Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dan Hereth, Secretary

HYBRID (IN-PERSON/VIRTUAL)
PHARMACY RULES COMMITTEE of the
PHARMACY EXAMINING BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison
Contact: Brad Wojciechowski (608) 266-2112
April 17, 2025

Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. A quorum of the Board may be present during any committee meetings.

AGENDA

9:00 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1-2)

B. Approval of Minutes of February 20, 2025 (3)

C. Administrative Rule Matters – Discussion and Consideration (4-71)
1. Phar 15, Relating to Compounding Pharmaceuticals **(5-16)**
2. Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check **(17-37)**
3. Phar 1, 6, 7 and 10, Relating to Pharmacy Workplace Conditions **(38-71)**
4. Pending or Possible Rulemaking Projects

D. Public Comments

ADJOURNMENT

NEXT MEETING: June 19, 2025

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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 virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters

for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
MEETING MINUTES
FEBRUARY 20, 2025

PRESENT: Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Brenda Taylor, Board Services Supervisor; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 9:02 a.m. A quorum was confirmed with four (4) members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF DECEMBER 5, 2024

MOTION: Anthony Peterangelo moved, seconded by Susan Kleppin, to approve the Minutes of December 5, 2024, as published. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 10:09 a.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**	**04/07/25** **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 Rules Committee

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
04/17/25	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Phar 15, Relating to Compounding Pharmaceuticals** **2. Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check** **3. Phar 1, 6, 7 and 10, Relating to Pharmacy Workplace Conditions** **4. 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 15 Legislative Report, Final Rule Draft, EIA, Public Comments from PSW
2. Phar 7 Redlined Code Text, 2/20 Public Comments
3. Phar 1, 6, 7, 10 Scope Statement, Comment on Scope Statement, Redlined Code Text, Virginia Language

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

11) Authorization

Nilajah D. Hardin — 04/07/25

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 RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
PHARMACY EXAMINING BOARD	**:**	**CR 24-092**

I. THE PROPOSED RULE:
The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:
The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:
The Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmacopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020. The Board will request approval from the Attorney General, as required by s. 227.21 (2), Stats., prior to submission of this rule for final adoption and publication.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:
The Pharmacy Examining Board held a public hearing on February 20, 2025 on CR 24-092. The following people either testified at the hearing, or submitted written comments:

- Danielle Womack, Vice President of Public Policy and Advocacy for the Pharmacy Society of Wisconsin

The Pharmacy Examining Board summarizes the comments received either by hearing testimony or by written submission as follows:

- The Pharmacy Society of Wisconsin submitted the following comments:
    - Is it the Board's intent to require compliance with USP General Chapter 800, whether they compound or not?
    - Can a pharmacy document a different timeframe or do 14-day beyond-use dates for flavoring under Phar 15.02 (1)(b) required?
    - What patient protection is offered if flavoring is not considered compounding?
    - What grounds does the Board have for disciplinary action for failure to meet "should" standards under USP General Chapter 797?

- Does USP General Chapter 797 being incorporated by reference into the Administrative Code mean that compliance is required with all other USP chapters cited in that chapter?
- Will copies of the incorporated chapters be available through the Legislative Reference Bureau?
- How should pharmacies label non-patient-specific or office use compounding products?

The Pharmacy Examining Board made the following modifications to its rule-making proposal based on public comments:

- Phar 15.02 (1) (b) is revised to read "the pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless a shorter beyond-use-date has been documented."
- The following has been added to section Phar 15.03: "**(2)** DIFFERING REQUIREMENTS. **(a)** Where any Board rule in this chapter differs from a requirement within a standard referenced in this chapter, the Board rule shall govern.

  (b) Except as provided in par. (a), where a provision of this chapter prescribes a general requirement and another provision of this chapter prescribes a specific or more detailed requirement regarding the same subject, the specific or more detailed requirement shall govern.

  (c) Except as provided in pars. (a) and (b), where different sections of this chapter specify conflicting requirements. The most restrictive requirement, as determined by the Board, shall govern."

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2b: "Should the material created in s. Phar 15.03 either be moved to, or at least referenced within, current s. Phar 10.03? Additionally, it is confusing that the provisions says it only "may" be considered a violation. Does that give adequate notice to practitioners about what is required?"

Response: The board accepts this comment and would like to note that the standards being incorporated are already required by the United States Food and Drug Administration, so there should be no need to give notice to licensees.

Comment 2c: "The agency could consider whether an initial applicability clause should be added to the proposed rule, if there could be circumstances in which the new rule could apply to compounding that was initiated before the effective date of the rule. [s. 1.06 (3), Manual.]"

Response: The board accepts this comment and would like to note that standards being incorporated are already required by the United States Food and Drug Administration, so there should be no need an initial applicability clause.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 24-092)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate chapter Phar 15, relating to Compounding Pharmaceuticals.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.01 (16), Stats.

Statutory authority: ss. 15.08 (5) (b), 227.21 (2) (a), and 450.02 (3) (d) and (e), Stats.

Explanation of agency authority:
Section 15.08 (5) (b), Stats. states that "~~The~~[t]he 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 227.21 (2)(a), Stats. states that "[e]xcept as provided in s. 601.41 (3) (b), to avoid unnecessary expense an agency may, with the consent of the attorney general, adopt standards established by technical societies and organizations of recognized national standing by incorporating the standards in its rules by reference to the specific issue or issues of the publication in which they appear, without reproducing the standards in full."

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

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules establishing minimum standards for the practice of pharmacy."

Related statute or rule: N/A

Plain language analysis:
The Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate

by reference United States Pharmacopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020. The Board will request approval from the Attorney General, as required by s. 227.21 (2), Stats., prior to submission of this rule for final adoption and publication.

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.The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]. In Illinois, the definition of "compounding" excludes flavorings [225 Illinois Compiled Statutes 85 s. 3 (o)].

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. Additionally, Iowa includes requirements for the use of flavoring agents. These requirements include that pharmacist may add flavoring in the amount of not more than percent of the total volume of the drug. The beyond-use date of the flavored drug must be no greater than 14 days and the pharmacist must document that a flavoring agent was

added to a drug. Compliance with USP Chapter 825 is not required, however Iowa does have its own rules for radiopharmaceuticals and nuclear pharmacy [Iowa Administrative Code ss.657.16 and 657.20].

Michigan: Michigan requires a pharmacy that provides compounding services to be licensed as a pharmacy and authorized to provide compounding services. The pharmacy must be accredited through a national accrediting organization and be in compliance with USP standards [Michigan Compiled Laws s. 333.17748a to c]. In Michigan, the definition of "compounding" does not include flavoring agents that are nonallergenic, inert, and not more than 5% of the drug's total volume [Michigan Administrative Rules R 338.501 (1) (e)].

Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

Summary of factual data and analytical methodologies: In addition to the four adjacent states listed above, the Pharmacy Examining Board also reviewed statutes and regulations regarding compounding pharmaceuticals from other states including Arizona, California, Colorado, Connecticut, Idaho, Kentucky, Louisiana, Massachusetts, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments were received.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:
These 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; 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, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held February 20, 2025, to be included in the record of rule-making proceedings.

TEXT OF RULE

Section 1. Chapter Phar 15 is repealed and recreated to read:

Chapter Phar 15
PHARMACEUTICAL COMPOUNDING, SAFE HANDLING OF HAZARDOUS DRUGS, AND RADIOPHARMACEUTICALS

Phar 15.01 Definitions. In this chapter,~~:~~
~~(1)~~ "USP-NF" means the United States Pharmacopeia-National Formulary published by the United States Pharmacopeial Convention.

Phar 15.02 Incorporation of Standards. (1) PHARMACEUTICAL COMPOUNDING - NONSTERILE PREPARATIONS. USP-NF general chapter 795, official as of November 1, 2023, is incorporated by reference into this chapter, subject to the exception that nonsterile compounding does not include the addition of nonallergenic, therapeutically inert flavoring agents to a conventionally manufactured drug product. The pharmacist shall also comply with the following requirements when adding flavoring agents to a drug product:

(a) The pharmacist shall ensure that the flavoring agent is not more than 5 percent of the product's total volume.

(b) The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless a shorter beyond-use date has been ~~otherwise~~ documented.

(c) The pharmacist shall document the addition of flavoring as part of the prescription record. The documentation shall include the type of flavoring agent, manufacturer, lot number, and expiration date.

(d) A prescription is required before a pharmacist may add flavoring to an over-the-counter product.

(2) PHARMACEUTICAL COMPOUNDING - STERILE PREPARATIONS. USP-NF general chapter 797, official as of November 1, 2023, is incorporated by reference into this chapter.
(3) SAFE HANDLING OF HAZARDOUS DRUGS. USP-NF general chapter 800, official as of July 1, 2020, is incorporated by reference into this chapter.
(4) RADIOPHARMACEUTICALS. USP-NF general chapter 825, official as of January 1, 2024, is incorporated by reference into this chapter.

Note: Copies of the above standards are on file in the office of the legislative reference bureau. A copy of the USP-NF can be purchased from the United States Pharmacopeial Convention at https://usp.org.

Phar 15.03 Compliance. (1) UNPROFESSIONAL CONDUCT. Noncompliance with ch. Phar 15 shall~~may~~ be considered a violation of s. Phar 10.03 and may result in disciplinary action by the Board against a credential holder.

(2) DIFFERING REQUIREMENTS. **(a)** Where any Board rule in this chapter differs from a requirement within a standard referenced in this chapter, the Board rule shall govern.

(b) Except as provided in par. (a), where a provision of this chapter prescribes a general requirement and another provision of this chapter prescribes a specific or more detailed requirement regarding the same subject, the specific or more detailed requirement shall govern.

(c) Except as provided in pars. (a) and (b), where different sections of this chapter specify conflicting requirements. The most restrictive requirement, as determined by the Board, shall govern.

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)

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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. Date
12/09/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 15

4. Subject
Compounding Pharmaceuticals

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

6. Chapter 20, Stats. Appropriations Affected
s20.165 (1) (hg)

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

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

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The Pharmacy Examining Board recently completed a revision to Wisconsin Administrative Code Chapter Phar 15 which became effective on August 1, 2022. The objective of this rule is to repeal and recreate the recent version of Phar 15 to incorporate by reference United States Pharmaceopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020

12. 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.
The rule was posted on the Department's website for 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.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. 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)
DSPS estimates a total of $5,955.00 in one-time costs for implementing this rule. The one-time staff costs support 0.1 limited term employee to undertake tasks such as rule drafting, regal review, training on new rules, and updating forms and website.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that there will be clear and up to date standards fo pharmaceutical compounding, safe handling of hazardous drugs, and radiopharmaceuticals in Pharmacy practice.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are increased safety in pharmacy practice in Wisconsin .

17. Compare With Approaches Being Used by Federal Government

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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P.O. BOX 7864
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FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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.The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions..

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

Illinois: For patient-specific prescriptions, sterile and unsterile pharmaceutical compounding is governed by the USP 42-NF 37 from the 2019 USP Compounding Compendium, except for USP Chapter 800. Additionally, all pharmacies that compound drugs must maintain a set of minimum standards and equipment. These requirements include a specific area for compounding materials, accurate scales or measuring equipment, a separate area for compounding, a record keeping system for tracking compounded drugs, drug distribution procedures, and labelling. Additional requirements for sterile compounding include current reference materials, pharmacist availability at all times to answer patient and health care professional questions, and emergency medications for adverse drug reactions to compounded sterile drugs. [Illinois Administrative Code s. 1330.640]. In Illinois, the definition of “compounding” excludes flavorings [225 Illinois Compiled Statutes 85 s. 3 (o)].

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Minnesota: Minnesota requires pharmacies compounding nonsterile drug preparations to follow USP chapter 795 standards. Pharmacies compounding sterile drug preparations are required to follow USP chapter 797 standards. [Minnesota Administrative Rules s.6800.3300]

19. Contact Name	20. 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.

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

Pharmacy Society of Wisconsin

February 20, 2025

TO: Pharmacy Examining Board
FROM: Danielle M. Womack
Vice President, Public Policy & Advocacy
Pharmacy Society of Wisconsin
SUBJECT: CR 24-092: Compounding Pharmaceuticals

Members of the Pharmacy Examining Board,

On behalf of the Pharmacy Society of Wisconsin, I appreciate the opportunity to provide testimony regarding the proposed updates to Phar 15 and the adoption of USP Chapters <795>, <797>, <800>, and <825>. PSW supports efforts to maintain compliance with current compounding standards. However, some concerns and questions regarding practical implementation and the clarity of certain provisions have been raised as we have shared these proposed changes with our members.

