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VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI 53705
Contact: Brad Wojciechowski (608) 266-2112
October 20, 2021

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

8:30 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1)

B. Administrative Rule Matters – Discussion and Consideration (2-109)

1) Phar 1, 6, 7, 8, 12, and 13, Relating to Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors
2) Phar 15, Relating to Compounding Pharmaceuticals
3) Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

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

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

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**10/08/21** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Pharmacy Examining Board - Rules Committee

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10/20/21	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Phar 1, 6, 7, 8, 12, and 13 Electronic Track and Trace Pedigree System, Drug Supply Chain Security, Manufacturers, and Distributors** 2. **Phar 15, Compounding Pharmaceuticals** 3. **Pending or Possible Rulemaking Projects**

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

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

Attachments:
1. Phar 1,6, 7, 8, 12, 13 Redlined Draft Text
2. 2007 WI Act 20 (pp. 588-594)
3. Title II of the Drug Quality and Security Act
4. Phar 15 Scope Statement
5. Phar 15 Code Chapter
6. USP FAQs on Compounding Appeals

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

11) Authorization

Nilajah D. Hardin — 10/08/21

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

Supervisor (if required) — **Date**

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

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

Chapter Phar 1

AUTHORITY AND DEFINITIONS

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

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

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

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

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

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

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

Note: The board office is located at 1400 East Washington Avenue, Madison, Wisconsin 53702.

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

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

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

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

"Electronic Database"

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(13) "PRN" means renew as needed.

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

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

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

"Repackager" means a person that repackages.

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

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

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

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

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

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

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

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

Chapter Phar 6

PHARMACY LICENSES AND EQUIPMENT

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

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

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

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

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

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

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

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

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

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

1. A secured, physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by unlicensed personnel. A secured barrier may be constructed of

other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

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

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

5. Signs of reasonable size are posted at the entrance of the building and the professional service area prominently displaying the hours the pharmacist will be on duty.

6. The manner in which the telephone is answered does not imply that the location is, at that time, operating as a pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Chapter Phar 7

PHARMACY PRACTICE

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

Subchapter I — General

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

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

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

(3) "NDC" means national drug code.

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

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

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

(a) Date of issue.

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

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

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

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

(f) Refills, if any.

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

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

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

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

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

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

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

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

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

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

6. Refills, if any.

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

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

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

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

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

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

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

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

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

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

(a) Known allergies.

(b) Rational therapy.

(c) Contraindications.

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

(e) Reasonable directions for use.

(f) Potential or actual adverse drug reactions.

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

(h) Therapeutic duplication.

(i) Reasonable utilization and optimum therapeutic outcomes.

(j) Potential abuse or misuse.

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

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

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

a. Verbal communication between two pharmacists.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Record the date of the transfer.

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

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

1. Date of issuance of the original prescription order.

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

3. Date of original dispensing.

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

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

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

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

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

1. The date of the original dispensing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Pharmacy name, address and telephone number.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

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

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

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

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

(c) Written or graphic product descriptions.

(d) Any cautions or other provisions.

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

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

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

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

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

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

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

(b) One of the following identifiers:

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

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

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

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

(c) Manufacturer lot number.

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

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

(f) Date of repackaging.

(g) Any pharmacy control numbers.

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

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

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

(c) Completion of the drug utilization review.

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

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

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

(b) Is a change in therapy.

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

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

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

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

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

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

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

(a) Name and description of the drug.

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

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

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

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

(f) Techniques for self-monitoring drug therapy.

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

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

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

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

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

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

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

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

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

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

(a) Timeliness of delivery.

(b) Condition of the prescription drug upon delivery.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The following minimum information shall be retrievable:

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

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

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

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

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

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

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

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

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

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

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

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

(a) Is at least 18 years old.

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

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

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

a. Drug name.

b. Strength.

c. Formulation.

d. Expiration date.

e. Beyond use date.

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

a. Wrong medication.

b. Wrong strength.

c. Wrong formulation.

d. Extra or insufficient quantity.

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

f. Expired medication.

g. Look-alike or sound-alike errors.

h. High-alert medications.

3. Eligible medications for delegate-check-delegate.

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

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

a. Procurement.

b. Ordering.

c. Dispensing.

d. Administration.

e. Monitoring.

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

a. Wrong drug.

b. Wrong strength.

c. Wrong formulation.

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

(d) Completed the following validation process:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Name of the product verification delegate.

2. Total number of product verifications performed.

3. Number of product verifications audited by the pharmacist.

4. Percentage of product verifications audited by pharmacist.

5. Percentage of accuracy.

6. Number of product verification errors identified.

7. Type of error under sub. (2) (c) 2. a. to c. and e.

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

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

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

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

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

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

indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.

3. Quality assurance audits and quarterly assessments.

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

Subchapter II — Central Shared Services

Phar 7.30 **Definitions.** In this subchapter:

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

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

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

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

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

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

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

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

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

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

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

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 **Definitions.** In this subchapter:

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

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

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

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

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

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

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

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

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

(a) Stocking of the delivery system.

(b) Determining access to the delivery system.

(c) Detection and mitigation of diversion and theft.

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

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

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

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

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

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

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

(a) Stocking.

(b) Determining access.

(c) Detection and mitigation of diversion and theft.

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

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

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

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

1. Prescriptions may be filled at this location.

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

a. Name of pharmacy.

b. Address of pharmacy.

c. Telephone of pharmacy.

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

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

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

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

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

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

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

(c) Final check under s. Phar 7.07.

(d) Federal law if dispensing controlled substances.

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

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

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

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

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

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

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

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

(a) Be 18 years of age or older.

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

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

Subchapter IV — Institutional Pharmacies

Phar 7.50 **Definitions.** In this subchapter:

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

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

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

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

(1) First and last name of the patient.

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

(3) Date of issuance.

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

(5) Directions for use.

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

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

(b) Electronic signature of the practitioner or delegate.

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

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

(1) Drug name, strength and form.

(2) Beyond use date or expiration date.

(3) Special storage conditions, if required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Located within a licensed pharmacy.

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

(c) Validated by the following process:

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

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

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

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

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

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

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

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

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

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

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

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

4. Documentation of the dates of all software upgrades.

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

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

Subchapter V — Unlicensed Persons

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

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

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

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

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

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

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

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

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

(d) Provide patient specific counseling or consultation.

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

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

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

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

Chapter Phar 8

REQUIREMENTS FOR CONTROLLED SUBSTANCES

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

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

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

(2m) Records required under s. 450.11 (1b) (bm), Stats., shall be maintained for at least 5 years from the date the drug was dispensed, or, for a record that is subject to s. 961.385, Stats., until the name of a person to whom a drug is dispensed is delivered to the controlled substances board under s. 961.385, Stats., whichever is sooner.

(3) Required records shall be maintained as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

Phar 8.04 **Purpose of issue of prescription order. (1)** Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. The person knowingly dispensing pursuant to such a purported order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

(2) A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid.

Phar 8.05 **Dispensing. (1)** All controlled substance prescription orders shall be dated as of, and signed on, the day issued and shall contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and

registration number of the practitioner. Prescription orders shall be written with ink or indelible pencil or be typewritten and shall be signed by the practitioner. Orders for controlled substances may be issued only by individual practitioners who are authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice and registered or exempt from registration under the federal controlled substances act.

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

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

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

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

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

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

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

1. Date authorization is received.

2. Quantity of drug authorized.

3. Number of renewals.

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

5. Identification of the pharmacist who received the authorization.

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

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

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

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

(2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.

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

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

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

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

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

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

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

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

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

(b) No appropriate alternative treatment is available, including the administration of a drug which is not a schedule II controlled substance.

(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.

(2) In an emergency a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a practitioner if:

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

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

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

(4) Within 7 days after authorizing an emergency oral prescription order, the practitioner shall cause a written or electronic order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of s. Phar 8.05, the order shall contain on its face “authorization for emergency dispensing" and the date of the oral order. The written or electronic order may be delivered to the pharmacist in person or by mail or

electronically, but if delivered by mail it shall be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the oral emergency order reduced to writing under sub. (2) (b). The pharmacist shall notify the board or department of safety and professional services if the practitioner fails to deliver the written or electronic order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written or electronic order of a practitioner.

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

Phar 8.11 **Controlled substances in emergency kits for long term care facilities.** Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

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

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

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

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

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

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

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

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

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

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

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

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

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

Phar 8.13 **Identification card exception for a health care facility.** In s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.

Chapter Phar 12

MANUFACTURER REQUIREMENTS

Phar 12.01 **Authority.** The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a) and 450.07 (4), Stats.

Phar 12.02 **Definitions.** In this chapter:

(1) "Device" has the meaning set forth in s. 450.01 (6), Stats.

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

(3) "Establishment" means a place of business under one management at one general physical location.

~~**(4)** "Manufacturer" means a person licensed by the board under this chapter.~~

(5) "Manufacturing" has the meaning set forth in s. 450.01 (13), Stats.

(6) "Prescription drug" has the meaning set forth in s. 450.01 (20), Stats.

Phar 12.03 **License; application.** **(1)** No person may engage in the manufacturing of any drug or device in this state unless a license is granted to the person by the board under this chapter.

(2) To obtain a license a person shall do all of the following:

(a) Submit an application on a form provided by the board.

(b) Pay the fee specified in s. ~~440.05 (1)~~ 440.03 (9) (a), Stats.

(c) Meet the inspection requirement under s. Phar 12.04.

(d) Register with the food and drug administration and comply with all applicable requirements of 21 CFR 200, 201, 202, 207, 210 and 211.

(e) If applicable, register with the drug enforcement administration and comply with all appropriate requirements of 21 CFR 1301, 1302, 1303, 1304, 1305, 1307, 1311 and 1312.

Note: An application form may be obtained from the ~~board office, 1400 East Washington Avenue, Madison, Wisconsin 53702~~ Department of Safety and Professional Services's website: http://dsps.wi.gov. Copies of federal applications, laws and regulations may be obtained from the Food and Drug Administration, 5600 Fischers Lane, Rockville, Maryland 20857 and the Drug Enforcement Administration, 500 Dirksen Federal Building, 219 Dearborn, Chicago, Illinois 60604.

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(3) A manufacturer license may not be transferred from one establishment to another nor from one person to another. Each establishment requires a separate license.

(4) If the license is denied, the applicant may request a hearing before the board on the denial.

(5) The board shall act on the application for a license within 60 business days after receiving the completed application, as provided in s. SPS 4.03.

Phar 12.04 **Inspections.** Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985).

Phar 12.05 **Compliance.** Failure to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

Phar 12.06 **Authorized distributors of record.** A manufacturer shall maintain and update at least once per month a list of the manufacturer's authorized distributors of record.

Chapter Phar 13

WHOLESALE DISTRIBUTOR REQUIREMENTS

Phar 13.01 **Authority.** The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 450.02 (3) (a) and 450.07 (4), Stats.

Phar 13.02 **Definitions.** In this chapter:

(1) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(2) "Blood component" means that part of blood separated by physical or mechanical means.

(3) "Controlled substance" has the meaning set forth in s. 961.01 (4), Stats.

(3m) "Department" means the department of safety and professional services.

(4) "Device" has the meaning set forth in s. 450.01 (6), Stats.

(5) "Distribute" has the meaning set forth in s. 450.01 (8), Stats.

(7) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

~~**(8)** "Facility" means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.~~

~~**(9)** "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidance implementing the federal prescription drug marketing act.~~

(10) "Prescription drug" has the meaning set forth in s. 450.01 (20), Stats.

(11) "Wholesale distribution" means distribution of a prescription drug to a person other than a consumer or patient, but does not include any of the following:

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(a) Intracompany sales of prescription drugs which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under common ownership or control of a corporate entity or any transaction between co-licensees or a co-licensed product.

(b) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples, if the distribution is permitted under 21 CFR 353 (d).

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution as provided in 21 CFR 203.23.

(e) Distributions to a practitioner for the purpose of general dispensing by the practitioner to his or her patients if all of the following apply:

1. The total number of dosage units of all prescription drugs distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all prescription drugs distributed and dispensed by the pharmacy during the same calendar year.

2. The total number of dosage units of all controlled substances distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of

the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the same calendar year.

(f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer states in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the drug and the supplying authorized distributor of record states in writing that the drug has previously been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the drug.

(j) A transaction excluded from the definition of "wholesale distribution" under 21 CFR 203.3 (cc).

(k) The donation or distribution of a prescription drug under s. 255.056, Stats.

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale distributor or to a 3rd-party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

(12) "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; manufacturers' authorized distributors of record; prescription drug wholesalers and distributors; independent wholesale prescription drug traders; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

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Phar 13.05 **License; other requirements.** In addition to providing the application information, to obtain a license a person shall:

(1) Pay the fee specified in s. ~~440.05 (1)~~ 440.03 (9) (a), Stats.

(2) Pass an inspection of the facility conducted by the board or its representative in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each inspection to determine if the location meets standards specified in ss. Phar 13.08 to 13.11.

(3) Register with the drug enforcement administration, if intending to distribute controlled substances.

Note: An application form may be obtained from the Department of Safety and Professional Service's website: http://dsps.wi.gov. Copies of federal applications may be obtained from the Drug Enforcement Administration, Suite 500, Dirksen Federal Building, 219 South Dearborn Street, Chicago, Illinois 60604. Copies of federal statutes and rules may be obtained from the Superintendent of Documents, Government Printing Office, Washington DC 20402-9325.

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Phar 13.055 **Surety bond, irrevocable letter of credit.** The applicant shall supply a surety bond or irrevocable letter of credit in the amount of $5,000.00, which is issued by a company authorized to do business in Wisconsin. The form of the bond or letter of credit shall be approved by the department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a wholesale distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this section more than one year after the date on which the applicant's wholesale distributor's license expires.

Phar 13.06 **License; factors considered.** In determining eligibility for a distributor's license, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under federal, state, or local laws, the circumstances of which are substantially related to the practice of a wholesale distributor;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or wholesale distribution;

(5) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any devices or drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with the requirements to maintain or make available to a state licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug or device distributors; and

(8) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

Phar 13.07 **Application review.** The board shall act upon an application for a license within 60 business days after receiving the completed application, as provided in s. SPS 4.03. If the license is denied, the applicant may request a hearing pursuant to ch. SPS 1.

Phar 13.08 **Personnel.** A wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

Phar 13.09 **Facility requirements.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

Phar 13.10 **Security requirements.** All facilities shall require that:

(1) Access from outside the premises is kept to a minimum and be well controlled;

(2) The outside perimeter of the premises is well lighted;

(3) Entry into areas where prescription drugs are held is limited to authorized personnel;

(4) An alarm system is maintained to detect entry after hours; and

(5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Phar 13.11 **Storage requirements. (1)** All prescription drugs stored in a facility shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such products, or with requirements in the current edition of an official compendium.

(2) If no storage requirements are established for a prescription drug, the product may be held at a controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, or logs shall be utilized to document proper storage of prescription drugs.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all stored drugs.

Phar 13.12 **Examination of materials requirements. (1)** Upon receipt by a facility, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs, or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment from a facility shall be carefully inspected for identity of the prescription drug and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in s. Phar 13.14 shall be followed for all incoming and outgoing prescription drugs at a facility.

Phar 13.13 **Returned, damaged and outdated prescription drug requirements. (1)** Notwithstanding the pedigree requirements in Phar 13.135, Prescription drugs in a facility that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. Wholesale distributors shall only return such prescription drugs to supplier that are either the original manufacturer of the products or to a 3rd party returns processor.

Commented [HN-D7]: Section 3530g of 2007 WI Act 20 (p. 592)

(2) Any prescription drugs in a facility whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned to a facility cast doubt on the product's safety, identity, strength, quality, or purity, then the product shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the product meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a product has been returned cast doubt on its safety, identity,

strength, quality, or purity, the distributor shall consider, among other things, the conditions under which the product has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(5) A wholesale distributor shall only receive drug returns or exchanges from a pharmacy, a pharmacist, or a pharmacy's intracompany warehouse.

(6) A manufacturer, wholesale distributor, pharmacy, or pharmacist shall ensure that the return process is secure from adulterated or counterfeit substances.

Commented [HN-D8]: Section 3530g of 2007 WI Act 20 (p. 592)

Phar 13.135 **Pedigree requirements**. (1) A wholesale distributor shall establish and maintain a pedigree for each prescription drug that that leaves the normal distribution channel.

(2) A wholesale distributor shall provide a copy of the pedigree to the entity receiving the drug before that prescription drug leaves the normal distribution channel.

(3) A prescription drug pedigree shall include all of the following:

(a) The name, address, phone number, and electronic mail address, if applicable, of each recipient or wholesale distributor in the distribution chain until the final sale or wholesale distribution of the prescription drug as described in s. 450.073 (2) (intro.), stats.

(b) The date of each distribution

(c) A certification that each recipient has verified the pedigree for the prescription drug before sending it to the next point in the distribution chain

(d) The name, dosage strength, lot number, quantity, and name of each prescription drug.

