Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way, 2nd Floor
PO Box 8366
Madison WI 53708-8366

Phone: 608-266-2112
Web: http://dsps.wi.gov
Email: dsps@wisconsin.gov

Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
December 2, 2021

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 actions of the Board.

AGENDA

11:00 A.M.
(OR IMMEDIATELY FOLLOWING THE RULES COMMITTEE MEETING)

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of October 20, 2021 (5-7)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. 11:00 A.M. Preliminary Hearing on Statement of Scope – SS 097-21 (Phar 18), Relating to Licensure of Third-party Logistics Providers (8-10)
1) Review Preliminary Hearing Comments

E. 11:00 A.M. Public Hearing – Clearinghouse Rule 21-074 (Phar 5, 6, 7, 11, and 12), Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction (11-22)
1) Review Public Hearing Comments and Respond to Clearinghouse Report

F. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates
   a. Kleppin, Susan – 7/1/2025
   b. O'Hagan, Tiffany – 7/1/2024
   c. Peterangelo, Anthony – 7/1/2023
   d. Walsh, Michael – 7/1/2024
   e. Weiss, Shana – 7/1/2023
   f. Weitekamp, John – 7/1/2022
   g. Wilson, Christa – 7/1/2025

G. Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State Boards of Pharmacy and the U.S. Food and Drug Administration – Discussion and Consideration

H. Education and Examination Matters- Discussion and Consideration

1) Multistate Pharmacy Jurisprudence Examination (MPJE) Update

I. Review of Pharmacy Self-Inspection Forms (#2550) – Discussion and Consideration (23-41)

J. Newsletter Matters – Discussion and Consideration (42)

K. Legislative and Policy Matters – Discussion and Consideration

1) Assembly Bill 281/Senate Bill 300 (Pharmacy Technicians)

L. Implement 2021 Wisconsin Act 9 – 100 Most Prescribed Drugs – Discussion and Consideration (43)

M. Administrative Rule Matters – Discussion and Consideration (44-63)

1) Phar 8, Relating to Requirements for Controlled Substances
2) Phar 15, Relating to Compounding Pharmaceuticals
3) Pending or Possible Rulemaking Projects

N. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration

1) Travel Report: NABP 2021 District IV meeting on October 20-22, 2021 in Columbus, Ohio – Tiffany O'Hagan
2) 2022 Annual Meeting Planning: NABP/American Association of Colleges of Pharmacy (AACP) District IV

O. COVID-19 – Discussion and Consideration

P. Pilot Program Matters – Discussion and Consideration

Q. Discussion and Consideration on Items Added After Preparation of Agenda

1) Introductions, Announcements and Recognition
2) Nominations, Elections, and Appointments
3) Administrative Matters
4) Election of Officers
5) Appointment of Liaisons and Alternates
6) Delegation of Authorities
7) Education and Examination Matters
8) Credentialing Matters
9) Practice Matters
10) Legislative and Policy Matters
11) Administrative Rule Matters
12) Pilot Program Matters
13) Variances
14) Liaison Reports
15) Board Liaison Training and Appointment of Mentors
16) Informational Items
17) Division of Legal Services and Compliance (DLSC) Matters
18) Presentations of Petitions for Summary Suspension
19) Petitions for Designation of Hearing Examiner
20) Presentation of Stipulations, Final Decisions and Orders
21) Presentation of Proposed Final Decisions and Orders

22) Presentation of Interim Orders
23) Pilot Program Matters
24) Petitions for Re-Hearing
25) Petitions for Assessments
26) Petitions to Vacate Orders
27) Requests for Disciplinary Proceeding Presentations
28) Motions
29) Petitions
30) Appearances from Requests Received or Renewed
31) Speaking Engagements, Travel, or Public Relation Requests, and Reports

R. 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.).

S. Deliberation on Division of Legal Services and Compliance Matters

1) Case Closings

a. 20 PHM 169 – C. **(64-67)**
b. 20 PHM 185 – P.N.S.P. **(68-74)**
c. 21 PHM 111 – V.R.X.D. **(75-78)**

2) Monitoring Matters

a. Andrew Seidlitz, R. Ph., Requesting for Auditor Approval for Controlled Substance Inventory and Accountability Audits of all Controlled Substances **(79-104)**

T. Deliberation of Items Added After Preparation of the Agenda
1) Education and Examination Matters
2) Credentialing Matters
3) Application Reviews
4) DLSC Matters
5) Monitoring Matters
6) Professional Assistance Procedure (PAP) Matters
7) Petitions for Summary Suspensions
8) Petitions for Designation of Hearing Examiner
9) Proposed Stipulations, Final Decisions and Orders
10) Proposed Interim Orders
11) Administrative Warnings
12) Review of Administrative Warnings
13) Proposed Final Decisions and Orders
14) Matters Relating to Costs/Orders Fixing Costs
15) Case Closings
16) Board Liaison Training
17) Petitions for Assessments and Evaluations
18) Petitions to Vacate Orders
19) Remedial Education Cases
20) Motions
21) Petitions for Re-Hearing

22) Appearances from Requests Received or Renewed

U. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

V. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

W. Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: JANUARY 27, 2022

****

MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
OCTOBER 20, 2021

PRESENT: Susan Kleppin *(excused at 1:05 p.m.)*, Anthony Peterangelo, John Weitekamp *(arrived at 11:17 a.m.)*, Michael Walsh, Shana Weiss, Christa Wilson

EXCUSED: Tiffany O'Hagan

STAFF: Brad Wojciechowski, Executive Director; Jon Derenne, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Advanced; and other Department staff

CALL TO ORDER

Susan Kleppin, Secretary, called the meeting to order at 11:04 a.m. A quorum was confirmed with five (5) members present.

ADOPTION OF AGENDA

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF SEPTEMBER 2, 2021

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to approve the Minutes of September 2, 2021 as published. Motion carried unanimously.

(John Weitekamp arrived at 11:17 a.m.)

CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, 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.). John Weitekamp, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Susan Kleppin-yes; Anthony Peterangelo-yes; Michael Walsh-yes; Shana Weiss-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:49 p.m.

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Case Closings

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to close the following DLSC Cases for the reasons outlined below:

a. 19 PHM 301 – Z.P. – No Violation
b. 20 PHM 073 – W. – Prosecutorial Discretion (P2)
c. 20 PHM 153 – C., K.L.M. – No Violation
d. 21 PHM 030 – T.L.V. – No Violation
e. 21 PHM 037 – E.C.P. – No Violation
f. 21 PHM 064 – O. – No Violation

Motion carried unanimously.

Administrative Warnings

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to issue an Administrative Warning in the matter of the following DLSC Cases:

a. 21 PHM 019 – O.H.E.
b. 21 PHM 019 – W.P.

Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

21 PHM 018– Jared G. Latus, R.Ph.

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Jared G. Latus, R.Ph., DLSC Case Number 21 PHM 018. Motion carried unanimously.

ORDERS FIXING COSTS

Jennifer L. Reithmeyer, R.Ph., Respondent (DHA Case Number SPS-20-0027/DLSC Case Number 18 PHM 180

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to adopt the Order Fixing Costs in the matter of disciplinary proceedings against Jennifer L. Reithmeyer, R.Ph., Respondent – DHA Case Number SPS-20-0027/DLSC Case Number 18 PHM 180. Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 1:04 p.m.

(Susan Kleppin was excused at 1:05 p.m.)

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

(Be advised that any recusals or abstentions reflected in the Closed Session motions stand for the purposes of the affirmation vote.)

ADJOURNMENT

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:07 p.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**11/17/21** **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
12/02/21	☒ Yes ☐ No	**11:00 A.M. Preliminary Hearing on Statement of Scope – SS 097-21 on Phar 18, Relating to Licensure of Third-party Logistics Providers** **1. Review Preliminary Hearing Comments**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

The Board will hold a Preliminary Hearing on this scope statement as directed by the Joint Committee for Review of Administrative Rules.

11) Authorization

Nilajah D. Hardin — 11/17/21

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.

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 18

Relating to: Licensure of third-party logistics providers.

Rule Type: Permanent and Emergency

1. Finding/nature of emergency (Emergency Rule only):

2021 Act 25, Section 9 (1) provides:

"The pharmacy examining board may promulgate emergency rules under s. 227.24 implementing s. 450.075. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until June 30, 2023, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection."

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to revise the Pharmacy administrative code consistent with 2021 Act 25 to provide criteria for the Wisconsin licensure of third-party logistics providers.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

The Board intends to update the Pharmacy code to bring it into alignment with the statutory provisions enacted by 2021 Act 25 relating to licensure of third-party logistics providers.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

Section 15.08 (5) (b), Stats. states that "The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.02 (3) (a), Stats.authorizes the board to "promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

Section 450.02 (3) (d), Stats. provides that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

Section 450.075 (4), Stats. says: "The board shall promulgate rules implementing this section. The rules shall ensure compliance with the federal drug supply chain security act, 21 USC 360eee, et seq. The board may not promulgate rules that impose requirements more strict than the federal drug supply chain security act or any regulations passed under the federal drug supply chain security act. The board may not promulgate rules that require a license under this section."

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

Approximately 100 hours.

6. List with description of all entities that may be affected by the proposed rule:

Pharmacies, pharmacists, licensed third-party logistics providers, those seeking licensure as a third-party logistics provider, and consumers of pharmaceuticals.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

The rules will comply with the federal drug supply chain security act, 21 USC 360eee, et seq., which establishes national standards for third-party logistics providers.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Nilajah Hardin, (608) 267-7139, DSPSAdminRules@wisconsin.gov

Approved for publication:

Authorized Signature

9/3/2021

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**11/17/21** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
12/02/21	☒ Yes ☐ No	**11:00 A.M. Public Hearing – Clearinghouse Rule 21-074 on Phar 5, 6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction** **1. Review Public Hearing Comments and Respond to Clearinghouse Report**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

The Board will hold a Public Hearing on this rule as required by the rulemaking process.

11) Authorization

Nilajah D. Hardin — 11/17/21

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 PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 6.04 (2) and (3) (a) 2. and 3., Phar 6.04 (3) (a) 7. (b) and (c) and (4), and Phar 11; to renumber and amend Phar 6.04 (3) (a) (intro.), 1., 5., and 6.; and to amend s. Phar 5.02 (1) and (2), Phar 6.04 (1), Phar 7.04 (3) (intro.), and Phar 12.04, relating to name and address change, floor design, procedures for disciplinary proceedings, superseded references, and technical correction.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.06 (1) and 450.09 (4), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), (b), (d), and 450.06 (1), Stats.

Explanation of agency authority:

Each examining board: shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession. [s. 15.08 (5) (b), Stats.]

The board may promulgate rules relating to the distribution and dispensing of prescription drug and establishing security standards for pharmacies. [s. 450.02 (3) (a) and (b), Stats.]

The Board may promulgate rules necessary for the administration and enforcement of this chapters 450 and 961, Stats. [s. 450.02 (3) (d), Stats.]

No pharmacist may dispense at any location in this state that is not licensed as a pharmacy by the board. No person in this state may use or display the title “pharmacy," “drugstore," “apothecary," or any other title, symbol, or insignia having the same or similar meanings, except for a place of practice which is licensed under this section as a pharmacy by the board. [s. 450.06 (1), Stats.]

Related statute or rule: N/A

Plain language analysis:

The Pharmacy Examining Board identified the following rules in its 2019 report filed with the Joint Committee for Review of Administrative Rules pursuant to s. 227.29, Stats.

Phar 5.02 is revised to delete obsolete or unnecessary provisions to require the notification to the Board regarding name or address change to be submitted in writing.

Phar 6.04 is revised to delete economically burdensome requirements and requirements which do not correspond with the evolving types of pharmacies.

Phar 7.04 (3) is revised to correct a typographical error occurring in CR 19-145 related to which should refer to Schedule III – V drugs instead of Schedule III – IV drugs. The omission of Schedule V creates inconsistency with the federal law and confusion for pharmacists.

Ch. Phar 11 is repealed as it is duplicative and unnecessary.

Phar 12.04 is revised as the federal standards referenced have been superseded.

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

Comparison with rules in adjacent states:

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.610 outlines the standards for pharmacy structure/equipment standards. The section does require a locked area for drugs. However, Illinois does not identify professional service area square footage requirements or signage requirements.

Iowa: The complete Iowa Board of Pharmacy rules are contained in 657 Iowa Administrative Code. The Iowa Pharmacy Practice Act is codified under administrative code chapter 155A, specifically related to licensed pharmacies under s. 155A.13. Rules do require a locked area for drugs. However, there are no comparable requirements for professional service area square footage or signage.

Michigan: Michigan administrative code MCL 338.536 for housing of pharmacies specifically requires pharmacies to have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that it includes a prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist on duty, workspace must be increased by not less than 4 square feet and pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling of substantial construction and must be securely lockable. There do not appear to be requirements for signage.

