



**HYBRID (IN-PERSON/VIRTUAL)
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
October 26, 2023**

*Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. **A quorum of the Board may be present during any committee meetings.** Be advised that committee members may attend meetings designated as “Hybrid” in-person or virtually.*

AGENDA

9:00 A.M.

OPEN SESSION – CALL TO ORDER

- A. Approval of Agenda (1)**
- B. Approval of Minutes of August 31, 2023 (2)**
- C. Administrative Rule Matters – Discussion and Consideration (3-16)**
 - 1) Phar 8, Relating to Controlled Substances Requirements (4-11)
 - 2) Phar 15, Relating to Compounding Pharmaceuticals (12-16)
 - 3) Pending or Possible Rulemaking Projects
- D. Public Comments**

ADJOURNMENT

NEXT MEETING: DECEMBER 7, 2023

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 RULES COMMITTEE
MEETING MINUTES
AUGUST 31, 2023**

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

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

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 9:01 a.m. A quorum was confirmed with four (4) 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 JUNE 15, 2023

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to approve the Minutes of June 15, 2023 as published. Motion carried unanimously.


ADJOURNMENT

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

The meeting adjourned at 10:49 a.m.

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

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Nilajah Hardin Administrative Rules Coordinator		2) Date when request submitted: 10/16/23 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 Rules Committee			
4) Meeting Date: 10/26/23	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Administrative Rule Matters – Discussion and Consideration 1. Phar 8, Relating to Controlled Substances Requirements 2. Phar 15, Relating to Compounding Pharmaceuticals 3. Pending or Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <i>(If yes, please complete Appearance Request for Non-DSPS Staff)</i> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Attachments: 1. Phar 8 Scope Statement 2. Wisc. Admin Code Chapter Phar 8 (10/1/22) 3. Wisc. Admin Code Chapter Phar 8 (09/01/22) 4. Phar 15 Preliminary Rule Draft Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx			
11) Authorization			
 Signature of person making this request		10/16/23 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 8

Relating to: Controlled Substances Requirements

Rule Type: Both Permanent and Emergency

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

Clearinghouse Rule 21-071 went into effect on October 1, 2022. This rule repealed and recreated all of Wisconsin Administrative Code Chapter Phar 8. Upon receiving feedback and completing an additional review, the Pharmacy Examining Board has determined that additional changes are needed to Phar 8 to address areas where requirements are no longer in effect or do not match federal regulations. Emergency rules are needed to ensure that these requirements can be updated to protect patient safety and allow effective regulation of the profession until permanent rules can be promulgated.

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

Wisconsin Administrative Code Chapter Phar 8 was recently repealed and recreated. As a result of this change, the Board has found additional areas of Phar 8 that may need to be revised to align with current Pharmacy practices and federal regulations.

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 8 includes requirements for controlled substance prescribing, record keeping, partial dispensing, and compliance with federal laws and regulations, among other requirements. The proposed rules would add to the existing requirements to address issues such as controlled substances prescribing, partial dispensing, and reporting and to create consistency between the code, current pharmacy practices and federal regulations.

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 adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

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.

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

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

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

5/8/2023

Date Submitted

Approved for implementation:



Authorized Signature

9/5/2023

Date Submitted

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

Phar 8.01	Federal registration and compliance with federal, state, and local laws and regulations.
Phar 8.02	Purpose of issue of prescription order.
Phar 8.03	Valid prescription requirements.
Phar 8.04	Notification of suspicious orders for and theft or loss of controlled

	substances.
Phar 8.05	Recordkeeping.
Phar 8.06	Identification card requirement under s. 450.11 (1b), Stats.
Phar 8.07	Partial Dispensing.
Phar 8.08	Controlled substances in emergency kits for long-term care facilities.

Note: Chapter Phar 8 as it existed on September 30, 2022, was repealed and a new chapter Phar 8 was created [Register September 2022 No. 801](#), effective October 1, 2022.

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.

