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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Brad Wojciechowski (608) 266-2112
December 5, 2024

Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. A quorum of the Board may be present during any committee meetings.

AGENDA

9:00 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1-2)

B. Approval of Minutes of October 24, 2024 (3)

C. Administrative Rule Matters – Discussion and Consideration (4-69)
1) Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check **(5-69)**
2) Pending or Possible Rulemaking Projects

D. Public Comments

ADJOURNMENT

NEXT MEETING: FEBRUARY 20, 2025

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters

for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

HYBRID (IN-PERSON/VIRTUAL)
PHARMACY RULES COMMITTEE
MEETING MINUTES
OCTOBER 24, 2024

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

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

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 9:08 a.m. A quorum was confirmed with four (4) members present.

ADOPTION OF AGENDA

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF AUGUST 29, 2024

MOTION: Susan Kleppin moved, seconded by Anthony Peterangelo, to approve the Minutes of August 29, 2024, as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Phar 15, Relating to Compounding Pharmaceuticals

MOTION: Tiffany O'Hagan moved, seconded by Anthony Peterangelo, to designate Susan Kleppin to work with DSPS Staff on drafting a reference guide on Phar 15, Relating to non-sterile Compounding. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 10:41 a.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**11/22/24** **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?
12/05/24	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Phar 7, Relating to Electronic Prescriptions, Prescription Labeling, CPR for Pharmacists, Epinephrine Delivery Systems, Controlled Substance Prescription Transfers, Remote Dispensing, Managing Pharmacist Definition, Initial Consultation, Alteration, and Final Check** **2. Pending or Possible Rulemaking Projects**

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

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

Attachments:

1. Phar 7 Redlined Code Text
2. 2023 DEA Rule – Prescription Transfers
3. Center for Medicare and Medicaid Services Memo 2/8/24
4. NABP Pharmacy Practice Act
5. Epinephrine Standing Order

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

11) Authorization

Nilajah D. Hardin — 11/22/24

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

Supervisor (if required) — **Date**

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

Directions for including supporting documents:

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

Chapter Phar 7

PHARMACY PRACTICE

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

Subchapter I — General

Phar 7.01 Definitions. In this chapter:

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

~~**(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.

Commented [NH1]: Changes for Electronic Prescriptions?

Commented [NH2R1]: Add sub c re: Rx via secure chat

Commented [NH3]: Changes for Alteration?

(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 II ~~III~~ – V shall meet the following requirements:

(a) The transfer of prescription order information is permissible only on a one-time basis. ~~Pharmacies electronically sharing a computer system meeting the requirements of sub. (4)~~ For an original prescription for a controlled substance listed in Schedule III – V, a pharmacy 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 for controlled substances listed in Schedule III – V, the pharmacist receiving the transferred prescription information shall write the word "TRANSFER" on the face of the transferred prescription and reduce to writing all information required to be on the prescription, including all of the following:

1. Date of issuance of the original prescription order.
2. Original number of refills authorized on the original prescription order.
3. Date of original dispensing.
4. Number of valid refills remaining and the dates and locations of previous refills.
5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
6. First and last name of the pharmacist making the transfer.
7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

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

1. The date of the original dispensing.
2. The number of refills remaining and the dates and locations of previous refills.
3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.
4. The first and last name of the pharmacist transferring the prescription.
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.

Commented [NH4]: Schedule II Transfers?

Commented [NH5R4]: Does original prescription order mean initial fill?

Commented [NH6R4]: Repeal and recreate - CII vs CIII-V

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

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

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

1. Except as provided in subds. 2. to 5., the first and last name of the patient.
2. For an antimicrobial drug dispensed under s. 450.11 (1g), Stats., the first and last name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT".
3. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the first and last name of the person to whom the opioid antagonist is delivered.
4. For an epinephrine ~~auto-injector~~ delivery system prescribed under s. 118.2925 (3) or 255.07 (2), Stats., the name of the school, authorized entity, or other person specified under s. 255.07 (3), Stats.
5. If the patient is an animal, the last name of the owner, name of the animal and animal species.

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

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

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

(e) Pharmacy name, address and telephone number.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

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

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

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

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

(c) Written or graphic product descriptions.

(d) Any cautions or other provisions.

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

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

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

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

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

Commented [NH7]: Labeling changes?

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

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

(b) One of the following identifiers:

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

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

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

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

(c) Manufacturer lot number.

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

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

(f) Date of repackaging.

(g) Any pharmacy control numbers.

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

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

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

(c) Completion of the drug utilization review.

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

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

Commented [NH8]: Initial Consultation changes?

(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 Pharmacy product verification technician-check-pharmacy technician. (1) DEFINITIONS. In this section:

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

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

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

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

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

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

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

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

(d) Completed the following validation process:

1. The pharmacy technician being validated shall make a product verification on the work of a pharmacist or another pharmacy technician for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the pharmacy technician during the validation process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Brand name.

(b) Generic equivalent drugs and biological products.

(c) Interchangeable biological products.

(d) Retail price.

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

Phar 7.16 Cardiopulmonary Resuscitation Certification for Pharmacists. Every licensed pharmacist shall obtain certification in cardiopulmonary resuscitation at least every 2 years.

Commented [NH9]: Tie to vaccine administration?

Subchapter II — Central Shared Services

Phar 7.30 Definitions. In this subchapter:

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

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

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

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

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

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

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

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

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

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

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

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 Definitions. In this subchapter:

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

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

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

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

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

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

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

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

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

(a) Stocking of the delivery system.

(b) Determining access to the delivery system.

(c) Detection and mitigation of diversion and theft.

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

(2) An automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any of the locations under s. ~~450.062 (1) to (4)~~450.09 (2) (b) 1. a. to d., Stats., may

operate for purposes of practitioner dispensing. The supervising practitioner will ensure all of the following requirements are met:

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

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

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

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

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

(a) Stocking.

(b) Determining access.

(c) Detection and mitigation of diversion and theft.

Phar 7.43 Remote dispensing. (2) LOCATION. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., a pharmacy technician registered under s. 450.068, Stats., or a pharmacy graduate as defined in s. Phar 1.02 (10m) may dispense at any of the locations under s. 450.09 (2) (b) 1. a. to d., Stats.

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

1. Prescriptions may be filled at this location.
2. This remote dispensing location is being supervised by a pharmacist employed by:
   a. Name of pharmacy.
   b. Address of pharmacy.
   c. Telephone of pharmacy.
3. Patient has a right to pharmacist consultation and information on how to file a complaint to the board.

(b) Remote dispensing may not occur if a pharmacist is not available remotely.

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

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

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

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

(c) Final check under s. Phar 7.07.

(d) Federal law if dispensing controlled substances.

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

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

(b) Implement an ongoing quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.

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

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

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

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

(a) Be 18 years of age or older.

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

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

Subchapter IV — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:

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

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

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

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

(1) First and last name of the patient.

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

(3) Date of issuance.

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

(5) Directions for use.

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

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

(b) Electronic signature of the practitioner or delegate.

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

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

(1) Drug name, strength and form.

(2) Beyond use date or expiration date.

(3) Special storage conditions, if required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Located within a licensed pharmacy.

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

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

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

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

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

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

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

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

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

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.
3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.
4. Documentation of the dates of all software upgrades.
5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

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

Subchapter V — Uncredentialed Pharmacy Staff

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

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

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

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

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

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

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

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

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.66 Virginia [Amended]

■ 2. Section 73.66 is amended as follows:

* * * * *

R–6602A Fort Pickett, VA [Removed]

R–6602B Fort Pickett, VA [Removed]

R–6602C Fort Pickett, VA [Removed]

R–6602A Fort Barfoot, VA [New]

Boundaries. Beginning at lat. 37°05′38″ N, long. 77°51′53″ W; to lat. 37°04′26″ N, long. 77°51′44″ W; thence along State Highway No. 40; to lat. 37°03′56″ N, long. 77°51′04″ W; to lat. 37°02′44″ N, long. 77°50′37″ W; to lat. 37°01′06″ N, long. 77°50′42″ W; to lat. 36°59′51″ N, long. 77°50′33″ W; to lat. 36°57′59″ N, long. 77°52′13″ W; to lat. 36°57′55″ N, long. 77°53′18″ W; to lat. 36°58′13″ N, long. 77°57′41″ W; to lat. 37°01′51″ N, long. 77°58′39″ W; to lat. 37°01′51″ N, long. 77°55′57″ W; to lat. 37°04′22″ N, long. 77°55′57″ W; to lat. 37°05′38″ N, long. 77°54′41″ W; to the point of beginning.

Designated altitudes. Surface to but not including 4,000 feet MSL.

Time of designation. Continuous May 1 to Sept. 15. Other times by NOTAM 24 hours in advance.

Controlling agency. FAA, Washington ARTCC.

Using agency. Virginia National Guard, Commander, Fort Barfoot, VA.

R–6602B Fort Barfoot, VA [New]

Boundaries. Beginning at lat. 37°05′38″ N, long. 77°51′53″ W; to lat. 37°04′26″ N, long 77°51′44″ W; thence along State Highway No. 40; to lat. 37°03′56″ N, long. 77°51′04″ W; to lat. 37°02′44″ N, long. 77°50′37″ W; to lat. 37°01′06″ N, long. 77°50′42″ W; to lat. 36°57′55″ N, long. 77°53′18″ W; to lat. 36°58′13″ N, long. 77°57′41″ W; to lat. 37°01′51″ N, long. 77°58′39″ W; to lat. 37°01′51″ N, long. 77°55′57″ W; to lat. 37°04′22″ N, long. 77°55′57″ W; to lat. 37°05′38″ N, long. 77°54′41″ W; to the point of beginning.

Designated altitudes. 4,000 feet MSL to but not including 11,000 feet MSL.

Time of designation. By NOTAM 24 hours in advance.

Controlling agency. FAA, Washington ARTCC.

Using agency. Virginia National Guard, Commander, Fort Barfoot, VA.

