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Tony Evers, Governor
Dan Hereth, Secretary

TELECONFERENCE/VIRTUAL
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
December 7, 2023

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. Be advised that board members may attend meetings designated as "Hybrid" in-person or virtually.

AGENDA

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

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda

B. Approval of Minutes of October 26, 2023 (5-9)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements, and Recognition

E. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates
   a. Kleppin, Susan – 7/1/2025
   b. O'Hagan, Tiffany – 7/1/2024
   c. Peterangelo, Anthony – 7/1/2027
   d. Walsh, Michael – 7/1/2024
   e. Weitekamp, John – 7/1/2026
   f. Wilson, Christa – 7/1/2025

F. Legislative and Policy Matters – Discussion and Consideration

G. Administrative Rule Matters – Discussion and Consideration
1) Final Rule Draft:
   a. Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing **(11-57)**
2) Preliminary Rule Draft:
   a. Phar 15, Relating to Compounding Pharmaceuticals **(58-62)**
3) Scope Statement:
   a. Phar 7, Relating to Comprehensive Review **(63-64)**
4) Possible Rule Project:
   a. Phar 6 – Storage of Controlled Substances **(65-66)**

5) Update:
   a. Pharmacy Examining Board Rules Committee Request to Controlled Substances Board Relating to Wis. Stat. s. 450.11
6) Pending or Possible Rulemaking Projects **(67)**

H. Credentialing Matters – Discussion and Consideration

I. Implement 2021 Wisconsin Act 9 – 100 Most Prescribed Drugs – Discussion and Consideration (68-71)

J. Improving Pharmacist Workplace Satisfaction – Discussion and Consideration

K. Liaison Reports – Discussion and Consideration (72)
1) Website Update

L. **Speaking Engagements, Travel, or Public Relation Requests, and Reports (73)**
1) 120th NABP Annual Meeting, May 14 – 17, 2024, Fort Worth, TX

M. NABP Pulse Regulator Monthly Champions Call – Discussion and Consideration

N. Pilot Program Matters – Discussion and Consideration

O. 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) Public Health Emergencies
13) Pilot Program Matters
14) Variances
15) Liaison Reports
16) Board Liaison Training and Appointment of Mentors
17) Informational Items
18) Division of Legal Services and Compliance (DLSC) Matters
19) Presentations of Petitions for Summary Suspension
20) Petitions for Designation of Hearing Examiner
21) Presentation of Stipulations, Final Decisions and Orders
22) Presentation of Proposed Final Decisions and Orders
23) Presentation of Interim Orders
24) Pilot Program Matters
25) Petitions for Re-Hearing
26) Petitions for Assessments
27) Petitions to Vacate Orders
28) Requests for Disciplinary Proceeding Presentations
29) Motions
30) Petitions

31) Appearances from Requests Received or Renewed
32) Speaking Engagements, Travel, or Public Relation Requests, and Reports

P. 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.).

Q. Credentialing Matters

1) Application Reviews (74-216)

a. Empower Pharmacy – Out of State Pharmacy Applicant

R. Deliberation on Division of Legal Services and Compliance Matters

1) Administrative Warning

a. 22 PHM 035 – H.P. 20 **(217-218)**
b. 22 PHM 149 – H.P. **(219-220)**
c. 22 PHM 154 – C.V.S. **(221-222)**
d. 22 PHM 154 – T.T.T., R.Ph. **(223-224)**
e. 23 PHM 057 – R.P.C., R.Ph. **(225-226)**
f. 23 PHM 094 – P.A.A., R.Ph. **(227-228)**

2) Case Closings

a. 21 PHM 162 – W.P. **(229-236)**
b. 22 PHM 035 – H.P. **(237-255)**
c. 22 PHM 084 – W **(256-262)**
d. 22 PHM 126 – R.U.P. **(263-267)**
e. 22 PHM 164 – W.P.I. & W.V.P. **(268-271)**
f. 22 PHM 179 – CVS **(272-275)**
g. 23 PHM 010 – W.P. & C.P.K. **(276-281)**
h. 23 PHM 057 – W. **(282-285)**
i. 23 PHM 094 – P.N.S. **(286-290)**
j. 23 PHM 098 – G.Z. **(291-295)**
k. 23 PHM 108 – L.C.P. **(296-298)**

3) Proposed Stipulations, Final Decisions and Orders

a. 21 PHM 157 – McGuff Compounding Pharmacy Services, Inc. **(299-304)**

S. 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

T. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: JANUARY 18, 2024

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
OCTOBER 26, 2023

PRESENT: Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo (*excused 3:30 p.m.)*, Michael Walsh, John Weitekamp, Christa Wilson *(via Zoom)*

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

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:05 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF AUGUST 31, 2023

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to approve the Minutes of August 31, 2023 as published/. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Preliminary Rule Draft: Phar 1, 5, 7, 10 and 19, Relating to Registration of Pharmacy Technicians

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to designate the Chair, John Weitekamp, to review and approve the preliminary rule draft of Phar 1, 5, 7, 10, and 19, relating to Registration of Pharmacy Technicians for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Possible Rule Project: Phar 7 Comprehensive Review

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to request DSPS staff draft a Scope Statement revising Phar 7, relating to Comprehensive Review. Motion carried unanimously.

IMPLEMENT 2021 WISCONSIN ACT 9 – 100 MOST PRESCRIBED DRUGS

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, to designate the Chair John Weitekamp to review and update the Top 100 Most Prescribed Drugs with DSPS Staff. Motion carried unanimously.

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

Upcoming Member Forum, November 29-30, Rosemont, IL

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to designate Tiffany O'Hagan and if funds are available, Susan Kleppin to attend the Member Forum on November 29-30, 2023, in Rosemont, Illinois. Motion carried unanimously.

CLOSED SESSION

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

The Board convened into Closed Session at 12:54 p.m.

MONITORING

Daniel J. Janke, R.Ph. – *Requesting Modification of Monitoring Order*

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to grant the request of Daniel J. Janke, R.Ph., for modification to C.26 of the Order, to require an initial audit at the time of hiring, and to require Respondent to submit evidence of lack of deviation during quarterly inspection reports required under Phar 8.05(2) and to grant Respondent's request for reduction in drug and alcohol screens to 14 screens per year and 1 hair test per year while not employed as a pharmacist. Upon gaining employment as a pharmacist, screens will return to 49 screens per year. Motion carried unanimously.

Robert Stevens, R.Ph. – ***Requesting Full Licensure per Governor Evers' Pardon***

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to grant the request of Robert Stevens, R.Ph., for Full Licensure. Motion carried unanimously.

PRESENTATION AND DELIBERATION OF PETITION FOR SUMMARY SUSPENSION AND DESIGNATION OF HEARING OFFICIAL

1:00 PM APPEARANCE: Gretchen Mrozinski, DLSC Attorney; Mario Mendoza, Respondent's attorney; and K.J.H, Respondent: 23 PHM 131, Kenneth J. Herrera, R.Ph.

(Tiffany O'Hagan recused herself and left the room for the summary suspension proceeding the matter concerning K.J.H, DLSC Case Number 23 PHM 131 including for deliberation and voting.)

Presentation by attorneys began at 1:55 p.m.

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to acknowledge that oral arguments in the Summary Suspension proceedings for DLSC Case Number 23 PHM 131 were presented to the Board by Gretchen Mrozinski, DLSC Attorney, and Mario Mendoza, Respondent's attorney; and Kenneth J. Herrera, R.Ph., Respondent. Motion carried unanimously.

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to find that notice was given to Kenneth J. Herrera, R.Ph., DLSC Case Number 23 PHM 131, of the Summary Suspension proceedings pursuant to Wis. Admin. Code SPS § 6.05. Motion carried unanimously.

MOTION: Michael Walsh moved, seconded by Christa Wilson, to confirm a finding of probable cause to believe that Kenneth J. Herrera, R.Ph., Respondent, has engaged in or is likely to engage in conduct such that the public health, safety or welfare imperatively requires emergency suspension of the Respondent's license and to issue the Order for Summary Suspension in the matter of disciplinary proceedings against Respondent, DLSC Case Number 23 PHM 131, pursuant to Wis. Admin. Code § SPS 6.06. Motion failed.

MOTION: John Weitekamp moved, seconded by Anthony Peterangelo, to request the respondent complete a fitness to practice assessment by a healthcare practitioner approved by the Board or its designee. Motion carried unanimously.

(Anthony Peterangelo excused 3:30 p.m.)

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

Administrative Warnings

22 PHM 067 – A.H.A.
22 PHM 067 – C.J.S.
22 PHM 067 – S.O.C.

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to refer back to DLSC for further investigation the following cases: A.H.A., DLSC Case Number 22 PHM 067, C.J.S., DLSC Case Number 22 PHM 067 and S.O.C., DLSC Case Number 22 PHM 067. Motion carried unanimously.

22 PHM 163 – C.H.

MOTION: John Weitekamp moved, seconded by Susan Kleppin, to issue an Administrative Warning in the matter of C.H., DLSC Case Number 22 PHM 163. Motion carried unanimously.

