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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE of the
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Brad Wojciechowski (608) 266-2112
February 20, 2025

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.

AGENDA

9:00 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1)

B. Approval of Minutes of December 5, 2024 (2)

C. Administrative Rule Matters – Discussion and Consideration (3-45)
1) Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check **(4-45)**
2) Pending or Possible Rulemaking Projects

D. Public Comments

ADJOURNMENT

NEXT MEETING: April 17, 2025

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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 any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
MEETING MINUTES
DECEMBER 5, 2024

PRESENT: Susan Kleppin, Anthony Peterangelo, John Weitekamp

ABSENT: Tiffany O'Hagan

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Tracy Drinkwater, Board Administration Specialist; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 9:10 a.m. A quorum was confirmed with three (3) members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES OF OCTOBER 24, 2024

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the Minutes of October 24, 2024, as published. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 10:18 a.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**02/07/25** 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?
02/20/25	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check** **2. Pending or Possible Rulemaking Projects**

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

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

Attachments:
1. Phar 7 Redlined Code Text
2. New Mexico language on Alteration
3. NABP Model Practice Act

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

11) Authorization

Nilajah D. Hardin — 02/07/25

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 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.

(1a) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 , Public Law 104-191.

~~**(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 AND PRESCRIPTION VIA SECURE TEXTING PLATFORM. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. Prescription orders via text may be received at a pharmacy through a HIPPA compliant secure texting platform. The verbal prescription or prescription order via secure texting platform 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.

Commented [NH1]: Changes for Alteration?

Commented [NH2R1]: Changes from New Mexico? Or Pharmacist discretion as in Phar 8?

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. (a) The electronic transfer of an original prescription ~~information~~ for initial dispensing of a controlled substance listed in Schedule II ~~III—V~~ shall comply with 21 CFR 1306. ~~meet the following requirements:~~

(b) The electronic transfer of an original prescription for initial dispensing or refill of a schedule III-V original prescription shall comply with 21 CFR 1306.

~~**(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)**~~**(c)** For paper prescriptions and prescriptions received verbally and reduced to writing by the pharmacist for controlled substances listed in Schedule III – V, 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.~~

Commented [NH3]: Any other Info on Transfers?

~~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~~ delivery system 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 products or devices dispensed by a pharmacist, the prescription record shall identify ~~the pharmacist~~ the individual responsible for each part of the final check. If sub. (1) (a) or (b) is completed by a pharmacy product verification technician under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the pharmacy product verification technician performing the check.

Phar 7.08 Patient consultation. (1) A pharmacist shall provide the patient or patient's agent consultation to optimize proper use of a prescription drug or device, that meets any of the following:
(a) Has not been dispensed previously to the patient by that pharmacy or a pharmacy within the same shared computer system.
(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 Pharmacy product verification technician-check-pharmacy technician. (1) DEFINITIONS. In this section:

(a) "Pharmacy product verification technician" means a registered pharmacy technician to whom the pharmacist has delegated the task of product verification.

(b) "Pharmacy product verification technician-check- pharmacy technician" means the process in which a pharmacy product verification technician conducts the task of product verification of technical dispensing functions completed by a pharmacy technician. A pharmacy product verification technician may not conduct product verification as part of the final check of their own product preparation.

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

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

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

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

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

1. Elements of correct product including all of the following:
   a. Drug name.
   b. Strength.
   c. Formulation.
   d. Expiration date.
   e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
   a. Wrong medication.
   b. Wrong strength.
   c. Wrong formulation.
   d. Extra or insufficient quantity.
   e. Omitted medications if utilizing unit dose or compliance packaging.
   f. Expired medication.
   g. Look-alike or sound-alike errors.
   h. High-alert medications.
3. Eligible products for pharmacy product verification technician-check-pharmacy technician.
4. Organizational policies and procedures on reporting of medication errors.
5. Overview of the medication use process including all of the following:
   a. Procurement.
   b. Ordering.
   c. Dispensing.
   d. Administration.
   e. Monitoring.
6. A practical training designed to assess the competency of the pharmacy technician prior to starting the validation process. The practical training shall include simulation of at least 2 occurrences of each of the following:
   a. Wrong drug.
   b. Wrong strength.
   c. Wrong formulation.
   d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The pharmacy technician being validated shall make a product verification on the work of a pharmacist or another pharmacy technician for accuracy and correctness of a minimum of

500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.

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

(e) Notwithstanding pars. (b) to (d), an individual who completed the board's pilot program validation process between October 1, 2016 and September 30, 2019, meets the pharmacy product verification technician qualifications unless the individual fails to meet the quality assurance standards under sub. (4).

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

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

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

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.
2. A drug utilization review performed by a pharmacist prior to dispensing.
3. A non-pharmacist shall be able to check the accuracy of the medication by one of the following:
   a. The drug product or device is in the original packaging from a manufacturer.
   b. The drug product or device includes a description of the drug product or device on the prescription label.
   c. The pharmacist shows the patient or patient's agent the drug product or device and provides a monograph that includes a description of the drug product or device.

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

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

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

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

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

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

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

1. All validation records of each pharmacy product verification technician that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising 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.

Phar 7.15 Consumer disclosures. (1) Each pharmacy shall post in a prominent place and maintain the consumer disclosures required in ss. 450.13 (5m) and 450.135 (8m), Stats.

(2) A link to the 100 most commonly prescribed generic drug product equivalents as determined by the board, shall be maintained on the department's website as required in s. 450.13 (5m) (b), Stats.

Note: Copies of the required consumer disclosures are located on the Department of Safety and Professional Service's website: https://dsps.wi.gov.

(3) Pursuant to s. 450.13 (5m) (c), Stats., each pharmacy shall maintain and make available to the public a list of the drugs from the list in sub. (2) that are available for purchase at that pharmacy. The list shall be updated monthly, with all of the following information included:

(a) Brand name.

(b) Generic equivalent drugs and biological products.

(c) Interchangeable biological products.

(d) Retail price.

(4) The list required under sub. (3) may differ depending on whether the drugs on the list from sub. (2) are available for purchase at a specific pharmacy.

Phar 7.16 Cardiopulmonary Resuscitation Certification for Pharmacists. Every licensed pharmacist who administers drug product or device or vaccines pursuant to s. 450.035, Stats., shall obtain certification in cardiopulmonary resuscitation at least every 2 years.

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)~~450.09 (2) (b) 1. a. to d., 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. (2) LOCATION. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. 450.09 (2) (b) 1. a. to d., Stats.
(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 employed by:
   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 a pharmacist is not available remotely.
(c) A prescribed drug or device may not be dispensed in the absence of the ability of a patient and pharmacist's delegate to communicate with a pharmacist.
(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 remote dispensing site as the licensed facility from which the prescribed drug or device was dispensed.