(4) An electronic track and trace pedigree system is required to monitor each prescription drug that is subject to wholesale distribution, and shall include all of the following:

(a) The transaction history

(b) The transaction information

(c) The pedigree

(5) A secure electronic database may be established by the wholesale distributor to store the information required under sub.(4). This database may be developed and operated by an entity other than the wholesale distributor. The owner of the database shall have the ability to respond to data access requests and provide data access to other members of the pharmaceutical supply chain.

(5) A wholesale distributor shall verify that each transaction on the pedigree for a prescription drug has occurred prior to proceeding with distribution.

(6) Each pedigree shall be maintained by the entity who purchased and the wholesale distributor of each prescription drug for a minimum of 3 years from the date of distribution.

(7) Exceptions

Phar 13.14 **Recordkeeping requirements. (1)** A wholesale distributor shall establish and maintain inventories and records of all transactions regarding the receipt and wholesale distribution or other disposition of prescription drugs. These records shall include the following information:

(a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped:

(b) The identity and quantity of the drugs received and distributed or disposed of; and

(c) The dates of receipt and wholesale distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and copying by the board, its authorized representatives, and authorized representatives of federal, state and local law enforcement agencies for a period of 3 years following wholesale distribution or other disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by the board or its authorized representative.

Phar 13.15 **Written policies and procedures.** A wholesale distributor shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. A wholesale distributor shall include in their written policies and procedures the following:

(1) A procedure to ensure that the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other governmental agency, including the board;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(c) Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that a wholesale distributor prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs are segregated from other products and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 3 years after disposition of the outdated drugs.

Phar 13.16 **Responsible persons.** A wholesale distributor shall establish and maintain lists of officers, directors, managers, and the designated representative in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Phar 13.17 **Compliance with federal, state and local laws. (1)** A wholesale distributor shall operate in compliance with applicable federal, state, and local laws and regulations. ~~A distributor shall operate in compliance with any applicable federal electronic track and trace pedigree system implemented after July 1, 2011, unless an earlier implementation date is mandated by federal law which explicitly preempts state law.~~ A wholesale distributor that deals in controlled substances shall register with the drug enforcement administration.

(2) Failure to comply with applicable federal, state, and local laws and regulations constitutes unprofessional conduct for purposes of s. 450.10, Stats.

(3) A wholesale distributor shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records, prescription drug pedigrees, and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to a wholesale distributor's premises and delivery vehicles.

447.05 Expiration and renewal. Renewal applications shall be submitted to the department on a form provided by the department on or before the applicable renewal date specified under s. 440.08 (2) (a) and shall include the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a). The examining board may not renew a license to practice dental hygiene unless the applicant for renewal attests that he or she has complied with s. 447.055 and any rules promulgated by the department under s. 447.055 and that he or she has a current certification in cardiopulmonary resuscitation.

SECTION 3519. 448.07 (2) of the statutes is amended to read:

448.07 **(2)** FEES. The fees for examination and licenses granted ~~or renewed~~ under this subchapter are specified in ~~ss.~~ s. 440.05, and ~~440.08~~ the renewal fee for such licenses is determined by the department under s. 440.03 (9) (a).

SECTION 3520. 448.55 (2) of the statutes is amended to read:

448.55 **(2)** The renewal dates for licenses granted under this subchapter, other than temporary licenses granted under rules promulgated under s. 448.53 (2), are specified under s. 440.08 (2) (a). Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) and proof of compliance with the requirements established in any rules promulgated under sub. (3).

SECTION 3521. 448.65 (2) (a) of the statutes is amended to read:

448.65 **(2)** (a) The renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under 440.03 (9) (a).

SECTION 3522. 448.86 (2) of the statutes is amended to read:

448.86 **(2)** The renewal dates for certificates granted under this subchapter, other than temporary certificates granted under s. 448.80, are specified under s. 440.08 (2) (a). Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a).

SECTION 3523. 448.955 (2) (intro.) of the statutes is amended to read:

448.955 **(2)** (intro.) Renewal applications shall be submitted to the department on a form provided, subject to sub. (3), by the department and shall include the renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) and evidence satisfactory to the affiliated credentialing board that the licensee has all of the following:

SECTION 3524. 448.967 (2) of the statutes is amended to read:

448.967 **(2)** The renewal dates for licenses granted under this subchapter are specified under s. 440.08 (2) (a). Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee ~~specified in s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) and a statement attesting compliance with the continuing education requirements established in rules promulgated under s. 448.965 (1) (b).

SECTION 3525. 449.06 (1) of the statutes is amended to read:

449.06 **(1)** Persons practicing optometry shall, on or before the applicable renewal date specified under s. 440.08 (2) (a), register with the department, pay the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a), and provide evidence satisfactory to the examining board that he or she has complied with the rules promulgated under sub. (2m).

SECTION 3526. 449.17 (8) of the statutes is amended to read:

449.17 **(8)** REIMBURSEMENT PROHIBITED. No optometrist may be reimbursed under s. 49.46 (2) (a) 3. or 49.471 (11) for any increase in charges or separate charge which is attributable to the use of topical ocular diagnostic pharmaceutical agents.

SECTION 3526a. 450.01 (1p) of the statutes is created to read:

450.01 **(1p)** "Affiliated group" has the meaning given in section 1504 of the Internal Revenue Code.

SECTION 3526b. 450.01 (1t) of the statutes is created to read:

450.01 **(1t)** "Authenticate" means to affirmatively verify, before wholesale distribution of a prescription drug occurs, that each transaction listed on a pedigree has occurred.

SECTION 3526c. 450.01 (1x) of the statutes is created to read:

450.01 **(1x)** "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. For purposes of this subsection, an ongoing relationship exists between a wholesale distributor and a manufacturer if all of the following apply:

(a) The wholesale distributor, including any affiliated group of the wholesale distributor, has in effect a written agreement with the manufacturer evidencing the ongoing relationship.

(b) The wholesale distributor, including any affiliated group of the wholesale distributor, is included in the manufacturer's current list of authorized distributors of record.

SECTION 3526d. 450.01 (2m) of the statutes is created to read:

450.01 **(2m)** "Colicensed" means, with respect to a partner or product, that 2 or more parties have the right to engage in marketing or manufacturing of a product consistent with the federal food and drug administration's implementation of the federal prescription drug marketing act.

Section 3526e. 450.01 (9m) of the statutes is created to read:

450.01 **(9m)** "Drop shipment" means a sale of a prescription drug to a wholesale distributor by the manufacturer of the drug, by the manufacturer's colicensed product partner, by the manufacturer's 3rd party logistics provider, or by the manufacturer's exclusive distributor, to which all of the following apply:

(a) The wholesale distributor or chain pharmacy warehouse takes title to, but not physical possession of, the drug.

(b) The wholesale distributor invoices a pharmacy, a chain pharmacy warehouse, or a person authorized to dispense or administer the drug to a patient.

(c) The pharmacy, chain pharmacy warehouse, or person authorized to dispense or administer the drug receives delivery of the drug directly from the manufacturer, the manufacturer's 3rd party logistics provider, or the manufacturer's exclusive distributor.

Section 3526f. 450.01 (11m) of the statutes is created to read:

450.01 **(11m)** "Facility" means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.

Section 3526g. 450.01 (11r) of the statutes is created to read:

450.01 **(11r)** "Intracompany sales" means any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity or any transaction or transfer between colicensees of a colicensed product.

Section 3526h. 450.01 (12) of the statutes is amended to read:

450.01 **(12)** "Manufacturer" means a person licensed ~~by the board under s. 450.07 (1)~~ or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidances implementing the federal prescription drug marketing act.

Section 3526i. 450.01 (12m) of the statutes is created to read:

450.01 **(12m)** "Manufacturer's exclusive distributor" means a person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer and who takes title to the manufacturer's prescription drug but who does not have general responsibility to direct the sale or disposition of the drug.

Section 3526j. 450.01 (13r) of the statutes is created to read:

450.01 **(13r)** (a) "Normal distribution channel" means a chain of custody for a prescription drug that runs, directly or by drop shipment, from the manufacturer of a drug, from the manufacturer to the manufacturer's colicensed partner, from the manufacturer to the manufacturer's 3rd−party logistics provider, or from the manufacturer to the manufacturer's exclusive distributor, and continues as described in any of the following:

1. To a pharmacy or to a person authorized to dispense or administer a drug to a patient.

2. To an authorized distributor of record, and then to a pharmacy or to a person authorized to dispense or administer a drug to a patient.

3. To an authorized distributor of record, then to one other authorized distributor of record, then to an office−based practitioner.

4. To a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

5. To an authorized distributor of record, then to a pharmacy warehouse, then to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

(b) For purposes of this subsection, a distribution of a prescription drug to a warehouse or to another entity that redistributes the drug by intracompany sale to a pharmacy or to another person authorized to dispense or administer the drug constitutes a distribution to the pharmacy or to the person authorized to dispense or administer the drug.

Section 3526k. 450.01 (14m) of the statutes is created to read:

450.01 **(14m)** "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug.

Section 3526km. 450.01 (15m) of the statutes is created to read:

450.01 **(15m)** "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales.

Section 3526kr. 450.01 (20) of the statutes is amended to read:

450.01 **(20)** "Prescription drug" means all of the following, but does not include blood, blood components intended for transfusion, or biological products that are also medical devices:

(a) ~~Any~~ A drug, drug product, or drug−containing preparation ~~which~~ that is subject to 21 USC 353 (b) or 21 CFR 201.105.

(b) ~~Any~~ A controlled substance included in schedules II to V of ch. 961, whether by statute or rule, except ~~substances which~~ a substance that by law may be dispensed without the prescription order of a practitioner. Con-

trolled substances are included within this definition for purposes of s. 450.11 (3), (4) (a), and (8) only and for violations thereof punishable under s. 450.11 (9).

Section 3526L. 450.01 (21e) of the statutes is created to read:

450.01 **(21e)** "Repackage" means to repack or otherwise change the container, wrapper, or label of a prescription drug, except that "repackage" does not include any of the following:

(a) An action by a pharmacist with respect to a prescription drug that the pharmacist is dispensing.

(b) An action by a pharmacist who receives a prescription drug or device that the pharmacist dispensed to a patient, if, after altering the packaging or labeling of the prescription drug or device, the pharmacist returns the prescription drug or device to the patient.

Section 3526m. 450.01 (21m) of the statutes is created to read:

450.01 **(21m)** "Repackager" means a person that repackages.

Section 3526n. 450.01 (21s) of the statutes is created to read:

450.01 **(21s)** "Third party logistics provider" means a person that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

Section 3526o. 450.01 (23) of the statutes is created to read:

450.01 **(23)** "Wholesale distribution" means distribution of a prescription drug to a person other than a consumer or patient, but does not include any of the following:

(a) Intracompany sales of prescription drugs.

(b) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples, if the distribution is permitted under 21 CFR 353 (d).

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution as provided in 21 CFR 203.23.

(e) The sale of minimal quantities, as defined by the board in an administrative rule, of prescription drugs by retail pharmacies to licensed practitioners for office use.

(f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer states in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the drug and the supplying authorized distributor of record states in writing that the drug has previously been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the drug.

(j) A transaction excluded from the definition of "wholesale distribution" under 21 CFR 203.3 (cc).

(k) The donation or distribution of a prescription drug under s. 255.056.

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale distributor or to a 3rd−party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

Section 3526p. 450.01 (24) of the statutes is created to read:

450.01 **(24)** "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including manufacturers, repackagers, own−label distributors, private label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, manufacturers' exclusive distributors, manufacturers' authorized distributors of record, prescription drug wholesalers and distributors, independent wholesale prescription drug traders, 3rd party logistics providers, retail pharmacies that conduct wholesale distribution, and chain pharmacy warehouses that conduct wholesale distribution.

Section 3527. 450.06 (2) (c) of the statutes is amended to read:

450.06 **(2)** (c) The initial credential fee ~~under s. 440.05 (1)~~ determined by the department under s. 440.03 (9) (a) is paid.

Section 3528. 450.065 (2) (d) of the statutes is amended to read:

450.065 **(2)** (d) Pays the initial credential fee ~~under s. 440.05 (1)~~ determined by the department under s. 440.03 (9) (a).

Section 3530a. 450.07 (title) of the statutes is amended to read:

450.07 (title) **Manufacturers ~~and distributors~~; licensure.**

Section 3530at. 450.07 (1) of the statutes is amended to read:

450.07 **(1)** No person may engage in manufacturing in this state unless the person obtains a manufacturer's license from the board. For the issuance of a license under this subsection, the applicant shall pay the initial credential fee ~~specified in s. 440.05 (1)~~ determined by the department under s. 440.03 (9) (a).

Section 3530b. 450.07 (2) of the statutes is repealed.

Section 3530c. 450.07 (3) of the statutes is repealed.

Section 3530d. 450.07 (4) (c) of the statutes is created to read:

450.07 **(4)** (c) The rules adopted by the board under par. (b) shall require a manufacturer to maintain and to update at least once per month a list of the manufacturer's authorized distributors of record.

Section 3530e. 450.071 of the statutes is created to read:

450.071 Wholesale distributors; licensure. (1) No person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license from the board for each facility from which the person distributes prescription drugs. The board shall exempt a manufacturer that distributes prescription drugs or devises manufactured by the manufacturer from licensing and other requirements under this section to the extent the license or requirement is not required under federal law or regulation, unless the board determines that it is necessary to apply a requirement to a manufacturer.

(2) An applicant shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's wholesale distribution business is a partnership, the name of each partner and the name of the partnership.

(f) If the applicant's wholesale distribution business is a corporation, the name of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's wholesale distribution business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person listed in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's places of residence for the 7−year period immediately preceding the date of the application.

3. The person's occupations, positions of employment, and offices held during the 7−year period immediately preceding the date of the application.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement indicating whether the person has been, during the 7−year period immediately preceding the date of the application, the subject of any proceeding for the revocation of any business or professional license and the disposition of the proceeding.

6. A statement indicating whether the person has been, during the 7−year period immediately preceding the date of the application, enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction.

7. A description of any involvement by the person during the past 7 years with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits in which such a business was named as a party.

8. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the applicant shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.

9. A photograph of the person taken within the 12−month period immediately preceding the date of the application.

(k) A statement that each facility used by the applicant for the wholesale distribution of prescription drugs has been inspected in the 3−year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.

(3) The board shall grant a license to the applicant to engage in the wholesale distribution of prescription drugs if all of the following apply:

(a) The applicant pays the fee under s. 440.05 (1) (a), except that before June 1, 2010, the amount of the initial fee is $350.

(b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements adopted by the board for wholesale distribution facilities.

(c) All of the following apply to each person identified by the applicant as a designated representative:

1. The person is at least 21 years old.

2. The person has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs.

3. The person is employed by the applicant full time in a managerial level position.

4. The person is physically present at the wholesale prescription drug distributor's facility during regular business hours and is involved in and aware of the daily operation of the wholesale prescription drug distributor. This subdivision does not preclude the designated representative from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

5. The person is actively involved in and aware of the daily operations of the wholesale distributor.

6. The person is a designated representative for only one applicant at any given time. This subdivision does not apply if more than one wholesale distributor is located at the facility and the wholesale distributors located at the facility are members of an affiliated group.

7. The person has not been convicted of violating any federal, state, or local law relating to wholesale or retail prescription drug distribution or distribution of a controlled substance.

8. The person has not been convicted of a felony.

9. The person submits to the department 2 fingerprint cards, each bearing a complete set of the applicant's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for the purposes of verifying the identity of the applicant and obtaining the applicant's criminal arrest and conviction record. This subdivision does not apply to a person accredited by the national association of boards of pharmacy's verified−accredited wholesale distributor program.

(3m) Notwithstanding subs. (2) and (3), the board may grant a license to engage in the wholesale distribution of prescription drugs to a person who is domiciled in another state and is licensed to engage in the wholesale distribution of prescription drugs in another state, if the board determines that the standards for licensure in the state in which the person is licensed are at least as stringent as the standards for licensure under this section.

(4) The board may set, by rule, continuing education requirements for designated representatives under this section.

(5) (a) The board shall require every wholesale distributor to submit a surety bond acceptable to the board in an amount not to exceed $100,000 or other equivalent means of security acceptable to the board, except that the board shall not require submission of a bond or other security under this subsection by a chain pharmacy warehouse that is engaged only in intracompany transfers. A wholesale distributor that operates more than one facility is not required to submit a bond or other security under this paragraph for each facility.

(b) The bond or other security under this subsection shall be used to secure payment of fees or costs that relate to the issuance of a license under this section and that have not been paid within 30 days after the fees or costs have become final. No claim may be made against a wholesale distributor's bond or other security under this subsection more than one year after the date on which the wholesale distributor's license expires.

(6) Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

Section 3530eg. 450.071 (3) (a) of the statutes, as created by 2007 Wisconsin Act .... (this act), is amended to read:

450.071 **(3)** (a) The applicant pays the fee under s. 440.05 (1) (a)~~, except that before June 1, 2010, the amount of the initial fee is $350~~.

