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HYBRID (IN-PERSON/VIRTUAL)
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor North, Madison, WI 53705
Contact: Brad Wojciechowski (608) 266-2112
September 1, 2022

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 board 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. Administrative Rule Matters – Discussion and Consideration

1) Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians **(2-32)**
2) Phar 1, 6, 7, 8, 12, and 13, Relating to Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors **(33-75)**
3) Phar 18, Relating to Licensure of Third-Party Logistics Providers **(76-82)**
4) Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer at 608-266-2112, or the Meeting Staff at 608-266-5439.

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**	**08/19/22** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Pharmacy Examining Board Rules Committee

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
09/01/22	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Phar 1, 5, 7, 10, and 19, Relating to Registration of Pharmacy Technicians** 2. **Phar 1, 6, 7, 8, 12, and 13, Relating to Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors** 3. **Phar 18, Relating to Licensure of Third-Party Logistics Providers** 4. **Pending or Possible Rulemaking Projects**

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

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

Attachments:

1. Phar 1, 5, 6, 10, and 19 Draft Rule Text
2. 2021 WI Act 100
3. Phar 1, 6, 7, 8, 12, and 13 Draft Rule Text
4. 2007 WI Act 20 pp. 588 to 594
5. Phar 18 Draft Rule Text
6. 2021 Wisconsin Act 25

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

11) Authorization

Nilajah D. Hardin — 08/19/22

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

Supervisor (if required) — **Date**

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

Directions for including supporting documents:

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

Chapter Phar 1

AUTHORITY AND DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(13) "PRN" means renew as needed.

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

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

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

Commented [HN-D1]: From DSCSA Rule

Commented [HN-D2]: From Remote Dispensing Rule

Commented [HN-D3]: From Remote Dispensing Rule

Chapter Phar 5

LICENSE RENEWAL

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

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

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

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

Commented [HN-D4]: From Remote Dispensing Rule

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

Commented [HN-D5]: Changes from CR 21-074 (Phar 5, 6, 7, 11, and 12 Clean Up Rule)

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

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

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

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

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

(b) If renewing a pharmacist license, certify ~~Certify~~ the completion of 30 hours of continuing education during the last biennium.

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

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

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

(b) If renewing a pharmacist license, ~~Evidence~~ evidence of having passed the multi−state pharmacy jurisprudence examination with Wisconsin designated as the primary state.

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

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

a. Completion of 160 hours of internship for each year the pharmacist license was expired, not to exceed 1000 hours.

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

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

a. Completion of 1000 hours of internship.

b. Passing the NAPLEX.

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

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

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

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

Chapter Phar 7

PHARMACY PRACTICE

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

Subchapter I — General

Phar 7.01 Definitions. In this chapter:

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

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

(3) "NDC" means national drug code.

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

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

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

(a) Date of issue.

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

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

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

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

(f) Refills, if any.

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

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

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

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

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

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

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

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

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

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

6. Refills, if any.

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

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

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

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

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

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

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

(4) VERBAL PRESCRIPTION. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. The verbal prescription shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

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

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

(a) Known allergies.

(b) Rational therapy.

(c) Contraindications.

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

(e) Reasonable directions for use.

(f) Potential or actual adverse drug reactions.

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

(h) Therapeutic duplication.

(i) Reasonable utilization and optimum therapeutic outcomes.

(j) Potential abuse or misuse.

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

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

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

a. Verbal communication between two pharmacists.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Record the date of the transfer.

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

(d) For paper prescriptions and prescriptions received verbally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information shall write the word "TRANSFER" on the face of the transferred prescription and reduce to writing all information required to be on the prescription, including all of the following:

1. Date of issuance of the original prescription order.

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

3. Date of original dispensing.

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

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

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

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

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

1. The date of the original dispensing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Pharmacy name, address and telephone number.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

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

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

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

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

(c) Written or graphic product descriptions.

(d) Any cautions or other provisions.

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

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

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

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

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

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

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

(b) One of the following identifiers:

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

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

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

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

(c) Manufacturer lot number.

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

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

(f) Date of repackaging.

(g) Any pharmacy control numbers.

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

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

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

(c) Completion of the drug utilization review.

(2) For all prescription drug product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by delegate check delegate under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the delegate performing the check.

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

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

(b) Is a change in therapy.

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

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

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

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

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

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

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

(a) Name and description of the drug.

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

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

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

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

(f) Techniques for self-monitoring drug therapy.

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

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

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

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

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

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

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

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

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

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

(a) Timeliness of delivery.

(b) Condition of the prescription drug upon delivery.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The following minimum information shall be retrievable:

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

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

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

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

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

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

Phar 7.14 Delegate-check-delegate. (1) DEFINITIONS. In this section:

(a) "Delegate" means a person to whom the pharmacist has delegated the task of product verification.

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

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

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

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

(a) Is at least 18 years old.

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

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

1. Elements of correct product including all of the following:
a. Drug name.
b. Strength.
c. Formulation.
d. Expiration date.
e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
a. Wrong medication.
b. Wrong strength.
c. Wrong formulation.
d. Extra or insufficient quantity.
e. Omitted medications if utilizing unit dose or compliance packaging.
f. Expired medication.
g. Look-alike or sound-alike errors.
h. High-alert medications.
3. Eligible medications for delegate-check-delegate.
4. Organizational policies and procedures on reporting of medication errors.

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

a. Procurement.

b. Ordering.

c. Dispensing.

d. Administration.

e. Monitoring.

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

a. Wrong drug.

b. Wrong strength.

c. Wrong formulation.

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

(d) Completed the following validation process:

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

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

(e) Notwithstanding pars. (a) to (d), a delegate who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4).

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

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.

2. A drug utilization review performed by a pharmacist prior to dispensing.

3. The drug product will be administered by an individual authorized to administer medications at the institution where the medication is administered.

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

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.

2. A drug utilization review performed by a pharmacist prior to dispensing.

3. A non-pharmacist shall be able to check the accuracy of the medication by one of the following:

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

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

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

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

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

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

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

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

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate which shall be made available to the board upon request.

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

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

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

Subchapter II — Central Shared Services

Phar 7.30 Definitions. In this subchapter:

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

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

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

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

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

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

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

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

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

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

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

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 Definitions. In this subchapter:

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

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

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

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

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

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

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

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

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

(a) Stocking of the delivery system.

(b) Determining access to the delivery system.

(c) Detection and mitigation of diversion and theft.

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

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

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

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

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

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

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

(a) Stocking.

(b) Determining access.

(c) Detection and mitigation of diversion and theft.

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

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(2) LOCATION. A pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i), Stats., may dispense at any of the locations under s. ~~450.062 (1) to (4)~~450.09 (2) (b) 1. a. to d., Stats.

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

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

1. Prescriptions may be filled at this location.

2. This remote dispensing location is being supervised by a pharmacist located at all of the following:

a. Name of pharmacy.

b. Address of pharmacy.

c. Telephone of pharmacy.

3. Patient has a right to pharmacist consultation and information on how to file a complaint to the board.

(b) Remote dispensing may not occur if the supervising pharmacy is closed.

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

(d) Remote dispensing locations shall have a centrally monitored alarm. For all after hour entries, the personnel entering the location shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for a minimum of 5 years.

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

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

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

(c) Final check under s. Phar 7.07.

(d) Federal law if dispensing controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACIST ~~OR SUPERVISING PHARMACIST~~. (a) The managing pharmacist of the supervising pharmacy ~~or the supervising pharmacist~~ shall do all of the following:

1. Have written policies and procedures for system operation, safety, security, accuracy and access.

2. Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.

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

4. Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.

5. Documentation indicating accepting responsibility for compliance with this section, signed and dated by ~~both~~ the managing pharmacist ~~and supervising pharmacist, indicating the name of the supervising pharmacist, and the dates the supervision responsibilities begin and end~~.

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

(7) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i), Stats., shall meet the following requirements to remote dispense:

(a) Be 18 years of age or older.

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

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

Subchapter IV — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:

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

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

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

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

(1) First and last name of the patient.

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

(3) Date of issuance.

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

(5) Directions for use.

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

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

(b) Electronic signature of the practitioner or delegate.

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

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

(1) Drug name, strength and form.

(2) Beyond use date or expiration date.

(3) Special storage conditions, if required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Located within a licensed pharmacy.

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

(c) Validated by the following process:

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

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

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

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

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

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

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

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

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

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

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

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

4. Documentation of the dates of all software upgrades.

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

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

Subchapter V — Unlicensed Persons

Phar 7.60 Definitions. (1) "Direct supervision" means immediate availability to continually coordinate, direct and inspect in real time the practice of another.

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

Phar 7.61 Persons who have completed their second year of pharmacy school or pharmacists from another state applying for licensure. A person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats., is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.

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

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

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

(a) Provide the final check on the accuracy and correctness of drug product or device dispensing under s. Phar 7.07 (1) (a) or (b), unless the person is validated for delegate-check-delegate under s. Phar 7.14.

(b) Complete the drug utilization review under s. Phar 7.03.

(c) Administer any prescribed drug products, devices or vaccines under s. 450.035, Stats.

(d) Provide patient specific counseling or consultation.

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

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

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

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

Subchapter VI – Pharmacy Technicians

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Phar 7.60 Definitions.

Phar 7.61 Pharmacy Technicians.

Chapter Phar 10

STANDARDS OF PROFESSIONAL CONDUCT

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

Phar 10.02 Definitions. In this chapter:

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

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

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

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

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

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

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

(4) Dispensing or causing to be dispensed a drug which is outdated or contaminated or known by the pharmacist to be unsafe for consumption;

(5) Falsifying patient records;

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

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

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

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

(9) Refusing to render professional services to a person because of race, color, sex, religion, or age;

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

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

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

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

(14) Participating in rebate or fee−splitting arrangements with health practitioners or with health care facilities;

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

(16) Using secret formula or code in connection with prescription orders;

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

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

(19) Practicing without a current credential ~~license~~.

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

(21) Failure to comply with ss. 450.13 (5m) or 450.0135 (8m), Stats.

Commented [HN-D10]: From Consumer Disclosure Rule

Chapter Phar 19

REGISTRATION OF PHARMACY TECHNICIANS

Phar 19.01 Definitions.

Phar 19.02 Registration. (1) No person may engage in the practice of a pharmacy technician or use the title "pharmacy technician" or "pharmacy tech" unless the person is registered as a pharmacy technician by the Board.

(2) A person applying for a pharmacy technician registration shall satisfy all of the following:

(a) Submit a completed application form.

Note: Instructions for applications are available on the department of safety and professional services' website at http://dsps.wi.gov.

(b) Pay the fee determined by the Department under s. 440.05 (1), Stats.