History: CR 21-071: cr. [Register September 2022 No. 801](#), eff. 10-1-22.

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.

History: CR 21-071: cr. [Register September 2022 No. 801](#), eff. 10-1-22.

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 prac-

itioner issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

History: CR 21-071: cr. [Register September 2022 No. 801](#), eff. 10-1-22.

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.

History: CR 21-071: cr. [Register September 2022 No. 801](#), eff. 10-1-22.

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.

History: CR 21-071: cr. [Register September 2022 No. 801](#), eff. 10-1-22.

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.

History: CR 21-071: cr. [Register September 2022 No. 801](#), eff. 10-1-22.

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

1. 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.

2. If the patient requests partial dispensing.

3. If the prescribing practitioner requests partial dispensing.

(b) The remaining portion of any partially dispensed prescription under this subsection 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 subsection. 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.

History: CR 21-071: cr. Register September 2022 No. 801, eff. 10-1-22; correction in numbering in (2) made under s. 13.92 (4) (b) 1., Stats., and correction in (2) (b), (3) made under s. 13.92 (4) (b) 7., Stats., Register September 2022 No. 801.

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 section may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

History: CR 21-071: cr. Register September 2022 No. 801, eff. 10-1-22; correction in (5) made under s. 13.92 (4) (b) 3., Stats., Register September 2022 No. 801.

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

Phar 8.01	Scope.
Phar 8.02	Records.
Phar 8.03	Filing prescription orders.
Phar 8.04	Purpose of issue of prescription order.
Phar 8.05	Dispensing.
Phar 8.06	Renewing prescriptions.
Phar 8.07	Partial dispensing.

Phar 8.08	Labeling prescriptions.
Phar 8.09	Emergency dispensing.
Phar 8.10	Disclosure of suspicious orders of controlled substances.
Phar 8.11	Controlled substances in emergency kits for long term care facilities.
Phar 8.12	Prescription orders transmitted by facsimile machine.
Phar 8.13	Identification card exception for a health care facility.

Phar 8.01 Scope. Procedures governing the manufacture, distribution and dispensing of controlled substances pursuant to ch. 961, Stats., are set forth generally by that chapter and specifically by sections of this chapter and chs. Phar 12 and 13.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; am. Register, December, 1998, No. 516, eff. 1-1-99.

Phar 8.02 Records. (1) Any pharmacy, practitioner, or other federal drug enforcement administration registrant, as referenced in ch. 961, Stats., shall maintain complete and accurate records of each controlled substance received, manufactured, distributed, dispensed or disposed of in any other manner.

(2) Records required by the federal controlled substances act and ch. 961, Stats., shall be maintained at the location where the drug is received, manufactured, distributed or dispensed, and be available for inspection by authorized persons for at least 5 years from the date of such record. Financial and shipping records such as invoices and packing slips, but not executed order forms, may be kept at a central location. A complete and accurate biennial physical inventory of all schedule II, III, IV and V controlled substances pursuant to ss. 961.16, 961.18, 961.20 and 961.22, Stats., and ch. CSB 2 on hand shall be made in conformance with all applicable federal and state laws.

(2m) Records required under s. 450.11 (1b) (bm), Stats., shall be maintained for at least 5 years from the date the drug was 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.

(3) Required records shall be maintained as follows:

(a) Records of schedule II controlled substances, other than prescription orders, shall be maintained separately from all other records.

(b) Records of schedule III, IV and V controlled substances shall be maintained either separately or in such form that the information required is readily retrievable from the registrant's ordinary records.

(c) The official drug enforcement administration order forms, DEA form 222, used in the procurement and distribution of schedule II substances shall be maintained at the locations from which the drug was distributed and where it is received.

(d) Any person authorized to manufacture, distribute or dispense controlled substances shall maintain complete and accurate records with the following information:

1. The name of the substance.
2. The dosage form, strength and quantity of the substance.
3. The quantity and date of distribution as well as the name, address and DEA registration number of the person to whom distributed.
4. The number of units and date of receipt as well as the name, address and DEA registration number of the person from whom received.