Section 3530g. 450.072 of the statutes is created to read:

450.072 Wholesale distributors; restrictions on transactions. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy, a person authorized to administer or dispense drugs, or a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. A wholesale distributor that receives returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs may distribute the prescription drugs only to the original manufacturer of the products or to a 3rd party returns processor. Notwithstanding s. 450.073, returns or exchanges of saleable or nonsaleable prescription drugs, including any redistribution by a receiving wholesaler, are not subject to pedigree requirements under s. 450.073 if the returns or exchanges are exempt from the pedigree requirement under the federal food and drug administration's current guidance on the federal prescription drug marketing act. A person licensed under s. 450.071 or a pharmacy or other person authorized to administer or dispense drugs shall ensure that the person or pharmacy's return process is secure and does not permit the entry of adulterated and counterfeit products.

(2) (a) A manufacturer or wholesale distributor may not deliver prescription drugs to a person unless the person is licensed under s. 450.071 or 450.06 or by the

appropriate licensing authority of another state. A manufacturer or wholesale distributor may not deliver prescription drugs to a person that is not known to the manufacturer or wholesale distributor unless the manufacturer or wholesale distributor has verified with the board or with the licensing authority of the state in which the person in located that the person is licensed to receive prescription drugs.

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization, except that a manufacturer or wholesale distributor may distribute the prescription drugs to an authorized agent of the person at the premises of the manufacturer or wholesale distributor if all of the following are true:

1. The manufacturer or wholesale distributor documents the authorized agent's name and address.

2. Distribution to an authorized agent is necessary to promote or protect the immediate health or safety of the authorized agent's patient.

(c) A manufacturer or wholesale distributor may distribute a prescription drug to a hospital pharmacy receiving area if a licensed pharmacist or another authorized recipient signs, at the time of the distribution, a receipt that shows the type and quantity of prescription drugs distributed. If there is a discrepancy between the type and quantity of prescription drugs indicated on the receipt and the type and quantity of prescription drugs received at the hospital pharmacy receiving area, the discrepancy shall be reported to the manufacturer or wholesale distributor that distributed the prescription drugs no later than the day immediately following the date on which the prescription drugs were distributed to the hospital pharmacy receiving area.

(d) No manufacturer or wholesale distributor may accept payment for, or allow the use of, a person's credit to establish an account for the purchase of a prescription drug from any person other than the owner of record, the chief executive officer, or the chief financial officer identified on the license or authorization of a person who may receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensed or authorized person.

Section 3530h. 450.073 of the statutes is created to read:

450.073 Wholesale distributors; pedigree. (1) A wholesale distributor shall establish and maintain a pedigree for each prescription drug that leaves, or has ever left, the normal distribution channel. Before a wholesale distribution of a prescription drug leaves the normal distribution channel, a wholesale distributor shall provide a copy of the pedigree to the person receiving the drug. This section does not apply to a retail pharmacy or pharmacy intracompany warehouse unless the pharmacy or pharmacy intracompany warehouse engages in the wholesale distribution of prescription drugs.

(2) A pedigree shall contain all necessary identifying information concerning each sale in the chain of the distribution of the prescription drug from the manufacturer of the prescription drug or the manufacturers 3rd−party logistics provider, colicensed product partner, or exclusive distributor until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. The pedigree shall include all of the following:

(a) The name, address, telephone number, and, if available, electronic mail address of each recipient or distributor of the prescription drug in the chain of distribution, until the final sale or distribution described in sub. (2) (intro.).

(b) The name and address of each facility from which the prescription drug was distributed, if different from the address provided in par. (a).

(c) The date of each distribution.

(d) A certification that every recipient has authenticated the pedigree before distribution of the prescription drug to the next point in the chain of distribution.

(e) The name, dosage strength, size and number of containers, lot number, and name of the manufacturer for each prescription drug.

(3) The board shall promulgate rules implementing an electronic track and trace pedigree system. Not later than July 1, 2010, the board shall determine the date on which the system will be implemented. The system may not be implemented before July 1, 2011, and the board may delay the implementation date in increments if the board determines that the technology to implement the system is not yet universally available across the prescription drug supply chain or is not capable of adequately protecting patient safety.

(4) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager but not including the original manufacturer of the prescription drug, who possesses a pedigree for the prescription drug, and who intends to further distribute the prescription drug, shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

(5) (a) A pedigree shall be maintained by a person who purchases prescription drugs identified in the pedigree and by a wholesale distributor who distributes prescription drugs identified in the pedigree for not less than 3 years from the date of sale or distribution.

(b) A person maintaining a pedigree under par. (a) shall make the pedigree available for inspection or use by a law enforcement officer within 7 days after the law enforcement officer's request.

Section 3530i. 450.074 of the statutes is created to read:

450.074 Wholesale distributors; prohibited actions, enforcement, penalties. (1) If the board finds that there is a reasonable probability that a wholesale distributor, other than a manufacturer, has done any of the

following, that continued distribution of a prescription drug involved in the occurrence could cause death or serious adverse health consequences, and that additional procedures would result in an unreasonable delay, the board shall issue an order requiring that distribution of a prescription drug in this state cease immediately:

(a) Violated a provision of ss. 450.071 to 450.073.

(b) Falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use.

(2) If the board issues an order under sub. (1), the board shall provide the person who is the subject of the order an opportunity for an informal hearing not more than 10 days after the date on which the order is issued. If, after a hearing, the board determines that the order was issued without sufficient grounds, the board shall vacate the order.

(3) Any person who knowingly does any of the following is guilty of a Class H felony:

(a) Fails to obtain a license required under s. 450.071.

(b) Purchases or otherwise receives a prescription drug from a pharmacy in violation of s. 450.072 (1).

(c) Violates s. 450.072 (2) (a), if the person is required to obtain a license under s. 450.071.

(d) Violates s. 450.072 (2) (b).

(e) Violates s. 450.072 (2) (d).

(f) Violates s. 450.073.

(g) Provides false or fraudulent records to, or makes a false or fraudulent statement to, the board, a representative of the board, or a federal official.

(h) Obtains or attempts to obtain a prescription drug by fraud, deceit, or misrepresentation, or engages in misrepresentation or fraud in the distribution of a prescription drug.

(i) Manufactures, repackages, sells, transfers, delivers, holds, or offers for sale a prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or otherwise unfit for distribution, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(j) Adulterates, misbrands, or counterfeits a prescription drug, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(k) Receives a prescription drug that has been adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeited, or suspected of being counterfeited, and delivers or proffers such a drug.

(L) Alters, mutilates, destroys, obliterates, or removes any part of the labeling of a prescription drug or commits another act that results in the misbranding of a prescription drug.

(4) Subsection (3) does not apply to a prescription drug manufacturer or an agent of a prescription drug manufacturer, if the manufacturer or agent is obtaining or attempting to obtain a prescription drug for the sole purpose of testing the authenticity of the prescription drug.

SECTION 3531. 450.08 (2) (a) of the statutes is amended to read:

450.08 **(2)** (a) A pharmacist's license may be renewed by complying with continuing education requirements under s. 450.085 and paying the applicable fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a). Failure to obtain renewal within the time period specified under this paragraph terminates the right of the person to be licensed as a pharmacist, and such right can only be acquired by passing an examination to the satisfaction of the board.

SECTION 3532. 450.08 (2) (b) of the statutes is amended to read:

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

SECTION 3533. 451.04 (4) of the statutes is amended to read:

451.04 **(4)** EXPIRATION AND RENEWAL. Renewal applications shall be submitted to the department on a form provided by the department on or before the applicable renewal date specified under s. 440.08 (2) (a) and shall include the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a).

SECTION 3534. 452.025 (1) (c) of the statutes is amended to read:

452.025 **(1)** (c) Each application for registration as a time−share salesperson shall be accompanied by an initial credential fee ~~specified in s. 440.05 (1)~~ determined by the department under s. 440.03 (9) (a) or the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a), whichever is appropriate.

SECTION 3535. 452.025 (5) (b) of the statutes is amended to read:

452.025 **(5)** (b) An application to renew a certificate of registration granted under this section shall be submitted with the applicable renewal fee ~~specified under s. 440.08 (2) (a)~~ determined by the department under s. 440.03 (9) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a).

SECTION 3536. 452.10 (3) of the statutes is amended to read:

452.10 **(3)** The fees for examinations and licenses granted ~~or renewed~~ under this chapter are specified under

Title II of the Drug Quality and Security Act

DRUG SUPPLY CHAIN SECURITY

SEC. 201. SHORT TITLE.

This title may be cited as the ``Drug Supply Chain Security Act".

SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

``Subchapter H--Pharmaceutical Distribution Supply Chain

``SEC. 581. DEFINITIONS.

``In this subchapter:

``(1) Affiliate.--The term `affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly--

``(A) one business entity controls, or has the power to control, the other business entity; or

``(B) a third party controls, or has the power to control, both of the business entities.

``(2) Authorized.--The term `authorized' means--

``(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510;

``(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act;

``(C) in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b); and

``(D) in the case of a dispenser, having a valid license under State law.

``(3) Dispenser.--The term `dispenser'--

``(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

``(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

``(4) Disposition.--The term `disposition', with respect to a product within the possession or control of an entity, means the

removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

``(5) Distribute or distribution.--The term `distribute' or `distribution' means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).

``(6) Exclusive distributor.--The term `exclusive distributor' means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

``(7) Homogeneous case.--The term `homogeneous case' means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

``(8) Illegitimate product.--The term `illegitimate product' means a product for which credible evidence shows that the product--

``(A) is counterfeit, diverted, or stolen;

``(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

``(C) is the subject of a fraudulent transaction; or

``(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

``(9) Licensed.--The term `licensed' means--

``(A) in the case of a wholesale distributor, having a valid license in accordance with section 503(e) or section 582(a)(6), as applicable;

``(B) in the case of a third-party logistics provider, having a valid license in accordance with section 584(a) or section 582(a)(7), as applicable; and

``(C) in the case of a dispenser, having a valid license under State law.

``(10) Manufacturer.--The term `manufacturer' means, with respect to a product--

``(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

``(B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or

``(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

``(11) Package.--

``(A) In general.--The term `package' means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

``(B) Individual saleable unit.--For purposes of this paragraph, an `individual saleable unit' is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

``(12) Prescription drug.--The term `prescription drug' means a drug for human use subject to section 503(b)(1).

``(13) Product.--The term `product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.

``(14) Product identifier.--The term `product identifier' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

``(15) Quarantine.--The term `quarantine' means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

``(16) Repackager.--The term `repackager' means a person who owns or operates an establishment that repacks and relabels a product or package for--

``(A) further sale; or

``(B) distribution without a further transaction.

``(17) Return.--The term `return' means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

``(18) Returns processor or reverse logistics provider.--The term `returns processor' or `reverse logistics provider' means a

person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

``(19) Specific patient need.--The term `specific patient need' refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

``(20) Standardized numerical identifier.--The term `standardized numerical identifier' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

``(21) Suspect product.--The term `suspect product' means a product for which there is reason to believe that such product--

``(A) is potentially counterfeit, diverted, or stolen;

``(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

``(C) is potentially the subject of a fraudulent transaction; or

``(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

``(22) Third-party logistics provider.--The term `third-party logistics provider' means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

``(23) Trading partner.--The term `trading partner' means--

``(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

``(B) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

``(24) Transaction.--

``(A) In general.--The term `transaction' means the transfer of product between persons in which a change of ownership occurs.

``(B) Exemptions.--The term `transaction' does not include--

``(i) intracompany distribution of any product between members of an affiliate or within a manufacturer;

``(ii) the distribution of a product among hospitals or other health care entities that are under common control;

``(iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

``(iv) the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1);

``(v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d);

``(vi) the distribution of blood or blood components intended for transfusion;

``(vii) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

``(viii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

``(ix) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

``(x) the dispensing of a product approved under section 512(c);

``(xi) products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

``(xii) a combination product that is not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act, and that is--

``(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

``(II) 2 or more separate products packaged together in a single package or as a unit and comprised

of a drug and device or device and biological product; or

``(III) 2 or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a `medical convenience kit' as described in clause (xiii);

``(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a `medical convenience kit') if--

``(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

``(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

``(III) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit--

``(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

``(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

``(IV) in the case of a medical convenience kit that includes a product, the product is--

``(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

``(bb) a product intended to maintain the equilibrium of water and minerals in the body;

``(cc) a product intended for irrigation or reconstitution;

``(dd) an anesthetic;

``(ee) an anticoagulant;

``(ff) a vasopressor; or

``(gg) a sympathomimetic;

``(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

``(xv) the distribution of an intravenous product used

to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

``(xvi) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

``(xvii) the distribution of a medical gas (as defined in section 575); or

``(xviii) the distribution or sale of any licensed product under section 351 of the Public Health Service Act that meets the definition of a device under section 201(h).

``(25) Transaction history.--The term `transaction history' means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

``(26) Transaction information.--The term `transaction information' means--

``(A) the proprietary or established name or names of the product;

``(B) the strength and dosage form of the product;

``(C) the National Drug Code number of the product;

``(D) the container size;

``(E) the number of containers;

``(F) the lot number of the product;

``(G) the date of the transaction;

``(H) the date of the shipment, if more than 24 hours after the date of the transaction;

``(I) the business name and address of the person from whom ownership is being transferred; and

``(J) the business name and address of the person to whom ownership is being transferred.

``(27) Transaction statement.--The `transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction--

``(A) is authorized as required under the Drug Supply Chain Security Act;

``(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

``(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

``(D) did not knowingly ship a suspect or illegitimate product;

``(E) had systems and processes in place to comply with verification requirements under section 582;

``(F) did not knowingly provide false transaction information; and

``(G) did not knowingly alter the transaction history.

``(28) Verification or verify.--The term `verification' or `verify' means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration

date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.

``(29) Wholesale distributor.--The term `wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).

``SEC. 582. REQUIREMENTS.

``(a) In General.--

``(1) Other activities.--Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements set forth in this section with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving product. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in this section, but shall not be required to duplicate requirements.

``(2) Initial standards.--

``(A) In general.--The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders, issue a draft guidance document that establishes standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for compliance with this subsection and subsections (b), (c), (d), and (e). In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data. The standards established under this paragraph shall take into consideration the standards established under section 505D and shall comply with a form and format developed by a widely recognized international standards development organization.

``(B) Public input.--Prior to issuing the draft guidance under subparagraph (A), the Secretary shall gather comments and information from stakeholders and maintain such comments and information in a public docket for at least 60 days prior to issuing such guidance.

``(C) Publication.--The Secretary shall publish the standards established under subparagraph (A) not later than 1 year after the date of enactment of the Drug Supply Chain Security Act.

``(3) Waivers, exceptions, and exemptions.--

``(A) In general.--Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall, by guidance--

``(i) establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in this section, which the Secretary may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;

``(ii) establish a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section; and

``(iii) establish a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of this section.

``(B) Content.--The guidance issued under subparagraph (A) shall include a process for the biennial review and renewal of such waivers, exceptions, and exemptions, as applicable.

``(C) Process.--In issuing the guidance under this paragraph, the Secretary shall provide an effective date that is not later than 180 days prior to the date on which manufacturers are required to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce consistent with this section.

``(4) Self-executing requirements.--Except where otherwise specified, the requirements of this section may be enforced without further regulations or guidance from the Secretary.

``(5) Grandfathering product.--

``(A) Product identifier.--Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall finalize guidance specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section shall be exempted from the requirements of this section.

``(B) Tracing.--For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015--

``(i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii);

``(ii) transaction history required under this section shall begin with the owner of such product on such date;

and

``(iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

``(6) Wholesale distributor licenses.--Notwithstanding section 581(9)(A), until the effective date of the wholesale distributor licensing regulations under section 583, the term `licensed' or `authorized', as it relates to a wholesale distributor with respect to prescription drugs, shall mean a wholesale distributor with a valid license under State law.

``(7) Third-party logistics provider licenses.--Until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered `licensed' under section 581(9)(B) unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.

``(8) Label changes.--Changes made to package labels solely to incorporate the product identifier may be submitted to the Secretary in the annual report of an establishment, in accordance with section 314.70(d) of chapter 21, Code of Federal Regulations (or any successor regulation).

``(9) Product identifiers.--With respect to any requirement relating to product identifiers under this subchapter--

``(A) unless the Secretary allows, through guidance, the use of other technologies for data instead of or in addition to the technologies described in clauses (i) and (ii), the applicable data--

``(i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package; and

``(ii) shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case; and

``(B) verification of the product identifier may occur by using human-readable or machine-readable methods.

``(b) Manufacturer Requirements.--

``(1) Product tracing.--

``(A) In general.--Beginning not later than January 1, 2015, a manufacturer shall--

``(i) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in an paper or electronic format; and

``(ii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction.

``(B) Requests for information.--Upon a request by the

Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

``(C) Electronic format.--

``(i) In general.--Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, except as provided under clause (ii), a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in electronic format.

``(ii) Exception.--A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in a paper format to a licensed health care practitioner authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.

``(2) Product identifier.--

``(A) In general.--Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.

``(B) Exception.--A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

``(3) Authorized trading partners.--Beginning not later than January 1, 2015, the trading partners of a manufacturer may be only authorized trading partners.