R–6602C Fort Barfoot, VA [New]

Boundaries. Beginning at lat. 37°05′38″ N, long. 77°51′53″ W; to lat. 37°04′26″ N, long. 77°51′44″ W; thence along State Highway No. 40; to lat. 37°03′56″ N, long. 77°51′04″ W; to lat. 37°02′44″ N, long. 77°50′37″ W; to lat. 37°01′06″ N, long. 77°50′42″ W; to lat. 36°57′55″ N, long. 77°53′18″ W; to lat. 36°58′13″ N, long. 77°57′41″ W; to lat. 37°01′51″ N, long. 77°58′39″ W; to lat. 37°01′51″ N, long. 77°55′57″ W; to lat. 37°04′22″ N, long. 77°55′57″ W; to lat. 37°05′38″ N, long. 77°54′41″ W; to the point of beginning.

Designated altitudes. 11,000 feet MSL to but not including 18,000 feet MSL.

Time of designation. By NOTAM 24 hours in advance.

Controlling agency. FAA Washington ARTCC.

Using agency. Virginia National Guard, Commander, Fort Barfoot, VA.

* * * * *

Issued in Washington, DC, on July 21, 2023.

Karen L. Chiodini,

Acting Manager, Airspace Rules and Regulations.

[FR Doc. 2023–15863 Filed 7–26–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–637]

RIN 1117–AB64

Transfer of Electronic Prescriptions for Schedules II–V Controlled Substances Between Pharmacies for Initial Filling

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations to allow the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial filling, upon request from the patient, on a one-time basis. This amendment specifies the procedure that must be followed and the information that must be documented when transferring such electronic controlled substance prescriptions between DEA-registered retail pharmacies.

DATES: This rule is effective August 28, 2023.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Executive Summary

On November 19, 2021, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (NPRM) proposing to permit the transfer of electronic prescriptions for controlled substances (EPCS) in schedules II–V between registered retail pharmacies for initial filling on a one-time basis only.[1] In this rulemaking, DEA is finalizing the regulatory text proposed in the NPRM with modifications to address concerns brought forth by commenters.

The final rule amends DEA regulations to explicitly state that an electronic prescription for a controlled substance in schedule II–V may be transferred between retail pharmacies for initial filling on a one-time basis only, upon request from the patient, and clarifies that any authorized refills included on a prescription for a schedule III, IV, or V controlled substance are transferred with the original prescription. The final rule requires that: the transfer must be communicated directly between two licensed pharmacists; the prescription must remain in its electronic form; and the contents of the prescription required by 21 CFR part 1306 must be unaltered during the transmission. The final rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law.

In addition, the final rule describes the information that must be recorded to document transfer of EPCS between pharmacies for initial dispensing. It also clarifies that, in lieu of manual data entry, the transferring and/or receiving pharmacy's prescription processing software may, if capable, capture the required information from the electronic prescription and automatically populate the corresponding data fields to document the transfer. The transferring and/or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate. The electronic records documenting EPCS transfers must be maintained by both pharmacies for two years from the date of the transfer. The existing requirements for all prescriptions, as outlined in 21 CFR part 1306, Prescriptions, and the requirements for prescribing and pharmacy applications, as outlined in 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions, remain unchanged in this final rule.

[1] 86 FR 64881.

Legal Authority

The Controlled Substances Act (CSA) grants the Attorney General the authority to promulgate and enforce any rules, regulations, and procedures that he may deem necessary and appropriate for the efficient executions of his functions under subchapter I (Control and Enforcement) of the CSA.[2] The Attorney General has delegated this authority to the Administrator of the DEA.[3]

Purpose

DEA is revising its regulations to state that, upon request from the patient, a registered retail pharmacy may transfer an electronic controlled substance prescription in schedules II–V to another registered retail pharmacy for initial filling. This final rule specifies the procedures that retail pharmacies must follow and the information that must be documented when transferring EPCS. DEA believes that allowing the electronic transfer of controlled substance prescriptions will decrease the potential for duplicate prescriptions and thus reduce the opportunity for diversion or misuse.

Background

The CSA and its implementing regulations specify the requirements for issuing and filling prescriptions for controlled substances. DEA regulations permit a pharmacist to dispense a controlled substance prescription in schedule II only pursuant to a written prescription (including an electronic prescription), except in limited emergency situations, when dispensing pursuant to an oral prescription is permitted.[4] No prescription for a controlled substance in schedule II may be refilled.[5] DEA regulations permit a pharmacist to dispense a controlled substance in schedules III, IV, and V pursuant to a signed paper prescription, a facsimile of a signed paper prescription, an electronic prescription, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist.[6] Prescriptions for controlled substances in schedules III and IV may not be filled or refilled more than six months after the date of issuance or be refilled more than five times.[7]

The CSA does not address the transfer of paper or electronic prescriptions for controlled substances in any schedule between pharmacies for initial filling. DEA regulations address the transfer of controlled substance prescriptions (schedules III–V) between pharmacies for refill dispensing, but not for initial dispensing.[8]

Unlike paper prescriptions which are issued directly to the patient, electronic prescriptions are transmitted directly from the practitioner to the pharmacy in the form of an electronic data file.[9] If a paper prescription is presented at a pharmacy that is unable to fill it, the paper prescription could be returned to the patient, and the patient could then take the prescription to another pharmacy. However, because the pharmacy receives an electronic prescription as an electronic data file and not a physical paper prescription, it cannot give the prescription to the patient to take to another pharmacy. In this scenario, the pharmacy can only inform the patient that the prescription cannot be filled. The patient could then call the prescribing practitioner to request that a new prescription be sent to a different pharmacy.

DEA realizes that this scenario creates the potential for duplication of prescriptions, if the practitioner transmits a new prescription to a different pharmacy and does not cancel or void the original prescription that was sent to the first pharmacy. It also recognizes that this scenario creates additional burden for patients, who have to get back in touch with the prescribing practitioner to request a new prescription. As more practitioners are issuing controlled substance prescriptions electronically (as discussed below), there is an increasing need to address how a pharmacy should handle an electronic controlled substance prescription that it receives but cannot fill.

DEA's March 2010 interim final rule (IFR), *Electronic Prescriptions for Controlled Substances,* provides practitioners with the option of issuing, and pharmacies with the option of receiving, dispensing, and archiving EPCS in schedules II–V.[10] In a request for information (RFI) published in August 2020, the Centers for Medicare and Medicaid Services (CMS) reported that it has seen a steady increase in the volume of controlled substance prescriptions submitted electronically since DEA published the EPCS IFR.[11] Additionally, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (''SUPPORT Act'') mandates electronic prescribing of schedules II–V controlled substances (with some exceptions) covered under Medicare Part D, beginning January 1, 2021.[12] Further, Surescripts, a health information network and electronic prescribing intermediary, stated in its 2021 National Progress Report that as of January 2022, 35 States require, or will soon require, electronic prescribing of opioids, all controlled substances, or all prescriptions.[13] In the same report, Surescripts also reported that the rate of electronic prescribing of controlled substances increased from 38 percent in 2019 to 58 percent in 2020 and to 73 percent in 2021. Thus, procedures for transferring EPCS between pharmacies for initial dispensing are needed urgently. In this final rule, DEA is amending its regulations to allow, upon request of the patient, the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial filling on a one-time basis.

Summary of the Notice of Proposed Rulemaking

DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** on November 19, 2021.[14] The NPRM proposed to permit the transfer of EPCS in schedules II–V between registered retail pharmacies for initial filling on a one-time basis only. The NPRM also proposed the procedures that would need to be followed and the information to be documented when transferring EPCS for initial filling. The proposed rule focused only on the transfer of EPCS for initial dispensing. The NPRM did not propose changes to 21 CFR 1306.25, which permits the transfer of paper, oral, or electronic prescriptions in schedules III, IV, and V for refill dispensing, or the existing requirements for prescriptions (paper or electronic) in 21 CFR part 1306, Prescriptions, and 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions. DEA invited comments

[2] 21 U.S.C. 871(b).

[3] 28 CFR 0.100(b).

[4] 21 CFR 1306.11(a) and (d).

[5] 21 U.S.C. 829(a) and 21 CFR 1306.12(a).

[6] 21 CFR 1306.21(a).

[7] 21 CFR 1306.22(a).

[8] 21 CFR 1306.25.

[9] An electronic prescription is defined as ''a prescription generated on an electronic application and transmitted as an electronic data file.'' 21 CFR 1300.03.

[10] 75 FR 16236 (Mar. 31, 2010). DEA subsequently reopened the comment period in 2020 to solicit public comment on certain issues. 85 FR 22018 (Apr. 21, 2020).

[11] *Medicare Program: Electronic Prescribing of Controlled Substances; RFI,* 85 FR 47151 (August 4, 2020).

[12] Public Law 115–271, sec. 2003(a)(b) (Oct. 24, 2018). This requirement is codified at 42 U.S.C. 1395w–104(e)(7).

[13] Surescripts, National Progress Report 2021 (*https://surescripts.com/docs/default-source/national-progress-reports/2021-national-progress-report.pdf?sfvrsn=71fcbe15_12*) (accessed June 2, 2022).

[14] 86 FR 64881.

from the public to be submitted on or before January 18, 2022.

Discussion of Public Comments

DEA received 183 comments in response to the NPRM.[15] The commenters included practitioner and professional organizations, pharmacy organizations, pharmacists' associations, State boards of pharmacy, a home delivery pharmacy, a health service organization, a health system, a health information technology developer, a standards developer, and members of the general public. DEA thanks all commenters for their input during the rulemaking process.

The majority of commenters expressed support for the rule. In fact, 89 comments were general statements of support, with no discussion of the proposed regulatory changes. Thirty-seven commenters shared personal accounts of occasions when they or a family member had an electronic prescription sent to the wrong pharmacy or a pharmacy that could not fill the prescription. While most commenters supported the rule in its entirety, some supported the rule's general purpose but were opposed to certain provisions and proposed changes to those particular provisions. Other commenters raised issues of concern, without proposing changes, or sought clarification. Only one commenter opposed the entire rule. Five comments were outside the scope of the rule. These comments, along with DEA's responses, are discussed below.