Case Closings

MOTION: John Weitekamp moved, seconded by Tiffany O'Hagan, to close the following DLSC Cases for the reasons outlined below:
20 PHM 173 – I.W.P. – No Violation (NV)
22 PHM 110 – H.B. – No Violation (NV)
22 PHM 114 – S.R.X. – Prosecutorial Discretion (P2)
22 PHM 187 – C.P.P. – No Violation (NV)
23 PHM 035 – W.P. – Insufficient Evidence (IE)
23 PHM 068 – C.P. – No Violation (NV)
23 PHM 074 – W. – Insufficient Evidence (IE)
23 PHM 089 – E.S.P. – No Violation (NV)
23 PHM 100 – S.S.P. – Insufficient Evidence (IE)
Motion carried unanimously.

22 PHM 032 – W.P.

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to refer back to DLSC for further investigation DLSC Case Number 22 PHM 032, against W.P. Motion carried unanimously.

CREDENTIALING MATTERS

Empower Pharmacy – Out of State Pharmacy Applicant

MOTION: Susan Kleppin moved, seconded by John Weitekamp, to table the Out of State Pharmacy application of Empower Pharmacy, and request the consultant reports required by the Stipulated Settlement and disciplinary order issued by California. Motion carried unanimously.

Wal-Mart Stores East – Out of State Pharmacy Applicant

MOTION: Tiffany O'Hagan moved, seconded by John Weitekamp, to approve the Out of State Pharmacy application of Wal-Mart Stores East, once all requirements are met. Motion carried unanimously.

Everwell Pharmacy – Out of State Pharmacy Applicant

MOTION: Michael Walsh moved, seconded by John Weitekamp, to approve the Out of State Pharmacy application of Everwell Pharmacy, once all requirements are met. Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 4:20 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

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

The meeting adjourned at 4:22 p.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**11/22/23** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
12/07/23	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Final Rule Draft:** a. **Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing** 2. **Preliminary Rule Draft:** a. **Phar 15, Relating to Compounding Pharmaceuticals** 3. **Scope Statement:** a. **Phar 7, Relating to Comprehensive Review** 4. **Possible Rule Project:** a. **Phar 6 – Storage of Controlled Substances** 5. **Update:** a. **Pharmacy Examining Board Rules Committee Request to Controlled Substances Board Relating to Wis. Stat. s. 450.11** 6. **Pending or Possible Rulemaking Projects**

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

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

Attachments:

1. Phar 1, 5, 6, 7, and 8 – Redlined Code Text, Final Rule Draft, Legislative Report, EIA, Public Comments
2. Phar 15 Preliminary Rule Draft
3. Phar 7 Scope Statement
4. Wisc. Admin Cod Ch. Phar 6
5. Rule Projects Chart

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

11) Authorization

Nilajah D. Hardin — 11/22/23

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) **Date**

Directions for including supporting documents:

1. **This form should be attached to any documents submitted to the agenda.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
3. **If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

Chapter Phar 1

AUTHORITY AND DEFINITIONS

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

Phar 1.01 Authority. Rules in chs. Phar 1 to ~~17~~19 are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats, and ch. 450, Stats.

Phar 1.02 Definitions. As used in chs. Phar 1 to ~~17~~19:

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

Note: The board office is located at ~~1400 East Washington Avenue~~4822 Madison Yards Way, Madison, Wisconsin ~~53702~~ 53705.

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

(3) "DEA" means the drug enforcement administration.

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

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

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

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

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

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

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

~~**(9)** "Pharmacist-in-charge" means a pharmacist who is physically present in the licensed facility and responsible for the routine operation of a pharmacy for the period of time specified by the managing pharmacist.~~

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

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

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

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

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

(13) "PRN" means renew as needed.

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

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

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

Commented [HND1]: Changes from Pharm Tech Rule

Commented [HND2]: Changes from Pharm Tech Rule

Commented [HND3]: Changes from Pharm Tech Rule

Commented [NH4]: Clearinghouse Comment #5b

Commented [HND5]: Changes from Pharm Tech Rule

Chapter Phar 5

LICENSE RENEWAL

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

(2) No one without a current renewal certificate may engage in the practice of pharmacy, nor hold himself or herself out to be a pharmacist nor use the title or letters "Pharmacist" or "Registered Pharmacist"or "R.Ph."

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

~~(3)~~(4) For the purposes of this chapter and pursuant to s. 450.09 (1) (a), stats., pharmacies shall include remote dispensing sites.

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

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

Commented [HN-D6]: Changes from CR 21-074 (Phar 5, 6, 7, 11, and 12 Clean Up Rule)

Phar 5.04 Renewal prohibited. Any person whose license is currently suspended or revoked may not renew his or her license.

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

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

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

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

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

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

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

(b) Evidence of having passed the multi−state pharmacy jurisprudence examination with Wisconsin designated as the primary state.

(c) If the person renewing the license does not have 2000 hours of practice as a pharmacist within last 24 months of submitting the application for renewal, the person shall meet one of the following requirements:

1. If the license has been expired for at least 5 years but not more than 10 years, the person shall submit evidence of all of the following:

a. Completion of 160 hours of internship for each year the pharmacist license was expired,

not to exceed 1000 hours.

b. Completion of 15 hours of continuing education for each year the pharmacist license was expired or within the last two years passing the NAPLEX.

2. If the license has been expired for more than 10 years, the person shall submit evidence of all of the following:

a. Completion of 1000 hours of internship.

b. Passing the NAPLEX.

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

(1) Evidence of completion of the requirements in s. Phar 5.05 (4) if the license has not been active within 5 years.

(2) Evidence of completion of the disciplinary requirements, if applicable.

(3) Evidence of rehabilitation or change in circumstances warranting reinstatement.

Phar 5.07 Pharmacy Technicians. **(1)** All requirements for renewal and reinstatement of a pharmacy technician registration are specified in chapter Phar 19.

(2) No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is eligible to be registered as a pharmacy technician.

Commented [HND7]: Changes from Pharm Tech Rule

Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

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

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

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

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

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

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

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

(1) The licensee provides notice to the Board of all of the information outlined in s. 450.06, Stats.

(2) The site meets all of the requirements listed in s. Phar 7.43.

(3) The site is any of the location types listed under s. 450.09 (2) (b) 1., Stats.

(4) A managing pharmacist shall report to the board if they are responsible for 5 or more remote dispensing sites. A managing pharmacist may not be responsible for more than 10 remote dispensing sites at any given time without approval from the board.

Commented [NH8]: Clearinghouse Comment #2b, 4, 5c, and 5d (Yellow highlights)

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

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

Commented [HN-D9]: Changes from CR 21-074 (Phar 5, 6, 7, 11, and 12 Clean Up Rule)

~~250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service area plan varies from the requirement.~~

~~**(2)** PRESCRIPTION COUNTER SPACE. A pharmacy shall have a prescription counter with a free working surface of 18 or more inches in width and at least 12 square feet in area. This free-working surface must be used only for the compounding and dispensing of prescriptions.~~

(3) ~~PROFESSIONAL SERVICE AREA REQUIREMENTS WHERE PHARMACIST IS ABSENT~~ REQUIREMENTS WHEN THE PROFESSIONAL SERVICE AREA IS CLOSED. (a) ~~Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet if~~ When the pharmacy professional service area is closed, the pharmacy shall meet all of the following requirements ~~are met~~:

(am)~~1.~~ A ~~secured~~ locked, secure physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by ~~unlicensed~~ unauthorized personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

~~2. The barrier is locked in the absence of the pharmacist.~~

~~3. A patient's telephone request to renew a certain prescription may be accepted, but a telephone message from a practitioner giving a new prescription order or renewal authority may not be accepted.~~

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

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

~~7. The pharmacy examining board office is notified of the hours during which the establishment is operated as a sundry outlet.~~

~~(b) The managing pharmacist is responsible for compliance with all professional service area security requirements.~~

~~(c) Where no pharmacist is present in the professional service area a pharmacy is not required to convert to a non-prescription or sundry outlet if the following requirements are met:~~

~~1. The pharmacist is absent for a time period of one half hour or less.~~

~~2. The pharmacist must be accessible for communication with the remaining pharmacy staff by phone, pager or other device.~~

~~3. The pharmacy must indicate that the pharmacist is not available in the professional service area and indicate the period of absence and the time of the pharmacist's return.~~

~~4. Pharmacy technicians may only perform duties allowed by s. Phar 7.015 (2).~~

~~**(4)** PROFESSIONAL SERVICE AREA REMODELING. Any modifications of the approved floor plan shall be submitted to and approved by the board or its designee. Board action must be taken within 60 days.~~

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

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

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

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

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

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

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

(2k) References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

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

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

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

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

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

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

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

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

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

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

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

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

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

Phar 6.08 **Security.** A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

Chapter Phar 7

PHARMACY PRACTICE

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

Subchapter I — General

Phar 7.01 Definitions. In this chapter:

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

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

(3) "NDC" means national drug code.

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

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

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

(a) Date of issue.

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

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

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

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

(f) Refills, if any.