``(4) Verification.--Beginning not later than January 1, 2015, a manufacturer shall have systems in place to enable the manufacturer to comply with the following requirements:

``(A) Suspect product.--

``(i) In general.--Upon making a determination that a product in the possession or control of the manufacturer is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a manufacturer is a suspect product, a manufacturer shall--

``(I) quarantine such product within the possession

or control of the manufacturer from product intended for distribution until such product is cleared or dispositioned; and

``(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the manufacturer and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, verifying the product at the package level, including the standardized numerical identifier.

``(ii) Cleared product.--If the manufacturer makes the determination that a suspect product is not an illegitimate product, the manufacturer shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

``(iii) Records.--A manufacturer shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

``(B) Illegitimate product.--

``(i) In general.--Upon determining that a product in the possession or control of a manufacturer is an illegitimate product, the manufacturer shall, in a manner consistent with the systems and processes of such manufacturer--

``(I) quarantine such product within the possession or control of the manufacturer from product intended for distribution until such product is dispositioned;

``(II) disposition the illegitimate product within the possession or control of the manufacturer;

``(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the manufacturer; and

``(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the Secretary (or other appropriate Federal or State official), as necessary and appropriate.

``(ii) Making a notification.--

``(I) Illegitimate product.--Upon determining that a product in the possession or control of the manufacturer is an illegitimate product, the

manufacturer shall notify the Secretary and all immediate trading partners that the manufacturer has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

``(II) High risk of illegitimacy.--A manufacturer shall notify the Secretary and immediate trading partners that the manufacturer has reason to believe may have in the trading partner's possession a product manufactured by, or purported to be a product manufactured by, the manufacturer not later than 24 hours after determining or being notified by the Secretary or a trading partner that there is a high risk that such product is an illegitimate product. For purposes of this subclause, a `high risk' may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the Secretary in guidance pursuant to subsection (h).

``(iii) Responding to a notification.--Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a manufacturer shall identify all illegitimate product subject to such notification that is in the possession or control of the manufacturer, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

``(iv) Terminating a notification.--Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a manufacturer shall promptly notify immediate trading partners that the manufacturer notified pursuant to clause (ii) that such notification has been terminated.

``(v) Records.--A manufacturer shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

``(C) Requests for verification.--Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be manufactured by such manufacturer, a manufacturer shall, not later than 24 hours after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer. If a

manufacturer responding to a request for verification identifies a product identifier that does not correspond to that affixed or imprinted by the manufacturer, the manufacturer shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the manufacturer has reason to believe the product is an illegitimate product, the manufacturer shall advise the person making the request of such belief at the time such manufacturer responds to the request for verification.

``(D) Electronic database.--A manufacturer may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a manufacturer of the requirement under this paragraph to respond to a request for verification submitted by means other than a secure electronic database.

``(E) Saleable returned product.--Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), upon receipt of a returned product that the manufacturer intends to further distribute, before further distributing such product, the manufacturer shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

``(F) Nonsaleable returned product.--A manufacturer may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information described in paragraph (1)(A)(i).

``(c) Wholesale Distributor Requirements.--

``(1) Product tracing.--

``(A) In general.--Beginning not later than January 1, 2015, the following requirements shall apply to wholesale distributors:

``(i) A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this subparagraph.

``(ii)(I)(aa) If the wholesale distributor purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that

purchased directly from the manufacturer, then prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, the wholesale distributor shall provide to the subsequent purchaser--

``(AA) a transaction statement, which shall state that such wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased the product directly from the manufacturer; and

``(BB) subject to subclause (II), the transaction history and transaction information.

``(bb) The wholesale distributor shall provide the transaction history, transaction information, and transaction statement under item (aa)--

``(AA) if provided to a dispenser, on a single document in a paper or electronic format; and

``(BB) if provided to a wholesale distributor, through any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package.

``(II) For purposes of transactions described in subclause (I), transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer (as defined in subparagraphs (F), (G), and (H) of section 581(26)).

``(iii) If the wholesale distributor did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, as described in clause (ii), then prior to, or at the time of, each transaction or subsequent transaction, the wholesale distributor shall provide to the subsequent purchaser a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the guidance document issued under subsection (a)(2).

``(iv) For the purposes of clause (iii), the transaction history supplied shall begin only with the wholesale distributor described in clause (ii)(I), but the wholesale distributor described in clause (iii) shall inform the subsequent purchaser that such wholesale distributor received a direct purchase statement from a wholesale distributor described in clause (ii)(I).

``(v) A wholesale distributor shall--

``(I) capture the transaction information (including lot level information) consistent with the

requirements of this section, transaction history, and transaction statement for each transaction described in clauses (i), (ii), and (iii) and maintain such information, history, and statement for not less than 6 years after the date of the transaction; and

``(II) maintain the confidentiality of the transaction information (including any lot level information consistent with the requirements of this section), transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) and (iii), and, as applicable, pursuant to an agreement under subparagraph (D).

``(B) Returns.--

``(i) Saleable returns.--Notwithstanding subparagraph (A)(i), the following shall apply:

``(I) Requirements.--Until the date that is 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and, notwithstanding subparagraph (A)(ii), may distribute such returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of such product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this subsection.

``(II) Enhanced requirements.--Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates.

``(ii) Nonsaleable returns.--A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such

product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A)(i).

``(C) Requests for information.--Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

``(D) Trading partner agreements.--Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between such wholesale distributor and such subsequent purchaser. Nothing in this subparagraph shall be construed to limit the applicability of subparagraphs (A) through (C).

``(2) Product identifier.--Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).

``(3) Authorized trading partners.--Beginning not later than January 1, 2015, the trading partners of a wholesale distributor may be only authorized trading partners.

``(4) Verification.--Beginning not later than January 1, 2015, a wholesale distributor shall have systems in place to enable the wholesale distributor to comply with the following requirements:

``(A) Suspect product.--

``(i) In general.--Upon making a determination that a product in the possession or control of a wholesale distributor is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a wholesale distributor is a suspect product, a wholesale distributor shall--

``(I) quarantine such product within the possession or control of the wholesale distributor from product intended for distribution until such product is cleared or dispositioned; and

``(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable

transaction history and transaction information in the possession of the wholesale distributor and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), verifying the product at the package level, including the standardized numerical identifier.

``(ii) Cleared product.--If the wholesale distributor determines that a suspect product is not an illegitimate product, the wholesale distributor shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

``(iii) Records.--A wholesale distributor shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

``(B) Illegitimate product.--

``(i) In general.--Upon determining, in coordination with the manufacturer, that a product in the possession or control of a wholesale distributor is an illegitimate product, the wholesale distributor shall, in a manner that is consistent with the systems and processes of such wholesale distributor--

``(I) quarantine such product within the possession or control of the wholesale distributor from product intended for distribution until such product is dispositioned;

``(II) disposition the illegitimate product within the possession or control of the wholesale distributor;

``(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the wholesale distributor; and

``(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

``(ii) Making a notification.--Upon determining that a product in the possession or control of the wholesale distributor is an illegitimate product, the wholesale distributor shall notify the Secretary and all immediate trading partners that the wholesale distributor has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making

such determination.

``(iii) Responding to a notification.--Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a wholesale distributor shall identify all illegitimate product subject to such notification that is in the possession or control of the wholesale distributor, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

``(iv) Terminating a notification.--Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a wholesale distributor shall promptly notify immediate trading partners that the wholesale distributor notified pursuant to clause (ii) that such notification has been terminated.

``(v) Records.--A wholesale distributor shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

``(C) Electronic database.--A wholesale distributor may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a wholesale distributor of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

``(D) Verification of saleable returned product.--Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the wholesale distributor intends to further distribute, before further distributing such product, the wholesale distributor shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

``(d) Dispenser Requirements.--

``(1) Product tracing.--

``(A) In general.--Beginning July 1, 2015, a dispenser--

``(i) shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;

``(ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall

provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and

``(iii) shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.

``(B) Agreements with third parties.--A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

``(C) Returns.--

``(i) Saleable returns.--A dispenser may return product to the trading partner from which the dispenser obtained the product without providing the information required under subparagraph (A).

``(ii) Nonsaleable returns.--A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under subparagraph (A).

``(D) Requests for information.--Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction statement, and transaction history which the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or wholesale distributor to the dispenser. The dispenser may respond to the request by providing the applicable information in either paper or electronic format. Until the date that is 4 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary or other appropriate Federal or State official shall

grant a dispenser additional time, as necessary, only with respect to a request to provide lot level information described in subparagraph (F) of section 581(26) that was provided to the dispenser in paper format, limit the request time period to the 6 months preceding the request or other relevant date, and, in the event of a recall, the Secretary, or other appropriate Federal or State official may request information only if such recall involves a serious adverse health consequence or death to humans.

``(2) Product identifier.--Beginning not later than 7 years after the date of enactment of the Drug Supply Chain Security Act, a dispenser may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).

``(3) Authorized trading partners.--Beginning not later than January 1, 2015, the trading partners of a dispenser may be only authorized trading partners.

``(4) Verification.--Beginning not later than January 1, 2015, a dispenser shall have systems in place to enable the dispenser to comply with the following requirements:

``(A) Suspect product.--

``(i) In general.--Upon making a determination that a product in the possession or control of the dispenser is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a dispenser is a suspect product, a dispenser shall--

``(I) quarantine such product within the possession or control of the dispenser from product intended for distribution until such product is cleared or dispositioned; and

``(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.

``(ii) Investigation.--An investigation conducted under clause (i)(II) shall include--

``(I) beginning 7 years after the date of enactment of the Drug Supply Chain Security Act, verifying whether the lot number of a suspect product corresponds with the lot number for such product;

``(II) beginning 7 years after the date of enactment of such Act, verifying that the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with

the product identifier for such product;

``(III) validating any applicable transaction history and transaction information in the possession of the dispenser; and

``(IV) otherwise investigating to determine whether the product is an illegitimate product.

``(iii) Cleared product.--If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed or dispensed.

``(iv) Records.--A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

``(B) Illegitimate product.--

``(i) In general.--Upon determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall--

``(I) disposition the illegitimate product within the possession or control of the dispenser;

``(II) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the dispenser; and

``(III) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

``(ii) Making a notification.--Upon determining that a product in the possession or control of the dispenser is an illegitimate product, the dispenser shall notify the Secretary and all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

``(iii) Responding to a notification.--Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a dispenser shall identify all illegitimate product subject to such notification that is in the possession or control of the dispenser, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

``(iv) Terminating a notification.--Upon making a

determination, in consultation with the Secretary, that a notification is no longer necessary, a dispenser shall promptly notify immediate trading partners that the dispenser notified pursuant to clause (ii) that such notification has been terminated.

``(v) Records.--A dispenser shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

``(C) Electronic database.--A dispenser may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity.

``(5) Exception.--Notwithstanding any other provision of law, the requirements under paragraphs (1) and (4) shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.

``(e) Repackager Requirements.--

``(1) Product tracing.--

``(A) In general.--Beginning not later than January 1, 2015, a repackager described in section 581(16)(A) shall--

``(i) not accept ownership of a product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement for the product;

``(ii) prior to, or at the time of, each transaction in which the repackager transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product; and

``(iii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction described in clauses (i) and (ii) and maintain such information, history, and statement for not less than 6 years after the transaction.

``(B) Returns.--

``(i) Nonsaleable product.--A repackager described in section 581(16)(A) may return a nonsaleable product to the manufacturer or repackager, or to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A)(ii).

``(ii) Saleable or nonsaleable product.--A repackager described in section 581(16)(B) may return a saleable or nonsaleable product to the manufacturer, repackager, or to the wholesale distributor from whom such product was received without providing the information required under

subparagraph (A)(ii) on behalf of the hospital or other health care entity that took ownership of such product pursuant to the terms and conditions of any agreement between such repackager and the entity that owns the product.

``(C) Requests for information.--Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a repackager described in section 581(16)(A) shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, provide the applicable transaction information, transaction history, and transaction statement for the product.

``(2) Product identifier.--

``(A) In general.--Beginning not later than 5 years after the date of enactment of the Drug Supply Chain Security Act, a repackager described in section 581(16)(A)--

``(i) shall affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction in commerce;

``(ii) shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction;

``(iii) may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)); and

``(iv) shall maintain records for not less than 6 years to allow the repackager to associate the product identifier the repackager affixes or imprints with the product identifier assigned by the original manufacturer of the product.

``(B) Exception.--A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

``(3) Authorized trading partners.--Beginning January 1, 2015, the trading partners of a repackager described in section 581(16) may be only authorized trading partners.

``(4) Verification.--Beginning not later than January 1, 2015, a repackager described in section 581(16)(A) shall have systems in place to enable the repackager to comply with the following requirements:

``(A) Suspect product.--

``(i) In general.--Upon making a determination that a product in the possession or control of the repackager is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a repackager is a suspect product, a repackager shall--

``(I) quarantine such product within the possession or control of the repackager from product intended for distribution until such product is cleared or dispositioned; and

``(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the repackager and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 5 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), verifying the product at the package level, including the standardized numerical identifier.

``(ii) Cleared product.--If the repackager makes the determination that a suspect product is not an illegitimate product, the repackager shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

``(iii) Records.--A repackager shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

``(B) Illegitimate product.--

``(i) In general.--Upon determining, in coordination with the manufacturer, that a product in the possession or control of a repackager is an illegitimate product, the repackager shall, in a manner that is consistent with the systems and processes of such repackager--

``(I) quarantine such product within the possession or control of the repackager from product intended for distribution until such product is dispositioned;

``(II) disposition the illegitimate product within the possession or control of the repackager;

``(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the repackager; and

``(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

``(ii) Making a notification.--Upon determining that a product in the possession or control of the repackager is

an illegitimate product, the repackager shall notify the Secretary and all immediate trading partners that the repackager has reason to believe may have received the illegitimate product of such determination not later than 24 hours after making such determination.

``(iii) Responding to a notification.--Upon the receipt of a notification from the Secretary or a trading partner, a repackager shall identify all illegitimate product subject to such notification that is in the possession or control of the repackager, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

``(iv) Terminating a notification.--Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a repackager shall promptly notify immediate trading partners that the repackager notified pursuant to clause (ii) that such notification has been terminated.

``(v) Records.--A repackager shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

``(C) Requests for verification.--Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized manufacturer, wholesale distributor, or dispenser that is in possession or control of a product they believe to be repackaged by such repackager, a repackager shall, not later than 24 hours after receiving the verification request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the repackager. If a repackager responding to a verification request identifies a product identifier that does not correspond to that affixed or imprinted by the repackager, the repackager shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the repackager has reason to believe the product is an illegitimate product, the repackager shall advise the person making the request of such belief at the time such repackager responds to the verification request.

``(D) Electronic database.--A repackager may satisfy the requirements of paragraph (4) by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a repackager of the requirement under subparagraph (C) to

respond to a verification request submitted by means other than a secure electronic database.

``(E) Verification of saleable returned product.--Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the repackager intends to further distribute, before further distributing such product, the repackager shall verify the product identifier for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier on each package.

``(f) Drop Shipments.--

``(1) In general.--A wholesale distributor that does not physically handle or store product shall be exempt from the provisions of this section, except the notification requirements under clauses (ii), (iii), and (iv) of subsection (c)(4)(B), provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for such wholesale distributor includes on the transaction information and transaction history to the dispenser the contact information of such wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser.

``(2) Clarification.--For purposes of this subsection, providing administrative services, including processing of orders and payments, shall not by itself, be construed as being involved in the handling, distribution, or storage of a product.".

SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.

Section 582, as added by section 202, is amended by adding at the end the following:

``(g) Enhanced Drug Distribution Security.--

``(1) In general.--On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

``(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

``(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

``(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such

subsection, which may include the use of aggregation and inference as necessary.

``(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

``(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required--

``(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

``(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

``(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

``(2) Compliance.--

``(A) Information maintenance agreement.--A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party shall confidentially maintain any information and statements required to be maintained under this section. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

``(B) Alternative methods.--The Secretary, taking into consideration the assessment conducted under paragraph (3), shall provide for alternative methods of compliance with any of the requirements set forth in paragraph (1), including--

``(i) establishing timelines for compliance by small businesses (including small business dispensers with 25 or fewer full-time employees) with such requirements, in order to ensure that such requirements do not impose undue economic hardship for small businesses, including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met, if the Secretary determines that such requirements under paragraph (1) would result in undue economic hardship; and

``(ii) establishing a process by which a dispenser may

request a waiver from any of the requirements set forth in paragraph (1) if the Secretary determines that such requirements would result in an undue economic hardship, which shall include a process for the biennial review and renewal of any such waiver.

``(3) Assessment.--

``(A) In general.--Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (h), the Secretary shall enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. Such assessment shall be completed not later than 8\1/2\ years after the date of enactment of the Drug Supply Chain Security Act.

``(B) Condition.--As a condition of the award of the contract under subparagraph (A), the private, independent consulting firm shall agree to consult with dispensers with 25 or fewer full-time employees when conducting the assessment under such subparagraph.

``(C) Content.--The assessment under subparagraph (A) shall assess whether--

``(i) the necessary software and hardware is readily accessible to such dispensers;

``(ii) the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and

``(iii) the necessary hardware and software can be integrated into business practices, such as interoperability with wholesale distributors, for such dispensers.