Minnesota: The Minnesota Administrative Code chapter 6800 related to pharmacies and pharmacists, provides the rules for the standards for pharmacies. Specifically, Minnesota Administrative Code section 6800.0700 provides minimum requirements for pharmacies. The pharmacy space requirements include the pharmacy must: contain more than 250 square feet in the dispensing and drug storage area; maintain a prescription dispensing counter at least 18 inches deep that provides 2 linear feet; maintain an aisle behind the prescription dispensing counter at least 36 inches wide, extending the full length of the counter; be surrounded by a continuous partition or wall extending from the floor to the permanent ceiling; and contain doors capable of being securely locked. There do not appear to be requirements for signage.

Summary of factual data and analytical methodologies:

The Board conducted a full review of its administrative codes in compliance with the Legislative Report to the Joint Committee of Review of Administrative Rules under s. 227.29, Stats. The items in this rule project are a result of that review.

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

The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

A fiscal estimate and economic impact analysis are 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 Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; phone (608) 267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on December 2, 2021, at a time to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 5.02 (1) and (2) are amended to read:

Phar 5.02 (1) A pharmacist shall notify the board ~~in writing~~ when ~~his or her~~ a pharmacist's name has been legally changed, within 30 days of the change.
(2) A pharmacist shall notify the board ~~in writing~~ when ~~his or her~~ a pharmacist's address has been changed, within 30 days of the change.

SECTION 2. Phar 6.04 (1) is amended to read:

Phar 6.04 (1) PROFESSIONAL SERVICE AREA. ~~The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk pharmaceuticals.~~ If the ~~pharmacy~~ building is open at any time ~~solely as a non-prescription or sundry outlet, without a pharmacist present~~ while the professional service area is closed, the professional service area shall be secured as specified in sub. (3). ~~A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service plan varies from the requirement~~.

SECTION 2. Phar 6.04 (2) is repealed.

SECTION 3. Phar 6.04 (3) (a) (intro.), and 1. are renumbered Phar 6.04 (3) (intro.) and (am) and are amended to read:

Phar 6.04 (3) (intro.) ~~PROFESSIONAL SERVICE AREA REQUIREMENTS WHERE PHARMACIST IS ABSENT~~ REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED

~~Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet if~~ When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements ~~are met~~:

(am) A locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by ~~unlicensed~~ unauthorized personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

SECTION 4. Phar 6.04 (3) (a) 2. and 3. are repealed.

SECTION 5. Phar 6.04 (3) (a) 5. and 6. are renumbered Phar 6.04 (3) (bm) and (cm) and amended to read:

Phar 6.04 (3) ~~(a) 5.~~(bm) Signs of reasonable size are posted at ~~the entrance of the building and~~ the professional service area which prominently ~~displaying~~ display the hours the ~~pharmacist will be on duty~~ professional services are available.

~~6.~~(cm) The manner in which the telephone is answered does not imply that the ~~location is, at that time, operating as a pharmacy~~ professional services are available.

SECTION 6. Phar 6.04 (3) (a) 7., (b) and (c) and (4) are repealed.

SECTION 7. Phar 7.04 (3) (intro.) is amended to read:

7.04 (3) (intro.) The transfer of original prescription information for a controlled substance listed in Schedule III – ~~IV~~V shall meet the following requirements:

SECTION 8. Chapter Phar 11 is repealed.

SECTION 9. Phar 12.04 is amended to read:

Phar 12.04 Inspections. Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets ~~the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985)~~ federal and state laws and regulations.

SECTION 10. 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)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Administrative Rule Chapter, Title and Number
Phar 5, 6, 7, 11, 12

3. Subject
Name and address change, floor design, procedures for disciplinary proceedings, superseded references, and technical correction

4. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

5. Chapter 20, Stats. Appropriations Affected

6. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget
☐ Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than $20 million?
☐ Yes ☐ No

9. Policy Problem Addressed by the Rule
The Pharmacy Examining Board

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

11. Identify the local governmental units that participated in the development of this EIA.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit to implementing the rule is providing updates reflecting current pharmacy practice. If the rule is not implemented, it will continue to provide outdated references and terminology and reflect practices that are no longer current.

14. Long Range Implications of Implementing the Rule
The long range implication of implementing the rule is updated references and terminology and reflecting current pharmacy practice.

15. Compare With Approaches Being Used by Federal Government
None.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.610 outlines the standards for pharmacy structure/equipment standards. The section does require a locked area for drugs. However, Illinois does not identify professional service area square footage requirements or signage requirements.

Iowa: The complete Iowa Board of Pharmacy rules are contained in 657 Iowa Administrative Code. The Iowa Pharmacy Practice Act is codified under administrative code chapter 155A, specifically related to licensed pharmacies under s. 155A.13. Rules do require a locked area for drugs. However, there are no comparable requirements for professional service area square footage or signage.

Michigan: Michigan administrative code MCL 338.536 for housing of pharmacies specifically requires pharmacies to have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that it includes a prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist on duty, workspace must be increased by not less than 4 square feet and pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling of substantial construction and must be securely lockable. There do not appear to be requirements for signage.

Minnesota: The Minnesota Administrative Code chapter 6800 related to pharmacies and pharmacists, provides the rules for the standards for pharmacies. Specifically, Minnesota Administrative Code section 6800.0700 provides minimum requirements for pharmacies. The pharmacy space requirements include the pharmacy must: contain more than 250 square feet in the dispensing and drug storage area; maintain a prescription dispensing counter at least 18 inches deep that provides 2 linear feet; maintain an aisle behind the prescription dispensing counter at least 36 inches wide, extending the full length of the counter; be surrounded by a continuous partition or wall extending from the floor to the permanent ceiling; and contain doors capable of being securely locked. There do not appear to be requirements for signage.

17. Contact Name	18. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	(608) 267-7139

This document can be made available in alternate formats to individuals with disabilities upon request.

LCRC
FORM 2

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **21-074**

AN ORDER to repeal Phar 6.04 (2) and (3) (a) 2., 3., and 7., (b) and (c) and (4), and Phar 11; to renumber and amend Phar 6.04 (3) (a) (intro.), 1., 5., and 6.; and to amend s. Phar 5.02 (1) and (2), 6.04 (1), 7.04 (3) (intro.), and 12.04, relating to name and address change, floor design, procedures for disciplinary proceedings, superseded references, and technical correction.

Submitted by **PHARMACY EXAMINING BOARD**

09-24-2021 RECEIVED BY LEGISLATIVE COUNCIL.
10-18-2021 REPORT SENT TO AGENCY.

MSK:KAM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☑ NO ☐

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☐ NO ☑

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☑ NO ☐

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit Kelley
Clearinghouse Assistant Director

Anne Sappenfield
Legislative Council Director

CLEARINGHOUSE RULE 21-074

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

2. Form, Style and Placement in Administrative Code

a. In the caption for the proposed rule, the designation "Phar" should be listed only once for each series of affected rule sections within each type of treatment. For example, the listing of repealed provisions should appear as "Phar 6.04 (2), (3) (a) 2., 3., and 7., (b), and (c), and (4), and ch. Phar 11". [s. 1.01 (1) (Example), Manual.]

b. In the text of the proposed rule, the designation for SECTION 2 occurs twice. The number for the second occurrence and all following SECTIONS should be corrected to be sequential.

c. SECTION 3 of the proposed rule should be separated into two SECTIONS: first, to repeal and recreate s. Phar 6.04 (3) (title); and second, to renumber and amend s. Phar 6.04 (3) (a) (intro.) and 1. The caption for the proposed rule should also be updated to reflect this change.

d. In the renumbering and amending of s. Phar 6.04 (3) (a) 5. and 6., the board should revise the amended text to show only the new designations. The former designations should not be stricken through or shown. [s. 1.04 (6) (b), Manual.]

4. Adequacy of References to Related Statutes, Rules and Forms

In s. Phar 12.04, the material from 1984 USC ss. 351 and 352 and 1985 21 CFR ss. 210 and 211 that was incorporated by reference is updated to "federal and state laws and regulations". The board should reconsider the use of the general reference to "federal and state laws and regulations". References should be as specific as possible, in order to adequately inform a reader as to what requirements must be met. [s. 1.15 (1) (c), Manual.] Additionally, if the board instead updates to revised federal law citations, that incorporation or update may be done only with the consent of the Attorney General. The rule summary should be revised to include a comment on compliance with that requirement, if a specific provision is incorporated. [s. 227.21 (2) (a), Stats.; and s. 1.14, Manual.]

6. Potential Conflicts With, and Comparability to, Related Federal Regulations

In the board's summary for the proposed rule, the entry for comparison to federal regulations says "none". However, elsewhere in the summary, the board notes that the current rules are inconsistent with federal law, and separately notes that a different part of federal law has been superseded. An explanation of the current status of federal law and the rules' relationship to those laws would be helpful.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Teresa Guiliani, Form Management Specialist	11/19/2021
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
12/2/2021	☐ Yes ☒ No	Pharmacy Self-Inspection Form (#2550) Discussion

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	

10) Describe the issue and action that should be addressed:

Discussion and review of proposed updates and suggestions related for Pharmacy Self-Inspection Form (#2550). (The currently posted, unrevised Form #2550 is available here.)

11) Authorization

Teresa Guiliani *11/19/2021*

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.

Wisconsin Department of Safety and Professional Services

Mail To: P.O. Box 8935
Madison, WI 53708-8935
FAX #: (608) 251-3036
Phone #: (608) 266-2112

Ship To: 4822 Madison Yards Way
Madison, WI 53705
E-Mail: dsps@wisconsin.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY SELF-INSPECTION INFORMATIONAL SHEET

The Board no longer requires the Department of Safety and Professional Services to send inspectors to conduct on-site inspections prior to licensure.

The Board does require the Managing Pharmacist to complete this "Pharmacy Self-Inspection Report" (Form #2550). Please complete each line indicating the date of compliance, either actual or anticipated, but in no event later than the proposed opening date indicated on the cover page. If the Pharmacy is in non-compliance with any portions of the "Pharmacy Self-Inspection Report" please indicate why the pharmacy is in non-compliance and when the pharmacy will be in compliance. Return the entire "Pharmacy Self-Inspection Report" to the Board office when completed. Please make a copy for your files.

After the "Pharmacy Self-Inspection Report" has been reviewed and is found to be in order, a license number will be issued if all other requirements have been satisfied.

The Department, on behalf of the Board, will conduct an unannounced audit of the pharmacy location within one year after the date the license was issued to verify that the pharmacy is in compliance with the "Pharmacy Self-Inspection Report" as well as the Wisconsin Statutes and Administrative Code relating to the practice of pharmacy.

This procedure will also be used for remodeling.

Notice To Credential Holders Conducting Self-Inspections

The Division of Legal Services and Compliance in the Department of Safety and Professional Services conducts a follow-up inspection to the self-inspection done by new Pharmacies prior to their opening for business.
Below is a list of the most frequently occurring problems we found during our follow-up inspections. The reference is to the Pharmacy Board Rule or Statute. This list is being provided to assist new businesses in conducting their self-inspections:

- Prescription labels – Not having the correct address of the facility or using the name of the previous pharmacy (Phar 7.02).
- Records – Inadequate recordkeeping of Schedule V substances (Phar 8.02(3)(e)(2)).
- Alarm systems – All facilities must have a functioning alarm system or alternate board approved security system at all times to detect entry after hours. Some facilities were found to have opened without an alarm system in place or the alarm system was not working at various times (Phar 13.10(4)).

Procedure for Reporting Theft or Loss of Controlled Substances

The Managing Pharmacist is responsible for reporting any theft or significant loss of controlled substances to the U.S. Department of Justice, DEA Kluczynski Building, Ste. 1200, 230 S. Dearborn Street, Chicago, IL 60604 (312-353-1236, or 1-800-478-7642 toll free 24 hours). Report the theft or loss on DEA Form #106 (Report of Theft or Loss of Controlled Substances), obtainable from DEA at www.deadiversion.usdoj.gov. In any instance, that a pharmacy, practitioner or other DEA registrant authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy, practitioner, or other DEA registrant shall also send a copy to the board within 2 weeks of filing with the DEA.

Procedure for Destroying Controlled Substances

Contact the US Department of Justice, 1000 N. Water Street, Room 1010, Milwaukee, WI 53202, or www.deadiversion.usdoj.gov for the proper forms.

Wisconsin Statutes and Administrative Codes

These can be viewed online at http://dsps.wi.gov/Boards-Councils/Administrative-Rules-and-Statutes/Pharmacy-Administrative-Rules-and-Statutes/.

Approved Prescription Drug Products and Code of Federal Regulations

These publications are obtainable from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20401.