(c) Subject to ss. 111.321, 111.322, and 111.335, stats., the applicant does not have an arrest or conviction record.

(d) The applicant satisfies one of the following:

1. Is at least 18 years of age and has graduated from high school or has attained high school graduation equivalency as determined by the department of public instruction.

2. Is enrolled in a youth apprenticeship program for pharmacy technicians that is on the list of youth apprenticeship programs approved by the department of workforce development under s. 106.13 (2m), Stats.

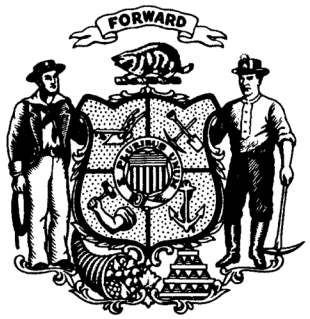
(3) Each pharmacy technician shall complete renewal of their registration every biennium as specified in chapter Phar 5.

Phar 19.03 Scope of Practice. Each pharmacy technician shall practice under their registration as determined under chapter Phar 7 subch. VI/Phar 7.14.

Phar 19.04 Change of Address or Employer. Pursuant to s. 450.068 (3), each pharmacy technician shall notify the department in writing of an address change or change of employer in writing within 10 days of the change.

Note: Instructions for providing notification of address change or change of employer are available on the department of safety and professional services' website at http://dsps.wi.gov.

State of Wisconsin



Date of enactment: **December 3, 2021**
2021 Senate Bill 300 Date of publication*: **December 4, 2021**

2021 WISCONSIN ACT 100

AN ACT ***to renumber and amend*** 450.02 (2); ***to amend*** 146.81 (1) (fm), 146.997 (1) (d) 8., 450.01 (16) (g), 450.01 (21e) (a), 450.02 (3) (f), 450.03 (1) (e), 450.03 (1) (i), 450.035 (2h), 450.035 (2i) (a) and (b), 450.035 (3), 450.035 (4), 450.062 (intro.), 450.08 (1), 450.08 (2) (b), 450.10 (1) (a) 1., 450.10 (1) (a) 2., 450.10 (1) (a) 3., 450.10 (1) (a) 6., 450.10 (1) (b) (intro.), 450.10 (1) (b) 3., 450.10 (2), 450.10 (3) (a) 1., 450.11 (1b) (bm), 450.11 (1b) (d), 450.11 (1b) (e) 2., 450.11 (3), 450.11 (7) (d), 450.11 (8) (a) and 450.17; ***to repeal and recreate*** 146.89 (1) (r) 4. and 450.08 (title); and ***to create*** 440.03 (13) (b) 48m., 440.08 (2) (a) 56m., 450.01 (15g), 450.01 (16c), 450.02 (2) (b), 450.03 (1) (gm) and 450.068 of the statutes; **relating to:** registration of pharmacy technicians, extending the time limit for emergency rule procedures, providing an exemption from emergency rule procedures, and granting rule−making authority.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 146.81 (1) (fm) of the statutes is amended to read:

146.81 **(1)** (fm) A pharmacist or pharmacy technician licensed or registered under ch. 450.

SECTION 2. 146.89 (1) (r) 4. of the statutes is repealed and recreated to read:

146.89 **(1)** (r) 4. Registered as a pharmacy technician under ch. 450.

SECTION 3. 146.997 (1) (d) 8. of the statutes is amended to read:

146.997 **(1)** (d) 8. A pharmacist or pharmacy technician licensed or registered under ch. 450.

SECTION 4. 440.03 (13) (b) 48m. of the statutes is created to read:

440.03 **(13)** (b) 48m. Pharmacy technician.

SECTION 5. 440.08 (2) (a) 56m. of the statutes is created to read:

440.08 **(2)** (a) 56m. Pharmacy technician: June 1 of each even−numbered year.

SECTION 6. 450.01 (15g) of the statutes is created to read:

450.01 **(15g)** "Pharmacy technician" means a person registered by the board under s. 450.068.

SECTION 7. 450.01 (16) (g) of the statutes is amended to read:

450.01 **(16)** (g) Supervision of pharmacy technicians and other pharmacist supportive personnel.

SECTION 8. 450.01 (16c) of the statutes is created to read:

450.01 **(16c)** "Practice of a pharmacy technician" means any of the following:

(a) The activities specified in rules promulgated by the board under s. 450.02 (2) (b).

(b) Administering vaccines or drugs as authorized under s. 450.035.

SECTION 9. 450.01 (21e) (a) of the statutes is amended to read:

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

450.01 **(21e)** (a) An action by a pharmacist or pharmacy technician with respect to a prescription drug that the pharmacist or pharmacy technician is dispensing.

Section 10. 450.02 (2) of the statutes is renumbered 450.02 (2) (intro.) and amended to read:

450.02 **(2)** (intro.) The board shall ~~adopt~~ promulgate rules ~~defining~~ to do all of the following:

(a) Define the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

Section 11. 450.02 (2) (b) of the statutes is created to read:

450.02 **(2)** (b) Define the activities that constitute the practice of a pharmacy technician for purposes of the registration requirement under s. 450.068.

Section 12. 450.02 (3) (f) of the statutes is amended to read:

450.02 **(3)** (f) Establishing procedures for identifying pharmacists and pharmacy technicians impaired by alcohol or other drugs or physical or mental disability or disease and for assisting those pharmacists and pharmacy technicians in obtaining treatment.

Section 13. 450.03 (1) (e) of the statutes is amended to read:

450.03 **(1)** (e) Any person lawfully practicing within the scope of a license, permit, registration, certificate, or certification granted to practice as a pharmacy technician under s. 450.068, to provide home medical oxygen under s. 450.076, to practice professional or practical nursing or nurse–midwifery under ch. 441, to practice dentistry or dental hygiene under ch. 447, to practice medicine and surgery under ch. 448, to practice optometry under ch. 449 or to practice veterinary medicine under ch. 89, or as otherwise provided by statute.

Section 14. 450.03 (1) (gm) of the statutes is created to read:

450.03 **(1)** (gm) A person who has applied for a registration under s. 450.068 and whose practice as a pharmacy technician is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board and during the period before which the board takes final action on the person's application.

Section 15. 450.03 (1) (i) of the statutes, as affected by 2021 Wisconsin Act 3, is amended to read:

450.03 **(1)** (i) Any person, other than a pharmacy technician, who is providing services~~, including administering vaccines or drugs as authorized under s. 450.035,~~ as directed, supervised, and inspected by a pharmacist who has the power to direct, decide, and oversee the implementation of the services rendered, subject to any rules promulgated by the board and subject to s. 450.035 (2m).

Section 16. 450.035 (2h) of the statutes, as created by 2021 Wisconsin Act 3, is amended to read:

450.035 **(2h)** (a) A ~~person engaged in the practice of pharmacy under s. 450.03 (1) (i)~~ pharmacy technician may not administer a vaccine unless all of the following are satisfied:

1. The ~~person~~ pharmacy technician has successfully completed at least 2 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education or the board, in hands–on injection technique and the recognition and treatment of emergency reactions to vaccines.

2. The ~~person~~ pharmacy technician acts under the direct supervision of a pharmacist and the supervising pharmacist has successfully completed a course of study and training specified in sub. (2) and has satisfied the requirements specified in sub. (2t).

3. The ~~person~~ pharmacy technician holds a current certification in basic life support or cardiopulmonary resuscitation.

4. The ~~person~~ pharmacy technician holds a certified pharmacy technician certification from either the Pharmacy Technician Certification Board, or its successor organization, or the National Healthcareer Association, or its successor organization.

(b) A ~~person engaged in the practice of pharmacy under s. 450.03 (1) (i)~~ pharmacy technician may not administer a vaccine under this subsection to a person who is under the age of 6.

Section 17. 450.035 (2i) (a) and (b) of the statutes, as affected by 2021 Wisconsin Act 3, are amended to read:

450.035 **(2i)** (a) Subject to subs. (2), (2g), and (2h), a pharmacist, a pharmacy technician, or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (fm), or (g)~~, or (i)~~ may administer without a prescription order any vaccine listed in the current immunization schedules recommended by the federal advisory committee on immunization practices and published by the federal centers for disease control and prevention.

(b) Subject to subs. (2), (2g), and (2h), a pharmacist, a pharmacy technician, or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (fm), or (g)~~, or (i)~~ may initiate and administer any vaccine not listed in the current immunization schedules recommended by the federal advisory committee on immunization practices and published by the federal centers for disease control and prevention if the vaccine is administered pursuant to a prescription order, vaccination protocol, or standing order.

Section 18. 450.035 (3) of the statutes, as affected by 2021 Wisconsin Act 3, is amended to read:

450.035 **(3)** A pharmacist, a pharmacy technician, or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (fm), or (g)~~, or (i)~~ who successfully completes a course of study and training specified in sub. (1r), (1t), (2), (2g), or (2h), or holds a certification under sub. (2h), shall maintain proof of completion or holding the

certification and, upon request, provide copies of such proof to the department or the board.

Section 19. 450.035 (4) of the statutes, as affected by 2021 Wisconsin Act 3, is amended to read:

450.035 **(4)** A pharmacist, pharmacy technician, or person engaged in the practice of pharmacy under s. 450.03 (1) (f), (fm), or (g), ~~or (i)~~ who administers a vaccine to a person under this section shall update, or cause a pharmacy to update, the Wisconsin Immunization Registry established by the department of health services within 7 days of administering the vaccine.

Section 20. 450.062 (intro.) of the statutes is amended to read:

450.062 Remote dispensing. (intro.) Pursuant to rules promulgated by the board, a pharmacist, a pharmacy technician, or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i) may dispense at any of the following locations:

Section 21. 450.068 of the statutes is created to read:

450.068 Pharmacy technicians; registration. (1) No person may engage in the practice of a pharmacy technician or use the title "pharmacy technician" or "pharmacy tech" unless the person is registered as a pharmacy technician by the board.

(2) Except as provided in s. 450.10, the board shall issue a registration as a pharmacy technician to an applicant who satisfies all of the following:

(a) The applicant submits an application for registration on a form provided by the board that specifies all of the following:

1. The applicant's home address.

2. If the applicant is employed, the name and address of the applicant's employer, and the applicant's place of employment.

(b) The applicant satisfies one of the following:

1. The applicant is at least 18 years of age and has graduated from high school or has attained high school graduation equivalency as determined by the department of public instruction.

2. The applicant is enrolled in a youth apprenticeship program for pharmacy technicians that is on the list of youth apprenticeship programs approved by the department of workforce development under s. 106.13 (2m).

(d) The applicant pays the fee specified in s. 440.05 (1).

(3) A pharmacy technician shall do all of the following:

(a) Notwithstanding s. 440.11, if the pharmacy technician moves from the last address provided to the department, notify the department of his or her new address within 10 days of the change in writing or in accordance with other notification procedures approved by the department.