``(D) Publication.--The Secretary shall--

``(i) publish the statement of work for the assessment under subparagraph (A) for public comment prior to beginning the assessment;

``(ii) publish the final assessment for public comment not later than 30 calendar days after receiving such assessment; and

``(iii) hold a public meeting not later than 180 calendar days after receiving the final assessment at which public stakeholders may present their views on the assessment.

``(4) Procedure.--Notwithstanding section 553 of title 5, United States Code, the Secretary, in promulgating any regulation pursuant to this section, shall--

``(A) provide appropriate flexibility by--

``(i) not requiring the adoption of specific business systems for the maintenance and transmission of data;

``(ii) prescribing alternative methods of compliance for any of the requirements set forth in paragraph (1) or

set forth in regulations implementing such requirements, including--

``(I) timelines for small businesses to comply with the requirements set forth in the regulations in order to ensure that such requirements do not impose undue economic hardship for small businesses (including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met), if the Secretary determines that such requirements would result in undue economic hardship; and

``(II) the establishment of a process by which a dispenser may request a waiver from any of the requirements set forth in such regulations if the Secretary determines that such requirements would result in an undue economic hardship; and

``(iii) taking into consideration--

``(I) the results of pilot projects, including pilot projects pursuant to this section and private sector pilot projects, including those involving the use of aggregation and inference;

``(II) the public meetings held and related guidance documents issued under this section;

``(III) the public health benefits of any additional regulations in comparison to the cost of compliance with such requirements, including on entities of varying sizes and capabilities;

``(IV) the diversity of the pharmaceutical distribution supply chain by providing appropriate flexibility for each sector, including both large and small businesses; and

``(V) the assessment pursuant to paragraph (3) with respect to small business dispensers, including related public comment and the public meeting, and requirements under this section;

``(B) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

``(C) provide a period of not less than 60 days for comments on the proposed regulation; and

``(D) publish in the Federal Register the final regulation not less than 2 years prior to the effective date of the regulation.

``(h) Guidance Documents.--

``(1) In general.--For the purposes of facilitating the successful and efficient adoption of secure, interoperable product tracing at the package level in order to enhance drug distribution security and further protect the public health, the Secretary shall issue the guidance documents as provided for in this subsection.

``(2) Suspect and illegitimate product.--

``(A) In general.--Not later than 180 days after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall issue a guidance document to aid trading partners in the identification of a suspect product and notification termination. Such guidance document shall--

``(i) identify specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain;

``(ii) provide recommendation on how trading partners may identify such product and make a determination on whether the product is a suspect product as soon as practicable; and

``(iii) set forth the process by which manufacturers, repackagers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Secretary regarding illegitimate product pursuant to subsections (b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B).

``(B) Revised guidance.--If the Secretary revises the guidance issued under subparagraph (A), the Secretary shall follow the procedure set forth in paragraph (5).

``(3) Unit level tracing.--

``(A) In general.--In order to enhance drug distribution security at the package level, not later than 18 months after conducting a public meeting on the system attributes necessary to enable secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary, the Secretary shall issue a final guidance document that outlines and makes recommendations with respect to the system attributes necessary to enable secure tracing at the package level as required under the requirements established under subsection (g). Such guidance document shall--

``(i) define the circumstances under which the sectors within the pharmaceutical distribution supply chain may, in the most efficient manner practicable, infer the contents of a case, pallet, tote, or other aggregate of individual packages or containers of product, from a product identifier associated with the case, pallet, tote, or other aggregate, without opening each case, pallet, tote, or other aggregate or otherwise individually scanning each package;

``(ii) identify methods and processes to enhance secure tracing of product at the package level, such as secure processes to facilitate the use of inference, enhanced verification activities, the use of aggregation and inference, processes that utilize the product identifiers to enhance tracing of product at the package level, including the standardized numerical identifier, or package security features; and

``(iii) ensure the protection of confidential

commercial information and trade secrets.

``(B) Procedure.--In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

``(4) Standards for interoperable data exchange.--

``(A) In general.--In order to enhance secure tracing of a product at the package level, the Secretary, not later than 18 months after conducting a public meeting on the interoperable standards necessary to enhance the security of the pharmaceutical distribution supply chain, shall update the guidance issued pursuant to subsection (a)(2), as necessary and appropriate, and finalize such guidance document so that the guidance document--

``(i) identifies and makes recommendations with respect to the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization;

``(ii) takes into consideration standards established pursuant to subsection (a)(2) and section 505D;

``(iii) facilitates the creation of a uniform process or methodology for product tracing; and

``(iv) ensures the protection of confidential commercial information and trade secrets.

``(B) Procedure.--In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

``(5) Procedure.--In issuing or revising any guidance issued pursuant to this subsection or subsection (g), except the initial guidance issued under paragraph (2)(A), the Secretary shall--

``(A) publish a notice in the Federal Register for a period not less than 30 days announcing that the draft or revised draft guidance is available;

``(B) post the draft guidance document on the Internet Web site of the Food and Drug Administration and make such draft guidance document available in hard copy;

``(C) provide an opportunity for comment and review and take into consideration any comments received;

``(D) revise the draft guidance, as appropriate;

``(E) publish a notice in the Federal Register for a period not less than 30 days announcing that the final guidance or final revised guidance is available;

``(F) post the final guidance document on the Internet Web site of the Food and Drug Administration and make such final guidance document available in hard copy; and

``(G) provide for an effective date of not earlier than 1 year after such guidance becomes final.

``(i) Public Meetings.--

``(1) In general.--The Secretary shall hold not less than 5 public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide for comment. The Secretary may hold the first such public meeting not earlier than 1 year after the date of enactment of the Drug Supply Chain Security Act. In carrying out the public meetings described in this paragraph, the Secretary shall--

``(A) prioritize topics necessary to inform the issuance of the guidance described in paragraphs (3) and (4) of subsection (h); and

``(B) take all measures reasonable and practicable to ensure the protection of confidential commercial information and trade secrets.

``(2) Content.--Each of the following topics shall be addressed in at least one of the public meetings described in paragraph (1):

``(A) An assessment of the steps taken under subsections (b) through (e) to build capacity for a unit-level system, including the impact of the requirements of such subsections on--

``(i) the ability of the health care system collectively to maintain patient access to medicines;

``(ii) the scalability of such requirements, including as it relates to product lines; and

``(iii) the capability of different sectors and subsectors, including both large and small businesses, to affix and utilize the product identifier.

``(B) The system attributes necessary to support the requirements set forth under subsection (g), including the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among sectors within the pharmaceutical distribution supply chain.

``(C) Best practices in each of the different sectors within the pharmaceutical distribution supply chain to implement the requirements of this section.

``(D) The costs and benefits of the implementation of this section, including the impact on each pharmaceutical distribution supply chain sector and on public health.

``(E) Whether electronic tracing requirements, including tracing of product at the package level, are feasible, cost effective, and needed to protect the public health.

``(F) The systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary.

``(G) The technical capabilities and legal authorities, if any, needed to establish an interoperable, electronic system that provides for tracing of product at the package level.

``(H) The impact that such additional requirements would have on patient safety, the drug supply, cost and regulatory burden, and timely patient access to prescription drugs.

``(I) Other topics, as determined appropriate by the

Secretary.

``(j) Pilot Projects.--

``(1) In general.--The Secretary shall establish 1 or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Such projects shall build upon efforts, in existence as of the date of enactment of the Drug Supply Chain Security Act, to enhance the safety and security of the pharmaceutical distribution supply chain, take into consideration any pilot projects conducted prior to such date of enactment, including any pilot projects that use aggregation and inference, and inform the draft and final guidance under paragraphs (3) and (4) of subsection (h).

``(2) Content.--

``(A) In general.--The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the pharmaceutical distribution supply chain and that the pilot projects, when taken as a whole, include participants representative of every sector, including both large and small businesses.

``(B) Project design.--The pilot projects under paragraph (1) shall be designed to--

``(i) utilize the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;

``(ii) improve the technical capabilities of each sector and subsector to comply with systems and processes needed to utilize the product identifiers to enhance tracing of a product;

``(iii) identify system attributes that are necessary to implement the requirements established under this section; and

``(iv) complete other activities as determined by the Secretary.

``(k) Sunset.--The following requirements shall have no force or effect beginning on the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act:

``(1) The provision and receipt of transaction history under this section.

``(2) The requirements set forth for returns under subsections (b)(4)(E), (c)(1)(B)(i), (d)(1)(C)(i), and (e)(4)(E).

``(3) The requirements set forth under subparagraphs (A)(v)(II) and (D) of subsection (c)(1), as applied to lot level information only.

``(l) Rule of Construction.--The requirements set forth in subsections (g)(4), (i), and (j) shall not be construed as a condition, prohibition, or precedent for precluding or delaying the provisions becoming effective pursuant to subsection (g).

``(m) Requests for Information.--On the date that is 10 years after

the date of enactment of the Drug Supply Chain Security Act, the timeline for responses to requests for information from the Secretary, or other appropriate Federal or State official, as applicable, under subsections (b)(1)(B), (c)(1)(C), and (e)(1)(C) shall be not later than 24 hours after receiving the request from the Secretary or other appropriate Federal or State official, as applicable, or in such other reasonable time as determined by the Secretary based on the circumstances of the request.".

SEC. 204. NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS.

(a) Amendments.--

(1) Requirement.--Section 503(e) (21 U.S.C. 353(e)) is amended by striking paragraphs (1), (2), and (3) and inserting the following:

``(1) Requirement.--Subject to section 583:

``(A) In general.--No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person--

``(i)(I) is licensed by the State from which the drug is distributed; or

``(II) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

``(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

``(B) Standards.--Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under section 583.

``(2) Reporting and database.--

``(A) Reporting.--Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall--

``(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary--

``(I) each State by which the person is licensed and the appropriate identification number of each such license; and

``(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

``(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

``(B) Database.--Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall--

``(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale distributor is appropriately licensed to engage in wholesale distribution;

``(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and

``(iii) be regularly updated on a schedule determined by the Secretary.

``(C) Coordination.--The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner.

``(D) Confidentiality.--Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

``(3) Costs.--

``(A) Authorized fees of secretary.--If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection (b), the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

``(B) State licensing fees.--Nothing in this Act shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.".

(2) Wholesale distribution.--Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (1), is further amended by adding at the end the following:

``(4) For the purposes of this subsection and subsection (d), the term `wholesale distribution' means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person

other than the consumer or patient, but does not include--

``(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

``(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

``(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

``(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

``(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

``(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

``(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

``(H) the distribution of a drug by the manufacturer of such drug;

``(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

``(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

``(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e);

``(L) salable drug returns when conducted by a dispenser;

``(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a `medical convenience kit') if--

``(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

``(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

``(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit--

``(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

``(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

``(iv) in the case of a medical convenience kit that includes a product, the product is--

``(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

``(II) a product intended to maintain the equilibrium of water and minerals in the body;

``(III) a product intended for irrigation or reconstitution;

``(IV) an anesthetic;

``(V) an anticoagulant;

``(VI) a vasopressor; or

``(VII) a sympathomimetic;

``(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

``(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

``(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

``(Q) the distribution of medical gas, as defined in section 575;

``(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

``(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.".

(3) Third-party logistics providers.--Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (2), is further amended by adding at the end the following:

``(5) Third-party logistics providers.--Notwithstanding paragraphs (1) through (4), each entity that meets the definition

of a third-party logistics provider under section 581(22) shall obtain a license as a third-party logistics provider as described in section 584(a) and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.".

(4) Affiliate.--Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (3), is further amended by adding at the end the following:

``(6) Affiliate.--For purposes of this subsection, the term `affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly--

``(A) one business entity controls, or has the power to control, the other business entity; or

``(B) a third party controls, or has the power to control, both of the business entities.".

(5) Standards.--Subchapter H of chapter V, as added by section 202, is amended by adding at the end the following:

``SEC. 583. NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS.

``(a) In General.--The Secretary shall, not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, establish by regulation standards for the licensing of persons under section 503(e)(1) (as amended by the Drug Supply Chain Security Act), including the revocation, reissuance, and renewal of such license.

``(b) Content.--For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under subsection (a) shall apply to all State and Federal licenses described under section 503(e)(1) (as amended by the Drug Supply Chain Security Act) and shall include standards for the following:

``(1) The storage and handling of prescription drugs, including facility requirements.

``(2) The establishment and maintenance of records of the distributions of such drugs.

``(3) The furnishing of a bond or other equivalent means of security, as follows:

``(A)(i) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the State.

``(ii) For purposes of clause (i), the State or other applicable authority may accept a surety bond in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesaler is $10,000,000 or less.

``(B) If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State shall be waived.

``(4) Mandatory background checks and fingerprinting of facility managers or designated representatives.

``(5) The establishment and implementation of qualifications for key personnel.

``(6) The mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable time frame from the initial application of the facility and to be conducted by the licensing authority or by the State, consistent with subsection (c).

``(7) In accordance with subsection (d), the prohibition of certain persons from receiving or maintaining licensure for wholesale distribution.

``(c) Inspections.--To satisfy the inspection requirement under subsection (b)(6), the Federal or State licensing authority may conduct the inspection or may accept an inspection by the State in which the facility is located, or by a third-party accreditation or inspection service approved by the Secretary or the State licensing such wholesale distributor.

``(d) Prohibited Persons.--The standards established under subsection (a) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person--

``(1) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of subsection (i) or (k) of section 301, or any felony violation of section 1365 of title 18, United States Code, relating to product tampering; or

``(2) has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

``(e) Requirements.--The Secretary, in promulgating any regulation pursuant to this section, shall, notwithstanding section 553 of title 5, United States Code--

``(1) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

``(2) provide a period of not less than 60 days for comments on the proposed regulation; and

``(3) provide that the final regulation take effect on the date that is 2 years after the date such final regulation is published.".

(b) Authorized Distributors of Record.--Section 503(d) (21 U.S.C. 353(d)) is amended by adding at the end the following:

``(4) In this subsection, the term `authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.".

(c) Effective Date.--The amendments made by subsections (a) and (b) shall take effect on January 1, 2015.

SEC. 205. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS; UNIFORM NATIONAL POLICY.

Subchapter H of chapter V, as amended by section 204, is further amended by adding at the end the following:

``SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

``(a) Requirements.--No third-party logistics provider in any State may conduct activities in any State unless each facility of such third-party logistics provider--

``(1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under subsection (d); or

``(B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (d); and

``(2) if the drug is distributed interstate, is licensed by the State into which the drug is distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

``(b) Reporting.--Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act, a facility of a third-party logistics provider shall report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary--

``(1) the State by which the facility is licensed and the appropriate identification number of such license; and

``(2) the name and address of the facility and all trade names under which such facility conducts business.

``(c) Costs.--

``(1) Authorized fees of secretary.--If a State does not establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics provider located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

``(2) State licensing fees.--

``(A) State established program.--Nothing in this Act shall prohibit a State that has established a program to license a third-party logistics provider from collecting fees from a third-party logistics provider for such a license.

``(B) No state established program.--A State that does not establish a program to license a third-party logistics provider in accordance with this section shall be prohibited from collecting a State licensing fee from a third-party logistics provider.

``(d) Regulations.--

``(1) In general.--Not later than 2 years after the date of

enactment of the Drug Supply Chain Security Act, the Secretary shall issue regulations regarding the standards for licensing under subsection (a), including the revocation and reissuance of such license, to third-party logistics providers under this section.

``(2) Content.--Such regulations shall--

``(A) establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section;

``(B) establish a process by which the Secretary shall issue a license to each third-party logistics provider that meets the requirements set forth in this section if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program;

``(C) require that the entity complies with storage practices, as determined by the Secretary for such facility, including--

``(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;

``(ii) maintaining adequate security; and

``(iii) having written policies and procedures to--

``(I) address receipt, security, storage, inventory, shipment, and distribution of a product;

``(II) identify, record, and report confirmed losses or thefts in the United States;

``(III) correct errors and inaccuracies in inventories;

``(IV) provide support for manufacturer recalls;

``(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

``(VI) ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;

``(VII) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

``(VIII) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

``(D) provide for periodic inspection by the licensing authority, as determined by the Secretary, of such facility warehouse space to ensure compliance with this section;

``(E) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation of subsection (i) or (k) of section 301 or any violation of section 1365 of title 18, United States Code relating to product tampering;

``(F) provide for mandatory background checks of a facility manager or a designated representative of such manager;

``(G) require a third-party logistics provider to provide the applicable licensing authority, upon a request by such authority, a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility; and

``(H) include procedures under which any third-party logistics provider license--

``(i) expires on the date that is 3 years after issuance of the license; and

``(ii) may be renewed for additional 3-year periods.

``(3) Procedure.--In promulgating the regulations under this subsection, the Secretary shall, notwithstanding section 553 of title 5, United States Code--

``(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

``(B) provide a period of not less than 60 days for comments on the proposed regulation; and

``(C) provide that the final regulation takes effect upon the expiration of 1 year after the date that such final regulation is issued.

``(e) Validity.--A license issued under this section shall remain valid as long as such third-party logistics provider remains licensed consistent with this section. If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logistics provider receiving accreditation, pursuant to subsection (d)(2)(A).

``SEC. 585. UNIFORM NATIONAL POLICY.