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

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

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

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

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

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

1. Date of issue.
2. First and last name and address of the practitioner.

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

4. Name, strength, and quantity of the drug product or device.

5. Directions for use of the drug product or device.

6. Refills, if any.

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

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

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

10. An indication that the prescription is pursuant to a standing order.

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

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

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

(4) VERBAL PRESCRIPTION. 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.

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

(a) Known allergies.

(b) Rational therapy.

(c) Contraindications.

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

(e) Reasonable directions for use.

(f) Potential or actual adverse drug reactions.

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

(h) Therapeutic duplication.

(i) Reasonable utilization and optimum therapeutic outcomes.

(j) Potential abuse or misuse.

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

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

1. The transfer of prescription order information is communicated in one of the following ways:

a. Verbal communication between two pharmacists.

b. Electronically or by facsimile machine between the two pharmacies.

2. A transfer of prescription information verbally shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(b) A pharmacist shall transfer a prescription upon patient request pursuant to this section.

(2) NON-CONTROLLED SUBSTANCES. The transfer of prescription order information for non-controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:

(a) The prescription record of the transferred prescription shall include the following information:

1. The word "VOID" is written on the face of the invalidated prescription order or recorded in a similar manner to "VOID" on a prescription order in a computer system meeting the requirements of s. Phar 7.11 (2) (a).

2. The name and address of the pharmacy to which it was transferred, the date and the first and last name of the pharmacist transferring the information are recorded on the invalidated prescription order or in a computer system meeting the requirements s. Phar 7.11 (2) (a).

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

1. The word "TRANSFER" on the face of the transferred prescription order or recorded in a similar manner in a computer system.

2. The first and last name and address of the patient, the first and last name and address of the prescribing practitioner.

3. Name, strength, form and quantity of the drug product or device prescribed and the directions for use.

4. The date of issuance of the original prescription order, the original prescription order number, the original number of refills authorized on the original prescription order and the date of original dispensing if the prescription order has previously been dispensed.

5. The number of valid refills or total quantity remaining and the date of the last refill.

6. The pharmacy's name and address from which the prescription order information was transferred.

7. The first and last name of the pharmacist transferring and receiving the prescription order information.

(3) CONTROLLED SUBSTANCES. The transfer of original prescription information for a controlled substance listed in Schedule III – ~~IV~~ V 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.

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(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 the prescription, including all of the following:

1. Date of issuance of the original prescription order.

2. Original number of refills authorized on the original prescription order.

3. Date of original dispensing.

4. Number of valid refills remaining and the dates and locations of previous refills.

5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.

6. First and last name of the pharmacist making the transfer.

7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

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

1. The date of the original dispensing.

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

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

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

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

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

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

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

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

1. Except as provided in subds. 2. to 5., the first and last name of the patient.

2. For an antimicrobial drug dispensed under s. 450.11 (1g), Stats., the first and last name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT".

3. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the first and last name of the person to whom the opioid antagonist is delivered.

4. For an epinephrine auto-injector prescribed under s. 118.2925 (3) or 255.07 (2), Stats., the name of the school, authorized entity, or other person specified under s. 255.07 (3), Stats.

5. If the patient is an animal, the last name of the owner, name of the animal and animal species.

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

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

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

(e) Pharmacy name, address and telephone number.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

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

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

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

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

(c) Written or graphic product descriptions.

(d) Any cautions or other provisions.

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

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

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

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

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

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

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

(b) One of the following identifiers:

1. Pharmacy control number.

2. NDC number and manufacturer lot number.

3. Name of manufacturer or distributer of the drug product, and the manufacturer lot number.

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

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

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

(c) Manufacturer lot number.

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

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

(f) Date of repackaging.

(g) Any pharmacy control numbers.

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

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(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~~products or ~~device dispensing~~devices dispensed by a pharmacist, 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~~ a pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the ~~delegate~~ pharmacy product verification technician performing the check.

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

(a) Has not been dispensed previously to the patient.

(b) Is a change in therapy.

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

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

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

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

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

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

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

(a) Name and description of the drug.

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

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

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

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

(f) Techniques for self-monitoring drug therapy.

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

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

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

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

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

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

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

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

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

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

(a) Timeliness of delivery.

(b) Condition of the prescription drug upon delivery.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device is for the same patient's use.

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

(5) It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.

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

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

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

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

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

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

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

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

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

(b) The following minimum information shall be retrievable:

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

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

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

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

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

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

Phar 7.14 ~~**Delegate check-delegate**~~ **Pharmacy Product Verification Technician-check-Pharmacy Technician. (1)** DEFINITIONS. In this section:

(a) "~~Delegate~~ Pharmacy Product Verification Technician" means a ~~person~~registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

(b) "~~Delegate check-delegate~~ Pharmacy Product Verification Technician-check-Pharmacy Technician" means the process in which ~~one delegate~~pharmacy product verification technician conducts the task of product verification of technical dispensing functions completed by ~~an unlicensed individual~~ a pharmacy technician. A ~~delegate~~pharmacy product verification technician may not conduct product verification as part of the final check of their own product preparation.

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

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

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

~~(a) Is at least 18 years old.~~

Commented [HND12]: Changes from Pharm Tech rule

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

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

1. Elements of correct product including all of the following:

a. Drug name.

b. Strength.

c. Formulation.

d. Expiration date.

e. Beyond use date.

2. Common dispensing medication errors and concepts including all of the following:

a. Wrong medication.

b. Wrong strength.

c. Wrong formulation.

d. Extra or insufficient quantity.

e. Omitted medications if utilizing unit dose or compliance packaging.

f. Expired medication.

g. Look-alike or sound-alike errors.

h. High-alert medications.

3. Eligible ~~medications~~products for ~~delegate check delegate~~product verification by a technician.

4. Organizational policies and procedures on reporting of medication errors.

5. Overview of the medication use process including all of the following:

a. Procurement.

b. Ordering.

c. Dispensing.

d. Administration.

e. Monitoring.

6. A practical training designed to assess the competency of the ~~delegate~~pharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:

a. Wrong drug.

b. Wrong strength.

c. Wrong formulation.

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

(d) Completed the following validation process:

1. The ~~delegate~~pharmacy technician being validated shall make a product verification on the work of a pharmacist or ~~unlicensed person~~another pharmacy technician for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the ~~delegate~~pharmacy technician during the validation process.

(e) Notwithstanding pars. ~~(a)~~(b) to (d), ~~a delegate~~an individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the

~~delegation~~pharmacy product verification technician qualifications unless the ~~delegate~~individual fails to meet the quality assurance standards under sub. (4).

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

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

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

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.
2. A drug utilization review performed by a pharmacist prior to dispensing.
3. A non-pharmacist shall be able to check the accuracy of the medication by one of the following:

a. The drug product or device is in the original packaging from a manufacturer.

b. The drug product or device includes a description of the drug product or device on the prescription label.

c. The pharmacist shows the patient or patient's agent the drug product or device and provides a monograph that includes a description of the drug product or device.

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

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

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

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

(d) A ~~delegate~~pharmacy product verification technician shall be revalidated if the ~~delegate~~individual fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed ~~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~~pharmacy product verification by technicians which shall be made available to the board upon request.

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

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

2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising ~~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

Phar 7.30 Definitions. In this subchapter:

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

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

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

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

(1) The central shared services pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract.

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

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

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

(5) The prescription label attached to the container shall contain the name and address of the labeling or originating pharmacy. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the labeling pharmacy filled the prescription order.

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

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

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 Definitions. In this subchapter:

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

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

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

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

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

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

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

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

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

(a) Stocking of the delivery system.

(b) Determining access to the delivery system.

(c) Detection and mitigation of diversion and theft.

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

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

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

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

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

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

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

(a) Stocking.
(b) Determining access.
(c) Detection and mitigation of diversion and theft.

Phar 7.43 Remote dispensing. ~~**(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) or~~,~~ (g)~~, or (i)~~, Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. ~~450.062 (1) to (4)~~450.09 (2) (b) 1. a. to d., 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.
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~~ a pharmacist is not available remotely.

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

~~(d) 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~~ remote dispensing site as the licensed facility from which the prescribed drug or device was dispensed.

(c) Final check under s. Phar 7.07.

(d) Federal law if dispensing controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACIST~~ OR SUPERVISING PHARMACIST~~. (a) The managing pharmacist of the remote dispensing~~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.

Commented [NH13]: Public Comment (DeBisschop): Clarify whether pharmacists who supervise a remote dispensing site also have to be at a pharmacy or if they can be at a non-pharmacy location.

Commented [NH14]: Clearinghouse Comment #5e

Commented [NH15]: Public Comment (PSW): In 7.43 (6) (a) and (b), remove "supervising pharmacy"

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 remote dispensing~~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 (gm), ~~or (i),~~ Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) shall meet the following requirements to remote dispense:

(a) Be 18 years of age or older.

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

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

Commented [HND16]: Changes from Pharm Tech rule

Commented [NH17]: Public Comment (DeBisschop): In 7.43 (7)(c), clarify whether 1.500 work requirement is paid time only or if it can include rotation/internship hours; Define "pharmacist delegate" or use a more descriptive term.