(b) If the pharmacy technician changes his or her employer or place of employment, notify the department of his or her new employer or address of employment within 10 days of the change in writing or in accordance with other notification procedures approved by the department and, if required by the department, pay the transfer fee under s. 440.05 (7).

Section 22. 450.08 (title) of the statutes is repealed and recreated to read:

450.08 (title) **Credential renewals.**

Section 23. 450.08 (1) of the statutes is amended to read:

450.08 **(1)** The renewal ~~date~~ dates for all licenses and registrations granted by the board ~~is~~ are specified under s. 440.08 (2) (a). Except as provided under sub. (2) (a), only a holder of an unexpired license or registration may engage in his or her licensed activity.

Section 24. 450.08 (2) (b) of the statutes is amended to read:

450.08 **(2)** (b) A pharmacy, pharmacy technician's, manufacturer's, distributor's, or home medical oxygen provider's license or registration may be renewed by paying the applicable fee determined by the department under s. 440.03 (9) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a).

Section 25. 450.10 (1) (a) 1. of the statutes is amended to read:

450.10 **(1)** (a) 1. Making any materially false statement or giving any materially false information in connection with an application for a license or registration or for renewal or reinstatement of a license or registration.

Section 26. 450.10 (1) (a) 2. of the statutes is amended to read:

450.10 **(1)** (a) 2. Violating this chapter or, subject to s. 961.38 (4r), ch. 961 or any federal or state statute or rule which substantially relates to the practice of the licensee or registrant.

Section 27. 450.10 (1) (a) 3. of the statutes is amended to read:

450.10 **(1)** (a) 3. ~~Practicing~~ Engaging in the practice of pharmacy or practicing as a pharmacy technician while the person's ability to practice is impaired by alcohol or other drugs or physical or mental disability or disease.

Section 28. 450.10 (1) (a) 6. of the statutes is amended to read:

450.10 **(1)** (a) 6. Engaging in conduct in the practice of the licensee or registrant ~~which~~ that evidences a lack of knowledge or ability to apply professional principles or skills.

Section 29. 450.10 (1) (b) (intro.) of the statutes is amended to read:

450.10 **(1)** (b) (intro.) Subject to subch. II of ch. 111 and the rules adopted under s. 440.03 (1), the board may reprimand the licensee or registrant or deny, revoke, suspend, or limit the license or registration or any combination thereof of any person licensed under this chapter who has:

Section 30. 450.10 (1) (b) 3. of the statutes is amended to read:

450.10 **(1)** (b) 3. Been found guilty of an offense the circumstances of which substantially relate to the practice of the licensee or registrant.

Section 31. 450.10 (2) of the statutes is amended to read:

450.10 **(2)** In addition to or in lieu of a reprimand or denial, limitation, suspension, or revocation of a license or registration under sub. (1), the board may, for the violations enumerated under sub. (1), assess a forfeiture of not more than $1,000 for each separate offense. Each day of violation constitutes a separate offense.

Section 32. 450.10 (3) (a) 1. of the statutes is amended to read:

450.10 **(3)** (a) 1. A pharmacist or pharmacy technician licensed or registered under this chapter.

Section 33. 450.11 (1b) (bm) of the statutes is amended to read:

450.11 **(1b)** (bm) A pharmacist, pharmacy technician, or other person dispensing or delivering a drug shall legibly record the name on each identification card presented under par. (b) to the pharmacist, pharmacy technician, or other person, and the name of each person to whom a drug is dispensed or delivered subject to par. (e) 2., and shall maintain that record for a time established by the board by rule or, for a record that is subject to s. 961.385, until the name is delivered to the controlled substances board under s. 961.385, whichever is sooner.

Section 34. 450.11 (1b) (d) of the statutes is amended to read:

450.11 **(1b)** (d) A pharmacist or pharmacy technician is immune from any civil or criminal liability and from discipline under s. 450.10 for any act taken by the pharmacist or pharmacy technician in reliance on an identification card that the pharmacist reasonably believed was authentic and displayed the name of the person to whom the drug was being delivered if the sale was made in good faith.

Section 35. 450.11 (1b) (e) 2. of the statutes is amended to read:

450.11 **(1b)** (e) 2. The pharmacist, pharmacy technician, 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.

Section 36. 450.11 (3) of the statutes is amended to read:

450.11 **(3)** Preparation of prescription drugs. Except as provided in sub. (1i) (b) and ss. 118.2925 (4), 255.07 (3), and 450.076, no person other than a pharmacist or practitioner or their agents and employees as directed, supervised, and inspected by the pharmacist or practitioner, including pharmacy technicians, may prepare, compound, dispense, or prepare for delivery for a patient any prescription drug.

Section 37. 450.11 (7) (d) of the statutes is amended to read:

450.11 **(7)** (d) No person may, for the purpose of obtaining a prescription drug, falsely assume the title of, or represent himself or herself to be, a manufacturer, distributor, pharmacist, pharmacy technician, or practitioner.

Section 38. 450.11 (8) (a) of the statutes is amended to read:

450.11 **(8)** (a) The board, insofar as this section applies to pharmacists and pharmacy technicians.

Section 39. 450.17 of the statutes is amended to read:

450.17 Violations. Each member of the board shall investigate and institute actions for violations of this chapter by any person and for violation of ch. 961 by pharmacists or pharmacy technicians. The district attorney of the proper county shall promptly prosecute any such violation upon notice from any source.

Section 40. Nonstatutory provisions.

(1) The pharmacy examining board may promulgate emergency rules under s. 227.24 necessary to implement this act. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until May 1, 2024, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the examining board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

Section 41. Effective dates. This act takes effect on the first day of the 13th month beginning after publication or on May 31, 2022, whichever is later, except as follows:

(1) Section 40 (1) of this act takes effect on the day after publication.

Chapter Phar 1

AUTHORITY AND DEFINITIONS

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

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

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

(1c) "Affiliated group" has the meaning given in s. 450.01 (1p), Stats./21 USC 1504

(1g) "Authenticate" has the meaning given in s. 450.01 (1t), Stats.

(1n) "Authorized distributor of record" has the meaning given in s. 450.01 (1x), Stats.

(1r) ~~**(1)**~~ "Board" means the pharmacy examining board.

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

(1w) "Colicensed" has the meaning given in s. 450.01 (2m), Stats.

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

(2m) "Drop shipment" has the meaning given in s. 450.01 (9m), Stats.

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

(3e) "Electronic Database"

(3m) "Facility" has the meaning given in s. 450.01 (11m), Stats.

(3s) "Intracompany sales" has the meaning given in s. 450.01 (11r), Stats.

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

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

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

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

Phar 7.01 (2) "Managing pharmacist" means a pharmacist who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, and who is personally in full and actual charge of the pharmacy and personnel.

(6g) "Manufacturer" has the meaning given in s. 450.01 (12), Stats.

(6r) "Manufacturer's exclusive distributor" has the meaning given in s. 450.01 (12m), Stats.

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

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

(7g) "Normal distribution channel" has the meaning given in s. 450.01 (13r) (a), Stats.

(7r) "Pedigree" has the meaning given in s. 450.01 (14m), Stats.

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

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

Commented [HN-D1]: From Remote Dispensing Rule

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

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

(11m) "Pharmacy warehouse" has the meaning given in s. 450.01 (15m), Stats.

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

(13) "PRN" means renew as needed.

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

(14b) "Quarantine" means the storage of a drug in a physically separate area to prevent distribution.

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

Commented [HN-D2]: From Remote Dispensing Rule

(14n) "Repackage" has the meaning given in s. 450.01 (21e), Stats.

(14p) "Repackager" means a person that repackages.

(14r) "Standardized numerical identifier" means a set of numbers or characters used to uniquely identify each prescription drug that is composed of the National Drug Code for that drug and a unique serial number.

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

(16) "Third party logistics provider" has the meaning given in s. 450.01 (21s), Stats.

(17) "Transaction" means the transfer of a prescription drug between entities during which a change of ownership occurs.

(18) "Transaction History" means a paper or electronic statement that includes the information for each transaction going back to the drug manufacturer.

(19) "Transaction Information" means the features used to identify a transaction.

(20) "Wholesale distribution" has the meaning given in s. 450.01 (23), Stats.

(21) "Wholesale distributor" has the meaning given in s. 450.01 (24), Stats.

Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

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

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

Note: Instructions for ~~Applications~~ applications are available ~~upon request to the board office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708~~ on the Department of Safety and Professional Service's website: http://dsps.wi.gov.

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

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

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

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

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

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

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

Commented [HN-D3]: Changes from CR 21-074 (Phar 5, 6, 7, 11, and 12 Clean Up Rule)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Chapter Phar 7

PHARMACY PRACTICE

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

Subchapter I — General

Phar 7.01 **Definitions.** In this chapter:

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

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

(3) "NDC" means national drug code.

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

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

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

(a) Date of issue.

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

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

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

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

(f) Refills, if any.

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

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

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

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

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

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

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

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

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

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

6. Refills, if any.

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

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

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

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

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

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

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

(4) VERBAL PRESCRIPTION. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. The verbal prescription shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

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

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

(a) Known allergies.

(b) Rational therapy.

(c) Contraindications.

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

(e) Reasonable directions for use.

(f) Potential or actual adverse drug reactions.

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

(h) Therapeutic duplication.

(i) Reasonable utilization and optimum therapeutic outcomes.

(j) Potential abuse or misuse.

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

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

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

a. Verbal communication between two pharmacists.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Commented [HN-D4]: Changes from CR 21-074 (Phar 5, 6, 7, 11, and 12 Clean Up Rule)

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

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

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

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

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

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

3. Record the date of the transfer.

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

(d) For paper prescriptions and prescriptions received verbally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information shall write the word "TRANSFER" on the face of the transferred prescription and reduce to writing all information required to be on the prescription, including all of the following:

1. Date of issuance of the original prescription order.

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

3. Date of original dispensing.

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

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

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

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

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

1. The date of the original dispensing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Pharmacy name, address and telephone number.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

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

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

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

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

(c) Written or graphic product descriptions.

(d) Any cautions or other provisions.

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

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

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

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

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

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

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

(b) One of the following identifiers:

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

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

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

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

(c) Manufacturer lot number.

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

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

(f) Date of repackaging.

(g) Any pharmacy control numbers.

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

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

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

(c) Completion of the drug utilization review.

(2) For all prescription drug product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by delegate check delegate under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the delegate performing the check.

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

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

(b) Is a change in therapy.

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

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

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

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

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

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

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

(a) Name and description of the drug.

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

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

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

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

(f) Techniques for self-monitoring drug therapy.