``(a) Product Tracing and Other Requirements.--Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with--

``(1) any waiver, exception, or exemption pursuant to section 581 or 582; or

``(2) any restrictions specified in section 582.

``(b) Wholesale Distributor and Third-Party Logistics Provider Standards.--

``(1) In general.--Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

``(2) State regulation of third-party logistics providers.--No State shall regulate third-party logistics providers as wholesale distributors.

``(3) Administration fees.--Notwithstanding paragraph (1), a State may administer fee collections for effectuating the wholesale drug distributor and third-party logistics provider licensure requirements under sections 503(e) (as amended by the Drug Supply Chain Security Act), 583, and 584.

``(4) Enforcement, suspension, and revocation.--Notwithstanding paragraph (1), a State--

``(A) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter;

``(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;

``(C) upon conviction of violations of Federal, State, or local drug laws or regulations, may provide for fines, imprisonment, or civil penalties; and

``(D) may regulate activities of licensed entities in a manner that is consistent with product tracing requirements under section 582.

``(c) Exception.--Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder).".

SEC. 206. PENALTIES.

(a) Prohibited Act.--Section 301(t) (21 U.S.C. 331(t)), is amended--

(1) by striking ``or" after ``the requirements of section 503(d),"; and

(2) by inserting ``, failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable," after ``in violation of section

503(e)".

(b) Misbranding.--Section 502 (21 U.S.C. 352), as amended by section 103, is further amended by adding at the end the following:

``(cc) If it is a drug and it fails to bear the product identifier as required by section 582.".

SEC. 207. CONFORMING AMENDMENT.

(a) In General.--Section 303(b)(1)(D) (21 U.S.C. 333(b)(1)(D)) is amended by striking ``503(e)(2)(A)" and inserting ``503(e)(1)".

(b) Effective Date.--The amendment made by subsection (a) shall take effect on January 1, 2015.

SEC. 208. SAVINGS CLAUSE.

Except as provided in the amendments made by paragraphs (1), (2), and (3) of section 204(a) and by section 206(a), nothing in this title (including the amendments made by this title) shall be construed as altering any authority of the Secretary of Health and Human Services with respect to a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) under any other provision of such Act or the Public Health Service Act (42 U.S.C. 201 et seq.).

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 15

Relating to: Compounding Pharmaceuticals

Rule Type: Permanent

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

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

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

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

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

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

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

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

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

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

200 hours

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

Pharmacies, including pharmacies located within hospitals, and pharmacists.

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

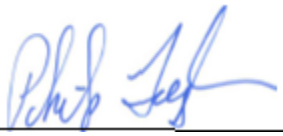
The states are primarily responsible for the oversight of compounding in pharmacies. Pursuant to the Drug Quality and Security Act, the federal government is responsible for outsourcing facilities, which by definition are not pharmacies, and are subject to current good manufacturing practice requirements,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

The Food, Drug and Cosmetic Act requires drugs to be prepared, packed or held under sanitary conditions.

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

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

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



Authorized Signature

February 27, 2019

Date Submitted

Chapter Phar 15

COMPOUNDING PHARMACEUTICALS

Note: Chapter Phar 15 is shown as repealed and recreated by CR 16−085, effective November 1, 2018, Register April 2018 No. 748.

Phar 15.01 Intent. The intent of this chapter is to create a state regulatory standard that aligns with compounding standards found in the United States Pharmaceopeia (USP) general chapters lower than the number 1000.

History: CR 16−085: cr. Register April 2018 No. 748 eff. 11−1−18.

Phar 15.015 Definitions. In this chapter:

(1) "Active pharmaceutical ingredient" or "API" means any substance or mixture of substances intended to be used in the compounding of a drug preparation and that, when used in the compounding of a drug preparation, becomes an active ingredient in the preparation intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

(2) "Added substances" means ingredients that are necessary to compound a drug preparation that are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation.

(3) "Adverse drug event" means an injury resulting from the use of a drug.

(4) "Beyond use date" or "BUD" means one of the following:

(a) The date after which a non−sterile compounded preparation shall not be used.

(b) The date and time after which a sterile compounded preparation shall not be used.

(5) "Certificate of analysis" means a report from the supplier of a component, container, or closure that accompanies the component, container, or closure and contains the specifications and results of all analyses and a description.

(6) "Chemical stability" means each active pharmaceutical ingredient retains its chemical integrity and labeled potency, within specified limits.

(7) "Classified area" means a space that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).

(8) "Component" means any active pharmaceutical ingredient, or added substances used in the compounding of a drug preparation.

(9) "Compounding" means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug delivery device, or a device in accordance with a prescription, or medication order. Compounding does not include repackaging. Compounding includes any of the following:

(a) Preparation of drug dosage forms for both human and animal patients.

(b) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(c) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients. Notwithstanding this paragraph, the reconstituting, mixing, or storage and beyond use dating that is performed for non−sterile preparations in accordance with the directions contained in approved labeling provided by the manufacturer is not compounding.

(d) Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching, or chemical analysis.

(10) "Container−closure system" means the sum of packaging components that together contain and protect a dosage form, including primary packaging components and secondary packaging components.

(11) "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit.

(12) "FDA" means the United States food and drug administration.

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

(14) "Microbiological stability" means sterility or resistance to microbial growth is retained according to specified requirements and antimicrobial agents that are present retain effectiveness within specified limits.

(15) "NF" means the National Formulary.

(16) "Physical stability" means the original physical properties, including appearance, palatability, uniformity, dissolution, and suspendability, are retained.

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

(18) "Stability" means the extent to which a compounded preparation retains, within specified limits and through its beyond use date, the same properties and characteristics that it possessed at the time of compounding.

(19) "Therapeutic stability" means the therapeutic effect remains unchanged.

(20) "Toxicological stability" means no significant increase in toxicity occurs.

(21) "USP" means the United States Pharmacopeia.

History: CR 16−085: cr. Register April 2018 No. 748 eff. 11−1−18.

Subchapter I – General

Phar 15.10 Facilities. A pharmacist engaged in compounding shall ensure all of the following:

(1) An area designated for compounding.

(2) Orderly placement of compounding equipment, materials, and components in order to minimize the potential for compounding errors.

(3) The compounding area is maintained in a clean and sanitary condition.

(4) The compounding area is easily accessible to all of the following:

(a) Hot and cold running water, exclusive of the bathroom sink.

(b) Soap or detergent.

(c) Single–use towels.

(5) All compounding equipment, materials, and components shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage areas.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.11 Equipment and Drug Preparation Containers. (1) A pharmacy shall possess equipment and drug preparation containers or packaging appropriate to the type of compounding performed at the pharmacy.

(2) Equipment and drug preparation containers or packaging used in compounding shall be of appropriate design and capacity, and shall be suitably stored in a manner to facilitate use, cleaning, maintenance, and protect it from contamination.

(3) Equipment and drug preparation containers or packaging used in compounding drug products shall be of suitable composition and may not be reactive, additive, adsorptive, or absorptive so as to alter the stability of the compounded preparation.

(4) Equipment used in compounding shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, according to written policies and procedures, in order to reduce bioburden and reduce the opportunity for cross–contamination.

(5) All equipment utilized in compounding preparations shall be inspected, maintained, calibrated, and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance. Records shall be kept indicating the equipment was inspected, maintained, calibrated, and validated.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.12 Records of compounding. The managing pharmacist shall ensure written or electronic compounding documentation to systematically trace, evaluate, and replicate the compounding steps throughout the process of a preparation. The compounding documentation shall be maintained for a period of 5 years after the date of the last refill. The compounding documentation shall include all of the following:

(1) Official or assigned name, strength, and dosage form of the preparation.

(2) List of all APIs and added substances and their quantities.

(3) Vendor or manufacturer, lot number and expiration date of each APIs and added substances.

(4) Equipment and supplies needed to prepare the preparation.

(5) Mixing instructions pertinent to the replication of the preparation as compounded.

(6) Compatibility and stability information, including references or laboratory testing.

(7) Container or container–closure system used in dispensing.

(8) Packaging and storage requirements.

(9) Quality control procedures.

(10) Sterilization method when using non–sterile ingredients to make a sterile preparation.

(11) Total quantity compounded.

(12) Name of the person who prepared the preparation.

(13) Name of the person who performed the quality control procedures.

(14) Name of the person who approved the preparation.

(15) Date of preparation.

(16) Assigned control or prescription number.

(17) Assigned BUD.

(18) Copy of the label to dispense final product.

(19) Documentation of any adverse reactions or preparation problems reported by the patient or caregiver.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.13 Quality control. (1) One or more pharmacists shall complete a verification of all the following before dispensing:

(a) Written procedures were followed in the compounding process.

(b) Preparation instructions were followed.

(c) Finished preparation appears as expected.

(d) Label includes all required elements.

(e) Quality control procedures were completed.

(f) Compounding records are complete.

(2) A pharmacist shall investigate any discrepancies found during any of verifications and take appropriate corrective action before dispensing.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.14 Training, Policies, and Procedures. (1) TRAINING. All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained and competency is assessed for the type of compounding conducted. It is the responsibility of the managing pharmacist to ensure personnel training and competency assessments are completed and documented.

(2) POLICIES AND PROCEDURES. The pharmacy and managing pharmacist shall establish written policies and procedures governing all of the following:

(a) Personnel qualifications and training, responsibilities, and competencies.

(b) Personal hygiene, garb, garbing, and personal protective gear.

(c) Use and maintenance of compounding facilities and equipment, including applicable certifications.

(d) Environmental monitoring.

(e) Cleaning and disinfection of compounding area.

(f) Component selection.

(g) Sterilization and depyrogenation, if pharmacy does sterilization and depyrogenation.

(h) Documentation requirements.

(i) Establishing BUD.

(j) Reporting of adverse drug events.

(k) A risk management program, including documentation of incidents, adverse drug reactions and product contamination.

(L) A quality assurance program.

(m) Maintaining the integrity of any classified work areas.

(n) Handling small and large spills of antineoplastic agents and other hazardous substances.

(o) Notification to patients or practitioners of a preparation which is recalled when there is potential for patient harm.

(3) REVIEW OF POLICIES AND PROCEDURES. The policy and procedures shall be reviewed at least once every 36 months and shall be updated, on a continuous basis, to reflect current practice. Doc-

umentation of the review shall be made available to the board upon request.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18; correction in (2) (o) made under s. 35.17, Stats., Register April 2018 No. 748.

Phar 15.15 Labeling. The label of a compounded preparation shall include all of the following:

(1) Labeling requirements in s. Phar 7.02 and 8.08.

(2) Storage conditions if other than controlled room temperature.

(3) BUD.

(4) Special handling instructions, when applicable.

(5) Indication that the preparation is compounded unless administered by health care personnel.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.16 Component Selection. (1) Active pharmaceutical ingredients or added substances used in compounding shall be manufactured by an FDA registered facility or accompanied by a certificate of analysis.

(2) APIs and added substances shall meet USP or NF monograph specifications when monographs are available. A pharmacist shall use professional judgement in selection of APIs if USP or NF grade is not available.

(3) All components shall be stored and handled consistent with the manufacturer's labeling or USP or NF monographs and in a manner that prevents contamination and deterioration.

(4) A pharmacist compounding for human use may not use components that have been withdrawn or removed from the market for safety or efficacy reasons by the FDA. A pharmacist compounding for food producing animal use may not use components prohibited for use in food producing animals.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.17 Non–patient specific compounding. Compounded preparations dispensed or distributed to a practitioner pursuant to a non–patient specific order to be administered by a practitioner or practitioner's agent shall meet all of the following:

(1) The order shall include the name and address of the practitioner, drug, strength, quantity, and the purpose of the compounded preparation.

(2) The label shall include the practitioner's name in place of the patient's name and state "For Practitioner Administration Only — Not for Dispensing or Distribution." If the sterility or integrity of the compounded preparation is not maintained after the initial opening of the container, the label shall state "Single–Dose Only."

(3) The pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, and the lot number and BUD of all preparations dispensed or distributed to the practitioner.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Subchapter II – Non–sterile Compounding

Phar 15.20 Component Selection. (1) Components with an expiration date from the manufacturer or distributor may be used before the expiration date provided all of the following:

(a) The component is stored in its original container under conditions to avoid decomposition.

(b) There is minimal exposure of the remaining component each time component is withdrawn from the container.

(2) Components without an expiration date assigned by the manufacturer or supplier shall be labeled with the date of receipt and assigned a conservative expiration date, not to exceed three years after receipt, based upon the nature of the component and its degradation mechanism, the container in which it is packaged and the storage conditions.

(3) Components transferred to another container which shall provide integrity that is minimally equivalent to the original container and shall be identified with all of the following:

(a) Component name.

(b) Original supplier.

(c) Lot or control number.

(d) Transfer date.

(e) Expiration date.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.21 Assigning BUD. (1) The BUD shall not be later than the expiration date on the container of any component.

(2) Only in the absence of stability information that is applicable to a specific drug product and preparation, the maximum BUD for a non–sterile compounded drug preparation that is packaged in a tight, light–resistant container is as follows:

(a) For nonaqueous formulations stored at controlled room temperature, the BUD shall not be later than the time remaining until the earliest expiration date of any active pharmaceutical ingredient or 6 months, whichever is earlier.

(b) For water–containing oral formulations, the BUD shall not be later than 14 days when stored in a refrigerator.

(c) For water–containing semisolid mucosal liquid, topical, or dermal formulations, stored at controlled room temperature, the BUD shall not be later than 30 days.

(3) Assignment of BUD shall include an assessment of the need for antimicrobial agents or storage in a refrigerator to protect against bacteria, yeast, and mold contamination introduced during or after the compounding process.

Subchapter III – Sterile Compounding

Phar 15.30 Definitions. In this subchapter:

(1) "Ante area" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, labeling and other high particulate generating activities are performed. The ante–area is the transition area between the unclassified area of the facility and the buffer area.

(2) "Buffer area" means an ISO Class 7 or ISO Class 8 if using an isolator or cleaner area where the primary engineering control that generates and maintains an ISO Class 5 environment is physically located.

(3) "Category 1" means a compounded sterile preparation compounded with a primary engineering control in a segregated compounding area.

(4) "Category 2" means a compounded sterile preparation compounded with a primary engineering control in a classified area.

(5) "Clean" means to physically remove debris, dirt, dust, and other impurities from surfaces or objects using a cleaning agent with a detergent.

(6) "Compounded sterile preparation" means a compounded final preparation intended to be sterile through the BUD.

(7) "Compounded stock solution" means a compounded solution to be used in the preparation of multiple units of a finished compounded sterile preparation.

(8) "Critical site" means a location that includes any component or fluid pathway surfaces or openings that are exposed and at risk of direct contact with air, moisture, or touch contamination.

(9) "Disinfect" means the killing of microorganisms when used according to the disinfectant's label.

(10) "HEPA" means high–efficiency particulate air.

(11) "ISO Class 5" means conditions in which the air particle count is no greater than a total of 3,520 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA–filtered air.

(12) "ISO Class 7" means conditions in which the air particle count is no greater than a total of 352,000 particles of 0.5 microm-

eters and larger per cubic meter of air that is supplied by HEPA or HEPA–filtered air.

(13) "ISO Class 8" means conditions in which the air particle count is no greater than a total of 3,520,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA–filtered air.

(14) "Isolator" means an enclosure that provides HEPA–filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. An isolator uses only decontaminated interfaces or rapid transfer ports for materials transfer.

(15) "Primary engineering control" means a device or zone that provides an ISO Class 5 environment for sterile compounding.

(16) "Restricted access barrier system (RABS)" means an enclosure that provides HEPA–filtered ISO Class 5 unidirectional air that allows for the ingress or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. RABS include compounding aseptic isolators and compounding aseptic containment isolators.

(17) "Sterility assurance level of 10^{-6}" means an equivalent to a probability that one unit in a million is nonsterile.

(18) "Segregated compounding area" means a designated, unclassified space, area, or room that contains a primary engineering control.

(19) "Urgent use compounded sterile preparation" means a preparation needed urgently for a single patient and preparation of the compounded sterile preparation under Category 1 or Category 2 requirements would subject the patient to additional risk due to delays.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.31 Facility design and environmental controls. (1) GENERAL. Facilities shall meet all of the following requirements:

(a) Be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

(b) Be accessible only to designated personnel.

(c) Have a heating, ventilation, and air conditioning system controlling the temperature and humidity.

(2) SEGREGATED COMPOUNDING AREA. A segregated compounding area shall meet all of the following requirements:

(a) Be located in an area away from unsealed windows and doors that connect to the outdoors, or significant traffic flow.

(b) Be located in an area which is not adjacent to construction sites, warehouses, and food preparation areas.

(c) Have a defined perimeter.

(d) Locate the primary engineering control at least one meter from any sink.

(3) CLASSIFIED AREA. A classified area shall meet all of the following:

(a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, and nonshedding.

(b) Work surfaces shall be constructed of smooth, impervious materials. All work surfaces shall be resistant to damage from cleaning and sanitizing agents.

(c) Junctures where ceilings meet walls shall be covered, caulked, or sealed to avoid cracks and crevices in which microorganisms and other contaminate can accumulate. All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(d) Ceilings that consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.