Subchapter IV — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:

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

(2) "Institutional facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 146.903 (1) (b), 233.40, 233.41, 233.42, or 252.10, Stats.; a hospice facility under s. 50.90 (1) (c), Stats.; a county jail; and a correctional facility operated under the authority of the department of corrections.

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

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

(1) First and last name of the patient.

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

(3) Date of issuance.

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

(5) Directions for use.

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

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

(b) Electronic signature of the practitioner or delegate.

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

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

(1) Drug name, strength and form.

(2) Beyond use date or expiration date.

(3) Special storage conditions, if required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Located within a licensed pharmacy.

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

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

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

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

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

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

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

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

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

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

2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.

3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.

4. Documentation of the dates of all software upgrades.

5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

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

Subchapter V — ~~Unlicensed Persons~~Uncredentialed Pharmacy Staff

Commented [HND18]: Changes from Pharm Tech rule

Phar 7.60 Definitions. In this subchapter:

(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.~~

(3) "Uncredentialed pharmacy staff" means any staff practicing in the pharmacy area who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats.

Phar 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.

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

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

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

~~(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 s. 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), Stats.

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

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

(7) A pharmacist may delegate to an ~~unlicensed~~ uncredentialed pharmacy staff person any delegated act approved by the managing pharmacist pursuant to sub. (3).

Commented [NH19]: Public Comment (DeBisschop): Also include pharmacy graduates in s. Phar 7.61

Commented [NH20]: Remote Dispensing Rule Change Only

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

(EFFECTIVE 09/01/22)

Phar 8.01 Federal registration and compliance with federal, state, and local laws and regulations. (1) FEDERAL REGISTRATION REQUIRED. To possess, manufacture, distribute, dispense, or conduct research with controlled substances in this state, pharmacies and pharmacists shall register with the drug enforcement administration as required under federal law.

(2) CONTROLLED SUBSTANCES AUTHORIZATION UNDER FEDERAL REGISTRATION. As provided under s. 961.32 (1m) (a), Stats., pharmacies and pharmacists registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, and conduct research with those substances in this state to the extent authorized by their federal registration and in conformity with the provisions of ch. 961, Stats.

(3) COMPLIANCE WITH LAWS AND REGULATIONS. Failure to register with the drug enforcement administration or otherwise comply with applicable federal, state, and local laws and regulations relating to possessing, manufacturing, distributing, dispensing, or conducting research with controlled substances constitutes unprofessional conduct for purposes of s. 450.10, Stats.

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

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

~~(4)~~(5) REMOTE DISPENSING SITES. For the purposes of this chapter and pursuant to s. 450.09 (1) (a), Stats., pharmacies shall include remote dispensing sites.

Commented [NH21]: Clearinghouse Comment #2d (Yellow highlight)

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

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

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

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

Phar 8.05 Recordkeeping. (1) Records shall be maintained as required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats.

(2) The managing pharmacist shall oversee quarterly inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

Phar 8.06 Identification card requirement under s. 450.11 (1b), Stats. (1) DEFINITION. In this section and s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community−based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.

(2) EXEMPTION. There shall be an exemption to the requirement for an identification card when the drug is lawfully delivered to the patient's home, or any address requested by the patient, through mail, common carrier or delivery service. A valid signature is required upon delivery.

Phar 8.07 Partial Dispensing. (1) A pharmacist may partially dispense a prescription containing a controlled substance listed in schedule III, IV and V.

(2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if one of the following conditions applies:

(a) If the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order.

(b) If the patient requests partial dispensing.

(c) If the prescribing practitioner requests partial dispensing.

The remaining portion of any partially dispensed prescription under this section may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.

(3) Prescription orders for schedule II controlled substances written for patients in long term care facilities (LTCF) or for patients with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units. The prescribing practitioner may document a terminal illness by writing upon the face of the prescription order the phrase "terminal illness" or words of similar meaning. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially dispensing the prescription. Documentation of a terminal illness, whether substantiated by the presence of an appropriate phrase written upon the face of the prescription order or through pharmacist contact with the prescribing practitioner, shall be placed within the individual medication profile record maintained under s. Phar 7.07. The pharmacist shall record on the prescription order whether the patient is "terminally ill" or an "LTCF patient." A prescription order that is partially dispensed and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been dispensed in violation of this section. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order or on another appropriate record, uniformly maintained and readily retrievable, the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Subsequent partial dispensing is not permitted under this section if the patient becomes deceased, or is no longer diagnosed as terminally ill, or no longer resides within an LTCF. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. Prescription orders for schedule II controlled substances for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless terminated earlier by the discontinuance of medication.

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

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

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

(c) Retrieval of partially dispensed schedule II prescription information identical to that required by s. Phar 7.05 (2) for all prescription renewal information.

Phar 8.08 Controlled substances in emergency kits for long term care facilities. Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

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

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

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

(4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-054)

PROPOSED ORDER

Commented [NH1]: Clearinghouse Comment #2a and 2c

An order of the Pharmacy Examining Board to repeal Phar 1.02 (9), 7.43 (1), (3); and (4) (d); amend Phar 7.43 (2), (4) (b), (5) (b), (6) (title), (a) (intro.), (a) 5., (b), and (7) (intro.), and 7.62 (1) and create Phar 1.02 (10m) and (14m), 5.01 (4), 6.025, and 8.01 (5)~~; repeal Phar 1.02 (9), 7.43 (1), (3); and (4) (d); and amend Phar 7.43 (2), (4) (b), (5) (b), (6) (title), (6) (a), (6) (a) 5, (6) (b), and (7), and 7.62 (1)~~, relating to remote dispensing.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.02 (5) and 450.09 (1) and (2) (b) 2, Stats.

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

Commented [NH2]: Clearinghouse Comment #1

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

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

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

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

Section 450.02 (5), Stats. provides that "the board may promulgate rules governing pharmacies that are operated as remote dispensing sites. Rules promulgated under this subsection may exempt pharmacies operated as remote dispensing sites from requirements governing pharmacies that are not operated as remote dispensing sites."

Related statute or rule: s. 961.31, Stats.

Plain language analysis: The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 101. These changes include the creation of s. Phar 6.025, which are rules that specifically apply to remote dispensing sites, as well as amendments to s. Phar 7.43 to allow for remote dispensing sites to operate without the presence of a pharmacist. Clarification was also added to ss. Phar 5.01 (4) and 8.01 (5) that pharmacies shall include remote dispensing sites. The Board also added a definition of pharmacy graduates to chapter Phar 1, and modified requirements in chapter Phar 7 to allow them to practice pharmacy while waiting for their license to be granted.

Commented [NH3]: Clearinghouse Comment #5a

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

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: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for pharmacy licensure and dispensing. There is a provision that allows a pharmacy that is not in the same location as its home pharmacy, and services are being provided during an emergency situation, to operate as an emergency remote pharmacy. The Illinois Department of Financial and Professional Regulation may also waive the requirement for a pharmacist to be on duty at all times for state facilities that are not treating human ailments. Additionally, automated pharmacy systems operated from a remote site must be under continuous supervision of a pharmacist however, that pharmacist is not required to be physically present if they can monitor the system electronically [225 Illinois Complied Statutes ch. 85 s. 15 and 22b]. The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include definitions for "emergency situation" and what is required in order to operate an emergency remote temporary pharmacy [Illinois Administrative Code s. 1330.420].

In Illinois, graduate of a pharmacy program approved by the Illinois Department of Financial and Professional Regulation may be registered as a pharmacy technician with the "student pharmacist" designation, if they have graduated from said program

within the last 18 months. Student pharmacists are allowed to practice pharmacy under the supervision of a pharmacist [225 Illinois Complied Statutes ch. 85 s. 9 (c)].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for remote dispensing in hospital pharmacies. Additionally, a pharmacist is required to be onsite at a telepharmacy site for at least 16 hours per month and can otherwise monitor the site remotely. The telepharmacy site is a separate licensure category from a correctional, hospital, nuclear, or general pharmacy site. If the average number of prescriptions dispensed per day exceeds 150 at a telepharmacy site, the pharmacist is required to be on site 100 percent of the time and the site must apply for licensure as a general pharmacy [657 Iowa Administrative Code sections 7.7 and 13.9 (6)].

In Iowa, graduates of a college of pharmacy approved by the Iowa Board can register as a "pharmacist-intern." Pharmacist-interns are required to practice under the supervision of a licensed pharmacist. This registration automatically terminates upon the pharmacist-intern receiving "licensure to practice pharmacy in any state, lapse in the pursuit of a degree in pharmacy, or one year following graduation from the college of pharmacy," whichever happens sooner [657 Iowa Administrative Code sections 4.1 and 4.6 (3)].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for pharmacy in Michigan, among several other occupations. Unless at a mental health facility or hospital, remote pharmacies cannot be located within 10 miles of another pharmacy, unless a waiver is granted by the Michigan Board. A pharmacist is required to oversee a remote pharmacy; however, a qualified pharmacy technician must be on site at all times that the pharmacy is open if the pharmacist in charge is not physically present. A Pharmacist may not be responsible for more than three remote pharmacy sites at any one time [Michigan Compiled Laws s. 333.17742a and b].

