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**TELECONFERENCE/VIRTUAL  
PHARMACY EXAMINING BOARD**  
**Virtual, 4822 Madison Yards Way, Madison, WI**  
**Contact: Christian Albouras (608) 266-2112**  
**June 4, 2020**

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

**AGENDA**

**11:00 A.M.**

**(OR IMMEDIATELY FOLLOWING PHARMACY RULES COMMITTEE MEETING)**

**OPEN SESSION – CALL TO ORDER – ROLL CALL**

- A. Adoption of Agenda (1-5)**
- B. Approval of Minutes of March 5, 2020 (6-9)**
- C. Conflicts of Interest**
- D. Administrative Matters – Discussion and Consideration**
  - 1) Department, Staff and Board Updates
  - 2) Board Members – Term Expiration Dates
- E. Legislative and Policy Matters – Discussion and Consideration**
- F. Administrative Rule Matters – Discussion and Consideration (10)**
  - 1) Adopt CR 19-145, Relating to the Practice of Pharmacy **(11-41)**
  - 2) Adopt CR 19-164, Relating to Internships **(42-46)**
  - 3) Adopt CR 19-165, Relating to Pharmacy Storage **(47-50)**
  - 4) Scope Amending Phar 2 Relating to Service Member Reciprocal License (2019 Act 143) **(51-52)**
  - 5) Scope Amending Phar 5, 6, 7, 11, and 12, Relating to Changes Identified in the Board’s Report Pursuant to s. 227.29, Wis. Stat., and Technical Correction **(53-54)**
  - 6) Pending or Possible Rulemaking Projects **(55)**
- G. COVID-19 – Discussion and Consideration**
  - 1) Variances
  - 2) License Renewal Deadlines
- H. Pilot Program Matters – Discussion and Consideration**
- I. Newsletter Planning – Discussion and Consideration**

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

- 1) National Association of Boards of Pharmacy (NABP)/American Association of Colleges of Pharmacy (AACCP) District IV – 2021 Annual Meeting Planning
- 2) Travel Report: Pharmacy Society of Wisconsin Legislative Day, February 12, Madison, WI

**K. Discussion and Consideration on Items Added After Preparation of Agenda**

- 1) Introductions, Announcements and Recognition
- 2) Nominations, Elections, and Appointments
- 3) Administrative Matters
- 4) Election of Officers
- 5) Appointment of Liaisons and Alternates
- 6) Delegation of Authorities
- 7) Education and Examination Matters
- 8) Credentialing Matters
- 9) Practice Matters
- 10) Legislative and Policy Matters
- 11) Administrative Rule Matters
- 12) Pilot Program Matters
- 13) Liaison Reports
- 14) Board Liaison Training and Appointment of Mentors
- 15) Informational Items
- 16) Division of Legal Services and Compliance (DLSC) Matters
- 17) Presentations of Petitions for Summary Suspension
- 18) Petitions for Designation of Hearing Examiner
- 19) Presentation of Stipulations, Final Decisions and Orders
- 20) Presentation of Proposed Final Decisions and Orders
- 21) Presentation of Interim Orders
- 22) Pilot Program Matters
- 23) Petitions for Re-Hearing
- 24) Petitions for Assessments
- 25) Petitions to Vacate Orders
- 26) Requests for Disciplinary Proceeding Presentations
- 27) Motions
- 28) Petitions
- 29) Appearances from Requests Received or Renewed
- 30) Speaking Engagements, Travel, or Public Relation Requests, and Reports

**L. Public Comments**

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

**M. Deliberation on Division of Legal Services and Compliance Matters**

- 1) **Administrative Warnings**
  - a. 17 PHM 171 – C.P.K. **(56-57)**
  - b. 17 PHM 183 – P.R.N. **(58-59)**

- c. 18 PHM 035 – G.R.K. **(60-61)**
  - d. 18 PHM 117 – B.E.N. **(62-63)**
  - e. 18 PHM 117 – M.C.P. **(64-65)**
  - f. 18 PHM 126 – M.E.M. **(66-67)**
  - g. 18 PHM 155 – A.T.O. **(68-69)**
  - h. 18 PHM 173 – J.A.K. **(70-71)**
  - i. 20 PHM 045 – D.G.K. **(72-73)**
- 2) Case Closings**
- a. 17 PHM 097 – K.L.G. & W.P. **(74-81)**
  - b. 17 PHM 106 – A.K.S. **(82-88)**
  - c. 17 PHM 147 – W. & P.E.T. **(89-92)**
  - d. 17 PHM 171 – W., M.O. & E.N. **(93-99)**
  - e. 17 PHM 183 – L.M.A. **(100-104)**
  - f. 18 PHM 035 – S.P., S.M.G. & R.L.S. **(105-108)**
  - g. 18 PHM 053 – A.I. **(109-112)**
  - h. 18 PHM 112 – C.L.R. & D.B.B. **(113-122)**
  - i. 18 PHM 114 – C.D.R. & S.P. **(123-126)**
  - j. 18 PHM 126 – M.J.P., S.P. **(127-131)**
  - k. 18 PHM 127 – J.M.F. & W. **(132-136)**
  - l. 18 PHM 132 – W. & C.P. **(137-140)**
  - m. 18 PHM 155 – W. **(141-146)**
  - n. 18 PHM 173 – S.P., S.P., & S.P. **(147-150)**
  - o. 18 PHM 193 – C.D.B. **(151-153)**
  - p. 18 PHM 215 – S.P. **(154-157)**
  - q. 18 PHM 222 – S.Y.R.X. **(158-171)**
  - r. 19 PHM 057 – L.H.P. (A), L.H.P. (B) **(172-175)**
  - s. 19 PHM 102 – W. **(176-179)**
  - t. 19 PHM 108 – H.P. **(180-184)**
  - u. 19 PHM 110 – P.C.I. **(185-187)**
  - v. 19 PHM 119 – C.P.K.L. **(188-191)**
  - w. 19 PHM 141 – W. & J.P.A. **(192-196)**
  - x. 19 PHM 153 – R.K.K. & W.P. **(197-201)**
  - y. 19 PHM 161 – A.L.L. **(202-205)**
  - z. 19 PHM 186 – W. & C.G. **(206-211)**
  - aa. 19 PHM 196 – A.P. **(212-216)**
  - bb. 19 PHM 197 – A.P.S. **(217-220)**
  - cc. 19 PHM 198 – A.P. **(221-225)**
  - dd. 19 PHM 199 – B.A.P. **(226-229)**
  - ee. 19 PHM 200 – B.S.P. **(230-233)**
  - ff. 19 PHM 201 – S.S.P. **(234-237)**
  - gg. 19 PHM 203 – C.P. **(238-242)**
  - hh. 19 PHM 204 – C.A.W.P. **(243-246)**
  - ii. 19 PHM 205 – C.P. **(247-250)**
  - jj. 19 PHM 206 – C.P.S.T. **(251-254)**

- kk. 19 PHM 209 – E.L.P. **(255-259)**
- ll. 19 PHM 211 – E.P. **(260-264)**
- mm. 19 PHM 212 – F.P. **(265-268)**
- nn. 19 PHM 214 – G.P. **(269-273)**
- oo. 19 PHM 215 – G.P. **(274-278)**
- pp. 19 PHM 217 – G.H.P. **(279-283)**
- qq. 19 PHM 218 – H.M.P. **(284-287)**
- rr. 19 PHM 219 – J.C.A.W. **(288-292)**
- ss. 19 PHM 220 – L.H. **(293-297)**
- tt. 19 PHM 221 – M.H. **(298-302)**
- uu. 19 PHM 223 – M.P.I. **(303-307)**
- vv. 19 PHM 224 – O.M.H.P. **(308-312)**
- ww. 19 PHM 226 – P.C.P. **(313-317)**
- xx. 19 PHM 228 – P.C.P.L. **(318-323)**
- yy. 19 PHM 232 – R.P. **(324-327)**
- zz. 19 PHM 233 – W. & C.G. **(328-330)**
- aaa. 19 PHM 237 – S.P. **(331-334)**
- bbb. 19 PHM 239 – T.D.S. **(335-338)**
- ccc. 19 PHM 240 – W.H.P. **(339-342)**
- ddd. 19 PHM 243 – M.F.P. **(343-348)**
- eee. 19 PHM 244 – E.T.P. **(349-352)**
- fff. 19 PHM 247 – M.M.C. & W. **(353-357)**
- ggg. 19 PHM 257 – D.I.P.C.L. **(358-361)**
- hhh. 19 PHM 258 – S.R.X.P. **(362-366)**
- iii. 19 PHM 259 – R.P. **(367-370)**
- jjj. 19 PHM 261 – L.S.P. **(371-374)**
- kkk. 19 PHM 267 – G.G.P. **(375-378)**
- lll. 19 PHM 270 – B.P. **(379-382)**
- mmm. 19 PHM 294 – H.P. **(383-387)**