(e) Walls shall be constructed of a durable material, panels locked together and sealed or of epoxy–coated gypsum board.

(f) Floors shall have a covering that shall be seamless or have heat–welded seams and coving to the sidewall. There shall be no floor drains.

(h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush, and sealed.

(i) Carts shall be constructed of stainless steel wire, nonporous plastic or sheet metal with cleanable casters.

(j) Tacky mats may not be used in a classified area.

(k) HEPA filters and unidirectional airflow shall be used to maintain the appropriate airborne particulate classification.

(L) The classified area shall measure not less than 30 air changes per hour of which at least half shall be HEPA–filtered fresh air.

(m) For classified areas physically separated through the use of walls, doors, and pass–throughs, a minimum differential positive pressure of 0.02–inch water column is required to separate each classified area. If a pass–through is used, only one door shall be opened at a time. A pressure gauge or velocity meter shall be used to monitor the pressure differential or airflow between classified areas with results documented at least daily.

(mm) For classified areas not physically separated, no sterile compounded preparation may be compounded using any ingredient that was at any time non–sterile in a classified area not physically separated and all of the following shall be met:

1. The buffer and ante areas shall be designated with a line of demarcation.

2. The principle of displacement airflow shall be used with an air velocity of 40 feet per minute or more from the buffer area across the entire plane of the line of demarcation.

(n) Devices and objects essential to compounding shall be located at an appropriate distance from the primary engineering control.

(p) The ante area shall meet all of the following requirements:

1. Be capable of maintaining an ISO Class 8 air or higher.

2. Have a sink with running hot and cold running water.

(q) The buffer area shall meet all of the following requirements:

1. Be capable of maintaining an ISO Class 7 air or better.

2. Only contain any of the following:

a. Items, including furniture, equipment, and supplies, that are required for the tasks to be performed in the buffer area.

b. Items that are smooth, impervious, free from cracks and crevices, nonshedding, and easily cleaned and disinfected.

c. Items that have been cleaned and disinfected immediately prior to their being placed in the buffer area.

3. Does not contain any sinks.

4. Does not contain any course cardboard, external shipping containers, and nonessential paper.

(4) PRIMARY ENGINEERING CONTROL. The primary engineering control shall be certified by an independent, qualified individual certified by the Controlled Environment Testing Association's National Board of Testing or another Board approved entity prior to initial use and then every six months. It shall also be certified when any of the following occurs:

(a) Redesign of the facility.

(b) Replacement of the primary engineering control.

(c) Relocation of the primary engineering control.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.32 Personnel hygiene, garbing and protective gear. (1) Personnel suffering from rashes, sunburn, oozing tattoos or sores, conjunctivitis, active respiratory infection, or other active communicable disease shall be excluded from working in compounding areas until the condition is resolved.

(2) All personnel who engage in compounding sterile preparations shall comply with all of the following requirements before entering the compounding area:

(a) Remove personal outer garments, all cosmetics, exposed jewelry and piercings, headphones, ear buds, and cell phones.

(b) Abstain from eating, chewing gum or drinking in the compounding area or bringing food, gum, or drink into the compounding area.

(c) Artificial nails, nail extenders or nail polish may not be worn while working in the compounding area. Nails shall be neat and trim.

(d) Don personnel protective equipment and perform hand hygiene in the following order:

1. Low–lint, disposable shoe covers.

2. Low–lint, disposable covers for head and facial hair that cover the ears and forehead and face masks.

3. Eye shields, if required due to working with irritants or hazardous drugs.

4. Wash hands and forearms up to the elbows with unscented soap and water for at least 30 seconds. Hands and forearms to the elbows shall be completely dried using either lint–free disposable towels or wipes.

5. Don low lint disposable gown or overalls.

6. Prior to donning sterile gloves, hand antisepsis shall be performed using an alcohol–based hand rub with sustained antimicrobial activity following the manufacturers labeled instructions and application times.

(3) Gloves on hands and gauntlet sleeves on RABS shall be routinely inspected for holes, punctures, or tears and shall be replaced immediately if any are detected. Sterile gloves shall be donned over the RABS gloves.

(4) Disinfection of contaminated gloved hands shall be accomplished by wiping or rubbing sterile 70% isopropyl alcohol on all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Routine application of sterile 70% isopropyl alcohol shall occur throughout the compounding process and whenever non–sterile surfaces, including vials, counter tops, chairs, and carts, are touched.

(5) When compounding personnel exit the buffer or segregated compounding area, a gown may be removed and retained in the ante area or segregated compounding area if not visibly soiled, to be worn again during the same work shift. Coveralls, shoe covers, hair and facial hair covers, face masks, eye shields, and gloves shall be replaced with new ones before re–entering the compounding area.

(6) Garbing items, including gowns, shall be segregated and stored before use in an enclosure to prevent contamination.

(7) Visibly soiled gowns shall be changed immediately.

(8) Gloves shall be sterile and powder free and tested by the manufacturer for compatibility with alcohol disinfection.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.33 Cleaning and Disinfecting the Compounding Area and Supplies. (1) Compounding personnel are responsible determining the cleaning and disinfecting products to be used and for ensuring that the frequency of cleaning and disinfecting compounding area is done.

(2) Compounding personnel shall clean in accordance with the following:

(a) Primary engineering control work surfaces, counters, floors and work surfaces in the buffer zone area, ante room and segregated compounding areas daily.

(b) Walls, ceilings and storage shelving monthly.

(c) When a spill occurs or the surface is visibly soiled.

(d) Sporicidal agents shall be used at least weekly to clean compounding areas.

(3) Compounding personnel shall disinfect in accordance with the following:

(a) Primary engineering control work surfaces at the beginning and end of each compounding business day and before each batch, but not longer than 4 hours following the previous disinfection when ongoing compounding activities are occurring.

(b) When microbial contamination is known to have been or is suspected of having been introduced into the compounding area.

(4) All cleaning and disinfecting practices and policies for the compounding area shall be included in written standard operating procedures and shall be followed by all compounding and environmental services personnel.

(5) Cleaning, detergents and disinfection agents shall be selected and used with consideration of compatibilities, effectiveness, and inappropriate or toxic residues. The selection and use of disinfectants shall be guided by microbicidal activities, inactivation by organic matter, residue, and shelf life. Disinfectants shall have antifungal, antibacterial and antiviral activity. Sporicidal agents shall be used at least weekly to clean compounding areas.

(6) Storage sites for compounding ingredients and supplies shall remain free from dust and debris.

(7) Floors, walls, ceiling, and shelving in the classified and segregated compounding areas are cleaned when no aseptic operations are in progress. Cleaning shall be performed in the direction from cleanest to dirtiest areas.

(8) All cleaning tools and materials shall be low–lint and dedicated for use in the buffer room, ante room and segregated compounding areas. If cleaning tools and materials are reused, procedures shall be developed based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.

(9) Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent delivered from a spray bottle or other suitable delivery method. After the disinfectant is wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.

(10) Entry points on bags and vials shall be wiped with small sterile 70% isopropyl alcohol swabs or comparable method for disinfecting, allowing the isopropyl alcohol to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile 70% isopropyl alcohol swabs used for disinfecting entry points of sterile package and devices may not contact any other object before contacting the surface of the entry point. Particle generating material may not be used to disinfect the sterile entry points of packages and devices.

(11) When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 primary engineering control without the need to disinfect the individual sterile supply items.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.34 Urgent use compounded sterile preparations. (1) The compounding process shall be a continuous process that does not exceed one hour, unless required for the preparation.

(2) Administration shall begin within one hour of the completion of the preparation.

(3) Aseptic technique shall be followed during preparation, and procedures shall be used to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix–ups with other compounded sterile products.

(4) Unless immediately and completely administered by the person who prepared the compounded sterile preparation or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall have a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation and the one hour BUD and time.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.35 Sterilization methods. (1) Sterilization methods employed shall sterilize while maintaining its physical and chemical stability and the packaging integrity of the compounding sterile preparations. The efficacy of sterilization and depyrogenation of container closure systems performed in the pharmacy shall be established, documented, and reproducible.

(2) Pre–sterilization requirements shall meet all of the following:

(a) During all compounding activities that precede terminal sterilization, including weighing and mixing, compounding personnel shall be garbed and gloved in the same manner as when performing compounding in an ISO Class 5 environment. All pre–sterilization procedures shall be completed in an ISO Class 8 or better environment.

(b) Immediately before use, all nonsterile measuring, mixing, and purifying devices used in the compounding process shall be thoroughly rinsed with sterile, pyrogen–free water and then thoroughly drained or dried.

(3) Sterilization shall be performed utilizing one of the following methods:

(a) *Sterilization by filtration.* Sterilization by filtration involves the passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent. Filtration may not be used when compounding a suspension when the suspended particles are removed by the filter being used. This method shall meet all of the following:

1. Sterile filters used to sterile filter preparations shall meet all of the following requirements:

a. Be pyrogen–free and have a nominal pore size of 0.22 microns.

b. Be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the compounded sterile preparations will be filtered.

c. Be chemically and physically stable at the compounding pressure and temperature conditions.

d. Have sufficient capacity to filter the required volumes.

e. Yield a sterile filtrate while maintaining pre–filtration pharmaceutical quality, including strength of ingredients of the specific compounded sterile preparations.

2. The filter dimensions and liquid material to be sterile filtered shall permit the sterilization process to be completed rapidly without the replacement of the filter during the filtering process.

3. When compounded sterile preparations are known to contain excessive particulate matter, one of the following shall occur:

a. A pre–filtration step using a filter of larger nominal pore size.

b. A separate filter of larger nominal pore size placed upstream of the sterilizing filter to remove gross particulate contaminants before the compounding sterile compound is passed through the sterilizing grade filter.

4. Sterilization by filtration shall be performed entirely within an ISO Class 5 or better air quality environment.

5. Filter units used to sterilize compounded sterile preparations shall be subjected to the manufacturers' recommended post–use integrity test.

(b) *Sterilization by steam heat.* The process of thermal sterilization using saturated steam under pressure shall be the method for terminal sterilization of aqueous preparations in their final, sealed container closure system. The effectiveness of steam sterilization shall be established and verified with each sterilization run or load by using biological indicators, physicochemical indicators and integrators. This method shall meet all of the following:

1. All materials shall be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile. The duration of the exposure period shall include sufficient time for the compounded sterile preparation to reach the sterilizing temperature.

2. The compounded sterile preparation and other items shall remain at the sterilizing temperature for the duration of the sterilization period. The sterilization cycle shall be designed to achieve a sterility assurance level of 10^{-6}.

3. Compounded sterile preparations shall be placed in trays which allow steam to reach the compounded sterile preparations without entrapment of air. Paper, glass, and metal devices or items shall be wrapped in low lint protective fabric, paper, or sealed in envelopes that will permit steam penetration and prevent post sterilization microbial contamination.

4. Immediately before filling ampules and vials, solutions shall be passed through a filter having a nominal pore size of not larger than 1.2 microns for removal of particulate matter.

5. Sealed containers shall be able to generate steam internally. Stoppered and crimped empty vials shall contain a small amount of moisture to generate steam. Deep containers, including beakers and graduated cylinders, shall be placed on their sides to prevent air entrapment or have a small amount of water placed in them.

6. Porous materials and items with occluded pathways shall only be sterilized by steam if the autoclave chamber has cycles for dry goods.

7. The steam supplied shall be free of contaminants and generated using clean water.

8. The seals on the doors of autoclave chambers shall be examined visually every day they are used for cracks or damage and the seal surfaces shall be kept clean.

9. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

10. Materials in direct contact with the compounded sterile preparation shall undergo a depyrogenation process before being sterilized using steam heat unless the materials used are certified to be pyrogen–free.

(c) *Sterilization by dry heat.* Dry heat sterilization shall be used only for those materials that cannot be sterilized by steam or filtration. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and temperature sensing devices. This method shall meet all of the following:

1. The duration of the exposure period shall include sufficient time for the compounding sterile preparation or items to reach the sterilizing temperature. The compounded sterile preparation and items shall remain at the sterilizing temperature for the duration of the sterilization period.

2. Heated air shall be evenly distributed throughout the chamber.

3. Sufficient space shall be left between materials to allow for good circulation of the hot air.

4. The oven shall be equipped with temperature controls and a timer.

5. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

6. Materials shall first undergo a depyrogenation process before being sterilized using dry heat, unless the materials used are certified to be pyrogen–free.

(4) Dry heat depyrogenation shall be used to render glassware and other thermostable containers pyrogen free. The duration of the exposure period shall include sufficient time for the items to reach the depyrogenation temperature. The items shall remain at the depyrogenation temperature for the duration of the depyrogenation period. The effectiveness of the dry heat depyrogenation cycle shall be established and verified annually using endotoxin challenge vials to demonstrate that the cycle is capable of achieving at least a 3–log reduction in endotoxins.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.36 Inspection, sterility testing and antimicrobial effectiveness. (1) PHYSICAL INSPECTION. (a) At the completion of compounding, the compounded sterile preparation shall be inspected by performing all of the following:

1. Visually inspect the container closure for leakage, cracks in the container, or improper seals.

2. Visually check the compounded sterile preparation for phase separation.

3. Each individual injectable unit shall be inspected against a lighted white background and a black background for evidence of visible particulates or other foreign matter or discoloration.

(b) For compounded sterile preparations which will not be dispensed promptly after preparation, an inspection shall be conducted immediately before it is dispensed for any defects, including precipitation, cloudiness, or leakage, which may develop during storage.

(c) Compounded sterile preparations with any observed defects shall be immediately discarded or marked and segregated from acceptable units in a manner that prevents them from being dispensed.

(2) STERILITY TESTING. (a) The membrane filtration method shall be used for sterility testing unless it is not possible due to the compounded sterile preparation formulation. The direct inoculation of the culture method shall be used when the membrane filtration method is not possible.

(b) If a preparation may be needed before the results of sterility testing have been received, the pharmacy shall daily observe the incubating test specimens and immediately recall the dispensed preparations when there is any evidence of microbial growth in the test specimens. The patient and the prescriber to whom a potentially contaminated compounded sterile preparation was administered shall be notified immediately of the potential risk.

(c) Positive sterility test results shall prompt a rapid and systematic investigation into the causes of the sterility failure, including identification of the contaminating organism and any aspects of the facility, process or personnel that may have contributed to the sterility failure. The investigation and resulting corrective actions shall be documented.

(d) All Category 2 compounded sterile preparations made from one or more nonsterile ingredients, except those for inhalation and ophthalmic administration, shall be tested to ensure that they do not contain excessive bacterial endotoxins.

(e) Notwithstanding par. (d), a compounded sterile preparation does not need to be tested for bacterial endotoxins if the material is stored under cool and dry conditions and one of the following:

1. The certificate of analysis for the nonsterile ingredient lists the endotoxins burden, and that burden is found acceptable.

2. The pharmacy has predetermined the endotoxins burden of the nonsterile ingredient and that burden is found acceptable.

(3) ANTIMICROBIAL EFFECTIVENESS. Compounded sterile preparations containing a preservative added by the compounder shall pass an antimicrobial effectiveness testing with the results obtained on the specific formulation before any of the compounded sterile preparation is dispensed. The test may be conducted only once on each formulation in the particular container–closure system in which it will be stored or dispensed. The antimicrobial effectiveness test shall occur at one of the following times:

(a) At the completion of the sterility test.

(b) At the time of preparation for compounded sterile preparations which have not undergone a sterility testing.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.37 Beyond use dating. (1) Sterility and stability considerations shall be taken into account when establishing a BUD. The following dates and times for storage and initiation of administration of the compounded sterile preparations shall apply:

(a) For compounded sterile preparations including components from conventionally manufactured products, the BUD shall not exceed the shortest expiration of any of the starting components. If the compounded sterile preparation includes non–conventionally manufactured products, the BUD may not exceed the shortest BUD of any of the starting components.

(b) For Category 1 compounded sterile preparations, one of the following:

1. May not exceed 12 hours when the preparation is stored at controlled room temperature.

2. May not exceed 24 hours when the preparation is stored in a refrigerator.

(c) For aseptically prepared Category 2 compounded sterile preparations, one of the following:

1. Prepared with one or more nonsterile ingredients, which are sterilized with a validated sterilization procedure prior to compounding, no preservative added and no sterility testing performed, one of the following:

a. Within 4 days when the preparation is stored at controlled room temperature.

b. Within 7 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

2. Prepared only with sterile ingredients, no preservative added and no sterility testing performed, one of the following:

a. Within 6 days when the preparation is stored at controlled room temperature.

b. Within 9 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

3. Prepared only with sterile ingredients, preservative added and no sterility testing performed, one of the following:

a. Within 28 days when the preparation is stored at controlled room temperature.

b. Within 42 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

4. Prepared only with sterile ingredients, no preservative added and sterility testing, one of the following:

a. Within 28 days when the preparation is stored at controlled room temperature.

b. Within 42 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

5. Prepared with only sterile ingredients, preservative added and sterility testing, one of the following:

a. Within 42 days when the preparation is stored at controlled room temperature.

b. Within 42 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

(d) For Category 2 compounded sterile preparations, terminally sterilized by a validated procedure, one of the following:

1. Prepared with no preservative added and no sterility testing performed, one of the following:

a. Within 14 days when the preparation is stored at controlled room temperature.

b. Within 28 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

2. Prepared with no preservative added and sterility testing performed, one of the following:

a. Within 28 days when the preparation is stored at controlled room temperature.

b. Within 42 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

3. Prepared with preservative added and no sterility testing performed, one of the following:

a. Within 28 days when the preparation is stored at controlled room temperature.

b. Within 42 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

4. Prepared with preservative added and sterility testing performed, one of the following:

a. Within 42 days when the preparation is stored at controlled room temperature.

b. Within 42 days when the preparation is stored in a refrigerator.

c. Within 45 days when the preparation is stored in a freezer.