Wisconsin Department of Safety and Professional Services

Mail To: P.O. Box 8935
Madison, WI 53708-8935
FAX #: (608) 251-3036
Phone #: (608) 266-2112

Ship To: 4822 Madison Yards Way
Madison, WI 53705
E-Mail: dsps@wisconsin.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY SELF-INSPECTION REPORT

Choose Type: ☐ Change of Ownership ☐ New Location ☐ Remodel ☐ Re-Inspection

Applicant Name:

Proposed Opening/Remodel Start Date: __ __ / __ __ / __ __ __ __

DBA Name:

Phone Number: __ __ __ - __ __ __ - __ __ __ __

Hours: (open - close)
__ __ - __ __

Pharmacy License Number: (for remodel or re-inspection)
__ __ __ __ __ __ **- 42**

Managing Pharmacist Name:

License #: __ __ __ __ __ __ **- 40**

Full or Part Time:

Other Pharmacists:

License #: __ __ __ __ __ __ **- 40**

Full or Part Time:

License #: __ __ __ __ __ __ **- 40**

Full or Part Time:

License #: __ __ __ __ __ __ **- 40**

Full or Part Time:

Compliance Date:

_____ 1. Pharmacy Label (contains all required information)

_____ 2. Professional service area _____ Sq. Ft.

_____ 3. Professional service area where Pharmacist is absent. See Phar 6.04(3)

_____ 4. RX counter surface area _____

_____ 5. Sink

_____ 6. Hot and cold running water

_____ 7. Suitable soap or detergent

_____ 8. Disposal container for waste

_____ 9. Secure narcotic storage or dispersed throughout stock

_____ 10. Centrally monitored alarm system (or prior Board approval for an alternate security system)

_____ 11. Operational refrigerator

_____ 12. Sufficient storage space

_____ 13. Proper storage of exempted narcotic preparations and poisons

Complaince Date:

_____ 14. Equipment of appropriate design and size for intended pharmacy practice and compounding

_____ 15. Exempt Narcotic Register - Schedule V

_____ 16. Poison Register

_____ 17. a) Prescription files, Wis. State Stat. § 450.11(2)

b) Controlled Substance RX Files, Wis. Admin. Code, § Phar 8.03(2)

c) Medication profile, Wis. Admin. Code, § Phar 7.07

Wisconsin Department of Safety and Professional Services

Mail To: P.O. Box 8935
Madison, WI 53708-8935
FAX #: (608) 251-3036
Phone #: (608) 266-2112

Ship To: 4822 Madison Yards Way
Madison, WI 53705
E-Mail: dsps@wisconsin.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY SELF-INSPECTION

It is recommended that pharmacies use the **Wisconsin Statutes and Administrative Code Relating to the Practice of Pharmacy** to facilitate this continuing educational and evaluation procedure.

Directions for completing Self-Inspection: On the line next to the requirement, please complete each line indicating the date of compliance, either actual or anticipated, but in no event later than the proposed opening date indicated on the cover page of (**Form #2550)**, or "**NA**" for not applicable. If answered "**NA**" please describe why this rule does not apply to your specific pharmacy under "**Self-Inspecion Notes**" on the last page of the self-inspection. For clarity, please write down the corresponding item number (listed on the left hand side of each requirement) for each description you write on the "**Self-Inspection Notes**."

CHAPTER PHAR 5 WISCONSIN ADMINISTRATIVE CODE (LICENSE RENEWAL)

Compliance Date:

PHAR 5.03 Display of licenses.

1. _____ Each pharmacist's license is displayed in public view. (Pharmacists need only display license at primary site of employment.) The current renewal card (and **no other visible renewal card**) is displayed with the license.

PHAR 5.04 Renewal prohibited; relicensure.

2. _____ A pharmacist whose license is currently suspended or revoked may not renew their license unless it has been reinstated by the Board and they are otherwise qualified for renewal.

PHAR 5.05 Requirements for late renewal; reinstatement.

3. _____ A pharmacist who files an application for renewal of a license within five (5) years after renewal date must file the following with the Board:
   (a) The DSPS' application for renewal.
   (b) The fee required under Wis. Stat. § 440.08(2), plus the late fee required under Wis. Stat. § 440.08(3).
4. _____ A pharmacist who files an application for renewal of a license five (5) years or more after the renewal date must file with the Board the requirements under Wis. Admin. Code Phar 5.05(1) and verification of successful completion of examinations and/or educational requirements, required by the Board.

CHAPTER PHAR 6 WISCONSIN ADMINISTRATIVE CODE

PHAR 6.03 Changes in managing pharmacist.

5. _____ Any change in **managing pharmacist** has been reported to the Pharmacy Examining Board. (This section requires notification within 5 days of the date of change.) (The Pharmacy Examining Board strongly suggests completion of this Pharmacy Self-Inspection by any new managing pharmacist.)

PHAR 6.04 Floor design.

6. _____ Professional service area has a minimum of 250 sq. ft. (20% limit on space used for storage of bulk pharmaceuticals)
7. _____ (If not, has variance been approved by the Pharmacy Examining Board)
8. _____ Prescription counter is at least 12 sq. ft. of **free working area** for compounding and dispensing and at least 18 inches wide. (Space for records, computer, and supplies not included)
9. _____ Professional service area secure **when pharmacist is absent**. If R.Ph. always present, enter "**N/A**" in item 10, skip items 11 to 17.
10. _____ The pharmacy can convert to a non-prescription or sundry outlet without a pharmacist present if:
11. _____ 1. Present barrier has been approved by the Pharmacy Examining Board
12. _____ 2. Barrier is **locked** in the absence of the pharmacist.
13. _____ 3. Telephone restrictions are observed
14. _____ 4. Signs are posted at the entrance to the building and the professional service area displaying the hours the pharmacist will be on duty.

Compliance Date:

15. _____ 5. The manner in which the telephone is answered does **not imply** that the location is, at that time, operating as a pharmacy. Note: Pharmacy services are **not** provided: including no prescription being picked up. [Wis. Admin. Code Phar 7.01(e)].
16. _____ 6. Pharmacy Examining Board has been notified of the hours the establishment will be operated as a sundry outlet.
17. _____ 7. The managing pharmacist is responsible for compliance with all professional service area security requirements.
18. _____ Modifications to the floor plan have been filed with the Board if remodeling has occurred.
19. _____ Where no pharmacist is present in the professional service area a pharmacy is not required to convert to a non-prescription or sundry outlet if the following requirements are met:
20. _____ 1. The pharmacist is absent for a time period of one half hour or less.
21. _____ 2. The pharmacist must be accessible for communication with the remaining pharmacy staff by phone, pager, or other device.
22. _____ 3. The pharmacy must indicate that the pharmacist is not available in the professional service area and indicate the period of absence and the time of the pharmacist's return.
23. _____ 4. Pharmacy technicians may only perform duties allowed by Wis. Admin. Code Phar 7.015(2).

PHAR 6.05 [Wis. Stat. § 450.09(4)] Sanitation.

24. _____ Pharmacy is maintained in a clean and orderly manner.
25. _____ Suitable sink supplied with hot and cold running water, detergent and adequate waste disposal container are provided.

PHAR 6.06 Equipment.

26. _____ The professional service area of a pharmacy has equipment of appropriate design and size for the intended pharmacy practice consisting of at least the following equipment:
27. _____ Latest available or immediately accessible version of federal and state pharmacy laws consisting of:
    1. DEA Regulations, 21 CFR 1300 to End**:** **www.access.gpo.gov/nara/cfr/cfr-table-search.html**
    2. Wisconsin pharmacy laws (Wis. Stat. § 450): **www.legis.state.wi.us/rsb/statutes.html**
    3. Wisconsin Controlled Substances Act (Wis. Stat. § 961): **www.legis.state.wi.us/rsb/statutes.html**
    4. Wisconsin Administrative Code (Rules of the Pharmacy Examining Board): **www.legis.state.wi.us/rsb/code/phar/phar.html**

    Note: Statutes and rules may be made available via electronic means with immediate accessibility to satisfy this portion of the rule.
28. _____ References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions, patient counseling, compounding and pharmaceutical calculations, and generic substitution.
29. _____ Telephone number of a poison center (conspicuously posted in the professional service area).

PHAR 6.07 Storage.

30. _____ Refrigerator adequate for biologicals and other drugs.
31. _____ Sufficient shelf, drawer, or cabinet space.
32. _____ Controlled substances are stored in a securely locked, substantially constructed cabinet or dispersed throughout the inventory in a manner that obstructs theft. (Alphabetical storage on open shelves of highly sought after controlled substances are not considered adequate.)

PHAR 6.08 Security.

33. _____ The Pharmacy has a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the Board.
34. _____ **PHAR 1.02(14)** Hypodermic needles and syringes, poisons and Schedule V controlled substances are **only** in the professional service area.

Compliance Date:

CHAPTER PHAR 7 WISCONSIN ADMINISTRATIVE CODE

PHAR 7.01 Minimum procedures for compounding and dispensing.

(1) **Only licensed pharmacists** (or interns under supervision),

35. _____ (a) Reviews all original and renewal prescription orders, whether electronic, written, or oral; and determines therapeutic compatibility and legality of the prescription order. The review shall include, when indicated or appropriate, consultation with the prescriber. (See Wis. Admin. Code PHAR 7.07(4) for responsibility to review profile.)

346. _____ Wis. Stat. § 450.13(1). Inform the patient of drug product equivalent options.

Note: Wis. Stat. § 450.13(5), amended in 1992 exempts hospitals with formularies for inpatients only.

37. _____ (b) Read and interpret a prescriber's directions for use for the purpose of accurately transferring instructions to the prescription label.

38. _____ (c) If an agent of the pharmacist procures, measures or counts prefabricated dosage forms or compounds, mixes and combines ingredients the pharmacist **verifies accuracy** of the agent's actions. (Agent of a pharmacist is allowed to compound, mix and combine ingredients with a **specific written protocol** and **pharmacist verification** as stated in Wis. Admin. Code Phar 7.015(j))

39. _____ (d) Make a final check on the accuracy and correctness of the prescription and identify the pharmacist responsible for the original or renewed prescription.

40. _____ (e) Give the patient or agent appropriate consultation relative to the prescription, except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a patient's residence, is not satisfied by only offering to provide consultation.

41. _____ (em) Transfer the prescription to the patient or agent of the patient.

42. _____ (f) Receive, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on reverse side of the prescription order, medication profile record, or uniformly maintained and readily retrievable document, the following information.

1. Date renewed.
2. Name of practitioner authorizing renewal **if different from original prescriber**.
3. Quantity of drug dispensed.
4. Pharmacist renewing the prescription.

43. _____ (2) Subsection (1)(d) and (e) does not prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug delivery systems. Sub (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharge patients.

44. _____ (3) Each pharmacist's supervision of compounding and dispensing activities **as defined in (1) (c)** is limited to one pharmacist intern and four pharmacy technicians at any time.

Note: Any higher ratio must be approved by the Pharmacy Examining Board.

PHAR 7.015 Pharmacy technician; defining roles/duties.

45. _____ (1) The pharmacy technician is a non-pharmacist or non-pharmacist intern who, under the general supervision of a pharmacist, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescription orders and inventory management.

Note: **Pharmacy technician does not include ancillary persons, which includes**: clerks, secretaries, cashiers, or delivery persons who may be present in the pharmacy, unless they are performing technical functions as delineated in Wis. Admin. Code Phar 7.015(2), in which case they are a technician when performing these functions.

46. _____ (2) The pharmacist delegates technical dispensing functions to a pharmacy technician, but only under the general supervision of the pharmacist where the delegated functions are performed. Technical dispensing functions include:

47. _____ (a) Accepting written or electronic prescription orders from the prescribing practitioner or from the prescribing practitioner's agent.

48. _____ (b) Accepting original oral prescription orders from the prescribing practitioner or their agent, if the conversation is recorded and listened to and verified by the pharmacist prior to dispensing.

49. _____ (c) Requesting authorization for a refill from the prescribing practitioner.

50. _____ (d) Accepting oral authorization for a refill from the prescribing practitioner or their agent, provided there are no changes to the original prescription order.

Compliance Date:

(e) Accepting a request from a patient to refill a prescription.
(f) Obtaining and entering patient or prescription data into the patient information system.
(g) Preparing a prescription label.
(h) Retrieving medication from stock, counting or measuring medication and placing the medication in its final container.
(i) Reconstituting prefabricated dosage forms.
(j) Compounding pharmaceuticals pursuant to written policies and procedures on file in the pharmacy at the time of compounding.
(k) Affixing a prescription label to its final container.
(l) Placing ancillary information on the prescription label.
(m) Prepackaging and labeling drugs for dispensing by a pharmacist.
(n) Preparing unit dose carts for final review by a pharmacist.
(o) Retrieving and transporting stock medication to and from pharmacist approved areas.
(p) Other technical functions that do not require the professional judgment of a pharmacist.

(3) The pharmacy technician may not do any of the following:
(a) Provide the final verification for the accuracy, validity, completeness or appropriateness of a filled prescription or medication order.
(b) Perform any of the following tasks: participation in final DURs; make independent therapeutic alternate drug selections, participation in final drug regimen screening; perform any act necessary to be a managing pharmacist, or administer any prescribed drug products, devices or vaccines.
(c) Provide patient counseling, consultation exercise or patient specific judgment.
(d) Transfer the prescription to the patient or agent of the patient.

(4) The pharmacist provides the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative.

PHAR 7.02 Prescription label; name of drug product dispensed.

The prescription label discloses brand name and strength or generic name, strength and **manufacturer or distributor** of the drug or drug product dispensed. Unless prescriber requests omission.