**3) Stipulations and Final Decisions and Orders**

- a. 17 PHM 097 – Gina L. Lusic, R.Ph. **(388-393)**
- b. 17 PHM 106 – Medpoint Pharmacy, Inc. **(394-399)**
- c. 18 PHM 112 – CVS Pharmacy #5390 **(400-405)**
- d. 18 PHM 121 – Michael Eanneli, R.Ph. **(406-412)**
- e. 18 PHM 124 – Jay R. Joshi, R.Ph. **(413-419)**
- f. 19 PHM 060 – Kayla F. Brisson, R.Ph. **(420-425)**
- g. 19 PHM 155 – Guaranteed Returns **(426-437)**

**N. Deliberation on Matters Relating to Costs/Orders Fixing Costs**

- 1) Walter P. Matoska, R.Ph., Respondent (DHA Case Number SPS-19-0050/DLSC Case Number 18 PHM 001) **(438-466)**

**O. Deliberation of Items Added After Preparation of the Agenda**

- 1) Education and Examination Matters

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

P. Consulting with Legal Counsel

**RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION**

- Q. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate
- R. Open Session Items Noticed Above Not Completed in the Initial Open Session
- S. Board Meeting Process (Time Allocation, Agenda Items) – Discussion and Consideration
- T. Board Strategic Planning and its Mission, Vision, and Values – Discussion and Consideration

**ADJOURNMENT**

**NEXT MEETING: JULY 23, 2020**

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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 at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board’s agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

**PHARMACY EXAMINING BOARD  
MEETING MINUTES  
MARCH 5, 2020**

**PRESENT:** Franklin LaDien, Anthony Peterangelo, Philip Trapskin, John Weitekamp, Cathy Winters

**EXCUSED:** Michael Walsh, Shana Weiss

**STAFF:** Yolanda McGowan, DPD Division Administrator; Jameson Whitney, Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Megan Glaeser, Bureau Assistant; and other Department staff

**CALL TO ORDER**

Philip Trapskin, Chairperson, called the meeting to order at 11:08 a.m. A quorum was confirmed with five (5) board members present.

**ADOPTION OF AGENDA**

**Amendments to the Agenda:**

- Under Item K. ADD:
  - NABP Annual Meeting, May 14-16, 2020

**MOTION:** Cathy Winters moved, seconded by Franklin LaDien, to adopt the Agenda as amended. Motion carried unanimously.

**APPROVAL OF MINUTES**

**Amendments to the Minutes:**

- Under Screening Panel Appointments: adjust 2019 to 2020

**MOTION:** Cathy Winters moved, seconded by John Weitekamp, to adopt the Minutes of January 30, 2020 as amended. Motion carried unanimously.

**ADMINISTRATIVE MATTERS**

**Department, Staff and Board Updates**

**MOTION:** Cathy Winters moved, seconded by Franklin LaDien, to recognize and thank Debra Sybell for her service as Executive Director to the Pharmacy Examining Board and the State of Wisconsin. Motion carried unanimously.

**APPROVAL PROCESS FOR BOARD APPROVAL OF CERTIFICATION ENTITIES  
SIMILAR TO THE CONTROLLED ENVIRONMENT TESTING ASSOCIATION'S  
NATIONAL BOARD TESTING CERTIFICATION**

**MOTION:** Philip Trapskin moved, seconded by Cathy Winters, to require entities seeking board approval under Phar 15.31(4) to submit documentation demonstrating substantial equivalence to CETA requirements for sterile compounding facility inspector certification. Motion carried unanimously.

**PILOT PROGRAM MATTERS**

**Request for Pilot Program – Use of Automation for Final Check in Community Pharmacy Setting**

**MOTION:** Franklin LaDien moved, seconded by Cathy Winters, to request the Department assist the Board in exploring development of a Pilot Program for the use of automation to complete portions of the final check outside of institutional settings. Motion carried unanimously.

**SPEAKING ENGAGEMENTS, TRAVEL, OR PUBLIC RELATION REQUESTS, AND REPORTS**

**NABP Annual Meeting – May 14-16, 2020 – Baltimore, MD**

**MOTION:** Anthony Peterangelo moved, seconded by John Weitekamp, to designate Cathy Winters, as the Board's delegate, and Franklin LaDien as the Board's alternate delegate, to attend the NABP Annual Meeting on May 14-16, 2020 in Baltimore, MD and to authorize travel. Motion carried unanimously.

**CLOSED SESSION**

**MOTION:** Franklin LaDien moved, seconded by Anthony Peterangelo, to convene to Closed Session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). Philip Trapskin, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Franklin LaDien-yes; Anthony Peterangelo-yes; Philip Trapskin-yes; John Weitekamp-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 1:21 p.m.

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

**Administrative Warning**

***18 PHM 096 – M.A.C.***

**MOTION:** Cathy Winters moved, seconded by Anthony Peterangelo, to issue an Administrative Warning in the matter of M.A.C., DLSC Case Number 18 PHM 096. Motion carried unanimously.

**Case Closings**

**MOTION:** Cathy Winters moved, seconded by John Weitekamp, to close the following DLSC Cases for the reasons outlined below:

1. 16 PHM 201 – C.M.P. – Prosecutorial Discretion (P3)
2. 17 PHM 158 – C.V.S. – No Violation
3. 18 PHM 069 – C.P. – Prosecutorial Discretion (P1)
4. 18 PHM 074 – B.S. – No Violation & P.S. – Prosecutorial Discretion (P2)
5. 18 PHM 095 – E.M. & C.V.S. – Insufficient Evidence
6. 19 PHM 183 – W.M.P. – Insufficient Evidence

Motion carried unanimously.

**Monitoring Matters**

**Michael Ivey, R.Ph. – Requesting Additional Pharmacist-in-Charge Hours**

**MOTION:** Franklin LaDien moved, seconded by Cathy Winters, to grant the request of Michael Ivey, R.Ph. for 16 Additional Pharmacist-in-Charge Hours, for a total of 24. Motion carried unanimously.

**RECONVENE TO OPEN SESSION**

**MOTION:** Cathy Winters moved, seconded by Anthony Peterangelo, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 1:41 p.m.

**VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION**

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

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

## **ADJOURNMENT**

**MOTION:** Cathy Winters moved, seconded by Anthony Peterangelo, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:45 p.m.

DRAFT

**State of Wisconsin  
Department of Safety & Professional Services**

**AGENDA REQUEST FORM**

|  |  |   |  |
|--|--|---|--|
| 1) Name and Title of Person Submitting the Request:<br>Sharon Henes<br>Administrative Rules Coordinator  |  | 2) Date When Request Submitted:<br>21 May 2020<br><small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>   |  |
| 3) Name of Board, Committee, Council, Sections:<br>Pharmacy Examining Board  |  |   |  |
| 4) Meeting Date:<br>4 June 2020  | 5) Attachments:<br><input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No                            | 6) How should the item be titled on the agenda page?<br><b>Administrative Rule Matters</b><br>1. Adopt CR 19-145 Relating to the Practice of Pharmacy<br>2. Adopt CR 19-164 Relating to Internships<br>3. Adopt CR 19-165 Relating to Pharmacy Storage<br>4. Scope Amending Phar 2 Relating to Service Member Reciprocal License (2019 Act 143)<br>5. Scope Amending Phar 5, 6, 7, 11, and 12 Relating to Changes Identified in the Board's Report pursuant to s. 227.29 and Technical Correction.<br>6. Updates on Pending or Possible Rulemaking Projects |  |
| 7) Place Item in:<br><input checked="" type="checkbox"/> Open Session<br><input type="checkbox"/> Closed Session   | 8) Is an appearance before the Board being scheduled?<br><input type="checkbox"/> Yes<br><input type="checkbox"/> No | 9) Name of Case Advisor(s), if required:  |  |
| 10) Describe the issue and action that should be addressed:  |  |   |  |
| 11) Authorization  |  |   |  |
| <i>Sharon Henes</i>  |  | <i>21 May 2020</i>  |  |
| Signature of person making this request  |  | Date  |  |
| Supervisor (if required)   |  | Date  |  |
| Executive Director signature (indicates approval to add post agenda deadline item to agenda)   |  | Date  |  |
| Directions for including supporting documents:<br>1. This form should be attached to any documents submitted to the agenda.<br>2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.<br>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