(2) The BUD established in sub. (1) may not be exceeded or extended for compounded sterile preparations without verifiable supporting valid scientific sterility and stability information that is directly applicable to the specific preparation or compound.

(3) For compounded sterile preparations which have been assigned a BUD based upon storage in a freezer, the integrity of the container–closure system with the specific compounded sterile preparation in it shall have been demonstrated for 45 days at frozen storage. The container–closure integrity test may be conducted only once on each formulation in the specific container closure–system in which it will be stored or dispensed.

(4) When a preservative is added, the compounded sterile formulation shall pass antimicrobial effectiveness testing that shall include inoculation of standardized microorganisms, incubation serial sampling, and calculation of the changes in colony forming unit concentrations in terms of log reduction. The results of antimicrobial effectiveness testing shall be obtained before any of the compounded sterile preparation is dispensed. Preservatives shall not be used as a substitute for good compounding practices.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

Phar 15.38 Training and evaluation. (1) GENERAL. The managing pharmacist, pharmacists, pharmacy technicians, pharmacy interns and pharmacy externs compounding sterile preparations shall successfully complete didactic or practical training. The didactic or practical training shall be done before any compounding personnel initially prepares compounded sterile preparations and annually thereafter and shall include all of the following:

(a) Hand hygiene and garbing.

(b) Cleaning and disinfection.

(c) Measuring and mixing.

(d) Aseptic manipulation.

(e) Cleanroom behavior.

(f) Sterilization and depyrogenation.

(g) Use of equipment.

(h) Documentation.

(i) Use of primary engineering controls.

(2) EVALUATION. Compounding personnel shall successfully complete an initial and annual evaluation which includes all of the following:

(a) Visual observation of hand hygiene and garbing.

(b) Visual observation of aseptic technique.

(c) Gloved fingertip and thumb sampling.

(d) Media–fill tests.

(3) GLOVED FINGERTIP. Successfully gloved and thumb sampling is measured by samplings resulting in zero colony–forming units no fewer than three times. Sampling shall be performed on sterile gloves inside of an ISO Class 5 primary engineering control. Gloved fingertip and thumb sampling in a RABS or an isolator shall be taken from the sterile gloves placed over the gauntlet gloves. When gloved fingertip sample results exceed action levels defined by the pharmacy, a review of hand hygiene and garbing procedures, glove and surface disinfection procedures and work practices shall be performed and documented.

(5) RECORDS. The pharmacy shall maintain written policies and procedures for the initial and ongoing training and evaluation of persons involved in compounding sterile preparations. Documentation of all training, assessments, gloved fingertip tests and media–fill simulations shall be maintained by the pharmacy for 5 years and made available to the Board upon request.

History: CR 16–085: cr. Register April 2018 No. 748 eff. 11–1–18.

FAQs on the Compounding Appeals

Appeals Status

1. What is the status of the Appeals on the USP Compounding Chapters?

On March 12, 2020, the USP Appeals Panel issued decisions on the Appeals to <795>, <797>, and <825>. Click here for more information.

As background, USP published revisions to General Chapter <795> for nonsterile compounding and General Chapter <797> for sterile compounding, as well as a new General Chapter <825> for radiopharmaceutical compounding on June 1, 2019. After publication of the revised and new compounding standards, USP received appeals on certain provisions in <795>, <797>, and <825>. In accordance with USP's Bylaws, the responsible Expert Committees considered the information raised in the appeals and issued decisions on the appeals (see Expert Committee Decisions on Appeals to USP <795> and <797> and <825>). As part of the formal USP appeals process, four (4) stakeholders who submitted appeals to the compounding chapters requested further review by an appointed Appeals Panel. An Appeals Panel was convened (see question 6 below for details), and hearings on the appeals were held on January 21 and 22, 2020 (see question 8 below for details).

After thoughtful deliberation and evaluation of the record and hearings from the appellants, the Appeals Panel made the following decisions on the appeals (see Appeals Panel Decision).

- The Appeals Panel granted the appeals to General Chapters <795> and <797> and has remanded the chapters to the Compounding Expert Committee (CMP EC) with the recommendation for further engagement on the issues raised concerning the beyond-use date provisions.
- The Appeals Panel denied the appeal to General Chapter <825> and has encouraged the appellant to submit the narrower request presented at the hearing before the Panel to the Chemical Medicines Monographs 4 Expert Committee (CHM4 EC) as a request for revision.

Per USP's Bylaws, the decisions of the Appeals Panel are final.

2. What does the final appeal decision mean for the revised General Chapters <795> and <797>?

Due to the remand of these chapters, the currently official versions of <795> (last revised in 2014) and <797> (last revised in 2008) remain official. The Appeals Panel did not determine that the Chapters require revision but noted that the issues raised in the appeals warrant additional dialogue and consideration. It is the purview of the CMP EC to determine the appropriateness of future revisions to the chapters, if any.

Recognizing the public health impact of these standards, USP is committed to further stakeholder engagement through stakeholder forums, roundtables, and other avenues to gather more input on the issues raised in the appeals. USP and the CMP EC are committed to moving forward in an open, transparent, and balanced manner as soon as practicable to enable the chapters to be finalized and implemented in a timely manner. To download the official chapters click here.

3. What does the final appeal decision mean for General Chapter <825>?

Consistent with the Appeals Panel decision to deny the appeal to <825>, the responsible Expert Committee, CHM4 EC, may reinstate the official date of <825>. Based on USP's Bylaws, the Expert Committee must provide at least another six-month implementation period for this Chapter. The CHM4 EC will announce an official date once it is determined.

General Chapter <825> will be **informational and not compendially applicable**. From a compendial standpoint, a USP general chapter numbered below <1000> becomes applicable and compendially required through reference in General Notices, a monograph, or another applicable general chapter numbered below <1000>. Since <825> is not referenced in the General Notices, a monograph, or another applicable general chapter numbered below <1000>, <825> is an informational chapter unless otherwise required by a regulatory body. Download the chapter here.

4. What is the role of the Appeals Panel going forward?

With decisions on these appeals having been made and communicated, the Appeals Panel has concluded its service. The members of the Appeals Panel will maintain strict confidentiality in connection with their involvement in the adjudication of the appeals. Any questions about these Chapters or the USP appeals process should be directed to USP Healthcare Quality & Safety staff at CompoundingSL@usp.org.

5. What sections, or provisions, in USP General Chapters <795>, <797>, and <825> were appealed?

First Level of Appeals

After the revisions were published on June 1, 2019, USP received appeals on key topics covered in USP <795>, <797>, and <825> including:

- Beyond-Use Date (BUD) provisions in <795>, <797>, and <825>
- Removal of Alternative Technology provision from <797>
- Applicability of <795> and <797> to veterinary practitioners
- Compounding from sterile substances in <825>
- Applicability of <825> within the radiopharmaceutical regulatory context

For a summary, see Decision on Appeals to <795> and <797> (August 16, 2019). Regarding <795> and <797>, the CMP EC reviewed the appeals, deliberated on the information related to <795> and <797> at an EC meeting on August 8, 2019, and issued decisions on all appeals on August 16, 2019.

Regarding <825>, the CMH4 EC reviewed the appeal, deliberated on the information related to <825> at an EC meeting on August 15, 2019, and issued its decision on August 19, 2019. For a summary, see Decision on Appeals to <825> (September 13, 2019).

Second Level of Appeals

In accordance with USP's formal appeals process, stakeholders who submitted appeals to the compounding chapters had the opportunity to request further review by an appointed Panel, and USP has received four (4) such requests.

The issues that were under further review were related to:

- Beyond-Use Date (BUD) provisions in <795> and <797>
- Framework and BUD provisions in <825>

6. What was the composition of the Appeals Panel that adjudicated the second-level appeals to <795>, <797>, and <825>?

The members of the Appeals Panel were:

- Jesse L. Goodman, M.D., M.P.H., President, USP Convention
- Mary Foster, Pharm.D., Council of Experts

- Dennis K.J. Gorecki, B.S.P., Ph.D., Council of Experts
- Amy J. Karren, B.Sc., Council of Experts
- Timothy R. Franson, B.S. Pharm., M.D., Board of Trustees
- Marilyn K. Speedie, Ph.D., Board of Trustees
- Thomas R. Temple, B.S.Pharm., M.S., FAPhA, Board of Trustees

7. What did the Appeals Panel consider in making their decisions on the appeals?

The Appeals Panel was charged with considering the sufficiency of the process used by the respective Expert Committees to develop and approve the Chapters under appeal. The Appeals Panel considered whether opportunity for public comment was provided, how the Expert Committees considered the input received from all stakeholders, and whether the basis for the resolution of such comments was communicated publicly. The Appeals Panel made no determination with respect to the scientific content of the Chapters under appeal.

8. When were the hearings on the appeals held?

The hearings for the appeals to <795>, <797>, and <825> were held at the following dates and times:

Tuesday, January 21
9:00 a.m. to 12:00 p.m.

Public hearing on <795> and <797>

- Appellants: Civic Center Pharmacy, Reed's Compounding Pharmacy, Camelback Compounding, Nationwide Compounding, White Mountain Pharmacy, Mountainview Pharmacy, Mixtures Pharmacy, Potter's House Apothecary, Raintree Apothecary, Mortar and Pestle Pharmacy, Community Clinical Pharmacy, Melrose Pharmacy, Rosy's Pharmacy, Prescription Lab Pharmacy, Acacia Pharmacy, MedMetrics Pharmacy, Strive Pharmacy, The Compounders Group (TCG)

1:30 to 4:30 p.m.

Public hearing on <825>

- Appellant: Fagron

Wednesday, January 22
9:00 a.m. to 12:00 p.m.

Public hearing on <795> and <797>

- Appellants: Alliance for Pharmacy Compounding, Innovation Compounding, and Wedgewood Village Pharmacy

1:30 to 4:30 p.m.

Closed hearing on <795> and <797> **[Hearing closed to public based on appellants' request for confidential treatment (transcript available for public review)]**

- Appellants: Five unnamed compounding pharmacies

The following is the agenda for each hearing:

- Administrative Opening Procedures (5-10 min.) – USP Legal
- Opening Remarks (5-10 min.) – Chair of Appeals Panel

- Appellants' presentation (2 hours) – Appellants
- Panel Opportunity to Ask Questions of Appellants (30 min.) – USP Appeals Panel
- Administrative Closing Procedures (5-10 min.) – USP Legal

9. How do I obtain transcripts of the hearings held on the appeals?

Transcripts of all hearings may be ordered directly from the court reporting service. Click here to submit your order.

USP Standard-Setting and Appeals Process

10. How does the USP standard-setting process work?

When it comes to the development and maintenance of quality standards, USP believes public input is critical to ensuring our standards have the intended effects of advancing quality and reducing patient risk. This is why USP has a robust standard setting process:

1. **Public Health Need:** USP – independently or with help from stakeholders – identifies a public health need and evaluates opportunities for possible standard development.
2. **Draft Standard:** USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.
3. **Public Comment Period:** The draft standard is published for stakeholder input. USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.
4. **Review and Approval:** Comments are evaluated and addressed. If needed, further revisions and comments and considered.
5. **Publication:** The final standard is published with an official date typically at least 6 months after publication.

For more information on USP's standard-setting process, please visit:

- Healthcare Quality & Safety Standard-Setting Process
- Quality Matters Blog: Quality Standards that Combine Science, Expertise, and Experience to Protect Patients and Healthcare Workers

11. How can I provide input into a standard?

There are multiple ways to contribute. Stakeholders can submit comments on USP standards or take part in one of our Expert Committees. USP welcomes stakeholder involvement in the standard setting process through the 2020–2025 Call for Candidates.

In the coming months, USP will additionally conduct further stakeholder engagement through stakeholder forums, roundtables, and other avenues to gather more input on the issues raised in the appeals. USP will announce information on these events once it is available. USP's public standards are in continuous revision, and the Expert Committees are committed to ongoing engagement with stakeholders. Sign up for updates to stay informed.

12. How does the USP appeals process work?

USP has an established process by which any interested party may appeal a published standard:

1. An appeal is considered timely if submitted within 60 days of a standard's publication date. USP requests that submitters include relevant information, including supporting data, context, and the basis for the appeal.
2. The responsible Expert Committee (EC) reviews the appeal(s) and has 90 days to issue a decision.
3. Following the EC's decision, the appellant(s) has/have 30 days to request further review by a panel consisting of three members of the Council of Experts appointed by the Chair, three members of the Board of Trustees appointed by the Chair of the Board, and up to three additional experts appointed by the President of the Convention in consultation with the Chair of the Council of Experts. The panel is chaired by the President of the Convention.
4. The panel is convened within 90 days of the request for an appeal, and the appellants are given the right to appear at a hearing of the panel. The panel's decision is final.

Compendial Applicability and Official Chapters

13. What is the status of General Chapter <800>?

General Chapter <800> is not subject to any pending appeals and became official on December 1, 2019. General Chapter <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health and has published additional information on the context for implementation of this chapter.

14. What does "compendially applicable" mean?

The USP is an official compendium of the U.S., and USP standards are therefore considered "compendial standards."

USP General Notices and Requirements section 3.10 describes the applicability of standards. A general chapter numbered below 1000 becomes compendially applicable and is considered a required standard when:

- The chapter is referenced in a monograph,
- The chapter is referenced in another general chapter below 1000, or
- The chapter is referenced in General Notices.

Because chapter <800> is not referenced in an official chapter nor in the General Notices, it is not compendially applicable.

States and other regulators with jurisdiction, may integrate <800> into their statutes and regulations, or through other steps in accordance with their own policy making processes, to apply and enforce <800> in their jurisdictions.

15. Does USP enforce standards?

USP plays no role in enforcement. State and other regulators may make their own determinations regarding enforceability of USP standards. USP remains committed to advancing public health and to promoting the quality of compounded preparations and the safe handling of hazardous drugs. USP will continue to communicate updates on the compounding chapters and the appeals process.

16. What should facilities do if they early adopted the revised appealed chapters?

The Appeals Panel did not determine that General Chapters <795> and <797> require revision but noted that the issues raised in the appeals warrant additional dialogue and consideration. It is the purview of the CMP EC to determine the appropriateness of future revisions to the chapters, if any. The revised <795> and <797> published on June 1, 2019 did not become official and are not appropriate for early adoption based on the appeals decision. Facilities that have already early adopted the revised standards should work with their states, regulators, and accreditation bodies to determine what may be required.

Consistent with the Appeals Panel decision to deny the appeal to <825>, the responsible Expert Committee, CHM4 EC, may reinstate the official date of <825>. Based on USP's Bylaws, the Expert Committee must provide at least another six-month implementation period for this Chapter. The CHM4 EC will announce an official date once it is determined. General Chapter <825> will be informational and not compendially applicable unless otherwise required by a regulatory body.

17. How can facilities implement <800> in light of conflicts with provisions in currently official <797>?

For facilities that implement <800>, there are two sections that are not harmonized between the currently official <797> and <800>: 1) Segregated Compounding Area and 2) "Low volume" hazardous drug (HD) compounding. Below we point out the differences between USP <800> and currently official <797>. States, regulators, and accreditation bodies may make their own determination on implementation and enforcement of USP standards. Stakeholders should speak with the appropriate regulators in their state to determine what may be required.

1. **Segregated Compounding Area (SCA)**

- Currently official USP <797> only allows low-risk level nonhazardous and radiopharmaceutical Compounded Sterile Preparations (CSPs) with 12 hour or less beyond-use date (BUD) to be prepared in an unclassified segregated compounding area.
- USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 12 air changes per hour (ACPH), and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas.
- Note the differences in terminology and requirements in the SCA in currently official USP <797> and C-SCA in <800>.
  - Under <800>, low- and medium-risk level HDs may be prepared in a C-SCA provided it meets the requirements in <800> and the CSP is assigned a BUD of 12 hours or less.
  - If not implementing <800>, only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA (as described in <797>).

2. **"Low volume" hazardous drug compounding**

- Currently official USP <797> allows facilities that prepare a "low volume" of HDs to compound these drugs in a non-negative pressure room if "two tiers of containment (e.g., closed system transfer device (CSTD) within a biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI) that is located in a non-negative pressure room)" are used.
- USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- Under <800>, HDs must be prepared in a C-SEC meeting the requirements in <800>.
- If not implementing <800>, facilities preparing a low volume of HDs may continue to compound these CSPs outside a negative pressure room if two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) are used.

Resources

- Download USP compounding standards
- USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings
- USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

For any questions, contact USP's Healthcare Quality & Safety Team at CompoundingSL@usp.org.