Scope of Enforcement and Federal Alignment

- **USP <800> Enforcement:** Federal law does not mandate compliance with USP <800> for pharmacies that do not engage in compounding, as there are no references to this chapter in federal law or other required general chapters. ***Is it the Board's intent to require compliance with <800> for all pharmacies, regardless of whether or not they compound?*** This should be clarified to avoid unintended regulatory burdens, as the activities within <800> extend far beyond compounding, and pharmacies may not be aware of the need for adherence if they are not compounding.

Flavoring Regulations

- The wording in Phar 15.02(1)(b) stating "unless otherwise documented" is ambiguous. ***Does this mean that 14-day beyond-use dates must be followed unless supported by credible drug information resources, or can a pharmacy arbitrarily document a different timeframe?*** Perhaps a revision to clarify that alternative beyond-use dates must be supported by "a professional reference or pharmacy-based data" rather than the vague "unless otherwise documented."
- The requirement for a prescription before adding flavoring to an OTC product is unclear. ***If flavoring is not considered compounding, what patient protection does this requirement offer?*** While several states require that a prescriber, patient, or patient's parent/legal guardian must request the flavoring, we could only find one state that mandates a prescription order for flavoring of OTC products.

701 Heartland Trail
Madison, WI 53717
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Practical Considerations and Language Clarity

- **Mandatory vs. Advisory Language:** USP <797> contains numerous "should" statements (64 instances), raising questions about enforceability. ***If a pharmacy fails to meet a "should" standard, what grounds does the Board have for disciplinary action?***
- **Incorporation by Reference:** USP chapters often cross-reference other chapters. ***Does incorporating USP 797 by reference implicitly require compliance with all chapters it cites? Additionally, will copies of these chapters be made available through the Legislative Reference Bureau?***

  Example:
  Facility Design and Environmental Controls
  In addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment (see *Physical Environments That Promote Safe Medication Use* ⟨1066⟩).

- **Non-Patient-Specific Compounding:** Non-patient-specific compounding has slightly different labeling requirements as currently listed in Phar 15.17. USP standards, however, do not explicitly address differences in labeling requirements for these prescription orders. Phar 7.05, which discusses label requirements, also does not have any exceptions for office use / non-patient-specific products. ***How should pharmacies label these products?***

While PSW fully supports the incorporation by reference and compliance with USP <795>, <797>, <800>, and <825>, I urge the Board to provide clear guidance on enforcement scope and language clarity in Phar 15. Addressing these concerns will improve regulatory clarity and ease compliance burdens for pharmacy professionals in Wisconsin.

Thank you for your time and consideration.

Chapter Phar 7

PHARMACY PRACTICE

Note: Chapter Phar 7 as it existed on December 31, 2020, was repealed and a new chapter Phar 7 was created, effective January 1, 2021.

Subchapter I — General

Phar 7.01 Definitions. In this chapter:

(1) "Control number" means a unique number used to identify a repackaged drug or drug product in reference to a record that contains NDC, expiration date, and lot number.

(1a) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 , Public Law 104-191.

~~**(2)** "Managing pharmacist" means a pharmacist who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, and who is personally in full and actual charge of the pharmacy and personnel.~~

(3) "NDC" means national drug code.

(4) "Repackaging for stock" means transferring a non-sterile drug product from the stock container in which it was distributed by the original manufacturer and placing it into a different stock container as a source for subsequent prescription dispensing without further manipulation of the drug.

(5) "Standing order" means an order transmitted electronically or in writing by a practitioner for a drug or device that does not identify a particular patient at the time it is issued for the purpose of drug or device dispensing or administration to individuals that meet criteria of the order.

Phar 7.02 Prescription. (1) REQUIREMENTS. A prescription drug order shall include all of the following:

(a) Date of issue.

(b) First and last name and address of the practitioner.

(c) Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.

(d) Name, strength, and quantity of the drug product or device.

(e) Directions for use of the drug product or device.

(f) Refills, if any.

(g) Symptom or purpose for which the drug is being prescribed if the patient indicates in writing to the practitioner that the patient wants the symptom or purpose for the prescription to be disclosed on the label.

(h) Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2) (a) 1., 448.035 (2) and 448.037 (2) (a) 1., Stats.

(i) If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.

(j) If prescription is issued under s. 255.07 (2), Stats., the name and address of the authorized entity or individual.

(k) Practitioner's written signature, or electronic or digital signature.

(2) STANDING ORDER. **(a)** A prescription pursuant to a standing order shall include all of the following:

1. Date of issue.
2. First and last name and address of the practitioner.
3. Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.
4. Name, strength, and quantity of the drug product or device.
5. Directions for use of the drug product or device.
6. Refills, if any.
7. Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2) (a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.
8. If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.
9. If prescription is issued under s. 255.07 (2), Stats., the name and address of the authorized entity or individual.
10. An indication that the prescription is pursuant to a standing order.

(b) A copy of the standing order shall be retained under s. Phar 7.11 (1).

(3) ELECTRONIC PRESCRIPTION. **(a)** Except as provided in s. 89.068 (1) (c) 4., Stats., and as otherwise prohibited by law, a practitioner may transmit a prescription order electronically only if the patient approves the transmission and the prescription order is transmitted to a pharmacy designated by the patient. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

(b) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided electronically with a prescription order.

(4) VERBAL PRESCRIPTION AND PRESCRIPTION VIA SECURE TEXTING PLATFORM. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. Prescription orders via text may be received at a pharmacy through a HIPAA compliant secure texting platform. The verbal prescription or prescription order via secure texting platform shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(5) ALTERATIONS. (a) Any alterations that modify the original intent of a prescription shall be documented including the identification of the pharmacist responsible for the alteration and the practitioner or practitioner's delegate who authorized the alteration.

(b) A pharmacist shall use their professional judgement when determining whether it is necessary to contact the practitioner or practitioner's delegate before performing the following alterations to an initial fill of a non-controlled substance prescription:

1. Changing the quantity, dosage, or directions for use of the medication.
2. Adding missing information on a prescription label required under s. Phar 7.05.

Commented [NH1]: Other Changes for Alteration?

3.

Phar 7.03 Drug utilization review. (1) A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing each prescription drug order for all of the following:

(a) Known allergies.

(b) Rational therapy.

(c) Contraindications.

(d) Reasonable dose, duration of use, and route of administration, considering the age and other patient factors.

(e) Reasonable directions for use.

(f) Potential or actual adverse drug reactions.

(g) Drug interactions with food, beverages, other drugs or medical conditions.

(h) Therapeutic duplication.

(i) Reasonable utilization and optimum therapeutic outcomes.

(j) Potential abuse or misuse.

(2) Upon recognizing a concern with any of the items in sub. (1) (a) to (j), the pharmacist shall take steps to mitigate or resolve the problem.

Phar 7.04 Transferring prescription order information. (1) GENERAL REQUIREMENTS. **(a)** A transfer of prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing of non-controlled substances and refills of controlled substances, may occur if all of the following conditions are satisfied:

1. The transfer of prescription order information is communicated in one of the following ways:
   a. Verbal communication between two pharmacists.
   b. Electronically or by facsimile machine between the two pharmacies.
2. A transfer of prescription information verbally shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(b) A pharmacist shall transfer a prescription upon patient request pursuant to 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 prescription record of the transferred prescription shall include 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 s. Phar 7.11 (2) (a).
2. The name and address of the pharmacy to which it was transferred, the date and the first and last name of the pharmacist transferring the information are recorded on the invalidated prescription order or in a computer system meeting the requirements s. Phar 7.11 (2) (a).

(b) Unless a computer system meeting the requirements in sub. (4) is used, the transferred prescription order information shall include the following:

1. The word “TRANSFER" on the face of the transferred prescription order or recorded in a similar manner in a computer system.
2. The first and last name and address of the patient, the first and last name and address of the prescribing practitioner.

3. Name, strength, form and quantity of the drug product or device prescribed and the directions for use.
4. The date of issuance of the original prescription order, the original prescription order number, the original number of refills authorized on the original prescription order and the date of original dispensing if the prescription order has previously been dispensed.
5. The number of valid refills or total quantity remaining and the date of the last refill.
6. The pharmacy's name and address from which the prescription order information was transferred.
7. The first and last name of the pharmacist transferring and receiving the prescription order information.

(3) CONTROLLED SUBSTANCES. (a) The electronic transfer of an original prescription ~~information~~ for initial dispensing of a controlled substance listed in Schedule II ~~III – V~~ shall comply with 21 CFR 1306. ~~meet the following requirements:~~

(b) The electronic transfer of an original prescription for initial dispensing or refill of a schedule III-V original prescription shall comply with 21 CFR 1306.

~~**(a)** The transfer of prescription order information is permissible only on a one-time basis. Pharmacies electronically sharing a computer system meeting the requirements of sub. (4) may transfer up to the maximum refills permitted by law and the prescriber's authorization.~~

~~**(b)** Notwithstanding sub. (1) (a), the transfer shall be communicated directly between 2 licensed pharmacists.~~

~~**(c)** The transferring pharmacist shall do all of the following:~~

~~1. Write the word "VOID" on the face of the invalidated prescription. For electronic prescriptions, information that the prescription has been transferred shall be added to the prescription record.~~

~~2. Record on the reverse of the invalidated prescription or in the electronic prescription record all of the following:~~

~~a. Name, address and DEA registration number of the pharmacy to which it was transferred.~~

~~b. The first and last name of the pharmacist receiving the prescription order.~~

~~3. Record the date of the transfer.~~

~~4. Record the first and last name of the pharmacist transferring the information.~~

~~**(d)**~~**(c)** For paper prescriptions and prescriptions received verbally and reduced to writing by the pharmacist for controlled substances listed in Schedule III – V, the pharmacist receiving the transferred prescription information shall write the word "TRANSFER" on the face of the transferred prescription and reduce to writing all information required to be on the prescription, including all of the following:

1. Date of issuance of the original prescription order.
2. Original number of refills authorized on the original prescription order.
3. Date of original dispensing.
4. Number of valid refills remaining and the dates and locations of previous refills.
5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
6. First and last name of the pharmacist making the transfer.
7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

~~**(e)** For electronic prescriptions being transferred electronically, the transferring pharmacist shall provide the receiving pharmacist with the original electronic prescription data and all of the following:~~

Commented [NH2]: Any other Info on Transfers?

~~1. The date of the original dispensing.~~
~~2. The number of refills remaining and the dates and locations of previous refills.~~
~~3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.~~
~~4. The first and last name of the pharmacist transferring the prescription.~~
~~5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.~~

(4) USE OF SHARED COMPUTER SYSTEM. A shared computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.11 (2) (a), contain a shared real time electronic file database with a complete record of all prescriptions filled and dispensed.

Phar 7.05 Label requirements. (1) This section does not apply to institutional pharmacies as defined in s. Phar 7.50 (3).

(2) All prescribed drugs or devices shall have a label attached to the container disclosing all of the following:

(a) Identification of the patient by one of the following:
1. Except as provided in subds. 2. to 5., the first and last name of the patient.
2. For an antimicrobial drug dispensed under s. 450.11 (1g), Stats., the first and last name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT".
3. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the first and last name of the person to whom the opioid antagonist is delivered.
4. For an epinephrine ~~auto-injector~~ delivery system prescribed under s. 118.2925 (3) or 255.07 (2), Stats., the name of the school, authorized entity, or other person specified under s. 255.07 (3), Stats.
5. If the patient is an animal, the last name of the owner, name of the animal and animal species.

(b) Symptom or purpose for which the drug is being prescribed if the prescription order specifies the symptom or purpose.

(c) Name and strength of the prescribed drug product or device dispensed, unless the prescribing practitioner requests omission of the name and strength of the drug product or device.

(d) The date for which the medication shall not be used after.

(e) Pharmacy name, address and telephone number.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

(k) Directions for use of the prescribed drug or device as contained in the prescription order.

(3) A label for prescribed drugs or devices may include the following:

(a) Symptom or purpose for which the drug is being prescribed if requested by the patient.