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

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

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

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

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

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

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

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

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

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

(a) Timeliness of delivery.

(b) Condition of the prescription drug upon delivery.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The following minimum information shall be retrievable:

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

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

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

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

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

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

Phar 7.14 **Delegate-check-delegate. (1)** DEFINITIONS. In this section:

(a) "Delegate" means a person to whom the pharmacist has delegated the task of product verification.

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

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

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

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

(a) Is at least 18 years old.

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

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

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

a. Drug name.

b. Strength.

c. Formulation.

d. Expiration date.

e. Beyond use date.

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

a. Wrong medication.

b. Wrong strength.

c. Wrong formulation.

d. Extra or insufficient quantity.

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

f. Expired medication.

g. Look-alike or sound-alike errors.

h. High-alert medications.

3. Eligible medications for delegate-check-delegate.

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

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

a. Procurement.

b. Ordering.

c. Dispensing.

d. Administration.

e. Monitoring.

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

a. Wrong drug.

b. Wrong strength.

c. Wrong formulation.

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

(d) Completed the following validation process:

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

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

(e) Notwithstanding pars. (a) to (d), a delegate who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4).

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

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.

2. A drug utilization review performed by a pharmacist prior to dispensing.

3. The drug product will be administered by an individual authorized to administer medications at the institution where the medication is administered.

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

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.

2. A drug utilization review performed by a pharmacist prior to dispensing.

3. A non-pharmacist shall be able to check the accuracy of the medication by one of the following:

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

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

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

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

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

1. Name of the product verification delegate.

2. Total number of product verifications performed.

3. Number of product verifications audited by the pharmacist.

4. Percentage of product verifications audited by pharmacist.

5. Percentage of accuracy.

6. Number of product verification errors identified.

7. Type of error under sub. (2) (c) 2. a. to c. and e.

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

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

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate which shall be made available to the board upon request.

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

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

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

indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.

3. Quality assurance audits and quarterly assessments.

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

Subchapter II — Central Shared Services

Phar 7.30 **Definitions.** In this subchapter:

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

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

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

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

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

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

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

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

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

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

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

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 **Definitions.** In this subchapter:

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

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

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

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

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

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

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

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

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

(a) Stocking of the delivery system.

(b) Determining access to the delivery system.

(c) Detection and mitigation of diversion and theft.

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

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

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

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

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

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

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

(a) Stocking.

(b) Determining access.

(c) Detection and mitigation of diversion and theft.

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

(2) LOCATION. A pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i), Stats., may dispense at any of the locations under s. ~~450.062 (1) to (4)~~450.09 (2) (b) 1. a. to d., Stats.

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

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

1. Prescriptions may be filled at this location.

2. This remote dispensing location is being supervised by a pharmacist located at all of the following:

a. Name of pharmacy.

b. Address of pharmacy.

c. Telephone of pharmacy.

3. Patient has a right to pharmacist consultation and information on how to file a complaint to the board.

(b) Remote dispensing may not occur if the supervising pharmacy is closed.

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

(d) Remote dispensing locations shall have a centrally monitored alarm. For all after hour entries, the personnel entering the location shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for a minimum of 5 years.

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

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

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

(c) Final check under s. Phar 7.07.

(d) Federal law if dispensing controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACIST~~ OR SUPERVISING PHARMACIST~~. (a) The managing pharmacist of the supervising pharmacy ~~or the supervising pharmacist~~ shall do all of the following:

1. Have written policies and procedures for system operation, safety, security, accuracy and access.

2. Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.

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

4. Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.

5. Documentation indicating accepting responsibility for compliance with this section, signed and dated by ~~both~~ the managing pharmacist ~~and supervising pharmacist, indicating the name of the supervising pharmacist, and the dates the supervision responsibilities begin and end~~.

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

(7) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i), Stats., shall meet the following requirements to remote dispense:

(a) Be 18 years of age or older.

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

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

Subchapter IV — Institutional Pharmacies

Phar 7.50 **Definitions.** In this subchapter:

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

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

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

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

(1) First and last name of the patient.

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

(3) Date of issuance.

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

(5) Directions for use.

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

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

(b) Electronic signature of the practitioner or delegate.

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

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

(1) Drug name, strength and form.

(2) Beyond use date or expiration date.

(3) Special storage conditions, if required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Located within a licensed pharmacy.

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

(c) Validated by the following process:

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

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

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

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

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

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

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

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

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

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

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

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

4. Documentation of the dates of all software upgrades.

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

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

Subchapter V — Unlicensed Persons

Phar 7.60 **Definitions. (1)** "Direct supervision" means immediate availability to continually coordinate, direct and inspect in real time the practice of another.

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

Phar 7.61 **Persons who have completed their second year of pharmacy school or pharmacists from another state applying for licensure.** A person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats., is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.

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

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

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

(a) Provide the final check on the accuracy and correctness of drug product or device dispensing under s. Phar 7.07 (1) (a) or (b), unless the person is validated for delegate-check-delegate under s. Phar 7.14.

(b) Complete the drug utilization review under s. Phar 7.03.

(c) Administer any prescribed drug products, devices or vaccines under s. 450.035, Stats.

(d) Provide patient specific counseling or consultation.

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

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

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

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

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

(EFFECTIVE 09/01/22)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) If the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency oral prescription order, and the pharmacist makes a notation of the quantity

supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order.

(b) If the patient requests partial dispensing.

(c) If the prescribing practitioner requests partial dispensing.

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

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

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

(a) Display or printout of: the original prescription order designation; date of issue; identification of prescribing practitioner; identification of patient; name and address of the LTCF or name and address of the hospital or residence of the patient; identification of medication authorized, including dosage form, strength and quantity; listing of partial

quantities that have been dispensed under each prescription order and the information required in sub. (3).

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

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

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

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

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

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

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

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

Chapter Phar 12

MANUFACTURER REQUIREMENTS

Phar 12.01 **Authority.** The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a) and 450.07 (4), Stats.

Phar 12.02 **Definitions.** In this chapter:

(1) "Device" has the meaning set forth in s. 450.01 (6), Stats.

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

(3) "Establishment" means a place of business under one management at one general physical location.

~~**(4)** "Manufacturer" means a person licensed by the board under this chapter.~~

(5) "Manufacturing" has the meaning set forth in s. 450.01 (13), Stats.

(6) "Prescription drug" has the meaning set forth in s. 450.01 (20), Stats.

Phar 12.03 **License; application.** **(1)** No person may engage in the manufacturing of any drug or device in this state unless a license is granted to the person by the board under this chapter.

(2) To obtain a license a person shall do all of the following:

(a) Submit an application on a form provided by the board.

(b) Pay the fee specified in s. ~~440.05 (1)~~ 440.03 (9) (a), Stats.

(c) Meet the inspection requirement under s. Phar 12.04.

(d) Register with the food and drug administration and comply with all applicable requirements of 21 CFR 200, 201, 202, 207, 210 and 211.

(e) If applicable, register with the drug enforcement administration and comply with all appropriate requirements of 21 CFR 1301, 1302, 1303, 1304, 1305, 1307, 1311 and 1312.

Note: Instructions for ~~An application form~~applications can ~~may~~ be ~~obtained from~~dfound ~~on the board office, 1400 East Washington Avenue, Madison, Wisconsin 53702~~ Department of Safety and Professional Services's website: http://dsps.wi.gov. Copies of federal applications, laws and regulations may be obtained from the Food and Drug Administration, 5600 Fischers Lane, Rockville, Maryland 20857 and the Drug Enforcement Administration, 500 Dirksen Federal Building, 219 Dearborn, Chicago, Illinois 60604.

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(3) A manufacturer license may not be transferred from one establishment to another nor from one person to another. Each establishment requires a separate license.

(4) If the license is denied, the applicant may request a hearing before the board on the denial.

(5) The board shall act on the application for a license within 60 business days after receiving the completed application, as provided in s. SPS 4.03.

Phar 12.04 **Inspections.** Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985).

Phar 12.05 **Compliance.** Failure to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

Phar 12.06 **Authorized distributors of record.** A manufacturer shall maintain and update at least once per month a list of the manufacturer's authorized distributors of record.

Chapter Phar 13

WHOLESALE DISTRIBUTOR REQUIREMENTS

Phar 13.01 **Authority.** The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 450.02 (3) (a) and 450.07 (4), Stats.

Phar 13.02 **Definitions.** In this chapter:

(1) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(2) "Blood component" means that part of blood separated by physical or mechanical means.

(3) "Controlled substance" has the meaning set forth in s. 961.01 (4), Stats.

(3m) "Department" means the department of safety and professional services.

(4) "Device" has the meaning set forth in s. 450.01 (6), Stats.

(5) "Distribute" has the meaning set forth in s. 450.01 (8), Stats.

(7) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

~~**(8)** "Facility" means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.~~

~~**(9)** "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidance implementing the federal prescription drug marketing act.~~

(10) "Prescription drug" has the meaning set forth in s. 450.01 (20), Stats.

(11) "Wholesale distribution" means distribution of a prescription drug to a person other than a consumer or patient, but does not include any of the following:

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(a) Intracompany sales of prescription drugs which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under common ownership or control of a corporate entity or any transaction between co-licensees or a co-licensed product.

(b) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples, if the distribution is permitted under 21 CFR 353 (d).

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution as provided in 21 CFR 203.23.

(e) Distributions to a practitioner for the purpose of general dispensing by the practitioner to his or her patients if all of the following apply:

1. The total number of dosage units of all prescription drugs distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all prescription drugs distributed and dispensed by the pharmacy during the same calendar year.

2. The total number of dosage units of all controlled substances distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of

the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the same calendar year.

(f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer states in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the drug and the supplying authorized distributor of record states in writing that the drug has previously been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the drug.

(j) A transaction excluded from the definition of "wholesale distribution" under 21 CFR 203.3 (cc).

(k) The donation or distribution of a prescription drug under s. 255.056, Stats.

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale distributor or to a 3rd-party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

(12) "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; manufacturers' authorized distributors of record; prescription drug wholesalers and distributors; independent wholesale prescription drug traders; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

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Phar 13.05 **License; other requirements.** In addition to providing the application information, to obtain a license a person shall:

(1) Pay the fee specified in s. ~~440.05 (1)~~ 440.03 (9) (a), Stats.

(2) Pass an inspection of the facility conducted by the board or its representative in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each inspection to determine if the location meets standards specified in ss. Phar 13.08 to 13.11.

(3) Register with the drug enforcement administration, if intending to distribute controlled substances.

Note: Instructions for applications may be obtained from the Department of Safety and Professional Service's website: http://dsps.wi.gov. Copies of federal applications may be obtained from the Drug Enforcement Administration, Suite 500, Dirksen Federal Building, 219 South Dearborn Street, Chicago, Illinois 60604. Copies of federal statutes and rules may be obtained from the Superintendent of Documents, Government Printing Office, Washington DC 20402-9325.