PHAR 7.03 Prescription renewal limitations.

Prescription orders for any drug other than a controlled substance bearing renewal authorization "**prn**" are limited to a period of one year from the date of **original order**.

All renewal authorizations are void when the patient-physician relationship has ceased (includes death or retirement of prescriber).

PHAR 7.04 Return or exchange of health items.

(1) In this section:
(a) "Health items" means drugs, devices, hypodermic syringes, needles, or other objects for injecting a drug, medicine, or items of personal hygiene.
(b) "Inpatient health care facility" means any hospital, nursing home, county homes, county mental hospital, tuberculosis sanitarium, or similar facility, but does not include community-based residential facilities, jails or prison facilities.
(c) "Original container" means the container in which a health item was sold, distributed, or dispensed.
(d) "Resident health care patient" means a patient residing in a community-based residential facility that controls a resident's prescribed and over-the-counter medications as specified by Wis. Stat. § HFS 83.33(3) (b) 2.
(e) "Secured institutional health care patient" means any of the following:
1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under Wis. Stat. § DOC 350.17, containing policies and procedures for the control and administration of medications complying with Wis. Stat. § DOC 350.20.
2. A juvenile patient who resides in a secured correctional facility, as defined in Wis. Stat. § 938.02(15m; a secured child caring institution, as defined in Wis. Stat. § 938.02(15g); a secured group home, as defined in Wis. Stat. § 938.02(15p); a secured detention facility, as defined in Wis. Stat. § 938.02(16); or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in Wis. Stat. § DOC 316.02(6) and provided to a juvenile patient under the provisions of Wis. Stat. § DOC 316.03.

Compliance Date:

(f) "Tamper-resistant package" means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned, except for any of the following:

(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

(b) Where the health items were dispensed in error, were defective, adulterated, misbranded or dispensed beyond their beyond use date.

(c) When in the professional judgment of the pharmacist substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient's family or agent, or other person.

(d) For a secured institutional health care patient or resident health care patient where all of the following apply:

1. The health item was never in the possession and control of the patient.
2. The health item was sold, distributed or dispensed in a tamper-resistant package and, for a drug, includes the beyond use date and manufacturer's lot number.
3. The health item is not commingled with a different health item unless the health item will be repackaged and re-dispensed to the same patient.
4. The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

(e) A health item that is prepackaged for consumer use and labeled in compliance with all applicable state and federal laws where all of the following apply:

1. The pharmacist determines that the original package is unopened, sealed, and intact and that package labeling is unaltered.
2. The pharmacist determines the contents are not adulterated.

(3) Health items returned to a pharmacy pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(3m) Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2)(d), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away , or otherwise sold, distributed or re-dispensed other than to a secured institutional health care patient.

(4) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient's use.
Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(5) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.
Note: Cancer and chronic disease drug returns and re-dispensing pursuant to Ch. HFS 148 are allowed provided the pharmacy follows the requirements in Ch. HFS 148.

PHAR 7.05 Prescription records.

(1) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purposes of original or refill dispensing if the system:

(a) Is capable of producing a printout of any prescription data, which the user pharmacy is responsible for maintaining. The system shall be designed so that the pharmacy can receive the printout within 48 hours after requesting the printout.

(b) Is equipped with an auxiliary procedure, which, during periods of down-time, shall be used for documentation of prescription dispensing. The auxiliary procedure shall ensure that prescription refills are authorized by the original prescription order, that the maximum number of prescription refills has not been exceeded and that all of the appropriate data are retained for on-line entry as soon as the computer system is again available for use.

(1m) A record of all prescriptions dispensed shall be maintained for a period of five (5) years after the date of the last refill.

Compliance Date:

(2) All systems used for maintaining a record of any prescription dispensing shall include:
(a) Patient's identification.
(b) Name, strength, and dosage form of the drug product dispensed.
(c) Quantity dispensed.
(d) Date of all instances of dispensing.
(e) Practitioner's identification
(f) Pharmacist's identification
(g) Retrieval designation.

PHAR 7.055 Transfer of prescription order information.

(1) General Requirements. A pharmacist may transfer prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing, if all of the following conditions are satisfied:
(a) The transfer is communicated directly between two (2) pharmacists either by verbal transfer or by a computer system transfer meeting the requirements of sub. (4). Communication by facsimile machine is not allowed unless the prescription order information being transferred is verified verbally between two (2) pharmacists.
(b) A computer system used to record a verbal transfer of prescription order information for a non-controlled substance meets the requirements of Wis. Admin. Code Phar 7.05(1)(a) and (b).
(c) The pharmacist receiving the verbal transfer of prescription order information for either a controlled or a non-controlled substance records the transferred information in writing unless a computer system transfer meeting the requirements of sub. (4) is used.
(d) All original and transferred prescription orders are maintained for a period of five (5) years from the date of the last refill.
(e) A written copy of any prescription order for a prescribed drug provided by a pharmacist is identified in writing as "**COPY-FOR INFORMATION ONLY**." No prescribed rug may be dispensed based on an information copy.
(f) A pharmacist making or receiving a transfer of prescription order information is licensed in the state in which he or she performs an act required by this section.
(2) Non-controlled substances. The transfer of prescription order information for non-controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:
(a) The pharmacist making the transfer records the following information:
1. The word "**VOID**" is written on the face of the invalidated prescription order or recorded in a similar manner to "**VOID**" on a prescription order in a computer system meeting the requirements of Wis. Admin. Code Phar 7.05(1)(a) and (b).
2. The name and address of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order, the date, and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order or in a computer system meeting the requirements of Wis. Admin. Code Phar 7.05(1)(a) and (b).
3. A transfer of prescription order information for a non-controlled substance for the purposes of refill dispensing is limited to the number of authorized refills.
(b) The pharmacist receiving the transferred prescription order information shall record in writing the following:
1. The word "**TRANSFER**" on the face of the transferred prescription order.
2. The name and address of the patient, the name and address of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.
3. The date of issuance of the original prescription order.
4. The original number of refills authorized on the original prescription order.
5. The date of original dispensing if the prescription order has previously been dispensed.
6. The number of valid refills remaining and the date of the last refill.
7. The pharmacy's name, address, and the prescription order number from which the prescription order information was transferred.
8. The name of the pharmacist making the transfer.
9. The name, address, and telephone number of the pharmacy from which the original prescription order was transferred if different from sub (d). 7.

Compliance Date:

131. _____ (3) Controlled Substances. The transfer of prescription order information for controlled substances for the purposes of refill dispensing is permissible pursuant to the following requirements:

132. _____ (a) The transfer of prescription order information is permissible only on a one-time basis unless a computer system meeting the requirements of sub. (4) is used.

133. _____ (b) If a computer system meeting the requirements of sub. (4) is used, a transfer of prescription order information for the purposes of refill dispensing is limited to the number of authorized refills.

134. _____ (c) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist making the transfer shall record in writing the following information:

135. _____ 1. The word "**VOID**" is written on the face of the invalidated prescription order.

136. _____ 2. The name, address, and DEA registration number of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order and the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

137. _____ (d) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist receiving the transferred prescription order information shall record in writing the following information:

138. _____ 1. The word "**TRANSFER**" on the face of the transferred prescription order.

139. _____ 2. The name and address of the patient, the name, address and DEA number of the prescribing practitioner, and the name, quantity, and dosage form of the drug product or device prescribed and the directions for use.

140. _____ 3. The date of issuance of the original prescription order.

141. _____ 4. The original number of refills authorized on the original prescription order.

142. _____ 5. The date of original dispensing.

143. _____ 6. The number of valid refills remaining and the dates and locations of previous refills, if applicable.

144. _____ 7. The name, address, telephone number, DEA registration number, and prescription order number of the pharmacy from which the prescription order information was transferred if different from the pharmacy from which the prescription order was originally dispensed.

145. _____ 8. The name of the pharmacist making the transfer.

146. _____ 9. The name, address, telephone number, DEA registration number, and prescription order number of the pharmacy from which the prescription order was originally dispensed.

147. _____ (4) Use of Computer System. A computer system used for transferring prescription order information shall, in addition to meeting the requirements of Wis. Admin. Code Phar 7.05(1)(a) and (b), contain a common central processing unit electronically sharing a real-time, on-line database to which both the transferring and receiving pharmacy have access.

PHAR 7.065 Answering machines in pharmacies.

148. _____ Oral prescription orders may be received at a pharmacy via telephone answering machine and dispensed by the pharmacist if the voice of the physician or agent is known to the pharmacist and providing other requirements for documenting and filling are met.

PHAR 7.07 Medication profile record system.

Medication profile record **system** for **each** patient includes:

149. _____ (1) An individual medication profile record system is maintained for all persons for whom prescriptions, original, or renewals are dispensed for outpatient use. The system allows retrieval of the information.

150. _____ (2) The following minimum information is retrievable: patient name, or other identifying information, address of the patient, birth date of the patient if obtainable, name, strength, dosage form, and quantity of the drug product dispensed, directions for use, retrieval designation assigned to the prescription order, practitioner identification, and the date of each dispensing for original and renewal prescriptions.

151. _____ (3) Allergies, adverse drug reactions, drug idiosyncrasies and chronic condition.

122. _____ (4) The pharmacist reviews the profile before dispensing. (See Wis. Admin. Code PHAR 7.01(a))

153. _____ (5) Medication profile records, if used as the only documentation of renewal dispensing, are maintained for not less than five (5) years following the last entry. If the profile records are not used as the only documentation of renewal dispensing, they are maintained not less than one year past the last entry.

PHAR 7.08 Prescription orders transmitted electronically.

Electronic transmission of prescription orders is available in the pharmacy. If not applicable, enter "**N/A**" in item 154 and skip to Phar 7.09, item 165

154. _____ (1) (a) Prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device.

Compliance Date:

155. _____ (b) Prescription orders for schedule II controlled substances may not be transmitted electronically except as emergency orders (Wis. Admin. Code Phar 8.09).

(2) In order to dispense a prescription transmitted electronically, the following must be assured by the pharmacist:

156. _____ (a) The transmission is only to the pharmacy of the patient's choice, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.

157. _____ (b) The transmission contains the sender's name and telephone number, the time and date of transmission, and the pharmacy intended to receive the transmission.

158. _____ (c) The transmission is designated "electronically transmitted prescription," or words or abbreviations to that effect.

159. _____ (d) Contains all other information that is required in a prescription order.

160. _____ (3) A secure method of validation such as the prescribing physician's electronic signature, accompanies the electronically transmitted prescription.

161. _____ (4) Any visual or electronic document received electronically are accessible only within the professional service area of the pharmacy (to protect patient confidentiality and assure security).

162. _____ (5) The pharmacist must ensure the security, integrity, and confidentiality of the prescription order. The electronic system has adequate security and system safeguards to prevent and detect unauthorized access, modification, or manipulation of patient records. Any alterations in the drug order are documented including the identification of the pharmacist responsible for the alteration.

163. _____ (6) Password(s), known only by those authorized to use the system, is required to gain access to mail containing prescription orders.

164. _____ (7) The pharmacist does not use any electronic device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying prescription orders or in order to circumvent pharmacy laws.

PHAR 7.09 Automated dispensing systems.

If pharmacy does not use an automated dispensing system (ADS), place "**N/A**" in item 165 and skip to Phar 7.10, item 184.

165. _____ (1) (a) The "ADS" performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

166. _____ (2) The "ADS" may be used in a community pharmacy, as provided in this section.

167. _____ (3) The "ADS" may be used as provided in this section by an institutional pharmacy serving an inpatient health care facility, that has an established program of receiving prescription orders, and dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. The "ADS" used by the institutional pharmacy shall only be located in that institutional pharmacy or within the inpatient health care facility.

(4) The managing pharmacist of a community or an institutional pharmacy is responsible for the following:

168. _____ (a) The "ADS" is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed and complies with record keeping and security safeguards pursuant to sub (5).

169. _____ (b) Implementing an ongoing quality assurance program that monitors performance of the "ADS", which is evidenced by written policies and procedures.

170. _____ (c) Providing the Board with prior written notice of the installation or removal of an "ADS" including: name and address of the pharmacy, initial location of the "ADS", and identification of the managing pharmacist.

171. _____ (d) Assigning, discontinuing or changing personnel access to the system.

172. _____ (e) Assuring access to the medications complies with state and federal laws.

173. _____ (f) Assuring the "ADS" is stocked accurately and in accordance with established written policies and procedures.

(5) The "ADS" complies with the following provisions:

174. _____ (a) The pharmacy maintains on-site documentation including: name and address of the pharmacy or inpatient health care facility where the system is being used, the system manufacturer's name, model and serial number, description of how the system is used, written quality assurance procedures to determine continued appropriate use of the system, and except as required pursuant to par (b), written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

175. _____ (b) All written policies and procedures are maintained in the pharmacy responsible for the "ADS".