(b) Both the generic name of the drug product equivalent and the brand name specified in the prescription order may be listed on the label if the brand name is listed on the prescription and the drug product equivalent is dispensed, unless the prescribing practitioner requests that the brand name be omitted from the label.

(c) Written or graphic product descriptions.

(d) Any cautions or other provisions.

(4) Subsection (2) does not apply to complimentary samples of drug products or devices dispensed in original packaging by a practitioner to his or her patients.

Phar 7.06 Repackaging for stock. A pharmacy repackaging for stock any non-sterile drugs shall do all of the following:

(1) The repackaging for stock process is conducted under conditions that ensure the integrity of the drug.

(2) Products repackaged for stock shall include a beyond use date that ensures the integrity of the drug.

(3) The repackaged container shall be selected to mitigate adulteration from light, temperature and humidity.

(4) The repackaged for stock drugs are labeled physically or electronically with all the following components:

(a) Drug name, strength, form and beyond use date.

(b) One of the following identifiers:

1. Pharmacy control number.
2. NDC number and manufacturer lot number.
3. Name of manufacturer or distributer of the drug product, and the manufacturer lot number.

(5) Records of all repackaging for stock operations are maintained and include all the following:

(a) Name, strength, form, quantity per container, and quantity of containers.

(b) NDC number or the name of the manufacturer or distributor of the drug product.

(c) Manufacturer lot number.

(d) Original container's expiration date and the beyond-use date for the new containers.

(e) First and last name of the pharmacist or delegate that repackaged the drug and the first and last name of the pharmacist that verified the accuracy of the repackaging.

(f) Date of repackaging.

(g) Any pharmacy control numbers.

Phar 7.07 Final check. (1) A final check of accuracy and correctness is required for any prescription drug product or device dispensed and shall include all of the following:

(a) Verifying label is correct and meets labeling requirements.

(b) Verifying the drug product or device is correct.

(c) Completion of the drug utilization review.

(2) For all prescription drug products or devices dispensed by a pharmacist, the prescription record shall identify ~~the pharmacist~~ the individual responsible for each part of the final check. If sub. (1) (a) or (b) is completed by a pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the pharmacy product verification technician performing the check.

Phar 7.08 Patient consultation. (1) A pharmacist shall provide the patient or patient's agent consultation to optimize proper use of a prescription drug or device, that meets any of the following:

(a) Has not been dispensed previously to the patient by that pharmacy or a pharmacy within the same shared computer system.

(b) Is a change in therapy.

(c) Upon request of a patient or patient's agent.

(d) Whenever deemed necessary based upon the professional judgement of the dispensing pharmacist.

(2) Notwithstanding sub. (1), consultation is not required when one of the following occurs:

(a) A drug or device will be administered, by ingestion, inhalation, injection, or any other route, by or in the presence of one of the following:

1. An individual with a scope of practice that includes the administration of a drug or device.
2. A delegate of an individual with authority to delegate the administration of a drug or device.

(b) A patient or patient's agent refuses consultation.

(3) Consultation shall contain any of the following information that, in the pharmacist's professional judgment, serves the best interest of the patient:

(a) Name and description of the drug.

(b) Form, dose, route of administration and duration for drug therapy.

(c) Intended use of the drug and expected action.

(d) Directions and precautions for the preparation, administration, and use.

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(f) Techniques for self-monitoring drug therapy.

(g) Action to be taken in the event of a missed dose.

(h) Proper storage and appropriate disposal method of unwanted or unused medication.

(4) The consultation required in this section shall be communicated verbally when in the pharmacist's professional judgment it is in the best interest of the patient.

(5) A pharmacist shall provide the patient or patient's agent, for all consultations required under sub. (1), a written patient drug education monograph.

(6) The consultation required in this section may occur before or after delivery of the prescription to the patient or patient's agent.

(7) Every licensed pharmacy dispensing directly to a patient or patient's agent inside the pharmacy shall conspicuously post a board approved sign stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board.

(8) A prescription drug or device delivered by common carrier, mail, or delivery service or picked up at a drive through window shall include a copy of information which is board-approved stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board.

Phar 7.085 Delivery by common carrier or delivery services. Utilization of common carrier or delivery services to deliver a prescription to a location of the patient's choice from the pharmacy which fills the prescription to the patient or patient's agent shall ensure all of the following:

(1) The delivery method is appropriate to prevent drug adulteration.

(2) The patient or patient's agent is provided a method by which the patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the prescription drug product or device, including all of the following:

(a) Timeliness of delivery.

(b) Condition of the prescription drug upon delivery.

(c) Failure to receive the proper prescription drug product or device.

(3) Any prescription drug product or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, a pharmacist at the dispensing pharmacy shall take steps to mitigate patient harm.

Phar 7.09 Procurement, recall and out-of-date drugs and devices. (1) A pharmacy shall have a system for identifying a drug or device subjected to a product recall and for taking appropriate actions as required by the recall notice.

(2) A drug or device may not be dispensed after the drug's or device's expiration date or beyond use date. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed.

Phar 7.10 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene.

(b) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(c) "Tamper-evident package" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.

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

(a) Where the health item was dispensed in error, was defective, adulterated, or misbranded.

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

(c) A health item that is prepackaged for consumer use without a prescription when returned in compliance with all applicable state and federal laws.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

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

(4) It is not a return of a health care item if a patient or agent of a patient delivers 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 is 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 of a health care item if a patient or agent of a patient delivers 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.

(6) This section does not prohibit participation in a drug repository program in accordance with ch. DHS 148.

Phar 7.11 Pharmacy records. (1) GENERAL. Pharmacy records shall be maintained for a minimum period of 5 years unless otherwise specified in state or federal law.

(2) PRESCRIPTION RECORDS. **(a)** 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 is:

1. Capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining.
2. 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.

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

(c) All systems used for maintaining a record of any prescription dispensing shall contain all items required in the medical profile record system.

(d) A paper prescription for non-controlled substances may be scanned and stored electronically in the computer system under par. (a). For purposes of this chapter, the prescription becomes an electronic prescription.

(3) MEDICATION PROFILE RECORD SYSTEM. **(a)** An individual medication profile record system shall be maintained in all pharmacies for humans and non-humans for whom prescriptions, original or refill, are dispensed. The system shall be capable of permitting the retrieval of information.

(b) The following minimum information shall be retrievable:

1. Patient's first and last name, or if not human, name of pet, species and last name of owner.
2. Address of the patient.
3. Birth date of the patient or, if not human, birth date of the owner.
4. Name of the drug product or device dispensed.
5. Strength of the drug product or device dispensed.
6. Form of the drug product or device dispensed.
7. Quantity of the drug product or device prescribed, dispensed and remaining.
8. Number of refills prescribed.
9. Directions for use.
10. Prescription order number.
11. Original date of issue.
12. Dates of dispensing.
13. Prescriber's first and last name.

(c) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(d) Medication profile records shall be maintained for a minimum period of 5 years following the date of the last dispensing.

Phar 7.12 Delegation by a physician. The pharmacist shall document the delegation by a physician under s. 450.033, Stats. The delegated act may not be started prior to the documentation. The documentation shall be maintained for a minimum of 5 years after the last delegated act under that delegation.

Phar 7.13 Administration of drug products and devices other than vaccines. (1) In this section, "course of study" means one or more classes, workshops, seminars, or continuing education programs.

(2) A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats. After the pharmacist administers a prescribed drug product or device, the pharmacist, a person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.

(3) A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.

(4) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., may not administer a prescribed drug product or device unless the person satisfies all of the following:

(a) Successfully completes a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.

(b) Administers the prescribed drug product or device only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council of Pharmacy Education or the board.

(c) After administering the prescribed drug product or device, notifies the prescribing practitioner or enters the information in a patient record system shared by the prescribing practitioner.

(5) The board may approve courses of study which meet criteria substantially equivalent to criteria used by the Accreditation Council for Pharmacy Education.

(6) A course of study and training in administration technique shall include all of the following topics:

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

(d) The 5 rights of administration including right patient, right drug, right dose, right route, and right time.

(e) Patient reassessment after administration including signs and symptoms of adverse drug reactions.

(f) Best practices in documentation of the medication administration.

(7) This section does not apply to the administration of vaccines.

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

Phar 7.14 Pharmacy product verification technician-check-pharmacy technician. (1) DEFINITIONS. In this section:

(a) "Pharmacy product verification technician" means a registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

(b) "Pharmacy product verification technician-check- pharmacy technician" means the process in which a pharmacy product verification technician conducts the task of product verification of technical dispensing functions completed by a pharmacy technician. A pharmacy product

verification technician may not conduct product verification as part of the final check of their own product preparation.

(c) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, as part of the final check and ensure the product has not reached its expiration or beyond use date.

(d) "Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a pharmacy product verification technician and ensuring for direct supervision of the pharmacy product verification technician.

(2) PHARMACY PRODUCT VERIFICATION TECHNICIAN QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a pharmacy technician who meets all of the following:

(b) Completed an accredited pharmacy technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:
   a. Drug name.
   b. Strength.
   c. Formulation.
   d. Expiration date.
   e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
   a. Wrong medication.
   b. Wrong strength.
   c. Wrong formulation.
   d. Extra or insufficient quantity.
   e. Omitted medications if utilizing unit dose or compliance packaging.
   f. Expired medication.
   g. Look-alike or sound-alike errors.
   h. High-alert medications.
3. Eligible products for pharmacy product verification technician-check-pharmacy technician.
4. Organizational policies and procedures on reporting of medication errors.
5. Overview of the medication use process including all of the following:
   a. Procurement.
   b. Ordering.
   c. Dispensing.
   d. Administration.
   e. Monitoring.
6. A practical training designed to assess the competency of the pharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:
   a. Wrong drug.
   b. Wrong strength.
   c. Wrong formulation.

d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The pharmacy technician being validated shall make a product verification on the work of a pharmacist or another pharmacy technician for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the pharmacy technician during the validation process.

(e) Notwithstanding pars. (b) to (d), an individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the pharmacy product verification technician qualifications unless the individual fails to meet the quality assurance standards under sub. (4).

(3) ELIGIBLE PRODUCT. **(a)** *Institutional pharmacies.* The pharmacy product verification technician may do the product verification in an institutional pharmacy if all of the following requirements are met:

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.
2. A drug utilization review performed by a pharmacist prior to dispensing.
3. The drug product will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The pharmacy product verification technician may do the product verification in a community pharmacy if all of the following requirements are met:

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.
2. A drug utilization review performed by a pharmacist prior to dispensing.
3. A non-pharmacist shall be able to check the accuracy of the medication by one of the following:
   a. The drug product or device is in the original packaging from a manufacturer.
   b. The drug product or device includes a description of the drug product or device on the prescription label.
   c. The pharmacist shows the patient or patient's agent the drug product or device and provides a monograph that includes a description of the drug product or device.

(4) QUALITY ASSURANCE. **(a)** A minimum of 5% of each pharmacy product verification technician's verifications shall be audited by a licensed pharmacist. The accuracy of each pharmacy product verification technician shall be tracked individually.

(b) A record of each pharmacy product verification technician-check-pharmacy technician audit shall include all of the following:

1. Name of the pharmacy product verification technician.
2. Total number of product verifications performed.
3. Number of product verifications audited by the pharmacist.
4. Percentage of product verifications audited by pharmacist.
5. Percentage of accuracy.
6. Number of product verification errors identified.
7. Type of error under sub. (2) (c) 2. a. to c. and e.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each pharmacy product verification technician's previous 12 months accuracy and correctness of pharmacy product verifications including a review of the quality assurance log.

(d) A pharmacy product verification technician shall be revalidated if the individual fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the pharmacy product verification by technicians which shall be made available to the board upon request.

(6) RECORDS. **(a)** Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each pharmacy product verification technician that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist, and the dates the supervision responsibilities begin and end.
3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

Phar 7.15 Consumer disclosures. (1) Each pharmacy shall post in a prominent place and maintain the consumer disclosures required in ss. 450.13 (5m) and 450.135 (8m), Stats.

(2) A link to the 100 most commonly prescribed generic drug product equivalents as determined by the board, shall be maintained on the department's website as required in s. 450.13 (5m) (b), Stats.

Note: Copies of the required consumer disclosures are located on the Department of Safety and Professional Service's website: https://dsps.wi.gov.