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Phar 13.055 **Surety bond, irrevocable letter of credit.** The applicant shall supply a surety bond or irrevocable letter of credit in the amount of $5,000.00, which is issued by a company authorized to do business in Wisconsin. The form of the bond or letter of credit shall be approved by the department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a wholesale distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this section more than one year after the date on which the applicant's wholesale distributor's license expires.

Phar 13.06 **License; factors considered.** In determining eligibility for a distributor's license, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under federal, state, or local laws, the circumstances of which are substantially related to the practice of a wholesale distributor;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or wholesale distribution;

(5) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any devices or drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with the requirements to maintain or make available to a state licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug or device distributors; and

(8) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

Phar 13.07 **Application review.** The board shall act upon an application for a license within 60 business days after receiving the completed application, as provided in s. SPS 4.03. If the license is denied, the applicant may request a hearing pursuant to ch. SPS 1.

Phar 13.08 **Personnel.** A wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

Phar 13.09 **Facility requirements.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

Phar 13.10 **Security requirements.** All facilities shall require that:

(1) Access from outside the premises is kept to a minimum and be well controlled;

(2) The outside perimeter of the premises is well lighted;

(3) Entry into areas where prescription drugs are held is limited to authorized personnel;

(4) An alarm system is maintained to detect entry after hours; and

(5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Phar 13.11 **Storage requirements.** **(1)** All prescription drugs stored in a facility shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such products, or with requirements in the current edition of an official compendium.

(2) If no storage requirements are established for a prescription drug, the product may be held at a controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, or logs shall be utilized to document proper storage of prescription drugs.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all stored drugs.

Phar 13.12 **Examination of materials requirements.** **(1)** Upon receipt by a facility, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs, or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment from a facility shall be carefully inspected for identity of the prescription drug and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in s. Phar 13.14 shall be followed for all incoming and outgoing prescription drugs at a facility.

Phar 13.13 **Returned, damaged and outdated prescription drug requirements.** **(1)** Notwithstanding the pedigree requirements in Phar 13.135, Prescription drugs in a facility that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. Wholesale distributors shall only return such prescription drugs to supplier that are either the original manufacturer of the products or to a 3rd party returns processor.

Commented [HN-D11]: Section 3530g of 2007 WI Act 20 (p. 592)

(2) Any prescription drugs in a facility whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned to a facility cast doubt on the product's safety, identity, strength, quality, or purity, then the product shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the product meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a product has been returned cast doubt on its safety, identity,

strength, quality, or purity, the distributor shall consider, among other things, the conditions under which the product has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(5) A wholesale distributor shall only receive drug returns or exchanges from a pharmacy, a pharmacist, or a pharmacy's intracompany warehouse.

(6) A manufacturer, wholesale distributor, pharmacy, or pharmacist shall ensure that the return process is secure from adulterated or counterfeit substances.

Commented [HN-D12]: Section 3530g of 2007 WI Act 20 (p. 592)

Phar 13.135 **Pedigree requirements**. (1) A wholesale distributor shall establish and maintain a pedigree for each prescription drug that that leaves the normal distribution channel.

(2) A wholesale distributor shall provide a copy of the pedigree to the entity receiving the drug before that prescription drug leaves the normal distribution channel.

(3) A prescription drug pedigree shall include all of the following:

(a) The name, address, phone number, and electronic mail address, if applicable, of each recipient or wholesale distributor in the distribution chain until the final sale or wholesale distribution of the prescription drug as described in s. 450.073 (2) (intro.), stats.

(b) The date of each distribution

(c) A certification that each recipient has verified the pedigree for the prescription drug before sending it to the next point in the distribution chain

(d) The name, dosage strength, lot number, quantity, and name of each prescription drug.

(4) An electronic track and trace pedigree system is required to monitor each prescription drug that is subject to wholesale distribution, and shall include all of the following:

(a) The transaction history

(b) The transaction information

(c) The pedigree

(5) A secure electronic database may be established by the wholesale distributor to store the information required under sub.(4). This database may be developed and operated by an entity other than the wholesale distributor. The owner of the database shall have the ability to respond to data access requests and provide data access to other members of the pharmaceutical supply chain.

(5) A wholesale distributor shall verify that each transaction on the pedigree for a prescription drug has occurred prior to proceeding with distribution.

(6) Each pedigree shall be maintained by the entity who purchased and the wholesale distributor of each prescription drug for a minimum of 3 years from the date of distribution.

(7) Exceptions

Phar 13.14 **Recordkeeping requirements. (1)** A wholesale distributor shall establish and maintain inventories and records of all transactions regarding the receipt and wholesale distribution or other disposition of prescription drugs. These records shall include the following information:

(a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped:

(b) The identity and quantity of the drugs received and distributed or disposed of; and

(c) The dates of receipt and wholesale distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and copying by the board, its authorized representatives, and authorized representatives of federal, state and local law enforcement agencies for a period of 3 years following wholesale distribution or other disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by the board or its authorized representative.

Phar 13.15 **Written policies and procedures.** A wholesale distributor shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. A wholesale distributor shall include in their written policies and procedures the following:

(1) A procedure to ensure that the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other governmental agency, including the board;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(c) Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that a wholesale distributor prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs are segregated from other products and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 3 years after disposition of the outdated drugs.

Phar 13.16 **Responsible persons.** A wholesale distributor shall establish and maintain lists of officers, directors, managers, and the designated representative in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Phar 13.17 **Compliance with federal, state and local laws. (1)** A wholesale distributor shall operate in compliance with applicable federal, state, and local laws and regulations. ~~A distributor shall operate in compliance with any applicable federal electronic track and trace pedigree system implemented after July 1, 2011, unless an earlier implementation date is mandated by federal law which explicitly preempts state law.~~ A wholesale distributor that deals in controlled substances shall register with the drug enforcement administration.

(2) Failure to comply with applicable federal, state, and local laws and regulations constitutes unprofessional conduct for purposes of s. 450.10, Stats.

(3) A wholesale distributor shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records, prescription drug pedigrees, and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to a wholesale distributor's premises and delivery vehicles.

447.05 Expiration and renewal. Renewal applications shall be submitted to the department on a form provided by the department on or before the applicable renewal date specified under s. 440.08 (2) (a) and shall include the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a). The examining board may not renew a license to practice dental hygiene unless the applicant for renewal attests that he or she has complied with s. 447.055 and any rules promulgated by the department under s. 447.055 and that he or she has a current certification in cardiopulmonary resuscitation.

SECTION 3519. 448.07 (2) of the statutes is amended to read:

448.07 **(2)** FEES. The fees for examination and licenses granted ~~or renewed~~ under this subchapter are specified in ~~ss.~~ s. 440.05, and ~~440.08~~ the renewal fee for such licenses is determined by the department under s. 440.03 (9) (a).

SECTION 3520. 448.55 (2) of the statutes is amended to read:

448.55 **(2)** The renewal dates for licenses granted under this subchapter, other than temporary licenses granted under rules promulgated under s. 448.53 (2), are specified under s. 440.08 (2) (a). Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) and proof of compliance with the requirements established in any rules promulgated under sub. (3).

SECTION 3521. 448.65 (2) (a) of the statutes is amended to read:

448.65 **(2)** (a) The renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under 440.03 (9) (a).

SECTION 3522. 448.86 (2) of the statutes is amended to read:

448.86 **(2)** The renewal dates for certificates granted under this subchapter, other than temporary certificates granted under s. 448.80, are specified under s. 440.08 (2) (a). Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a).

SECTION 3523. 448.955 (2) (intro.) of the statutes is amended to read:

448.955 **(2)** (intro.) Renewal applications shall be submitted to the department on a form provided, subject to sub. (3), by the department and shall include the renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) and evidence satisfactory to the affiliated credentialing board that the licensee has all of the following:

SECTION 3524. 448.967 (2) of the statutes is amended to read:

448.967 **(2)** The renewal dates for licenses granted under this subchapter are specified under s. 440.08 (2) (a). Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) and a statement attesting compliance with the continuing education requirements established in rules promulgated under s. 448.965 (1) (b).

SECTION 3525. 449.06 (1) of the statutes is amended to read:

449.06 **(1)** Persons practicing optometry shall, on or before the applicable renewal date specified under s. 440.08 (2) (a), register with the department, pay the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a), and provide evidence satisfactory to the examining board that he or she has complied with the rules promulgated under sub. (2m).

SECTION 3526. 449.17 (8) of the statutes is amended to read:

449.17 **(8)** REIMBURSEMENT PROHIBITED. No optometrist may be reimbursed under s. 49.46 (2) (a) 3. or 49.471 (11) for any increase in charges or separate charge which is attributable to the use of topical ocular diagnostic pharmaceutical agents.

SECTION 3526a. 450.01 (1p) of the statutes is created to read:

450.01 **(1p)** "Affiliated group" has the meaning given in section 1504 of the Internal Revenue Code.

SECTION 3526b. 450.01 (1t) of the statutes is created to read:

450.01 **(1t)** "Authenticate" means to affirmatively verify, before wholesale distribution of a prescription drug occurs, that each transaction listed on a pedigree has occurred.

SECTION 3526c. 450.01 (1x) of the statutes is created to read:

450.01 **(1x)** "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. For purposes of this subsection, an ongoing relationship exists between a wholesale distributor and a manufacturer if all of the following apply:

(a) The wholesale distributor, including any affiliated group of the wholesale distributor, has in effect a written agreement with the manufacturer evidencing the ongoing relationship.

(b) The wholesale distributor, including any affiliated group of the wholesale distributor, is included in the manufacturer's current list of authorized distributors of record.

SECTION 3526d. 450.01 (2m) of the statutes is created to read:

450.01 **(2m)** "Colicensed" means, with respect to a partner or product, that 2 or more parties have the right to engage in marketing or manufacturing of a product consistent with the federal food and drug administration's implementation of the federal prescription drug marketing act.

Section 3526e. 450.01 (9m) of the statutes is created to read:

450.01 **(9m)** "Drop shipment" means a sale of a prescription drug to a wholesale distributor by the manufacturer of the drug, by the manufacturer's colicensed product partner, by the manufacturer's 3rd party logistics provider, or by the manufacturer's exclusive distributor, to which all of the following apply:

(a) The wholesale distributor or chain pharmacy warehouse takes title to, but not physical possession of, the drug.

(b) The wholesale distributor invoices a pharmacy, a chain pharmacy warehouse, or a person authorized to dispense or administer the drug to a patient.