176. _____ (c) The "ADS" has adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

Compliance Date:

177. _____ (d) Records and data kept by the "AD"S meet the following requirements: all events involving the contents of the ADS are recorded electronically, records are maintained by the pharmacy and are available to the Board (including: the time and location of the system accessed, identification of the individual accessing the system, type of transaction, name, strength, dosage form and quantity of the drug accessed; name of the patient for whom the drug was ordered, such additional information as the managing pharmacist may deem necessary.)

1788. _____ (e) The stocking of all medications in the "ADS" is accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an "ADS" is, located within a pharmacy the supervision is direct.

179. _____ (f) A record of medications stocked into the "ADS" is maintained for five (5) years and includes identification of the person stocking and pharmacist checking for accuracy.

180. _____ (g) All containers of medications stored in the "ADS" are packaged and labeled in accordance with state and federal law.

181. _____ (h) All aspects of handling controlled substances meet the requirements of all state and federal laws.

182. _____ (i) The "ADS" provides a mechanism for securing and accounting for medications removed from and subsequently returned to the "ADS", in accordance with state and federal law.

183. _____ (j) The "ADS" provides a mechanism for securing and accounting for medication returned to the system and accounting for wasted medications in accordance with state and federal law.

PHAR 7.10 Administration of drug products and devices other than vaccines.

A pharmacist may administer a drug product or device in the course of teaching a patient self-administration technique. Pharmacists administering a prescribed drug product or device by injection must satisfy each of the following:

184. _____ Completed a 12-hour course of study and training, approved by the American Council on Pharmaceutical Education (ACPE) or the Board in injection techniques, emergency procedures, and record keeping.

185. _____ Maintain at least $1,000,000 in liability insurance for each occurrence, and $2,000,000 for all occurrences in any one-policy year, for errors, omissions or neglect in the administration by injection. The pharmacist must maintain proof of this requirement and provide upon request of the Board or Department.

186. _____ Maintain 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.

PHAR 7.12 Central fill pharmacy.

187. _____ (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.

(b) "Originating pharmacy" means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

188. _____ (2) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:

189. _____ (a) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

190. _____ (b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the Board or its agent.

191. _____ (c) The central fill pharmacy and originating pharmacy maintain a written filling protocol delineating each pharmacy's assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of this chapter and Wis. Admin. Code Phar 8.

192. _____ (d) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirem3ents of this chapter and Wis. Admin. Code Phar 8, and which are not assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

193. _____ (e) The originating pharmacy shall at all times remain solely responsible to perform and comply with the requirements of Wis. Admin. Code Phar 7.01(1)(e) and (em).

194. _____ (f) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review of the patient, drug initialization review, refill authorizations, interventions and drug interactions.

Compliance Date:

195. _____ (g) The prescription label attached to the container shall contain the name and address of the originating pharmacy as the licensed facility from which the prescribed rug or device was dispensed for purposes of s. 450.11(4)(a)1., Stats. The date on which the prescription was dispensed for purposes of s. 450.11(4)(a)2., Stats., shall be the date on which the central fill pharmacy filled the prescription order.

196. _____ (h) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

197. _____ (i) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law.

198. _____ (j) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding dispensing pursuant to a prescription order and track the prescription order during each step in the dispensing process.

199. _____ (k) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with this section.

200. _____ (l) The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law.

UNIFORM CONTROLLED SUBSTANCES ACT

Wis. Stat. § 961.23, Dispensing of schedule V substances. (Non-legend)

201. _____ (1) Products are **sold in good faith as a medicine**.
Even without 48-hour violations, pharmacists must be prepared to substantiate the clinical need for frequent sales to the same individual. (Wis. Stat. § 961.38(4))

202. _____ (2) Sold only by the pharmacist.

203. _____ (3) The name and address of the pharmacy is attached to the **immediate** container.

204. _____ (4) **The pharmacist** records the name and address of the purchaser, as well as the name and quantity of product sold.

205. _____ If purchaser is unknown to the pharmacist, identification is validated.

206. _____ The pharmacist and the purchaser sign the record.

_____ (5) Sales are restricted:

207. _____ (a) 8 ounces of a produce containing opium.

208. _____ (b) 4 ounces of any other Schedule V substance.

209. _____ (c) 48-hour interval is observed.

CHAPTER PHAR 8 WISCONSIN ADMINISTRATIVE CODE

PHAR 8.02 Records for controlled substances.

210. _____ (1) Records are **complete and accurate** for each controlled substance received, distributed, dispensed or disposed of in any other manner.

(2) Records required by federal controlled substances act and Wis. Stat. § 961, are:

211. _____ (a) Maintained at the pharmacy location where **received and dispensed or manufactured**.

212. _____ (b) Available **for inspection** for at least five (5) years.

213. _____ (c) Includes a biennial inventory of all Schedule II, III, IV, and V substances (readily retrievable). Wisconsin DEA district office, 1000 N. Water St., Suite 1010, Milwaukee, WI 53202, (414-297-3395) provides instructions and forms for destruction of controlled substances.

(3) Records are maintained as follows:

214. _____ (a) Records of Schedule II controlled substances (other than prescription orders) are maintained separately.

215. _____ (b) Records of Schedule III, IV, and V controlled substances are separate or are readily retrievable.

216. _____ (c) Executed Schedule II order forms (**DEA Form #222**) **completed and kept in** the pharmacy.

217. _____ (d) Records of controlled substances distributed or dispensed include:

218. _____ 1. Name of the substance.

219. _____ 2. Dosage form, strength, and quantity.

220. _____ 3. Quantity and date of distribution, as well as name, address and DEA registration number to whom distributed.

Compliance Date:

4. Number of units, date of receipt, and name, address and DEA registration number from whom received.
5. Name and address to whom **dispensed**, date, quantity dispensed, and name or initials of pharmacist dispensing.

(e) Records for dispensed Schedule V substances:

1. If dispensed as a prescription, it is filed the same as Schedule III and IV orders.
2. If dispensed other than pursuant to prescription order, the required entry (see Wis. Stat. § 961.23) is placed in a **bound Schedule V register** at the time of transaction.

(f) In any instance that a pharmacy authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy shall also send a copy to the Board within 2 weeks of filing with the DEA.

PHAR 8.03 Filing prescription orders.

Controlled Rx orders are filed chronologically, are readily accessible; and maintained for at least five (5) years.

Schedule II prescription orders are filed separately **or** are filed with Schedule III, IV, and V orders (which have a one-inch red "C" in the lower right corner).

Schedule III, IV and V prescription orders are filed separately **or** have a one-inch red "C" if filed with non-controlled Rx orders. (Schedule II Rx orders are **not** filed with non-controlled Rx orders.) The requirement to mark with a red "C" may be waived if the pharmacy has an automated processing system or electronic record keeping that permits identification by prescription order number and retrieval of original documents by prescriber's name, patient name, drug dispensed and date filled.

PHAR 8.04 Purpose of issue of prescription.

Pharmacists are aware of their responsibility to dispense for legitimate medical purposes.

Controlled substances are **not** dispensed (**pursuant to a prescription order**) to a practitioner for the purpose of administration or general dispensing to patients.

Controlled substances (Schedule II, III, or IV) are **not** dispensed pursuant to a prescription order to a practitioner for their own personal use. [Wis. Stat. § 961.38(5)]

PHAR 8.05 Dispensing controlled substances.

(1) Written prescription orders for all controlled substances are **dated** and **signed** on the day issued and contain the following:

(a) Full name and address of patient.
(b) Name, address, and DEA number of practitioner.
(c) Name, strength, dosage form and quantity of drug prescribed.
(d) Directions for use.

Prescription orders (in ink or typewritten) are **signed by the practitioner**.
DEA registration of practitioner is validated by pharmacist.

(2) The **pharmacist** initials and dates prescription orders for **all** controlled substances.

Note: If the party receiving a Schedule II prescription is not personally known to the pharmacist, the printed name, signature and address of that person is recorded on the reverse side of the prescription order.

(3) Prescriptions containing Schedule II substances are dispensed pursuant to **written prescription orders signed by the practitioner**.

Controlled substance prescriptions must be dispensed within 60 days following the date of issue of the prescription order.
Note: **Date of receipt on face of Rx order**.

(4) Prescription orders for controlled substances are not dispensed unless the prescription order contains all of the information required in sub. (1). For any controlled substances prescription order, a pharmacist may not add, modify or clarify the patient's name, drug prescribed, except for generic substitution as permitted by law and the prescribing practitioner's signature. After consultation with the prescribing practitioner, a pharmacist may add, modify, or clarify the strength, dosage form, quantity prescribed, date of issuance and directions for use for a schedule II controlled substance prescription order. For a schedule II controlled substance prescription order, a pharmacist may add, modify, or clarify the registration number of the practitioner, and the address of the practitioner and the patient if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation with the practitioner. A pharmacist may add, modify, or clarify any information allowed in this subsection missing from a prescription order for a Schedule III, IV, or V controlled substance that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner. A patient may only provide information to a pharmacist to add, modify or clarify the patient'' address. The prescription order shall be initialed and dated by the pharmacist and shall indicate the addition, modification or clarification of information and the manner by which the pharmacist obtained that information.

Compliance Date:

PHAR 8.06 Renewing prescriptions for controlled substances.

237. _____ (1) Prescriptions for Schedule II controlled substances are **not** renewed.

238. _____ (2) The prescribing practitioner may authorize renewals of Schedule III or IV controlled substances on the original prescription order or through an electronic or oral renewal authorization.

239. _____ (a) The pharmacist obtaining an electronic or oral authorization notes the following on the prescription order, medication profile, or document:

240. _____ 1. Date authorization is received.

241. _____ 2. Quantity of drug authorized.

242. _____ 3. Number of renewals.

243. _____ 4. Identification of practitioner authorizing the renewals if different from the original prescriber.

244. _____ 5. Identification of the pharmacist who received the authorization.

245. _____ (b) The quantity of each renewal authorized is equal to or less than the quantity authorized for the initial dispensing of the original prescription.

246. _____ (3) Renewal of prescriptions for Schedule III and IV substances is limited to:

247. _____ (a) Within 6 months of date of **original order**.

248. _____ (b) No more than five (5) **authorized** renewals.

249. _____ (4) Prescriptions for Schedule V substances are renewed **only** as expressly authorized by the practitioner.
Note: **The 6-month/5 renewal limitations do not apply to prescription orders for Schedule V substances**.

PHAR 8.07 Partial dispensing of controlled substances.

250. _____ (1) Substances in Schedules III, IV, and V may be partially dispensed.

251. _____ (2) Partial dispensing of Schedule II substances is permissible: If pharmacist unable to supply full quantity ordered. Remaining portion may be dispensed within 72 hours of the first partial dispensing (or prescriber notified).
No further quantity dispensed after 72 hours. A new prescription order will be required.

252. _____ (3) Partial dispensing of Schedule II substances is permissible if patient is in long term care facility (LTCF), or has a medical diagnosis documenting a "terminal illness". Valid for 60-day period.
Pharmacist enters each partial dispensing. Enter "LTCF" or "terminal illness" on prescription.

253. _____ (4) Information pertaining to current prescription orders for Schedule II controlled substances for patients in an "LTCF" or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

254. _____ (a) Display or printout of: the original prescription order designation, date of issue, identification of prescribing practitioner, identification of patient, name and address of the "LTCF" or name of address of the hospital or residence of the patient, identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3).

255. _____ (b) Immediate updating of the prescription order record each time there is partial dispensing of the prescription.

256. _____ (c) Retrieval of partially dispensed Schedule II prescription information identical to that required by Wis. Admin. Code Phar 7.05(2) for all prescription renewal information.

PHAR 8.08 Labeling prescriptions containing controlled substances.

257. _____ The prescription label for controlled substances includes: Date dispensed, pharmacy name and address, Rx number; full name of patient; name of the practitioner; directions for use; and appropriate cautionary statements.

PHAR 8.09 Emergency dispensing of Schedule II substances.

(1) The pharmacists understand the criteria for "emergency" to mean that the practitioner has determined that:

258. _____ (a) Immediate administration of the CS II substance is necessary.

259. _____ (b) No appropriate alternative, including non-Schedule II substance.

260. _____ (c) Not possible to provide written order prior to dispensing.

Note: **It is important for pharmacists to be aware that the "emergency" procedure should not be used for routine dispensing of Schedule II substances**.

(2) In an emergency when the pharmacist dispenses a Schedule II substance with an electronic or oral authorization:

261. _____ (a) The quantity prescribed and dispensed is limited to the amount adequate for the emergency situation.

262. _____ (b) The Rx order is immediately reduced to writing by the pharmacist, including all information listed in Wis. Admin. Code Phar 8.05 except the signature of the practitioner.

Compliance Date:

263. _____ (3) If the practitioner is not known to the pharmacist, reasonable effort is made to authenticate the prescriber.
264. _____ (4) The pharmacist assures receipt of a written order within 7-days after the authorized emergency dispensing (or it is postmarked within 7-days). The written order will include:
265. _____ (a) "authorization for emergency dispensing" on the front.
266. _____ (b) date of the electronic or oral order.
267. _____ Upon receipt, the pharmacist attaches the written order to the oral emergency prescription order.
268. _____ **If the practitioner fails to deliver the written order**, the Department of Safety and Professional Services is notified. **(Failure to provide this notification voids the authority to dispense emergency orders.)**

PHAR 8.11 Controlled substances in emergency kits for long-term care facilities.