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|                              |   |                             |
|------------------------------|---|-----------------------------|
| IN THE MATTER OF RULE-MAKING | : | ORDER OF THE                |
| PROCEEDINGS BEFORE THE       | : | PHARMACY EXAMINING BOARD    |
| PHARMACY EXAMINING BOARD     | : | ADOPTING RULES              |
|                              | : | (CLEARINGHOUSE RULE 19-145) |

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ORDER

An order of the Pharmacy Examining Board to repeal and recreate ch. Phar 7 relating to the practice of pharmacy.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** ss. 450.033, 450.035, 450.062, 450.09, 450.11, 450.12, Stats.

**Statutory authority:** ss. 15.08 (5) (b), 450.02 (2), and 450.02 (3) (a) to (e), and 961.31, Stats.

**Explanation of agency authority:**

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

The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05. [s. 450.02, Stats.]

The board may promulgate rules:

- (a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
  - (b) Establishing security standards for pharmacies.
  - (c) Relating to the manufacture, distribution and dispensing of hypodermic syringes, needles and other objects used, intended for use or designed for use in injecting a drug.
  - (d) Necessary for the administration and enforcement of this chapter and ch. 961.
  - (e) Establishing minimum standards for the practice of pharmacy.
- [ss. 450.02 (3) (a) to (e), Stats.]

The pharmacy examining board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state. [s. 961.31, Stats.]

**Related statute or rule:** Phar 6 and 8

**Plain language analysis:**

This rule repeals and recreates the chapter delineating the practice of pharmacy.

A prescription is required to have the date of issue, name and address of the prescriber (and if delegated that person's name), directions for use, the drug's name, strength, and quantity, whether there are any refills authorized, name and address of the patient (unless omission is required by statute) and the prescriber's signature. A standing order is required to have all the same elements as a prescription with the exception of prescriber's signature and indicate that it is pursuant to a standing order. A pharmacist may dispense pursuant to an electronic prescription, if the prescription is sent to the patient's choice of pharmacy, contains the elements of a prescription and may be signed with the prescriber's electronic signature. Verbal prescriptions may be received and reduced to writing on paper or in a computer system. Any alterations to a prescription which changes the prescriber's original intent must be documented including the pharmacist who made the alteration and the prescriber who authorized the change.

A drug utilization review must be completed prior to dispensing a prescription drug. It includes checking the prescription for the following: known allergies, rational therapy, contraindications, reasonable dose, duration of use and route of administration, reasonable directions for use, potential or actual adverse drug reactions, drug interactions with food, beverages, other drugs or medical conditions, therapeutic duplication, reasonable utilization and optimum therapeutic outcomes and potential abuse or misuse. If there is a concern with any of these items, the pharmacist will take steps to mitigate or resolve the matter.

A prescription can be transferred either orally between two pharmacists or between two pharmacies by fax machine or electronically. New or refill prescriptions for non-controlled substances can be transferred by indicating the prescription is void at the original pharmacy and indicating the prescription is a transfer at the receiving pharmacy. Unless a real time shared computer is used between the pharmacies, for non-controlled substances the receiving pharmacy will record the name and address of the patient, name and address of the prescribing practitioner, name, strength, form and quantity of the drug product or device, date of issue of the original prescription, the original prescription order number, original number of refills authorized, dates of last fills, number of valid refills or quantity remaining, original pharmacy name and address and the names of the transferring and receiving pharmacists. Refill prescriptions for controlled substances can be transferred by communication directly between 2 licensed pharmacists utilizing the same procedures as a non-controlled with the addition of recording the drug enforcement administration (DEA) registration numbers of the originating pharmacy and prescriber, and dates and locations of previous fills..

All prescription drugs and devices shall have a label. The label will identify the patient, symptom or purpose (if indicated on prescription), name and strength of drug, date the drug should not be used after, the name, address and telephone number of the pharmacy, prescriber name, date prescription filled, prescription number, quantity, and number of refills or quantity remaining, and directions for use. A label may include the symptom or purpose if requested by the patient, both generic and brand names unless the prescriber requests the brand name be omitted, written or graphic product descriptions and any other cautions or provisions. A label is not required on complimentary drug or device samples dispensed in original packaging by a prescriber.

A pharmacist can repack non-sterile drugs into different containers for stocking purposes. When repackaging drugs into other containers, the pharmacist must ensure the process is done under conditions which will not compromise the integrity of the drug, select containers which mitigate adulteration from light, temperature or humidity, and label the new container(s) with drug name, strength and form, beyond use date and a set of identifiers (pharmacy control or national drug code (NDC) and manufacturer lot number, or manufacturer or distributor name, and manufacturer lot number. Records must include the drug name, strength and form, the quantity in each container and number of containers the drug was repackaged into, the NDC number (or if not available manufacturer or distributor), manufacturer lot number, the original container's expiration date and the beyond use date for the new containers, the name of the pharmacist or delegate that repackaged the drug, the name of the pharmacist that verified the accuracy of the repackaging and the date the repackaging was done.

All prescription drugs and devices must have a final check prior to dispensing. A final check includes checking that label requirements are met, it is the correct drug product or device, and a drug utilization review was completed. The check can be done by one or multiple pharmacists, with the prescription record reflecting which pharmacist was responsible for each part of the final check. If the label and product verification was done by automated technology or delegate check delegate, the prescription record will reflect the name of the delegate.

A pharmacist must consult the patient or patient's agent for every new prescription which has not been dispensed previously to the patient, any change in the patient's therapy, upon request of a patient or patient's agent and whenever it is in the pharmacist's professional judgement a consultation should occur. Consultation is not required when the drug or device is administered by or in the presence of an individual with a scope of practice that includes administration of a drug or device or the individual's delegate or a patient or patient's agent refuses consultation. Patient consultation includes, based upon the pharmacist's professional judgment, the name and description of the drug, form, dose, route of administration and duration for drug therapy, intended use of the drug and expected action, directions and precautions, common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid and action if they occur, techniques for self-monitoring drug therapy, proper storage and disposal and action to be taken in the event of a missed dose. The consultation is required to be verbal when the pharmacist deems it is in the patient's best interest to do so. In addition, when a consultation is required, the pharmacist shall provide a written patient drug education monograph. Every pharmacy shall post a sign stating a patient's right to consultation and information on how to file a complaint to the board and board approved information stating patient's rights shall accompany all delivered prescriptions by common carrier or delivery service or picked up at a drive through window.

Delivery of prescription drugs by common carrier or delivery services shall ensure the delivery method is appropriate to prevent drug adulteration. The patient must be provided with a method to report any irregularities in the delivery including timeliness, condition of the drug and failure to receive the correct drug or device. Any drug compromised by delivery or lost must be replaced at no additional cost to the patient. If the timing of the replacement will lead to interruption in therapy, steps must be taken by a pharmacist to mitigate patient harm.

A pharmacy must have a system for identifying any drugs or devices subject to a recall and to take appropriate action as required in a recall notice. A drug or device can't be dispensed after its expiration or beyond use date. All outdated drugs or devices must be removed from dispensing stock and quarantined until properly disposed.

The only health care items that may be returned to a pharmacy are health care items dispensed in error, defective, adulterated or misbranded, when in the pharmacist's professional judgment substantial harm could result to the public or patient if they were to remain in the possession of the patient, patient's family or others, or a health item is prepackaged for consumer use without a prescription when returned in compliance with state or federal laws. The DEA does not permit the return of controlled substances to a pharmacy under any circumstances. Only returned health items that are prepackaged for consumer use without a prescription may be sold, resold or dispensed. It is not considered a return if the health care item is returned to the pharmacy for purposes of packaging, relabeling and returned to the same patient. This rule does not prohibit participation in a drug repository program in accordance with ch. DHS 148.