In Michigan, pharmacy graduates can apply for an educational limited license if they are within 180 days of competing an approved educational program. Pharmacy graduates practicing under an educational limited license may only do so under the "personal charge of a pharmacist" [Michigan Administrative Code R 338.513].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. [Minnesota Administrative Rules part 6800]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations. According to Section 34 (10) of this chapter, it is unlawful to run a pharmacy without a pharmacist in charge. Operation of a pharmacy without a pharmacist present and on duty is only allowed under an approved variance by the

Board. [Minnesota Statutes 151.34 (10), 151.071 (2) (13)].

In Minnesota, pharmacy graduates can apply for a "pharmacist-intern" registration if they are a graduate of a pharmacy college approved by the Minnesota Board. Pharmacist interns must practice under the direct supervision of a licensed pharmacist [Minnesota Administrative Rules Chapter 6800 Parts 5100-5600].

Summary of factual data and analytical methodologies: The Board reviewed the statutory changes from 2021 Wisconsin Act 101 and updated Wisconsin Administrative Code Chapters Phar 1, 5, 6, 7, and 8 accordingly. While completing this review, the Board also identified a need to create a definition of a Pharmacy Graduate and include them in certain pharmacy practice circumstances.

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

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

Effect on small business:
These 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on October 26, 2023, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1 Phar 1.02 (9) is repealed.

Commented [NH4]: Public Comment (DeBisschop): Clarify whether pharmacists who supervise a remote dispensing site also have to be at a pharmacy or if they can be at a non-pharmacy location.

SECTION 2 Phar 1.02 (10m) and (14m) are created to read:

Phar 1.02 (10m) "Pharmacy graduate" means a graduate of a school of pharmacy approved by the ~~pharmacy examining~~ board, who has submitted an application for pharmacist licensure or a qualified applicant awaiting examination for licensure approved by the board.

Phar 1.02 (14m) "Remote dispensing site" has the meaning given in s. 450.01 (21c), Stats.

SECTION 3 Phar 5.01 (4) is created to read:

Phar 5.01 (4) For the purposes of this chapter and pursuant to s. 450.09 (1) (a), Stats., pharmacies shall include remote dispensing sites.

SECTION 4 Phar 6.025 is created to read:

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

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

SECTION 5 Phar 7.43 (1) is repealed.

SECTION 6 Phar 7.43 (2) is amended to read:

Phar 7.43 (2) LOCATION. A ~~pharmacist or a~~ person engaged in the practice of pharmacy under s. 450.03 (1) (f)~~,~~ or (g), ~~or (i),~~ Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. ~~450.62 (1) to (4)~~ 450.09 (2) (b) 1. a. to d., Stats.

SECTION 7 Phar 7.43 (3) is repealed.

SECTION 8. Phar 7.43 (4) (b) is amended to read:

Phar 7.43 (4) (b) Remote dispensing may not occur if ~~the supervising pharmacy is closed~~ a pharmacist is not available remotely.

Commented [NH5]: Clearinghouse Comment #5b

Commented [NH6]: Clearinghouse Comment #2b, 4, 5c, and 5d

Commented [NH7]: Clearinghouse Comment #5e

SECTION 9. Phar 7.43 (4) (d) is repealed.

SECTION 10. Phar 7.43 (5) (b); (6) (title), ~~(6)~~ (a)(intro.), ~~(6)~~ (a) 5., and ~~(6)~~ (b); and (7) (intro.) are amended to read:

Phar 7.43 (5) (b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the ~~supervising pharmacy~~ remote dispensing site as the licensed facility from which the prescribed drug or device was dispensed.

(6) (title) RESPONSIBILITIES OF MANAGING PHARMACIST ~~OR SUPERVISING PHARMACIST~~.

(6) (a) (intro.) The managing pharmacist of the supervising pharmacy ~~or the supervising pharmacist~~ shall do all of the following:

(6) (a) 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~~.

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

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

SECTION 11. Phar 7.62 (1) is amended to read:

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

SECTION 12. Phar 8.01 (5) is created to read:

Phar 8.01 (5) REMOTE DISPENSING SITES. For the purposes of this chapter and pursuant to s. 450.09 (1) (a), ~~s~~Stats., pharmacies shall include remote dispensing sites.

SECTION 13. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

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

Commented [NH8]: Clearinghouse Comment #2c and 5f

Commented [NH9R8]: Public Comment (DeBisschop): In 7.43 (7)(c), clarify whether 1.500 work requirement is paid time only or if it can include rotation/internship hours; Define "pharmacist delegate" or use a more descriptive term.

Commented [NH10R8]: Public Comment (PSW): In 7.43 (6) (a) and (b), remove "supervising pharmacy"

Commented [NH11]: Public Comment (DeBisschop): Also include pharmacy graduates in s. Phar 7.61

Commented [NH12]: Clearinghouse Comment #2d

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
PHARMACY EXAMINING BOARD	**:**	**CR 23-054**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 101. These changes include the creation of s. Phar 6.025, which are rules that specifically apply to remote dispensing sites, as well as amendments to s. Phar 7.43 to allow for remote dispensing sites to operate without the presence of a pharmacist. Clarification was also added to ss. Phar 5.01 (4) and 8.01 (5) that pharmacies shall include remote dispensing sites. The Board also added a definition of pharmacy graduates to chapter Phar 1, and modified requirements in chapter Phar 7 to allow them to practice pharmacy while waiting for their license to be granted.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Pharmacy Examining Board held a public hearing on October 26, 2023. The following people either testified at the hearing, or submitted written comments:

- Richelle Andrae, Government Relations Specialist, Wisconsin Primary Health Care Association (WCHA)
- Xin Rippel, Director of Pharmacy, Family Health Center Pharmacy – Marshfield
- Michael DeBisschop, Pharm.D.
- Danielle Womack, Vice President – Public Affairs, Pharmacy Society of Wisconsin (PSW)

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

- The WCHA expressed their support of the proposed rule project and requested expedited implementation be prioritized by the Board. The WCHA also requested that the Board address an issue with labelling prescriptions from remote dispensing sites. Specifically, whether a separate label is allowed with the remote dispensing site's location listed.

- Xin Rippel provided background information on Family Heath Center of Marshfield as it relates to pharmacy services to a rural population. They also requested clarification on the process for registering as a remote dispensing site and how that works with licensure, DEA registration and other regulatory requirements.
- Michael DeBisschop provided suggestions for changes in the following areas of the rule project:
    - Pharmacy graduates should also be included in s. Phar 7.61.
    - Clarify whether pharmacists who supervise a remote dispensing site also have to be located at a pharmacy or if they can be supervising a remote dispensing site from a non-pharmacy location.
    - In s. Phar 7.43 (7) (c), clarify whether the 1500 hour work requirement includes internship or rotation time, or if it only applies to paid work time. Also, clarify the term "pharmacist delegate" with a definition or replace it with a more descriptive term.
- The PSW provided suggestions for changes to ss. Phar 7.43 (6) (a) and (b). They recommended removing the term "supervising pharmacy," as the term does not accurately describe what is happening with remote dispensing sites.

The Pharmacy Examining Board explains modifications to its rule-making proposal prompted by public comments as follows:

-

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment: 5c. In s. Phar 6.025 (intro.), consider revising the introductory statements to use the active voice. [s. 1.05 (1) (d), Manual] Also, consider revising the first sentence of the introduction, is it intended that any time a pharmacist remotely supervises a location, that it is a sufficient condition to apply the specific rules for remote dispensing?

Response: The Board has accepted this comment and would like to note that any time a pharmacist remotely supervises a location, the rules for remote dispensing apply.

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

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

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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

2. Date
September 29, 2023

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 1, 5, 6, 7, and 8 - Permanent Rule

4. Subject
Remote Dispensing

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

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (1) (g)

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

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

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

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

11. Policy Problem Addressed by the Rule
These rules implement the statute changes form 2021 Wisconsin Act 101. The Board also added a definition of pharmacy graduates, and modified requirements to allow them to practice pharmacy while waiting for their license to be granted.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule will be poseted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
DSPS estimates a total of $8,900 in one-time costs and $2,800 in annual costs for staffing and an indeterminate IT impact to implement the rule. This rule permanently implements the statutory changes from the 2021 Wisconsin Act 101. The estimated one-time staffing need for .1 limited term employees (LTE) is for staff training, forms and sites updates, and developing reference materials to reflect new statutory provisions. The estimated annual staffing need addresses an increase in questions and workload related to processing submitted applications for the department, the applicant, and the call center, as well as necessary board coordination to implement the rule. The one-time and annual estimated costs cannot be absorbed in the currently appropriated agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefits of implementing this rule are that the Pharmacy Examining Board's sections of the Administrative Code will be aligned with Wisconsin State Statues.

16. Long Range Implications of Implementing the Rule

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

The long range implications of implementing this rule are clear rules for remote dispensing for pharmacies in Wisconsin.

