



PHARMACY EXAMINING BOARD
Contact: Dan Williams (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison, WI 53703
July 21, 2016

Notice: The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the action and deliberation of the Board.

AGENDA

8:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-4)**
- B. Approval of Minutes of May 25, 2016 (5-8)**
- C. Administrative Updates – Discussion and Consideration**
 - 1) Staff Updates
 - 2) Board Member – Term Expiration Date
 - a. Franklin LaDien – 7/1/2016 (*Reappointed, not yet confirmed*)
 - b. Terry Maves – 7/1/2018
 - c. Thaddeus Schumacher – 7/1/2019
 - d. Kristi Sullivan – 7/1/2016
 - e. Philip Trapskin – 7/1/2017
 - f. Cathy Winters – 7/1/2017
 - g. Public Member – **Vacancy**
- ~~**D. APPEARANCE: St. Vincent de Paul Request as to Remote Dispensing Deviation**~~
- E. Legislation/Administrative Rule Matters – Discussion and Consideration (9-45)**
 - 1) Adoption of Clearinghouse Rule 15-064 Relating to Definitions and Controlled Substances
 - 2) Adoption of Clearinghouse Rule 15-081 Relating to Renewal and Reinstatement
 - 3) Adoption of Clearinghouse Rule 16-017 Relating to Application and Examination
 - 4) Adoption of Clearinghouse Rule 16-018 Relating to ID Required for Controlled Substances (Act 199)
 - 5) Phar 6 Relating to Temperature/Humidity
 - 6) Phar 7.10 Relating to Administration of Drug Products (Act 290)
 - 7) Phar 15 Relating to Compounding
 - 8) Rule Projects List
 - 9) Update on Legislation and Pending or Possible Rulemaking Projects
- F. Pilot Programs – Discussion and Consideration**
 - 1) Hospital Tech-Check-Tech
 - 2) Pharmacy Technician Ratio
 - 3) Automated Dispensing Technology Final Check
 - 4) Possible Pilot Programs

- G. **Speaking Engagement(s), Travel, or Public Relations Request(s) – Discussion and Consideration**
- 1) Travel Report from National Association of Boards of Pharmacy (NABP) 2016 Program Review and Training Session – June 28-29, 2016
- H. Informational Items
- I. **Items Received After Preparation of the Agenda**
- 1) Introductions, Announcements and Recognition
 - 2) Election of Board Officers
 - 3) Appointment of Board Liaisons
 - 4) Administrative Updates
 - 5) Education and Examination Matters
 - 6) Credentialing Matters
 - 7) Practice Matters
 - 8) Legislation/Administrative Rule Matters
 - 9) Informational Items
 - 10) Disciplinary Matters
 - 11) Presentations of Petitions for Summary Suspension
 - 12) Petitions for Designation of Hearing Examiner
 - 13) Presentation of Proposed Stipulations, Final Decisions and Orders
 - 14) Presentation of Proposed Final Decision and Orders
 - 15) Presentation of Interim Orders
 - 16) Petitions for Re-Hearing
 - 17) Petitions for Assessments
 - 18) Petitions to Vacate Orders
 - 19) Requests for Disciplinary Proceeding Presentations
 - 20) Motions
 - 21) Petitions
 - 22) Appearances from Requests Received or Renewed
 - 23) Speaking Engagement(s), Travel, or Public Relations Request(s)
 - 24) Division of Legal Services and Compliance (DLSC) Matters
 - 25) Prescription Drug Monitoring Program Information
 - 26) Consulting with Legal Counsel
 - 27) **Liaison Report(s)**
 - a. Appointed to Controlled Substances Board per Wis. Stats. §15.405(5g): Franklin LaDien
 - b. Continuing Education (CE) and Education and Examinations Liaison: Terry Maves
 - c. Credentialing Liaison(s): Terry Maves, Cathy Winters
 - d. Digest Liaison: Philip Trapskin
 - e. DLSC Liaison: Thaddeus Schumacher, Cathy Winters
 - f. Legislative Liaison: Philip Trapskin, Thaddeus Schumacher, Terry Maves
 - g. Monitoring Liaison(s): Franklin LaDien, Cathy Winters
 - h. PHARM Rep to State Council on Alcohol and Other Drug Abuse (SCAODA): Kristi Sullivan
 - i. Pharmacy Rules Committee: Thaddeus Schumacher, Franklin LaDien, Philip Trapskin, Kristi Sullivan
 - j. Professional Assistance Procedure (PAP) Liaison: Franklin LaDien
 - k. Screening Panel: Cathy Winters, Kristi Sullivan, Philip Trapskin
 - l. Variance Report Liaison: Philip Trapskin, Cathy Winters

- J. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

K. Deliberation on Division of Legal Services and Compliance (DLSC) Matters

- 1) **Administrative Warnings**
 - a. 15 PHM 007 (R.S.) **(46-47)**
 - b. 15 PHM 162 (R.W.K.) **(48-49)**
- 2) **Proposed Stipulations, Final Decision and Orders**
 - a. 14 PHM 128 (Walgreens # 04533) **(50-55)**
 - b. 15 PHM 004 (S.V.H.) **(56-61)**
- 3) **Case Closings**
 - a. 15 PHM 001 (M.M.H.) **(62-66)**
 - b. 15 PHM 007 (Walgreens #02927) **(67-71)**
 - c. 15 PHM 162 (S.D., Inc.) **(72-74)**
 - d. 15 PHM 176 (S.D.C.) **(75-76)**
 - e. 15 PHM 195 (P.R.C.) **(77-79)**
 - f. 16 PHM 038 (P.E.M. and O.O.M.) **(80-82)**
 - g. 16 PHM 041 (W.C.P. d/b/a D.D.) **(83-84)**
 - h. 16 PHM 057 (A.P.) **(85-86)**
 - i. 16 PHM 058 (D.D.) **(87-88)**
 - j. 16 PHM 059 (B.H.I.) **(89-90)**
 - k. 16 PHM 064 (H.O.A.) **(91-92)**
 - l. 16 PHM 067 (S.L.H.P.) **(93-94)**
 - m. 16 PHM 071 (M.C. and Walgreens #09740) **(95-97)**
 - n. 16 PHM 077 (O.S.R.) **(98-99)**
- 4) **Monitoring (100-126)**
 - a. Dirk Larson, R.Ph. – Requesting Reduction in Drug and Alcohol Screens **(101-126)**

L. Deliberation of Items Received After Preparation of Agenda

- 1) Education and Examination Matters
- 2) Credentialing Matters
- 3) Disciplinary Matters
- 4) Monitoring Matters
- 5) Professional Assistance Procedure (PAP) Matters
- 6) Petitions for Summary Suspension
- 7) Petitions for Designation of Hearing Examiner
- 8) Proposed Stipulations, Final Decisions and Orders
- 9) Administrative Warnings
- 10) Review of Administrative Warnings
- 11) Proposed Final Decisions and Orders
- 12) Orders Fixing Costs/Matters Related to Costs
- 13) Case Closings
- 14) Proposed Interim Orders
- 15) Petitions for Assessments and Evaluations
- 16) Petitions to Vacate Orders
- 17) Remedial Education Cases
- 18) Motions
- 19) Petitions for Re-Hearing
- 20) Appearances from Requests Received or Renewed

M. Consult with Legal Counsel

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

N. **Voting on Items Considered or Deliberated upon in Closed Session, if Voting is Appropriate**

O. **Board Meeting Process (Time Allocation, Agenda Items) – Discussion and Consideration**

ADJOURNMENT

The Next Scheduled Meeting is September 22, 2016.

**PHARMACY EXAMINING BOARD
MEETING MINUTES
MAY 25, 2016**

PRESENT: Franklin LaDien, Terry Maves, Thaddeus Schumacher, Kristi Sullivan, Philip Trapskin, Cathy Winters

STAFF: Dan Williams – Executive Director, Nilajah Hardin – Bureau Assistant, Sharon Henes – Administrative Rules Coordinator, and other Department staff

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 11:08 a.m. A quorum of six (6) members was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda:

- *Under Item E. 4) Possible Pilot Programs: Add Item a. “Community Pharmacy Tech-Check-Tech Pilot Program - Pharmacy Society of Wisconsin (PSW) Application”*
- *Remove Item: “D. APPEARANCE: St. Vincent de Paul Charitable Pharmacy Request as to Remote Dispensing Deviation”*

MOTION: Terry Maves moved, seconded by Cathy Winters, to adopt the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF FEBRUARY 24, 2016

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to approve the minutes of April 7, 2016 as published. Motion carried unanimously.

PILOT PROGRAMS

Hospital Tech-Check-Tech

MOTION: Terry Maves moved, seconded by Cathy Winters, to request DSPS staff draft language relating to Institutional Pilot Programs to be distributed to stakeholders as directed by the Chair for comments and returned by July 1, 2016. Motion carried unanimously.

Possible Pilot Programs

Community Pharmacy Tech-Check-Tech Pilot Program - Pharmacy Society of Wisconsin (PSW) Application

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to acknowledge the appearance of Anna Legreid-Dopp from the Pharmacy Society of Wisconsin (PSW). The Board is supportive of PSW’s continuing efforts to prepare a proposal for a Community Pharmacy Tech-Check-Tech Pilot Program for review at a future meeting. Motion carried unanimously.

Pharmacy Technician Ratio

MOTION: Franklin LaDien moved, seconded by Terry Maves, to request DSPS staff draft language relating to Pharmacy Technician Ratio Pilot Programs to be distributed to stakeholders as directed by the Chair for comments and returned by July 1, 2016. Motion carried unanimously.