Commented [NH4]: Add: No vaccines shall be administered at a remote dispensing site. (include drug products and devices also?)?

(c) Final check under s. Phar 7.07.

(d) Federal law if dispensing controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACIST. The managing pharmacist responsible for the remote dispensing pharmacy shall do all of the following:

(a) Have written policies and procedures for system operation, safety, security, accuracy and access.

(b) Implement an ongoing 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.

(c) 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.

(d) Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.

(e) Documentation indicating accepting responsibility for compliance with this section, signed and dated by the managing pharmacist.

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

(a) Be 18 years of age or older.

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

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

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 — Uncredentialed Pharmacy Staff

Phar 7.60 Definition. In this subchapter, "uncredentialed pharmacy staff" means any staff practicing in the pharmacy who are not otherwise licensed or registered under s. 450.03 (1) (f), (g), or (gm), Stats.

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

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

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

(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 uncredentialed pharmacy staff person prior to the uncredentialed pharmacy staff person performing a delegated act.

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

(7) A pharmacist may delegate to an uncredentialed pharmacy staff person any delegated act approved by the managing pharmacist outside of the restrictions in sub. (3).

From: Tiffany OHagan
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Subject: Phar 7
Date: Wednesday, October 23, 2024 9:05:33 PM

New Mexico
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(d) as required by the provision of patient counseling regulations.

I. Prescription adaptation

(1) A pharmacist, using professional judgment, may determine in filling a new non-controlled substance prescription whether it is necessary to attempt to contact the prescriber before performing the following adaptations:

(a) change the quantity, dosage, dosage form, or directions for use of the medication dispensed if it meets the *intent of the prescriber*, or

(b) complete *missing information* on a prescription if there is sufficient evidence to support the change.

(c) The pharmacist will document the prescription adaptation as part of the original prescription record.

(d) The pharmacist will notify the prescriber of the prescription adaptation within 24 hours; and will maintain documentation of notification.

(e) The pharmacist will provide patient counseling, in accordance with Subsection F of 16.19.4.16 NMAC, to include information pertinent to the prescription adaptation.

[16.19.6.23 NMAC - Rp 16 NMAC 19.6.23, 3/30/2002; A, 6/30/2006; A, 03/22/2015; A, 12/15/2020; A 10/10/2023]

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Model Rules for the Practice of Pharmacy

Section 1. Pharmacy Licensure.

(1) To obtain a license for a pharmacy, an applicant shall:
  (a) have submitted an application in the form prescribed by the board of pharmacy;
  (b) have attained the age of 18 years; and
  (c) have paid the fees specified by the board of pharmacy for the issuance of the license.

(2) The facility owner, if an individual, shall have undergone a state and federal fingerprint-based criminal background check.

(3) The facility shall have undergone a pharmacy inspection by the board or authorized agent thereof.

(4) The pharmacy shall have sufficient space, references, equipment, and storage to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and/or preparing and dispensing of prescription drug orders.

(5) The pharmacy, if operating a website or other digital content, shall be accredited by a program approved by the board.[103]

(6) Upon renewal, the licensee shall provide to the board the NABP e-Profile ID of the pharmacy and the pharmacist-in-charge.

Section 2. Security.

(1) Basic Provisions
  (a) Each pharmacist, while on duty, shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of drugs and/or devices.
  (b) The pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the pharmacist is not present. In the event of separation of employment of an employee, suitable action shall be taken to ensure the security of the pharmacy.
  (c) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information.
  (d) The Pharmacy shall implement and maintain processes and technologies that will aid in theft prevention, detection, and investigation. The pharmacy shall implement and maintain processes and technologies that will aid in theft prevention, detection, and investigation.

Section 3. Personnel.

(1) Pharmacist-in-Charge
  (a) No person shall operate a pharmacy without a pharmacist-in-charge. A pharmacist may not serve as pharmacist-in-charge unless engaged in the pharmacy a sufficient amount of time to provide supervision and control.

[103] Boards of Pharmacy are strongly encouraged to recognize the NABP Healthcare Merchant Accreditation or, if a higher standard is desired, the Digital Pharmacy Accreditation for this purpose.

A pharmacist may serve as pharmacist-in-charge for more than one pharmacy at any one time upon obtaining permission from the board.

(b) The pharmacist-in-charge has the following responsibilities:

(i) Ensuring that all pharmacists, pharmacy interns, certified pharmacy technicians, and certified pharmacy technician candidates employed at the pharmacy are currently licensed by the board of pharmacy.[104]

(ii) Notifying the board of pharmacy, as required, of any of the following[105] changes:

(A) change of employment or responsibility as the pharmacist-in-charge;

(B) the separation of employment of any pharmacist, pharmacy intern, certified pharmacy technician candidate, or certified pharmacy technician for any confirmed drug-related reason, including but not limited to, adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination: if it is the employment of the pharmacist-in-charge that is terminated, the owner and/or pharmacy permit holder shall notify the board of pharmacy;

(C) change of ownership of the pharmacy;

(D) change of address of the pharmacy;

(E) permanent closing of the pharmacy;

(F) significant quality-related events;

(G) the installation or removal of automated pharmacy systems. Such notice must include, but is not limited to:

(-a-) the name and address of the pharmacy;

(-b-) the location of the automated pharmacy system; and

(-c-) the identification of the responsible pharmacist.

(-d-) Such notice must occur prior to the installation or removal of the system.

(iv) Making or filing any reports required by state or federal laws and rules.

(v) Reporting any theft, suspected theft, diversion, or other significant loss of any prescription drug within one business day of discovery to the board of pharmacy and as required by US DEA or other state or federal agencies for prescription drugs and controlled substances.

(vi) Responding to the board of pharmacy regarding any minor violations.

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[104] While it is strongly encouraged that all pharmacy personnel be licensed, there may still be jurisdictions that allow non-licensed individuals, such as cashiers, to work in a pharmacy, and in such instances the pharmacist-in-charge is responsible for their supervision.

[105] If states require the pharmacist-in-charge or other person in charge of the pharmacy to submit information regarding the separation of employment of licensees, especially in circumstances of suspected or confirmed abuse, theft, or diversion of drugs, states should also be aware of confidentiality and employment laws that may restrict the release of information and be cautioned that the release of such information may create a liability for the reporting pharmacy.

In instances where the pharmacist-in-charge and the owner and/or pharmacy permit holder are the same person and that person is no longer employed or designated as the person in charge, then the board must take action to cease operation of the pharmacy.