Pharmacy records are to be kept for a minimum of five years. A computerized system may be used if it is capable of producing a printout of the data contained in it and there is another procedure for documentation if dispensing and refills are authorized during periods of time the computer is not working. Prescription records are to be kept for 5 years after the date of the last refill. A paper prescription for non-controlled substances can be scanned and stored electronically (and at that point becomes an electronic prescription). A medication profile record system must contain the patient's name, address, date of birth, name of drug product or device dispensed, strength and form of the drug product or device dispensed, quantity dispensed and remaining, number of refills prescribed, directions for use, prescription order number, original date of issue, date of dispensing and the prescriber's name. A pharmacist will 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. Medication profile records are to be kept for 5 years following the date of the last dispensing.

Any delegation by a physician to a pharmacist shall be documented by the pharmacist. The delegated act may not begin until it is documented. The documentation shall be maintained for a minimum of 5 years after the last delegated act under the delegation.

A pharmacist may not administer by injection a prescribed drug product or device (other than vaccines) unless the pharmacist has completed a course of study and training in administration techniques. A person who has successfully completed their second year and is enrolled in a school of pharmacy or a pharmacist licensed in another state who has applied for a Wisconsin pharmacist license may not administer a drug product or device (other than vaccines) unless they successfully complete a course of study and training in administration technique and administers the drug product or device only under the direct supervision of a pharmacist who has successfully completed the course of study.

The course of study must be from a course provider approved by the Accreditation Council for Pharmacy Education or the Board. The Board will evaluate programs using criteria substantially equivalent to the criteria used by the Accreditation Council or Pharmacy Education. After the pharmacist administers a prescribed drug product or device (other than vaccines), the pharmacist

or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system the pharmacist shares with the prescribing practitioner.

Delegate-check-delegate allows a supervising pharmacist to delegate the product verification of a product prepared by another person delegated by the pharmacist.

In order for a person to be delegated product verification, the individual must meet all of the following: be 18 years of age; completed an accredited technician training program or has a minimum of 500 hours of experience in product selection labeling and packaging; completed a didactic and practical training curriculum; and completed a validation process.

The didactic and practical training curriculum must include elements of a package label; medication and pharmacy abbreviations needed to match ordered medication with dispensed medication; common dispensing medication errors and concepts; eligible medications; policies and procedures on reporting of medication errors; overview of the pharmacy's medication use process and a practical training designed to assess the competency of the individual. The validation process requires a check of 500 product verifications over at least 5 days with an accuracy rate of at least 99.8%. A product is eligible in institutional pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In an institutional pharmacy the medication is required to be administered by a health care provider or a person authorized to administer drugs at the institution. Product verifications can be done by delegates in community pharmacies if the medication is contained in an original package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In a community pharmacy the medication is required to have a method for a patient to be able to check the accuracy of the medication. Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, documentation of supervising and managing pharmacist responsibilities and dates of supervision responsibilities.

A pharmacy may use a central shared services pharmacy acting as its agent. The central shared services pharmacy must be owned by the same owner as the originating pharmacy or have a written contact with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy. The central shared services pharmacy must keep a record of all originating pharmacies it serves including name, address and DEA number. The originating and central shared services pharmacies shall maintain a written protocol outlining each pharmacy's assumption of responsibility for compliance with state and federal law. If the central shared services pharmacy and originating pharmacy share a computer system, the central shared services pharmacy may perform drug utilization review. The prescription label will have the name and address of either pharmacy. The date the prescription was dispensed will be the date the pharmacy filled the prescription order.

A prescription can be delivered to a secure delivery system. The system must be designed in a manner which only the patient or patient's agent is able to open the door or locker containing only the patient's prescription and designed in a manner which does not disclose protected health information. It also must maintain appropriate environmental controls to prevent drug adulteration. Using a delivery system does not create an exemption to the controlled substances

photo identification requirement. The dispensing pharmacy is to maintain a log of all prescriptions delivered to the delivery system and inventory it at least weekly so that unclaimed prescriptions can be reviewed by a pharmacist. The managing pharmacist shall develop written policies and procedures for stocking, access, and mitigation of diversion or theft.

Automated direct-to-patient dispensing systems (more generally described as vending machines) may be used in health care facilities, office or clinic of a practitioner, a county jail, rehabilitation facility, state prison, or county house of correction or a juvenile correctional facility, juvenile detention facility, residential care center, and a secured residential care center for children and youth. The automated direct-to-patient dispensing system may operate for purposes of practitioner dispensing. The supervising practitioner is responsible for: ensuring the stocking, inventory, and monitoring is limited to the supervising practitioner or delegate; labeling of the prescriptions in compliance with Phar 7.05; records of all prescription fills and dispenses are maintained for 5 years; and all monitored prescription drugs dispensed are reported to the prescription drug monitoring program.

Remote dispensing may be done at health care facilities, office or clinic of a practitioner, a county jail, rehabilitation facility, state prison, or county house of correction or a juvenile correctional facility, juvenile detention facility, residential care center, and a secured residential care center for children and youth. The managing pharmacist will designate a supervising pharmacist for the remote dispensing. A sign shall be posted indicating prescriptions may be filled at the location and the supervising pharmacy. Remote dispensing can't occur if the supervising pharmacy is closed. No prescribed drug or device may be dispensed in the absence of a patient and pharmacist's delegate to communicate with a pharmacist. The prescription label shall contain the name and address of the supervising pharmacy. The managing or supervising pharmacist shall have written policies and procedures, implement on-going quality assurance program, visit the remote dispensing location at least monthly to confirm delivery status of all drugs and to ensure compliance with federal and state laws and retain documentation of the visits for a minimum of 5 years. A pharmacist delegate who is remote dispensing must be 18 years of age or older, a high school graduate or equivalent and completed 1500 hours of work as a pharmacist delegate within 3 years prior to remote dispensing or completed an accredited technician training program.

Institutional pharmacies are pharmacies serving institutional facilities. Chart orders shall contain patient's name, patient's medical record number or date of birth, date of issuance, name, strength and form of the drug product or device prescribed, directions for use, practitioner's signature, and if prepared by a delegate of the practitioner the delegate's signature and name of the practitioner. All drug products and devices dispensed for administration by a health care provider at the institutional facility shall have a label that includes the drug name, strength and form, beyond use date or expiration date, and any special storage conditions. The managing pharmacist shall make arrangements for access of drugs by health care staff when a pharmacist is not available to do the dispensing. In the absence of a pharmacist, drugs shall be stored in a manner that only authorized personnel may obtain access and is secure enough to deny access to unauthorized persons. Policies and procedures must be in place to mitigate and prevent theft and diversion. A health item can be returned to the institutional pharmacy if it has not left control of the health care facility staff authorized to have access to prescription drug products. A returned health item may be dispensed at the institutional facility if the health item was never in the

possession and control of the patient, it is in a tamper-evident package, it is in the original container and the pharmacist determines the contents are not adulterated or misbranded.

Automated technology can be utilized for the product verification of a prescription if the machine is located within the pharmacy, utilizes barcodes or other machine-readable technology for product verification and the automated technology is validated for accuracy. Product verifications can be done by automated technology if it is contained in a final package from a manufacturer or if a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, strength, form, control or lot number and beyond use date.

The medication is required to be administered by a person authorized to administer drugs within the institution. Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, names of supervising pharmacist, managing and supervising pharmacist responsibilities, manufacturer's recommended maintenance and quality assurance measures, dates of all software upgrades, and documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

A person practicing pharmacy who has completed their second year of pharmacy school or is a pharmacist from another state applying for license in Wisconsin, can perform duties under direct supervision.