Patients' Consent for EPCS Transfers

Comments. Two commenters expressed concern that the proposed rule appears to allow the pharmacy to decide when and where a prescription is transferred instead of the patient. One commenter stated that patients should be allowed to request transfers of their prescriptions. Another commenter stated that the rule should require the transferring pharmacy to do the following: (1) Inform the patient of the need to transfer the prescription and the name and location of the pharmacy where the prescription will be transferred, and (2) obtain and document the patient's consent to transfer the prescription to the specified pharmacy location.

DEA Response. To prevent treatment delays, reduce patient burden, and minimize opportunities for diversion, DEA is allowing the transfer of EPCS between pharmacies for initial filling upon the patients' request. If a patient is notified by a pharmacy that the pharmacy is unable to fill an EPCS, the patient may ask to have the prescription transferred to another pharmacy, chosen by the patient, that is able to fill the prescription. For additional clarity, DEA is adding ''upon request from the patient'' to 21 CFR 1306.08(e) in this final rule. However, DEA believes requiring a pharmacy to obtain and document a patient's consent to transfer a prescription would be unnecessarily burdensome.

Initial Dispensing Only

Comments. Two commenters expressed concern that the NPRM proposed allowing the transfer of EPCS between pharmacies for initial dispensing only, and did not address the transfer of EPCS for refill dispensing.

DEA Response. DEA currently permits the transfer of prescription information for refill dispensing of prescriptions for schedule III, IV, and V controlled substances on a one-time basis, if allowed under existing State or other applicable law.[16] DEA notes that prescriptions for controlled substances in schedule II may not be refilled. The existing requirements for transferring EPCS for refill dispensing remain unchanged by this final rule.

EPCS Transferred as Electronic Data Files

Comments. Seventeen commenters mentioned the proposed provision in 21 CFR 1306.08(f)(1), which requires that the prescription be transferred from one pharmacy to another pharmacy in its electronic form. Two commenters supported this provision; one stated that they would no longer support the rule if this provision is removed. Eleven commenters expressed concern that most pharmacies' applications and prescription management software do not have the technology needed to transfer prescriptions electronically. Two commenters noted that pharmacies within the same chain may be able to transfer controlled substance prescriptions electronically because they share a common database but independent community pharmacies are not integrated in this way. Thus, one commenter stated that independent pharmacies would be disproportionately burdened by the rule, and the other commenter stated that the rule appears to be written in favor of keeping a prescription within a chain pharmacy network. One commenter noted that although this functionality became available when the National Council for Prescription Drug Programs (NCPDP) released the SCRIPT Standard Version 2017071, the technology standard that facilitates electronic prescribing, many pharmacy vendors have not implemented the functionality. However, another commenter stated that the SCRIPT Standard Version 2017071 does not facilitate the electronic transfer of controlled substance prescription information at this time and noted that an updated version of the standard that would facilitate this transfer has been approved by NCPDP. The commenter also stated that implementation of the updated version of the standard will likely be a multi-year process. NCPDP confirmed in its comment that the recently approved changes to the standard include support for the one-time transfer of EPCS between pharmacies.

Two commenters stated that DEA should allow the electronic transfer of controlled substance prescriptions for initial filling as one option, but should not mandate electronic transfer as the only option for transferring EPCS. Six commenters suggested that the final rule should allow the transfer of EPCS between pharmacies through pharmacist-to-pharmacist communication by phone or via facsimile. One commenter, noting that pharmacists have been transferring prescriptions successfully for a long time, stated that pharmacists should be trusted and allowed to transfer EPCS by oral communication between the two pharmacists, or by transmitting via facsimile a printed copy of the prescription, annotated with all the required documentation to indicate that the prescription was transferred.

DEA Response. DEA disagrees with the commenter's suggestion that the rule is written in favor of keeping a prescription within a chain pharmacy network and does not believe independent pharmacies will be disproportionately burdened by this rule. DEA has always required, since it began allowing controlled substances to be prescribed electronically, that all records related to such prescriptions must be retained electronically.[17] The final rule permits the transfer of EPCS between pharmacies for initial filling upon request from the patient.[18] Thus, the patient decides if, and to which pharmacy, a prescription is transferred. In addition, NCPDP confirmed in its comment that the new SCRIPT Standard Version 2017071, which is available to both independent and chain

[15] A total of 183 comments were received; however, five commenters submitted duplicate comments.

[16] *See* 21 CFR 1306.25.

[17] See 75 FR 16235 at 16243 and 21 CFR 1311.305(a).

[18] New 21 CFR 1306.08(e).

pharmacies, enables the transfer of prescriptions between pharmacies. DEA acknowledges that some pharmacies may need to coordinate with their pharmacy technology vendors to have certain SCRIPT transactions, including the transaction used to transfer prescriptions between pharmacies, incorporated into their pharmacy applications. The cost associated with this incorporation, if any, is not set by DEA and is beyond the scope of DEA's authority. Further, in 2018, CMS adopted SCRIPT 2017071 as the official electronic prescribing standard for prescriptions covered under Medicare Part D.[19] Consequently, pharmacies that wish to transfer EPCS covered under a Medicare Part D drug plan are already required to have and use the SCRIPT 2017071 transaction that facilitates the transfer of prescriptions between pharmacies.[20] Hence, the final rule continues to require that once a controlled substance prescription is created electronically, it must remain in its electronic format and all records related to the prescription must be retained electronically.

Transfer of EPCS for Initial Filling on a One-Time Basis Only

Comments. Six commenters mentioned the provision that permits the transfer of EPCS between pharmacies for initial dispensing on a ''one-time basis only.'' Two commenters opposed the one-time only limitation. The commenters stated that DEA should at a minimum, allow pharmacies that share a real-time online database, if not all pharmacies, to transfer EPCS for initial dispensing more than once, if needed. One of the commenters also noted that DEA permits pharmacies that share a real-time, online database to transfer prescriptions for schedule III–V controlled substances for refill dispensing up to the maximum number of refills permitted by law and the prescriber's authorization. Four commenters asked DEA to clarify the applicability of the one-time only limitation in specific scenarios. For example, two commenters noted that a prescription could be transferred from one pharmacy that cannot fill it to another pharmacy that is also unable to fill the prescription. One of the commenters stated that as written, the rule would not allow the prescription to be transferred again and thus the patient would be burdened with having to contact the prescribing practitioner to request a new prescription, which is the specific scenario the rule seeks to prevent. Two commenters asked about the transfer of EPCS issued with authorized refills. The commenters asked whether the refills would be transferred with the prescription or remain at the pharmacy that received the prescription from the prescribing practitioner. Another commenter asked if the one-time only transfer allowed for initial dispensing is in addition to the transfer allowed for refill dispensing under 21 CFR 1306.25. One commenter asked if the one-time only limit prohibits the transfer of subsequent controlled substance prescriptions issued to the same pharmacy that transferred the previous prescription to an alternate pharmacy for initial dispensing.

DEA Response. DEA believes the one-time transfer allowance is sufficient to accommodate most situations in which a transfer would be needed for initial dispensing. In an article discussing the adoption of the SCRIPT Standard Version 2017071, Surescripts notes that the receiving pharmacy has to initiate the prescription transfer, when a transfer is requested.[21] In the interest of patient care, as well as good business practice, DEA believes a pharmacy would not request the transfer of a prescription that it cannot fill. As such, the scenario described by the commenters in which a prescription is transferred from one pharmacy to another pharmacy that is also unable to fill the prescription should occur rarely, if ever. Nonetheless, DEA recommends that the patient confirms the ability of the receiving pharmacy to fill the prescription before requesting the transfer.

DEA wishes to clarify that the one-time basis stipulation for transferring EPCS for initial filling is per prescription. In other words, each prescription transmitted from a practitioner to a retail pharmacy may be transferred one time, upon request from the patient, regardless of whether any previous EPCS were transferred. If the prescription being transferred includes authorized refills, the refills are transferred with the prescription to the pharmacy receiving the transfer. This final rule adds additional text to 21 CFR 1306.08(e) to provide this clarification. As proposed in the NPRM, this final rule permits the transfer of EPCS between pharmacies for initial dispensing on a one-time basis only. This is consistent with the current regulations at 21 CFR 1306.25 for the transfer of prescription information between pharmacies for refill dispensing of schedule III–V EPCS on a one-time basis only.[22] DEA notes that 21 CFR 1306.25 remains unchanged by this final rule.

Comments. One commenter asked that DEA clarify in the final rule that a pharmacy that receives transfers of EPCS will not be held responsible for filling a transferred prescription that may have been transferred multiple times.

DEA Response. Pharmacists continue to have a corresponding responsibility to ensure they are filling valid controlled substance prescriptions; nothing in DEA's regulations on EPCS alters a pharmacy's responsibilities to ensure the validity of a controlled substance prescription.[23] Therefore, DEA does not believe any further clarifications are needed in this final rule.

Transfers Communicated Between Two Licensed Pharmacists

Comments. One commenter suggested that DEA allow the transfer of EPCS to be communicated between pharmacy personnel (*e.g.,* pharmacy technicians, pharmacist interns, etc.), as permitted by State laws, instead of requiring the communication to be between two licensed pharmacists.

DEA Response. Existing DEA regulations ''. . . include any other person (*e.g.,* pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State'' in the definition of a pharmacist.[24] As such, DEA does not believe any further clarification is needed, as the existing regulations include the allowance requested by the commenter. However, DEA emphasizes that a pharmacist continues to have a corresponding responsibility to fill only those prescriptions that conform in all respects with the requirements of DEA regulations.[25]

Pharmacy Software that Automatically Populates Prescription Data

Comments. Five commenters asked that DEA allow the transferring and receiving pharmacies' prescription processing software, if capable, to

[19] *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program,* 83 FR 16440 (April 16, 2018).

[20] 42 CFR 423.160(b)(2)(iv).

[21] Swartz, L. and Whittemore, K. A giant leap: The industry adopts a new version of the national e-prescribing standard. November 2019. *https://surescripts.com/docs/default-source/intelligence-in-action/ncpa-surescripts_script_2017071_pharmacist_ce_article_11-2019.pdf* (accessed April 14, 2023).