Robotic

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to request DSPS staff draft language relating to Automated Dispensing Technology Final Check Pilot Programs to be distributed to stakeholders as directed by the Chair for comments and returned by July 1, 2016. Motion carried unanimously.

CLOSED SESSION

MOTION: Terry Maves moved, seconded by Philip Trapskin, to convene to closed session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). Thaddeus Schumacher, Chair, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Franklin LaDien –yes; Terry Maves-yes; Thaddeus Schumacher-yes; Kristi Sullivan- yes; Philip Trapskin-yes; Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 3:53 p.m.

RECONVENE TO OPEN SESSION

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to reconvene into open session. Motion carried unanimously.

The Board reconvened into Open Session at 4:59 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Philip Trapskin moved, seconded by CathyWinters, to affirm all motions made in closed session. Motion carried unanimously.

DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Monitoring

APPEARANCE: Cynthia Hennen, R.Ph. – Requesting Full Licensure

MOTION: Franklin LaDien moved, seconded by Philip Trapskin, to deny the request of Cynthia Hennen, R.Ph. for full licensure. **Reason for Denial:** Respondent needs to fully comply with the complete terms and conditions of the original Board Order (05/22/2013). Motion carried unanimously.

Case Closings

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to close the DLSC cases for the reasons outlined below:

1. 14 PHM 130 (R.G.) – Prosecutorial Discretion (P3)
2. 15 PHM 105 (Walgreens # 11858) – No Violation
3. 15 PHM 192 (C.D.) - Prosecutorial Discretion (P2)
4. 15 PHM 206 (F.C.) - Prosecutorial Discretion (P2)
5. 15 PHM 219 (M.O.W.) - Prosecutorial Discretion (P2)
6. 15 PHM 222 (S.W.T. and M.S.) - Prosecutorial Discretion (P2)
7. 16 PHM 004 (A.W. and G.V.P.) - No Violation
8. 16 PHM 007 (M.P.) - Prosecutorial Discretion (P2)
9. 16 PHM 008 (C.A.P.S.) - Prosecutorial Discretion (P2)
10. 16 PHM 044 (A.S.P.) - Prosecutorial Discretion (P2)
11. 16 PHM 045 (V.F.C.) - No Violation
12. 16 PHM 047 (C.S.P.) - Prosecutorial Discretion (P2)

Motion carried unanimously.

Administrative Warning(s)

14 PHM 128 - J.J.A.

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to issue an Administrative Warning in the matter of 14 PHM 128 (J.J.A.). Motion carried. Recused: Franklin LaDien

(Franklin LaDien recused himself and left the room for deliberation, and voting in the matter concerning 14 PHM 128 (J.J.A.).)

15 PHM 105 - Z.D.L.

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to issue an Administrative Warning in the matter of 15 PHM 105 (Z.D.L.). Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against:

1. 14 PHM 081 (N.B.P.)
2. 14 PHM 081 (R.A.S.)
3. 14 PHM 130 (H.P. #8)
4. 15 PHM 154 (O.M.H.L.)
5. 15 PHM 212 (W.V.P.)

Motion carried unanimously.

14 PHM 128 - A.M.G.

MOTION: Terry Maves moved, seconded by Kristi Sullivan, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Amanda M. Grycowski, R.Ph., DLSC case number 14 PHM 128. Motion carried. Recused: Franklin LaDien

(Franklin LaDien recused himself and left the room for deliberation, and voting in the matter concerning 14 PHM 128 (A.M.G.).)

14 PHM 085 and 14 PHM 136 - W.F.

MOTION: Terry Maves moved, seconded by Franklin LaDien, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against WelldyneRx-FL, DLSC case numbers 14 PHM 085 and 14 PHM 136. Motion carried.

ORDER(S) FIXING COSTS

Khushboo S. Modi, R.Ph., Respondent (ORDER0004596)(DHA Case # SPS-15-0042)(DLSC Case # 14 PHM 062)

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, to adopt the Order Fixing Costs in the matter of disciplinary proceedings against *Khushboo S. Modi, R.Ph., Respondent (ORDER0004596)(DHA Case # SPS-15-0042)(DLSC Case # 14 PHM 062)*. Motion carried unanimously.

ADJOURNMENT

MOTION: Philip Trapskin moved, seconded by Terry Maves, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 4:59 p.m.

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 11 July 2016 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 21 July 2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislation and Rule Matters – Discussion and Consideration 1. Adoption of CR 15-064 Relating to Definitions and Controlled Substances 2. Adoption of CR 15-081 Relating to Renewal and Reinstatement 3. Adoption of CR 16-017 Relating to Application and Examination 4. Adoption of CR 16-018 Relating to ID Required for Controlled Substances (Act 199) 5. Phar 6 Relating to Temperature/Humidity 6. Phar 7.10 Relating to Administration of Drug Products (Act 290) 7. Phar 15 Relating to Compounding 8. Rules Project List 9. Update of Pending and Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both		8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i>Sharon Henes</i>		<i>11 July 2016</i>	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 15-064)

ORDER

An order of the Pharmacy Examining Board to amend Phar 1.02 (10) and 8.07 (2) relating to definitions and controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.06, 450.065, 961.38, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), and 961.31 Stats.

Explanation of agency authority:

The Pharmacy Examining Board shall promulgate rules for its own guidance and for the guidance of the profession and define and enforce professional conduct and unethical practices not inconsistent with the law relating to pharmacy.

The Pharmacy Examining Board shall adopt rules defining the active practice of pharmacy.

The Pharmacy Examining Board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state.

Related statute or rule: N/A

Plain language analysis:

Section 1 clarifies that the definition pharmacy includes out-of-state pharmacies licensed by the board.

Section 2 moves the word “emergency” to only modify an oral prescription order. Electronic prescriptions are allowed for controlled substances regardless of whether it is an emergency. Oral prescriptions are allowed for controlled substances only in an emergency. Later in this sentence, the word “emergency” correctly only modifies oral prescription. This rule creates consistency in the treatment of electronic orders within the subsection.

Summary of, and comparison with, existing or proposed federal regulation:

21 CFR 1311 allows electronic prescriptions for controlled substances.

Comparison with rules in adjacent states:

Illinois: Illinois does not have a definition for the word “pharmacy”. Their definitions define specific types of pharmacies. Electronically transmitted prescriptions for controlled substances may be dispensed only as provided by federal law.

Iowa: Iowa does not have a definition for the word “pharmacy”. Electronic prescriptions may be accepted for controlled substances.

Michigan: Michigan does not have a definition for the word “pharmacy”. Electronic prescriptions of controlled substances are allowed, if not prohibited by federal law.

Minnesota: Minnesota does not have a definition for the word “pharmacy”. Electronic prescriptions are allowed if they conform to the rules of the federal Drug Enforcement Administration.

Summary of factual data and analytical methodologies:

The Board reviewed the rule and clarified provisions for consistency purposes.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule was posted for 14 days for economic impact comments and none were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at Jeff.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 1.02 (10) is amended to read:

Phar 1.02 (10) "Pharmacy" means any place of practice licensed by the board under s. ss. 450.06 or 450.065, Stats. unless otherwise provided for in s. 450.065.

SECTION 2. Phar 8.07 (2) is amended to read:

Phar 8.07 (2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written, ~~or emergency~~ electronic or emergency oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.

SECTION 3. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

Chair
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 15-081)

ORDER

An order of the Pharmacy Examining Board to amend Phar 5.01(1) and (3) and 5.04; to repeal and recreate Phar 5.05; and to create Phar 5.06 relating to renewal and reinstatement.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 440.08 (3) (b) and 450.08

Statutory authority: ss. 15.08 (5) (b), 440.08 (3) (b), and 450.02 (3) (d)

Explanation of agency authority:

The Pharmacy Examining Board shall promulgate rules for its own guidance and for the guidance of the profession and define and enforce professional conduct and unethical practices not inconsistent with the law relating to pharmacy.

The Pharmacy Examining Board may promulgate rules requiring the holder of a license who fails to renew the license within 5 years after its renewal date to complete requirements in order to restore the license, in addition to the applicable requirements for renewal established in chapter 450, that the examining board determines are necessary to protect the public health, safety or welfare. The rules may not require the holder to complete educational requirements or pass examinations that are more extensive than the educational or examination requirements that must be completed in order to obtain an initial license from the examining board. s. 440.08 (3) (b)

The board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961. s. 450.02 (3) (d)

Related statute or rule: n/a

Plain language analysis:

Sections 1 and 2 add home medical oxygen providers which are new license under the board's jurisdiction pursuant to 2015 Act 3. It also updates the rule to reflect there is a process for determining the renewal fee instead of the amount being listed in the statute.

Section 3 removes the unnecessary sentence stating a person who has a license reinstated may renew his or her license.

Section 4 indicates that a person with an expired license may not apply for a new license. Once a person has a license, the person either renews or reinstates a license rather than using an initial licensing process. Renewal within a 5 year period requires a renewal fee and a late fee if it is past the expiration date, and certify the completion of 30 hours of continuing education. If the renewal is after 5 years but no more than 10 years and the person has not been practicing 2000 hours in the last 24 months, the person is required to pay the renewal fee and late fee, pass the jurisprudence exam, complete 160 hours of internship for each year the license has been expired, with a cap of 1000 hours, and complete 15 hours of continuing education for each year the license has been expired or pass the NAPLEX (national pharmacy exam) with the last 2 years. If the renewal is more than 10 years and the person has not been practicing 2000 hours in the last 24 months, the person is required to pay the renewal fee and late fee, pass the jurisprudence exam, complete 1000 hours of internship and pass the NAPLEX.