17. Compare With Approaches Being Used by Federal Government

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

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

Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of Pharmacy in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Pharmacy Practice Act contains requirements for pharmacy licensure and dispensing. There is a provision that allows a pharmacy that is not in the same location as its home pharmacy, and services are being provided during an emergency situation, to operate as an emergency remote pharmacy. The Illinois Department of Financial and Professional Regulation may also waive the requirement for a pharmacist to be on duty at all times for state facilities that are not treating human ailments. Additionally, automated pharmacy systems operated from a remote site must be under continuous supervision of a pharmacist however, that pharmacist is not required to be physically present if they can monitor the system electronically [225 Illinois Complied Statutes ch. 85 s. 15 and 22b]. The Illinois Department of Financial and Professional Regulation is also responsible for the promulgation of rules to implement certain sections of the Illinois Pharmacy Practice Act. These rules in the Illinois Administrative Code include definitions for “emergency situation” and what is required in order to operate an emergency remote temporary pharmacy [Illinois Administrative Code s. 1330.420].

In Illinois, graduate of a pharmacy program approved by the Illinois Department of Financial and Professional Regulation may be registered as a pharmacy technician with the “student pharmacist” designation, if they have graduated from said program within the last 18 months. Student pharmacists are allowed to practice pharmacy under the supervision of a pharmacist [225 Illinois Complied Statutes ch. 85 s. 9 (c)].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for remote dispensing in hospital pharmacies. Additionally, a pharmacist is required to be onsite at a telepharmacy site for at least 16 hours per month and can otherwise monitor the site remotely. The telepharmacy site is a separate licensure category from a correctional, hospital, nuclear, or general pharmacy site. If the average number of prescriptions dispensed per day exceeds 150 at a telepharmacy site, the pharmacist is required to be on site 100 percent of the time and the site must apply for licensure as a general pharmacy [657 Iowa Administrative Code sections 7.7 and 13.9 (6)].

In Iowa, graduates of a college of pharmacy approved by the Iowa Board can register as a “pharmacist-intern.” Pharmacist-interns are required to practice under the supervision of a licensed pharmacist. This registration automatically terminates upon the pharmacist-intern receiving “licensure to practice pharmacy in any state, lapse in the pursuit of a degree in pharmacy, or one year following graduation from the college of pharmacy,” whichever happens sooner [657 Iowa Administrative Code sections 4.1 and 4.6 (3)].

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

open if the pharmacist in charge is not physically present. A Pharmacist may not be responsible for more than three remote pharmacy sites at any one time [Michigan Compiled Laws s. 333.17742a and b].

In Michigan, pharmacy graduates can apply for an educational limited license if they are within 180 days of competing an approved educational program. Pharmacy graduates practicing under an educational limited license may only do so under the "personal charge of a pharmacist" [Michigan Administrative Code R 338.513].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Minnesota. Part 6800 of the Minnesota Administrative Code includes the regulations for pharmacy in Minnesota. [Minnesota Administrative Rules part 6800]. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes pharmacy regulations. According to Section 34 (10) of this chapter, it is unlawful to run a pharmacy without a pharmacist in charge. Operation of a pharmacy without a pharmacist present and on duty is only allowed under an approved variance by the Board. [Minnesota Statutes 151.34 (10), 151.071 (2) (13)].

In Minnesota, pharmacy graduates can apply for a "pharmacist-intern" registration if they are a graduate of a pharmacy college approved by the Minnesota Board. Pharmacist interns must practice under the direct supervision of a licensed pharmacist [Minnesota Administrative Rules Chapter 6800 Parts 5100-5600].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	(608) 267-7139

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

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

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

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

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

5. Describe the Rule's Enforcement Provisions

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

WPHCA
Wisconsin Primary Health Care Association

October 26, 2023

To: Chair Weitekamp
Pharmacy Examining Board

From: Wisconsin Primary Health Care Association (WPHCA)

Re: Implementation of Remote Dispensing Rules

Chair Weitekamp and PEB,

On behalf of the Wisconsin Primary Health Care Association and the 19 Federally Qualified Health Centers in the state, thank you for your service on the PEB. Federally Qualified Health Centers, also known as Community Health Centers, provide primary medical, dental, and behavioral health care to patients at over 200 locations in Wisconsin, serving nearly 300,000 children and adults in 2022. Facilitating access to affordable medications is also an essential role of Community Health Centers who provide this access through both entity-owned and contract pharmacy models. WPHCA and our members respectfully ask that the PEB prioritizes expeditious implementation of the Remote Dispensing Site rules.

Without urgent action, Community Health Centers are limited in their ability to extend access to affordable medications for their patients. Some are currently making continency plans to establish a standard pharmacy if remote dispensing rules are not implemented soon. This is not ideal given the current staffing shortages across the health care workforce, and for pharmacy in particular. WPHCA's members are dedicated to providing high quality care regardless of a patient's insurance status, and remote dispensing will help improve this access, especially in rural areas of the state with limited brick-and-mortar community pharmacies.

We also request that through rule-making, the PEB address labeling. In particular, are pharmacies permitted to have the supervising address on the label and the Remote Dispensing Site location on a separate label affixed to the prescription? One Community Health Center notes that both their main pharmacy and Remote Dispensing Site are under one NPI, and has been using stickers with the address and phone number on them for this purpose.

Finally, I share the following comment on behalf of a Community Health Center member in central Wisconsin:

Hello, my name is Xin Ruppel, and I am the Director of Pharmacy at Family Health Center Pharmacy. We are part of the Family Health Center of Marshfield, a federally qualified health center serving communities across ~10,000 sq. miles in northcentral region of the state. We

are starting our primary care services and integrating pharmacy services as we expand. Due to limitations in staff availability and other resources like physical space, we are seeking to use the remote dispensing site model to provide access to pharmacy in our predominantly rural service area. Our pharmacy services specifically serve underserved patient populations (e.g. <200% FPL) and provide assistance to patients with high out of pocket costs, bridging the gap to therapy caused by financial and geographic barriers. We look to the board to provide clarification on the path forward in registering remote dispensing sites as well as licensure to allow for ease in establishing DEA registration and other regulatory components. Again, remote dispensing model is critical in our ability to provide pharmacy care to patients in new service lines. Thank you for your work in removing barriers to access for our communities.

Thank you for your consideration of our input on Remote Dispensing. Please contact Richelle Andrae, WPHCA Government Relations Specialist, with any questions, at randrae@wphca.org.

Sincerely,

Richelle Andrae
Government Relations Specialist
Wisconsin Primary Health Care Association
randrae@wphca.org | (608) 571-6168

Date: October 25, 2023

To: Pharmacy Examining Board

From: Michael DeBisschop, Pharm.D.

Re: Feedback on Clearinghouse Rule 23-054

Thank you for allowing me to express my comments on the rulemaking process around remote dispensing locations. I appreciate the board's work in this area. Please note that the comments in this document are my own personal opinions and do not represent those of my employer.

I am grateful for the opportunity to provide comments and suggestions in the following areas:

1. I appreciate the definition of a "pharmacy graduate" in these new rules; I am assuming that the authority for a pharmacy graduate to engage in the practice of pharmacy devolves from 450.03(1)(i) as a special case of that statute. In any case, I appreciate they are now specifically defined and have privileges. I also appreciate their exclusion from the provisions in Phar 7.62 dealing with unlicensed persons. **Should they also be included in Phar 7.61 for direct supervision?**
2. **I would request clarification in the remote dispensing rules as to whether the pharmacist who is remotely available to a RDS must be working at a "supervising pharmacy" while doing so, or may be just supervising remotely from another non-pharmacy location.**
    a. Statutes (450.09) do not state that a pharmacist must be working in a pharmacy, just remotely supervising, opening up the possibility of remote supervision by a licensed pharmacist from a non-pharmacy work location.
    b. Some current and proposed rules in Phar 7.43 imply that a supervising pharmacist might not have to be working in a pharmacy at the time of supervision; (examples include proposed Phar 7.43(4)(b); existing Phar 7.43(4)(c); proposed Phar 7.43(5)(b).
    c. Different current and proposed rules in Phar 7.43 imply that a "supervising pharmacy" plays a role, namely, the signage requirements in Phar 7.43(4)(a), and the managing pharmacist requirement in Phar 7.43(6)(a).
3. Regarding delegate requirements in Phar 7.43(7), I appreciate potentially allowing student pharmacists in years 3-4 and pharmacy graduates to be dispensers. **I would request clarification on whether the 1500 hours of "work" might include time in rotation/internship, or if this applies to paid work only?** Due to the rigors of pharmacy education especially in the APPE year, some might not have this amount of paid work in the past 3 years. Also, **could the term "pharmacist delegate" be either defined or replaced with something more descriptive/definitive?** Especially since the term delegate is replaced in the technician emergency rules? Perhaps, wording like "1500 hours of work engaged in the practice of pharmacy or a pharmacy technician in a community setting" or similar could make this clearer.

Thank you for taking these items into consideration in development of the permanent rules. I really appreciate the board's hard work in this area and efforts to foster modern pharmacy practice. Please do not hesitate to reach out with any questions.