An unlicensed person performing tasks delegated to the person by a pharmacist is working under general supervision. A pharmacist must be available to the unlicensed person for consultation either in person or contact by telecommunication means. An unlicensed person may not provide the final verification for accuracy, validity, or completeness of a filled prescription or order unless the person is validated for delegate-check-delegate. An unlicensed person may not complete the drug utilization review, administer any prescribed drug products, devices or vaccines or provide patient specific counseling or consultation (general education is allowed). The managing pharmacist shall provide training to or verify competency of an unlicensed person in performing a delegated act. The managing pharmacist shall determine what acts may be delegated in the pharmacy. The managing pharmacist has a responsibility to notify all pharmacists practicing in the pharmacy of what acts may be delegated to specific unlicensed persons. A pharmacist may delegate to an unlicensed person any delegated act approved by the managing pharmacist.

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

Generally, the practice of pharmacy is under state jurisdiction.

There are federal regulations related to controlled substances and drug supply chain.

21 CFR 1306.25 governs the transfer of controlled substances prescriptions for refill purposes.

This proposed rule mirrors the federal requirements.

Title II of the Drug Quality and Security Act requires all health care providers who dispense or administer prescription drugs to patients to purchase their prescription drug products only from authorized trading partners licensed by or registered with the state or federal government.

## **Comparison with rules in adjacent states:**

**Illinois:** Illinois has elements required to be on a prescription and labels. Transfers for the purpose of original fill or refill shall include name, address and original prescription number, and all prescription data. A prescription for a Schedule III-IV controlled substance must follow federal law. A drug being removed from the original manufacturer container and placed in a dispensing container for other than immediate dispensing to a patient must contain a label indicating the name and strength of the drug, manufacturer or distributor name, beyond use date, and lot number. Illinois requires consultation for a prescription to a new patient, new medication to existing patient and medication that changes dose, strength, route or directions. An offer to consult is required on all other prescriptions. Consult is not required if a patient refuses consult or if a health care provider is administering the drug. There are designated required elements to be included in consultation. If oral counseling is not practicable, then alternative forms of patient information are provided and shall advise the patient that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service. Every licensed pharmacy must post a sign with patient's rights to a consultation and information on how to file a complaint for failure to consult. Pharmacies without a physical location directly serving patients must include a copy of the sign with any dispensed prescriptions. A mail order pharmacy is required to provide a toll-free telephone service available not less than 6 days per week for a minimum of 40 hours per week. Once a drug is removed from the premises by a patient or the patient's agent, that drug shall not be accepted for return or exchange by a pharmacy or pharmacist. Drugs can be returned for destruction; the wrong medication was dispensed or drug recall. Pharmacy and prescription records are to be maintained for 5 years. Pharmacies providing centralized prescription filling shall share a common electronic file to allow access to sufficient information necessary to fill or refill a prescription order. Appropriate records shall be maintained to identify a responsible pharmacist in the dispensing process and to track the prescription drug order during each step in the process. A delivery system must be secured against a wall or floor, provide a method to identify the patient and deliver the prescription only to that patient or the patient's agent. The delivery system must have adequate security systems to prevent unauthorized access, maintain patient confidentiality and record the time and date the patient removed the prescription from the delivery system. A remote dispensing site is under the supervision of a pharmacy. All records must be maintained at the home pharmacy. Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy. A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site. Counseling must be done by a pharmacist via video link and audio link before the drug or device is released. A pharmacist must make monthly inspections of the remote site. There shall be a working computer link, video link and audio link working at all times between the remote site and the home pharmacy unless a pharmacist is present at the remote site. The sign must clearly identify it as a remote dispensing site. Remote consulting sites can't have any prescription inventory-only filled prescriptions by the home pharmacy. Institutional labels for administration shall include drug name, strength, beyond use date and reference code to identify source and lot number. An after-hour cabinet shall contain a minimal supply of the most frequently required medication and shall only be used in the absence of a pharmacist. Only personnel specifically authorized by the institution may obtain access and it is sufficiently secure to deny access to unauthorized persons. In an institutional health care facility where a licensed healthcare professional administers the drug, a drug may be returned if the drug is not contaminated, deteriorated or beyond the use date, returns

are properly documented and obtaining payment twice for the same drug is prohibited. Illinois does not allow for delegation to unlicensed persons. Illinois certifies technicians.

**Iowa:** In Iowa, the original prescription shall be retained in the original format. Each prescription shall have specified elements. Dispensing documentation shall include the date of fill; the name, strength, NDC of the drug; and the initials of the pharmacist, pharmacist-intern, or technician in an approved tech-check-tech program. The pharmacy shall ensure that the prescription drug or medication order has been issued for a legitimate medical purpose by a prescriber. The pharmacist shall do a prospective drug use review to promote therapeutic appropriateness and rational drug therapy. If there are any problems, the pharmacist shall take appropriate steps to resolve. When transferring a prescription, both the transferring and receiving pharmacies shall maintain records of the prescription drug order information. Non-controlled substances prescriptions are permissible to be transferred as long as the number of transfers does not exceed the number of authorized refills and the prescription is still valid. Transfer of Schedule III – IV prescriptions are permissible on a one-time basis except as provided by federal law. The prescription label shall include prescription number, name, telephone number and address of the pharmacy, name of the prescriber, date dispensed, directions for use and unless directed by the prescriber, the name, strength and quantity of the drug dispensed. Iowa requires a consultation for new prescriptions and change in drug therapy. Consultation is not required when other licensed health care professionals are authorized to administer drugs or if the patient refuses consultation. There are discretionary elements to the consultation. An offer to counsel shall not fulfill the requirements of the rule. If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. "Not practicable" refers to the patient variables and does not include pharmacy variables. Nonresident pharmacies shall ensure that Iowa patients receive appropriate counseling pursuant to the Iowa rule. Prescriptions may be delivered by common carrier or delivery service to the patient at the office or home of the prescriber, at the residence of the patient or caregiver, at the hospital or medical care facility, an outpatient medical care facility or place of employment. Prescriptions may be delivered to the place of employment only if the pharmacy has the patient's written authorization, the prescription is delivered directly to or received directly from the patient or agent and the pharmacy ensures the security of confidential information. Pharmacies shipping or delivering drugs shall ensure accountability, safe delivery, and compliance with temperature requirements. There shall be a patient record system. Records shall be stored for 2 years. Iowa allows automated technology to conduct the product verification if the system utilizes barcode scanning technology and the product is prestocked and no manipulation of drug or package other than affixing a patient label is taking place. If the product is going to require further manipulation than a pharmacist is required to do the product verification prior to dispensing to a patient. Iowa allows technician-check-technician. The technician must have active Iowa registration, hold national technician certification, have experience as a technician and be trained in technician-check-technician (including medication errors). There shall be a supervising pharmacist. The pharmacy is required to have policies and procedures in place and maintain records. The drug utilization review must be performed by a pharmacist. The medication checked by a technician must be checked by a licensed health care practitioner prior to administration. When utilizing a central fill pharmacy, the originating pharmacy shall be responsible for all dispensing functions. A central fill pharmacy that shares a common central processing unit with the originating pharmacy may perform prospective drug use review. The label on the prescription shall indicate it was

filled at a central fill pharmacy and have the name, address, and telephone number of the originating pharmacy. A hospital may implement the InstyMeds dispensing system in the hospital emergency department. Stocking, inventory and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns. It should be located in a secure location. The stock shall be limited to acute care drugs for a 72-hour supply except antimicrobials may be dispensed in a quantity to provide the full course of therapy. The prescriber shall provide the patient with consultation. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours (or the first day the pharmacy is open) to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity greater than a 72-hour supply. Telepharmacy is allowed in Iowa. There shall be a written agreement between the managing pharmacy and telepharmacy site. In the event that a verifying pharmacist is not available or that the audiovisual communication connection between the telepharmacy site and the managing pharmacy is not available, the telepharmacy site shall close. The site shall inform the public it is a telepharmacy site. The telepharmacy site shall be secure. Patient counseling is required utilizing the audiovisual technology employed between the two sites. The label shall include the name, telephone number and address of the telepharmacy site and the name and telephone number of the managing pharmacy. A pharmacist shall monthly inspect the telepharmacy site. A technician working in a telepharmacy site shall have completed a minimum of 2,000 hours and completed training. In an institutional pharmacy, supplies for drugs for use in medical emergencies shall be immediately available pursuant to policies and procedures. All drug storage areas within the facility shall be routinely inspected to ensure that no outdated or unusable items are available for administration and all stock items are properly labeled and stored. Iowa does not allow for delegation to unlicensed persons. Iowa registers technicians.