Section 5 provides the requirements for reinstating a license which has not been renewed for more than 5 years with unmet disciplinary action requirements or a license which has been surrendered or revoked. A person applying for reinstatement shall provide evidence of completing any disciplinary requirements and provide evidence of rehabilitation or change in circumstances which would warrant a license to be reinstated. In addition, if the license has not been active within the last 5 years the requirements necessary for renewal after 5 years would need to be met.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: If a license is expired for more than 5 years and the licensee has not been practicing in another state during this time, a licensee shall submit proof of completion of 30 hours of continuing education and either 600 hours of clinical practice under the supervision of a licensed pharmacist completed within 2 years prior to renewal or the successful completion of the Pharmacist Assessment for Remediation Evaluation. To be successful on the Pharmacist Assessment for Remediation Evaluation, the person must receive an overall score of 80 or higher, as well as a minimum score of 75 in each of the 3 content areas on the examination.

Iowa: If a license has been inactive for more than 5 years and the licensee has not been practicing in another state, the licensee shall do one or more of the following: (a) Successfully pass all components of the licensure examination required for initial licensure; (b) Complete 160 hours of internship for each year the pharmacist was on inactive status, not to exceed 1,000 hours; (c) Obtain one and one-half times the number of continuing education credits required for each renewal period the pharmacist was inactive; (d) Complete a Continuing Professional

Development portfolio identifying minimum of 45 learning outcomes for each renewal period the pharmacist was inactive.

Michigan: If a license has been expired for at least 3 years but not more than 8 years, a licensee shall complete 30 hours of continuing education within the 2 years preceding the application for renewal; pass the jurisprudence examination and complete within 6 months of renewal, not less than 200 clock hours under the personal charge of a currently licensed pharmacist. Practical pharmacy experience shall include: pharmacy administration and management; drug distribution, use and control; legal requirements; providing health information services and advising patients; pharmacist's ethical and professional responsibilities; and drug and product information. If a license has lapsed for at least 8 years, the licensee shall complete 30 hours of continuing education within the 2 years preceding the application for renewal; pass the jurisprudence examination; complete within 6 months of renewal not less than 400 clock hours under the personal charge of a currently licensed pharmacist; and pass the NAPLEX. The person may be granted a temporary, nonrenewable license to complete the practical experience.

Minnesota: If a license is lapsed more than 2 years and the licensee is not practicing in another state, the licensee shall complete one of the following set of requirements: Payment of back renewal fees and penalty fees up to a maximum of \$1,000; complete at least 60 hours of continuing education within the last two years; pass the jurisprudence exam; pass the NAPLEX; and complete of 400 hours of work as a pharmacist intern OR pass the jurisprudence exam, pass the NAPLEX; and complete 1,600 hours as a pharmacist intern.

Summary of factual data and analytical methodologies:

The Board utilized their professional expertise, statutory language and a comparison of adjacent states.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule was posted for economic comments for 14 days and none were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jeff.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 5.01 (1) is amended to read:

Phar 5.01 Requirements. (1) Pharmacists, pharmacies, manufacturers, ~~and~~ distributors and home medical oxygen providers licensed under ch. 450, Stats., and otherwise qualified for renewal, may continue to be licensed biennially by applying for renewal and paying the fee ~~specified in s. 440.08(2), Stats~~ as determined by the department under s. 440.03(9)(a), Stats.

SECTION 2. Phar 5.01 (3) is amended to read:

Phar 5.01 (3) No pharmacy, manufacturer, ~~or~~ distributor or home medical oxygen provider may operate without a current license.

SECTION 3. Phar 5.04 is amended to read:

Phar 5.04 Renewal prohibited; relicensure. Any person whose license is currently suspended or revoked may not renew his or her license. ~~A person whose license has been suspended or revoked and subsequently reinstated by the board, and who is otherwise qualified for renewal, may renew his or her license upon completion of a renewal form and filing of the required renewal fee.~~

SECTION 4. Phar 5.05 is repealed and recreated to read:

Phar 5.05 Renewal. (1) GENERAL. A person with an expired license may not reapply for a license using the initial application process.

(2) RENEWAL WITHIN 5 YEARS. A person renewing the license within 5 years shall do all of the following:

(a) Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats., and any applicable late renewal fee.

(b) Certify the completion of 30 hours of continuing education during the last biennium.

(3) RENEWAL AFTER EXPIRATION DATE. Notwithstanding sub. (2), if a pharmacist fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacist's license and may require the pharmacist to pass an examination to the satisfaction of the board to restore that license.

(4) RENEWAL AFTER 5 YEARS. This subsection does not apply to license holders who have unmet disciplinary requirements. A person renewing the license after 5 years shall do all of the following:

- (a) Pay the renewal fee as determined by the department under s. 440.03 (9) (a), Stats. and the renewal late fee.
- (b) Evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin designated as the primary state.
- (c) If the person renewing the license does not have 2000 hours of practice as a pharmacist within last 24 months of submitting the application for renewal, the person shall meet one of the following requirements:
 - 1. If the license has been expired for at least 5 years but not more than 10 years, the person shall submit evidence of all of the following:
 - a. Completion of 160 hours of internship for each year the pharmacist license was expired, not to exceed 1000 hours.
 - b. Completion of 15 hours of continuing education for each year the pharmacist license was expired or within the last two years passing the NAPLEX.
 - 2. If the license has been expired for more than 10 years, the person shall submit evidence of all of the following:
 - a. Completion of 1000 hours of internship.
 - b. Passing the NAPLEX.

SECTION 5. Phar 5.06 is created to read:

Phar 5.06 Reinstatement. A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:

- (1) Evidence of completion of the requirements in Phar 5.05 (4) if the license has not been active within 5 years.
- (2) Evidence of completion of the disciplinary requirements, if applicable.
- (3) Evidence of rehabilitation or change in circumstances warranting reinstatement.

SECTION 6. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

 (END OF TEXT OF RULE)

Dated _____

Agency _____

Chair
 Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 16-017)

ORDER

An order of the Pharmacy Examining Board to repeal Phar 2.01, 2.03, 2.04, 2.06, 4.01, 4.03 (3), 4.04, 4.045, 4.046, 4.05; to amend Phar 2.02 (1) (intro) and (a), and 4.03; to repeal and recreate Phar 2.05; and to create Phar 1.02 (6m) and 2.02 (1) (f) and (g) relating to application and examination.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.03 (2), 450.04, 450.05, Stats.

Statutory authority: ss. 15.08 (5) (b) and 450.02 (3) (d) and (e), Stats.

Explanation of agency authority:

The Pharmacy Examining Board shall promulgate rules for its own guidance and for the guidance of the profession and define and enforce professional conduct and unethical practices not inconsistent with the law relating to pharmacy.

The Pharmacy Examining Board may promulgate rules necessary for the administration and enforcement of chapters 450 and 961; and establishing minimum standards for the practice of pharmacy.

Related statute or rule: n/a

Plain language analysis:

Section 1 creates a definition for NABP which is the National Association of Boards of Pharmacy.

Section 2 repeals the qualifications for licensure as duplicative.

Section 3 removes the requirement that the completed application be submitted prior to examination. The application requires components which may be done prior to taking the examination. 2013 Wisconsin Act 114 prohibits the board from requiring a person to complete the required education prior to taking the examination.

Section 4 adds passing the examinations to the application procedure requirements.

Section 5 repeals the examinations for licensure as it is now addressed as part of the application requirements. It also repeals the qualifications for persons licensed in another state as duplicative.

Section 6 repeals and recreates the application procedure for applicants who hold a license in another state. The rule specifies that the a person who holds a license in another state complete the application, pay a fee, utilize the National Association of Boards of Pharmacy's Clearinghouse transfer application and take the multi-state pharmacy jurisprudence examination.

Section 7 repeals the examinations required for applicants who hold a license in another state as it is now addressed in the application procedure section.

Section 8 repeals the section on administration of the examinations due to the rule being out of date and the Board no longer administers the examinations.

Section 9 is amended to recognize the board may adopt the recommended passing score of the examination provider.

Section 10 repeals examination provisions which are obsolete due to the test n longer being a Board administered or developed test.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois applicants are required to: pay a fee, provide proof of graduation and internship, and pass an examination. Applicants holding a license in another state applying for an Illinois license are required to show the requirements in the state they were licensed by examination were substantially equivalent to the requirements in Illinois.

Iowa: Iowa applicants are required to: pay a fee, provide proof of graduation and internship and pass the North American Pharmacist Licensure Examination and Multistate Pharmacy Jurisprudence Examination, Iowa Edition. Applicants holding a license in another state applying for an Iowa license are required to utilize the National Association of Boards of Pharmacy license transfer process.

Michigan: Michigan applicants are required to: pay a fee, provide proof of graduation and internship and pass the North American Pharmacist Licensure Examination and Multistate Pharmacy Jurisprudence Examination. Applicants holding a license in another state applying for a Michigan license are required to establish that they hold a license in another state and were licensed by exam in that state and pass the Multistate Pharmacy Jurisprudence Examination.

Minnesota: Minnesota applicants are required to: pay a fee, provide proof of graduation and internship and pass the North American Pharmacist Licensure Examination and Multistate Pharmacy Jurisprudence Examination. Applicants holding a license in another state applying for a Minnesota license requirements are: passing the Multistate Pharmacy Jurisprudence exam,

Minnesota version; evidence of internship or work experience and the Board may compel applicants who have not engaged in the practice of pharmacy in the two years preceding the filing of their application to take the North American Pharmacist Licensure Examination.