(3) Pursuant to s. 450.13 (5m) (c), Stats., each pharmacy shall maintain and make available to the public a list of the drugs from the list in sub. (2) that are available for purchase at that pharmacy. The list shall be updated monthly, with all of the following information included:

(a) Brand name.

(b) Generic equivalent drugs and biological products.

(c) Interchangeable biological products.

(d) Retail price.

(4) The list required under sub. (3) may differ depending on whether the drugs on the list from sub. (2) are available for purchase at a specific pharmacy.

Phar 7.16 Additional Certification for Pharmacists. Every licensed pharmacist who administers drug product or devices or vaccines pursuant to s. 450.035, Stats., shall maintain current certification in cardiopulmonary resuscitation and basic life support.

Subchapter II — Central Shared Services

Phar 7.30 Definitions. In this subchapter:

(1) "Central shared services pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy.

(2) "Labeling pharmacy" means the central shared services pharmacy or originating pharmacy which is responsible for product verification under s. Phar 7.07 (1) (a) and (b).

(3) "Originating pharmacy" means a pharmacy licensed in this state that uses a central shared services pharmacy.

Phar 7.31 Requirements. An originating pharmacy may use a central shared services pharmacy only pursuant to the following requirements:

(1) The central shared services 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.

(2) The central shared services pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number that it provides services to.

(3) The central shared services pharmacy and originating pharmacy maintain a written protocol delineating each pharmacy's assumption of responsibility for compliance with state and federal law.

(4) Unless the central shared services pharmacy shares a computer system with the originating pharmacy meeting the requirements of s. Phar 7.04 (4) and contains the medication profile record under s. Phar 7.11 (3), it may not perform drug utilization review under s. Phar 7.03 to satisfy the final check requirement under s. Phar 7.07 (1) (c).

(5) The prescription label attached to the container shall contain the name and address of the labeling or originating pharmacy. 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 labeling pharmacy filled the prescription order.

(6) The originating pharmacy or central shared services pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

(7) In addition to meeting the other recordkeeping requirements required by state and federal law, the central shared services pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for the final check under s. Phar 7.07 (1).

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 Definitions. In this subchapter:

(1) "Delivery system" means a structure, controlled by a pharmacy licensed in this state, that a prescription is placed in for patient pick-up.

~~**(2)** "Supervising pharmacy" means a licensed pharmacy that oversees the operations and administration of remote dispensing.~~

Phar 7.41 Delivery system. (1) A prescription shall be stored in a secure delivery system immediately upon delivery to the location of the delivery system. Only the patient or patient's agent shall be able to open the door or locker containing only the patient's prescription.

(2) The delivery system shall be designed in a manner which does not disclose protected health information.

(3) The delivery system shall maintain appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.

(4) The use of a delivery system does not create an exemption to s. 450.11 (1b), Stats.

(5) A log shall be maintained by the dispensing pharmacy of all prescriptions delivered to the delivery system.

(6) The delivery system shall be inventoried at least weekly and a list of unclaimed prescriptions shall be reviewed by a pharmacist.

(7) The managing pharmacist shall establish written policies and procedures for all of the following:

(a) Stocking of the delivery system.

(b) Determining access to the delivery system.

(c) Detection and mitigation of diversion and theft.

Phar 7.42 Automated direct-to-patient dispensing system. (1) In this section "supervising practitioner" means the practitioner who is responsible for the operation of the automated direct-to-patient dispensing system and requirements of this section.

(2) An automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any of the locations under s. ~~450.062 (1) to (4)~~450.09 (2) (b) 1. a. to d., Stats., may operate for purposes of practitioner dispensing. The supervising practitioner will ensure all of the following requirements are met:

(a) Individuals with access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to the supervising practitioner or a delegate.

(b) The automated direct-to-patient dispensing system shall label the prescription in compliance with s. Phar 7.05.

(c) The automated direct-to-patient dispensing system shall maintain records of all prescription fills and dispenses in compliance with s. Phar 7.11 (1).

(d) The reporting of all monitored prescription drugs dispensed from the automated direct-to-patient dispensing system to the prescription drug monitoring program.

(3) The supervising practitioner or delegate shall establish written policies and procedures for automated direct-to-patient dispensing system for all of the following:

(a) Stocking.

(b) Determining access.

(c) Detection and mitigation of diversion and theft.

Phar 7.43 Remote dispensing. (2) LOCATION. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. 450.09 (2) (b) 1. a. to d., Stats.

(4) REQUIREMENTS. **(a)** A remote dispensing location shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.
2. This remote dispensing location is being supervised by a pharmacist employed by:
   a. Name of pharmacy.
   b. Address of pharmacy.
   c. Telephone of pharmacy.
3. Patient has a right to pharmacist consultation and information on how to file a complaint to the board.

(b) Remote dispensing may not occur if a pharmacist is not available remotely.

(c) A prescribed drug or device may not be dispensed in the absence of the ability of a patient and pharmacist's delegate to communicate with a pharmacist.

(d) No vaccines shall be administered at a remote dispensing site.

(5) DISPENSING REQUIREMENTS. Remote dispensing shall comply with all of the following:

(a) Visually inspecting all prescription orders, labels and dispensed product.

(b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the remote dispensing site as the licensed facility from which the prescribed drug or device was dispensed.

(c) Final check under s. Phar 7.07.

(d) Federal law if dispensing controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACIST. The managing pharmacist responsible for the remote dispensing pharmacy shall do all of the following:

(a) Have written policies and procedures for system operation, safety, security, accuracy and access.

(b) Implement an ongoing quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.

(c) Visit the remote dispensing location at least monthly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy.

(d) Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.

(e) Documentation indicating accepting responsibility for compliance with this section, signed and dated by the managing pharmacist.

(7) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) shall meet the following requirements to remote dispense:

(a) Be 18 years of age or older.

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

(c) Have completed 1500 hours of work as a pharmacist delegate within the 3 years prior to engaging in remote dispensing or completed an accredited pharmacy technician training program.

Subchapter IV — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:

(1) "Chart order" means an order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or practitioner's delegate for a drug product or device.

(2) "Institutional 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 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, 146.903 (1) (b), 233.40, 233.41, 233.42, or 252.10, Stats.; a hospice facility under s. 50.90 (1) (c), Stats.; a county jail; and a correctional facility operated under the authority of the department of corrections.

(3) "Institutional pharmacy" means a pharmacy that provides pharmacy services to an institutional facility. This definition is not for purposes under s. 450.09 (1) (a), Stats.

Phar 7.51 Chart orders. A chart order shall contain all of the following:

(1) First and last name of the patient.

(2) Patient's medical record number or date of birth.
(3) Date of issuance.
(4) Name, strength, and form of the drug product or device prescribed.
(5) Directions for use.
(6) The signature by one of the following methods:
(a) If handwritten, the practitioner's or delegate's signature.
(b) Electronic signature of the practitioner or delegate.
(7) Chart orders prepared by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name of the practitioner.

Phar 7.52 Labels. All prescribed drug products and devices dispensed for administration by a health care provider at the institutional facility shall have a label attached to the container disclosing all of the following:
(1) Drug name, strength and form.
(2) Beyond use date or expiration date.
(3) Special storage conditions, if required.

Phar 7.53 Security and access. (1) Arrangements shall be made in advance by the managing pharmacist for access of drugs by the health care staff of the institutional facility when dispensing by a pharmacist is not available.
(2) In the absence of a pharmacist, drugs shall be stored in a manner in which only authorized personnel may obtain access and is sufficiently secure to deny access to unauthorized persons.
(3) The managing pharmacist shall develop policies and procedures in place to mitigate and prevent theft and diversion.

Phar 7.54 Return or exchange of health items. (1) In this section:
(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene.
(b) "Original container" means the container in which a health item was sold, distributed, or dispensed.
(c) "Tamper-evident package" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.
(2) A health item which has been sold, distributed or dispensed, may be returned to the institutional pharmacy under s. Phar 7.10 (2) or if the health item has not left the control of the health care facility staff authorized to have access to prescription drug products.
(3) A health item returned to an institutional pharmacy may be sold, distributed, or dispensed to the institutional facility if all of the following apply:
(a) The health item was never in the possession and control of the patient.
(b) The health item was sold, distributed or dispensed in a tamper-evident package and, for a drug product, includes the beyond use date or expiration date and manufacturer's lot number.
(c) The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

Phar 7.55 Automated technology product verification. (1) DEFINITIONS. In this section:

(a) “Product verification” means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) “Supervising pharmacist” means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Product verification may be done only by an automated technology which meets all of the following:

(a) Located within a licensed pharmacy.

(b) Utilizing barcodes or another machine-readable technology to complete the product verification.

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer’s standard maintenance recommendations.

(3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:

(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.

(b) Has a drug utilization review performed by a pharmacist prior to delivery.

(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(4) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request.

(5) RECORDS. **(a)** Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.
3. Documentation of the completion of the manufacturer’s recommended maintenance and quality assurance measures.
4. Documentation of the dates of all software upgrades.
5. Documentation of all service performed outside of the manufacturer’s standard maintenance recommendations.

(b) Records shall be made available to the board upon request.

Subchapter V — Uncredentialed Pharmacy Staff

Phar 7.60 Definition. In this subchapter, "uncredentialed pharmacy staff" means any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats.

Phar 7.62 Uncredentialed pharmacy staff. (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m).

(2) A pharmacist shall provide direct supervision of uncredentialed pharmacy staff. A pharmacist shall be available to the uncredentialed pharmacy staff person for consultation either in person or contact by telecommunication means.

(3) An uncredentialed pharmacy staff person may not engage in the practice of pharmacy as defined in s. 450.01 (16), Stats., or the practice of a pharmacy technician as defined in s. Phar 19.02.

(4) The prohibitions in sub. (3), do not apply to a person completing an internship for purposes of meeting the internship requirement under s. 450.03 (2) (b), Stats.

(5) A managing pharmacist shall provide training to or verify competency of an uncredentialed pharmacy staff person prior to the uncredentialed pharmacy staff person performing a delegated act.

(6) The managing pharmacist shall determine which acts may be delegated in a pharmacy. The managing pharmacist has a duty to notify all pharmacists practicing in that pharmacy which acts may be delegated to specific uncredentialed pharmacy staff. This record shall be provided to the board upon request.

(7) A pharmacist may delegate to an uncredentialed pharmacy staff person any delegated act approved by the managing pharmacist outside of the restrictions in sub. (3).

From: Michael DeBisschop
To: Wojciechowski, Brad - DSPS; DSPS Admin Rules
Subject: Public comment from PEB rules committee 2-20-2025
Date: Thursday, February 20, 2025 10:52:11 AM

Dear Brad and Nilajah,

Thank you for allowing me to comment on the proceedings of the Rules committee for the PEB on February 20, 2025. My comments are listed below. Please do not hesitate to contact me with any questions you have about these. Thank you and the board for taking these into account. I am an instructor of pharmacy law at a Wisconsin school of pharmacy, and these opinions are my own and don't necessarily represent those of my employer.

Thank you,
Mike DeBisschop

- Regarding a pharmacist using professional judgment to make prescription changes: I think this is a separate issue from drug product equivalent substitution as described in s. 450.13 and permitted in s. 450.01(16)(f). I fully support pharmacists being able to do this. It technically falls under "therapeutic alternate drug selection" (which is not formally defined that I know of) and is permitted only as described in s. 450.01(16)(h), (hm), and (hr). What I was trying to say in the meeting is that I believe this may need to be a statute change first (perhaps adding to the practice of pharmacy definition an allowance for therapeutic alternate drug selection that in the pharmacist's judgment, does not modify the intent of the prescription, and further described by board rule).
- Regarding controlled substance transfers:
    - Phar 7.04(1)(a) still states "purpose of original or refill dispensing of non-controlled substances and refills of controlled substances." My comment was that this should change to include original and refills of controlled and non-controlled prescriptions now, since we can transfer electronic CS prescriptions. Perhaps it would be clearer to take this phrase out altogether?
    - Ensure fax transmitted prescriptions are included (perhaps they still are)
    - Agree with the observation to either just reference federal regulation for all types of CS transfers, or to spell it all out, copying DEA regs. Spelling it all out in Phar 7 would be least confusing both for the pharmacist reading this and student learning. Except for the new original electronic CS transfer regs, the DEA regs have been consistent for a long time.
    - Also, Phar 7.04(3)(a) which allows multiple transfers for pharmacies sharing a realtime database was crossed out; this is important and should be left in.
    - Note that 21 CFR, Part 1300's definition of a "pharmacist" includes other persons who are state-authorized to dispense controlled substances under the supervision of a licensed pharmacist. If we incorporate DEA regs by reference, I would encourage the board to be aware of this and make sure the language in all areas is consistent and reflects who may perform transfers. Phar 7.04(1) describes who

can perform transfers. It has been my interpretation that this includes students, grad interns, pharmacists awaiting reciprocity, and even technicians (since it is not prohibited as a delegated activity in Phar 19). There is an opportunity to make the board's intent clear on who may perform this task.