**Michigan:** In Michigan, a prescription shall be legible and include the name of the patient, prescriber's name and address, drug name and strength, the quantity prescribed, directions for use, and number of refills authorized. The label shall include mandatory elements. A consultation is required for each prescription for a drug not previously prescribed for the patient or by request of the patient or agent for any prescription. Consultation is not required if the patient refuses or for prescriptions administered to a patient while the patient is in a medical institution. The elements of the consultation are to encourage intended, positive patient outcomes, necessary and appropriate information regarding safe and effective medication use at the time a prescription is dispensed. The consultation shall be communicated orally and in person, except when the patient or caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed material designed to help the patient use the medication safely and effectively satisfies the requirement. Prescription records shall be maintained for 5 years. Prescription drugs or devices which have been dispensed and have left the control of the pharmacist shall not be returned except for pharmacies operated by the department of corrections or county jail, or a pharmacy that participates in the program for the utilization of unused prescription drugs. A pharmacy engaging in centralized prescription processing shall be responsible for each function of the prescription's processing performed by that pharmacy. A delivering pharmacist shall be responsible for complying with patient counseling. The prescription label for a prescription that was filled by a centralized processing center shall identify each pharmacy that was involved in preparing and delivering a prescription. Both pharmacies shall maintain records. An automated

device may be used only in the following locations: pharmacy, hospital, county medical care facility, hospice, nursing home, other skilled nursing facility or office of a dispensing prescriber. The pharmacist or pharmacy personnel shall be responsible for the stocking of the automated device unless located in a dispensing prescriber's office (then it is the responsibility of the dispensing prescriber). A pharmacist shall review the prescription or medication order before removal of any medication from the system unless it being used as an after-hours cabinet or in place of an emergency kit. Michigan does not allow for delegation to unlicensed persons. Michigan credentials technicians.

**Minnesota:** In Minnesota, a pharmacist shall examine the patient's profile record and conduct a prospective drug review. Upon recognizing any drug-related problems, the pharmacist shall take appropriate steps to avoid or resolve the problem. A pharmacy may transfer prescription drug order information for the purpose of refilling a prescription if the information is communicated directly by a licensed pharmacist or registered intern to another licensed pharmacist or registered intern. A pharmacy may transfer prescription drug order information for the purpose of initial filing only for non-controlled substance. There are specific elements to a label. Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing. Each prepackaged container shall bear a label providing the name of drug, strength, name of the manufacturer or distributor of the finished dosage form of the drug, a beyond use date, internal control number or date and a physical description including any identification code that may appear on tablets and capsules or a bar code based on the NDC. A consultation is required for new prescriptions. Consultation is not required for inpatients where other licensed health care professionals are authorized to administer the drugs or if the patient has expressed a desire not to receive a consultation. There are mandatory elements to the consultation; however, the pharmacist may vary or omit if in the pharmacist's professional judgment, it is in the best interest of the patient. The pharmacist shall document variations from the required consultation elements. The consultation discussion shall be in person and may be supplemented with written material. When a prescription for which counseling is required is being mailed or delivered to the patient by common carrier or delivery services, the consultation must still be provided but may be accomplished by providing the written information and the availability of the pharmacist to answer questions through the provision of a toll-free phone number. Pharmacies are prohibited from accepting returns of drugs or medical devices except from a hospital items which were dispensed for hospital inpatient use only. Drugs from nursing home and assisted living facilities can be returned and redispensed if the pharmacist can assure proper storage conditions for the drugs, the facility as 24-hour on-site licensed nursing coverage 7-days a week, the drugs are returned to the same pharmacy which dispensed the drugs, and the integrity of the packaging remains intact. A patient profile record system must be maintained in all pharmacies. Pharmacy records shall be kept not less than 2 years. A pharmacy may perform or outsource centralized prescription drug order filling or centralized prescription drug order processing services. The parties must have the same owner or a written contract outlining the services to be provided. There shall be an agreement to how the parties will comply with federal and state laws. Both pharmacies are to maintain records. The pharmacy that delivers the completed prescription drug order to the patient is responsible for certifying the completed prescription drug order and is responsible for counseling the patient. Minnesota does not allow for delegation to unlicensed persons. Minnesota registers technicians.

### **Summary of factual data and analytical methodologies:**

The Pharmacy Examining Board did a comprehensive review of the practice of pharmacy in order to update the rules to current standards and practices. In addition, the Pharmacy Examining Board reviewed the National Association of Boards of Pharmacy’s model rules, the rules of the surrounding states as well as other states and considered stakeholder input.

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

This rule was posted for economic comments for 14 days. The Pharmacy Examining Board invited those who submitted economic comments to a board meeting to discuss economic concerns.

**Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis is attached.

**Effect on small business:**

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

**Agency contact person:**

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

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TEXT OF RULE

SECTION 1. Chapter 7 is repealed and recreated to read:

**Chapter Phar 7  
PHARMACY PRACTICE**

**Subchapter I — General**

**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.
- (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.

**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), 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), the name and address of the authorized entity or individual.
10. Indicate 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.** Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. The verbal prescription 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.** 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.

**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.

**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.** The transfer of original prescription information for a controlled substance listed in Schedule III – IV shall meet the following requirements:

(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) For paper prescriptions and prescriptions received verbally and reduced to writing by the pharmacist, 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 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 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 distributor 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 product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by delegate check delegate under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the delegate 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.
- (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 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.

**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 five 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 birthdate 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 450.033, Stats. The delegated act may not be started prior to the documentation. The documentation shall be maintained for a minimum of five 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 five 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 Delegate-check-delegate. (1) DEFINITIONS.** In this section:

- (a) “Delegate” means a person to whom the pharmacist has delegated the task of product verification.
  - (b) “Delegate-check-delegate” means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate 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 delegate and ensuring for direct supervision of the delegate.
- (2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:
- (a) Is at least 18 years old.
  - (b) Completed an accredited 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 medications for delegate-check-delegate.
  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 delegate prior to starting the validation process. The practical training shall include simulation of at least two 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 delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person 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 delegate during the validation process.
- (e) Notwithstanding, pars. (a) to (d), a delegate who completed the Pharmacy Examining Board's pilot program validation process between October 1, 2016 and September 30, 2019 meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4).
- (3) ELIGIBLE PRODUCT.** (a) *Institutional pharmacies.* The delegate 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 delegate 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 delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A record of each delegate-check-delegate audit shall include all of the following:

1. Name of the product verification delegate.
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. through c. and e.

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

(d) A delegate shall be revalidated if the delegate 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 delegate-check-delegate product verifications within the last 6 months.

(5) **POLICIES AND PROCEDURES.** Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate 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 delegate 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 delegate-check-delegate pharmacist, indicating the name of the supervising delegate-check-delegate 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.

## **Subchapter II — Central Shared Services**

**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.

**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 Definition.** 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) 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), 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:
- 1. Stocking.
  - 2. Determining access.
  - 3. Detection and mitigation of diversion and theft.

**Phar 7.43 Remote dispensing.** (1) In this section, “supervising pharmacist” means a Wisconsin licensed pharmacist, appointed by the managing pharmacist, who is responsible for the remote dispensing and compliance with this section.

(2) LOCATION. A pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i) may dispense at any of the locations under s. 450.062 (1) to (4), Stats.

(3) TITLE. No person may use or display the title “pharmacy”, “drugstore,” “apothecary,” or any other title, symbol or insignia having the same or similar meanings in connection with remote dispensing.

(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.<sup>54</sup>
- 2. This remote dispensing location is being supervised by a pharmacist located at all of the following:
  - 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 the supervising pharmacy is closed.
  - (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) Remote dispensing locations shall have a centrally monitored alarm. For all after hour entries, the personnel entering the location shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for a minimum of 5 years.
- (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 supervising pharmacy 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 OR SUPERVISING PHARMACIST.** (a) The managing pharmacist of the supervising pharmacy or the supervising pharmacist shall do all of the following:
  - 1. Have written policies and procedures for system operation, safety, security, accuracy and access.
  - 2. Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.
  - 3. 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.
  - 4. Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.
  - 5. 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.
 (b) The managing pharmacist at the supervising pharmacy or supervising pharmacist is responsible for all remote dispensing connected to the supervising pharmacy.
- (7) DELEGATE REQUIREMENTS.** A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i), Stats., 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.

