes  
  Douglas Lang- yes  
  Pamela Marshall – yes  
  Anita Parran – yes  
  Christina Lindsay – yes

- **20 CSR Chapter 3:** A motion was made by Christina Lindsay, and seconded by Douglas Lang, to approve the proposed revisions to Chapter 3 for filing. Motion passed 5:0:0:0 by roll call vote as follows:

  Barbara Bilek – yes  
  Douglas Lang- yes  
  Pamela Marshall – yes  
  Anita Parran – yes  
  Christina Lindsay – yes

- **20 CSR Chapter 5:** The following changes were proposed:

  a. 20 CSR 2220-5.020: Amend (1)(B)(6) to provide “Drugs sold, purchased, transferred, or traded pursuant to this section will only be sold, purchased, transferred, or traded directly from an importer or manufacturer authorized by or registered with the United States Food and Drug Administration, . . .”

  b. 20 CSR 2220-5.025: Amend section (2)(A) to provide: “(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the drug distributor terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred.”

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• 20 CSR 2220-5.060: Board consensus to rescind the rule since the substantive requirements are included in 20 CSR 2220-5.030.

A motion was made by Christina Lindsay, and seconded by Douglas Lang, to approve the proposed Chapter 5 revisions as amended with the rescission of 20 CSR 2220-5.060. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

• 20 CSR Chapter 6: A motion was made by Christina Lindsay, and seconded by Barbara Bilek, to approve the proposed revisions to Chapter 6 for filing. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

• 20 CSR Chapter 7: The following changes were made:
  c. 20 CSR 2220-7.025: Board consensus to change “nay” to “may.”
  d. 20 CSR 2220-7.030: Douglas Lang asked to consider regulation of special sites during strategic planning.

A motion was made by Christina Lindsay, and seconded by Barbara Bilek, to approve the proposed revisions to Chapter 7 changes for filing as amended. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christina Lindsay – yes

#A10. Board Member Meetings Reports

• Nuclear Sub-Committee
• DMH/MPA Naloxone Training

DISCUSSION: The following reports were received:

• Douglas Lang reported the Nuclear Sub-Committee met on November 15, 2017 and January 9, 2018 to discuss major issues affecting nuclear pharmacies and to review current rules. The Sub-Committee will likely meet again in February 2018 to finalize comments/suggestions. Mr. Lang thanked members of the Sub-Committee for volunteering their time and traveling to Jefferson City.

• Pamela Marshall attended the naloxone training program recently sponsored by the Missouri Dept. of Mental Health and the Missouri Pharmacy Association in Springfield, Missouri. Ms. Marshall reported training was provided by Nicolle Gattas from STLCoP and was both informative and beneficial.
#A11. General Administration Report
- Staff/Office Update
- Financial Report
- 2018 Renewal Fee Decrease
- Rule Update
- Patient Safety Conference Survey
- Springfield Board Compliance Conference Survey
- NABP Annual Meeting (May 5-8 2018 – Denver, Colorado)

**DISCUSSION:** Kimberly Grinston provided the following updates:
- The 2018 legislative session has convened; Several pharmacy and licensing related proposals have been introduced. PDMP bills have been filed in both the House and Senate. Additional updates will be provided as session progresses.
- NABP is changing to a fully electronic pharmacist licensing process. The new provisions should simplify the licensure process, however, the licensing rules may need to be revised to incorporate NABP’s changes.
- The pharmacy technician coordinator position has been reclassified to a Technician II with a salary increase. The change will help with recruitment and retention.
- Inspectors presented the Board’s compliance program in Springfield, Missouri. Approximately thirty-eight (38) people attended. Licensees gave positive feedback and suggested the Board hold additional conferences in the Springfield area.
- The NABP annual meeting will be held in Denver, Colorado. Pamela Marshall and Douglas Lang are interested in attending.

#A12. Inspection/Investigation Report
- Inspection/Investigation Updates

**DISCUSSION:** Tom Glenski provided the following updates:
- Inspections/Investigations remained consistent in the 4th quarter;
- Inspectors Vandersand and DeBold attended NABP’s Interactive Compliance Officer Conference in Chicago. Mr. Vandersand reported the first part of the program was presented by the FDA and included information on USP Chapter 797, outsourcing facilities and FDA inspections. The remainder of the conference was presented by NABP and included information on state inspection trends/issues as well as an interesting presentation on physician dispensing.
- Inspector Miller attended the annual DEA conference on behalf of the Board. Mrs. Miller reported the DEA presented information on state and DEA efforts to combat the opioid crisis and shut pharmacies/healthcare offices acting as pill mills. Information was also provided on take-back programs, tele-medicine, CARA and vulnerable populations such as adolescent athletes.
- Mr. Glenski and Douglas Lang attended the American Society of Pharmacy Law annual conference. The conference was informative.
#A13. Hospital Advisory Committee Update

