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

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

Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
October 20, 2021

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

AGENDA

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

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of September 2, 2021 (5-9)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. 11:00 A.M. Public Hearing – Clearinghouse Rule 21-071 (Phar 8), Relating to Requirements for Controlled Substances (10-22)
1) Review Public Hearing Comments and Respond to Clearinghouse Report

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 – 7/1/2023
   d. Walsh, Michael – 7/1/2024
   e. Weiss, Shana – 7/1/2023
   f. Weitekamp, John – 7/1/2022
   g. Wilson, Christa – 7/1/2025

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

G. Legislative and Policy Matters – Discussion and Consideration
1) Assembly Bill 281/Senate Bill 300 (Pharmacy Technicians)

H. Administrative Rule Matters – Discussion and Consideration (23-26)
1) Phar 15, Compounding Pharmaceuticals

2) Pending or Possible Rulemaking Projects

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

1) 2022 Annual Meeting Planning: NABP/American Association of Colleges of Pharmacy (AACP) District IV

J. COVID-19 – Discussion and Consideration

K. Pilot Program Matters – Discussion and Consideration

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

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

M. 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.).

N. Deliberation on Division of Legal Services and Compliance Matters

1) Case Closings

a. 19 PHM 301 – Z.P. **(27-32)**
b. 20 PHM 073 – W. **(33-37)**
c. 20 PHM 153 – C., K.L.M. **(38-43)**
d. 21 PHM 030 – T.L.V. **(44-48)**
e. 21 PHM 037 – E.C.P. **(49-52)**
f. 21 PHM 064 – O. **(53-58)**

2) Administrative Warnings

a. 21 PHM 019 – O.H.E. **(59-60)**
b. 21 PHM 019 – W.P. **(61-62)**

3) Proposed Stipulations, Final Decisions and Orders

a. 21 PHM 018 – Jared G. Latus, R.Ph. **(63-68)**

O. Deliberation on Matters Relating to Costs/Orders Fixing Costs

1) Jennifer L. Reithmeyer, R.Ph., Respondent (DHA Case Number SPS-20-0027/ DLSC Case Number 18 PHM 180) **(69-93)**

P. 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

Q. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: DECEMBER 2, 2021

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

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

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
SEPTEMBER 2, 2021

PRESENT: Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo *(arrived at 9:13 a.m.)*, John Weitekamp, Christa Wilson

EXCUSED: Michael Walsh, Shana Weiss

STAFF: Brad Wojciechowski, Executive Director; Jameson Whitney, Legal Counsel; Katlin Schwartz, Bureau Assistant; Megan Glaeser, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Advanced; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 9:01 a.m. A quorum was confirmed with four (4) members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF JUNE 24, 2021

MOTION: Tiffany O'Hagan moved, seconded by Christa Wilson, to approve the Minutes of June 24, 2021 as published. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Election of Officers

Secretary

NOMINATION: Susan Kleppin nominated herself for the Office of Secretary. Susan Kleppin accepted the nomination.

Anthony Peterangelo arrived at 9:13 a.m.

Brad Wojciechowski, Executive Director, called for nominations three (3) times.

Susan Kleppin was elected as Secretary by unanimous voice vote.

ELECTION RESULTS	
Secretary	Susan Kleppin

Appointment of Liaisons

LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Anthony Peterangelo, Tiffany O'Hagan, Christa Wilson
Office of Education and Examinations Liaison(s)	Susan Kleppin *Alternate:* John Weitekamp
Monitoring Liaison(s)	Shana Weiss *Alternate*: Anthony Peterangelo
Professional Assistance Procedure (PAP) Liaison(s)	Anthony Peterangelo *Alternate*: Susan Kleppin
Travel Liaison	Chairperson *Alternate:* Vice Chairperson
Legislative Liaison(s)	Anthony Peterangelo, Tiffany O'Hagan, John Weitekamp
Pilot Program Liaison(s)	Tiffany O'Hagan, Anthony Peterangelo
Newsletter Liaison(s)	Christa Wilson *Alternate:* John Weitekamp
Website Liaison(s)	Michael Walsh
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)	John Weitekamp
PHARM Rep to SCAODA	Anthony Peterangelo *Alternate:* John Weitekamp
Variance Liaison	Tiffany O'Hagan *Alternate:* Anthony Peterangelo
SCREENING PANEL APPOINTMENTS	
January – December 2021	John Weitekamp, Tiffany O'Hagan, Michael Walsh *Alternate:* Anthony Peterangelo
COMMITTEE MEMBER APPOINTMENTS	
Pharmacy Rules Committee	Susan Kleppin, Tiffany O'Hagan, Anthony Peterangelo, John Weitekamp

REVIEW OF PHARMACY SELF-INSPECTION FORMS

MOTION: Tiffany O'Hagan moved, seconded by Anthony Peterangelo, to designate John Weitekamp and Susan Kleppin to work with DSPS Staff to propose changes to form 2550-Pharmacy Self-Inspection Form and to report back to the Board at the next meeting. Motion carried unanimously.