Pharmacy Society of Wisconsin

TO: Members, Pharmacy Examining Board

FROM: Danielle M. Womack, MPH, HIVPCP
Vice President, Public Affairs
Pharmacy Society of Wisconsin

DATE: October 26, 2023

SUBJECT: Testimony Regarding CR 23-054 (Remote Dispensing)

Thank you for the opportunity to provide testimony regarding CR 23-054, relating to remote dispensing. The Pharmacy Society of Wisconsin (PSW) is grateful to the Pharmacy Examining Board (PEB) for their work in implementing 2021 Wisconsin Act 101.

Upon review of the final rule, we have two suggested modifications for clarity:

> Section 8: Phar 7.43(6)(a) and Phar 7.43(6)(b) provide requirements for "the managing pharmacist of the supervising pharmacy." As the rule is written, however, there is no longer a "supervising pharmacy" for remote dispensing sites, as they are licensed on their own as pharmacies; instead, there is a managing pharmacist who is responsible for the operations. We recommend revising these two sections to remove "of the supervising pharmacy" to ensure consistency between the statute and the rest of the rule.

Thank you for the opportunity to provide testimony regarding CR 23-054.

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STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

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

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

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

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

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

Related statute or rule: N/A

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

Summary of, and comparison with, existing or proposed federal regulation:
The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compounded drugs in response to an order that is not patient specific. The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

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

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

Iowa: Iowa requires compliance with the current revisions of USP Chapters 795 and 797. Additionally, Iowa includes requirements for the use of flavoring agents. These requirements include that pharmacist may add flavoring in the amount of not more than percent of the total volume of the drug. The beyond-use date of the flavored drug must be no greater than 14 days and the pharmacist must document that a flavoring agent was added ot a drug. Compliance with USP Chapter 825 is not required, however Iowa does have its own rules for radiopharmaceuticals and nuclear pharmacy [Iowa Administrative Code ss.657.16 and 657.20].

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

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

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

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule will be posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

Effect on small business:
These rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

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

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

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

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

(a) The pharmacist shall ensure that the flavoring agent is not more than 5 percent of the product's total volume.
(b) The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented.
(c) The pharmacist shall document the addition of flavoring as part of the prescription record. The documentation shall include the type of flavoring agent, manufacturer, lot number, and expiration date.
(d) A prescription is required before a pharmacist may add flavoring to an over-the-counter product.

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

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

Phar 15.03 Compliance. Noncompliance with ch. Phar 15 may be considered a violation of s. Phar 10.03 and may result in disciplinary action by the Board against a licensee.

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

(END OF TEXT OF RULE)

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 7

Relating to: Comprehensive Review

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 proposed rule is to update requirements in Wisconsin Administrative Code Phar 7 to align with current pharmacy practice. Additionally, the rule will implement the statutory changes from 2023 Wisconsin Act 27.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
Wisconsin Administrative Code Phar 7 includes requirements for the practice of pharmacy. These requirements have the potential to become outdated on a regular basis. If the Board does not make regular updates via the permanent rules process, there will be inconsistencies between current pharmacy practice and what is required in the Wisconsin Administrative Code. This project will ensure that the Wisconsin Administrative Code continues to be current in this area.

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

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

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

450.02 (3) (b) The Board may promulgate rules establishing security standards for pharmacies.

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

450.02 (3) (e) The Board may promulgate rules establishing minimum standards for the practice of pharmacy.

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

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

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):
None to minimal. It is not likely to have a significant economic impact on small businesses.

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

Approved for publication:

Authorized Signature

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

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

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

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

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; correction made under s. 13.93 (2m) (b) 7., Stats., Register, January, 1989, No. 397; am. Register, August, 1991, No. 428, eff. 9–1–91; am., Register, December, 1998, No. 516, eff. 1–1–99; correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.

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

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

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

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; am. Register, August, 1991, No. 428, eff. 9–1–91; cr. (1m), Register, February, 1996, No. 482, eff. 3–1–96.

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

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83.

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

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

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

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

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

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; cr. (4), Register, August, 1991, No. 428, eff. 9–1–91; r. (3) (a) 4., Register, January, 1996, No. 481, eff. 2–1–96; CR 03–096: am. (3) (a) (intro.), cr. (3) (c) Register May 2004 No. 581, eff. 6–1–04; **CR 21–074: am. (1), r. (2), r. and recr. (3) (title), renum. (3) (a) (intro.), 1. to (3) (intro.), (am) and am., r. (3) (a) 2., 3., renum. (3) (a) 5., 6. to (3) (bm), (cm), r. (3) (a) 7., (b), (c), (4) Register June 2023 No. 810, eff. 7–1–23; correction in renumbering (3) (intro.) made under s. 13.92 (4) (b) 1., Register June 2023 No. 810.**

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

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83.

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

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

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

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

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

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

(2k) References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

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

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; r. and recr. Register, January, 1989, No. 397, eff. 2–1–89; correction in (2) made under 13.93 (2m) (b) 6., Stats., Register, January, 1989, No. 397; am. (1) (j) 3., Register, December, 1998, No. 516, eff. 1–1–99; CR 01–023: am. (1) (intro.) and (a) to (c), (j) (intro.) and (k), Register, August 2001 No. 548 eff. 9–1–01; 2017 Wis. Act 18: r. and recr. (title), renum. (1) (intro.) to (intro.) and am., r. (1) (a) to (i), renum. (1) (j), (k), (L) to (1j), (2k), (3L), r. (2) Register June 2017 No. 738, eff. 7–1–17.

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

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

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; CR 19–165: r. and recr. (1), r. (2), am. (3) Register July 2020 No. 775, eff. 8–1–20.

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

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

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

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

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

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

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

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

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

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

History: CR 16−073: cr. Register November 2017 No. 743, eff. 12−1−17; corrections in (1) (b) and (c), (6) made under s. 35.17, Stats., Register November 2017 No. 743; CR 19−165: r. (1) (b), am. (2), r. and recr. (4) Register July 2020 No. 775, eff. 8−1−20.

Phar 6.08 Security. A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

History: Cr. Register, December, 1998, No. 516, eff. 1−1−99; CR 05−001: am. Register August 2005 No. 596, eff. 9−1−05; CR 09−098: am. Register May 2010 No. 653, eff. 6−1−10.

Pharmacy Examining Board
Rule Projects (updated 11/22/23)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet (EmR 2303)	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Permanent Preliminary Rule Draft Posted for EIA Comment; Emergency Rule Effective 02/03/23-05/01/24	Submission to Clearinghouse for Review
23-054 (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Final Permanent Rule Reviewed at 12/07/23 Meeting ; Emergency Rule Effective 11/01/22-05/01/24	Submission to Governor's Office and Legislature
Not Assigned Yet	Not Assigned Yet	TBD	Phar 7	Comprehensive Review	Scope Statement Reviewed at 12/07/23 Meeting	Submission to Governor's Office and for Publication
23-015	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Legislative Review	Adoption Order Presented at a Future Board Meeting
Not Assigned Yet	044-23	01/10/2026	Phar 8	Controlled Substances Requirements	Drafting	Board Review and Approval of Preliminary Rule Draft
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Preliminary Rule Draft Reviewed at 12/07/23 Meeting	Board Approval of Permanent Preliminary Rule Draft for Posting for EIA Comment and Submission to Clearinghouse for Review
23-031	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Final Rule and Legislative Report Ready for Submission to Governor's Office	Governor's Office Approval and Legislature for Review

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski		**2) Date when request submitted:** 11/21/2023 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 12/07/2023	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Implement 2021 Wisconsin Act 9 – 100 Most Prescribed Drugs – Discussion and Consideration	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☒ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: Please see PDF attachment with Top 100 Most Prescribed Drugs			
11) Authorization  **Signature of person making this request**		**12/21/2023** **Date**	
Supervisor (Only required for post agenda deadline items)		**Date**	
Executive Director signature (Indicates approval for post agenda deadline items)		**Date**	

Directions for including supporting documents:
1. **This form should be saved with any other documents submitted to the Agenda Items folders.**
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3. **If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

*** PUBLIC NOTICE *** Under Wis. Stats. s. 450.13 (5m) (a), the Pharmacist may substitute a less expensive drug product equivalent, unless the consumer or prescribing practitioner have indicated otherwise.