If you do not service a "LTCF," place "**N/A**" in item 269 and skip to Phar 8.12, item 274.

Long-term care facilities, which are not registered with the DEA, meet the following requirements regarding emergency kits containing controlled substances:

269. _____ (1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.
270. _____ (2) The pharmaceutical services committee of the facility have security safeguards for each emergency kit stored in the "LTCF", which include the designation of the individuals who may have access to the kits and a specific limitation on the type and quantity of controlled substances permitted to be placed in each emergency kit.
271. _____ (3) A pharmacist is responsible for control and accountability for kits within the "LTCF", which includes the requirement that the "LTCF" and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.
272. _____ (4) The pharmaceutical services committee established the emergency medical conditions under which the controlled substances may be administered to patients in the "LTCF", which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.
273. _____ (5) The pharmacist is aware that noncompliance with these rules may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in "LTCF".

PHAR 8.12 Facsimile Transmission.

274. _____ (1) A pharmacist may dispense a prescription, other than a Schedule II based on a fax prescription from a practitioner or their agent.
275. _____ (a) It shall contain all the information of a valid written prescription as well as the date and time of transmission and the telephone number and name of the transmitter.
276. _____ (b) If fading paper, it must be copied and attached to the copy received.
277. _____ (2) Schedule II prescriptions may be received if all the requirements of section (1) are met and any of the following:
278. _____ (a) The prescription is to be compounded for the direct parenteral, intravenous, intra muscular, subcutaneous or intra spinal infusion to a patient.
279. _____ (b) The patient resides in a long term care facility or meets the eligibility requirements for placement in a long term care facility but elects to reside at home, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.
280. _____ (c) The patient is enrolled in a hospice certified by Medicare under title XVIII or licensed by this state.
281. _____ (3) A prescription order transmitted by facsimile shall be considered the original written prescription order.

CHAPTER PHAR 10 WISCONSIN ADMINISTRATIVE CODE (STANDARDS OF PROFESSIONAL CONDUCT)

282. _____ All pharmacists at this pharmacy are aware of the specific practices enumerated in Wis. Admin. Code Phar 10.03.
283. _____ The pharmacist avoids dispensing or **causing to be dispensed** a drug, which is outdated or contaminated or known by the pharmacist to be unsafe for consumption.

Note: While it is not the objective of this self-inspection project to enumerate conduct considered unprofessional, as listed in Wis. Admin. Code Phar 10, there is a need to identify problems created when a pharmacy's inventory includes examples of long-outdated and/or unacceptable numbers of outdated pharmaceuticals and chemicals. Reasonable effort should be demonstrated to remove such items from regular inventory and expedite their return or destruction. In the opinion of the Pharmacy Examining Board, antique containers and display pieces containing crude drugs are not viewed as violations. But good faith requires the removal of chemicals (undated or outdated) from containers in the professional service area unless they are conspicuously set apart in display containers.

284. _____ Pharmacists are required to report to the Board any information that reasonably suggests there is a probability that a prescription drug or device dispensed by a pharmacist has caused or contributed to substantial bodily injury or death of a patient.

CHAPTER PHAR 15 WISCONSIN ADMINISTRATIVE CODE (STERILE PHARMACEUTICALS)

These rules apply to pharmacies engaged in the preparation of sterile pharmaceuticals. If pharmacy does not compound sterile pharmaceuticals, please place "**NA**" in item 285 and skip to Phar 16, item 329.

Compliance Date:

PHAR 15.03 Policy and procedure manual

285. _____ Pharmacy prepares and maintains a policy and procedure manual for compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceuticals.

286. _____ The manual includes a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, guidelines regarding patient education and provision of pharmaceutical services and up-to-date information on preparation of sterile pharmaceuticals.

287. _____ The policy and procedure manual is available to all personnel and updated annually or as needed to reflect current practice.

288. _____ The policy and procedure manual is available for inspection by the Board or its designee.

PHAR 15.04 Physical requirements

289. _____ (1) The pharmacy has a structurally isolated area designated for preparation and documentation associated with sterile pharmaceuticals. Entry and access is restricted to designated personnel to avoid traffic and airflow disturbances. The designated area is of sufficient size to accommodate a laminar airflow hood and proper storage of drugs and supplies.

(2) Environment maintains:

290. _____ (a) A class 100 environment during the normal activity in the workplace where critical objects are exposed and critical activities are performed.

291. _____ (b) Appropriate disposal containers as required by OSHA in 29 CFR Part 1910 for timely disposal of needles, syringes, infectious and cytotoxic wastes.

292. _____ (c) Appropriate environmental controls, including a class II biological safety cabinet if cytotoxic drug products are prepared.

293. _____ (d) Temperature-controlled delivery containers as necessary.

294. _____ (e) For hand washing, a sink with hot and cold running water in close proximity.

295. _____ (f) Administration devices, if necessary.

296. _____ (3) Sufficient reference materials related to sterile pharmaceuticals are available.

297. _____ (4) The designated area is closed and disinfected regularly with appropriate agents.

PHAR 15.05 Records and Reports

298. _____ (1) Maintains records and reports of:

299. _____ (a) Training and competency evaluations of personnel.

300. _____ (b) Documentation of refrigerator and freezer temperatures.

301. _____ (c) Certification of laminar flow hoods.

302. _____ (2) Minimal labeling requirements for sterile pharmaceuticals prepared for a single patient if the pharmaceuticals are to be completely administered within 28 hours:

303. _____ (a) The identity of all solutions and ingredients and their corresponding amounts, concentration or volumes on the final preparation container in such a manner as to allow the locating of problematic final products.

304. _____ (b) The identity of personnel involved in preparation.

305. _____ (c) The date and time of pharmacy preparation where applicable.

306. _____ (d) The final sterile pharmaceuticals expiration date and storage requirements, where applicable.

PHAR 15.06 Delivery of service

307. _____ The pharmacist assures the appropriate environmental control of all products shipped.

PHAR 15.07 Emergency kits

308. _____ When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy supplies the patient or the patient's agent with emergency drugs, when authorized by the physician under protocol, if an emergency situation has been anticipated by either the physician, nurse or pharmacist.

309. _____ The pharmacy provides written instructions on the storage and record keeping requirements for the emergency kit.

Compliance Date:

PHAR 15.08 Cytotoxic drugs

If pharmacy does not compound cytotoxic drugs, place "**NA**" in item 320 and skip to Phar 15.09, item 326.

310. _____ All cytotoxic drugs are compounded in a vertical flow, class II biological safety cabinet. If non-exposed surfaces become contaminated with cytotoxic drugs, no products other than cytotoxic drugs are compounded in this cabinet until the cabinet is decontaminated utilizing appropriate techniques

311. _____ Personnel are protected by a protective barrier or apparel which includes gloves, gowns and other applicable protective apparel as described in 29 CFR PART 1910 of OSHA regulations.

312. _____ Appropriate safety and containment techniques for compounding cytotoxics are used in conjunction with aseptic techniques required for preparation of sterile pharmaceuticals.

313. _____ Pharmacy disposal and patient and caregiver education regarding disposal of cytotoxic waste complies with all applicable local, state, and federal requirements.

314. _____ Written procedures for the handling of both major and minor spills of cytotoxic drugs are included in the pharmacy policy and procedure manual.

315. _____ Prepared doses of cytotoxic drugs are dispensed, labeled with proper precautions on the primary and shipping container and are shipped in a manner that minimizes the risk of accidental rupture of the primary container.

PHAR 15.09 Labeling

In addition to the labeling requirements of Wis. Stat. § 450.11(4).

316. _____ Control or lot number.

317. _____ Expiration date and time, when applicable

318. _____ Appropriate auxiliary labeling, including precautions.

319. _____ Storage requirements.

320. _____ Identification of the responsible pharmacist

PHAR 15.10 Patient training

321. _____ A Pharmacist is responsible for documenting the patient's training and competency in managing the type of therapy provided by the pharmacist to the patient if administered by the patient or a caregiver. Pharmacists are responsible for the provision or supervision of the patient training process in any area that relates to compounding, administration, labeling, storage, stability, or incompatibility. A pharmacist is responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

PHAR 15.11 Quality Assurance

322. _____ There is a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.

323. _____ The area designated in Wis. Admin. Code Phar 15.04 (2)(a) for preparing sterile pharmaceuticals is certified by an independent contractor. Certification takes place before initial use or after relocation and at least annually.

324. _____ The pharmacy has written procedures requiring sampling for microbial contamination through a validation procedure, simulation of actual aseptic preparation, and by using bacterial growth medium to culture environmental samples.

325. _____ If compounding of parenteral solutions is performed using non-sterile chemicals, extensive end product sterility testing is documented. Quarantine procedures shall be developed if there is a test failure.

326. _____ A pharmacy has written justification of the assigned expiration date for pharmacy prepared sterile pharmaceuticals.

327. _____ A pharmacy has documentation of quality assurance audits, including infection control and sterile technique audits at least annually.

328. _____ A pharmacy has procedures to assure consistent preparation of sterile pharmaceuticals.

CHAPTER PHAR 16 WISCONSIN ADMINISTRATIVE CODE (CONTINUING EDUCATION)

PHAR 16.02 Continuing education required; waiver

329. _____ (1) At the time of making application for renewal of a license: Each pharmacist required to complete the continuing education requirement provided under Wis. Stat. § 450.085, shall:

330. _____ (a) Sign a statement on the application for renewal certifying that the pharmacist has completed at least 30 hours of acceptable continuing education programs within the 2-year period immediately proceeding the date of his or her application for renewal. (This subsection does not apply to an application for renewal of a license that expires on the first renewal date after the date on which the Board initially granted the license.)

Note: The PEB will grant 15 hours of continuing education credit for every one credit of academic training received in coursework, which leads to a degree granted by an American Council on Pharmaceutical Education (ACPE) approved school of pharmacy.

Compliance Date:

331. _____ (2) A pharmacist may apply to the Board for waiver of the requirements of this chapter on grounds of exceptional circumstances such as prolonged illness, disability or other similar circumstances that the pharmacist indicates have prevented him or her from meeting the requirements. The Board will consider each application for waiver individually on its merits.

PHAR 16.03 Acceptable continuing educational programs

332. _____ The educational programs used for CE are approved by the American Council on Pharmaceutical Education (ACPE) at the time of the pharmacist's attendance or other Board approved programs. To date the Board has only approved ACPE as a provider.

PHAR 16.04 Evidence of compliance

333. _____ The Board accepts as evidence of compliance with this chapter certification by a providing institution or organization that a pharmacist has attended and completed approved continuing education programs. Certification may be the original or verified copies of, documents certifying attendance and completion.

PHAR 16.05 Retention requirement

334. _____ The pharmacist shall retain evidence of compliance for 3 years following the renewal date for the biennium for which 30 hours of credit are required for renewal of a license.

PHAR 16.06 Audit

335. _____ The Board may require any pharmacist to submit his or her evidence of compliance with the continuing education requirements to audit compliance.

In the space provided below, for each item that received "NA" following your inspection, indicate why this rule does not apply to your pharmacy. (Attach additional pages if necessary.)

Certification of Applicant:

The undersigned attests that the facts and statements herin contained are true and correct based upon personal knowledge of the undersigned.

Signature **Date** __/__/____

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Kimberly Wood, Program Assistant Supervisor-Advanced, on behalf of Christa Wilson	10/26/2021
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
12/2/2021	☐ Yes ☒ No	Newsletter Matters

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if applicable:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	N/A

10) Describe the issue and action that should be addressed:

Newsletter Liaison Christa Wilson will discuss potential newsletter content topics. The Board should consider the possible topics noted below and consider how to proceed in terms of sending out a communication.

- Administrative Rules:
  - Phar 8, Controlled Substances Requirements
- Other Topics:
  - Gabapentin

11) Authorization

Kimberly Wood	*10/26/2021*
Signature of person making this request	Date
Supervisor (Only required for post agenda deadline items)	Date
Executive Director signature (Indicates approval for post agenda deadline items)	Date

Directions for including supporting documents:

1. This form should be saved with any other documents submitted to the Agenda Items folders.
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
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski		**2) Date when request submitted:** Tuesday, November 23, 2021 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: December 2, 2021	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** Implement WI Act 9 – 100 most prescribed drugs	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☒ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	

10) Describe the issue and action that should be addressed:

"Motion for the Board to delegate authority to a board member to work with DSPS staff to develop and distribute a list of the 100 most commonly prescribed drugs as required under s. 450.13 (5m) (b)."