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

Consider Attendance: NABP 2021 District IV Meeting on October 20-22, 2021 in Columbus, Ohio

MOTION: Anthony Peterangelo moved, seconded by Susan Kleppin, to designate Tiffany O'Hagan, as the Board's delegate to attend the NABP 2021 District IV Meeting on October 20-22, 2021 in Columbus, Ohio and to authorize travel. Motion carried unanimously.

CLOSED SESSION

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

The Board convened into Closed Session at 10:44 a.m.

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

Case Closings

MOTION: Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to close the following DLSC Cases for the reasons outlined below:

a. 19 PHM 192 – L.A.H. – Insufficient Evidence
b. 19 PHM 277 – T.A.P. – Prosecutorial Discretion (P2)
c. 20 PHM 041 – J.O., W. – No Violation
d. 20 PHM 071 – W., M.D.L., S.M.R. – Prosecutorial Discretion (P1)
e. 20 PHM 105 – P.S. – No Violation
f. 20 PHM 160 – H.C. – No Violation
g. 20 PHM 164 – R.C. – No Violation

h. 20 PHM 167 – W. – No Violation
i. 20 PHM 171 – C.P. – Prosecutorial Discretion (P2)
j. 20 PHM 174 – P.P. – Prosecutorial Discretion (P2)
k. 20 PHM 177 – C. – No Violation
l. 21 PHM 004 & 21 PHM 054 – G. – No Violation
m. 21 PHM 006 – S.B.P. – Prosecutorial Discretion (P2)
n. 21 PHM 018 – C.H.W. – No Violation
o. 21 PHM 023 – W. – No Violation
p. 21 PHM 035 – O.P. – No Violation
q. 21 PHM 044 – W. – No Violation
r. 21 PHM 046 – P.P. – Prosecutorial Discretion (P1)
s. 21 PHM 063 – A.I.S. – Prosecutorial Discretion (P2)
t. 21 PHM 070 – E.P. – Prosecutorial Discretion (P2)

Motion carried unanimously.

Administrative Warnings

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

a. 19 PHM 166 – A.P.W.
b. 20 PHM 044 – W.
c. 21 PHM 011 – W.
d. 21 PHM 014 – O.

Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

MOTION: Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to adopt the Findings of Fact, Conclusions of Laws and Orders in the matter of the following cases.

a. 20 PHM 044 – Kathrine D. Lindberg, R.Ph.
b. 20 PHM 087 – Peter A. Dickman, R.Ph.
c. 20 PHM 109 – Meds in Motion
d. 20 PHM 118 – Darrin D. Wirkes, R.Ph.
e. 21 PHM 028 – Daniel J. Janke, R.Ph.

Motion carried unanimously.

Monitoring Matters

Robert Stevens, R.Ph.
Requesting Full Reinstatement of Licensure

MOTION: Anthony Peterangelo moved, seconded by Christa Wilson, to deny the request of Robert Stevens, R.Ph., for full licensure. **Reason for Denial**: Insufficient time under the Board order (1/3/2017) to demonstrate compliance. Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 12:34 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

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

ADJOURNMENT

MOTION: Anthony Peterangelo moved, seconded by Tiffany O'Hagan, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 12:37 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**	**10/08/21** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10/20/21	☒ Yes ☐ No	**11:00 A.M. Public Hearing – Clearinghouse Rule 21-071 on Phar 8, Relating to Requirements for Controlled Substances** 1. **Review Public Hearing Comments and Respond to Clearinghouse Report**

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

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

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

11) Authorization

Nilajah D. Hardin — 10/08/21

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

Supervisor (if required) — **Date**

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

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.31, Stats.

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

Explanation of agency authority:

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

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

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

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

(b) Establishing security standards for pharmacies.

…

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

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

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

Related statute or rule: N/A

Plain language analysis:

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

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

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

Comparison with rules in adjacent states:

Illinois: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.600 to 68/1330.800 outlines requirements for pharmacy standards and pharmacy operations. Illinois law requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA (IL 68/1330.710). Illinois administrative rule requires that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years (IAC 3100.360). Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription (IAC 3100.400).