(c) The pharmacist-in-charge shall be assisted by a sufficient number of pharmacists, certified pharmacy technicians, and certified pharmacy technician candidates as may be required to competently and safely provide pharmacy services.

(i) The pharmacist-in-charge shall develop or adopt, implement, and maintain written policies and procedures to specify the duties to be performed by certified pharmacy technicians and certified pharmacy technician candidates. The duties and responsibilities of these personnel shall be consistent with their education, training, and experience and shall address the method and level of necessary supervision specific to the practice site.

(ii) The pharmacist-in-charge shall develop or adopt, implement, and maintain a training program that is site-specific to the practice setting of which the pharmacist is in charge for all individuals employed by the pharmacy.[106]

(2) Policies and Procedures

The pharmacist-in-charge is responsible for developing or adopting, implementing, and maintaining policies and procedures[107] addressing the following:

(a) the practice of pharmacy;[108]

(b) the procurement, storage, security, and disposition of drugs and devices, particularly controlled substances and drugs of concern;

(c) record retention systems;

(d) automated pharmacy systems;[109]

(e) shared pharmacy services;[110]

(f) operation of the pharmacy in the event of a fire, flood, pandemic, or other natural or man-made disaster or emergency, to the extent that the pharmacy can be safely and effectively operated, and the drugs contained therein can be safely stored and dispensed. Such policies and procedures shall include reporting to the board;[111]

(g) the proper management of drug recalls;

(h) the duties to be performed by pharmacy personnel; the duties and responsibilities of these personnel shall be consistent with their education, training, experience, and license and shall address the method and level of necessary supervision specific to the practice site;

(i) activities related to prescription drug shipment by mail or common carrier:

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[106] All training programs should be subject to approval by the board of pharmacy.

[107] The owner and/or pharmacy permit holder, along with the pharmacist-in-charge, are responsible for these policies and procedures.

[108] The pharmacist-in-charge, as part of the responsibilities to manage as effectively as possible a patient's therapy to avoid a harmful interruption of therapy because of a shortage or limited distribution of drugs, can proactively improve pharmacy operations by developing a systematic approach to address such circumstances. References, such as the American Society of Health-System Pharmacists (ASHP) Guidelines in Managing Drug Product Shortages, could be used as resources for developing policies and procedures if appropriate. Additionally, US FDA maintains a list of current and resolved drug shortages, as well as discontinued drugs on the agency's Drug Shortages web page at https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.

[109] See Section 9. Automated Pharmacy Systems.

[110] See Section 8. Shared Pharmacy Services.

[111] States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of drugs in areas outside the licensed pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed pharmacy area to accommodate the need to store emergency supplies.

(i) properly transferring prescription information to an alternative pharmacy of the patient's choice in situations where the drug is not delivered or deliverable;
(ii) verifying that common carriers have in place security provisions, such as criminal background checks and random drug screens on its employees who have access to prescription drugs;
(iii) tracking all shipments; and
(iv) taking measures to prevent drugs from becoming adulterated in transit;

(j) quality assurance programs addressing pharmacy services and equipment;

(k) activities related to security, internal theft, and diversion, including:
(i) inspection of shipments;
(ii) receipt verification oversight and checking in shipments;
(iii) reconciliation of orders; and
(iv) inventory management, including:
(A) determination of drugs that need to be monitored and controlled beyond existing systems such as controlled substances and drugs of concern; and
(B) conducting quarterly reconciliations at a minimum but shall be more frequent up to perpetual, depending on the potential for or incidence of diversion for a particular drug;
(v) restrictions and control over and access to the locks, barriers, and systems used to secure the pharmacy and pharmacy systems in accordance with state laws and rules;
(vi) actions to be taken to prevent and react to pharmacy robberies and thefts, including, but not limited to, coordinating with law enforcement, training, mitigation of harm, and protecting the crime scene;
(vii) the prevention and detection of drug diversion;[112]

(l) operational aspects of the computerized record-keeping system;

(m) the pharmacy continuous quality improvement program.

(2) Pharmacy Labor Standards/Shift Lengths and Breaks

(a) A pharmacy licensed under this Act shall not require a pharmacist, pharmacist intern, certified pharmacy technician, or certified pharmacy technician candidate to work longer than 12 continuous hours in any 24-hour period, inclusive of the breaks required under subsection (b).

(b) A pharmacist who works 6 continuous hours or longer per day shall be allowed to take, at a minimum, one 30-minute, uninterrupted meal break and one 15-minute break during that 6-hour period. If such pharmacist is required to work 12 continuous hours in any 24-hour period, at a minimum, the pharmacist qualifies for an additional 15-minute break.

(c) A pharmacy may, but is not required to, close when a pharmacist is allowed to take a break under subsection (b). If the pharmacy does not

[112] The pharmacist-in-charge, if the practice setting warrants, may also consider implementing diversion prevention and detection policies and procedures that address the following: periodic reviews of employee access to any secure controlled substance storage areas, which may include:

- alarm codes and lock combinations;
- passwords; and
- keys and access badges.

close, the pharmacist shall either remain within the pharmacy or within the establishment in which the pharmacy is located in order to be available for emergencies. In addition, the following applies:

(i) certified pharmacy technicians, certified pharmacy technician candidates, and pharmacist interns authorized by the pharmacist on duty may continue to perform duties as allowed under this Act;

(ii) no duties reserved to pharmacists and pharmacist interns under this Act, or that require the professional judgment of a pharmacist, may be performed by certified pharmacy technicians or certified pharmacy technician candidates;

(iii) only prescription drug orders that have received final verification may be dispensed while the pharmacist is on break, except those prescription drug orders that require patient counseling by a pharmacist, including all new prescription drug orders and those refilled prescription drug orders for which a pharmacist has determined that counseling is necessary and/or is conducted pursuant to counseling laws and/or rules;[113] and

(iv) a pharmacist using their professional judgment may waive subsections (a) and (b).

(4) If any action of the pharmacy is deemed to contribute to or cause a violation of any provision of this Section, the board may hold the owner and/or pharmacy permit holder responsible and/or absolve the pharmacist-in-charge from the responsibility of that action.

Section 4. Prescription Drug Order Processing.

(1) Prescription Drug Order

A prescription drug order shall contain the following information at a minimum:

(a) full name, date of birth, and street address of the patient;

(b) name, prescribing practitioner's license designation, address, and, if required by law or rules of the board, DEA registration number of the prescribing practitioner;

(c) date of issuance;

(d) name, strength, dosage form, and quantity of drug prescribed;

(e) directions for use;

(f) refills authorized, if any;

(g) if a written prescription drug order, prescribing practitioner's signature;

(h) if an electronically transmitted prescription drug order, prescribing practitioner's electronic or digital signature;

(i) if a hard copy prescription drug order generated from electronic media, prescribing practitioner's electronic or manual signature. For those with electronic signatures, such prescription drug orders shall be applied to paper that utilizes security features[114] that will ensure that the prescription drug order is not subject to any form of copying and/or alteration.