11) Authorization

Signature of person making this request	**Date** November 23, 2021
Supervisor (Only required for post agenda deadline items)	**Date**
Executive Director signature (Indicates approval for post agenda deadline items)	**Date**

Directions for including supporting documents:

1. **This form should be saved with any other documents submitted to the Agenda Items folders.**
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
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**11/18/21** **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
12/02/21	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Phar 8, Requirements for Controlled Substances** **2. Phar 15, Compounding Pharmaceuticals** **3. Pending or Possible Rulemaking Projects**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete **Appearance Request** for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

Attachments:
1. Phar 8 Rule Draft with Comments
2. Phar 15 Redlined Code Text
3. Rule Projects Chart

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization

Nilajah D. Hardin — 11/18/21

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 PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate ch. Phar 8 relating to requirements for controlled substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.31, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.11 (1b) (a) (1), 450.02 (2), 450.02 (3) (a), (b) (d) and (e), ~~and~~ 961.31, and 961.38 (2) Stats.

Commented [HN-D1]: Clearinghouse Comment #1

Explanation of agency authority:

Commented [HN-D2]: Clearinghouse Comment #1 and 5

Section 15.08 (5) (b) provides that the board "[s]hall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 450.11 (1b) (a) (1) states ""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 s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10; and any other facility identified by the board by rule."

Section 450.02 (2) states that the board "shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05."

Section 450.02 (3) provides that "[t]he board may promulgate rules:

(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

(b) Establishing security standards for pharmacies.

…

(d) Necessary for the administration and enforcement of this chapter and ch. 961.

(e) Establishing minimum standards for the practice of pharmacy."

Section 961.31 gives the Pharmacy Examining Board authority to "promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state."

Section 961.38 (2) states that "In emergency situations, as defined by rule of the pharmacy examining board, schedule II drugs may be dispensed upon an oral prescription of a practitioner, reduced promptly to a written hard copy or electronic record and filed by the pharmacy. Prescriptions shall be retained in conformity with rules of the pharmacy examining board promulgated under s. 961.31. No prescription for a schedule II substance may be refilled."

Related statute or rule: N/A

Plain language analysis:

This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. The rule project simplifies recordkeeping requirements for controlled substances, removes restrictions on receipt of prescriptions via facsimile machine, partial dispensing, renewals, labeling, and emergency kits in long-term care facilities.

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

The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

Comparison with rules in adjacent states:

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.600 to 68/1330.800 outlines requirements for pharmacy standards and pharmacy operations. Illinois law requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA (IL 68/1330.710). Illinois administrative rule requires that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years (IAC 3100.360). Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available,

and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription (IAC 3100.400).

Iowa: The Iowa Pharmacy Board requires a pharmacy to maintain controlled substance records for at least 2 years and to segregate Schedule I and II drug records from other controlled substance records (Iowa Admin. Code 657-10.36). Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand (Iowa Admin. Code 657-10.18). Iowa only requires a pharmacist to report theft or loss of controlled substances to the Pharmacy Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to merely report to the DEA (Iowa Admin. Code 657-10.21). Iowa also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Iowa Admin. Code 657-10.26).

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the DEA within 10 days. There does not appear to be a separate requirement to report it to the Pharmacy Board (Mich. R 338.3141). Inventory must be taken of all controlled substances at least annually (Mich. R 338.3151 and 338.3152). Controlled substance records must be retained for at least 5 years, with the first 3 in hard copy form and in the last 2 may be kept electronically. Michigan also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Michigan R 338.3164 and 338.3165).

Minnesota: Minnesota requires a perpetual inventory of Schedule II substances which must be reconciled monthly (Minn. Admin. Code 6800.4600). Pharmacists must report loss or theft of controlled substances to the DEA immediately. There is no requirement that a separate report be made to the state (Minn. Admin. Code 6800.4800). All prescription information must be maintained for at least 2 years (Minn. Admin. Code 6800.3100).

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board completed a comprehensive review of ch. Phar 8, Requirements for Controlled Substances, in order to identify and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices. The board also evaluated ch. Phar 8 for ways to reduce the regulatory impact on pharmacies without negatively impacting public safety.

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

The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

A fiscal estimate and economic impact analysis are 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.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; phone (608) 267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on October 20, 2021 at 9:00 a.m. to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Phar 8 is repealed and recreated to read:

Chapter Phar 8
REQUIREMENTS FOR CONTROLLED SUBSTANCES

Phar 8.01 Federal registration and compliance with federal, state, and local laws and regulations.
(1) FEDERAL REGISTRATION REQUIRED. To possess, manufacture, distribute, dispense, or conduct research with controlled substances in this state, pharmacies and pharmacists shall register with the drug enforcement administration as required under federal law.
(2) CONTROLLED SUBSTANCES AUTHORIZATION UNDER FEDERAL REGISTRATION. As provided under s. 961.32 (1m) (a), Stats., pharmacies and pharmacists registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, and conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the provisions of ch. 961, Stats.
(3) COMPLIANCE WITH LAWS AND REGULATIONS. Failure to register with the drug enforcement administration or otherwise comply with applicable federal, state, and local laws and regulations relating to possessing, manufacturing, distributing, dispensing, or conducting research with controlled substances constitutes unprofessional conduct for purposes of s. 450.10, Stats.

(4) Nothing in these rules shall prohibit long term care facilities from obtaining an emergency kit, from a DEA registered pharmacy, in compliance with federal law.

Commented [HN-D3]: Public Comment (John Long)

Note: The United States Department of Justice Drug Enforcement Administration has published a pharmacist's manual, which provides an informational outline of the federal Controlled Substances Act. It can be found online at: https://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

Phar 8.02 Purpose of issue of prescription order. Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

Phar 8.03 Valid prescription requirements. (1) A pharmacist may not dispense controlled substances for a prescription the pharmacist knows, or reasonably should know, is not a valid prescription under applicable federal, state, and local laws and regulations.

(2) An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid. A pharmacist knowingly dispensing pursuant to such a purported order, as well as the practitioner issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

~~**(3)** As provided under s. 961.38 (4r), Stats., a pharmacist is immune from any civil or criminal liability and from discipline under s. 450.10, Stats., for any act taken by the pharmacist in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.~~

(4) A valid signature is required for controlled substance dispensing and shall include all of the following:

(a)

(b)

Phar 8.04 Notification of suspicious orders for and theft or loss of controlled substances. A pharmacy or pharmacist shall notify the board of a suspicious order or series of orders for controlled substances or the theft or loss of controlled substances on the same day notification is required to be provided to the drug enforcement administration. Notification to the board shall include all information required to be provided in the notification to the drug enforcement administration.

Phar 8.05 Recordkeeping. (1) Records required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats., shall be maintained for at least ~~5~~ 2 years from the date the drug was received, manufactured, distributed, or 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, Stats., whichever is sooner.

(2) Records shall be readily retrievable, easily readable, and available for inspection by authorized persons for at least ~~5~~ 2 years from the date of such record.

(3) An electronic recordkeeping system shall have the capability of producing a printout of records as required under this section.

(4) The pharmacist-in-charge shall oversee monthly inspections, maintenance, ~~and reconciliation~~ of all controlled substances, as well as quarterly reconciliation of targeted schedule III-IV substances as identified by the pharmacist-in-charge, including maintaining a perpetual inventory for all Schedule II controlled substances.

~~**Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats. (1)** DEFINITION. In this section and s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats., any hospital, nursing home, community-based residential facility, county home, county infirmary, county~~

Commented [HN-D4]: Public Comment (Dawn Wypiszynski): "Would this note make the entire DEA pharmacist's manual enforceable law?"

DSPS Admin Rules Comments: Notes are provided for additional information for the reader, they are not intended to introduce outside standards into WI law

Commented [HN-D5]: Public Comment (Dawn Wypiszynski): "What defines what a pharmacist 'reasonably should know?"

Commented [HN-D6]: Public Comment (Dawn Wypiszynski): "Is this simply separating a prescription for practitioner general dispensing from a medication order for practitioner general dispensing"

Commented [HN-D7]: Clearinghouse Comment #4 "A number of provisions, including ss. Phar 8.03 (3), 8.06 (2), and 8.08, appear to be reiterations of statutes without additional interpretation or effect. Consider whether those provisions need to be included in the administrative code."

Commented [HN-D8]: Public Comment (PSW): Define "valid signature"

Public Comment (Dawn Wypiszynski): "Request clarification of definition of valid signature for controlled substance orders"

Commented [HN-D9]: Public Comment (Dawn Wypiszynski): Provide proper method for contacting the Board

Commented [HN-D10]: Clearinghouse Comment #2 (add sections or reorganize)

Commented [HN-D11]: Public Comment (PSW): Should be 2 years not 5 to be consistent with s. 961.325 (2), stats.

Commented [HN-D12]: Public Comment (John Long)

Commented [HN-D13]: Public Comment (PSW): Definition of "perpetual inventory"?

Commented [HN-D14]: Clearinghouse Comment #4 "A number of provisions, including ss. Phar 8.03 (3), 8.06 (2), and 8.08, appear to be reiterations of statutes without additional interpretation or effect. Consider whether those provisions need to be included in the administrative code."

Public Comment (John Long): Add "2d. The drug is delivered to the patient's home, or any address as requested by the patient, through mail, common carrier or delivery service"

~~hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 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 s. 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) (e), Stats.~~

~~**(2)** IDENTIFICATION CARD REQUIREMENT. As provided under s. 450.11 (1b) (b) and (e), Stats., a controlled substance included in schedule II or III of ch. 961, Stats., may not be dispensed, and may not be delivered to a representative of the ultimate user, without an identification card belonging to the person to whom the drug is being dispensed or delivered. An identification card is not required if any of the following applies:~~

~~**(a)** The drug is administered or dispensed directly to the ultimate user by a practitioner.~~

~~**(b)** The pharmacist or other person dispensing or delivering the drug has personal knowledge of the person to whom the drug is dispensed or delivered, and that the person is the ultimate user or the ultimate user's authorized representative.~~

~~**(c)** The drug is delivered to a health care facility to be administered in the health care facility.~~

Phar 8.07 Dispensing schedule II controlled substances in emergency situations under s. 961.38 (2), Stats. (1) DEFINITION. For purposes of dispensing a schedule II controlled substance under s. 961.38 (2), Stats., "emergency situation" means a situation in which the prescribing practitioner determines all of the following:

(a) Immediate administration of the schedule II controlled substance is necessary for proper treatment of the patient.

(b) No appropriate alternative treatment is available, including the administration of a drug that is not a schedule II controlled substance.

(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.

(2) REQUIRED NOTIFICATION. A dispensing pharmacist shall notify the board of the failure of a prescribing practitioner to deliver a written or electronic prescription within 7 days after authorizing an emergency oral prescription for a schedule II controlled substance. The notification shall be provided to the board on the same day notification is required to be provided to the drug enforcement administration and shall include all information required to be provided in the notification to the drug enforcement administration.

~~**Phar 8.08 Dispensing and sale of pseudoephedrine products.** The dispensing and sale of pseudoephedrine products shall meet all applicable federal, state, and local laws and regulations relating to schedule V controlled substances, including all the following requirements:~~

~~**(1)** The requirements under ss. 961.23 and 961.38 (4), Stats., for dispensing schedule V controlled substances.~~

~~**(2)** The requirements under s. 961.235, Stats., for records relating to sales of pseudoephedrine products~~.

Phar 8.09 **Controlled substances in emergency kits for long term care facilities.** Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

(1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.

(2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

(3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.

(4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by

Commented [HN-D15]: Public Comment (Michael DeBisschop): Add partial Refills of Schedule II substances consistent with federal Law; Add partial refills for Schedule II, IV, and V

Public Comment (PSW): Endorse federal allowance for partial refills up to the total dosage units; Also allow partial refills of schedule II

DSPS Admin Rules Comment: This would likely require legislation to change s. 961.38 (2) and (3), stats.

Commented [HN-D16]: Public Comment (PSW): Add electronic prescription option

Commented [HN-D17]: Public Comment (Dawn Wypiszynski): Provide proper method for contacting the Board

Commented [HN-D18]: Clearinghouse Comment #4 "A number of provisions, including ss. Phar 8.03 (3), 8.06 (2), and 8.08, appear to be reiterations of statutes without additional interpretation or effect. Consider whether those provisions need to be included in the administrative code."

Commented [HN-D19]: Public Comment (PSW): Add back in Phar 8.11 Controlled Substances in Emergency Kits for Long Term Care Facilities

Public Comment (John Long): Keep most of current Phar 8.11 language.

authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

(5) Noncompliance with this rule may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

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)

Commented [HN-D20]: Other Public Comments from Dawn Wypiszynski:

"It appears that currently, Phar 6.04(3)(a) (4) is missing….. goes from 3 to 5…."

"Phar 8.12(1) and (2)(b)(c). Request clarification of definition of 'practitioner's agent'. In LTC, this verbiage causes confusion when we try to determine if a faxed controlled order can be dispensed. Considering the many staff
roles that may be involved in sending controlled prescriptions to LTC pharmacy: medical office nurse/staff faxing
from medical office, traveling provider nurse/staff on site at LTC facility or from provider office, LTC nurse/staff (not employed the same as prescriber), hospice nurse/staff at LTC facility or at hospice office. Does the employer have to be the same as the prescriber? Can the fax be received from a 3rd party, like the facility?"

"Phar 8.12(3) Request clarification for requirements of original hard copy prescription. I'm concerned about where the original hard copy will be located if we accept a faxed copy of a written order."