[22] 21 CFR 1306.25(a).

[23] 21 CFR 1306.04(a) and 1311.100(f).

[24] 21 CFR 1300.01(b).

[25] 21 CFR 1306.04(a).

capture the required information from the electronic prescription and automatically populate the corresponding data fields to document prescription transfers on behalf of the pharmacists.

DEA Response. In light of the comments received on this issue, DEA is revising this final rule to permit a transferring or receiving pharmacy's prescription processing software, if capable, to capture the information required from the electronic prescription and automatically populate the corresponding data fields to document the transfer of prescriptions between pharmacies. However, the transferring or receiving pharmacist must ensure that the populated information is complete and accurate. This provision is added in a new paragraph (f)(6) in 21 CFR 1306.08.

Schedule II Controlled Substances Prescriptions

Comments. One commenter stated that, when a practitioner issues multiple prescriptions for schedule II controlled substances pursuant to 21 CFR 1306.12, the rule should allow one or all of those prescriptions to be transferred for initial dispensing, if requested by the patient.

DEA Response. Although issued at the same time, each prescription for schedule II controlled substances issued pursuant to 21 CFR 1306.12 is a separate prescription. Therefore, if issued electronically, any of these prescriptions may be transferred between pharmacies on a one-time basis for initial dispensing under the conditions set forth in this final rule.

Partial Fills

Comments. Two commenters noted that the proposed rule does not address partial fills of EPCS. The commenters requested clarification regarding the ability of a pharmacy to partially fill a controlled substance prescription and then transfer the remainder to another pharmacy for dispensing of the remaining portion. One of the commenters specifically asked about partial filling of schedule II controlled substance prescriptions while the other commenter asked about all controlled substance prescriptions.

DEA Response. Current DEA regulations permit partial filling of prescriptions for controlled substances in schedules III–V.[26] Existing regulations also permit partial filling of a prescription for a schedule II controlled substance if the pharmacy is unable to supply the full quantity.[27] In this case, the remaining portion of the prescription may be filled within 72 hours of the first partial filling; no additional quantity may be supplied after the 72-hour period without a new prescription.[28] In addition, DEA published a final rule [29] on July 21, 2023, which amends 21 CFR 1306.13 to allow a pharmacist to partially fill a prescription for a schedule II controlled substance at the request of the prescribing practitioner or the patient, if permissible under State law.[30] This rule becomes effective on August 21, 2023.

Regarding the transfer of prescriptions for controlled substances, existing regulations permit the transfer of schedules III–V controlled substance prescriptions for refill dispensing only.[31] Further, under this final rule, the regulations will permit the transfer of EPCS in schedules II–V between DEA-registered retail pharmacies for initial dispensing upon request from the patient. At this time, however, no DEA regulation permits a partially-filled controlled substance prescription to be transferred from one DEA-registered pharmacy to another for dispensing of the remaining portion of the prescription. DEA did not propose any revisions related to the partial filling of controlled substances prescriptions in the proposed rule; thus, such a change would be outside the scope of this final rule. Nonetheless, DEA believes these regulations provide adequate options for patients to obtain their medication without significant treatment disruptions or delays when pharmacies are unable to fill controlled substances prescriptions received electronically. DEA does not believe further revisions to these regulations are warranted at this time.

Economic Impact Analysis

Comments. Four commenters mentioned the economic impact analysis that was included in the NPRM. One commenter, while supporting the proposed rule, stated that the analysis focused only on monetary benefits and did not include unquantifiable benefits such as the reduced stress and improved productivity patients will experience as a result of the rule. A practitioner organization agreed with DEA's conclusion that the rule will result in net cost savings overall. However, the commenter noted that the analysis assumed that a practitioner's administrative staff would handle calls from patients requesting new prescriptions, but some practitioners do not employ administrative staff and must handle the calls themselves. Thus, the commenter stated that the actual net cost savings of the rule will be higher than DEA's estimate.

One pharmacists' association supports DEA's proposal to allow the transfer of EPCS between pharmacies for initial filling from a patient care perspective, but expressed concern about the economic impact of the proposed rule on pharmacies. The association noted that although DEA estimates the rule will result in overall health system cost savings of $22 million annually, pharmacies will actually incur significant costs of $91,625,000 annually, as estimated by DEA.[32] The association also noted that while DEA acknowledges that pharmacies will incur additional expenses, including modifying software configurations, updating business processes, and training personnel, these costs were not included in DEA's analysis. Another commenter agreed that the analysis did not include costs for software upgrades and further noted that the analysis underestimated the time required to process prescription transfers. The commenter stated that processing a prescription transfer can take 15 minutes or more, depending on how busy the pharmacies are at the time of the request. Moreover, the commenter stated that the economic impact analysis did not include additional time and expenses incurred by patients who may need to travel farther to pick up medication from the pharmacy receiving the transfer.

DEA Response. DEA agrees that, in addition to saving time, as indicated in the analysis below, this rule is likely to benefit patients in many other ways, including reducing stress, as noted by the commenter. In addition to minimizing opportunities for diversion, DEA's chief reasons for this rulemaking are to provide patients with the option of transferring EPCS for initial filling to prevent treatment delays and reduce patient burden. However, this final rule does not require a patient to request a transfer. DEA emphasizes that the patient decides if, and to which pharmacy, a prescription is transferred. Thus, this rule does not impose any additional travel burden on patients.

[26] 21 CFR 1306.23.

[27] 21 CFR 1306.13.

[28] 21 CFR 1306.13(a).

[29] *Partial Filling of Prescriptions for Schedule II Controlled Substances,* 88 FR 46983 (July 21, 2023).

[30] 21 CFR 1306.13(b).

[31] 21 CFR 1306.25.

[32] The analysis has been updated since the NPRM using the most recent data available. The updated estimated overall health system cost savings is $29 million and the cost to pharmacies is $50,005,000. See the Executive Order 12866 and Regulatory Flexibility Act sections below under Regulatory Analyses for the detailed analysis.

DEA also agrees the cost savings per transfer would be higher for prescribing practitioners who do not have administrative staff and would have to handle calls from patients requesting new prescriptions themselves under current regulations. According to Surescripts' ''2021 National Progress Report,'' the rate of electronic prescribing of controlled substances was 73 percent in 2021.[33] DEA believes it is reasonable to assume that, on average, EPCS utilization will skew toward practitioners with larger infrastructure and administrative staff, while recognizing that there are some small and independent offices without administrative staff that may experience greater cost savings than estimated. This is because, under this final rule, the prescribing practitioners at those small and independent offices (versus administrative staff at larger practices), would no longer have to handle calls from patients requesting new prescriptions be sent to alternate pharmacies for initial dispensing.

In regards to the estimated additional costs that pharmacies will incur, DEA notes that, although the rule allows EPCS to be transferred at the request of a patient, it does not require a pharmacy to transfer EPCS if it is unable to do so (*e.g.,* due to system limitations). In the economic analysis, DEA estimated that there will be additional costs to the transferring and receiving pharmacies. However, a pharmacy is expected to participate in transfers of EPCS based on its own analysis of benefits and costs. While only costs were quantified, benefits to pharmacies may include customer retention, increased customer traffic, increased customer loyalty, good will, etc., leading to increased sales over time. DEA estimates each transfer of EPCS will cost $2.92 and $4.38 for the transferring and receiving pharmacies, respectively.[34] Since pharmacies are likely to transfer and receive, an average was taken to determine the typical cost per EPCS transfer for a pharmacy. The average cost is $3.65 per transfer.[35] Applying this total to the estimated maximum number of transfers of 13.7 million per year results in a maximum total net cost, to all pharmacies combined, of $50,005,000 annually.[36] As noted above, this $50 million estimate does not reflect the costs that are mandated by this rule, as this rule by its terms does not require pharmacies either to transfer EPCS or receive EPCS, but it does reflect the estimated cost of doing business for pharmacies that choose to transfer EPCS or receive EPCS under this rule.

In the Regulatory Flexibility Act analysis below, DEA compared the estimated cost of this rule to the annual revenues of the smallest of small pharmacy firms, those with less than $100,000 in annual revenue. The estimated cost of this rule is $9 annually for the 666 smallest of small pharmacies.[37] The average cost per firm of $9 equates to 0.01745 percent of average receipt per firm of $51,565.[38] DEA anticipates this rule will not have a significant economic impact for the smallest of small pharmacies; and therefore, this rule will also not have a significant economic impact for larger pharmacies. Additionally, as noted in the analysis, DEA expects minor system and implementation expenses, which consist of modifying software configurations, updating business processes, and minimal personnel training. DEA estimates the cost of these changes is minimal. As discussed above, these costs are not being mandated by this rule, but would be voluntarily borne by the various pharmacies in order to improve or expand their abilities for transferring EPCS.

Other Comments

Comments. One commenter recommended that EPCS transmitted to one pharmacy and dispensed at another pharmacy should not be considered transferred prescriptions if the pharmacy that received the prescription and the pharmacy that dispensed the prescription are both owned by the same entity and share the same integrated information technology (IT) system.

DEA Response. The CSA and DEA regulations require each registrant to maintain complete and accurate records of controlled substances.[39] Each pharmacy, not the entity who owns the pharmacy, is a DEA registrant and is therefore, subject to DEA's recordkeeping requirements. Consequently, a prescription that is received at one pharmacy and dispensed at a different pharmacy is a transferred prescription because the transaction is occurring between two different DEA registrants, even if they are owned by the same entity and share an integrated IT system.

Comments. One commenter recommended that DEA require a pharmacy transferring EPCS to verify that the pharmacy receiving the transferred prescription will be able to dispense the prescription's full quantity prior to transferring the prescription to that receiving pharmacy.

DEA Response. This rule provides for transfers of EPCS at the request of the patient. Although DEA suggests that the transferring pharmacy or the patient verify, prior to the transfer, that the receiving pharmacy is able to fill the transferred prescription, DEA is not requiring pharmacies to do so.

Comments. One commenter stated that the prescribing practitioner should receive an automatic notification when a controlled substance prescription that they issued is transferred.