Summary of factual data and analytical methodologies:

The Board reviewed their rules to ensure statutory compliance and updated to current practices.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at Jeffrey.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 1.02 (6m) is created to read:

Phar 1.02(6m) “NABP” means the National Association of Boards of Pharmacy.

SECTION 2. Phar 2.01 is repealed.

SECTION 3. Phar 2.02 (1) (intro) and (a) are amended to read:

Phar 2.02 Application procedure for original licensure. (1) Each applicant for original licensure as a pharmacist shall submit a completed notarized application prior to the examination date on forms provided by the board. The application shall include all of the following:

(a) ~~The~~ Completed application form with the signature of the applicant.

SECTION 4. Phar 2.02 (1) (f) and (g) are created to read:

Phar 2.02 (1) (f) Evidence of having passed the NAPLEX.

(g) Evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin as primary state.

SECTION 5. Phar 2.03 and 2.04 is repealed.

SECTION 6. Phar 2.05 repealed and recreated:

Phar 2.05 Application procedure for persons licensed in another state. Each applicant licensed as a pharmacist in another state shall submit all of the following:

- (1) Completed application form with the signature of the applicant and fee as determined by the department under s. 440.05, Stats.
- (2) NABP Clearinghouse license transfer application.
- (3) Evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin as primary state.

SECTION 7. Phar 2.06 is repealed.

SECTION 8. Phar 4.01 is repealed.

SECTION 9. Phar 4.03 is amended to read:

Phar 4.03 Passing scores. (1) The passing scores set by the board represent the minimum competency required to protect public health and safety. The board may adopt the recommended passing score of the examination provider.

SECTION 10. Phar 4.03 (3) is repealed.

SECTION 11. Phar 4.04, 4.045, 4.046 and 4.05 are repealed.

SECTION 12. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

Chair
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 16-018)

ORDER

An order of the Pharmacy Examining Board to create Phar 8.02 (2m) and 8.13 relating to identification card required for certain controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.11 (1b), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.11 (1b) (a) 1. and 450.11 (1b) (bm), Stats.

Explanation of agency authority:

The Pharmacy Examining Board shall promulgate rules for its own guidance and for the guidance of the profession and define and enforce professional conduct and unethical practices not inconsistent with the law relating to pharmacy. [s. 15.08 (5) (b)]

Health care facility means any other facility identified by the board by rule and the pharmacist shall maintain the record for a time established by the board by rule. [s. 450.11 (1b) (a) 1. and 450.11 (1b) (bm)].

Related statute or rule: Phar 7.05 (1m)

Plain language analysis:

The statutes requiring an identification card for certain controlled substances contains an exemption for drugs delivered to a health care facility and allows the board to identify other facilities by rule to the definition of health care facility provided in the statute. This rule adds an inpatient hospice to the definition of health care facility.

The rule also requires the record of the name of the person the drug is dispensed or delivered to shall be maintained for 5 years or until the name is submitted to the prescription drug monitoring program, whichever is sooner.

Summary of, and comparison with, existing or proposed federal regulation: None

Comparison with rules in adjacent states:

Illinois: Illinois requires identification for a prescription to be dispensed. The name and address of the purchaser is recorded and maintained for not less than 2 years.

Iowa: Iowa does not require identification for a prescription to be dispensed.

Michigan: Michigan does not require identification for a prescription to be dispensed.

Minnesota: Minnesota requires identification for a controlled substance being dispensed if the purchase is not covered in whole or in part by a health plan company or other third party payor. Minnesota requires prescription records to be kept for a minimum of 2 years.

Summary of factual data and analytical methodologies:

The Board recognizes an inpatient hospice is similar in nature to the other health care facilities in the definition. The 5 year timeframe to maintain records is consistent with the length of time other pharmacy records are to be maintained.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at Jeffrey.Weigand@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at Sharon.Henes@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 8.02 (2m) is created to read:

Phar 8.02 (2m) Records required under s. 450.11 (1b) (bm) shall be maintained for at least 5 years from the date the drug was dispensed, or, for a record that is subject to s. 961.385, Stats.,

until the name of a person to whom a drug is dispensed is delivered to the controlled substances board under s. 961.385, whichever is sooner.

SECTION 2. Phar 8.13 is created to read:

Phar 8.13 Identification card exception for a health care facility. In s. 450.11 (1b) (e) 3., Stats, "Health care facility" means a facility, as defined in s. 647.01(4); any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under ss. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under ss. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.

SECTION 3. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

Chair
Pharmacy Examining Board

TEXT OF RULE

SECTION 1. Phar 6.075 is created to read:

Phar 6.075 Temperature. (1) DEFINITIONS. In this section:

- (a) Business day is a day the pharmacy is open for business.
- (b) Dry place means a place that does not exceed 40% average relative humidity at 68 degree Fahrenheit or the equivalent water vapor pressure at other temperatures.
- (c) Freezer means a place in which the temperature is maintained between -13 and 14 degrees Fahrenheit.
- (d) Mean kinetic temperature means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.
- (e) Refrigerator means a place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

(2) STORAGE. Drugs shall be stored at appropriate temperature and under appropriate conditions, including in a dry place, according to the manufacturer recommendation or an official pharmaceutical compendium.

(3) RECORDING DEVICES. Manual, electromechanical or electronic temperature and humidity recording devices shall be placed within the storage space to accurately determine the area's temperature and humidity.

(4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy shall be monitored at least once during each business day. A minimum and maximum temperature over the course of the time a pharmacy is closed shall be obtained.

(5) RECORDS. Temperature and humidity records shall be maintained for a minimum of 5 years.

(6) DISPENSING OF SAFE DRUGS. The pharmacist shall use professional judgement, including consideration of the mean kinetic temperature, to determine whether a drug is safe to be dispensed.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

(Member of the Board or Secretary)
(board or department name)

(b) “Managing pharmacist” means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

(c) “Practitioner” means a person licensed in this state to prescribe and administer drugs or licensed in another state and recognized by this state as a person authorized to prescribe and administer drugs.

(d) “Remote dispensing site” means a dispensing site that is not licensed as a pharmacy. Remote does not mean geographical distance or location.

(e) “Supervising pharmacy” means a licensed pharmacy that oversees the operations and administration of all aspects of the remote dispensing site.

(2) LICENSING REQUIREMENTS AND USE OF TITLES RELATING TO THE OPERATION OF REMOTE DISPENSING SITES. (a) A remote dispensing site shall not be licensed as a pharmacy.

(b) No person may use or display the title “pharmacy,” “drug-store,” “apothecary,” or any other title, symbol or insignia having the same or similar meanings in connection with a remote dispensing site.

(3) LOCATION OF REMOTE DISPENSING SITES. A pharmacist may dispense at the following locations:

(a) A health care facility or a facility identified under s. 980.065, Stats.

(b) The office or clinic of a practitioner.

(c) A county jail, rehabilitation facility under s. 59.53 (8), Stats., state prison under s. 302.01, Stats., or county house of correction under s. 303.16 (1), Stats.

(d) A juvenile correctional facility under s. 938.02 (10p), Stats., juvenile detention facility under s. 938.02 (10r), Stats., residential care center for children and youth under s. 938.02 (15d), Stats., secured residential care center for children and youth under s. 938.02 (15g), Stats., type 1 juvenile correctional facility under s. 938.02 (19), Stats., type 2 residential care center for children and youth under s. 938.02 (19r), Stats., or type 2 juvenile correctional facility under s. 938.02 (20), Stats.

(4) REQUIREMENTS FOR THE OPERATION OF REMOTE DISPENSING SITES. (a) A remote dispensing site shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.
2. This store is a remote dispensing site being supervised by a pharmacist located at all of the following:
 - a. Name of store.
 - b. Address of store.
 - c. Telephone number of store.
3. The pharmacist is required to talk to you each time you pick up a prescription.

(b) A remote dispensing site shall not open for operation if the supervising pharmacy is closed.

(c) A remote dispensing site shall not dispense a prescribed drug or device in the absence of the ability of a patient to communicate with the pharmacist.

(d) When closed, a remote dispensing site shall have a centrally monitored alarm. For all after hour entries, the personnel entering the site shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for 2 years.

(e) A remote dispensing site shall submit written notification to the board 30 days prior to operating the remote dispensing site.

(5) DISPENSING REQUIREMENTS. A remote dispensing site shall meet all of the following:

(a) Comply with the requirements under s. Phar 7.01 and visually inspect prescription orders, labels and dispensed product.

(b) Comply with the labeling requirements under s. Phar 7.12 (2) (g). The prescription label shall contain the name and address

of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed.

(c) Comply with federal law if a remote dispensing site dispenses controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACISTS. (a) The managing pharmacist of a remote dispensing site shall, in accordance with s. Phar 7.09, do all of the following:

1. Have written policies and procedures for system operation, safety, security, accuracy and access.

2. Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion of inventory, and documentation of remedial training to prevent future errors.

3. Visit the remote dispensing site at least monthly to conduct controlled substance inventory, to ensure written policies and procedures are being followed, and to ensure that remote dispensing site personnel comply with all federal and state laws regulating the practice of pharmacy.

4. Retain documentation of the monthly inspection visits at the remote dispensing site for 2 years.

(b) The managing pharmacist at the supervising pharmacy is responsible for all remote dispensing sites connected to the supervising pharmacy.