**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 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 — Unlicensed Persons**

### **7.60 Definitions.**

(1) "Direct supervision" means immediate availability to continually coordinate, direct and inspect in real time the practice of another.

(2) "General supervision" means to continually coordinate, direct and inspect the practice of another.

### **7.61 Persons who have completed their second year of pharmacy school or pharmacists**

**from another state applying for licensure.** A person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats. is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.

**7.62 Unlicensed persons.** (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats.

(2) A pharmacist shall provide general supervision of unlicensed personnel. A pharmacist shall be available to the unlicensed person for consultation either in person or contact by telecommunication means.

(3) An unlicensed person may not do any of the following:

- (a) Provide the final check on the accuracy and correctness of drug product or device dispensing under s. Phar 7.07 (1) (a) or (b), unless the person is validated for delegate-check-delegate under s. Phar 7.14.
- (b) Complete the drug utilization review under Phar 7.03.
- (c) Administer any prescribed drug products, devices or vaccines under s. 450.035, Stats.
- (d) Provide patient specific counseling or consultation.

(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).

(5) A managing pharmacist shall provide training to or verify competency of unlicensed person prior to the unlicensed 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 unlicensed persons. This record shall be provided to the board upon request.

(7) A pharmacist may delegate to an unlicensed person any delegated act approved by the managing pharmacist.

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.

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(END OF TEXT OF RULE)  
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Dated \_\_\_\_\_

\_\_\_\_\_  
Chair of the Pharmacy Examining Board

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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|                              |   |                             |
|------------------------------|---|-----------------------------|
| IN THE MATTER OF RULE-MAKING | : | ORDER OF THE                |
| PROCEEDINGS BEFORE THE       | : | PHARMACY EXAMINING BOARD    |
| PHARMACY EXAMINING BOARD     | : | ADOPTING RULES              |
|                              | : | (CLEARINGHOUSE RULE 19-164) |

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ORDER

An order of the Pharmacy Examining Board to repeal Phar 17.02 (1), (2), (3), (5), (6), (7) and (8), 17.03, 17.04, 17.05, 17.06 and 17.07; to amend Phar 2.02 (1) (c) and (d) 1., and 3., Phar 17.01, 17.02 (4); and to create Phar 17.02 (3m) and 17.035 relating to pharmacy internships.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** s. 450.03 (2) (b), Stats.

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

**Explanation of agency authority:**

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

The board may promulgate rules necessary for the administration of chs. 450 and 961. [s. 450.02 (3) (d), Stats.]

The board may promulgate rules establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (e), Stats.]

**Related statute or rule:** Ch. Phar 2

**Plain language analysis:**

This rule simplifies and brings into statutory compliance ch. Phar 17.

SECTION 1 removes the reference to foreign graduate internship and the associated requirements which are rendered obsolete by the proposed rule revisions to Phar 17. It adds that this provision refers to those who were foreign educated because just removing the reference would not have

the qualifier that was previously in the rule referencing foreign graduate. In addition, it removes references which are rendered obsolete by the proposed rule revisions to Phar 17.

SECTION 2 amends the statutory citations to correctly reflect the statutory authority.

SECTIONS 3 and 6 repeal unnecessary definitions due to the simplification of the rules.

SECTION 4 creates the definition “general supervision” to mean continually coordinate, direct and inspect the practice of another.

SECTION 5 amends the definition for “intern” to mean a person who is completing an internship for purposes of meeting the requirement under s. 450.03 (2) (b), Stats.

SECTIONS 7 and 9 repeal the different types of internships (academic, foreign graduate, practical experience, postgraduate and student non-academic).

SECTION 7 creates general requirements for an internship. The intern performs duties under the general supervision of a supervising pharmacist. Documentation of hours are to be maintained either by the school through a method of their choice or by the supervising pharmacist which will detail the hours and location worked under the pharmacist and is signed by the intern and the pharmacist. The documentation of hours will be disclosed to the Board upon request.

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

There are no federal regulations relating to pharmacist interns.

#### **Comparison with rules in adjacent states:**

**Illinois:** Illinois requires approved pharmacy programs to contain a minimum of 400 hours of direct contact hours in clerkship and externship experience including supervised training in inpatient environments providing for interdisciplinary experiences with other health professionals and distributive aspects of pharmacy practice.

**Iowa:** In Iowa an intern is a person who is enrolled in a college of pharmacy or actively pursuing a pharmacy degree, or as otherwise provided by the board is registered for the purpose of obtaining instruction in the practice of pharmacy from a preceptor pursuant to Iowa Code section 155A.6. A licensed pharmacist must be on duty and responsible for intern during all periods of training and tasks usually restricted to a pharmacist may be delegated to interns at the discretion of the supervising pharmacist.

**Michigan:** Michigan requires an intern to obtain an intern license. Before training an intern, a licensed pharmacist must obtain board approval. The preceptor is responsible for the overall internship program at the pharmacy.

**Minnesota:** Minnesota requires a person to register with the board before beginning an internship. Pharmacists intending to act as preceptors for interns must also register with the

board. An intern performing tasks associated with dispensing or compounding shall be immediately and directly supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the actions of the intern. Immediate and direct supervision by a licensed pharmacist is not required when the intern performs tasks that do not involve dispensing and compounding. However, all drug therapy and related recommendations that an intern proposes to make to other health professionals and patients must be reviewed and approved by a licensed pharmacist before they are made.

**Summary of factual data and analytical methodologies:**

The Pharmacy Examining Board did a comprehensive review of chapter Phar 17 to ensure the chapter is statutorily compliant and current with professional standards and practices.

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

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

**Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis is attached.

**Effect on small business:**

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

**Agency contact person:**

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

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TEXT OF RULE

SECTION 1. Phar 2.02 (1) (c) and (d) 1., and 3. are amended to read:

**Phar 2.02 (1) (c)** If the applicant ~~was foreign educated, intends to engage in a foreign graduate internship, under s. Phar 17.04,~~ evidence satisfactory to the board that the applicant has obtained certification by the foreign pharmacy graduate examination committee ~~and disclosure of the applicant’s supervising pharmacist. Any change of a supervising pharmacist shall be disclosed to the board by filing an amendment to the application prior to further performing duties constituting the practice of pharmacy as a foreign graduate intern.~~

(d) Evidence of having completed an internship in the practice of pharmacy, consisting of a minimum of 1500 hours, which shall consist of one or more of the following:

1. A statement from the dean of the school of pharmacy or the academic records office of the ~~respective educational institution~~ certifying the number of hours that the applicant has successfully completed in a practical experience program ~~described in ch. Phar 17 of the respective educational institution.~~

3. Verification of practical experience acquired by the applicant in another state ~~as described in ch. Phar 17~~, which is approved and verified by the board or by the agency which is the equivalent of the board in the state in which the practical experience was acquired.

SECTION 2. Phar 17.01 is amended to read:

**Phar 17.01 Authority.** The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2), and ~~450.03 (1) (g) and (2) (b)~~ 450.02 (3) (d) and (e), Stats.

SECTION 3. Phar 17.02 (1), (2), and (3) are repealed.

SECTION 4. Phar 17.02 (3m) is amended to read:

**Phar 17.02 (3m)** “General supervision” means to continually coordinate, direct and inspect the practice of another.

SECTION 5. Phar 17.02 (4) is amended to read:

**Phar 17.02 (4)** “Intern” means a person ~~engaged in the practice of pharmacy pursuant to subs. (1), (3), (6) and (8) or s. 450.03 (1) (g)~~, Stats completing an internship in order to meet the requirement under s. 450.03 (2) (b), Stats.

SECTION 6. Phar 17.02 (5), (6), (7) and (8) are repealed.

SECTION 7. Phar 17.03 is repealed.

SECTION 8. Phar 17.035 is created to read:

**Phar 17.035 Internship. (1)** The internship is a practical experience consisting of the practice of pharmacy under the general supervision of a supervising pharmacist.

**(2)** A record of the internship hours shall be maintained by one of the following methods:

(a) The school of pharmacy in a manner determined by the school of pharmacy to track and record the hours and locations worked by an intern.