- Regarding CPR certification: pharmacy students and reciprocating pharmacists in s. 450.03(1) (f),(fm), and (g) can also administer vaccinations per s. 450.035(2g)(a). Should these individuals also be subject to the requirement for CPR certification?

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 1, 6, 7, and 10

Relating to: Pharmacy Workplace Conditions

Rule Type: Both Permanent and Emergency

1. Finding/nature of emergency (Emergency Rule only): The Pharmacy Examining Board has identified a concern related to workplace safety including concerning behavior involving prescription accuracy, performing vaccinations, and patient care, among other areas of Pharmacy practice in the workplace. Due to these concerns, the Board deems an emergency rule to be appropriate to address the imminent public safety and welfare.

2. Detailed description of the objective of the proposed rule: The objective of the proposed rule is to amend requirements in the Wisconsin Administrative Code to increase public safety by improving working conditions in pharmacies.

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:
Wisconsin Administrative Code Chapters Phar 1, 6, 7, and 10 currently outline requirements for authority and definitions, pharmacy licenses and equipment, pharmacy practice, and unprofessional conduct. These areas could be expanded upon to include requirements that improve working conditions for pharmacy staff, as well as patient safety. An alternative to amending these provisions is that the administrative code will continue to be silent on the issue of workplace conditions in the pharmacy profession.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):
15.08 (5) (b), Stats., states 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."

450.02 (2), Stats., states that "[t]he board shall promulgate rules that do all of the following:
(a) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.
(b) Define the activities that constitute the practice of a pharmacy technician for purposes if the registration requirement under s. 450.68."

450.02 (3) (b), Stats., states "[t]he board may promulgate rules establishing security standards for pharmacies."

450.02 (3) (d), Stats., states "[t]he board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

450.02 (3) (e), Stats., states "[t]he board may promulgate rules establishing minimum standards for the practice of pharmacy."

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

6. List with description of all entities that may be affected by the proposed rule:
Licensed Pharmacies, Pharmacists; Registered Pharmacy Technicians, and their employers.

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: None.

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. This rule is not likely to have a significant economic impact on small businesses.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, (608) 267-7139

Approved for publication:

Authorized Signature

11/25/2024

Date Submitted

Approved for implementation:

Authorized Signature

3/12/2025

Date Submitted

From:	Rachel Ver Velde
To:	DSPS Admin Rules
Subject:	Comments on SS 002-25 on Phar 1, 6, 7, and 10 relating to Pharmacy Workplace Conditions
Date:	Thursday, February 20, 2025 11:41:12 AM
Attachments:	Outlook-4cyfkwo3.png Outlook-w4vsvxwy Outlook-rpqmwnu4 Outlook-fjfqp3po Outlook-zlhhklp0

Comments on SS 002-25 on Phar 1, 6, 7, and 10 relating to Pharmacy Workplace Conditions

Chairman Weitekamp and members of the Board,

Wisconsin Manufacturers & Commerce (WMC) is concerned about the lack of information in this statement of scope. Under Wisconsin State Statute 227.135 (1) (b), statements of scope of proposed rules shall include a description of existing policies relevant to the rule and of new policies proposed to be included in the rule and analysis of policy alternatives.

This information was not included in SS 002-25, which deprived WMC and our members from the ability to provide comments on this statement of scope.

WMC encourages the Pharmacy Examining Board to provide additional information on the new policies that are being pursued in this rule and to fully comply with 227.135 (1) (b).

Sincerely,

Rachel Ver Velde
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Chapter Phar 1

AUTHORITY AND DEFINITIONS

Note: Chapter Phar 1 as it existed on January 31, 1983 was repealed and a new chapter Phar 1 was created effective February 1, 1983.

Phar 1.01 Authority. Rules in chs. Phar 1 to 19 are adopted under authority of ss. 15.08 (5) (b) and 227.11 (2), Stats., and ch. 450, Stats.

Phar 1.02 Definitions. As used in chs. Phar 1 to 19:

(1) "Board" means the pharmacy examining board.

Note: The board office is located at 4822 Madison Yards Way, Madison, WI 53705.

(2) "Community pharmacy" means practice in a licensed pharmacy providing pharmaceutical services primarily on an out- patient basis.

(2m) "Department" means the Wisconsin department of safety and professional services.

(3) XDEAY means the drug enforcement administration.

(3m) "Direct supervision" means immediate, whether in per- son or real time video conferencing where all parties can communicate by simultaneous means of audio, video, or data communications, availability to continually coordinate, direct and inspect in real time the practice of another.

(4) "Institutional pharmacy" means practice in a licensed pharmacy providing pharmaceutical services primarily on an in- patient basis.

(4m) "Long term care facility" has the meaning given in 21 CFR 1300.01.

(5) "LTCF" means a long term care facility.

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

(6m) "NABP" means the National Association of Boards of Pharmacy.

(7) "NAPLEX" means the North American Pharmacy Licensing Examination.

(8) "Pharmacist" has the meaning given in s. 450.01 (15), Stats.

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

(10m) "Pharmacy graduate" means a graduate of a school of pharmacy approved by the board, who has submitted an application for pharmacist licensure or a qualified applicant awaiting ex amination for licensure approved by the board.

(11) "Pharmacy owner" means a person or entity to whom a pharmacy license is issued.

(11m) "Pharmacy technician" means a person registered by the board under s. 450.068, Stats.

(12) "Practice of pharmacy" has the meaning under s. 450.01 (16), Stats.

(13) "PRN" means renew as needed.

(14) "Professional service area" means the area of a pharmacy in which prescriptions are compounded or dispensed, hypodermic needles, syringes, poisons and schedule V controlled substances as listed in s. 961.22, Stats., and ch. CSB 2 are available, or where patients are consulted.

(14m) "Remote dispensing site" has the meaning given in s. 450.01 (21c), Stats.

(15) "Terminal illness" means an incurable condition caused by injury or illness that reasonable medical judgment finds would cause death.

Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

Note: Chapter Phar 6 as it existed on January 31, 1983, was repealed and a new chapter Phar 6 was created effective February 1, 1983.

Phar 6.01 Licenses; application. Requirements and procedures for applying for a pharmacy license are specified in s. 450.06, Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by contacting the board office. A license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy license. A pharmacy may not operate unless a pharmacy license has been granted. Board action shall be taken within 60 business days of receipt of a completed pharmacy application, as provided in s. SPS 4.03.

Note: Applications are available upon request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

Phar 6.02 Licenses; change of location or owner- ship. (1) A pharmacy license authorizes a pharmacy to operate only at the location designated on the license. Licenses may not be transferred to another location.

(1m) A hospital which has a pharmacy area providing outpatient pharmacy services which is physically separate from, and not contiguous to the area from which inpatient pharmacy ser- vices are provided, shall have a pharmacy license for the outpatient pharmacy in addition to a license for the inpatient pharmacy.

(2) Any change in pharmacy ownership shall be reported to the board office and the pharmacy license of the former owner re- turned. A pharmacy license shall be granted to the new pharmacy owner before the pharmacy may operate.

Phar 6.025 Licenses; remote dispensing sites. A pharmacy may be subject to rules in this section that apply only to remote dispensing sites, if a pharmacist remotely supervises the location for any period of time. The following conditions shall also be met:

(1) The licensee provides notice to the board of all of the information outlined in s. 450.06, Stats.
(2) The site meets all of the requirements listed in s. Phar 7.43.
(3) The site is any of the location types listed under s. 450.09 (2) (b) 1., Stats.
(4) A managing pharmacist shall report to the board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist may not be responsible for more than 10 remote dispensing sites at any given time without approval from the board.

Phar 6.03 Changes in managing pharmacist. The pharmacy owner shall report to the board any change of managing pharmacist within 5 days following the change.

Phar 6.04 Floor design. (1) PROFESSIONAL SERVICE AREA. If the building is open at any time while the professional service area is closed, the professional service area shall be se- cured as specified in sub. (3).

(2) REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED. When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements:

(am) A locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by unauthorized personnel. A secured barrier may be

con- structed 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 re- moved, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

(bm) Signs of reasonable size are posted at the professional service area which prominently display the hours the professional services are available.

(cm) The manner in which the telephone is answered does not imply that the professional services are available.

Phar 6.05 Sanitation. The professional service area of a pharmacy shall have a sink convenient and suitable for cleaning pharmaceutical equipment and supplied with hot and cold running water. Detergent and a waste disposal container also shall be provided in the professional service area.

Phar 6.06 Laws and other references. The professional service area of a pharmacy shall have equipment of appropriate design and size for the intended pharmacy practice and shall have all of the following:

(1j) The latest available or immediately accessible version of federal and state pharmacy laws consisting of:

(a) Drug enforcement administration regulations, 21 CFR 1300 to end.

(b) Wisconsin pharmacy laws, ch. 450, Stats.

(c) Wisconsin controlled substances act, ch. 961, Stats.

(d) Wisconsin administrative code, rules of the pharmacy examining board.

(2k) 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.

(3L) The telephone number of a poison center. This number shall be conspicuously posted in the prescription department.

Phar 6.07 Storage. (1) The storage of drugs shall be se- cure, neat, clean and orderly.

(3) All controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft or diversion.

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

(a) "Business day" means a day the pharmacy is open for business.

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

(d) "Mean kinetic temperature" means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

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

(2) STORAGE. Drugs shall be stored at appropriate conditions, including temperature and humidity, to prevent drug adulteration.

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

(4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy and the humidity of the pharmacy shall be continuously monitored. At least once each business day, the minimum and maximum temperature and humidity since the previous documented reading shall be recorded.

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

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

Phar 6.08 Security. A pharmacy shall have 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.

Only changes from current Phar 7 project marked

Chapter Phar 7

PHARMACY PRACTICE

Note: Chapter Phar 7 as it existed on December 31, 2020, was repealed and a new chapter Phar 7 was created, effective January 1, 2021.

Subchapter I — General

Phar 7.01 Definitions. In this chapter:

(1) "Control number" means a unique number used to identify a repackaged drug or drug product in reference to a record that contains NDC, expiration date, and lot number.

(1a) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 , Public Law 104-191.

~~**(2)** "Managing pharmacist" means a pharmacist who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, and who is personally in full and actual charge of the pharmacy and personnel.~~

(3) "NDC" means national drug code.

(4) "Repackaging for stock" means transferring a non-sterile drug product from the stock container in which it was distributed by the original manufacturer and placing it into a different stock container as a source for subsequent prescription dispensing without further manipulation of the drug.

(5) "Standing order" means an order transmitted electronically or in writing by a practitioner for a drug or device that does not identify a particular patient at the time it is issued for the purpose of drug or device dispensing or administration to individuals that meet criteria of the order.

Phar 7.02 Prescription. (1) REQUIREMENTS. A prescription drug order shall include all of the following:

(a) Date of issue.

(b) First and last name and address of the practitioner.

(c) Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.

(d) Name, strength, and quantity of the drug product or device.

(e) Directions for use of the drug product or device.

(f) Refills, if any.

(g) Symptom or purpose for which the drug is being prescribed if the patient indicates in writing to the practitioner that the patient wants the symptom or purpose for the prescription to be disclosed on the label.

(h) Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2) (a) 1., 448.035 (2) and 448.037 (2) (a) 1., Stats.

(i) If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.

(j) If prescription is issued under s. 255.07 (2), Stats., the name and address of the authorized entity or individual.

(k) Practitioner's written signature, or electronic or digital signature.