(7) REQUIREMENTS FOR PHARMACY TECHNICIANS AND INTERNS. Pharmacy technicians and interns employed at a remote dispensing site shall satisfy all of the following requirements:

(a) Be 18 years of age or older.

(b) Be a high school graduate or have equivalent education.

(c) Have completed 1500 hours of work as a technician within the 3 years prior to the date of employment at the remote dispensing site or completed a training program approved by the board.

History: CR 09-099; cr. Register March 2010 No. 651, eff. 4-1-10.

Phar 7.10 Administration of drug products and devices other than vaccines. A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats., in the course of teaching a patient self-administration techniques except a pharmacist may not administer by injection a prescribed drug product or device unless he or she satisfies each of the following:

(1) The pharmacist has successfully completed 12 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education or the board, in injection techniques, emergency procedures, and record keeping.

(2) The pharmacist has in effect liability insurance against loss, expense and liability resulting from errors, omissions or neglect in the administration by injection of prescribed drug products or devices in an amount that is not less than \$1,000,000 for each occurrence and \$2,000,000 for all occurrences in any one policy year. The pharmacist shall maintain proof that he or she satisfies this requirement and, upon request, shall provide copies of such proof to the department or board.

(3) The pharmacist has written procedures regarding the administration by injection of a prescribed drug product or device in the course of teaching self-administration techniques to a patient.

Note: To administer a vaccine a pharmacist must meet the requirements in s. 450.035, Stats.

History: Cr. Register, December, 1999, No. 528, eff. 1-1-00; CR 14-023; am. (1) Register August 2014 No. 704, eff. 9-1-14.

Phar 7.12 Central fill pharmacy. (1) In this section:

(a) “Central fill pharmacy” means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

- Phar 7.10 Administration of drug products and devices other than vaccines. (1)** A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats. After the pharmacist administers a prescribed drug product or device, the pharmacist or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.
- (2)** A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has successfully completed 12 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education, or the board, in administration techniques, emergency procedures, and record keeping.
- (3)** A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a prescribed drug product or device unless the person satisfies all of the following:
- (a) Successfully completes a course of study and training in administration technique approved by the Accreditation Council of Pharmacy Education or the board.
 - (b) Administers the prescribed drug product or device only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique approved by the Accreditation Council of Pharmacy Education or the board.

TEXT OF RULE

SECTION 1. Repeals and recreates ch Phar 15 to read:

15.01 Definitions. In this chapter:

- (1) Active pharmaceutical ingredient (API) means any substance or mixture of substances intended to be used in the compounding of a drug preparation and that, when used in the compounding of a drug preparation, becomes an active ingredient in the preparation intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease in humans and animals or affecting the structure and function of the body.
- (2) Added substances means ingredients that are necessary to compound a drug preparation that are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation.
- (3) Adverse Drug Event means an injury resulting from the use of a drug.
- (4) Beyond Use Date (BUD) means one of the following:
 - (a) The date after which a non-sterile compounded preparation shall not be used.
 - (b) The date and time after which a sterile compounded sterile preparation shall not be used.
- (5) Certificate of analysis means a report from the supplier of a component, container or closure that accompanies the component, container or closure and contains the specifications and results of all analyses and a description.
- (6) Classified area means a space that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).
- (7) Component means any, active pharmaceutical ingredient, or added substances used in the compounding of a drug preparation.
- (8) Compounding means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug delivery device, or a device in accordance with a prescription, or medication order. Compounding does not include repackaging. Compounding includes any of the following:
 - (a) Preparation of drug dosage forms for both human and animal patients.
 - (b) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
 - (c) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients. Notwithstanding this paragraph, the reconstitution or mixing that is performed in accordance with the directions contained in approved labeling provided by the manufacturer is not compounding.
 - (d) Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching or chemical analysis.
- (9) Container-closure system is the sum of packaging components that together contain and protect a dosage form including primary packaging components and secondary packaging components.
- (10) Controlled room temperature means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit.

- (11) Freezer means a place in which the temperature is maintained between -13 degrees and 14 degrees Fahrenheit
- (12) NF means the National Formulary.
- (13) Refrigerator means a cold place in which the temperature is maintained between 36 degrees and 46 degrees Fahrenheit
- (14) Stability means the extent to which a compounded preparation retains, within specified limits and throughout its beyond use date, the same properties and characteristics that it possessed at the time of compounding.
- (a) Chemical stability means each active pharmaceutical ingredient retains its chemical integrity and labeled potency, within specified limits.
 - (b) Physical stability means the original physical properties, including appearance, palatability, uniformity, dissolution, and suspendability, are retained.
 - (c) Microbiological stability means sterility or resistance to microbial growth is retained according to specified requirements and antimicrobial agents that are present retain effectiveness within specified limits.
 - (d) Therapeutic stability means the therapeutic effect remains unchanged.
 - (e) Toxicological stability means no significant increase in toxicity occurs.
- (15) USP means the United States Pharmacopeia.

SUBCHAPTER I – General

15.10 Facilities. A pharmacist engaged in compounding shall ensure all of the following:

- (1) An area designated for compounding.
- (2) Orderly placement of compounding equipment, materials, and components in order to minimize the potential for compounding errors.
- (4) The compounding area is maintained in a clean and sanitary condition.
- (5) The compounding area is easily accessible to all of the following:
 - (a) Hot and cold running water, exclusive of the bathroom sink.
 - (b) Soap or detergent.
 - (c) Single-use towels.
- (6) All compounding equipment, materials and components shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage areas

15.11 Equipment and Drug Preparation Containers.

- (1) A pharmacy shall possess equipment and drug preparation containers or packaging appropriate to the type of compounding performed at the pharmacy.
- (2) Equipment and drug preparation containers or packaging used in compounding shall be of appropriate design and capacity, and shall be suitably stored in a manner to facilitate use, cleaning, maintenance, and protect it from contamination.
- (3) Equipment and drug preparation containers/packaging used in compounding drug products shall be of suitable composition. Equipment surfaces that contact components may not be reactive, additive, adsorptive or absorptive so as to alter the stability of the compounded preparation.

- (4) Equipment used in compounding shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, according to written policies and procedures, in order to reduce bioburden and reduce the opportunity for cross-contamination.
- (5) All equipment utilized in compounding preparations shall be inspected, maintained, calibrated and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance. Records shall be kept indicating the equipment was inspected, maintained, calibrated and validated.

15.12 Records. The managing pharmacist shall ensure written or electronic compounding documentation to systematically trace, evaluate, and replicate the compounding steps throughout the process of a preparation. The compounding documentation shall be maintained for a period of 5 years after the date of the last refill. The compounding documentation shall include all of the following:

- (1) Official or assigned name, strength, and dosage form of the preparation.
- (2) List of all APIs and added substances and their quantities.
- (3) Vendor or manufacturer, lot number and expiration date of each APIs and added substances.
- (4) Equipment and supplies needed to prepare the preparation.
- (5) Mixing instructions including all of the following:
 - (a) Order of mixing.
 - (b) Mixing temperatures or other environmental controls.
 - (c) Duration of mixing.
 - (d) Other factors pertinent to the replication of the preparation as compounded.
- (6) Compatibility and stability information, including references or laboratory testing.
- (7) Container or container-closure system used in dispensing.
- (8) Packaging and storage requirements.
- (9) Quality control procedures and expected results.
- (10) Sterilization method when using non sterile ingredients to make a sterile preparation.
- (11) Total quantity compounded.
- (12) Name of the person who prepared the preparation.
- (13) Name of the person who performed the quality control procedures.
- (14) Name of the person who approved the preparation.
- (15) Date of preparation.
- (16) Assigned control or prescription number.
- (17) Assigned BUD.
- (18) Copy of the label to dispense final product.
- (19) Documentation of any adverse reactions or preparation problems reported by the patient or caregiver.

15.13 Quality control.

- (1) A pharmacist shall complete a final check which shall include verification of all the following:
 - (a) Written procedures were followed in the compounding process.
 - (b) Preparation instructions were followed.
 - (c) Finished preparation appears as expected.
 - (d) Label includes all required elements.
 - (e) Quality control procedures were completed.

- (f) Compounding records are complete
- (2) A pharmacist shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed.

15.14 Training, Policies and Procedures. (1) TRAINING. All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained and competency is assessed for the type of compounding conducted. It is the responsibility of the managing pharmacist to ensure personnel training and competency assessments are completed and documented.

(2) POLICIES AND PROCEDURES. The pharmacy and managing pharmacist shall establish written policies and procedures governing all of the following:

- (a) Personnel qualifications and training, responsibilities, and competencies.
- (b) Personal hygiene, garb, garbing, and personal protective gear.
- (c) Use and maintenance of compounding facilities and equipment, including applicable certifications.
- (d) Environmental monitoring including storage, handling, packaging and transport.
- (e) Cleaning and disinfection of compounding area.
- (f) Component selection.
- (g) Sterilization and depyrogenation, if pharmacy does sterile compounding.
- (h) Documentation requirements.
- (i) Establishing BUD.
- (j) Reporting of adverse drug events.
- (k) A risk management program, including documentation of incidents, adverse drug reactions and product contamination.
- (L) Quality assurance program.
- (m) Maintaining the integrity of the classified work area of the laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators and biological safety cabinets.
- (n) Handling small and large spills of antineoplastic agents and other hazardous substances.