(2) Manner of Issuance of a Prescription Drug Order

[113] The pharmacy shall have policies and procedures to ensure that the patient is provided an opportunity to receive patient counseling.

[114] Examples of security features for prescription paper include those that prevent copying, such as hidden background words or darker-colored areas of the paper (which, when photocopied appear as black), those that prevent adulteration, such as solvent dye and brownstain features, and those that verify authenticity, such as the incorporation of fluorescent threads or watermarks.

A prescription drug order for a controlled substance should comply with federal regulations.[115] A prescription drug order, to be valid, must be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.[116]

(3) Transfer of a Prescription Drug Order

Pharmacies utilizing manual as well as automated data-processing systems shall satisfy all the information and documentation requirements for a prescription drug order transfer listed below, except as noted below for those pharmacies accessing a common electronic file. The transfer of original prescription drug order information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) The information for a prescription, other than for a controlled substance,[117] must be communicated directly between pharmacists, pharmacy interns, or certified pharmacy technicians.

(b) The following information must be recorded by the transferring pharmacy:
  (i) the fact that the original prescription drug order has been deemed void/closed;
  (ii) the name and address of the pharmacy to which it was transferred;
  (iii) the name of the pharmacist, pharmacy intern, or certified pharmacy technician receiving the prescription drug order;
  (iv) the date of the transfer; and
  (v) the name of the pharmacist, pharmacy intern, or certified pharmacy technician transferring the information.

(c) The following information must be recorded by the pharmacy receiving the transferred prescription drug order:
  (i) the fact that the prescription drug order has been received via transfer;
  (ii) the date of issuance of the original prescription drug order;
  (iii) the original number of refills authorized on the original prescription drug order;
  (iv) the date of original dispensing;
  (v) the number of valid refills remaining and the date of last refill;
  (vi) the pharmacy's name, address, and original prescription number from which the prescription drug order information was transferred; and
  (vii) the name of the transferring pharmacist, pharmacy intern, or certified pharmacy technician.

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[115] Electronically transmitted prescriptions should be transmitted from prescriber to pharmacy with no intervening persons making illegal alterations that may be considered as engaging in the practice of pharmacy without the authority to do so or without being licensed to do so to such prescriptions. Evolving technologies and systems have alleviated previous concerns regarding the routes by which electronic prescriptions are transmitted, but any attempts to return to illegal prescription altering practices will be halted.

[116] While pharmacists have a corresponding responsibility to ensure that a controlled substance is dispensed only pursuant to a valid prescription drug order written for a legitimate medical purpose, this should not impede patients from receiving legitimately prescribed controlled substances or non-controlled substances, as patient care should be the primary consideration.

[117] According to 21 CFR §1306.25 (b)(1), the transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing must be communicated directly between two licensed pharmacists.

(d) Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of pharmacist care services.

(e) Both the original and transferred prescription drug order information shall be maintained for a period of five years from the date of last refill.

(f) Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each prescription drug order and refill dispensed, and shall protect against the illegal use or disclosure of protected health information.

(g) In an emergency, a pharmacy may transfer original prescription drug order information for a non-controlled substance to a second pharmacy for the purpose of dispensing up to a 72-hour supply without voiding the original prescription drug order.

(4) Drug Product Selection by the Pharmacist

(a) A pharmacist dispensing a prescription drug order for a drug product prescribed by its brand name may select any equivalent drug product provided that the manufacturer or distributor holds, if applicable, either an approved New Drug Application (NDA) or an approved Abbreviated New Drug Application (ANDA), unless other approval by law or from the US FDA is required.

(b) The pharmacist shall not select an equivalent drug product if the practitioner instructs otherwise, either orally or in writing, on the prescription drug order.

(c) The pharmacist shall notify the patient or patient's agent if a drug other than the brand name drug prescribed is dispensed.

(5) Labeling

(a) All drugs dispensed to ambulatory or outpatients, including drugs dispensed by practitioners, shall have a label affixed to the container in which such drug is dispensed. The label shall conform with the USP chapter addressing prescription container labeling.

Section 5. Record Keeping.

(1) Patient Records[118]

(a) A patient record system shall be maintained by all pharmacies and dispensing practitioners for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing and be created and stored in a manner to

[118] The pharmacist should have access to clinical and laboratory data concerning each patient and should monitor each patient's response to drug therapy. Any unexpected or untoward response should be reported to the prescribing physician. If the pharmacist is not doing this monitoring, the identity of the health care provider that has assumed this responsibility should be documented in the patient's profile.

It is acceptable for new prescription drug order data to be added to the patient profile, but original entries may not be altered.

protect against illegal use or disclosure of protected health information. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

(i) full name of the patient for whom the drug is intended;
(ii) street address and telephone number of the patient;
(iii) patient's age or date of birth;
(iv) patient's gender;
(v) a list of the drugs taken by the patient during the preceding 24 months; and
(vi) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(b) The pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs or devices currently being used by the patient which may relate to prospective drug review.

(c) A patient record shall be maintained for a period of not less than 10 years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(d) Serious adverse dug experiences shall be reported to the practitioner and an appropriate entry shall be made in the patient's record.

(2) Records of Dispensing/Delivery[119]

(a) Records of receipt, dispensing, delivery, distribution, or other disposition of all drugs or devices are to be made in accordance with federal law and kept by pharmacies for five years and shall include, but not be limited to:

(i) quantity dispensed for original and refills, if different from original;
(ii) date of receipt, dispensing, delivery, distribution, or other disposition;
(iii) serial number (or equivalent if an institution);
(iv) the identification of the pharmacist, certified pharmacy technician, or certified pharmacy technician candidate responsible for dispensing;
(v) name and manufacturer of drug dispensed if drug product selection occurs; and
(vi) records of refills to date.

(b) Pharmacies that ship drugs by mail, common carrier, or other type of delivery service shall implement a mechanism to verify that a patient or caregiver has actually received the delivered drug.[120]

(3) Electronic Record Keeping

(a) Data Storage and Retrieval

(i) The system shall provide online retrieval of original prescription drug order information; such information shall include, but not be

[119] If a board requires the presentation of identification or patient signature in order for a patient to receive prescribed drugs, it may consider waiving such requirements during a state of emergency, in compliance with federal law.