5. The name and address of the person for whom dispensed, date of dispensing, quantity dispensed and name or initials of the individual who dispensed the substance.

(e) Records for dispensed schedule V substances shall be maintained as follows:

1. If a schedule V drug is dispensed pursuant to the prescription order of a practitioner, the prescription shall be labeled properly and the order filed in accordance with the requirements for schedule III and IV orders.

2. If a schedule V drug is dispensed other than pursuant to a prescription order, the dispenser shall make the record required by s. 961.23, Stats., in a bound controlled substance V register at the time of the transaction.

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

Note: The Drug Enforcement Administration regional office is at 1800 Dirksen Federal Building, 219 S. Dearborn, Chicago, Illinois 60604.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (3) (f), r. (4) (a) and (b), Register, August, 1991, No. 428, eff. 9-1-91; am. (1), (2) and (3) (e) 2., Register, December, 1998, No. 516, eff. 1-1-99; CR 06-052: am. (3) (f) Register October 2006 No. 610, eff. 11-1-06; **CR 16-018: cr. (2m) Register September 2016 No. 729, eff. 10-1-16; correction in (2m) made under s. 35.17, Stats., Register September 2016 No. 729.**

Phar 8.03 Filing prescription orders. (1) All controlled substance prescription orders shall be maintained on file, in chronological order, for a period of at least 5 years. The orders shall be readily accessible to enforcement personnel authorized by s. 961.51, Stats.

(2) Schedule II prescription orders may be filed separately from all other orders or they may be filed with those for schedule III, IV and V drugs provided all orders in the file for schedule III, IV and V drugs are stamped in red ink with the letter "C" one inch in height, in the lower right hand corner of the order. Under no circumstances may schedule II orders be filed together with those for non-controlled drugs.

(3) Schedule III, IV and V prescription orders may be filed with those for non-controlled drugs provided that orders for schedule III, IV and V drugs are stamped in red ink with the letter "C" one inch in height in the lower right hand corner of the order or orders for schedule III, IV and V substances may be filed separately. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescription orders which permits identification by prescription order number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription order with a red "C" is waived.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (2) and (3), Register, August, 1991, No. 428, eff. 9-1-91; am. (1) and (3), Register, December, 1998, No. 516, eff. 1-1-99.

Phar 8.04 Purpose of issue of prescription order.

(1) 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. 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 prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. The person knowingly dispensing pursuant to such a purported order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

(2) 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.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; am. (1), Register, December, 1998, No. 516, eff. 1-1-99.

Phar 8.05 Dispensing. (1) All controlled substance prescription orders shall be dated as of, and signed on, the day issued and shall contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. Prescription orders shall be written with ink or indelible pencil or be typewritten and shall be signed by the practitioner. Orders for controlled substances may be issued only by individual practitioners who are authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice and registered or exempt from registration under the federal controlled substances act.

(2) A pharmacist may dispense a controlled substance listed in schedule II, III or IV only pursuant to a prescription order issued by an individual practitioner. The order shall be initialed and dated by the dispensing pharmacist as of the date the prescription is dispensed. If the person accepting the medication pursuant to any prescription order for a schedule II controlled substance, specified in s. 961.16, Stats., is not personally known to the pharmacist, there shall be written in ink, on the reverse side, the printed name, signature and address of the person.

(3) An individual practitioner may dispense directly a controlled substance listed in schedule II, III or IV provided that the prescription container is labeled and records are maintained in accordance with the requirements of this code.

(4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written hard copy or electronic order signed by the prescribing individual practitioner, except in emergency situations. A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order.