(3) REVIEW OF POLICIES AND PROCEDURES The policy and procedures shall be reviewed at least once every 36 months and shall be updated, on a continuous basis, to reflect current practice. Documentation of the review shall be made available to the board upon request.

15.15 Labeling. The label of a compounded preparation shall include all of the following:

- (1) Labeling requirements in s. Phar 7.02 and 8.08.
- (2) Storage conditions if other than controlled room temperature.
- (3) BUD.
- (4) Special handling instructions.

15.16 Component Selection. (1) Active pharmaceutical ingredients or added substances used in compounding shall be manufactured by an FDA registered facility or accompanied by a certificate of analysis.

(2) APIs and added substances shall meet USP or NF monograph specifications when monographs are available.

- (3) All components shall be stored and handled consistent with the manufacturer's labeling or USP-NF monographs and in a manner that prevents contamination and deterioration.
- (4) A pharmacist compounding for human use may not use components that have been withdrawn or removed from the market for safety or efficacy reasons by the FDA. A pharmacist compounding for food producing animal use may not use components prohibited for use in food producing animals.

15.17 Non-patient specific compounding. Compounded preparations dispensed or distributed directly to a practitioner to be administered to an individual patient without a patient specific prescription shall meet all of the following:

- (1) The prescription order shall include the name, address, drug, quantity and the purpose of the compounded preparation.
- (2) The label shall include the practitioner's name in place of the patient's name and state "For Practitioner Use Only – Not for Dispensing or Distribution". If the sterility or integrity of the compounded preparation is not maintained after the initial opening of the container, the label shall state "Single-Dose Only".
- (3) The pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, and the lot number and BUD of all preparations dispensed or distributed to the practitioner.
- (4) There shall be a procedure for immediate notification to all practitioners of a preparation which is recalled.

SUBCHAPTER II – Non-sterile Compounding

15.20 Component Selection. (1) Components with an expiration date from the manufacturer or distributor may be used before the expiration date provided all of the following:

- (a) The component is stored in its original container under conditions to avoid decomposition
 - (b) There is minimal exposure of the remaining component each time component is withdrawn from the container.
 - (c) When any withdrawals from the container are performed by those trained in the proper handling of the component.
- (2) Components without an expiration date assigned by the manufacturer or supplier, shall be labeled with the date of receipt and assigned a conservative expiration date, not to exceed three years after receipt, based upon the nature of the component and its degradation mechanism, the container in which it is packaged and the storage conditions.
- (3) Components transferred to another container which shall provide integrity that is minimally equivalent to the original container and shall be identified with all of the following:
- (a) Component name.
 - (b) Original supplier.
 - (c) Lot or control number.
 - (d) Transfer date.
 - (e) Expiration date.

15.21 Assigning BUD. (1) The BUD shall not be later than the expiration date on the container of any component.

(2) In the absence of stability information that is applicable to a specific drug product and preparation, the maximum BUD for a non-sterile compounded drug preparation that is packaged in a tight, light-resistant container is as follows:

- (a) For nonaqueous formulations stored at controlled room temperature, the BUD shall not be later than the time remaining until the earliest expiration date of any active pharmaceutical ingredient or 6 months, whichever is earlier.
- (b) For water-containing oral formulations, the BUD shall not be later than 14 days when stored in a refrigerator
- (c) For water-containing semisolid, mucosal liquid, topical or dermal formulations, stored at controlled room temperature, the BUD shall not be later than 30 days.

(3) Assignment of BUD shall include an assessment of the need for antimicrobial agents and or storage in a refrigerator to protect against bacteria, yeast, and mold contamination introduced during or after the compounding process.

SUBCHAPTER III – Sterile Compounding

15.30 Definitions. In this subchapter:

- (1) Ante area means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, labeling and other high particulate generating activities are performed. The ante-area is the transition area between the unclassified area of the facility and the buffer area.
- (2) Buffer area means an ISO Class 7 or ISO Class 8 if using an isolator or cleaner area where the PEC that generates and maintains an ISO Class 5 environment is physically located.
- (3) Category 1 means a compounded sterile preparation compounded with a primary engineering control in a segregated compounding area.
- (4) Category 2 means a compounded sterile preparation compounded with a primary engineering control in a classified area.
- (5) Compounded sterile preparation means a compounded final preparation intended to be sterile through the BUD.
- (6) Compounded stock solution means a compounded solution to be used in the preparation of multiple units of a finished compounded sterile preparation.
- (7) Critical site means a location that includes any component or fluid pathway surfaces or openings that are exposed and at risk of direct contact with air, moisture or touch contamination.
- (8) HEPA means high-efficiency particulate air.
- (9) ISO Class 5 air quality conditions means conditions in which the air particle count is no greater than a total of 3,520 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.
- (10) ISO Class 7 air quality conditions means conditions in which the air particle count is no greater than a total of 352,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.
- (11) ISO Class 8 air quality conditions means conditions in which the air particle count is no greater than a total of 3,520,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.
- (12) Isolator means an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is

decontaminated using an automated system. An isolator uses only decontaminated interfaces or rapid transfer ports for materials transfer.

(13) Primary engineering control means a device or zone that provides an ISO Class 5 environment for sterile compounding.

(14) Restricted access barrier system (RABS) means an enclosure that provides HEPA filtered ISO Class 5 unidirectional air that allows for the ingress or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. RABS include compounding aseptic isolators and compounding aseptic containment isolators.

(15) Sterility assurance level of 10^{-6} means an equivalent to a probability that 1 unit in a million is nonsterile.

(16) Segregated compounding area means a designated, unclassified space, area, or room that contains a primary engineering control.

(17) Urgent use compounded sterile preparation means a preparation needed urgently for a single patient and preparation of the compounded sterile preparation under Category 1 or Category 2 requirements would subject the patient to additional risk due to delays.

15.31 Facility design and environmental controls. (1) GENERAL. Facilities shall meet all of the following requirements:

- (a) Be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.
- (b) Be accessible only to designated personnel.
- (c) Have a heating, ventilation, and air conditioning system controlling the temperature and humidity.

(2) SEGREGATED COMPOUNDING AREA. A segregated compounding area shall meet all of the following requirements:

- (a) Be located in an area away from unsealed windows and doors that connect to the outdoors, or significant traffic flow.
- (b) Be located in an area which is not adjacent to construction sites, warehouses and food preparation areas.
- (c) Have a defined perimeter.
- (d) Locate the primary engineering control at least 1 meter from any sink.

(3) CLASSIFIED AREA. A classified area shall meet all of the following:

- (a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets shall be smooth, impervious, free from cracks and crevices and nonshedding.
- (b) Work surfaces shall be constructed of smooth, impervious materials. All work surfaces shall be resistant to damage from cleaning and sanitizing agents.
- (c) Junctures where ceilings meet walls shall be covered, caulked, or sealed to avoid cracks and crevices in which microorganisms and other contaminate can accumulate. All areas in ceilings and walls where the surface has been penetrated shall be sealed.
- (d) Ceilings that consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.
- (e) Walls shall be constructed of a durable material, panels locked together and sealed or of epoxy-coated gypsum board.
- (f) Floors shall have a covering that shall be seamless or have heat-welded seams and coving to the sidewall. There shall be no floor drains.

- (g) All sprinkler heads shall be flush with the ceiling.
- (h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush and sealed.
- (i) Carts shall be constructed of stainless steel wire, nonporous plastic or sheet metal with cleanable casters.
- (j) Tacky mats may not be used in a classified area.
- (k) HEPA filters and unidirectional airflow shall be used to maintain the appropriate airborne particulate classification.
- (L) The classified area shall measure not less than 30 air changes per hour of which at least half shall be HEPA-filtered fresh air.
- (m) A minimum differential positive pressure of 0.02-inch water column is required to separate each classified area. A pressure gauge or velocity meter shall be used to monitor the pressure differential or airflow between classified areas with results documented at least daily.
- (n) Devices and objects essential to compounding shall be located at an appropriate distance from the primary engineering control.
- (o) The ante area and buffer area shall be separate rooms, with walls and doors between them and controls to prevent the flow of lower quality air into the higher ISO class areas. If a pass through is used, only one door shall be opened at a time.
- (p) The ante area shall meet all of the following requirements:
 1. Be capable of maintaining an ISO class 8 air or higher.
 2. Have a sink with running hot and cold running water.
- (q) The buffer area shall meet all of the following requirements:
 1. Be capable of maintaining an ISO class 7 air or better.
 2. Only contain any of the following:
 - a. Items, including furniture, equipment, and supplies, that are required for the tasks to be performed in the buffer area.
 - b. Items that are smooth, impervious, free from cracks and crevices, nonshedding, and easily cleaned and disinfected.
 - c. Items that have been cleaned and disinfected immediately prior to their being placed in the buffer area.
 3. Does not contain any sinks.
 4. Does not contain any course cardboard, external shipping containers and nonessential paper.

(4) PRIMARY ENGINEERING CONTROL. The primary engineering control shall be certified by an independent, qualified individual prior to initial use and then every six months. It shall also be certified when any of the following occurs:

- (a) Redesign of the facility.
- (b) Replacement of the primary engineering control.
- (c) Relocation of the primary engineering control.

15.32 Personnel hygiene, garbing and protective gear. (1) Personnel suffering from rashes, sunburn, oozing tattoos or sores, conjunctivitis, active respiratory infection, or other active communicable disease shall be excluded from working in compounding areas until the condition is resolved.