**DISCUSSION:** Committee member David Wolfrath provided the following updates:

- HAC members have been working with the Department of Health and the Missouri Hospital Association to review hospital rules pursuant to SB 501 to eliminate areas of duplication/conflict with CMS hospital standards.
- Committee members have consulted with MHA to develop rule language that would allow remote technician supervision and technician final product verification (tech-check-tech)

#A14. Implementation of SB 501/Rx Cares for Missouri Program

**DISCUSSION:** No discussion held; Board consensus to hold for strategic planning.

#A16. Review of Board Meeting Procedures/Operations

**DISCUSSION:** No discussion held; Board consensus to hold for strategic planning.

#A17. Fiscal Year 2018-2019 Strategic Plan

**DISCUSSION:** Kimberly Grinston reported the annual strategic planning meeting is scheduled for April 2018, however, the April agenda will be full. Mrs. Grinston suggested holding strategic planning in June or July to allow adequate time for discussion and review. Board discussion held; Board consensus to survey available dates during June/July.

#A18. Compounding For Office Use/Repackaging

**DISCUSSION:** Board members questioned if a response was appropriate at this time given the FDA’s position on compounding for office use and the 2013 Drug Quality and Security Act. Barbara Bilek indicated support for allowing compounding for office use under appropriate guidelines; Board consensus to hold for strategic planning.

#A15. 20 CSR 2220-2.950 (Automated Filling Systems)

**DISCUSSION:** No discussion held; Board consensus to discuss after consultation with legal counsel.

#A19. NABP Telepharmacy Request for Comments

**DISCUSSION:** No discussion held; Board consensus to hold for strategic planning.

#A21. Special Sites/Non-Pharmacist Preceptors
**DISCUSSION:** Tom Glenski recommended approval of all sites and preceptors listed. A motion was made by Pamela Marshall, seconded by Douglas Lang, to approve the special sites/non-pharmacist preceptors listed for 500 hours. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes      Christina Lindsay – yes

THE FOLLOWING ITEMS WERE PROVIDED TO THE BOARD FOR INFORMATIONAL PURPOSES; NO DISCUSSION WAS HELD.

#A22. Board Disciplinary Report

#A23. Board Licensing Statistics

#A24A. Approval of Minutes
- July 12-13, 2017
- August 9, 2017

A motion was made by Barbara Bilek, seconded by Douglas Lang, to approve the open session minutes for July 12-13, 2017. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes      Christina Lindsay – yes

Christina Lindsay asked to amend the minutes to indicate Christian Tadrus presided as President; Board consensus to amend as requested. A motion was made by Barbara Bilek, seconded by Anita Parran, to approve the open session minutes for August 9, 2017 as amended. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes      Christina Lindsay – yes

**MOTION TO CLOSE**
At 3:05 p.m., Barbara Bilek made a motion, seconded by Douglas Lang, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (6), (7), (13) and (14). Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes      Christina Lindsay – yes

**RETURN TO OPEN**
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on January 10, 2018, at approximately 3:43 P.M.
#A15. 20 CSR 2220-2.950 (Automated Filling Systems)

- Review of current requirements/Pharmacist verification standards

**DISCUSSION:** Christian Tadrus asked if Board members would like to open the rule given legal counsel advice; Board consensus not to revise the rule at this time. Douglas Lang abstained from the consensus opinion but commented the practice of pharmacy will not move forward unless the Board disengages product assembly functions and allows pharmacies to leverage technology to enhance patient safety which is the Board’s ultimate goal.

**MOTION TO CLOSE**

At 3:54 p.m., Barbara Bilek made a motion, seconded by Christina Lindsay, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (6), (7), (13) and (14). Motion passed 5:0:0:0 by roll call vote as follows:

Barbara Bilek – yes
Anita Parran – yes
Pamela Marshall – yes
Douglas Lang- yes
Christina Lindsay – yes

January 11, 2018

***Due to inclement weather, the meeting on January 11, 2018 was convened via conference call***

**RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session on January 11, 2018, at approximately 10:01 A.M. All Board members/staff in attendance on January 10, 2018, were also in attendance on January 11, 2018.

**MOTION TO ADJOURN 10:02 AM**

At approximately 10:02 a.m., a motion was made by Douglas Lang, seconded by Barbara Bilek, to adjourn the January 2018 meeting. Motion passed 5:0:0:0 by roll call vote as follows:

Barbara Bilek – yes
Anita Parran – yes
Douglas Lang- yes
Christina Lindsay – yes
Pamela Marshall – yes

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
4. **20 CSR 2220-6.050 (Immunization by Protocol) Final Order**
   
a. MO Register (3/15/18)
Missouri Register

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(1) Clinical sites shall be selected which will provide direct care and observational learning experiences to meet the objectives of the course.