*** PUBLIC NOTICE *** Under Wis. Stats. s. 450.135 (8m), the Pharmacist may substitute a less expensive interchangable biological product, unless the consumer or prescribing practitioner have indicated otherwise. The public may access a full list of interchangeable biological products that have been approved by the Food and Drug Administration (FDA) here: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

*** PUBLIC NOTICE *** Under Wis. Stats. s. 450.13 (5m) (b), each pharmacy must provide notice to the public on how it may access the Pharmacy Examining Board's list of the 100 most commonly prescribed generic drug product equivalents. The public may access this list here: https://dsps.wi.gov/Pages/BoardsCcouncils/Pharmacy/Default.aspx

TOP 100 DRUGS A TO Z BRAND NAME

BRAND NAME	DRUG GENERIC NAME	QUANTITY
ABILIFY	ARIPIPRAZOLE 10MG TABLET	30
ADVAIR DISKUS	FLUTICASONE PROPIONATE/SALMETEROL DISKUS	60
AMARYL	GLIMEPIRIDE 2MG TABLET	30
AMOXIL	AMOXICILLIN 500MG CAPSULE	30
ARICEPT	DONEPEZIL 10MG TABLET	30
AUGMENTIN	AMOX TR-K CLAV 875-125 MG TABLET	20
AVAPRO	IRBESARTAN 150MG	30
BACTRIM DS	SULFAMETH/TRIMETH DS TABLET	20
BACTROBAN	MUPIROCIN OINTMENT	22 GRAM
BENICAR	OLMESARTAN 20MG TABLET	30
CATAPRES	CLONIDINE 0.1MG TABLET	90
CELEBREX	CELECOXIB 200MG CAPSULE	30
CELEXA	CITALOPRAM 20MG TABLET	30
CIPRO	CIPROFLOXACIN 500MG TABLET	20
COREG	CARVEDILOL 6.25MG TABLET	60
COUMADIN	WARFARIN 5MG TABLET	30
COZAAR	LOSARTAN 50MG TABLET	30
CRESTOR	ROSUVASTATIN 10MG TABLET	30
CYMBALTA	DULOXETINE 30MG CAPSULE	30
DELTASONE	PREDNISONE 10MG TABLET	30
DELTASONE	PREDNISONE 20MG TABLET	30
DEPAKOTE	DIVALPROEX 500MG EC TABLET	90
DESYREL	TRAZODONE 50MG TABLET	30
DIFLUCAN	FLUCONAZOLE 150MG TABLET	1
DILANTIN	PHENYTOIN SOD EXT 100 MG CAPSULE	90
DIOVAN	VALSARTAN 80MG TABLET	30
EFFEXOR XR	VENLAFAXINE XR 75MG CAPSULE	30
ELIQUIS	APIXABAN 5MG TABLET	30
FLAGYL	METRONIDAZOLE 500MG TABLET	20
FLEXERIL	CYCLOBENZAPRINE 10MG TABLET	30
FLOMAX	TAMSULOSIN 0.4MG CAPSULE	30

FLONASE	FLUTICASONE 50MCG NASAL	16 GRAM
FLOVENT HFA	FLUTICASONE HFA 110MCG INHALER	12 GRAM
FOLVITE	FOLIC ACID 1MG TABLET	30
FOSAMAX	ALENDRONATE 70MG TABLET	4
GLUCOPHAGE	METFORMIN HCL 1,000 MG TABLETLET	60
GLUCOPHAGE	METFORMIN HCL 500 MG TABLETLET	60
GLUCOPHAGE XR	METFORMIN ER 500MG TABLET	60
GLUCOTROL XL	GLIPIZIDE ER 10MG TABLET	30
GLUCOTROL XL	GLIPIZIDE ER 5MG TABLET	30
HYDRODIURIL	HYDROCHLOROTHIAZIDE 12.5MG CAPSULE	30
HYDRODIURIL	HYDROCHLOROTHIAZIDE 25MG TABLET	30
IMITREX	SUMATRIPTAN 100MG TABLET	9
JANUVIA	SITAGLIPTAN 100MG TABLET	30
K-DUR	POTASSIUM 20MEQ TABLET	30
KEFLEX	CEPHALEXIN 500MG CAPSULE	28
LAMICTAL	LAMOTRIGINE 25MG TABLET	30
LAMISIL	TERBINAFINE 250MG TABLET	30
LASIX	FUROSEMIDE 20MG TABLET	30
LASIX	FUROSEMIDE 40MG TABLET	30
LEXAPRO	ESCITALOPRAM 10MG TABLET	30
LIPITOR	ATORVASTATIN 10MG TABLET	30
LIPITOR	ATORVASTATIN 20MG TABLET	30
LOPRESSOR	METOPROLOL 50MG TABLET	60
LYRICA	PREGABALIN 50MG CAPSULE	60
MACROBID	NITROFURANTOIN MONO 100MG CAPSULE	14
MAXZIDE	TRIAMTERENE/HCTZ 37.5MG TABLET	30
MOBIC	MELOXICAM 15MG TABLET	30
MOTRIN	IBUPROFEN 600MG TABLET	90
MOTRIN	IBUPROFEN 800MG TABLET	90
NAPROSYN	NAPROXEN 500MG TABLET	60
NEURONTIN	GABAPENTIN 300MG CAPSULE	90
NEXIUM	ESOMEPRAZOLE 40MG CAPSULE	30
NORVASC	AMLODIPINE 10MG TABLET	30
PAXIL	PAROXETINE 20MG TABLET	30
PLAVIX	CLOPIDOGREL 75MG TABLET	30
PRAVACHOL	PRAVASTATIN 20MG TABLET	30
PRILOSEC	OMEPRAZOLE 20MG CAPSULE	30
PROCARDIA XL	NIFEDIPINE ER 30MG TABLET	30
PROSCAR	FINASTERIDE 5MG TABLET	30
PROTONIX	PANTOPRAZOLE 40MG TABLET	30
PROZAC	FLUOXETINE 20MG CAPSULE	30
RISPERDAL	RISPERIDONE 1MG TABLET	30
SEROQUEL	QUETIAPINE 100MG TABLET	30
SINGULAIR	MONTELUKAST SOD 10 MG TABLET	30
SYNTHROID	LEVOTHYROXINE 100MCG	30
SYNTHROID	LEVOTHYROXINE 50MCG	30
TENORMIN	ATENOLOL 25MG TABLET	30
TENORMIN	ATENOLOL 50MG TABLET	30
TOPAMAX	TOPIRAMATE 50MG TABLET	30
TOPROL XL	METOPROLOL XL 50MG TABLET	30
TRICOR	FENOFIBRATE 145MG TABLET	30
V-CILLIN-K	PENICILLIN -VK 500MG TABLET	40
VALTREX	VALACYCLOIVIR 500MG TABLET	30
VASOTEC	ENALAPRIL 10MG TABLET	30
VENTOLIN INHALER	ALBUTEROL HFA INHALER	18 GRAM
VIBRAMYCIN	DOXYCYCLINE 100MG CAPSULE	30
WELLBUTRIN SR	BUPROPION SR 150MG TABLET	60
XALATAN	LATANOPROST 0.005% DROPS	2.5 ML
XARELTO	RIVAROXABAN 20MG TABLET	30

ZESTORETIC	LISINOPRIL/HCTZ 20/12.5MG	30
ZESTRIL	LISINOPRIL 10MG TABLET	30
ZESTRIL	LISINOPRIL 20MG TABLET	30
ZETIA	EZETIMIBE 10MG TABLET	30
ZITHROMAX	AZITHROMYCIN 250MG TABLET	6
ZOCOR	SIMVASTATIN 20MG TABLET	30
ZOCOR	SIMVASTATIN 40MG TABLET	30
ZOLOFT	SERTRALINE 100MG TABLET	30
ZOLOFT	SERTRALINE 50MG TABLET	30
ZYLOPRIM	ALLOPURINOL 100MG TABLET	30
ZYPREXA	OLANZAPINE 5MG TABLET	30

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4) Meeting Date: 12/7/2023	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** Liaison Reports – Discussion and Consideration 1) Website Update	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: 1. Will discuss the inclusion of Top 100 Prescription Drug List 2. Will discuss the DEA Changes to Prescription Transfers			
11) Authorization 11/27/2023 **Signature of person making this request** — **Date** **Supervisor (Only required for post agenda deadline items)** — **Date** **Executive Director signature (Indicates approval for post agenda deadline items)** — **Date**			
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4) Meeting Date: 12/7/2023	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration 1) 120th NABP Annual Meeting, May 14 – 17, 2024, Fort Worth, TX
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>

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

NABP Annual Meeting CPE Overall Learning Objectives

The knowledge-based continuing pharmacy education (CPE) sessions presented at the Annual Meeting are developed specifically for pharmacists and pharmacy technicians. Activities are also relevant to the Association's member boards of pharmacy, which are composed of executive officers, board staff, board members, compliance staff, and board counsel. Sessions are also relevant to other attendees in the practice of pharmacy. By actively participating in the meeting's CPE programming, at the conclusion of the Annual Meeting, participants should be able to:

- Identify the latest legislative and regulatory issues being addressed by the state boards of pharmacy.
- Explain how the changing regulatory environment impacts the state boards of pharmacy and the practice of pharmacy.
- Identify gaps in regulatory oversight and best practices for state pharmacy boards to overcome them.
- Discuss emerging roles of pharmacists and pharmacy technicians with respect to the public's access to quality health care.
- Discuss how poster session research findings further the protection of the public health.
- Describe best practices for regulating pharmacist care services in a changing health care environment.
- Compare licensing standards between state boards of pharmacy.

Contact CPE Program staff at 847/391-4406 or via email at CPE@nabp.pharmacy for more details.

11) Authorization

Signature of person making this request	**Date** 11/21/2023
Supervisor (Only required for post agenda deadline items)	**Date**
Executive Director signature (Indicates approval for post agenda deadline items)	**Date**

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