DEA Response. DEA does not believe that it is necessary to require pharmacies to notify practitioners when an electronic controlled substance prescription that they issued is transferred. DEA believes this would be unnecessarily burdensome to pharmacies.

Comments. One commenter asked that DEA expand exceptions to the definition of ''online pharmacy'' to clarify that using the internet to transfer prescription information between pharmacies does not render a pharmacy an ''online pharmacy.''

DEA Response. DEA does not believe further clarification is necessary. The definition of an online pharmacy contains ten exceptions, which include a DEA-registered pharmacy whose dispensing of controlled substances via the internet consists solely of filling prescriptions that were electronically prescribed in a manner otherwise consistent with DEA regulations and the CSA.[40]

Comments. One commenter recommended that DEA work with State prescription drug monitoring programs (PDMPs) to require pharmacies receiving transferred EPCS to report the transfers to the PDMP. The commenter stated that prescribers should be able to easily identify transferred prescriptions when searching a PDMP database.

DEA Response. PDMP reporting is beyond the scope of this rule and DEA's authority, as PDMPs are regulated by the States.

Comments. One commenter suggested that DEA should preempt any State requirements for transferring EPCS that exceed the requirements established by DEA.

[33] The numbers have been updated since the NPRM with 2021 data. See the Executive Order 12866 section below under Regulatory Analyses for the detailed analysis.

[34] Id.

[35] The numbers have been updated since the NPRM with 2021 data. See the Regulatory Flexibility Act section below under Regulatory Analyses for the detailed analysis.

[36] Id.

[37] Id.

[38] Id.

[39] 21 U.S.C. 827 and 21 CFR 1304.21(a).

[40] *See* 21 CFR 1300.04(h)(9).

DEA Response. DEA generally will not preempt any State laws or regulations related to dispensing controlled substances,[41] including the transfer of EPCS between pharmacies for initial dispensing.

Comments. One commenter recommended that DEA revise the language in the proposed 21 CFR 1306.08(g), which states that EPCS transfers for initial dispensing are permissible only if allowable under existing State or other applicable law. The commenter stated that, as currently written, a State would have to enact a law to expressly allow this activity. The commenter recommended replacing ''only if allowable under existing State or other applicable law'' with ''unless prohibited by existing State or other applicable law.''

DEA Response. DEA understands the commenter's concern. However, DEA is not amending this language at this time. The regulations for the transfer of EPCS between pharmacies for initial dispensing were written to parallel those for the transfer of prescription information for refill dispensing, as well as those for prescriptions in general. DEA notes that the phrase, ''only if allowable under existing State or other applicable law,'' is included in several provisions in 21 CFR part 1306.[42]

Comments. One commenter recommended that DEA use the term ''forward'' instead of ''transfer'' when referring to the transfer of prescription information for initial dispensing. The commenter was concerned that the transfer of prescription information for initial dispensing would be confused with the transfer of prescription information for refill dispensing outlined in 21 CFR 1306.25. The commenter noted that while schedule II controlled substance prescriptions cannot be transferred for refill dispensing because refills are not permitted, this rule, if promulgated, will allow the transfer of schedule II controlled substance prescriptions between pharmacies for initial dispensing.

DEA Response. DEA understands the commenter's concern and preference for differentiating between prescriptions transferred for initial dispensing and those transferred for refill dispensing. However, DEA uses ''transfer'' to refer to the exchange of prescription information between pharmacies for both initial and refill dispensing. Therefore, this final rule continues to use the term ''transfer.''

[41] *See* 21 U.S.C. 903.

[42] *See* 21 CFR 1306.12(b)(1)(iv) and (v) and 1306.25(e).

Out of Scope

Five comments were outside the scope of this rule. Three commenters asked DEA to also allow controlled substance prescriptions prescribed orally and via facsimile to be transferred between pharmacies for initial dispensing. This is beyond the scope of this rule which only addresses the one-time transfer of EPCS between pharmacies for initial dispensing. One commenter disagreed with health insurance entities requiring prior authorization for medications currently being prescribed and those prescribed to treat chronic illnesses. The commenter also stated that after patients have been prescribed medications to treat chronic illnesses for an extended period of time, the prescriptions should be allowed to be refilled without requiring patients to revisit the prescribing practitioner or requiring the practitioner to issue new prescriptions. Additionally, the commenter stated that practitioners should be allowed to prescribe stimulants for less than a 30-day supply. One commenter wanted medications used to treat attention-deficit/hyperactivity disorder removed from the controlled substances lists. These comments are beyond the scope of this rulemaking and therefore are not addressed.

Summary of Changes From the NPRM

DEA is finalizing the proposed regulatory text with modifications to address concerns brought forth by commenters. The final rule adds ''upon request from the patient,'' to the proposed text in 21 CFR 1306.08(e) to clarify that prescription transfers must be requested by the patient. Further, a new sentence is also added to 21 CFR 1306.08(e) to clarify that, when a prescription for a schedule III, IV, or V controlled substance issued with authorized refills is transferred, the authorized refills are transferred with the original prescription.

Additionally, a new paragraph is added to 21 CFR 1306.08(f) to state that a transferring or receiving pharmacy's prescription processing software, if capable, is permitted to capture the information required from the electronic prescription and automatically populate the corresponding data fields to document the transfer of prescriptions between pharmacies. The new paragraph also states that the transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

Summary of the Final Rule

DEA is amending its regulations to allow, upon request from the patient, the transfer of EPCS between registered retail pharmacies for initial filling on a one-time basis only. The final rule explicitly states that an electronic prescription for a controlled substance in schedule II–V may be transferred between retail pharmacies for initial filling on a one-time basis only, upon request from the patient, and clarifies that any authorized refills included on a prescription for a schedule III, IV, or V controlled substance are transferred with the original prescription. The final rule specifies the following requirements that must be met when EPCS are transferred between pharmacies for initial dispensing. The prescription must be transferred in its electronic form and may not be converted to another form (*e.g.,* paper, facsimile) for transmission. The information required to be on a controlled substance prescription pursuant to 21 CFR part 1306 must be unaltered during the transmission. The transfer must be communicated between two licensed pharmacists. The final rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law.

The final rule describes the documentation requirements for pharmacies transferring EPCS for initial filling. A pharmacist transferring an electronic controlled substance prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also update the prescription record with the following information: the name, address, and DEA registration number of the pharmacy to which the prescription was transferred; the name of the pharmacist receiving the transfer; the name of the transferring pharmacist; and the date of the transfer. Similarly, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture the aforementioned required information from the electronic prescription and automatically populate the corresponding data fields to document the transfer. However, the transferring or receiving pharmacist, as applicable, must ensure that the

populated information is complete and accurate. The final rule requires the electronic records documenting EPCS transfers to be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the prescription and the pharmacy receiving and filling the prescription.[43] The existing requirements for all prescriptions, as outlined in 21 CFR part 1306, Prescriptions, and the requirements for prescribing and pharmacy applications, as outlined in 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions, remain unchanged in this final rule.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. The Office of Management and Budget (OMB) has determined that this rule is not a ''significant regulatory action'' under E.O. 12866, section 3(f).

Analysis of Benefits and Costs

DEA is amending its regulations to allow the transfer of electronic prescriptions for schedule II–V controlled substances between registered retail pharmacies for initial dispensing, upon request from the patient, on a one-time basis only. This amendment specifies the procedure that must be followed and the information that must be documented when transferring EPCS between DEA-registered retail pharmacies. As described below, DEA estimates the annual cost savings of this rule is $29 million.[44]

The final rule specifies that: the transfer must be communicated directly between two licensed pharmacists; the prescription must be transferred in its electronic form and may not be converted to another form (*e.g.,* facsimile) for transmission; the required prescription information must be unaltered during the transmission; and the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law. In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also record the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. Finally, the final rule requires that the electronic records documenting the transfer be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the prescription.

As DEA regulations previously did not permit the transfer of schedule II–V EPCS from one retail pharmacy to another retail pharmacy for initial filling, DEA anticipates the ability to transfer EPCS under this final rule will affect the following parties: the first (transferring) pharmacy, patient, prescriber, and second (receiving) pharmacy. To quantify the economic impact of this rule, DEA estimated the average cost and cost savings for each transfer and applied this cost or cost savings to the estimated number of transfers.[45] DEA notes, however, that nothing in this rule mandates that pharmacies must transfer EPCS, or must receive EPCS; so, the economic analysis addresses the estimated costs and cost savings in instances where the transferring and receiving pharmacies agree to engage in such transfers under the terms of this rule.

Estimated Cost or Cost Savings per Transfer

To estimate the unit cost or cost savings, DEA compared the anticipated activities for each of the affected parties when a pharmacy receives EPCS it cannot fill under current practices (prior to the final rule) versus the final rule. The term ''current'' is used in the analysis to mean prior to the implementation of this final rule. The anticipated activities for each of the affected parties under current practices are described below. DEA understands there may be many operational variations; however, DEA believes the scenarios described below are good representations for the purposes of estimating costs.

The anticipated activities for each of the affected parties under current practice are described below.

1. The first (transferring) pharmacy contacts the patient to inform the patient that it is unable to fill the prescription.
2. The first pharmacy notes action taken, as needed.
3. The patient receives the call from the first pharmacy notifying the patient that it is unable to fill the prescription.
4. The patient contacts the prescriber and requests a new prescription.
5. The prescriber's secretary or administrative personnel receives the phone call from the patient.
6. The prescriber cancels the EPCS at the first pharmacy and issues a new EPCS at an alternate (receiving) pharmacy.
7. The alternate pharmacy receives and fills the EPCS.
8. The patient receives the filled prescription from the alternate pharmacy.

By contrast, the anticipated activities for each of the affected parties under the final rule and the economic impact are described below.

1. The first (transferring) pharmacy contacts the patient to inform them that it is unable to fill the prescription. DEA assumes the duration of the call to the patient is the same under the current and final rule scenarios, and therefore, there is no impact on the transferring pharmacy.
2. The patient receives a call from the transferring pharmacy notifying the patient that it is unable to fill the prescription; the patient requests that the prescription be transferred to an alternate (receiving) pharmacy. DEA assumes the duration of the call from the transferring pharmacy is the same under current and final rule scenarios. Therefore, there is no impact to the patient.
3. The patient (nor the transferring or receiving pharmacy) does not need to contact the prescriber to request a new prescription under the final rule. Therefore, there are cost savings for the patient from not contacting the prescriber.
4. The prescriber does not receive a call from the patient. Therefore, there are cost savings for the prescriber.