(A) Select interprofessional educational experiences may be utilized to provide learning experiences to meet course and program objectives and outcomes. Clinical personnel with professional licensure or certification in a health-related field may be utilized to augment student learning in their respective areas. Observational/interprofessional experiences [shall] may not exceed twenty percent (20%) of the total clinical program hours. Orientation to the facility does not contribute to the twenty percent (20%).

(D) The ratio of faculty to students in the clinical area shall be designed to promote patient safety and to facilitate student learning with the proper supervision.


PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075, or via email at nursing@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2200—State Board of Nursing
Chapter 8—Minimum Standards for Approved Veteran’s Bridge Programs of Practical Nursing

PROPOSED AMENDMENT

20 CSR 2200-8.085 Preceptors. The board is amending subsection (4)(F).

PURPOSE: This rule is being amended to reduce unnecessary regulatory restrictions.

(4) Responsibilities of the nursing program faculty in regards to utilization of preceptors shall include:

(F) [Shall meet periodically] Periodic meetings with the clinical preceptors and student(s) for the purpose of monitoring and evaluating learning experiences.


PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075, or via email at nursing@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2200—State Board of Nursing
Chapter 6—Pharmaceutical Care Standards

PROPOSED AMENDMENT

20 CSR 2220-6.050 Administration of Vaccines Per Protocol. The board is amending all sections of the rule.

PURPOSE: This amendment eliminates unnecessary restrictions/requirements and updates/clarifies requirements for pharmacists
Proposed Rules

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1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician’s name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

B. The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

C. Vaccines must be stored in accordance with CDC guidelines and within the manufacturer’s labeled requirements, including, when vaccinating outside of a pharmacy.

D. A pharmacist may only delegate vaccine administration to an intern pharmacist who has met the qualifications of subsections (3)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines. Proof of an intern’s compliance with subsections (3)(B) and (C) must be maintained by both the supervising pharmacist and the intern pharmacist for a minimum of two (2) years.

E. Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

F. Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

G. On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

5. Administration by Written Protocol with a Missouri Licensed Physician.

A. A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. A pharmacist may enter into a written protocol with an active Missouri licensed physician who is actively engaged in the practice of medicine. Unless otherwise restricted by the governing protocol, vaccines may be administered at any Missouri licensed pharmacy or at any non-pharmacy location identified in the governing protocol.

A. A pharmacist shall administer vaccines to another person, except to a pharmacist intern who has met the qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines. Proof of an intern’s compliance with subsections (3)(B) and (C) must be maintained by both the supervising pharmacist and the intern pharmacist for a minimum of two (2) years.

B. A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines.

C. Vaccines must be stored in accordance with CDC guidelines/recommendations and within the manufacturer’s labeled requirements, including, when vaccinating outside of a pharmacy.

D. A pharmacist may only delegate vaccine administration to an intern pharmacist who has met the qualifications of subsections (3)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines. Proof of an intern’s compliance with subsections (3)(B) and (C) must be maintained by both the supervising pharmacist and the intern pharmacist for a minimum of two (2) years.

E. Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

F. Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

G. On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

5. Administration by Written Protocol with a Missouri Licensed Physician.

A. A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician’s name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

B. The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

(3) Pharmacist Qualifications. Pharmacists administering vaccines by protocol as authorized by Chapter 338, RSMo, must first file a Notification of Intent (NOI) to administer vaccines with the Missouri Board of Pharmacy. To file a NOI, a pharmacist must—

A. Hold a current Missouri pharmacist license;
B. Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association, the American Red Cross, or an equivalent organization. The qualifying BLS or CPR certification program must have included a live in-person skills assessment; and
C. Have successfully completed a certificate program in administering vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or approved by the
Board of Pharmacy. The required certificate program must include a live/in-person training component and include instruction in:

1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including recommended immunization schedules;
2. Basic immunology and vaccine protection;
3. Physiology and techniques for vaccine administration, including hands-on training in intramuscular, intradermal, subcutaneous and nasal administration routes, and other common routes of vaccine administration;
4. Pre- and post-vaccine screening or assessment; and
5. Identifying and treating adverse immunization reactions;

[D] Notifications of Intent must be filed on the board’s website or on a form approved by the board.

(4) Protocol Requirements.

(A) In addition to filing a NOI, pharmacists administering vaccines under this rule must first enter into a written protocol with a Missouri licensed physician. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must be renewed annually and include the following:

1. The identity of the participating pharmacist and physician;
2. Time period of the protocol;
3. Authorized vaccines;
4. The patient or groups of patients authorized for vaccination;
5. Allowed routes and anatomic sites of administration;
6. If applicable, authorization to create a prescription for each administration under the physician’s name;
7. Emergency response procedures, including, but not limited to, procedures for handling/addressing adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. The length of time the pharmacist must observe an individual for adverse events following an injection;
9. Procedures for disposing of used and contaminated supplies;
10. The street addresses of any non-pharmacy locations at which the pharmacist may administer vaccines;
11. Record-keeping requirements and any required notification procedures; and
12. A provision allowing termination of the protocol at any time at the request of any party.