Chapter Phar 15

COMPOUNDING PHARMACEUTICALS

Note: Chapter Phar 15 is shown as repealed and recreated by CR 16-085, effective November 1, 2018, Register April 2018 No. 748.

Phar 15.01 **Intent.** The intent of this chapter is to create a state regulatory standard that aligns with compounding standards found in the United States Pharmaceopeia (USP) general chapters lower than the number 1000.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 15.015 **Definitions.** In this chapter:

(1) "Active pharmaceutical ingredient" or "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" or "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 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) "Chemical stability" means each active pharmaceutical ingredient retains its chemical integrity and labeled potency, within specified limits.

(7) "Classified area" means a space that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).

(8) "Component" means any active pharmaceutical ingredient, or added substances used in the compounding of a drug preparation.

(9) "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 reconstituting, mixing, or storage and beyond use dating that is performed for non-sterile preparations 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.

(10) "Container-closure system" means the sum of packaging components that together contain and protect a dosage form, including primary packaging components and secondary packaging components.

(11) "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit.

(12) "FDA" means the United States food and drug administration.

(13) "Freezer" means a place in which a the temperature is maintained between -13 degrees and 14 degrees Fahrenheit.

(14) "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.

(15) "NF" means the National Formulary.

(16) "Physical stability" means the original physical properties, including appearance, palatability, uniformity, dissolution, and suspendability, are retained.

(17) "Refrigerator" means a cold place in which the temperature is maintained between 36 degrees and 46 degrees Fahrenheit.

(18) "Stability" means the extent to which a compounded preparation retains, within specified limits and through its beyond use date, the same properties and characteristics that it possessed at the time of compounding.

(19) "Therapeutic stability" means the therapeutic effect remains unchanged.

(20) "Toxicological stability" means no significant increase in toxicity occurs.

(21) "USP" means the United States Pharmacopeia.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Subchapter I - General

Phar 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.

(3) The compounding area is maintained in a clean and sanitary condition.

(4) 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.

(5) 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 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 or packaging used in compounding drug products shall be of suitable composition and 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 15.12 **Records of compounding.** 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 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.

(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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 15.13 **Quality control.** **(1)** One or more pharmacists shall complete a verification of all the following before dispensing:

(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 found during any of verifications and take appropriate corrective action before dispensing.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 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.

(e) Cleaning and disinfection of compounding area.

(f) Component selection.

(g) Sterilization and depyrogenation, if pharmacy does sterilization and depyrogenation.

(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) A quality assurance program.

(m) Maintaining the integrity of any classified work areas.

(n) Handling small and large spills of antineoplastic agents and other hazardous substances.

(o) Notification to patients or practitioners of a preparation which is recalled when there is potential for patient harm.

(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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18; correction in (2) (o) made under s. 35.17, Stats., Register April 2018 No. 748.

Phar 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, when applicable.

(5) Indication that the preparation is compounded unless administered by health care personnel.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 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. A pharmacist shall use professional judgement in selection of APIs if USP or NF grade is not available.

(3) All components shall be stored and handled consistent with the manufacturer's labeling or USP or 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 15.17 **Non-patient specific compounding.** Compounded preparations dispensed or distributed to a practitioner pursuant to a non-patient specific order to be administered by a practitioner or practitioner's agent shall meet all of the following:

(1) The order shall include the name and address of the practitioner, drug, strength, 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 Administration 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Subchapter II - Non-sterile Compounding

Phar 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.

(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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

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

(2) Only 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 or storage in a refrigerator to protect against bacteria, yeast, and mold contamination introduced during or after the compounding process.

Subchapter III - Sterile Compounding

Phar 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 primary engineering control 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) "Clean" means to physically remove debris, dirt, dust, and other impurities from surfaces or objects using a cleaning agent with a detergent.

(6) "Compounded sterile preparation" means a compounded final preparation intended to be sterile through the BUD.

(7) "Compounded stock solution" means a compounded solution to be used in the preparation of multiple units of a finished compounded sterile preparation.

(8) "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.

(9) "Disinfect" means the killing of microorganisms when used according to the disinfectant's label.

(10) "HEPA" means high-efficiency particulate air.

(10m)"High-risk level compounded sterile preparations" means preparations compounded from non-sterile ingredients or from ingredients that are incorporated using non-sterile equipment before terminal sterilization, or from commercially manufactured sterile products that lack effective antimicrobial preservatives and whose preparation, transfer, sterilization, and packaging is performed in air quality worse than ISO class 5 for more than one hour. Water containing preparations that are stored for more than six hours before terminal sterilization are also classified as high-risk level compounded sterile preparations.

(11) "ISO Class 5" 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.

(12) "ISO Class 7" 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.

(13) "ISO Class 8" 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.

(14) "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.

(14g) "Low-risk level compounded sterile preparations" means preparations compounded with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, products, components, and devices. The compounding process involves only transfer, measuring, and mixing, using no more than three commercially manufactured sterile products, and not more than two entries into one sterile container or package to make the compounded sterile preparations. The compounding process is limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing

(14r) "Medium-risk level compounded sterile preparations" means preparations compounded under low-risk level conditions but which require multiple individual or small doses of sterile products to be combined or pooled to prepare compounded sterile preparations that will be administered either to multiple patients or to one patient on multiple occasions. The compounding process includes complex aseptic manipulations other than single volume transfer, and requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

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

(16) "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.

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

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

(19) "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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 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 one 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.

(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) For classified areas physically separated through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02-inch water column is required to separate each classified area. If a pass-through is used, only one door shall be opened at a time. 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.

(mm) For classified areas not physically separated, no sterile compounded preparation may be compounded using any ingredient that was at any time non-sterile in a classified area not physically separated and all of the following shall be met:

1. The buffer and ante areas shall be designated with a line of demarcation.

2. The principle of displacement airflow shall be used with an air velocity of 40 feet per minute or more from the buffer area across the entire plane of the line of demarcation.

(n) Devices and objects essential to compounding shall be located at an appropriate distance from the primary engineering control.

(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 certified by the Controlled Environment Testing Association's National Board of Testing or another Board approved entity 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 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) Don personnel protective equipment and perform hand hygiene 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 and face masks.

3. Eye shields, if required due to working with irritants or hazardous drugs.

4. Wash hands and forearms up to the elbows with unscented soap and water for at least 30 seconds. Hands and forearms to the elbows shall be completely dried using either lint-free disposable towels or wipes.

5. Don low lint disposable gown or overalls.

6. 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.

(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. Sterile gloves shall be donned over the RABS gloves.

(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, a 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, shoe covers, hair and facial hair covers, face masks, eye shields, and gloves shall be replaced with new ones before re-entering the compounding area.

(6) Garbing items, including gowns, shall be segregated and stored before use in an enclosure to prevent contamination.

(7) 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 15.33 **Cleaning and Disinfecting the Compounding Area and Supplies.** **(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.

(2) Compounding personnel shall clean in accordance with the following:

(a) Primary engineering control work surfaces, counters, floors and work surfaces in the buffer zone area, ante room and segregated compounding areas daily.

(b) Walls, ceilings and storage shelving monthly.

(c) When a spill occurs or the surface is visibly soiled.

(d) Sporicidal agents shall be used at least weekly to clean compounding areas.

(3) Compounding personnel shall disinfect in accordance with the following:

(a) Primary engineering control work surfaces at the beginning and end of each compounding business day and before each batch, but not longer than 4 hours following the previous disinfection when ongoing compounding activities are occurring.

(b) When 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 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 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~~ ampules. 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

~~Phar 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 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 one hour BUD and time.~~

~~**History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.**~~

Phar 15.34 Immediate use compounded sterile preparations. Immediate-use compounded sterile preparations are exempt from the requirements described for low-risk level, Category 1, and Category 2 compounding sterile preparations only when all the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container or device.

(2) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

(3) During preparation, aseptic technique is followed and, if not immediately administered, the finished compound sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compound sterile preparations, and direct contact of outside surfaces.

(4) Administration begins not later than 1 hour following the start of the preparation.

(5) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared it, and the exact 1-hour BUD and time.

(6) If administration of the compounded sterile preparation has not begun within 1 hour following the start of preparation, it shall be promptly, properly, and safely discarded.

Phar 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 sterility assurance level 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 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 added by the compounder 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 15.37 **Beyond use dating.** **(1)** Sterility and stability considerations shall be taken into account when establishing a BUD. Either Category 1 and 2, or low, medium, and high risk compounding preparation standards may be used, but not a combination of the two within the same pharmacy. 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 1 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~~ processed Category 2 compounded sterile preparations, one of the following:

1. No sterility testing performed or sterility testing not passed, and ~~Prepared~~ prepared with one or more nonsterile ~~ingredients~~ starting components, ~~which are sterilized with a validated sterilization procedure prior to compounding, 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 ~~7~~ 4 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~~No sterility testing performed or sterility testing not passed, and prepared with only sterile starting components, one of the following:

a. Within ~~4~~6 days when the preparation is stored at controlled room temperature.

b. Within 10~~9~~ days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

3. ~~Prepared only with sterile ingredients, preservative added and no sterility testing performed~~Sterility testing performed and passed, one of the following:

a. Within ~~28~~30 days when the preparation is stored at controlled room temperature.

b. Within ~~42~~45 days when the preparation is stored in a refrigerator.

c. Within ~~45~~60 days when the preparation is stored in a freezer.

~~4. Prepared only with sterile ingredients, no preservative added and 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 only 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 Category 2 compounded sterile preparations, terminally sterilized by a validated procedure, one of the following:

1. ~~Prepared with no preservative added and no sterility testing performed~~No sterility testing performed or sterility testing not passed, 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~~Sterility testing performed and passed, one of the following:

a. Within ~~28~~45 days when the preparation is stored at controlled room temperature.

b. Within ~~42~~60 days when the preparation is stored in a refrigerator.

c. Within ~~45~~90 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 BUD 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.

(4) When a preservative is added, the compounded sterile formulation shall pass antimicrobial effectiveness testing that shall include inoculation of standardized microorganisms, incubation serial sampling, and calculation of the changes in colony forming unit concentrations in terms of log reduction. The results of antimicrobial effectiveness testing shall be obtained before any of the compounded sterile preparation is dispensed. Preservatives shall not be used as a substitute for good compounding practices.

(5) For low-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 48 hours when the preparation is stored at controlled room temperature.

(b) Within 14 days when the preparation is stored at cold temperatures between 2 and 8 degrees Celsius.

(c) Within 45 days when the preparation is stored in a solid frozen state at -20 degrees Celsius.

(d) For products prepared in an airflow workbench not located in a buffer area, administration shall begin within 12 hours or less of preparation.

(6) For medium-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) within 30 hours when the preparation is stored at controlled room temperature.

(b) within nine days when the preparation is stored at cold temperatures between 2 and 8 degrees Celsius.

(c) within 45 days when the preparation is stored in a solid frozen state at -20 degrees Celsius.

(7) For high-risk level compounded sterile preparations, in the absence of passing a sterility test:

(a) Within 24 hours when the preparation is stored at controlled room temperature.

(b) Within three days when the preparation is stored at cold temperatures.

(c) Within 45 days when the preparation is stored in a solid frozen state.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Phar 15.38 **Training and evaluation. (1)** GENERAL. The managing pharmacist, pharmacists, pharmacy technicians, pharmacy interns and pharmacy externs compounding sterile preparations shall successfully complete didactic or practical training. The didactic or 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.

History: CR 16-085: cr. Register April 2018 No. 748 eff. 11-1-18.

Pharmacy Examining Board
Rule Projects (updated 11/19/21)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	137-20	4/19/2023	Phar 1, 6, 7, 8, 12, 13	Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors	Drafting	Board Review and Approve for Posting for EIA Comments and Submission to Clearinghouse
21-028	080-20	12/22/2022	Phar 2	Reciprocal Credentials for Service Members, Former Service Members, and their Spouses	Senate and Assembly Standing Committee Review	JCRAR Review
Not Assigned Yet	079-20	12/22/2022	Phar 5, 6, 7, 11, 12	Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction	Public Hearing at 12/02/21 Meeting	Submission of Final Rule Draft and Legislative Report to Governor's Office
Not Assigned Yet	Not Assigned Yet	Determined After Governor Approval	Phar 7 and 10	Consumer Disclosures	Scope Submitted to Governor's Office on 09/09/21	Submission of Scope for Publication After Approval by the Governor
Not Assigned Yet	074-19	2/12/2022	Phar 8	Controlled Substances Requirements	Review of Public Hearing Comments and Clearinghouse Report	Submission of Final Rule Draft and Legislative Report to Governor's Office
Not Assigned Yet	096-19	03/09/2022	Phar 15	Compounding Pharmaceuticals	Drafting	Board Review and Approve for Posting for EIA Comments and Submission to Clearinghouse
Not Assigned Yet	Not Assigned Yet	Determined After Governor Approval	Phar 18	Third Party Logistics Providers	Preliminary Hearing on Statement of Scope at 12/02/21	Submission of Scope for Publication After Approval by the Governor