[43] 21 CFR 1304.06(g).

[44] This analysis has been updated since the NPRM with the latest available data.

[45] DEA expects minor system and implementation expenses, which consist of modifying software configurations, updating business processes, and minimal personnel training. DEA estimates the cost of these changes is minimal.

5. The prescriber does not need to issue a new EPCS. Therefore, there are cost savings for the prescriber.

6. The transferring pharmacy transfers the prescription (including contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer). Transferring the prescription will take longer than simply informing the patient that the prescription cannot be filled. Therefore, there is an additional cost to the transferring pharmacy to transfer a prescription.

7. The alternate (receiving) pharmacy receives the transfer and fills the transferred EPCS (including being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer). DEA anticipates there will be additional costs related to being contacted by the transferring pharmacy and exchanging information. Therefore, there is an additional cost to the receiving pharmacy to transfer a prescription, but the receiving pharmacy also obtains full reimbursement for the cost of filling the prescription.

8. The patient receives the filled prescription from the alternate (receiving) pharmacy. DEA assumes the burden is the same under the current and final rule scenarios, and therefore, there is no impact on the patient. Note that there may be a burden for the patient in needing to travel to a different pharmacy, but that is a cost that arises in every case where the patient must go to a different pharmacy than expected because the first pharmacy is unable to fill the prescription. There is no difference under this rule in the patient's burden in traveling to a different pharmacy, whether the EPCS is transferred under this rule, or the prescriber sends a new EPCS to the second pharmacy, or the patient takes a paper prescription to the second pharmacy.

Table 1 summarizes the activity scenarios under current practices (prior to the final rule) and final rule and the anticipated economic impact.

TABLE 1—PERSONS AND ACTIVITIES, CURRENT VS. FINAL RULE

Persons	Change in activity		Economic impact
	Current	Final Rule	
First or Transferring Pharmacy.	First pharmacy contacts patient to inform that they are unable to fill the prescription.	Transferring pharmacy contacts patient to inform that it is unable to fill the prescription.	Assume duration of call/contact is same ==> no impact.
	Note action taken (*i.e.,* void, cancel, etc.), as needed.	Transfer prescription. "Transfer" includes: contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer.	Additional cost to transfer vs. noting action taken.
Patient	Receive call from pharmacy that it is unable to fill the prescription.	Receive call from pharmacy that it is unable to fill the prescription, request transfer of the prescription to an alternate (receiving) pharmacy.	Assume duration of call/contact is same ==> no impact.
	Contact prescriber to request new prescription.	N/A	Cost savings from not having to contact prescriber.
	Receive filled prescription from second (receiving) pharmacy.	Receive filled prescription from receiving pharmacy.	Assume same burden ==> no impact.
Prescriber	Receive call from patient. (prescriber's secretary).	N/A	Cost savings.
	Cancel prescription sent to first pharmacy and issue new prescription at second (receiving) pharmacy.	N/A	Cost savings.
Second (Receiving) Pharmacy.	Receive prescription and fill	Receive transfer and fill. "Transfer" includes: being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer.	Additional cost to receive and record transfer, but the receiving pharmacy gets full reimbursement for filling prescription.

Cost or cost savings is based on applying the loaded labor rate for each of the affected persons to the estimated time to conduct the activity. The Bureau of Labor Statistics (BLS) hourly wage data for various occupation codes was used to estimate the labor rates for each of the affected persons. Occupation codes 29–1051 Pharmacists, 00–0000 All Occupations, and 43–6013 Medical Secretaries and Administrative Assistants are used as best representations of first (transferring) and second (receiving) pharmacists, patient, and prescriber's secretary, respectively. DEA estimates the best representation for prescribers are the occupation codes 29–1215 Family Medicine Physicians, 29–1171 Nurse Practitioners, and 29–1071 Physician Assistants for practitioner, nurse practitioner, and physician assistant prescribers, respectively. The occupation code 29–1215 Family Medicine Physicians was chosen to represent practitioners as DEA estimates that it best represents the typical prescribing practitioner.

DEA estimates the median hourly wages for the first (transferring) and second (receiving) pharmacist, patient, prescriber's secretary, and prescriber are $61.81, $22.00, $18.01, and $99.18, respectively.[46] [47] Additionally, BLS reports that average benefits for private industry is 29.5 percent of total compensation. The 29.5 percent of total compensation equates to 41.8 percent (29.5 percent/70.5 percent) load on

[46] BLS, May 2021 National Occupational Employment and Wage Estimates United States. *http://www.bls.gov/oes/current/oes_nat.htm.*

[47] The prescriber median hourly wage is a weighted average of the hourly wages of the occupation codes 29–1215 Family Medicine Physicians, 29–1171 Nurse Practitioners, and 29–1071 Physician Assistants, with the weights based on 1,368,536 Practitioner, 331,410 Nurse Practitioner, and 143,725 Physician Assistant active DEA registrations on 6/10/2022.

wages and salaries.[48] The load of 41.8 percent is added to each of the hourly rates to estimate the loaded hourly rates. The loaded hourly rates for the first (transferring) and second (receiving) pharmacy, patient, prescriber's secretary, and weighted average prescriber are $87.65, $31.20, $25.54, and $140.64, respectively. Table 2 summarizes the calculation for the loaded hourly wages for each of the affected persons.

TABLE 2—LOADED HOURLY WAGES

Affected persons	Occupation code	Occupation code description	Median hourly wage	Loaded hourly median wage
Patient	00–0000	All Occupations	$22.00	$31.20
Pharmacist	29–1051	Pharmacists	61.81	87.65
Medical secretary	43–6013	Medical Secretaries and Administrative Assistants.	18.01	25.54
Prescriber		Prescriber (Weighted Average)	99.18	140.64

The below sections describe the calculation conducted to quantify the economic impact associated with the changes in activities under the current and final rule scenarios described above.

1. Currently, the first pharmacy contacts the patient to inform the patient that the pharmacy is unable fill the prescription. DEA estimates that it takes three minutes for the first pharmacist to call the patient. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 by 0.05 (3/60) hours results in a cost of $4.38. Under the final rule, the first (transferring) pharmacist would also contact the patient regarding the inability to fill the prescription. DEA estimates that it would also take three minutes for the transferring pharmacist to call the patient under the final rule, resulting in the same cost of $4.38. Therefore, there is no economic impact to the transferring pharmacy associated with this activity under the final rule.

2. Currently, the first pharmacist notes in the electronic prescription record that the prescription was not filled. DEA estimates that it takes one minute for the first pharmacist to make the entry in the electronic prescription record. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 by 0.0167 (1/60) hours results in a cost of $1.46. Under the final rule, the transferring pharmacy may transfer the prescription, upon request from the patient, to the receiving pharmacy. Additionally, the transferring pharmacy must also contact the receiving pharmacy and exchange and document information such as the transferring pharmacy's name, address and DEA registration number, the name of the transferring pharmacist, and the name of the pharmacist receiving the transfer. DEA estimates that it takes three minutes for the transferring pharmacist to transfer the prescription. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 multiplied by 0.05 (3/60) hours results in a cost of $4.38. Therefore, the net cost to the transferring pharmacy under the final rule is $2.92 ($4.38–$1.46) per transfer.

3. Under current practices, the patient first receives a call from the pharmacist who informs him/her that his/her prescription cannot be filled. DEA estimates that the call between the pharmacist and the patient lasts three minutes. From Table 2, the estimated loaded hourly rate of a patient is $31.20. Multiplying the loaded hourly rate of $31.20 multiplied by 0.05 (3/60) hours results in a cost of $1.56 to the patient. Under the final rule, this activity does not change. With transfers of EPCS, the pharmacist must still contact the patient. Thus, under the final rule, the patient also receives a call from the pharmacist. Estimating three minutes for the call, there is still a cost of $1.56 to the patient. Therefore, there is no economic impact to the patient associated with this activity under the final rule.

4. Under current practices, the patient must contact the prescriber to request a new prescription. DEA estimates that it takes five minutes for the patient to contact the prescriber. From Table 2, the estimated loaded hourly rate of the patient is $31.20. Multiplying the loaded hourly rate of $31.20 by 0.083 (5/60) hours results in a cost of $2.60. Under the final rule, the patient no longer needs to contact the prescriber; the patient requests an electronic transfer of the prescription from the first (transferring) pharmacy to the second (receiving) pharmacy; thus, there is zero cost to the patient. Therefore, this activity under the final rule results in a cost savings to the patient of $2.60 per transfer.

5. Under current practices, the patient has to contact the prescriber asking for a new prescription. DEA estimates that it takes five minutes for the prescriber's medical secretary to receive the call from the patient. From Table 2, the estimated loaded hourly rate of a medical secretary is $25.54. Multiplying the loaded hourly rate of $25.54 by 0.083 (5/60) hours results in a cost of $2.13. Under the final rule, the patient no longer needs to contact the prescriber; thus, this interaction will not occur. Therefore, this activity under the final rule results in a cost savings to the prescriber of $2.13 per transfer.

6. Under current practices, after the medical secretary receives the call from the patient and the information is relayed to the prescriber, the prescriber issues a new prescription. DEA estimates the prescriber takes two minutes to cancel the first prescription and issue a new prescription. From Table 2, the estimated loaded hourly rate of a prescriber is $140.64. Multiplying the loaded hourly rate of $140.64 by 0.03 (2/60) hours results in a cost of $4.69. Under the final rule, the prescriber does not need to issue a new prescription; the original prescription is simply transferred to the receiving pharmacy. Therefore, this activity under the final rule results in a cost savings to the prescriber of $4.69 per transfer.