[120] States that require pharmacies that ship drugs by mail, common carrier, or other type of delivery service to implement a mechanism to verify that the patient or caregiver has actually received the delivered drug may want to consider allowing the mechanism to include a waiver provision that allows the patient or caregiver to request delivery without verification and advises the patient or caregiver of the possible consequences of receiving delivery without verification.

limited to, the prescription drug order requirements and records of dispensing as indicated in Section 4 of this Rule; and

(ii) The storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV are subject to federal regulations.

(b) Security

To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented, including the identification of the pharmacist responsible for the alteration.

(c) System Backup (Auxiliary Records Maintenance)

(i) In the event of an unscheduled system interruption, sufficient patient data and prescription drug order data should be available to permit reconstruction of such data as soon as possible for the pharmacist to dispense drugs with sound professional judgment.

(ii) An auxiliary system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason and to ensure that all refills are authorized by the original prescription drug order and that the maximum number of refills is not exceeded.

(iii) The auxiliary system shall be in place to provide for the maintenance of all necessary patient drug information (as outlined in this rule) until the automated system becomes operational. However, nothing in this Section shall preclude the pharmacist from using professional judgment for the benefit of a patient's health and safety.

(iv) When the automated system is restored to operation, the information regarding prescription drug orders dispensed and refilled during the inoperative period shall be entered into the automated system as soon as possible.

(v) Routine backup systems and procedures (hard copy, copy, disk, etc) shall be in place and operational to ensure against loss of patient data.

(vi) In the event that permanent dispensing information is lost due to unscheduled system interruption, the board of pharmacy shall be notified as soon as possible.

Section 6. Pharmacist Care Services.

(1) Pharmacist care services are services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination or reduction of symptoms, and promotion of health and wellness. Pharmacist care services include, but are not limited to:

(a) drug utilization review;

(b) emergency use prescribing and dispensing;[121]

(c) medication therapy management;

[121] Pharmacist may prescribe drugs for emergency use pursuant to specific statewide protocols or standing orders.

(d) reviewing, selecting, and developing formularies and/or practice guidelines;
(e) performing drug product selection, substitution, therapeutic interchange[122] prescription adaptation or continuation of therapy;
(f) performing drug product selection, substitution, therapeutic interchange[123] prescription adaptation or continuation of therapy; and
(g) ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived[124] lab tests.

(2) Drug Utilization Review (DUR)[125]

A pharmacist shall obtain and review the patient records and medical history for each prescription drug order for:
(a) known allergies;
(b) rational therapy contraindications;
(c) reasonable dose, duration of use, and route of administration, considering age, gender, and other patient factors;
(d) reasonable directions for use;
(e) potential or actual adverse drug reactions;
(f) drug-drug interactions;
(g) drug-food interactions;
(h) drug-disease contraindications;
(i) therapeutic duplication;
(j) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(k) abuse/misuse.

Upon recognizing any of the above, which may also include information obtained from reviewing data found in the prescription monitoring program, the pharmacist shall take appropriate steps to avoid or resolve the problem which, if necessary, includes consultation with the practitioner.

(3) Patient Counseling[126]

(a) Upon receipt of a prescription drug order and following a review of the patient's record, a pharmacist shall engage in discussion of matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone or other audio/visual means of communication and shall include appropriate elements of patient counseling. Such elements may include the following:
(i) the name and description of the drug;
(ii) the dosage form, dose, route of administration, and duration of drug therapy;
(iii) intended use of the drug and expected action;

[122] Provided it is within the same FDA Drug class and not prohibited by the prescriber.

[123] Provided it is within the same FDA Drug class and not prohibited by the prescriber.

[124] Most recent version.

[125] Pharmacists should be permitted to use computer software, if available, to accomplish this review.

[126] The intent of this Section is to require that the pharmacist personally initiate patient counseling for all new prescription drug orders and exercise their professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

(iv) special directions and precautions for preparation, administration, and use by the patient;
(v) 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;
(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(b) An offer for patient counseling can be made by a certified pharmacy technician or certified pharmacy technician candidate. An offer for patient counseling can be made by a certified pharmacy technician or certified pharmacy technician candidate.

(c) Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(d) Patient counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(e) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

(4) Medication Adherence Monitoring Services and Patient Intervention Programs
Medication adherence monitoring services and patient intervention programs designed to promote improved medication use behaviors, such as compliance and adherence, appropriate monitoring and self-reporting, increased patient knowledge, and improved therapy options, shall comply with federal and state law addressing the privacy of protected health information.

(5) Collaborative Pharmacy Practice

(a) Collaborative Pharmacy Practice Agreement
A pharmacist planning to engage in collaborative pharmacy practice shall have on file at their place of practice the collaborative pharmacy practice agreement. Any additional information the board may require concerning the collaborative pharmacy practice agreement, including the agreement itself, shall be made available to the board for review upon request. The agreement may allow the pharmacist, within the pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement, to conduct activities approved by the practitioner in good standing, and as defined by law and by the rules of the board. The collaboration that the practitioner agrees to conduct with the pharmacist must be within the scope of the practitioner's current practice.

(b) Contents
The collaborative pharmacy practice agreement shall include:
(i) identification of the practitioner(s) and pharmacist(s) who are parties to the agreement;
(ii) the types of decisions that the pharmacist is allowed to make;
(iii) a process for generating any necessary medical orders, including prescription drug orders, required to initiate allowed activities;

(iv) a method for the practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary;
(v) a description of the continuous quality improvement program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
(vi) a provision that allows the practitioner to override a collaborative practice decision made by the pharmacist whenever the practitioner deems it necessary or appropriate;
(vii) a provision that allows either party to cancel the agreement by written notification;
(viii) an effective date;
(ix) signatures of all collaborating pharmacists and practitioners who are party to the agreement, as well as dates of signing; and
(x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

(c) Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated.

(d) Documentation of pharmacist activities
Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals who are providing care to that patient and who are authorized to receive it.

(6) Emergency Use Prescribing and Dispensing
Prescribing and dispensing drugs for emergency use shall be pursuant to a pharmacist-issued prescription drug order and include appropriate patient counseling. Drugs or devices for emergency use include, but are not limited to:
(a) Opioid overdose reversal agents, such as naloxone;
(b) Epinephrine;
(c) Antidote kits;
(d) Short-acting beta-agonist inhalers; and
(e) Medication for opioid use disorder for the purpose of initiating therapy for opioid use disorder. The pharmacist must:
(i) obtain a DEA registration and a state controlled substance license or registration, if required; and
(ii) use professional judgment to assess the clinical appropriateness of the patient's request and the length of time until the patient obtains treatment from an authorized practitioner.[127]

(7) Emergency Refills
A pharmacist may authorize and dispense a refill of a prescription drug without practitioner authorization if:[128]
(a) in the pharmacist's professional judgment, the prescription drug is essential to the maintenance of the patient's life or to the continuation of therapy;
(b) the pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates that it is an "Emergency Refill Prescription," and maintains the record as

[127] It is contemplated that for long-term treatment, pharmacists should be prescribing under a collaborative practice agreement rather than under an emergency use provision.