(b) The supervising pharmacist detailing the hours and location worked by an intern under the pharmacist’s supervision, signed by the intern and the supervising pharmacist.

**(3)** The written record of internship hours shall be disclosed to the board upon request.

SECTION 9. Phar 17.04, 17.05, 17.06 and 17.07 are repealed.

SECTION 10. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

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(END OF TEXT OF RULE)  
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Dated \_\_\_\_\_

\_\_\_\_\_  
Chair of the Pharmacy Examining Board

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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|------------------------------|---|-----------------------------|
| IN THE MATTER OF RULE-MAKING | : | ORDER OF THE                |
| PROCEEDINGS BEFORE THE       | : | PHARMACY EXAMINING BOARD    |
| PHARMACY EXAMINING BOARD     | : | ADOPTING RULES              |
|                              | : | (CLEARINGHOUSE RULE 19-165) |

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ORDER

An order of the Pharmacy Examining Board to repeal Phar 6.07 (2) and 6.075 (1) (b); to amend Phar 6.07 (3), and 6.075 (2); and to repeal and recreate Phar 6.075 (4) and 6.07 (1) relating to storage.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:** s. 450.09 (4), Stats.

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

**Explanation of agency authority:**

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

The Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs. [s. 450.02 (3) (a), Stats.]

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

The Board may promulgate rules establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (e), Stats.]

**Related statute or rule:** N/A

**Plain language analysis:**

Section 1 and 2 repeals the specific requirement that a pharmacy have a refrigerator, sufficient shelf, drawer or cabinet space for prescription labels, prescription containers and adequate stock

of prescription drugs, chemicals and pharmacy equipment. This is replaced with the storage of drugs shall be secure, neat, clean and orderly.

Section 3 clarifies that all controlled substances are to be stored securely or dispersed in a way which obstructs theft or diversion.

Section 4 repeals the definition of “dry place” as it is no longer being used.

Section 5 amends the manner in which drugs are to be stored. Drugs are to be stored at appropriate conditions including, temperature and humidity, to prevent drug adulteration. It also clarifies that the pharmacy will record each business day the maximum and minimum temperature and humidity since the last documented readings.

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

Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. [21 C.F.R. §13.01.75 (b)]

**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:** Illinois requires all pharmacies and equipment in the pharmacy to be maintained in a clean condition and in good repair. Illinois does require a sink to be required in all pharmacies that maintain drug inventory. Refrigeration shall be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

**Iowa:** Iowa requires effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program.

**Michigan:** Michigan requires all prescription drugs to be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings. Michigan requires a pharmacy to have necessary drawers, shelves, storage cabinets, prescription files, a sink with hot and cold running water and a refrigerator of reasonable capacity. In Michigan, controlled substances are required to be stored in a securely locked, substantially constructed cabinet, room, or cart or they may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.

**Minnesota:** Minnesota requires a refrigerator and a sink with hot and cold running water. The refrigerator designated for drug storage shall have a manual, electromechanical, or electronic temperature recording equipment, devices, or logs to document proper storage of legend drugs every business day.

**Summary of factual data and analytical methodologies:**

The Pharmacy Examining Board reviewed the storage requirements in light of health care evolving and recognizing that there are different types of pharmacies which may not require the specific items required in the current rule.

In addition, stakeholders raised concerns regarding the implementation of CR 16-073 and the Pharmacy Examining Board made clarifications to the temperature and humidity provisions as a result of the concerns raised.

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

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

**Fiscal Estimate and Economic Impact Analysis:**

The Fiscal Estimate and Economic Impact Analysis is attached.

**Effect on small business:**

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

**Agency contact person:**

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

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TEXT OF RULE

SECTION 1. Phar 6.07 (1) is repealed and recreated to read:

**Phar 6.07 (1)** The storage of drugs shall be secure, neat, clean and orderly.

SECTION 2. Phar 6.07 (2) is repealed.

SECTION 3. Phar 6.07 (3) is amended to read:

**Phar 6.07 (3)** ~~Controlled~~ 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.

SECTION 4. Repeal Phar 6.075 (1) (b) is repealed.

SECTION 5. Phar 6.075 (2) is amended to read:

**Phar 6.075 (2) STORAGE.** Drugs shall be stored at appropriate ~~temperature and under~~ appropriate conditions, including ~~in a dry place temperature and humidity, according to the~~ manufacturer recommendation or an official pharmaceutical compendium prevent drug adulteration.

SECTION 6. Phar 6.075 (4) is repealed and recreated to read:

**Phar 6.075 (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.

SECTION 7. 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.

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(END OF TEXT OF RULE)  
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Dated \_\_\_\_\_

\_\_\_\_\_  
Chair of the Pharmacy Examining Board

# STATEMENT OF SCOPE

## Pharmacy Examining Board

**Rule No.:** Phar 2

**Relating to:** Reciprocal credentials for service members, former service members and their spouses

**Rule Type:** Permanent

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

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

The objective of the rule is to implement 2019 Act 143.

**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:**

2019 Act 143 entitles service members, former service members who were discharged within the prior four years under conditions other than dishonorable, and spouses of service members or former service members to obtain a license in Wisconsin if the person resides in Wisconsin and holds a license in good standing granted by a different jurisdiction to practice pharmacy. The license can be renewed indefinitely.

This proposed rule will promulgate rules necessary to implement 2019 Act 143.

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

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

The department or credentialing board, as appropriate, may promulgate rules necessary to implement this section. [s. 440.09 (5), Stats.]

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

60 hours

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

Service members, former service members and spouses of service members or former service members applying for a pharmacist license.

**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:**

There is no existing or proposed federal regulation that addresses pharmacist licensure requirements.

**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 economic impact. It is not likely to have a significant economic impact on small businesses.

**Contact Person:** Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

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Authorized Signature

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Date Submitted

# STATEMENT OF SCOPE

## PHARMACY EXAMINING BOARD

**Rule No.:** Phar 5, 6, 7, 11, 12

**Relating to:** Name and address change, floor design, procedures for disciplinary proceedings, superseded references, and technical correction.

**Rule Type:** Permanent

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

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

The objective of the rule is to repeal or modify provisions of the rule identified in the Pharmacy Examining Board's report to the Joint Committee for Review of Administrative Rules pursuant to s. 227.29, Stats. In addition, the rule will make a typographical correction in Phar 7.04 (3).

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

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

- In Phar 5.02, it is obsolete or unnecessary to require the notification to the Board regarding name or address change to be submitted in writing.
- In Phar 6.04, there are economically burdensome requirements and requirements which do not correspond with the evolving types of pharmacies.
- Ch. Phar 11 is duplicative and unnecessary.
- In Phar 12.04, the federal standards referenced have been superseded.

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

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

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

The board shall adopt rules defining the active practice of pharmacy. [s. 450.02 (2), Stats.]

The board may adopt rules:

Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs

Establishing security standards for pharmacies.

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

Establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (a), (b), (d) and (e), Stats.]

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

60 hours

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

Pharmacies and pharmacists

**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. It is not likely to have a significant economic impact on small business.

**Contact Person:** Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

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Authorized Signature

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Date Submitted

**PHARMACY RULES LIST**  
**June 2020**

**Current Rule Projects**

*In Process*

- Phar 6 (Storage) – Adopting at June 2020 meeting
- Phar 7 (Practice of Pharmacy) – Adopting at June 2020 meeting
- Phar 17 (Intern) – Adopting at June 2020 meeting
- Phar 2 (Service Member Reciprocal License) – Scope
- Phar 5, 6, 7, 11 and 12 (227.29 Report Items) – Scope
- Phar 8 (Scope) – Drafting (New scope expires February 12, 2022)
- Projects specifically identified which fall under this chapter
  - Partial fill of controlled substances
  - Security of controlled substances
- Phar 15 (Compounding) – Drafting (Scope expires March 9, 2022)

**Identified Future Rule Projects**

- Rules resulting from 2019-2020 Legislative Session
- Required rules pursuant to 450.073 (3), Wis. Stats. (Electronic track and trace)
- Compliance with Drug Supply Chain Security Act
  - Wholesale and Distributor Requirements
  - Product Tracing Requirements
- Phar 12 Update (including security requirements)
- Phar 13 Clean-Up
- Out of state pharmacies
- Phar 2 – Foreign educated applicants