(c) The pharmacy, chain pharmacy warehouse, or person authorized to dispense or administer the drug receives delivery of the drug directly from the manufacturer, the manufacturer's 3rd party logistics provider, or the manufacturer's exclusive distributor.

Section 3526f. 450.01 (11m) of the statutes is created to read:

450.01 **(11m)** "Facility" means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.

Section 3526g. 450.01 (11r) of the statutes is created to read:

450.01 **(11r)** "Intracompany sales" means any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity or any transaction or transfer between colicensees of a colicensed product.

Section 3526h. 450.01 (12) of the statutes is amended to read:

450.01 **(12)** "Manufacturer" means a person licensed ~~by the board under s. 450.07 (1)~~ or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidances implementing the federal prescription drug marketing act.

Section 3526i. 450.01 (12m) of the statutes is created to read:

450.01 **(12m)** "Manufacturer's exclusive distributor" means a person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer and who takes title to the manufacturer's prescription drug but who does not have general responsibility to direct the sale or disposition of the drug.

Section 3526j. 450.01 (13r) of the statutes is created to read:

450.01 **(13r)** (a) "Normal distribution channel" means a chain of custody for a prescription drug that runs, directly or by drop shipment, from the manufacturer of a drug, from the manufacturer to the manufacturer's colicensed partner, from the manufacturer to the manufacturer's 3rd−party logistics provider, or from the manufacturer to the manufacturer's exclusive distributor, and continues as described in any of the following:

1. To a pharmacy or to a person authorized to dispense or administer a drug to a patient.

2. To an authorized distributor of record, and then to a pharmacy or to a person authorized to dispense or administer a drug to a patient.

3. To an authorized distributor of record, then to one other authorized distributor of record, then to an office−based practitioner.

4. To a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

5. To an authorized distributor of record, then to a pharmacy warehouse, then to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

(b) For purposes of this subsection, a distribution of a prescription drug to a warehouse or to another entity that redistributes the drug by intracompany sale to a pharmacy or to another person authorized to dispense or administer the drug constitutes a distribution to the pharmacy or to the person authorized to dispense or administer the drug.

Section 3526k. 450.01 (14m) of the statutes is created to read:

450.01 **(14m)** "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug.

Section 3526km. 450.01 (15m) of the statutes is created to read:

450.01 **(15m)** "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales.

Section 3526kr. 450.01 (20) of the statutes is amended to read:

450.01 **(20)** "Prescription drug" means all of the following, but does not include blood, blood components intended for transfusion, or biological products that are also medical devices:

(a) ~~Any~~ A drug, drug product, or drug−containing preparation ~~which~~ that is subject to 21 USC 353 (b) or 21 CFR 201.105.

(b) ~~Any~~ A controlled substance included in schedules II to V of ch. 961, whether by statute or rule, except ~~substances which~~ a substance that by law may be dispensed without the prescription order of a practitioner. Con-

trolled substances are included within this definition for purposes of s. 450.11 (3), (4) (a), and (8) only and for violations thereof punishable under s. 450.11 (9).

Section 3526L. 450.01 (21e) of the statutes is created to read:

450.01 **(21e)** "Repackage" means to repack or otherwise change the container, wrapper, or label of a prescription drug, except that "repackage" does not include any of the following:

(a) An action by a pharmacist with respect to a prescription drug that the pharmacist is dispensing.

(b) An action by a pharmacist who receives a prescription drug or device that the pharmacist dispensed to a patient, if, after altering the packaging or labeling of the prescription drug or device, the pharmacist returns the prescription drug or device to the patient.

Section 3526m. 450.01 (21m) of the statutes is created to read:

450.01 **(21m)** "Repackager" means a person that repackages.

Section 3526n. 450.01 (21s) of the statutes is created to read:

450.01 **(21s)** "Third party logistics provider" means a person that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

Section 3526o. 450.01 (23) of the statutes is created to read:

450.01 **(23)** "Wholesale distribution" means distribution of a prescription drug to a person other than a consumer or patient, but does not include any of the following:

(a) Intracompany sales of prescription drugs.

(b) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples, if the distribution is permitted under 21 CFR 353 (d).

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution as provided in 21 CFR 203.23.

(e) The sale of minimal quantities, as defined by the board in an administrative rule, of prescription drugs by retail pharmacies to licensed practitioners for office use.

(f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer states in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the drug and the supplying authorized distributor of record states in writing that the drug has previously been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the drug.

(j) A transaction excluded from the definition of "wholesale distribution" under 21 CFR 203.3 (cc).

(k) The donation or distribution of a prescription drug under s. 255.056.

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale distributor or to a 3rd−party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

Section 3526p. 450.01 (24) of the statutes is created to read:

450.01 **(24)** "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including manufacturers, repackagers, own−label distributors, private label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, manufacturers' exclusive distributors, manufacturers' authorized distributors of record, prescription drug wholesalers and distributors, independent wholesale prescription drug traders, 3rd party logistics providers, retail pharmacies that conduct wholesale distribution, and chain pharmacy warehouses that conduct wholesale distribution.

Section 3527. 450.06 (2) (c) of the statutes is amended to read:

450.06 **(2)** (c) The initial credential fee ~~under s. 440.05 (1)~~ determined by the department under s. 440.03 (9) (a) is paid.

Section 3528. 450.065 (2) (d) of the statutes is amended to read:

450.065 **(2)** (d) Pays the initial credential fee ~~under s. 440.05 (1)~~ determined by the department under s. 440.03 (9) (a).

Section 3530a. 450.07 (title) of the statutes is amended to read:

450.07 (title) **Manufacturers ~~and distributors~~; licensure.**

Section 3530at. 450.07 (1) of the statutes is amended to read:

450.07 **(1)** No person may engage in manufacturing in this state unless the person obtains a manufacturer's license from the board. For the issuance of a license under this subsection, the applicant shall pay the initial credential fee ~~specified in s. 440.05 (1)~~ determined by the department under s. 440.03 (9) (a).

Section 3530b. 450.07 (2) of the statutes is repealed.

Section 3530c. 450.07 (3) of the statutes is repealed.

Section 3530d. 450.07 (4) (c) of the statutes is created to read:

450.07 **(4)** (c) The rules adopted by the board under par. (b) shall require a manufacturer to maintain and to update at least once per month a list of the manufacturer's authorized distributors of record.

Section 3530e. 450.071 of the statutes is created to read:

450.071 Wholesale distributors; licensure. (1) No person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license from the board for each facility from which the person distributes prescription drugs. The board shall exempt a manufacturer that distributes prescription drugs or devises manufactured by the manufacturer from licensing and other requirements under this section to the extent the license or requirement is not required under federal law or regulation, unless the board determines that it is necessary to apply a requirement to a manufacturer.

(2) An applicant shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's wholesale distribution business is a partnership, the name of each partner and the name of the partnership.

(f) If the applicant's wholesale distribution business is a corporation, the name of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's wholesale distribution business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person listed in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's places of residence for the 7−year period immediately preceding the date of the application.

3. The person's occupations, positions of employment, and offices held during the 7−year period immediately preceding the date of the application.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement indicating whether the person has been, during the 7−year period immediately preceding the date of the application, the subject of any proceeding for the revocation of any business or professional license and the disposition of the proceeding.

6. A statement indicating whether the person has been, during the 7−year period immediately preceding the date of the application, enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction.

7. A description of any involvement by the person during the past 7 years with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits in which such a business was named as a party.

8. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the applicant shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.

9. A photograph of the person taken within the 12−month period immediately preceding the date of the application.

(k) A statement that each facility used by the applicant for the wholesale distribution of prescription drugs has been inspected in the 3−year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.

(3) The board shall grant a license to the applicant to engage in the wholesale distribution of prescription drugs if all of the following apply:

(a) The applicant pays the fee under s. 440.05 (1) (a), except that before June 1, 2010, the amount of the initial fee is $350.

(b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements adopted by the board for wholesale distribution facilities.

(c) All of the following apply to each person identified by the applicant as a designated representative:

1. The person is at least 21 years old.

2. The person has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs.

3. The person is employed by the applicant full time in a managerial level position.

4. The person is physically present at the wholesale prescription drug distributor's facility during regular business hours and is involved in and aware of the daily operation of the wholesale prescription drug distributor. This subdivision does not preclude the designated representative from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

5. The person is actively involved in and aware of the daily operations of the wholesale distributor.

6. The person is a designated representative for only one applicant at any given time. This subdivision does not apply if more than one wholesale distributor is located at the facility and the wholesale distributors located at the facility are members of an affiliated group.

7. The person has not been convicted of violating any federal, state, or local law relating to wholesale or retail prescription drug distribution or distribution of a controlled substance.

8. The person has not been convicted of a felony.

9. The person submits to the department 2 fingerprint cards, each bearing a complete set of the applicant's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for the purposes of verifying the identity of the applicant and obtaining the applicant's criminal arrest and conviction record. This subdivision does not apply to a person accredited by the national association of boards of pharmacy's verified−accredited wholesale distributor program.

(3m) Notwithstanding subs. (2) and (3), the board may grant a license to engage in the wholesale distribution of prescription drugs to a person who is domiciled in another state and is licensed to engage in the wholesale distribution of prescription drugs in another state, if the board determines that the standards for licensure in the state in which the person is licensed are at least as stringent as the standards for licensure under this section.

(4) The board may set, by rule, continuing education requirements for designated representatives under this section.

(5) (a) The board shall require every wholesale distributor to submit a surety bond acceptable to the board in an amount not to exceed $100,000 or other equivalent means of security acceptable to the board, except that the board shall not require submission of a bond or other security under this subsection by a chain pharmacy warehouse that is engaged only in intracompany transfers. A wholesale distributor that operates more than one facility is not required to submit a bond or other security under this paragraph for each facility.

(b) The bond or other security under this subsection shall be used to secure payment of fees or costs that relate to the issuance of a license under this section and that have not been paid within 30 days after the fees or costs have become final. No claim may be made against a wholesale distributor's bond or other security under this subsection more than one year after the date on which the wholesale distributor's license expires.

(6) Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

SECTION 3530eg. 450.071 (3) (a) of the statutes, as created by 2007 Wisconsin Act .... (this act), is amended to read:

450.071 **(3)** (a) The applicant pays the fee under s. 440.05 (1) (a)~~, except that before June 1, 2010, the amount of the initial fee is $350~~.

SECTION 3530g. 450.072 of the statutes is created to read:

450.072 Wholesale distributors; restrictions on transactions. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy, a person authorized to administer or dispense drugs, or a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. A wholesale distributor that receives returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs may distribute the prescription drugs only to the original manufacturer of the products or to a 3rd party returns processor. Notwithstanding s. 450.073, returns or exchanges of saleable or nonsaleable prescription drugs, including any redistribution by a receiving wholesaler, are not subject to pedigree requirements under s. 450.073 if the returns or exchanges are exempt from the pedigree requirement under the federal food and drug administration's current guidance on the federal prescription drug marketing act. A person licensed under s. 450.071 or a pharmacy or other person authorized to administer or dispense drugs shall ensure that the person or pharmacy's return process is secure and does not permit the entry of adulterated and counterfeit products.