[128] Boards may consider contacting US DEA ahead of time to ensure that these provisions are applicable to controlled substances.

required by state and federal law, as well as state and federal disaster agencies, for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency;

(c) the pharmacist informs the patient or the patient's agent at the time of dispensing that the prescription drug is being provided without the practitioner's authorization and that authorization of the practitioner is required for future refills; and

(d) the pharmacist informs the prescriber of the emergency refill as soon as practicable.

Unit-of-use quantities may be dispensed when appropriate.

Section 7. Continuous Quality Improvement Program.

(1) Continuous Quality Improvement Program

(a) Compliance with this Section may be considered by the board as a mitigating factor in the investigation and evaluation of a quality-related event (QRE).

(b) Each pharmacy shall establish a continuous quality improvement (CQI) program for the purpose of detecting, documenting, assessing, and preventing QREs. At a minimum, a CQI program shall include provisions to:

(i) designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI program;

(ii) initiate documentation of QREs as soon as possible, but no more than three (3) days, after determining their occurrence;

(iii) analyze data collected in response to QREs to assess causes and any contributing factors such as staffing levels, workflow, and technological support;

(iv) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.

For those persons utilizing a drug formulary, a periodic review of such formulary shall be undertaken to ensure that appropriate drugs are being offered/selected in the best interest of patients.

(c) As a component of its CQI program, each pharmacy shall ensure that periodic meetings are held, at least annually, by staff members of the pharmacy to consider the effects on the quality of the pharmacy system due to staffing levels, workflow, and technological support. Such meetings shall review data showing evidence of the quality of care for patients served by the pharmacy and shall develop plans for improvements in the system of pharmacy practice so as to increase good outcomes for patients.

(d) Appropriately blinded incidents of QREs shall be reported to a nationally recognized error reporting program designated by the board.

(e) Quality Self-Audit

Each Pharmacy shall conduct a quality self-audit at least quarterly to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future. Each

pharmacy shall conduct a quality self-audit upon change of pharmacist-in-charge to familiarize that person with the pharmacy's CQI program.

(f) Protection from Discovery[129]

All information, communications, or data maintained as a component of a pharmacy CQI program are privileged and confidential and not subject to discovery in civil litigation.[130] This shall not prevent review of a pharmacy's CQI program, and records maintained as part of a system by the board, pursuant to subpoena, as necessary to protect the public health and safety. All information, communications, or data furnished to any peer review committee, and any findings, conclusions, or recommendations resulting from the proceedings of such committee, board, or entity are privileged. The records and proceedings of any peer review committee are confidential and shall be used by such committee, and the members thereof, only in the exercise of the proper functions of the committee and shall not be public records nor be available for court subpoena or for discovery proceedings. The disclosure of confidential, privileged peer review committee information during advocacy, or as a report to the board of pharmacy, or to the affected pharmacist or pharmacy auxiliary personnel under review, does not constitute a waiver of either confidentiality or privilege.

(g) Compliance with Subpoena

All persons shall comply fully with a subpoena issued by the board for documents or information as otherwise authorized by law. The disclosure of documents or information under subpoena does not constitute a waiver of the privilege associated with a CQI program. Failure to comply with the subpoena is grounds for disciplinary action against the person by the appropriate licensing board.

Section 8. Shared Pharmacy Services.

(1) General Requirements[131, 132]

(a) The pharmacy must possess a resident or nonresident permit issued by the board prior to engaging in shared pharmacy services.[133]

(b) A pharmacy may provide or utilize shared pharmacy services only if the pharmacies involved:

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[129] Boards of pharmacy may have more or less authority to inspect CQI records, depending on state law. When authorizing the implementation of CQI Programs the extent of authority needed to obtain these materials must be determined.

[130] States should continue efforts to develop and implement requirements for CQI programs in pharmacies recognizing that CQI programs enhance patient safety and operate most effectively when privilege of discovery laws or rules protecting CQI data and information are enacted and included as a component of CQI.

[131] The Board may want to consider the extent to which this General Requirements Section is applicable to institutional-based shared pharmacy services pharmacies, as such application may be subject to interpretation of existing state and federal law governing institutional facilities.

[132] In order to ensure accountability, the pharmacist-in-charge of a pharmacy engaging in shared pharmacy services must possess a license to practice pharmacy in all jurisdictions that they are engaging in such series until such a time in which provisions for multistate practice exist.

[133] Often the terms "licensure," "registration," and "permit" are used interchangeably throughout the *Model Act*. In the case of shared pharmacy services pharmacies that utilize automated pharmacy systems, boards may determine that it is appropriate to issue a permit for the automated pharmacy system but not for the physical site where the automated pharmacy system is located.

(i) have the same owner; or
(ii) have a written contract or agreement that outlines the services provided and the shared responsibilities of each pharmacy in complying with federal and state pharmacy laws and rules; and
(iii) share a common electronic file or technology that allows access to information necessary or required to perform shared pharmacy services in conformance with the pharmacy act and the board's rules.

(c) A pharmacy engaged in shared pharmacy services shall comply with appropriate federal and state controlled substance registrations for each pharmacy if controlled substances are maintained.

(2) Operations

(a) Pharmacies engaging in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services shall:
(i) maintain records identifying, individually, for each prescription drug order processed, the name of each pharmacist or pharmacy intern who took part in the drug utilization review, refill authorization, or therapeutic intervention functions performed at that pharmacy and the name of any certified pharmacy technician or certified pharmacy technician candidate if they assisted in any of those functions;
(ii) maintain a mechanism for tracking the prescription drug order during each step of the processing and filling procedures performed at the pharmacy;
(iii) maintain a mechanism for the patient, upon request, to identify all pharmacies involved in filling the prescription drug order;
(iv) be able to obtain for inspection any required record or information requested by the board or its designee; and
(v) operate a continuous quality improvement program for shared pharmacy services.

(3) Policies and Procedures

(a) Each pharmacy in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services that outline the responsibilities of each pharmacy and describe policies reflecting operational requirements.