(B) The protocol, and any subsequent amendments or alterations, must be reviewed and manually or electronically signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its contents and agree to follow the terms of the protocol. A copy of the protocol must be maintained by both the pharmacist and the authorizing physician for a minimum of eight (8) years after termination of the protocol.

(C) Additional pharmacists or immunization locations may be added to an existing protocol if the amendment is signed and dated by the authorizing physician(s) and, if applicable, any newly added pharmacist(s). Existing pharmacists are not required to re-sign the protocol unless other protocol terms or provisions are changed.

[6/(5) Record Keeping.

(A) [A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include] The pharmacist shall ensure a record is maintained for each vaccine administered by protocol that includes:

1. The patient’s name, address, and date of birth [of the patient];
2. The date, route, and anatomic site of the administration;
3. The vaccine’s name, dose, manufacturer, lot number, and expiration date [of the vaccine];
4. The name and address of the patient’s primary health care provider, as [identified] provided by the patient;
5. [The name or identifiable initials of the administering pharmacist] The identity of the administering pharmacist or, if applicable, the identity of the administering intern pharmacist and supervising pharmacist; and
6. The nature of any adverse reaction and who was notified, if applicable.

I(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection (6)(A) of this rule are promptly delivered to the pharmacy.

I(C)/(B) [Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug.] Within seventy-two (72) hours after a vaccine is administered, a prescription must be obtained from the authorizing physician for the drug dispensed or a prescription must be created in the physician’s name documenting the dispensing as authorized by protocol. Notwithstanding any other provision of this rule, prescription records [shall] must be maintained as provided by Chapter 338, RSMo, and the rules of the board.

I(D)/I(C) The records required by this rule [shall be maintained] must be securely and confidentially maintained as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure [that all records required by this rule are maintained at the pharmacy] the records required by subsection (5)(A) are promptly delivered to and maintained at the pharmacy separate from the pharmacy’s prescription files [of the pharmacy];
2. If the vaccine is not being administered on behalf of a pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine; [and]
3. Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the board; and
4. [2.] Records [shall] required by this rule must be maintained for two (2) years [from the date of such record and shall be] and made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy [shall] must be produced within three (3) business days after a request from the State Board of Pharmacy, the Board of Registration for the Healing Arts and/or [its] their authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

I(7) Notification Requirement.

(A) A pharmacist administering vaccines authorized by Chapter 338, RSMo, shall notify the authorizing physician within seventy-two (72) hours after administration of the following:

1. The identity of the patient;
2. The identity of the vaccine(s) administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) The pharmacist shall provide a written report to the patient’s primary health care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.
In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient’s primary health care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

A pharmacist administering vaccine(s) shall report the administration to all entities as required by state or federal law.

Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule.

### (6) Notification of Immunizations

Pharmacists immunizing by protocol must—

(A) Notify all persons or entities as required by state and federal law;
(B) Notify the protocol physician as required by the governing protocol;
(C) Notify the patient’s primary care provider as required by Chapter 338, RSMo; and
(D) Notify the patient’s primary health care provider and, if different, the protocol physician, within twenty-four (24) hours after learning of any adverse event or reaction experienced by the patient. Adverse events or reactions must also be reported to the Vaccine Adverse Event Reporting System (VAERS) or its successor, within thirty (30) days.
(E) Unless otherwise provided by the governing protocol, notification may be made via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Proof of notification must be maintained in the pharmacist’s records as provided in subsection (5)(B) of this rule.

### (7) Notification of Intent Renewal

A Notification of Intent (NOI) to immunize by protocol must be renewed biennially with the immunizing pharmacist’s Missouri pharmacist license. To renew a NOI, pharmacists must—

(A) Have a current healthcare provider cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification that complies with subsection (3)(B) of this rule; and
(B) Have completed a minimum of two (2) hours of continuing education (0.2 CEU) related to administering vaccines or CDC immunization guidelines in a course approved by the Board of Pharmacy or provided by an ACPE accredited continuing education provider within the applicable pharmacist biennial renewal period (November 1 to October 31 of the immediately preceding even numbered years).
(C) The required continuing education (CE) shall be governed by 20 CSR 2220-7.080 and may be used to satisfy the pharmacist’s biennial continuing education requirements. The initial training program required by section (3) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within the applicable pharmacist biennial renewal cycle.

### Authority


### Public Cost

Public cost: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

### Private Cost

Private cost: This proposed amendment will not cost private enti-