- (2) All personnel who engage in compounding sterile preparations shall comply with all of the following requirements before entering the compounding area:
- (a) Remove personal outer garments, all cosmetics, exposed jewelry and piercings, headphones, ear buds, and cell phones.
 - (b) Abstain from eating, chewing gum or drinking in the compounding area or bringing food, gum or drink into the compounding area.
 - (c) Artificial nails, nail extenders or nail polish may not be worn while working in the compounding area. Nails shall be neat and trim.
 - (d) Personnel protective equipment shall be put on in the following order:
 - 1. Low-lint, disposable shoe covers.
 - 2. Low-lint, disposable covers for head and facial hair that cover the ears and forehead.
 - 3. Face masks if compounding Category 2 compounded sterile preparations using laminar airflow system and biological safety cabinet.
 - 4. Eye shields, if required due to working with irritants or hazardous drugs.
 - (e) A hand hygiene procedure shall be performed after performing the protective equipment in par (d). The hand hygiene procedure includes all of the following:
 - 1. Wash hands and forearms up to the elbows with unscented soap and water for at least 30 seconds.
 - 2. Hands and forearms to the elbows shall be completely dried using either lint-free disposable towels or wipes.
 - 3. Prior to donning sterile gloves hand antisepsis shall be performed using an alcohol-based hand rub with sustained antimicrobial activity following the manufacturers labeled instructions and application times.
 - (f) Personnel shall wear one of the following:
 - 1. Non-cotton, low-lint sterile gown and sterile gloves.
 - 2. Non-cotton, low-lint gown, sterile sleeves and sterile gloves.
- (3) Gloves on hands and gauntlet sleeves on RABS shall be routinely inspected for holes, punctures, or tears and shall be replaced immediately if any are detected.
- (4) Disinfection of contaminated gloved hands shall be accomplished by wiping or rubbing sterile 70% isopropyl alcohol on all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Routine application of sterile 70% isopropyl alcohol shall occur throughout the compounding process and whenever non-sterile surfaces, including vials, counter tops, chairs and carts, are touched.
- (5) When compounding personnel exit the buffer or segregated compounding area during a work shift, a nonsterile gown may be removed and retained in the ante area or segregated compounding area if not visibly soiled, to be worn again during the same work shift. Coveralls, sterile gowns, shoe covers, hair and facial hair covers, face masks, eye shields, gloves and sleeves shall be replaced with new ones before re-entering the compounding area.
- (6) Garbing items, including gowns, shall be segregated and stored before use in an enclosure to prevent contamination.
- (7) Coveralls and sterile gowns shall not be reused. Visibly soiled gowns shall be changed immediately.
- (8) Gloves shall be sterile and powder free and tested by the manufacturer for compatibility with alcohol disinfection.

15.33 Cleaning and Disinfecting the Compounding Area. (1) Compounding personnel are responsible determining the cleaning and disinfecting products to be used and for ensuring that the frequency of cleaning and disinfecting compounding area is done in accordance with the following minimum frequency:

- (a) Primary engineering control work surfaces, excluding isolators, at the beginning of each shift, end of each shift and before each batch, but not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring.
 - (b) Counters and work surfaces outside the primary engineering control in the buffer area, ante room and segregated compounding areas daily.
 - (c) Floors daily.
 - (d) Walls, ceilings and storage shelving monthly.
- (2) An isolator shall be cleaned each time it is opened and decontaminated once it is closed after each time it is opened. If cleaning occurs without opening, decontaminate after each cleaning cycle.
- (3) Cleaning and disinfecting sterile compounding areas shall occur on a regular basis at the intervals in sub. (1) or when any of the following occurs:
- (a) Spills occur.
 - (b) The surface is visibly soiled.
 - (c) Microbial contamination is known to have been or is suspected of having been introduced into the compounding area.
- (4) All cleaning and disinfecting practices and policies for the compounding area shall be included in written standard operating procedures and shall be followed by all compounding and environmental services personnel.
- (5) Cleaning, detergents and disinfection agents shall be selected and used with consideration of compatibilities, effectiveness and inappropriate or toxic residues. The selection and use of disinfectants shall be guided by microbicidal activities, inactivation by organic matter, residue, and shelf life. Disinfectants shall have antifungal, antibacterial and antiviral activity. Sporicidal agents shall be used at least weekly to clean compounding areas.
- (6) Storage sites for compounding ingredients and supplies shall remain free from dust and debris.
- (7) Floors, walls, ceiling and shelving in the classified and segregated compounding areas are cleaned when no aseptic operations are in progress. Cleaning shall be performed in the direction from cleanest to dirtiest areas.
- (8) All cleaning tools and materials shall be sterile, low-lint and dedicated for use in the buffer room, ante room and segregated compounding areas. If cleaning tools and materials are reused, procedures shall be developed based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.
- (9) Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.
- (10) Entry points on bags and vials shall be wiped with small sterile 70% isopropyl alcohol swabs or comparable method for disinfecting, allowing the isopropyl alcohol to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile

70% isopropyl alcohol swabs used for disinfecting entry points of sterile package and devices may not contact any other object before contacting the surface of the entry point. Particle generating material may not be used to disinfect the sterile entry points of packages and devices. (11) When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 primary engineering control without the need to disinfect the individual sterile supply items.

15.34 Urgent use compounded sterile preparations.

- (1) The compounding process shall be a continuous process that does not exceed one hour, unless required for the preparation.
- (2) Administration shall begin within one hour of preparation of the completion of the preparation.
- (3) Aseptic technique shall be followed during preparation, and procedures shall be used to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other compounded sterile products.
- (4) Unless immediately and completely administered by the person who prepared the compounded sterile preparation or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall have a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation and the 1 hour BUD and time.

15.35 Sterilization methods.

- (1) Sterilization methods employed shall sterilize while maintaining its physical and chemical stability and the packaging integrity of the compounding sterile preparations. The efficacy of sterilization and depyrogenation of container closure systems performed in the pharmacy shall be established, documented, and reproducible.
- (2) Pre-sterilization requirements shall meet all of the following:
 - (a) During all compounding activities that precede terminal sterilization, including weighing and mixing, compounding personnel shall be garbed and gloved in the same manner as when performing compounding in an ISO Class 5 environment. All pre-sterilization procedures shall be completed in an ISO Class 8 or better environment.
 - (b) Immediately before use, all nonsterile measuring, mixing, and purifying devices used in the compounding process shall be thoroughly rinsed with sterile, pyrogen-free water and then thoroughly drained or dried.
- (3) Sterilization shall be performed utilizing one of the following methods:
 - (a) *Sterilization by filtration.* Sterilization by filtration involves the passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent. Filtration may not be used when compounding a suspension when the suspended particles are removed by the filter being used. This method shall meet all of the following:
 1. Sterile filters used to sterile filter preparations shall meet all of the following requirements:
 - a. Be pyrogen-free and have a nominal pore size of 0.22 microns.
 - b. Be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeter of upstream

filter surface area under conditions similar to those in which the compounded sterile preparations will be filtered.

c. Be chemically and physically stable at the compounding pressure and temperature conditions.

d. Have sufficient capacity to filter the required volumes.

e. Yield a sterile filtrate while maintaining pre-filtration pharmaceutical quality, including strength of ingredients of the specific compounded sterile preparations

2. The filter dimensions and liquid material to be sterile filtered shall permit the sterilization process to be completed rapidly without the replacement of the filter during the filtering process.

3. When compounded sterile preparations are known to contain excessive particulate matter, one of the following shall occur:

a. A pre-filtration step using a filter of larger nominal pore size.

b. A separate filter of larger nominal pore size placed upstream of the sterilizing filter to remove gross particulate contaminants before the compounding sterile compound is passed through the sterilizing grade filter.

4. Sterilization by filtration shall be performed entirely within an ISO Class 5 or better air quality environment.

5. Filter units used to sterilize compounded sterile preparations shall be subjected to the manufacturers' recommended post-use integrity test.

(b) *Sterilization by steam heat.* The process of thermal sterilization using saturated steam under pressure shall be the method for terminal sterilization of aqueous preparations in their final, sealed container closure system. The effectiveness of steam sterilization shall be established and verified with each sterilization run or load by using biological indicators, physicochemical indicators and integrators. This method shall meet all of the following:

1. All materials shall be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile. The duration of the exposure period shall include sufficient time for the compounded sterile preparation to reach the sterilizing temperature.

2. The compounded sterile preparation and other items shall remain at the sterilizing temperature for the duration of the sterilization period. The sterilization cycle shall be designed to achieve a SAL of 10^{-6} .

3. Compounded sterile preparations shall be placed in trays which allow steam to reach the compounded sterile preparations without entrapment of air. Paper, glass and metal devices or items shall be wrapped in low lint protective fabric, paper or sealed in envelopes that will permit steam penetration and prevent post sterilization microbial contamination.

4. Immediately before filling ampules and vials, solutions shall be passed through a filter having a nominal pore size of not larger than 1.2 microns for removal of particulate matter.

5. Sealed containers shall be able to generate steam internally. Stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.

Deep containers, including beakers and graduated cylinders, shall be placed on their sides to prevent air entrapment or have a small amount of water placed in them.

6. Porous materials and items with occluded pathways shall only be sterilized by steam if the autoclave chamber has cycles for dry goods.

7. The steam supplied shall be free of contaminants and generated using clean water.

8. The seals on the doors of autoclave chambers shall be examined visually every day they are used for cracks or damage and the seal surfaces shall be kept clean.

9. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

10. Materials in direct contact with the compounded sterile preparation shall undergo a depyrogenation process before being sterilized using steam heat unless the materials used are certified to be pyrogen-free.