(4) Individual Practice

(a) Nothing in this Section shall prohibit an individual pharmacist licensed in the state, who is an employee of or under contract with a pharmacy or a licensed certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the prescription drug order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:
(i) the pharmacy establishes controls to protect the confidentiality and integrity of protected health information; and
(ii) no part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

Section 9. Automated Pharmacy Systems.

(1) Automated pharmacy systems can be utilized in licensed pharmacies and other locations approved by the board in accordance with all state and federal laws and rules. A pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is appropriately secured and monitored. Automated pharmacy systems shall comply with the following provisions:

(a) Documentation as to type of equipment, facility-specific unique identifiers, and policies and procedures. Such documentation shall include, but is not limited to:

(i) name and address of the pharmacy and the name and address of the location where the automated pharmacy system is being used;

(ii) manufacturer's name and model, if applicable; and

(iii) description of how the automated pharmacy system is used.

(b) Continuous quality assurance procedures
In order to facilitate communication between the pharmacy and the site where the automated pharmacy system is located, a pharmacy should provide a method of communication so that the pharmacist is accessible at all times the automated pharmacy system is operational.

(c) For remote dispensing to outpatients,[134] a video/auditory communication system shall allow for the appropriate exchange of oral and written communication and patient counseling; if the video/auditory communication system malfunctions, then all operations of the automated pharmacy system shall cease until the system is fully functional.

(d) Automated pharmacy systems shall have adequate security systems to:

(i) prevent unauthorized access;

(ii) comply with federal and state rules; and

(iii) prevent the illegal use or disclosure of protected health information.

(e) Records and/or electronic data kept by automated pharmacy systems must be maintained by the pharmacy and must be readily available to the board. Such records shall include:

(i) identification of the system accessed;

(ii) identification of the individual accessing the system:

(iii) type of transaction;

(iv) name, strength, dosage form, and quantity of the drug accessed;

(v) name of the patient for whom the drug was ordered; and

(vi) such additional information as the pharmacist-in-charge may deem necessary.

(f) Access to and limits on access (ie, security levels) to the automated pharmacy system shall be defined.[135]

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[134] Although an "outpatient" generally refers to a person who receives drugs for use outside of an institutional facility, the definition of "outpatient" must be defined by each state. For example, although the *Model Act* classifies penal institutions as a type of institutional facility and therefore its inmates as inpatients, the pharmacist is exempt from providing patient counseling. However, some states may consider inmates of penal institutions as outpatients and therefore should decide if a video/audio communication system is required in such facilities so that the pharmacist is able to provide patient counseling.

[135] This Section anticipates that decisions regarding which health care professionals may access the automated pharmacy system and the level of access allowed (eg, access to drugs, access to patient profiles for viewing only, access to patient profiles for modification) will be left up to the individual(s) responsible for the automated pharmacy system; however, states may decide to take on this responsibility and define those who may have access to the system and the levels of access allowed.

(g) Each automated pharmacy system shall have a designated pharmacist who shall have the responsibility to:
    (i) assign, discontinue, or change access to the system; and
    (ii) ensure that access to the drugs complies with federal and state rules.
(h) The filling/stocking of all drugs in the automated pharmacy system shall be accomplished by qualified personnel under the supervision of a licensed pharmacist. A record of drugs filled/stocked into an automated pharmacy system shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.[136]
(i) All prescription fulfillment activities shall take place in accordance with federal and state laws and rules.
(j) The automated pharmacy system shall provide a mechanism for securing and accounting for wasted or discarded drugs in accordance with existing state and federal law.

Section 10. Return and Reuse of Prescription Drugs.

(1) Prescription drugs may only be returned and reused providing that the prescription drugs were packaged in:
    (a) the original, sealed, and tamper-evident bulk, unit-of-use,[137] or unit dose packaging; or
    (b) the dispensing pharmacy's original packaging that maintains the product quality.
(2) All returned packaging must indicate that the prescription drug's integrity and stability have been maintained.
(3) All returned prescription drugs must be evaluated by appropriate pharmacy staff to ensure that such prescription drugs are not adulterated or misbranded.

Section 11. Prescription Drug Repository Programs.

(1) Repository programs must have written policies and procedures, which include at a minimum:
    (a) qualifications of acceptable drugs for reuse. Such qualifications must include the following provisions:
        (i) only non-controlled drugs will be accepted;[138]
        (ii) all drugs will be inspected by appropriate pharmacy staff and determined to be:
            (A) unadulterated;
            (B) unexpired; and
            (C) in unopened unit dose or manufacturer's tamper-evident original packaging, or otherwise approved by the board of pharmacy;
        (iii) maintenance of a separate physical inventory;
        (iv) completion of a monthly expiration date review for all drugs;

[136] This Section anticipates that states will allow non-pharmacist personnel to fill/stock automated pharmacy systems under a pharmacist's supervision; however, the state may decide to only allow a pharmacist to perform this function. Should the state allow non-pharmacist personnel to perform this function, it should define the level of pharmacist supervision necessary (eg, immediate, direct, or general).

[137] Unit-of-use is not intended to include co-mingled, multi-drug unit-of-use packages, also known as compliance packs.

[138] Except for federally scheduled controlled substance drugs that may be prescribed for substance use disorders and as allowed by federal and state laws and rules.

(v) prohibition for charging or accepting compensation for drugs except for administrative or minimal dispensing fees;
(vi) dispensing by a pharmacist or a practitioner within the practitioner's scope of practice; and
(vii) record keeping, including the source and dispensation of all drugs.

(b) A requirement that the patient receives notification that the drug is being dispensed by a repository program.

Section 12. Disposal of Controlled Substances.[139]

Any persons legally authorized to possess controlled substances in the course of their professional practice or the conduct of their business shall dispose of such drugs in compliance with federal law.

Section 13. Repackaging by Pharmacies for Own Use.

(1) A pharmacy may repackage drugs for its own use under the following circumstances:

(a) Containers utilized for repackaging shall meet, as a minimum requirement, Class B container standards as referenced by USP;

(b) The repackaging processes are conducted under conditions that ensure the integrity of the drug and under the direct supervision of a pharmacist;

(c) The repackaged drugs are labeled with the following components:
(i) drug name;
(ii) drug strength;
(iii) pharmacy control and manufacturer lot number;
(iv) name of the manufacturer or distributor of the drug or the national drug code; and
(v) beyond-use date, which shall be the manufacturer's expiration date or one that is required under the most current USP standards, whichever is earlier;

(d) Records of all repackaging operations are maintained and include the following:
(i) the name (nonproprietary and proprietary name), strength, dosage form, quantity per container, and quantity of containers of the drug being repackaged;
(ii) the name of the manufacturer or distributor of the drug;
(iii) pharmacy control and manufacturer lot number;
(iv) expiration date of the drug according to the original manufacturer or distributor container and the beyond-use date;
(v) the name, initials, or identification codes of the certified pharmacy technician or certified pharmacy technician candidate that repackaged the drug and the name or initials of the pharmacist that verified the appropriateness of the repackaged drug; and
(vi) the date the drug is repackaged.