7. Under current practices, the second (receiving) pharmacy receives and fills the prescription. DEA estimates that it takes 15 minutes for the second (receiving) pharmacy to receive and fill the prescription. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 by 0.25 (15/60) hours results in a cost of $21.91. Under the final rule, DEA also estimates the receiving pharmacist still conducts this activity at the same loaded labor

[48] BLS, ''Employer Costs for Employee Compensation—December 2021'' (ECEC).

rate and time duration, resulting in a cost of $21.91. However, under the final rule, the receiving pharmacist must also receive and record transfer information from the transferring pharmacy. DEA estimates that it takes three minutes for the receiving pharmacy to receive and record transfer information. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 by 0.05 (3/60) hours results in a cost of $4.38. Therefore, this activity under the final rule results in a cost to the receiving pharmacy of $4.38 per transfer, but the receiving pharmacy would get the full reimbursement for filling the prescription.

8. Under current practices, DEA assumes that the patient is informed that the first pharmacy is unable to fill the prescription prior to traveling to pick it up; thus, the patient only makes one trip to the second pharmacy where the prescription was transferred. DEA estimates that it takes 20 minutes for the patient to pick up the filled prescription. From Table 2, the estimated loaded hourly rate of a patient is $31.20. Multiplying the loaded hourly rate of $31.20 by 0.33 (20/60) hours results in a cost of $10.40. Under the final rule, DEA also assumes that the patient is informed that the first pharmacy is unable to fill the prescription prior to traveling to pick up the prescription; thus, the patient only makes one trip. Estimating 20 minutes for the patient to pick up the filled prescription, under the final rule, there is still a cost of $10.40 to the patient. Therefore, there is no economic impact to the patient associated with this activity under the final rule.

As shown by Table 3, the final rule results in a total cost of $8.76 and a total cost savings of $10.88 per transfer. This results in an overall net cost savings of $2.12 per transfer.

TABLE 3—COST/COST SAVINGS CALCULATION, CURRENT VS. FINAL RULE

Person/activity	Current		Final rule		Costs/(cost savings) ($)
	Estimated time (minutes)	Cost, current ($)	Estimated time (minutes)	Cost, final rule ($)	
Transferring pharmacist:					
1. Contact patient	3	4.38	3	4.38	
2.a. Void/transfer prescription	1	1.46			(1.46)
2.b. Transfer prescription			3	4.38	4.38
Patient:					
3. Receive call from pharmacist	3	1.56	3	1.56	
4. Contact prescriber	5	2.60			(2.60)
5. Received filled prescription	20	10.40	20	10.40	
Prescriber:					
6. Receive call from patient (secretary)	5	2.13			(2.13)
7. Issue new prescription (prescriber)	2	4.69			(4.69)
Receiving pharmacist:					
8.a. Receive prescription and fill	15	21.91	15	21.91	
8.b. Receive and record transfer info			3	4.38	4.38
Total Costs					8.76
Total Cost Savings					(10.88)
Net Cost Savings					(2.12)

Estimated Number of Transfers

As mentioned earlier, in order to calculate the total cost savings, DEA applied the $2.12 net cost savings per transaction, from above, to the estimated number of total transfers. DEA estimated the number of total transfers by estimating the number of EPCS for the analysis period, the first five years after the rule goes into effect, and applying an estimated percentage of EPCS that will be transferred.[49]

Surescripts' National Progress Reports for 2019, 2020, and 2021 form the basis for estimating the number of EPCS for the five-year analysis period.[50] The reports indicate that the rate of electronic prescribing for non-controlled substances (E–RX) was 76, 83, 86, 89, and 97 percent in 2017, 2018, 2019, 2020, and 2021, respectively.[51] Additionally, the reports indicate that the rate of EPCS is rising rapidly; the rate was 17, 26, 38, 58, and 73 percent in 2017, 2018, 2019, 2020, and 2021, respectively.[52] Furthermore, there were 65, 96.8, 134.2, 203.6, and 256.9 million EPCS filled in 2017, 2018, 2019, 2020, and 2021, respectively.[53] Dividing the total EPCS by the rate of EPCS, DEA estimates the total controlled substances prescriptions, electronic and non-electronic, were 382.4, 372.3, 353.2, 351.0, and 351.9 million in 2017, 2018, 2019, 2020, and 2021, respectively. Table 4 summarizes the data provided by the reports and the estimated total prescriptions for controlled substances for years 2017–2021.

[49] Due to the rapidly evolving industry and regulatory conditions, the analysis period is five years.

[50] Surescripts, ''2019 National Progress Report'' for 2017 data, ''2020 National Progress Report'' for 2018–2020 data, and ''2021 National Progress Report'' for 2018–2021 data.

[51] Ibid.

[52] Ibid.

[53] Ibid.

TABLE 4—ESTIMATED TOTAL PRESCRIPTIONS FOR CONTROLLED SUBSTANCES
[2017–2021]

	2017	2018	2019	2020	2021
Non-Controlled Substances:					
Rate of E–Rx (%)	76	83	86	89	97
Controlled Substances:					
Total Rx, E and non-E (millions of Rx)	382.4	372.3	353.2	351.0	351.9
Rate of EPCS (%)	17	26	38	58	73
Total EPCS (millions of Rx)	65.0	96.8	134.2	203.6	256.9

As shown in Table 4, the estimated total prescriptions for controlled substances decreased from 382.4 million in 2017 to 351.9 million in 2021. For the purposes of this analysis, DEA estimates the total number of controlled substances prescriptions will stay constant at 351.9 million per year for the five-year analysis period.

Also, from Table 4, the rate of electronic prescribing for non-controlled substances is higher than that of controlled substances. However, DEA estimates the rate of electronic prescribing for controlled substances will match that of non-controlled substances in year one due to a CMS December 2020 rule, which requires electronic prescribing for all controlled substances (with some exceptions) covered under Medicare Part D.[54] The 2021 rate of electronic prescriptions for non-controlled substances was 97 percent. While it is possible that this rate could continue to increase in the future, DEA has no basis to estimate how much higher the rate would go. As the rate of increase has been slowing over the past several years, DEA conservatively estimates that the rate of electronic prescribing for non-controlled substances has peaked at 97 percent and the rate of electronic prescribing for controlled substances will be 97 percent for the analysis period. Multiplying the estimated total number of controlled substance prescriptions, 351.9 million per year, by the estimated rate of EPCS of 97 percent, the estimated total EPCS is 341.3 million per year for the analysis period, the first five years after the rule goes into effect.

CMS estimates that as much as four percent of electronic prescriptions for non-controlled substances in 2019 were transfers.[55] Applying the four percent transfer rate to the total EPCS prescriptions, DEA estimates the number of transfers is 13.7 million per year for each of the first five years.

Total Cost Savings

In order to calculate the total cost savings, DEA applied the $2.12 net cost savings per transaction to the estimated 13.7 million transfers, resulting in a total annual net cost savings of $29.0 million over the five-year analysis period. The net present value (NPV) of the cost savings is $132.8 million at three percent discount rate and $118.9 million at seven percent discount rate. The annualized cost savings from year one to year five is $29.0 million at three percent and seven percent. Table 5 summarizes the NPV and annualized cost savings calculation.

TABLE 5—NPV AND ANNUALIZED COST SAVINGS

	3 Percent	7 Percent
NPV of Cost Savings	$132.8	$118.9
Annualized Cost Savings	29.0	29.0

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of E.O. 13132. The final rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will not have a significant economic impact on a substantial number of these small entities.

The RFA requires an agency to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. DEA has analyzed the economic impact of each provision of this final rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

DEA is amending its regulations to allow the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial dispensing, upon request from the patient, on a one-time basis only. This amendment specifies the procedure that must be followed and the information that must be documented when transferring EPCS between DEA-registered retail pharmacies.

The final rule specifies that: the transfer must be communicated directly between two licensed pharmacists; the prescription must be transferred in its electronic form and may not be converted to another form (*e.g.,* facsimile) for transmission; the required prescription information must be unaltered during the transmission; and the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law. In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also record

[54] 85 FR 84472 (Dec. 28, 2020).

[55] Conference call between CMS and DEA, January 2021. CMS's estimate is a ''high'' estimate and ''four percent'' is considered the maximum percent of electronic prescriptions that are transfers.

the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. Finally, the final rule requires that the electronic records documenting the transfer be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the prescription.

DEA anticipates this final rule will affect pharmacies, offices of physicians, and hospitals, as the majority of prescribers are employed by offices of physicians or hospitals. Table 6 indicates the sectors, as defined by the North American Industry Classification System (NAICS), affected by this final rule. There may be other small entities under Small Business Administration size standards in other NAICS code industries affected by this final rule. However, DEA believes the list in Table 6 is a good general representation of affected small entities and their industries as defined by NAICS.

TABLE 6—AFFECTED INDUSTRIAL SECTORS

Business activity	NAICS code	NAICS Code description
Pharmacy	446110	Pharmacies and Drug Stores.
Prescriber	621111	Offices of Physicians (except Mental Health Specialists).
	622110	General Medical and Surgical Hospitals.

CMS estimates that as much as four percent of electronic prescriptions for non-controlled substances in 2019 were transfers.[56] DEA assumes, for the purposes of this analysis, that such transfers of EPCS are distributed proportionally across all prescribers and pharmacies. Therefore, DEA estimates a substantial number of small entities in the affected industries will be affected by this final rule.

In order to determine whether the final rule will result in a significant impact on the affected small entities, the following steps were taken:

1. Estimate the cost or cost savings per transfer.
2. Estimate the total cost or cost savings of transfers.
3. Allocate the total cost or cost savings across all affected entities in proportion to their revenue to estimate the cost or cost savings per entity.
4. Compare the cost or cost savings to the annual revenue for the smallest of small entities. If the impact is not significant for the smallest of small entities, then the impact is not significant for the larger small entities.