Iowa: The Iowa Pharmacy Board requires a pharmacy to maintain controlled substance records for at least 2 years and to segregate Schedule I and II drug records from other controlled substance records (Iowa Admin. Code 657-10.36). Iowa also requires that pharmacies keep a perpetual inventory of all Schedule II drugs on hand (Iowa Admin. Code 657-10.18). Iowa only requires a pharmacist to report theft or loss of controlled substances to the Pharmacy Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to merely report to the DEA (Iowa Admin. Code 657-10.21). Iowa also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate

administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. Like Wisconsin, the prescriber must provide a written prescription within 7 days (Iowa Admin. Code 657-10.26).

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

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

Summary of factual data and analytical methodologies:

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

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

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

Fiscal Estimate and Economic Impact Analysis:

A fiscal estimate and economic impact analysis are attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats.

Agency contact person:

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

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

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

TEXT OF RULE

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

Chapter Phar 8
REQUIREMENTS FOR CONTROLLED SUBSTANCES

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

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

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

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

(2) An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid. A pharmacist knowingly dispensing pursuant to such a purported order, as well as the practitioner issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.
(3) As provided under s. 961.38 (4r), Stats., a pharmacist is immune from any civil or criminal liability and from discipline under s. 450.10, Stats., for any act taken by the pharmacist in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

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. Records required by the federal controlled substances act, ch. 961, Stats., and s. 450.11 (2), Stats., shall be maintained for at least 5 years from the date the drug was received, manufactured, distributed, or dispensed or, for a record that is subject to s. 961.385, Stats., until the name of a person to whom a drug is dispensed is delivered to the controlled substances board under s. 961.385, Stats., whichever is sooner. Records shall be readily retrievable, easily readable, and available for inspection by authorized persons for at least 5 years from the date of such record. An electronic recordkeeping system shall have the capability of producing a printout of records as required under this section. The pharmacist-in-charge shall oversee monthly 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) IDENTIFICATION CARD REQUIREMENT. As provided under s. 450.11 (1b) (b) and (e), Stats., a controlled substance included in schedule II or III of ch. 961, Stats., may not be dispensed, and may not be delivered to a representative of the ultimate user, without an identification card belonging to the person to whom the drug is being dispensed or delivered. An identification card is not required if any of the following applies:
(a) The drug is administered or dispensed directly to the ultimate user by a practitioner.
(b) The pharmacist or other person dispensing or delivering the drug has personal knowledge of the person to whom the drug is dispensed or delivered, and that the person is the ultimate user or the ultimate user's authorized representative.
(c) The drug is delivered to a health care facility to be administered in the health care facility.

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

(a) Immediate administration of the schedule II controlled substance is necessary for proper treatment of the patient.
(b) No appropriate alternative treatment is available, including the administration of a drug that is not a schedule II controlled substance.
(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.
(2) REQUIRED NOTIFICATION. A dispensing pharmacist shall notify the board of the failure of a prescribing practitioner to deliver a written prescription within 7 days after authorizing an emergency oral prescription for a schedule II controlled substance. The notification shall be provided to the board on the same day notification is required to be provided to the drug enforcement administration and shall include all information required to be provided in the notification to the drug enforcement administration.

Phar 8.08 Dispensing and sale of pseudoephedrine products. The dispensing and sale of pseudoephedrine products shall meet all applicable federal, state, and local laws and regulations relating to schedule V controlled substances, including all the following requirements:
(1) The requirements under ss. 961.23 and 961.38 (4), Stats., for dispensing schedule V controlled substances.
(2) The requirements under s. 961.235, Stats., for records relating to sales of pseudoephedrine products.

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)

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
09/01/21

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 8

4. Subject
Requirements for Controlled Substances

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

6. Chapter 20, Stats. Appropriations Affected
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
The objective of the proposed rule is to complete a comprehensive review of Phar 8, Requirements for Controlled Substances and make revisions to ensure the chapter is statutorily compliant with state and federal law and are current with professional standards and practices.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted for 14 days on the Department of Safety and Professional Services' website to solicit comments on the potential economic impact. No comments were received.

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

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
No economic or fiscal impacts are anticipated for specific businesses, business sectors, public utility rate payers, local governmental units, or the state's economy as a whole. A total of $1,107.54 in one time costs are anticipated to be absorbed within the operating budget of the Department of Safety and Professional Services.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The Board intends to modernize Phar 8 to bring it in line with current pharmacy standards and practices. The Board will evaluate reducing the regulatory impact on pharmacies without negatively impacting public safety. The board will also incorporate minimum standards to prevent controlled substance diversion.