(2) (a) A manufacturer or wholesale distributor may not deliver prescription drugs to a person unless the person is licensed under s. 450.071 or 450.06 or by the

appropriate licensing authority of another state. A manufacturer or wholesale distributor may not deliver prescription drugs to a person that is not known to the manufacturer or wholesale distributor unless the manufacturer or wholesale distributor has verified with the board or with the licensing authority of the state in which the person in located that the person is licensed to receive prescription drugs.

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization, except that a manufacturer or wholesale distributor may distribute the prescription drugs to an authorized agent of the person at the premises of the manufacturer or wholesale distributor if all of the following are true:

1. The manufacturer or wholesale distributor documents the authorized agent's name and address.

2. Distribution to an authorized agent is necessary to promote or protect the immediate health or safety of the authorized agent's patient.

(c) A manufacturer or wholesale distributor may distribute a prescription drug to a hospital pharmacy receiving area if a licensed pharmacist or another authorized recipient signs, at the time of the distribution, a receipt that shows the type and quantity of prescription drugs distributed. If there is a discrepancy between the type and quantity of prescription drugs indicated on the receipt and the type and quantity of prescription drugs received at the hospital pharmacy receiving area, the discrepancy shall be reported to the manufacturer or wholesale distributor that distributed the prescription drugs no later than the day immediately following the date on which the prescription drugs were distributed to the hospital pharmacy receiving area.

(d) No manufacturer or wholesale distributor may accept payment for, or allow the use of, a person's credit to establish an account for the purchase of a prescription drug from any person other than the owner of record, the chief executive officer, or the chief financial officer identified on the license or authorization of a person who may receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensed or authorized person.

Section 3530h. 450.073 of the statutes is created to read:

450.073 Wholesale distributors; pedigree. (1) A wholesale distributor shall establish and maintain a pedigree for each prescription drug that leaves, or has ever left, the normal distribution channel. Before a wholesale distribution of a prescription drug leaves the normal distribution channel, a wholesale distributor shall provide a copy of the pedigree to the person receiving the drug. This section does not apply to a retail pharmacy or pharmacy intracompany warehouse unless the pharmacy or pharmacy intracompany warehouse engages in the wholesale distribution of prescription drugs.

(2) A pedigree shall contain all necessary identifying information concerning each sale in the chain of the distribution of the prescription drug from the manufacturer of the prescription drug or the manufacturers 3rd−party logistics provider, colicensed product partner, or exclusive distributor until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. The pedigree shall include all of the following:

(a) The name, address, telephone number, and, if available, electronic mail address of each recipient or distributor of the prescription drug in the chain of distribution, until the final sale or distribution described in sub. (2) (intro.).

(b) The name and address of each facility from which the prescription drug was distributed, if different from the address provided in par. (a).

(c) The date of each distribution.

(d) A certification that every recipient has authenticated the pedigree before distribution of the prescription drug to the next point in the chain of distribution.

(e) The name, dosage strength, size and number of containers, lot number, and name of the manufacturer for each prescription drug.

(3) The board shall promulgate rules implementing an electronic track and trace pedigree system. Not later than July 1, 2010, the board shall determine the date on which the system will be implemented. The system may not be implemented before July 1, 2011, and the board may delay the implementation date in increments if the board determines that the technology to implement the system is not yet universally available across the prescription drug supply chain or is not capable of adequately protecting patient safety.

(4) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager but not including the original manufacturer of the prescription drug, who possesses a pedigree for the prescription drug, and who intends to further distribute the prescription drug, shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

(5) (a) A pedigree shall be maintained by a person who purchases prescription drugs identified in the pedigree and by a wholesale distributor who distributes prescription drugs identified in the pedigree for not less than 3 years from the date of sale or distribution.

(b) A person maintaining a pedigree under par. (a) shall make the pedigree available for inspection or use by a law enforcement officer within 7 days after the law enforcement officer's request.

Section 3530i. 450.074 of the statutes is created to read:

450.074 Wholesale distributors; prohibited actions, enforcement, penalties. (1) If the board finds that there is a reasonable probability that a wholesale distributor, other than a manufacturer, has done any of the

following, that continued distribution of a prescription drug involved in the occurrence could cause death or serious adverse health consequences, and that additional procedures would result in an unreasonable delay, the board shall issue an order requiring that distribution of a prescription drug in this state cease immediately:

(a) Violated a provision of ss. 450.071 to 450.073.

(b) Falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use.

(2) If the board issues an order under sub. (1), the board shall provide the person who is the subject of the order an opportunity for an informal hearing not more than 10 days after the date on which the order is issued. If, after a hearing, the board determines that the order was issued without sufficient grounds, the board shall vacate the order.

(3) Any person who knowingly does any of the following is guilty of a Class H felony:

(a) Fails to obtain a license required under s. 450.071.

(b) Purchases or otherwise receives a prescription drug from a pharmacy in violation of s. 450.072 (1).

(c) Violates s. 450.072 (2) (a), if the person is required to obtain a license under s. 450.071.

(d) Violates s. 450.072 (2) (b).

(e) Violates s. 450.072 (2) (d).

(f) Violates s. 450.073.

(g) Provides false or fraudulent records to, or makes a false or fraudulent statement to, the board, a representative of the board, or a federal official.

(h) Obtains or attempts to obtain a prescription drug by fraud, deceit, or misrepresentation, or engages in misrepresentation or fraud in the distribution of a prescription drug.

(i) Manufactures, repackages, sells, transfers, delivers, holds, or offers for sale a prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or otherwise unfit for distribution, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(j) Adulterates, misbrands, or counterfeits a prescription drug, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(k) Receives a prescription drug that has been adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeited, or suspected of being counterfeited, and delivers or proffers such a drug.

(L) Alters, mutilates, destroys, obliterates, or removes any part of the labeling of a prescription drug or commits another act that results in the misbranding of a prescription drug.

(4) Subsection (3) does not apply to a prescription drug manufacturer or an agent of a prescription drug manufacturer, if the manufacturer or agent is obtaining or attempting to obtain a prescription drug for the sole purpose of testing the authenticity of the prescription drug.

SECTION 3531. 450.08 (2) (a) of the statutes is amended to read:

450.08 **(2)** (a) A pharmacist's license may be renewed by complying with continuing education requirements under s. 450.085 and paying the applicable fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a). Failure to obtain renewal within the time period specified under this paragraph terminates the right of the person to be licensed as a pharmacist, and such right can only be acquired by passing an examination to the satisfaction of the board.

SECTION 3532. 450.08 (2) (b) of the statutes is amended to read:

450.08 **(2)** (b) A pharmacy, manufacturer's or distributor's license may be renewed by paying the applicable fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a).

SECTION 3533. 451.04 (4) of the statutes is amended to read:

451.04 **(4)** EXPIRATION AND RENEWAL. Renewal applications shall be submitted to the department on a form provided by the department on or before the applicable renewal date specified under s. 440.08 (2) (a) and shall include the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a).

SECTION 3534. 452.025 (1) (c) of the statutes is amended to read:

452.025 **(1)** (c) Each application for registration as a time−share salesperson shall be accompanied by an initial credential fee ~~specified in s. 440.05 (1)~~ determined by the department under s. 440.03 (9) (a) or the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a), whichever is appropriate.

SECTION 3535. 452.025 (5) (b) of the statutes is amended to read:

452.025 **(5)** (b) An application to renew a certificate of registration granted under this section shall be submitted with the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a).

SECTION 3536. 452.10 (3) of the statutes is amended to read:

452.10 **(3)** The fees for examinations and licenses granted ~~or renewed~~ under this chapter are specified under

CHAPTER PHAR 18
THIRD-PARTY LOGISTICS PROVIDERS

Phar 18.01 Authority. The rules in this chapter are adopted pursuant to the authority delegated by ss. 15.08 (5) (b), 450.02 (3), and 450.075 (4), Stats.

Phar 18.02 Definitions. In this chapter:

(1) "Designated representative" means an individual who functions on behalf of a third-party logistics provider or an out-of-state third-party logistic provider as specified in Phar 18.05.
(2) "Facility" has the meaning given in s. 450.01 (11m), Stats.
(3) "Out-of-state third-party logistics provider" has the meaning given s. 450.01 (13w), Stats.
(4) "Third-party logistics provider" has the meaning given in s. 450.01 (21s), Stats.

Phar 18.03 Licensure, Renewal, and Reinstatement.

(1) LICENSE ALLOWED. A person acting as a third-party logistics provider or an out-of-state third-party logistics provider of any drug or device may apply to obtain a license from the board.
(2) LICENSURE. Except as provided under Phar 18.03 (4), the board shall grant a license to operate as a third-party logistics provider or out-of-state third-party logistics provider, to any applicant that satisfies all of the following requirements, as determined by the Board:
    (a) The applicant shall submit all of the following:
        1. A completed application form.
        Note: Application forms are available from the department of safety and professional services' website at http://dsps.wi.gov.
        2. The fee specified in s. 440.05, Stats.
        3. All of the following information relating to a designated representative:
            a. Name, address, and telephone number
            b. Date and place of birth
            c. A photograph of the person taken within the 12-month period immediately preceding the date of the application
            d. A personal information statement that includes all of the following for the 7-year period immediately preceding the application:
                i. Place of residence
                ii. Occupations, positions of employment, and offices held
                iii. The name and addresses for each business, corporation or entity listed in subs. ii.
                iv. Whether the person has been the subject of any proceeding for the revocation of any business or professional licensure and the disposition of that proceeding.
                v. Whether the person has been enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction

vi. A description of any involvement with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and list of any lawsuits in which such a business was names as a party.

e. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld, or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the person shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.

f. Verification that the requirements in Phar 18.05 (1) have been met.

4. A statement that each facility used by the applicant for third-party logistics provider services has been inspected in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.

~~(b) The inspections required under Phar 18.04.~~

~~(c)~~(b) Subject to ss. 111.321, 111.322, and 111.335, ~~stats~~Stats., the applicant does not have an arrest or conviction record.

~~(d)~~(c) Where operations are conducted at more than one facility, a person acting as a third-party logistics provider or out-of-state logistics provider may apply for a license for each such facility.

(3) RENEWAL. (a) Each license shall be renewed biennially. The renewal date and fee are specified by s. 440.08 (2), Stats.

(b) Every even-numbered year, each license shall complete a renewal application and return it with the required fee prior to July 1 of that year.