(2) STANDING ORDER. **(a)** A prescription pursuant to a standing order shall include all of the following:

1. Date of issue.
2. First and last name and address of the practitioner.
3. Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.
4. Name, strength, and quantity of the drug product or device.
5. Directions for use of the drug product or device.
6. Refills, if any.
7. Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2) (a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.
8. If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.
9. If prescription is issued under s. 255.07 (2), Stats., the name and address of the authorized entity or individual.
10. An indication that the prescription is pursuant to a standing order.

(b) A copy of the standing order shall be retained under s. Phar 7.11 (1).

(3) ELECTRONIC PRESCRIPTION. **(a)** Except as provided in s. 89.068 (1) (c) 4., Stats., and as otherwise prohibited by law, a practitioner may transmit a prescription order electronically only if the patient approves the transmission and the prescription order is transmitted to a pharmacy designated by the patient. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

(b) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided electronically with a prescription order.

(4) VERBAL PRESCRIPTION AND PRESCRIPTION VIA SECURE TEXTING PLATFORM. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. Prescription orders via text may be received at a pharmacy through a HIPAA compliant secure texting platform. The verbal prescription or prescription order via secure texting platform shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(5) ALTERATIONS. (a) Any alterations that modify the original intent of a prescription shall be documented including the identification of the pharmacist responsible for the alteration and the practitioner or practitioner's delegate who authorized the alteration.

(b) A pharmacist shall use their professional judgement when determining whether it is necessary to contact the practitioner or practitioner's delegate before performing the following alterations to an initial fill of a non-controlled substance prescription:

1. Changing the quantity, dosage, or directions for use of the medication.
2. Adding missing information on a prescription label required under s. Phar 7.05.
3. _____

Phar 7.03 Drug utilization review. (1) A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing each prescription drug order for all of the following:

(a) Known allergies.

(b) Rational therapy.

(c) Contraindications.

(d) Reasonable dose, duration of use, and route of administration, considering the age and other patient factors.

(e) Reasonable directions for use.

(f) Potential or actual adverse drug reactions.

(g) Drug interactions with food, beverages, other drugs or medical conditions.

(h) Therapeutic duplication.

(i) Reasonable utilization and optimum therapeutic outcomes.

(j) Potential abuse or misuse.

(2) Upon recognizing a concern with any of the items in sub. (1) (a) to (j), the pharmacist shall take steps to mitigate or resolve the problem.

Phar 7.04 Transferring prescription order information. (1) GENERAL REQUIREMENTS. **(a)** A transfer of prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing of non-controlled substances and refills of controlled substances, may occur if all of the following conditions are satisfied:

1. The transfer of prescription order information is communicated in one of the following ways:
   a. Verbal communication between two pharmacists.
   b. Electronically or by facsimile machine between the two pharmacies.
2. A transfer of prescription information verbally shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(b) A pharmacist shall transfer a prescription upon patient request pursuant to 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 prescription record of the transferred prescription shall include 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 s. Phar 7.11 (2) (a).
2. The name and address of the pharmacy to which it was transferred, the date and the first and last name of the pharmacist transferring the information are recorded on the invalidated prescription order or in a computer system meeting the requirements s. Phar 7.11 (2) (a).

(b) Unless a computer system meeting the requirements in sub. (4) is used, the transferred prescription order information shall include the following:

1. The word “TRANSFER" on the face of the transferred prescription order or recorded in a similar manner in a computer system.
2. The first and last name and address of the patient, the first and last name and address of the prescribing practitioner.
3. Name, strength, form and quantity of the drug product or device prescribed and the directions for use.

4. The date of issuance of the original prescription order, the original prescription order number, the original number of refills authorized on the original prescription order and the date of original dispensing if the prescription order has previously been dispensed.
5. The number of valid refills or total quantity remaining and the date of the last refill.
6. The pharmacy's name and address from which the prescription order information was transferred.
7. The first and last name of the pharmacist transferring and receiving the prescription order information.

(3) CONTROLLED SUBSTANCES. (a) The electronic transfer of an original prescription ~~information~~ for initial dispensing of a controlled substance listed in Schedule II ~~III – V~~ shall comply with 21 CFR 1306. ~~meet the following requirements:~~

(b) The electronic transfer of an original prescription for initial dispensing or refill of a schedule III-V original prescription shall comply with 21 CFR 1306.

~~**(a)** The transfer of prescription order information is permissible only on a one-time basis. Pharmacies electronically sharing a computer system meeting the requirements of sub. (4) may transfer up to the maximum refills permitted by law and the prescriber's authorization.~~

~~**(b)** Notwithstanding sub. (1) (a), the transfer shall be communicated directly between 2 licensed pharmacists.~~

~~**(c)** The transferring pharmacist shall do all of the following:~~

~~1. Write the word "VOID" on the face of the invalidated prescription. For electronic prescriptions, information that the prescription has been transferred shall be added to the prescription record.~~

~~2. Record on the reverse of the invalidated prescription or in the electronic prescription record all of the following:~~

~~a. Name, address and DEA registration number of the pharmacy to which it was transferred.~~

~~b. The first and last name of the pharmacist receiving the prescription order.~~

~~3. Record the date of the transfer.~~

~~4. Record the first and last name of the pharmacist transferring the information.~~

~~(d)~~**(c)** For paper prescriptions and prescriptions received verbally and reduced to writing by the pharmacist for controlled substances listed in Schedule III – V, the pharmacist receiving the transferred prescription information shall write the word "TRANSFER" on the face of the transferred prescription and reduce to writing all information required to be on the prescription, including all of the following:

1. Date of issuance of the original prescription order.
2. Original number of refills authorized on the original prescription order.
3. Date of original dispensing.
4. Number of valid refills remaining and the dates and locations of previous refills.
5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
6. First and last name of the pharmacist making the transfer.
7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

~~**(e)** For electronic prescriptions being transferred electronically, the transferring pharmacist shall provide the receiving pharmacist with the original electronic prescription data and all of the following:~~

~~1. The date of the original dispensing.~~

~~2. The number of refills remaining and the dates and locations of previous refills.~~

~~3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.~~

~~4. The first and last name of the pharmacist transferring the prescription.~~

~~5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.~~

(4) USE OF SHARED COMPUTER SYSTEM. A shared computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.11 (2) (a), contain a shared real time electronic file database with a complete record of all prescriptions filled and dispensed.

Phar 7.05 Label requirements. (1) This section does not apply to institutional pharmacies as defined in s. Phar 7.50 (3).

(2) All prescribed drugs or devices shall have a label attached to the container disclosing all of the following:

(a) Identification of the patient by one of the following:

1. Except as provided in subds. 2. to 5., the first and last name of the patient.
2. For an antimicrobial drug dispensed under s. 450.11 (1g), Stats., the first and last name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT".
3. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the first and last name of the person to whom the opioid antagonist is delivered.
4. For an epinephrine ~~auto-injector~~ delivery system prescribed under s. 118.2925 (3) or 255.07 (2), Stats., the name of the school, authorized entity, or other person specified under s. 255.07 (3), Stats.
5. If the patient is an animal, the last name of the owner, name of the animal and animal species.

(b) Symptom or purpose for which the drug is being prescribed if the prescription order specifies the symptom or purpose.

(c) Name and strength of the prescribed drug product or device dispensed, unless the prescribing practitioner requests omission of the name and strength of the drug product or device.

(d) The date for which the medication shall not be used after.

(e) Pharmacy name, address and telephone number.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

(k) Directions for use of the prescribed drug or device as contained in the prescription order.

(3) A label for prescribed drugs or devices may include the following:

(a) Symptom or purpose for which the drug is being prescribed if requested by the patient.

(b) Both the generic name of the drug product equivalent and the brand name specified in the prescription order may be listed on the label if the brand name is listed on the prescription and the drug product equivalent is dispensed, unless the prescribing practitioner requests that the brand name be omitted from the label.

(c) Written or graphic product descriptions.

(d) Any cautions or other provisions.

(4) Subsection (2) does not apply to complimentary samples of drug products or devices dispensed in original packaging by a practitioner to his or her patients.

Phar 7.06 Repackaging for stock. A pharmacy repackaging for stock any non-sterile drugs shall do all of the following:

(1) The repackaging for stock process is conducted under conditions that ensure the integrity of the drug.

(2) Products repackaged for stock shall include a beyond use date that ensures the integrity of the drug.

(3) The repackaged container shall be selected to mitigate adulteration from light, temperature and humidity.

(4) The repackaged for stock drugs are labeled physically or electronically with all the following components:

(a) Drug name, strength, form and beyond use date.

(b) One of the following identifiers:

1. Pharmacy control number.
2. NDC number and manufacturer lot number.
3. Name of manufacturer or distributer of the drug product, and the manufacturer lot number.

(5) Records of all repackaging for stock operations are maintained and include all the following:

(a) Name, strength, form, quantity per container, and quantity of containers.

(b) NDC number or the name of the manufacturer or distributor of the drug product.

(c) Manufacturer lot number.

(d) Original container's expiration date and the beyond-use date for the new containers.

(e) First and last name of the pharmacist or delegate that repackaged the drug and the first and last name of the pharmacist that verified the accuracy of the repackaging.

(f) Date of repackaging.

(g) Any pharmacy control numbers.

Phar 7.07 Final check. (1) A final check of accuracy and correctness is required for any prescription drug product or device dispensed and shall include all of the following:

(a) Verifying label is correct and meets labeling requirements.

(b) Verifying the drug product or device is correct.

(c) Completion of the drug utilization review.

(2) For all prescription drug products or devices dispensed by a pharmacist, the prescription record shall identify ~~the pharmacist~~ the individual responsible for each part of the final check. If sub. (1) (a) or (b) is completed by a pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the pharmacy product verification technician performing the check.

Phar 7.08 Patient consultation. (1) A pharmacist shall provide the patient or patient's agent consultation to optimize proper use of a prescription drug or device, that meets any of the following:

(a) Has not been dispensed previously to the patient by that pharmacy or a pharmacy within the same shared computer system.

(b) Is a change in therapy.

(c) Upon request of a patient or patient's agent.

(d) Whenever deemed necessary based upon the professional judgement of the dispensing pharmacist.

(2) Notwithstanding sub. (1), consultation is not required when one of the following occurs:

(a) A drug or device will be administered, by ingestion, inhalation, injection, or any other route, by or in the presence of one of the following:

1. An individual with a scope of practice that includes the administration of a drug or device.
2. A delegate of an individual with authority to delegate the administration of a drug or device.

(b) A patient or patient's agent refuses consultation.

(3) Consultation shall contain any of the following information that, in the pharmacist's professional judgment, serves the best interest of the patient:

(a) Name and description of the drug.

(b) Form, dose, route of administration and duration for drug therapy.

(c) Intended use of the drug and expected action.

(d) Directions and precautions for the preparation, administration, and use.

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(f) Techniques for self-monitoring drug therapy.

(g) Action to be taken in the event of a missed dose.

(h) Proper storage and appropriate disposal method of unwanted or unused medication.

(4) The consultation required in this section shall be communicated verbally when in the pharmacist's professional judgment it is in the best interest of the patient.

(5) A pharmacist shall provide the patient or patient's agent, for all consultations required under sub. (1), a written patient drug education monograph.

(6) The consultation required in this section may occur before or after delivery of the prescription to the patient or patient's agent.

(7) Every licensed pharmacy dispensing directly to a patient or patient's agent inside the pharmacy shall conspicuously post a board approved sign stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board.

(8) A prescription drug or device delivered by common carrier, mail, or delivery service or picked up at a drive through window shall include a copy of information which is board-approved stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board.

Phar 7.085 Delivery by common carrier or delivery services. Utilization of common carrier or delivery services to deliver a prescription to a location of the patient's choice from the pharmacy which fills the prescription to the patient or patient's agent shall ensure all of the following:

(1) The delivery method is appropriate to prevent drug adulteration.

(2) The patient or patient's agent is provided a method by which the patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the prescription drug product or device, including all of the following:

(a) Timeliness of delivery.

(b) Condition of the prescription drug upon delivery.

(c) Failure to receive the proper prescription drug product or device.

(3) Any prescription drug product or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, a pharmacist at the dispensing pharmacy shall take steps to mitigate patient harm.

Phar 7.09 Procurement, recall and out-of-date drugs and devices. (1) A pharmacy shall have a system for identifying a drug or device subjected to a product recall and for taking appropriate actions as required by the recall notice.