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

17. Compare With Approaches Being Used by Federal Government

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ADMINISTRATIVE RULES
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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: Statutes outlining Illinois' Pharmacy Practice Act are found under 225 ILCS 85 and codified under IL 68/1330 for the Pharmacy Practice. Specifically, IL 68/1330.600 to 68/1330.800 outlines requirements for pharmacy standards and pharmacy operations. Illinois law requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA (IL 68/1330.710). Illinois administrative rule requires that inventory of controlled substances be done annually, with an exact count for Schedule II drugs and an approximation for Schedule III and IV. Illinois also requires that a record of all written prescription orders received and verbal prescriptions filled, compounded or dispensed for controlled substances be retained for at least 5 years (IAC 3100.360). Illinois also allows a pharmacist to fill an oral prescription for a Schedule II controlled substance where immediate administration is necessary for proper treatment, no appropriate alternative treatment is available, and it is not possible for the prescriber to provide a written prescription. There does not appear to be a requirement that the prescriber follow up with a written prescription (IAC 3100.400).

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

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

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

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.

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DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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

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

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

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

5. Describe the Rule's Enforcement Provisions

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

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit Kelley
Clearinghouse Assistant Director

Anne Sappenfield
Legislative Council Director

CLEARINGHOUSE REPORT TO AGENCY

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

CLEARINGHOUSE RULE **21-071**

AN ORDER to repeal and recreate ch. Phar 8, relating to requirements for controlled substances.

Submitted by **PHARMACY EXAMINING BOARD**

09-01-2021 RECEIVED BY LEGISLATIVE COUNCIL.
09-27-2021 REPORT SENT TO AGENCY.

SG:SM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

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

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

   Comment Attached YES ☑ NO ☐

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

   Comment Attached YES ☑ NO ☐

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☑ NO ☐

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

   Comment Attached YES ☑ NO ☐

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

   Comment Attached YES ☐ NO ☑

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

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

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Clearinghouse Director

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Clearinghouse Assistant Director

CLEARINGHOUSE RULE 21-071

Comments

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

1. Statutory Authority

The rule should cite ss. 450.11 (1b) (a) 1. and 961.38 (2), Stats., as additional sources of statutory authority. Section 450.11 (1b) (a) 1., Stats., authorizes the board to identify additional types of health care facilities for the purposes of identification card requirements under s. Phar 8.06 (1) of the proposed rule, and s. 961.38 (2), Stats., authorizes the board to define "emergency situations" for the purposes of dispensing schedule II controlled substances under s. Phar 8.07 of the proposed rule.

2. Form, Style and Placement in Administrative Code

Section Phar 8.05 appears to contain a number of different requirements relating to recordkeeping and recordkeeping systems. Consider organizing the material into subsections for clarity and readability.

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

A number of provisions, including ss. Phar 8.03 (3), 8.06 (2), and 8.08, appear to be reiterations of statutes without additional interpretation or effect. Consider whether those provisions need to be included in the administrative code.

5. Clarity, Grammar, Punctuation and Use of Plain Language

In the "Explanation of Agency Authority" section of the rule analysis, the description of s. 450.02 (3), Stats., should change "[t]" to "[t]he".

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**	**10/08/21** **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

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

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10/20/21	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Phar 15, Compounding Pharmaceuticals** **2. Pending or Possible Rulemaking Projects**

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

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

Attachments:
1. Phar 15 Scope Statement
2. 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 — 10/08/21

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

Supervisor (if required) — **Date**

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

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

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 15

Relating to: Compounding Pharmaceuticals

Rule Type: Permanent

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

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

The objective of the rule is to review the updated United States Pharmaceopeia (USP) 797 standards, which have an intended publication date of June 1, 2019 with an anticipated official date of December 1, 2019, and amend Phar 15 to align with the USP 795 and 797 chapters without creating an unnecessary burden on Wisconsin pharmacies.

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

The Pharmacy Examining Board recently completed a major revision to Phar 15 which became effective on November 1, 2018. During the legislative review period, the Pharmacy Examining Board represented to the Joint Committee on Review of Administrative Rules and stakeholder associations that when the new USP 797 chapter is published the Pharmacy Examining Board would monitor relevant USP compounding chapters and update Phar 15 so that it remains aligned with USP standards.

This proposed rule would review chapter Phar 15 with the USP compounding chapters and make necessary updates to chapter Phar 15.

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 (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:

200 hours

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

Pharmacies, including pharmacies located within hospitals, and pharmacists.

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

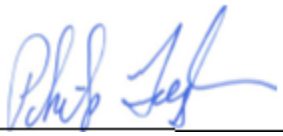
The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements, labeling requirements and may distribute compunded 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.

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

Moderate economic impact. It may have an economic impact on small businesses.

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



Authorized Signature

February 27, 2019
Date Submitted

Pharmacy Examining Board
Rule Projects (updated 10/08/21)

Permanent Rules

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