(c) *Sterilization by dry heat.* Dry heat sterilization shall be used only for those materials that cannot be sterilized by steam or filtration. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and temperature sensing devices. This method shall meet all of the following:

1. The duration of the exposure period shall include sufficient time for the compounding sterile preparation or items to reach the sterilizing temperature. The compounded sterile preparation and items shall remain at the sterilizing temperature for the duration of the sterilization period.

2. Heated air shall be evenly distributed throughout the chamber.

3. Sufficient space shall be left between materials to allow for good circulation of the hot air.

4. The oven shall be equipped with temperature controls and a timer.

5. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

6. Materials shall first undergo a depyrogenation process before being sterilized using dry heat, unless the materials used are certified to be pyrogen-free.

(4) Dry heat depyrogenation shall be used to render glassware and other thermostable containers pyrogen free. The duration of the exposure period shall include sufficient time for the items to reach the depyrogenation temperature. The items shall remain at the depyrogenation temperature for the duration of the depyrogenation period. The effectiveness of the dry heat depyrogenation cycle shall be established and verified annually using endotoxin challenge vials to demonstrate that the cycle is capable of achieving at least a 3-log reduction in endotoxins.

15.36 Inspection, sterility testing and antimicrobial effectiveness.

(1) PHYSICAL INSPECTION. (a) At the completion of compounding, the compounded sterile preparation shall be inspected by performing all of the following:

1. Visually inspect the container closure for leakage, cracks in the container or improper seals.

2. Visually check the compounded sterile preparation for phase separation.

3. Each individual injectable unit shall be inspected against a lighted white background and a black background for evidence of visible particulates or other foreign matter or discoloration.

(b) For compounded sterile preparations which will not be dispensed promptly after preparation, an inspection shall be conducted immediately before it is dispensed for any defects, including precipitation, cloudiness or leakage, which may develop during storage.

(c) Compounded sterile preparations with any observed defects shall be immediately discarded or marked and segregated from acceptable units in a manner that prevents them from being dispensed.

(2) STERILITY TESTING.

(a) The membrane filtration method shall be used for sterility testing unless it is not possible due to the compounded sterile preparation formulation. The direct inoculation of the culture method shall be used when the membrane filtration method is not possible.

(b) If a preparation may be needed before the results of sterility testing have been received, the pharmacy shall daily observe the incubating test specimens and immediately recall the dispensed preparations when there is any evidence of microbial growth in the test specimens. The patient and the prescriber to whom a potentially contaminated compounded sterile preparation was administered shall be notified immediately of the potential risk.

(c) Positive sterility test results shall prompt a rapid and systematic investigation into the causes of the sterility failure, including identification of the contaminating organism and any aspects of the facility, process or personnel that may have contributed to the sterility failure. The investigation and resulting corrective actions shall be documented.

(d) All Category 2 compounded sterile preparations made from one or more nonsterile ingredients, except those for inhalation and ophthalmic administration, shall be tested to ensure that they do not contain excessive bacterial endotoxins.

(e) Notwithstanding par. (d), a compounded sterile preparation does not need to be tested for bacterial endotoxins if the material is stored under cool and dry conditions and one of the following:

1. The certificate of analysis for the nonsterile ingredient lists the endotoxins burden, and that burden is found acceptable.
2. The pharmacy has predetermined the endotoxins burden of the nonsterile ingredient and that burden is found acceptable.

(3) ANTIMICROBIAL EFFECTIVENESS. Compounded sterile preparations containing a preservative shall pass an antimicrobial effectiveness testing with the results obtained on the specific formulation before any of the compounded sterile preparation is dispensed. The test may be conducted only once on each formulation in the particular container-closure system in which it will be stored or dispensed. The antimicrobial effectiveness test shall occur at one of the following times:

(a) At the completion of the sterility test.

(b) At the time of preparation for compounded sterile preparations which have not undergone a sterility testing.

15.37 Beyond Use Dating.

(1) Sterility and stability considerations shall be taken into account when establishing a BUD. The following dates and times for storage and initiation of administration of the compounded sterile preparations shall apply:

(a) For compounded sterile preparations including components from conventionally manufactured products, the BUD shall not exceed the shortest expiration of any of the starting components. If the compounded sterile preparation includes non-conventionally manufactured products, the BUD may not exceed the shortest BUD of any of the starting components.

(b) For Category I compounded sterile preparations, one of the following:

1. May not exceed 12 hours when the preparation is stored at controlled room temperature.
2. May not exceed 24 hours when the preparation is stored in a refrigerator.

(c) For aseptically prepared Category 2 compounded sterile preparations, one of the following:

1. Prepared with one or more nonsterile ingredients, no preservative added and no sterility testing performed, one of the following:
 - a. Within 4 days when the preparation is stored at controlled room temperature.
 - b. Within 7 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
2. Prepared only with sterile ingredients, no preservative added and no sterility testing performed, one of the following:
 - a. Within 6 days when the preparation is stored at controlled room temperature.
 - b. Within 9 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
3. Prepared with sterile ingredients, no preservative added and sterility testing performed, one of the following:
 - a. Within 28 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
4. Prepared with sterile ingredients, preservative added and no sterility testing, one of the following:
 - a. Within 28 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
5. Prepared with sterile ingredients, preservative added and sterility testing, one of the following:
 - a. Within 42 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.

(d) For terminally sterilized Category 2 compounded sterile preparations, one of the following:

1. Prepared with no preservative added and no sterility testing performed, one of the following:

- a. Within 14 days when the preparation is stored at controlled room temperature.
 - b. Within 28 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
2. Prepared with no preservative added and sterility testing performed, one of the following:
- a. Within 28 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
3. Prepared with preservative added and no sterility testing performed, one of the following:
- a. Within 28 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
4. Prepared with preservative added and sterility testing performed, one of the following:
- a. Within 42 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.

(2) The administration dates and times established in sub. (1) may not be exceeded or extended for compounded sterile preparations without verifiable supporting valid scientific sterility and stability information that is directly applicable to the specific preparation or compound.

(3) For compounded sterile preparations which have been assigned a BUD based upon storage in a freezer, the integrity of the container closure system with the specific compounded sterile preparation in it shall have been demonstrated for 45 days at frozen storage. The container closure integrity test may be conducted only once on each formulation in the specific container closure system in which it will be stored or dispensed.

15.38 Training and evaluation. (1) GENERAL. The managing pharmacist, all pharmacists, pharmacy technicians, pharmacy interns and pharmacy externs involved in compounding sterile preparations shall successfully complete didactic and practical training. The didactic and practical training shall be done before any compounding personnel initially prepares compounded sterile preparations and annually thereafter and shall include all of the following:

- (a) Hand hygiene and garbing.
- (b) Cleaning and disinfection.
- (c) Measuring and mixing.
- (d) Aseptic manipulation.
- (e) Cleanroom behavior.
- (f) Sterilization and depyrogenation.
- (g) Use of equipment.
- (h) Documentation.
- (i) Use of primary engineering controls.

(2) EVALUATION. Compounding personnel shall successfully complete an initial and annual evaluation which includes all of the following:

- (a) Visual observation of hand hygiene and garbing.
- (b) Visual observation of aseptic technique.
- (c) Gloved fingertip and thumb sampling.
- (d) Media-fill tests.

(3) GLOVED FINGERTIP. Successfully gloved and thumb sampling is measured by samplings resulting in zero colony-forming units no fewer than three times. Sampling shall be performed on sterile gloves inside of an ISO Class 5 primary engineering control. Gloved fingertip and thumb sampling in a RABS or an isolator shall be taken from the sterile gloves placed over the gauntlet gloves. When gloved fingertip sample results exceed action levels defined by the pharmacy, a review of hand hygiene and garbing procedures, glove and surface disinfection procedures and work practices shall be performed and documented.

(5) RECORDS. The pharmacy shall maintain written policies and procedures for the initial and ongoing training and evaluation of persons involved in compounding sterile preparations. Documentation of all training, assessments, gloved fingertip tests and media-fill simulations shall be maintained by the pharmacy for 5 years and made available to the Board upon request.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

PHARMACY RULES LIST

Current Rule Projects

Presenting to Board for adoption in July)

- Phar 1, 8 (definitions; misplaced word “emergency”)
- Phar 2, 4 (application and examinations)
- Phar 5 (renewal/reinstatement)
- Phar 8 (Act 199)

Drafting

- Phar 6 (Temperature/Humidity) – Anticipate holding Public Hearing in the fall
- Phar 7.10 (Act 290) – Anticipate holding Public Hearing in the fall
- Phar 14 (Medical Oxygen) – Anticipate holding Public Hearing in the fall
- Phar 15 (Compounding) – Anticipate holding Public Hearing in the fall
- Phar 7 (Practice of Pharmacy)

Projects identified on previous Goals Lists which fall under this chapter

- 7.015 Technicians
- 7.09 (1) (b) Automated Dispensing Systems (include jails, prisons, etc)
- 7.02 Prescription Labels
- Pharmacists working from home
- Patient consultation
- Collaborative Practice Agreements

Potential Rule Projects

- Required rules pursuant to 450.073 (3), Wis. Stats. (Electronic track and trace)
- Compliance with Drug Supply Chain Security Act
 - Third Party Logistics Providers
 - Wholesale Distributor Requirements
 - Product Tracing Requirements
- Phar 12 Update (including security requirements)
- Phar 13 Clean-Up
- Phar 17.02 (Intern)
- Phar 1 (add definitions apply to chapter 17)
- Out of state pharmacies