(2) A drug or device may not be dispensed after the drug's or device's expiration date or beyond use date. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed.

Phar 7.10 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene.

(b) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(c) "Tamper-evident package" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.

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

(a) Where the health item was dispensed in error, was defective, adulterated, or misbranded.

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

(c) A health item that is prepackaged for consumer use without a prescription when returned in compliance with all applicable state and federal laws.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

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

(4) It is not a return of a health care item if a patient or agent of a patient delivers 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 is 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 of a health care item if a patient or agent of a patient delivers 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.

(6) This section does not prohibit participation in a drug repository program in accordance with ch. DHS 148.

Phar 7.11 Pharmacy records. (1) GENERAL. Pharmacy records shall be maintained for a minimum period of 5 years unless otherwise specified in state or federal law.

(2) PRESCRIPTION RECORDS. **(a)** 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 is:

1. Capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining.
2. 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.

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

(c) All systems used for maintaining a record of any prescription dispensing shall contain all items required in the medical profile record system.

(d) A paper prescription for non-controlled substances may be scanned and stored electronically in the computer system under par. (a). For purposes of this chapter, the prescription becomes an electronic prescription.

(3) MEDICATION PROFILE RECORD SYSTEM. **(a)** An individual medication profile record system shall be maintained in all pharmacies for humans and non-humans for whom prescriptions, original or refill, are dispensed. The system shall be capable of permitting the retrieval of information.

(b) The following minimum information shall be retrievable:

1. Patient's first and last name, or if not human, name of pet, species and last name of owner.
2. Address of the patient.
3. Birth date of the patient or, if not human, birth date of the owner.
4. Name of the drug product or device dispensed.
5. Strength of the drug product or device dispensed.
6. Form of the drug product or device dispensed.
7. Quantity of the drug product or device prescribed, dispensed and remaining.
8. Number of refills prescribed.
9. Directions for use.
10. Prescription order number.
11. Original date of issue.
12. Dates of dispensing.
13. Prescriber's first and last name.

(c) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(d) Medication profile records shall be maintained for a minimum period of 5 years following the date of the last dispensing.

Phar 7.12 Delegation by a physician. The pharmacist shall document the delegation by a physician under s. 450.033, Stats. The delegated act may not be started prior to the documentation. The documentation shall be maintained for a minimum of 5 years after the last delegated act under that delegation.

Phar 7.13 Administration of drug products and devices other than vaccines. (1) In this section, "course of study" means one or more classes, workshops, seminars, or continuing education programs. **(2)** A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats. After the pharmacist administers a prescribed drug product or device, the pharmacist, a person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.

(3) A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.

(4) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., may not administer a prescribed drug product or device unless the person satisfies all of the following:

(a) Successfully completes a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.

(b) Administers the prescribed drug product or device only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council of Pharmacy Education or the board.

(c) After administering the prescribed drug product or device, notifies the prescribing practitioner or enters the information in a patient record system shared by the prescribing practitioner.

(5) The board may approve courses of study which meet criteria substantially equivalent to criteria used by the Accreditation Council for Pharmacy Education.

(6) A course of study and training in administration technique shall include all of the following topics:

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

(d) The 5 rights of administration including right patient, right drug, right dose, right route, and right time.

(e) Patient reassessment after administration including signs and symptoms of adverse drug reactions.

(f) Best practices in documentation of the medication administration.

(7) This section does not apply to the administration of vaccines.

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

Phar 7.14 Pharmacy product verification technician-check-pharmacy technician. (1) DEFINITIONS. In this section:

(a) "Pharmacy product verification technician" means a registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

(b) "Pharmacy product verification technician-check- pharmacy technician" means the process in which a pharmacy product verification technician conducts the task of product verification of technical dispensing functions completed by a pharmacy technician. A pharmacy product verification technician may not conduct product verification as part of the final check of their own product preparation.

(c) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, as part of the final check and ensure the product has not reached its expiration or beyond use date.

(d) "Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a pharmacy product verification technician and ensuring for direct supervision of the pharmacy product verification technician.

(2) PHARMACY PRODUCT VERIFICATION TECHNICIAN QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a pharmacy technician who meets all of the following:

(b) Completed an accredited pharmacy technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:
   a. Drug name.
   b. Strength.
   c. Formulation.
   d. Expiration date.
   e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
   a. Wrong medication.
   b. Wrong strength.
   c. Wrong formulation.
   d. Extra or insufficient quantity.
   e. Omitted medications if utilizing unit dose or compliance packaging.
   f. Expired medication.
   g. Look-alike or sound-alike errors.
   h. High-alert medications.
3. Eligible products for pharmacy product verification technician-check-pharmacy technician.
4. Organizational policies and procedures on reporting of medication errors.
5. Overview of the medication use process including all of the following:
   a. Procurement.
   b. Ordering.
   c. Dispensing.
   d. Administration.
   e. Monitoring.
6. A practical training designed to assess the competency of the pharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:
   a. Wrong drug.
   b. Wrong strength.
   c. Wrong formulation.
   d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The pharmacy technician being validated shall make a product verification on the work of a pharmacist or another pharmacy technician for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the pharmacy technician during the validation process.

(e) Notwithstanding pars. (b) to (d), an individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the pharmacy product verification technician qualifications unless the individual fails to meet the quality assurance standards under sub. (4).

(3) ELIGIBLE PRODUCT. **(a)** *Institutional pharmacies.* The pharmacy product verification technician may do the product verification in an institutional pharmacy if all of the following requirements are met:

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.
2. A drug utilization review performed by a pharmacist prior to dispensing.
3. The drug product will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The pharmacy product verification technician may do the product verification in a community pharmacy if all of the following requirements are met:

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.
2. A drug utilization review performed by a pharmacist prior to dispensing.
3. A non-pharmacist shall be able to check the accuracy of the medication by one of the following:
   a. The drug product or device is in the original packaging from a manufacturer.
   b. The drug product or device includes a description of the drug product or device on the prescription label.
   c. The pharmacist shows the patient or patient's agent the drug product or device and provides a monograph that includes a description of the drug product or device.

(4) QUALITY ASSURANCE. **(a)** A minimum of 5% of each pharmacy product verification technician's verifications shall be audited by a licensed pharmacist. The accuracy of each pharmacy product verification technician shall be tracked individually.

(b) A record of each pharmacy product verification technician-check-pharmacy technician audit shall include all of the following:

1. Name of the pharmacy product verification technician.
2. Total number of product verifications performed.
3. Number of product verifications audited by the pharmacist.
4. Percentage of product verifications audited by pharmacist.
5. Percentage of accuracy.
6. Number of product verification errors identified.
7. Type of error under sub. (2) (c) 2. a. to c. and e.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each pharmacy product verification technician's previous 12 months accuracy and correctness of pharmacy product verifications including a review of the quality assurance log.

(d) A pharmacy product verification technician shall be revalidated if the individual fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the pharmacy product verification by technicians which shall be made available to the board upon request.

(6) RECORDS. **(a)** Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each pharmacy product verification technician that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist, and the dates the supervision responsibilities begin and end.
3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

Phar 7.15 Consumer disclosures. (1) Each pharmacy shall post in a prominent place and maintain the consumer disclosures required in ss. 450.13 (5m) and 450.135 (8m), Stats.

(2) A link to the 100 most commonly prescribed generic drug product equivalents as determined by the board, shall be maintained on the department's website as required in s. 450.13 (5m) (b), Stats.

Note: Copies of the required consumer disclosures are located on the Department of Safety and Professional Service's website: https://dsps.wi.gov.

(3) Pursuant to s. 450.13 (5m) (c), Stats., each pharmacy shall maintain and make available to the public a list of the drugs from the list in sub. (2) that are available for purchase at that pharmacy. The list shall be updated monthly, with all of the following information included:

(a) Brand name.

(b) Generic equivalent drugs and biological products.

(c) Interchangeable biological products.

(d) Retail price.

(4) The list required under sub. (3) may differ depending on whether the drugs on the list from sub. (2) are available for purchase at a specific pharmacy.

Phar 7.16 Additional Certification for Pharmacists. Every licensed pharmacist who administers drug product or devices or vaccines pursuant to s. 450.035, Stats., shall maintain current certification in cardiopulmonary resuscitation and basic life support.

Subchapter II — Central Shared Services

Phar 7.30 Definitions. In this subchapter:

(1) "Central shared services pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy.

(2) "Labeling pharmacy" means the central shared services pharmacy or originating pharmacy which is responsible for product verification under s. Phar 7.07 (1) (a) and (b).

(3) "Originating pharmacy" means a pharmacy licensed in this state that uses a central shared services pharmacy.

Phar 7.31 Requirements. An originating pharmacy may use a central shared services pharmacy only pursuant to the following requirements:

(1) The central shared services 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.

(2) The central shared services pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number that it provides services to.

(3) The central shared services pharmacy and originating pharmacy maintain a written protocol delineating each pharmacy's assumption of responsibility for compliance with state and federal law.

(4) Unless the central shared services pharmacy shares a computer system with the originating pharmacy meeting the requirements of s. Phar 7.04 (4) and contains the medication profile record under s. Phar 7.11 (3), it may not perform drug utilization review under s. Phar 7.03 to satisfy the final check requirement under s. Phar 7.07 (1) (c).

(5) The prescription label attached to the container shall contain the name and address of the labeling or originating pharmacy. 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 labeling pharmacy filled the prescription order.

(6) The originating pharmacy or central shared services pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

(7) In addition to meeting the other recordkeeping requirements required by state and federal law, the central shared services pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for the final check under s. Phar 7.07 (1).

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 Definitions. In this subchapter:

(1) "Delivery system" means a structure, controlled by a pharmacy licensed in this state, that a prescription is placed in for patient pick-up.

~~**(2)** "Supervising pharmacy" means a licensed pharmacy that oversees the operations and administration of remote dispensing.~~

Phar 7.41 Delivery system. (1) A prescription shall be stored in a secure delivery system immediately upon delivery to the location of the delivery system. Only the patient or patient's agent shall be able to open the door or locker containing only the patient's prescription.

(2) The delivery system shall be designed in a manner which does not disclose protected health information.

(3) The delivery system shall maintain appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.

(4) The use of a delivery system does not create an exemption to s. 450.11 (1b), Stats.

(5) A log shall be maintained by the dispensing pharmacy of all prescriptions delivered to the delivery system.

(6) The delivery system shall be inventoried at least weekly and a list of unclaimed prescriptions shall be reviewed by a pharmacist.

(7) The managing pharmacist shall establish written policies and procedures for all of the following:

(a) Stocking of the delivery system.

(b) Determining access to the delivery system.

(c) Detection and mitigation of diversion and theft.

Phar 7.42 Automated direct-to-patient dispensing system. (1) In this section "supervising practitioner" means the practitioner who is responsible for the operation of the automated direct-to-patient dispensing system and requirements of this section.

(2) An automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any of the locations under s. ~~450.062 (1) to (4)~~450.09 (2) (b) 1. a. to d., Stats., may operate for purposes of practitioner dispensing. The supervising practitioner will ensure all of the following requirements are met:

(a) Individuals with access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to the supervising practitioner or a delegate.

(b) The automated direct-to-patient dispensing system shall label the prescription in compliance with s. Phar 7.05.

(c) The automated direct-to-patient dispensing system shall maintain records of all prescription fills and dispenses in compliance with s. Phar 7.11 (1).

(d) The reporting of all monitored prescription drugs dispensed from the automated direct-to-patient dispensing system to the prescription drug monitoring program.

(3) The supervising practitioner or delegate shall establish written policies and procedures for automated direct-to-patient dispensing system for all of the following:

(a) Stocking.

(b) Determining access.

(c) Detection and mitigation of diversion and theft.

Phar 7.43 Remote dispensing. (2) LOCATION. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. 450.09 (2) (b) 1. a. to d., Stats.

(4) REQUIREMENTS. **(a)** A remote dispensing location shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.
2. This remote dispensing location is being supervised by a pharmacist employed by:
   a. Name of pharmacy.
   b. Address of pharmacy.
   c. Telephone of pharmacy.
3. Patient has a right to pharmacist consultation and information on how to file a complaint to the board.

(b) Remote dispensing may not occur if a pharmacist is not available remotely.