(7) A prescription order for a controlled substance may not be dispensed unless the prescription order contains all of the information required in sub. (1). For any controlled substance prescription order, a pharmacist may not add, modify or clarify the patient's name, the controlled substance prescribed, except for generic substitution as permitted by law, and the prescribing practitioner's signature. After consultation with the prescribing practitioner, a pharmacist may add, modify or clarify the strength, dosage form, quantity prescribed, date of issuance and directions for use for a schedule II controlled substance prescription order. For a schedule II controlled substance prescription order, a pharmacist may add, modify or clarify the registration number of the practitioner, and the address of the practitioner and the patient if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation with the practitioner. A pharmacist may add, modify or clarify any information allowed in this subsection missing from a prescription order for a schedule III, IV or V controlled substance that is verifiable and retrievable from

information maintained by the pharmacist or that is obtained through consultation with a practitioner. A patient may only provide information to a pharmacist to add, modify or clarify the patient's address. The prescription order shall be initialed and dated by the pharmacist and shall indicate the addition, modification or clarification of information and the manner by which the pharmacist obtained that information.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (1), (2), (3) and (5), cr. (6), Register, August, 1991, No. 428, eff. 9-1-91; cr. (7), Register, January, 1996, No. 481, eff. 2-1-96; am. (4), Register, February, 1996, No. 482, eff. 3-1-96; am. (2), Register, December, 1998, No. 516, eff. 1-1-99; am. (1) and (7), r. (6), Register, February, 2001, No. 542, eff. 3-1-01; CR 01-154; am. (4), r. (5), Register 2002 No. 559, eff. 8-1-02; CR 13-075; am. (4) Register August 2014 No. 704, eff. 9-1-14.

Phar 8.06 Renewing prescriptions. (1) No prescription containing a schedule II substance may be renewed.

(2) The prescribing practitioner may authorize renewals of schedule III or IV controlled substances on the original prescription order or through an electronic or oral renewal authorization transmitted to the pharmacist. The following conditions must be met:

(a) The pharmacist obtaining the electronic or oral authorization shall note on the prescription order, medication profile record or readily retrievable and uniformly maintained document the following information:

1. Date authorization is received.
2. Quantity of drug authorized.
3. Number of renewals.

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

5. Identification of the pharmacist who received the authorization.

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

(3) No prescription containing a controlled substance listed in schedule III or IV may be dispensed or renewed more than 6 months after the date on which the prescription order was issued and no prescription authorized to be renewed may be renewed more than 5 times.

(4) A prescription containing a drug listed in schedule V may be renewed only as expressly authorized by the practitioner.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; renum. (2) and (3) to be (3) and (4) and am. (3), cr. (2), Register, August, 1991, No. 428, eff. 9-1-91; am. (2) (intro.) and (a) (intro.), Register, November, 1999, No. 527, eff. 12-1-99.

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 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. The remaining portion of the prescription 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.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; r. and recr. Register, August, 1991, No. 428, eff. 9-1-91; am. (3), (4) (intro.) and (a), r. (5), Register, September, 1994, No. 465, eff. 10-1-94; am. (2), Register, November, 1999, No. 527, eff. 12-1-99; CR 13-075: am. (2) Register August 2014 No. 704, eff. 9-1-14; CR 15-064: am. (2) Register September 2016 No. 729, eff. 10-1-16.

Phar 8.08 Labeling prescriptions. (1) The pharmacist dispensing a prescription containing a controlled substance shall affix to the immediate container a label showing the date of dispensing; the pharmacy name and address; serial number of the prescription; full name of the patient; name of the prescribing practitioner; directions for use; and cautionary statements, contained in the prescription order or required by law.

(2) Practitioners who personally dispense any controlled substance to patients in the course of their professional practice other than by prescribing or administering shall conform to ch. Med 17, standards for dispensing drugs.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91.

Phar 8.09 Emergency dispensing. (1) For the purpose of authorizing an oral prescription order for a schedule II controlled substance, the term “emergency” means those situations in which the prescribing practitioner determines that:

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

(b) No appropriate alternative treatment is available, including the administration of a drug which 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) In an emergency a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a practitioner if:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

(b) The prescription order is immediately reduced to writing by the pharmacist and contains all information required in s. Phar 8.05, except for the signature of the practitioner.