(e) All drugs repackaged are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the

[139] Boards may give hospitals the authority to dispose of wasted quantities of controlled substances without prior authorization under specified conditions.

labeling of such drugs, or with requirements in the current edition of an official compendium.

(2) Pharmacies that store drugs within an automated counting device or automated pharmacy system may, in place of the required label, maintain records of lot numbers and beyond-use dates that are required on the label as long as they are fully traceable and readily retrievable.

(3) The pharmacist-in-charge is responsible for developing or adopting, implementing, and maintaining[140] policies and procedures addressing repackaging processes.

Section 14. Telepharmacy

(1) General Requirements
- (a) The pharmacy shall:
  - (i) obtain a resident or nonresident permit issued by the board prior to engaging in the practice of telepharmacy;
  - (ii) comply with appropriate federal and state controlled substance laws and rules for each pharmacy if controlled substances are maintained;
  - (iii) maintain additional policies and procedures specific to telepharmacy.

(2) Remote Dispensing Site Requirements[141]
- (a) The pharmacy shall obtain approval from the board to operate the remote dispensing site.
- (b) The pharmacist-in-charge of the supervising pharmacy shall be responsible for all operations.[142]
- (c) The pharmacy shall have a written contract or agreement that outlines the services provided and the responsibilities of each party in complying with federal and state pharmacy laws and rules.
- (d) Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least one (1) certified pharmacy technician.[143] All certified pharmacy technicians and certified pharmacy technician candidates shall be under the supervision of a pharmacist at all times that the remote site is operational. The pharmacist shall supervise telepharmacy operations electronically.
- (e) The remote dispensing site and the supervising pharmacy must utilize a common electronic record-keeping system that must be capable of the following:
  - (i) Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site at all times of operations; and

[140] The owner and/or pharmacy permit holder, along with the pharmacist-in-charge, are responsible for these policies and procedures.

[141] To allow for emerging practice models, states should not impose volume restrictions, mileage restrictions, or unnecessary limitations that would limit patient access to remote dispensing sites.

[142] The pharmacist-in-charge shall oversee inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

[143] States may allow pharmacy interns to perform the functions of a certified pharmacy technician at a remote dispensing site.

(ii) Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed from the supervising pharmacy.

(f) Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, state and federal law.

(g) A supervising pharmacy of a remote dispensing site must maintain a video and audio communication system that provides for effective communication between a pharmacist and the remote dispensing site personnel and patients or caregivers. The system must facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or delivery of drugs. The remote dispensing site must use telepharmacy technology that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription drug order.

(h) A pharmacist must be present at the supervising site or the remote dispensing site for the remote dispensing site to be open for employees to be allowed to access it. The security system must allow for tracking of entries into the remote dispensing site, and the pharmacist-in-charge must periodically review the provision of access and record of entries.

(i) A remote dispensing site must display a sign, easily visible to the public, which informs patients that a pharmacist is available to counsel the patient using audio and video communication systems each time a new drug is dispensed and at the time it is refilled, if necessary, at a remote dispensing site.

Section 15. Provision of Pharmacist Care Services Outside of a Licensed Pharmacy.

In order for a pharmacist to provide pharmacist care services outside the premises of a licensed pharmacy, an applicant shall:

(1) register/license with the board(s) or; if located out of state, have an active NABP Verify credential;

(2) have appropriate security and protections in place to ensure the confidentiality of records or other patient-specific information;

(3) maintain such records in readily retrievable form; and

(4) follow the patient care process approved by the board.[144]

Section 16. Approval of Pharmacy Practice Initiatives.[145]

(1) Application[146]

[144] It is anticipated that boards use the current *Pharmacists' Patient Care Process* approved by the Joint Commission of Pharmacy Practitioners.

[145] This may also be referred to as Approval of Rule Waiver Requests.

[146] Boards may want to develop language addressing the time frame within which they will take action on an application for approval of a pharmacy practice initiative.

An application for approval of a pharmacy practice initiative that improves the quality of or access to pharmacist care services, but which falls outside the scope of present regulations, shall be submitted to the board and shall contain at least the following information:

(a) The name, address, telephone number, and the license number of the pharmacist responsible for overseeing the initiative;

(b) The specific location and, if a pharmacy, the pharmacy name, address, telephone, and license number where the proposed pharmacy practice initiative will be conducted; and

(c) A detailed summary of the proposed pharmacy practice initiative, which includes:

(i) the goals and/or objectives of the proposed pharmacy practice initiative;

(ii) a full explanation of the initiative and how it will be conducted;

(iii) the time frame for the pharmacy practice initiative, including the proposed start date;

(iv) background information or literature review to support the proposal, if applicable;

(v) the rule(s) that will have to be waived in order to complete the pharmacy practice initiative and a request to waive the rule(s); and

(vi) procedures to be used during the pharmacy practice initiative to ensure that the public's health and safety are not compromised as a result of the rule waiver.

(2) Approval by the Board

The board shall approve a pharmacy practice initiative if it determines that:

(a) the pharmacy practice initiative will improve the quality of or access to pharmacist care services;

(b) the pharmacy practice initiative will not adversely affect, directly or indirectly, the health, safety, or well-being of the public; and

(c) the alternative measures to be taken, if any, are equivalent or superior to those prescribed in the part for which the rule waiver is requested.

The board shall deny, revoke, or refuse to renew an application for a pharmacy practice initiative if the board determines that the above requirements have not been met. In issuing an approval for a pharmacy practice initiative, the board may impose such terms and conditions it deems appropriate to carry out the purposes of Section 213(1)(o) of this Act and the rules adopted thereunder.

(3) Notification

The board shall notify the applicant in writing within sixty (60) days of the board's decision. If an approval is granted, the notification shall specify the period of time for which the approval and rule waiver will be effective and any conditions to be met by the applicant.

(4) Extension of Approval of Pharmacy Practice Initiatives

A request for an extension of an approval of a pharmacy practice initiative shall be submitted in writing at least _____ days prior to the expiration date of the existing approval. Renewal requests shall contain the information specified in subsection (1). An approval of a pharmacy practice initiative shall be renewed by the board if the applicant continues to satisfy the criteria contained in subsection (2) and demonstrates compliance with the alternative measures or conditions imposed at the time the original pharmacy practice initiative was approved.