(c) A prescribed drug or device may not be dispensed in the absence of the ability of a patient and pharmacist's delegate to communicate with a pharmacist.

(d) No vaccines shall be administered at a remote dispensing site.

(5) DISPENSING REQUIREMENTS. Remote dispensing shall comply with all of the following:

(a) Visually inspecting all prescription orders, labels and dispensed product.

(b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the remote dispensing site as the licensed facility from which the prescribed drug or device was dispensed.

(c) Final check under s. Phar 7.07.

(d) Federal law if dispensing controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACIST. The managing pharmacist responsible for the remote dispensing pharmacy shall do all of the following:

(a) Have written policies and procedures for system operation, safety, security, accuracy and access.

(b) Implement an ongoing quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.

(c) Visit the remote dispensing location at least monthly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy.

(d) Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.

(e) Documentation indicating accepting responsibility for compliance with this section, signed and dated by the managing pharmacist.

(7) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) shall meet the following requirements to remote dispense:

(a) Be 18 years of age or older.

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

(c) Have completed 1500 hours of work as a pharmacist delegate within the 3 years prior to engaging in remote dispensing or completed an accredited pharmacy technician training program.

Subchapter IV — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:

(1) "Chart order" means an order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or practitioner's delegate for a drug product or device.

(2) "Institutional 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 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, 146.903 (1) (b), 233.40, 233.41, 233.42, or 252.10, Stats.; a hospice facility under s. 50.90 (1) (c), Stats.; a county jail; and a correctional facility operated under the authority of the department of corrections.

(3) "Institutional pharmacy" means a pharmacy that provides pharmacy services to an institutional facility. This definition is not for purposes under s. 450.09 (1) (a), Stats.

Phar 7.51 Chart orders. A chart order shall contain all of the following:

(1) First and last name of the patient.

(2) Patient's medical record number or date of birth.

(3) Date of issuance.

(4) Name, strength, and form of the drug product or device prescribed.

(5) Directions for use.

(6) The signature by one of the following methods:

(a) If handwritten, the practitioner's or delegate's signature.

(b) Electronic signature of the practitioner or delegate.

(7) Chart orders prepared by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name of the practitioner.

Phar 7.52 Labels. All prescribed drug products and devices dispensed for administration by a health care provider at the institutional facility shall have a label attached to the container disclosing all of the following:

(1) Drug name, strength and form.

(2) Beyond use date or expiration date.

(3) Special storage conditions, if required.

Phar 7.53 Security and access. (1) Arrangements shall be made in advance by the managing pharmacist for access of drugs by the health care staff of the institutional facility when dispensing by a pharmacist is not available.

(2) In the absence of a pharmacist, drugs shall be stored in a manner in which only authorized personnel may obtain access and is sufficiently secure to deny access to unauthorized persons.

(3) The managing pharmacist shall develop policies and procedures in place to mitigate and prevent theft and diversion.

Phar 7.54 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene.

(b) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(c) "Tamper-evident package" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.

(2) A health item which has been sold, distributed or dispensed, may be returned to the institutional pharmacy under s. Phar 7.10 (2) or if the health item has not left the control of the health care facility staff authorized to have access to prescription drug products.

(3) A health item returned to an institutional pharmacy may be sold, distributed, or dispensed to the institutional facility if all of the following apply:

(a) The health item was never in the possession and control of the patient.

(b) The health item was sold, distributed or dispensed in a tamper-evident package and, for a drug product, includes the beyond use date or expiration date and manufacturer's lot number.

(c) The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

Phar 7.55 Automated technology product verification. (1) DEFINITIONS. In this section:

(a) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Product verification may be done only by an automated technology which meets all of the following:

(a) Located within a licensed pharmacy.

(b) Utilizing barcodes or another machine-readable technology to complete the product verification.

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:

(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.

(b) Has a drug utilization review performed by a pharmacist prior to delivery.

(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(4) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request.

(5) RECORDS. **(a)** Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.
3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.
4. Documentation of the dates of all software upgrades.
5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

(b) Records shall be made available to the board upon request.

Subchapter V — Uncredentialed Pharmacy Staff

Phar 7.60 Definition. In this subchapter, "uncredentialed pharmacy staff" means any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats.

Phar 7.62 Uncredentialed pharmacy staff. (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m).

(2) A pharmacist shall provide direct supervision of uncredentialed pharmacy staff. A pharmacist shall be available to the uncredentialed pharmacy staff person for consultation either in person or contact by telecommunication means.

(3) An uncredentialed pharmacy staff person may not engage in the practice of pharmacy as defined in s. 450.01 (16), Stats., or the practice of a pharmacy technician as defined in s. Phar 19.02.

(4) The prohibitions in sub. (3), do not apply to a person completing an internship for purposes of meeting the internship requirement under s. 450.03 (2) (b), Stats.

(5) A managing pharmacist shall provide training to or verify competency of an uncredentialed pharmacy staff person prior to the uncredentialed pharmacy staff person performing a delegated act.

(6) The managing pharmacist shall determine which acts may be delegated in a pharmacy. The managing pharmacist has a duty to notify all pharmacists practicing in that pharmacy which acts may be delegated to specific uncredentialed pharmacy staff. This record shall be provided to the board upon request.

(7) A pharmacist may delegate to an uncredentialed pharmacy staff person any delegated act approved by the managing pharmacist outside of the restrictions in sub. (3).

Chapter Phar 10

STANDARDS OF PROFESSIONAL CONDUCT

Phar 10.01 Authority. The rules in this chapter are adopted pursuant to the authority in ss. 15.08, 227.11 and 450.02, Stats.

Phar 10.02 Definitions. In this chapter:

(1) "Dispense" has the meaning given in s. 450.01 (7), Stats.

(2) "Drug" has the meaning given in s. 450.01 (10), Stats.

(3) "Patient" has the meaning given in s. 450.01 (14), Stats.

Phar 10.03 Unprofessional conduct. The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional con- duct in addition to those grounds specified under s. 450.10 (1), Stats.:

(1) Administering, dispensing, supplying or obtaining a drug other than in legitimate practice, or as prohibited by law.

(2) Engaging in any pharmacy practice which constitutes a danger to the health, welfare, or safety of patient or public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist or pharmacy technician which harmed or could have harmed a patient.

(3) Dispensing a drug which the pharmacist should have known would harm the patient for whom the medication was prescribed.

(4) Dispensing or causing to be dispensed a drug which is outdated or contaminated or known by the pharmacist to be un- safe for consumption.

(5) Falsifying patient records.

(6) Disclosing to the public information concerning a patient without the consent of the patient unless the information is re- quested by the pharmacy examining board or the department of safety and professional services or unless release is otherwise authorized by law.

(7) Failing to report to the pharmacy examining board any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public.

(7m) Failing to report to the board information that reasonably suggests there is a probability that a prescription drug or device dispensed by a pharmacist has caused or contributed to the substantial bodily injury or death of a customer or patient.

(8) Providing false information to the pharmacy examining board or its agent.

(9) Refusing to render professional services to a person be- cause of race, color, sex, religion, or age.

(10) Aiding or abetting the unlicensed practice of pharmacy.

(11) Advertising in a manner which is false, deceptive or misleading.

(12) Dispensing sample drug products for any financial consideration.

(13) Exercising undue influence on or taking unfair advantage of a patient in the promotion or sale of services, drugs or other products for the financial gain of the pharmacist or a third party.

(14) Participating in rebate or fee-splitting arrangements with health practitioners or with health care facilities.

(15) Furnishing a prescriber with any prescription order blanks imprinted with the name of a specific pharmacist or pharmacy.

(16) Using secret formula or code in connection with pre- scription orders.

(17) Having a pharmacist license or pharmacy technician registration revoked or suspended in another state or United States jurisdiction or having been subject to other disciplinary action by the licensing authority thereof.

(18) Violating or attempting to violate any formal disciplinary order of the board.

(19) Practicing without a current license or registration.

(20) Violating or attempting to violate any provision or term of ch. 450, Stats., or of any rule of the board.

(21) Failure to comply with s. 450.13 (5m) or 450.135 (8m), Stats.

Effective dates: 9/29/2023 – 3/28/2025

Board of Pharmacy

Pharmacy working conditions

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist may, however, volunteer to work longer than 12 continuous hours. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break. Breaks, including uninterrupted rest periods and meal breaks, shall be provided consistent with 18VAC110-20-113 B 5.

C. The PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

E. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedules II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-113. Pharmacy working conditions.

A. A pharmacy permit holder shall protect the health, safety, and welfare of patients by consulting with the PIC or pharmacist on duty and other pharmacy staff to ensure patient care services are safely provided in compliance with applicable standards of patient care. A permit holder's decisions shall not override the control of the PIC or other pharmacist on duty regarding appropriate working environments for all pharmacy personnel necessary to protect the health, safety, and welfare of patients.

B. To provide a safe working environment in a pharmacy, a permit holder shall, at a minimum:

1. Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels shall not be solely based on prescription volume, but shall consider any other requirements of pharmacy staff during working hours;

2. Provide sufficient tools and equipment in good repair and minimize excessive distractions to support a safe workflow for a pharmacist to practice with reasonable competence and safety to address patient needs in a timely manner;

3. Avoid the introduction of external factors, such as productivity or production quotas, or other programs to the extent that they interfere with the pharmacist's ability to provide appropriate professional services to the public;

4. Ensure staff are sufficiently trained to safely and adequately perform their assigned duties, ensure staff demonstrate competency, and ensure that pharmacy technician trainees work closely with pharmacists and pharmacy technicians with sufficient experience as determined by the PIC;

5. Provide appropriate opportunities for uninterrupted rest periods and meal breaks consistent with 18VAC110-20-110 and the following:

a. A pharmacy may close when a pharmacist is on break based on the professional judgment of the pharmacist on duty provided that it has complied with the 14-day notice to the public pursuant to § 54.1-3434 of the Code of Virginia and 18VAC110-20-135;

b. If a pharmacy does not close while the pharmacist is on break, the pharmacist must ensure adequate security of drugs by taking his break within the prescription department or on the premises. The pharmacist on duty must determine if pharmacy technicians or pharmacy interns may continue to perform duties and if the pharmacist is able to provide adequate supervision; and

c. If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel any person filling a new prescription must be offered pursuant to § 54.1-3319 of the Code of Virginia. Persons who request to speak to the pharmacist shall be told that the pharmacist is on break and that they may wait to speak with the pharmacist or provide a telephone number for the pharmacist to contact them upon return from break. Pharmacists returning from break shall immediately attempt to contact persons who requested counseling and document when such counseling is provided;

6. Provide adequate time for a pharmacist to complete professional duties and responsibilities, including:

a. drug utilization review;

b. immunization;

c. counseling;

d. verification of prescriptions;

e. patient testing; and

f. all other duties required by §§ 54.1-3300 *et seq.* and 54.1-3400 *et seq.* of the Code of Virginia and 18VAC110-20-10 *et seq;* and

7. Ensure that pharmacy technicians shall never perform duties otherwise restricted to a pharmacist.

C. A pharmacy permit holder shall not override the control of the pharmacist on duty regarding all aspects of the practice of pharmacy, including a pharmacist's decision not to administer vaccines when one pharmacist is on duty and, in the pharmacist's professional judgment, vaccines cannot be administered safely.

D. Staffing requests or concerns shall be communicated by the PIC or pharmacist on duty to the permit holder using a form developed by the board.

1. Executed staffing forms shall be provided to the immediate supervisor of the PIC or pharmacist on duty, with one copy maintained in the pharmacy for three years, and produced for inspection by the board.

2. The PIC or pharmacist on duty may report any staffing issues directly to the board if the PIC or pharmacist on duty believes the situation warrants immediate board review.

3. Under no circumstances shall a good faith report of staffing concerns by the PIC, pharmacist on duty, or notification of such issues by pharmacy personnel to the PIC or pharmacist on duty result in workplace discipline against the reporting staff member.

E. Permit holders shall review completed staffing reports and shall:

1.Respond to reporting staff member to acknowledge receipt of the staffing request or concern;

2. Resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff and appropriate medication access for patients;

3. Document any corrective action taken, steps taken toward corrective action as of the time of inspection, or justification for inaction, which documentation shall be maintained on-site or produced for inspection by the board within 48 hours of request; and

4. Communicate corrective action taken or justification for inaction to the PIC or reporting pharmacist on duty.