(3) If the practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from an authorized practitioner, which may include a call back to the prescribing practitioner using good faith efforts to insure the practitioner’s identity.

(4) Within 7 days after authorizing an emergency oral prescription order, the practitioner shall cause a written or electronic order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of s. Phar 8.05, the order shall contain on its face “authorization for emergency dispensing” and the date of the oral order. The written or electronic order may be delivered to the pharmacist in person or by mail or electronically, but if delivered by mail it shall be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the oral emergency order reduced to writing under sub. (2) (b). The pharmacist shall notify the board or department of safety and professional services if the practitioner fails to deliver the written or electronic order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written or electronic order of a practitioner.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; am. (4), Register, December, 1998, No. 516, eff. 1-1-99; am. (1) (intro.), (2) (intro.), (3) and (4), Register, November, 1999, No. 527, eff. 12-1-99; correction in (4) made under s. 13.92 (4) (b) 6., Stats., Register February 2012 No. 674; CR 13-075: am. (1) (intro.), (2) (intro.), (3), (4) Register August 2014 No. 704, eff. 9-1-14.

Phar 8.10 Disclosure of suspicious orders of controlled substances. Manufacturers and distributors of controlled substances shall disclose suspicious orders of controlled substances. Suspicious orders include, without limitation because of enumeration, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. The licensee shall notify the regional office of the DEA and the board of all suspicious orders.

History: Cr. Register, August, 1991, No. 428, eff. 9-1-91.

Phar 8.11 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.

History: Cr. Register, August, 1991, No. 428, eff. 9-1-91.

Phar 8.12 Prescription orders transmitted by facsimile machine. (1) PRESCRIPTION DRUGS OTHER THAN SCHEDULE II CONTROLLED SUBSTANCES. A pharmacist may dispense a prescription drug, other than a schedule II controlled substance, pursuant to a prescription order transmitted by a facsimile machine from the practitioner or the practitioner's agent to the dispensing pharmacy if all of the following conditions are met:

(a) The transmitted facsimile prescription order shall contain all of the information required for a valid written prescription order. The order shall also contain the time and date of the transmission, as well as the telephone number and name of the transmitter.

(b) Unless the facsimile paper is non-fading, the facsimile prescription order received shall be duplicated by copy machine or other similar device and the copy must be physically attached to the order received.

(2) SCHEDULE II CONTROLLED SUBSTANCES. A pharmacist may not dispense a schedule II controlled substance pursuant to a prescription order transmitted by a facsimile machine unless all of the conditions stated in sub. (1) are satisfied, and any of the following conditions are met:

(a) The prescription order is written for a schedule II controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(b) The prescription order is written for a schedule II controlled substance for a patient who resides in a long term care facility, or who meets the eligibility requirements for placement in a long term care facility but elects to reside at home, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(c) The prescription order is written for a schedule II controlled substance for a patient enrolled in a hospice certified by medicare under Title XVIII or licensed by this state, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(3) PRESCRIPTION ORDERS TRANSMITTED BY FACSIMILE CONSIDERED WRITTEN ORDERS. For all purposes under chs. 450 and 961, Stats., and the rules of the board, a prescription order transmitted by facsimile machine shall be considered the original written prescription order.

History: Cr. Register, December, 1998, No. 516, eff. 1-1-99; CR 09-098: am. (2) (b) Register May 2010 No. 653, eff. 6-1-10.

Phar 8.13 Identification card exception for a health care facility. In 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.

History: CR 16-018: cr. Register September 2016 No. 729, eff. 10-1-16; correction made under s. 35.17, Stats., Register September 2016 No. 729.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
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 Pharmacopeia (USP) General Chapters 795 and 797, published on November 1, 2022. The Board will also be incorporating USP General Chapter 800, published on December 1, 2019, as well as USP General Chapter 825, published on December 1, 2020.

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

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

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

Comparison with rules in adjacent states:

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

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

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

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

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

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

The rule 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)

DRAFT