Note: Instructions for renewal applications can be found on the department of safety and professional services' website at http://dsps.wi.gov.

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

(a) Evidence of completion of the requirements in Phar 18.03 (2) if the license has not been active within 5 years.

(b) Evidence of completion of disciplinary requirements, if applicable.

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

Phar 18.04 Inspections. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and

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delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to the third-party logistics provider or out-of-state third-party logistics provider's premises and delivery vehicles.

Phar 18.05 Responsible Persons. (1) DESIGNATED REPRESENTATIVE. The individual acting as the designated representative for a third-party logistics provider or an out-of-state third-party logistics provider shall meet all of the following requirements:

(a) Be at least 21 years old

(b) Has been employed full-time for at least three years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and recordkeeping related to, prescription drugs.

(c) Is employed full-time in a managerial position

(d) Is physically present at the third-party logistics provider's or out-of-state third-party logistics provider's facility during regular business hours This subsection does not preclude the person from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

(e) Is actively involved in and aware of the daily operation of the third-party logistics provider or the out-of-state third-party logistics provider.

(f) Is a designated representative for only one applicant at any given time. This subsection does not apply if more than one third-party logistics provider or out-of-state third-party logistics provider is located at the facility and the third-party logistics provider or out-of-state third-party logistics providers located at the facility are members of an affiliated group.

(g) Have not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.

(h) Has not been convicted of a felony

(i) Submits to the department 2 fingerprint cards, each bearing a complete set of the person's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for purposes of verifying the identity of the person and obtaining the person's criminal arrest and conviction record.

~~(i)~~ **(2)** OFFICERS, DIRECTORS AND MANAGERS. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall maintain a list of officers, directors, and managers, including a description of their duties and a summary of their qualifications.

Phar 18.06 Facility and Storage Requirements. All facilities licensed as third-party logistics providers or out-of-state third-party logistics providers shall ensure the following:

(1) Maintain access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;

(2) Have written policies and procedures for all of the following:

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21 U.S. Code § 360eee–3 - National standards for third-party logistics providers | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)

(a) Address receipt, security, storage, inventory, shipment, and distribution of a product;
(b) Identify, record, and report confirmed losses or thefts;
(c) Correct errors and inaccuracies in inventories;
(d) Provide support for manufacturer recalls;
(e) Prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;
(f) Ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;
(g) Maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and
(h) Quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

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Phar 18.07 Security Requirements. All facilities shall require the following:

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(1) Access from outside the premises is kept to a minimum and is well controlled;
(2) The outside perimeter of the premises is well lighted;
(3) Entry into areas where prescription drugs are held is limited to authorized personnel;
(4) An alarm system is maintained to detect entry after hours; and
(5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

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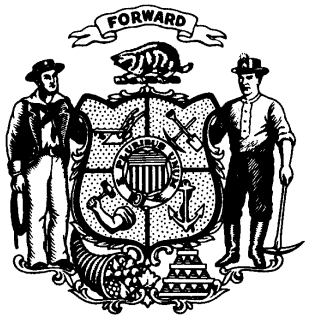
Phar 18.0~~8~~6 Compliance. A licensee who fails to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

State of Wisconsin



Date of enactment: **April 15, 2021**
2021 Assembly Bill 120 Date of publication*: **April 16, 2021**

2021 WISCONSIN ACT 25

AN ACT ***to amend*** 440.15, 450.01 (11m), 450.01 (21s) and 450.02 (1); and ***to create*** 440.08 (2) (a) 69g., 450.01 (13w), 450.01 (23) (p) and 450.075 of the statutes; **relating to:** third−party logistics providers, extending the time limit for emergency rule procedures, providing an exemption from emergency rule procedures, and granting rule−making authority.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 440.08 (2) (a) 69g. of the statutes is created to read:

440.08 **(2)** (a) 69g. Third−party logistics provider: July 1 of each even−numbered year.

SECTION 2. 440.15 of the statutes is amended to read:

440.15 No fingerprinting. Except as provided under ss. 440.03 (13) (c), 441.51 (5) (a) 5., 448.980 (5) (b) 3., ~~and~~ 448.985 (3) (a) 4., 450.071 (3) (c) 9., and 450.075 (3) (c) 9., the department or a credentialing board may not require that an applicant for a credential or a credential holder be fingerprinted or submit fingerprints in connection with the department's or the credentialing board's credentialing.

SECTION 3. 450.01 (11m) of the statutes is amended to read:

450.01 **(11m)** "Facility" means a location where a wholesale distributor or 3rd−party logistics provider stores, distributes, handles, repackages, or offers ~~for sale~~ other services related to prescription drugs.

SECTION 4. 450.01 (13w) of the statutes is created to read:

450.01 **(13w)** "Out−of−state 3rd−party logistics provider" means a person located outside this state that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services within this state on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

SECTION 5. 450.01 (21s) of the statutes is amended to read:

450.01 **(21s)** "~~Third party~~ Third−party logistics provider" means a person that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

SECTION 6. 450.01 (23) (p) of the statutes is created to read:

450.01 **(23)** (p) The services of a 3rd−party logistics provider or out−of−state 3rd−party logistics provider.

SECTION 7. 450.02 (1) of the statutes is amended to read:

450.02 **(1)** The department shall keep a record of the proceedings and a register of the names and places of practice or business of pharmacies, manufacturers, wholesale distributors, 3rd−party logistics providers,

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

out–of–state 3rd–party logistics providers, and other persons licensed under this chapter, and the books, registers and records of the department shall be prima facie evidence of the matters recorded.

Section 8. 450.075 of the statutes is created to read:

450.075 Third–party logistics providers; licensure. (1) License allowed. A person acting as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider of any drug or device may apply to obtain a license from the board under this section. Where operations are conducted at more than one facility, a person acting as a 3rd–party logistics provider or out–of–state 3rd–party logistics provider may apply to obtain a license from the board for each such facility.

(2) Application. An applicant for a license under this section shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the warehousing, distribution, or other services on behalf of the manufacturer of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's 3rd–party logistics provider business is a partnership, the name of each partner and the name of the partnership.

(f) If the applicant's 3rd–party logistics provider business is a corporation, the name of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's 3rd–party logistics provider business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to warehouse or distribute prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person identified as the designated representative in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's place of residence for the 7–year period immediately preceding the date of the application.

3. The person's occupations, positions of employment, and offices held during the 7–year period immediately preceding the date of the application.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement indicating whether the person has been, during the 7–year period immediately preceding the date of the application, the subject of any proceeding for the revocation of any business or professional license and the disposition of the proceeding.

6. A statement indicating whether the person has been, during the 7–year period immediately preceding the date of the application, enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction.

7. A description of any involvement by the person during the past 7 years with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits in which such a business was named as a party.

8. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the person shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.

9. A photograph of the person taken within the 12–month period immediately preceding the date of the application.

(k) A statement that each facility used by the applicant for 3rd–party logistics provider services has been inspected in the 3–year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.

(3) Licensure. The board shall grant a license to an applicant to act as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider if all of the following apply:

(a) The applicant pays the fee specified in s. 440.05 (1).

(b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements adopted by the board for 3rd–party logistics providers or out–of–state 3rd–party logistics providers.

(c) All of the following apply to each person identified by the applicant as a designated representative:

1. The person is at least 21 years old.

2. The person has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and record keeping related to, prescription drugs.

3. The person is employed by the applicant full time in a managerial position.

4. The person is physically present at the 3rd–party logistics provider's or out–of–state 3rd–party logistics provider's facility during regular business hours and is

involved in and aware of the daily operation of the 3rd–party logistics provider or the out–of–state 3rd–party logistics provider. This subdivision does not preclude the person from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

5. The person is actively involved in and aware of the daily operation of the 3rd–party logistics provider or the out–of–state 3rd–party logistics provider.

6. The person is a designated representative for only one applicant at any given time. This subdivision does not apply if more than one 3rd–party logistics provider or out–of–state 3rd–party logistics provider is located at the facility and the 3rd–party logistics providers or out–of–state 3rd–party logistics providers located at the facility are members of an affiliated group.

7. The person has not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.

8. The person has not been convicted of a felony.

9. The person submits to the department 2 fingerprint cards, each bearing a complete set of the applicant's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for purposes of verifying the identity of the person and obtaining the person's criminal arrest and conviction record.

(d) The applicant satisfies any other requirements established by the board by rule.

(4) RULES. The board shall promulgate rules implementing this section. The rules shall ensure compliance with the federal drug supply chain security act, 21 USC 360eee, et seq. The board may not promulgate rules that impose requirements more strict than the federal drug supply chain security act, or any regulations passed under the federal drug supply chain security act. The board may not promulgate rules that require a license under this section.

(5) ACCESS TO RECORDS. Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

(6) INSPECTIONS. A 3rd–party logistics provider or an out–of–state 3rd–party logistics provider shall allow the board and authorized federal, state, and local law enforcement officials to enter and inspect its facilities and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law, rule, or regulation.

(7) APPLICABILITY. (a) If the federal government establishes a licensing program for 3rd–party logistics providers, the board shall evaluate the federal licensing program to determine whether licensing by this state of resident 3rd–party logistics providers is required for a resident 3rd–party logistics provider to provide 3rd–party logistics provider services in another state. If the board determines under this subsection that licensing by this state is not required, this section does not apply.

(b) By 2 years after the effective date of this paragraph .... [LRB inserts date], and biennially thereafter, the board shall evaluate whether continued licensing by this state of resident 3rd–party logistics providers is required for a resident 3rd–party logistics provider to provide 3rd–party logistics provider services in another state and, if the board determines licensing in this state is required, submit to the legislative reference bureau for publication in the Wisconsin Administrative Register a notice continuing the licensing under this section. This section does not apply unless the board submits the notice under this paragraph.

SECTION 9. Nonstatutory provisions.

(1) EMERGENCY RULES RELATED TO 3RD–PARTY LOGISTICS PROVIDERS. The pharmacy examining board may promulgate emergency rules under s. 227.24 implementing s. 450.075. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until June 30, 2023, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

(2) INTERIM LICENSURE OF 3RD–PARTY LOGISTICS PROVIDERS.

(a) In this subsection, the definitions under s. 450.01 apply.

(b) The board shall grant an interim license to an applicant to act as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider if, in the opinion of the board, the applicant is currently in compliance with federal law relating to 3rd–party logistics providers. The holder of an interim license under this subsection shall apply for a license under s. 450.075 on or after the date that emergency rules take effect under sub. (1), or the date on which permanent rules take effect, whichever is sooner. An interim license granted under this subsection expires 90 days after the date that emergency rules take effect under sub. (1), or 90 days after the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 440.05, no fee is required for an interim license issued under this subsection.