Table 3 summarizes the cost or cost savings on a per-transfer basis. The net cost to the transferring pharmacy is $2.92 (the cost of transferring the prescription, $4.38 (2.b.), minus the cost of updating the prescription record to note that the prescription was not filled, $1.46 (2.a.)). The cost to the receiving pharmacy is $4.38 (8.b.) per transfer. Each transfer affects two different pharmacies, the transferring and receiving pharmacies. Since pharmacies are likely to transfer and receive, an average was taken to determine the typical cost per transfer for a pharmacy. The average cost is $3.65 (($2.92 + $4.38)/2) per transfer. Also, from Table 3, the total cost savings to a prescriber (office of physician or hospital) is $6.82, the sum of the cost savings from not receiving a call from the patient $2.13 (6.) and the cost savings from not issuing a new prescription $4.69 (7.).

To calculate the total cost to pharmacies and total cost savings to prescribers, the unit cost and cost savings are multiplied by the estimated total annual transfers. From above, the estimated number of transfers is 13.7 million per year. Multiplying the average net cost of $3.65 per transfer for pharmacies by 13.7 million transfers, the estimated total cost of transfers to all pharmacies is $50,005,000 per year. Multiplying the cost saving of $6.82 per transfer for prescribers (office of physician or hospital) by 13.7 million transfers, the estimated total cost saving to all prescribers is $93,434,000 per year.

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) is an annual series that provides national and subnational data on the distribution of economic data by enterprise size and industry. SUSB data includes the number of firms at various size ranges. For the purposes of this analysis, the term ''firm'' as defined in the SUSB is used interchangeably with ''entity'' as defined in the RFA. Based on SUSB data, there are 19,234, 161,286, and 2,560 firms in 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively.[57] Furthermore, the total receipts for all firms, including all size ranges, are $282 billion, $474 billion, and $997 billion (rounded) for 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively.[58] Table 7 summarizes the SUSB data and provides receipt values without rounding.

TABLE 7—NUMBER OF FIRMS AND TOTAL RECEIPTS

NAICS Code	NAICS Code description	Receipt size ($)	Number of firms	Receipts ($000)
446110	Pharmacies and Drug Stores	All size ranges	19,234	281,653,229
621111	Offices of Physicians (except Mental Health Specialists)	All size ranges	161,286	473,954,346
622110	General Medical and Surgical Hospitals	All size ranges	2,560	997,368,727

[56] Conference call between CMS and DEA, January 2021. CMS's estimate is a ''high'' estimate and ''four percent'' is considered the maximum percent of electronic prescriptions that are transfers.

[57] SUSB, 2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size, U.S., 6-digit NAICS, *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html* (*https://www2.census.gov/programs-surveys/susb/tables/2017/us_6digitnaics_rcptsize_2017.xlsx*). (Accessed June 8, 2022.) 2017 data by enterprise receipt size is the latest available.

[58] Ibid.

SUSB data also includes the number of firms and receipts for various receipt-size ranges. The smallest size range is firms with annual revenue less than $100,000. The average receipt per firm was calculated based on the number of firms and for the receipts for the firms in the size range. For example, in the 446110—Pharmacies and Drug Stores industry sector, there are 666 firms with receipts under $100,000, and their combined receipts is $34,342,000. Dividing $34,342,000 by 666 results in an average receipt of $51,565 per firm. Performing the same calculation for all three industries, the average receipt per firm is $51,565, $50,554, and $259,478 for the smallest size category in 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively. Table 8 summarizes the calculation for the average receipt per firm.

TABLE 8—AVERAGE RECEIPT PER FIRM

NAICS Code	NAICS Code description	Receipt size ($)	Number of firms	Receipts ($000)	Average receipt per firm ($)
446110	Pharmacies and Drug Stores	<100,000	666	34,342	51,565
621111	Offices of Physicians (except Mental Health Specialists)	<100,000	14,302	723,029	50,554
622110	General Medical and Surgical Hospitals	100,000–*499,999	23	5,968	259,478

*"Receipts" not available for the smallest size range of "<100,000; therefore, used next size range of "100,000–499,000" for comparison.

To compare the average cost per firm with the average receipt per firm, DEA allocated the cost and cost savings proportionally by revenue, divided by the number of firms to calculate the average cost per firm, and compared the average cost per firm as a percent of receipt per firm. For example, the receipts for the 666 firms with receipts under $100,000 in 446110—Pharmacies and Drug Stores industry sector is $34,342,000. This is 0.0121930 percent of total receipt of $281,653,229,000 for all size ranges. Allocating 0.0121930 percent of total cost to pharmacies of $50,005,000 to the 666 firms, the average cost per firm is $9.[59] Dividing the average cost per firm of $9 by the average receipt per firm of $51,565, the average cost per firm is 0.01745 percent of average receipt per firm.

This calculation is repeated for 621111—Offices of Physicians (except Mental Health Specialists) and 622110—General Medical and Surgical Hospitals industry sectors. However, the economic impact for 621111—Offices of Physicians (except Mental Health Specialists) and 622110—General Medical and Surgical Hospitals industry sectors is a cost savings, rather than a cost. Although employment of prescribers is expected to be split between these two industries, to be conservative, the total cost savings (rather than estimating a split between the two industries) is compared to the average receipt per firm. In summary, the average cost or cost savings per firm as percent of receipt is 0.01745 percent, 0.01978 percent, and 0.00925 percent for 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively. Table 9 summarizes the calculation and results.

TABLE 9—COST OR COST SAVINGS PER FIRM AS PERCENTAGE OF RECEIPTS

NAICS Code	NAICS Code description	Receipt size ($)	Number of firms	Receipt as percent of total (percent)	Allocated cost to firms in size range ($)	Average cost per firm ($)	Average cost/ cost savings per firm as percent of receipt (percent)
446110	Pharmacies and Drug Stores	<100,000	666	0.012193	6,097	9	0.01745
621111	Offices of Physicians (except Mental Health Specialists).	<100,000	14,302	0.152552	142,536	10	*(0.01978)
622110	General Medical and Surgical Hospitals.	100,000–499,999	23	0.000598	559	24	*(0.00925)

*Cost savings.

In conclusion, the average cost or cost savings per firm as percent of receipt of 0.01745 percent, 0.01978 percent, and 0.00925 percent are not significant economic impacts. Therefore, DEA concludes this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this final rule will not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA), DEA has identified the following collection of information related to this rule and has submitted this collection request to the Office of Management and Budget (OMB) for review and approval.[60] This final rule establishes the recordkeeping requirements for pharmacies electronically transferring of schedules II–V EPCS for initial dispensing. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be

[59] ($50,005,000 x 0.0121930 percent)/666 = $9.

[60] 44 U.S.C. 3501 *et seq.*

obtained at *https://www.reginfo.gov/public/do/PRAMain.*

A. Collections of Information Associated With the Rule

Title: Recordkeeping Requirements for the electronic transfer of electronic prescriptions for schedules II–V controlled substances between pharmacies for initial filling.

OMB Control Number: 1117–0061.

DEA Form Number: N/A.

DEA is creating a new collection of information by requiring pharmacies to create and maintain certain records relating to the transfer of unfilled EPCS between pharmacies for initial filling. The rule requires the transferring pharmacy to note in the electronic prescription record that the prescription was transferred. The transferring pharmacy is also required to add to the prescription record the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, as well as the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the rule requires the pharmacy receiving the transfer to record the name, address, and DEA registration number of the transferring pharmacy, the name of the transferring pharmacist, the name of the pharmacist receiving the transfer, and the date of the transfer. In addition, the rule required the records to be maintained by both pharmacies for at least two years from the date of the transfer. DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 70,567.
- *Frequency of response: 354.273244* (calculated average).
- *Number of responses:* 25,000,000.
- *Burden per response:* 0.05 hour.
- *Total annual hour burden:* 1,250,000.

The activities described in this information collection are usual and ordinary business activities and no additional cost is anticipated.

If you need additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

Any additional comments on this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117–AB64/Docket No. DEA–637.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 20, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons stated in the preamble, DEA amends 21 CFR part 1306 as follows:

PART 1306—PRESCRIPTIONS

■ 1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 823, 829, 829a, 831, 871(b) unless otherwise noted.

■ 2. Amend § 1306.08 by adding paragraphs (e) through (i) to read as follows:

§ 1306.08 Electronic prescriptions.

* * * * *

(e) The transfer for initial dispensing of an electronic prescription for a controlled substance in Schedule II–V is permissible between retail pharmacies, upon request from the patient, on a one-time basis only. If the transferred prescription is for a controlled substance in Schedule III, IV, or V and includes authorized refills, the refills are transferred with the initial prescription to the pharmacy receiving the transfer.

(f) The transfer of an electronic prescription for a controlled substance in Schedule II–V between retail pharmacies for the purpose of initial dispensing is subject to the following requirements:

(1) The prescription must be transferred from one retail pharmacy to another retail pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (*e.g.,* facsimile) for transmission.

(2) The contents of the prescription required by this part must not be altered during transfer between retail pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(3) The transfer must be communicated directly between two licensed pharmacists.

(4) The transferring pharmacist must add the following to the electronic prescription record:

(i) Information that the prescription has been transferred.

(ii) The name, address, and DEA registration number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.

(iii) The date of the transfer and the name of the pharmacist transferring the prescription information.

(5) The receiving pharmacist must do the following:

(i) Add the word ''transfer'' to the electronic prescription record at the receiving pharmacy.

(ii) Annotate the prescription record with the name, address, and DEA registration number of the pharmacy from which the prescription was transferred and the name of the pharmacist who transferred the prescription.

(iii) Record the date of the transfer and the name of the pharmacist receiving the prescription information.

(6) In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture the information required, as outlined in this paragraph (f), from the electronic prescription and automatically populate the corresponding data fields to document the transfer of an electronic controlled substance prescription between pharmacies. The transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

(g) The transfer of an electronic prescription for a controlled substance in Schedule II–V for the purpose of initial dispensing is permissible only if allowable under existing State or other applicable law.

(h) The electronic records documenting the transfer of the electronic prescription must be maintained for a period of two years

from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the electronic prescription.

(i) A pharmacy may transfer electronic prescription information for a controlled substance in Schedule III, IV, and V to another pharmacy for the purpose of refill dispensing pursuant to § 1306.25.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–15847 Filed 7–26–23; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 222 and 235

[Docket No. 2023–4]

Copyright Claims Board: Agreement-Based Counterclaims

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: Pursuant to the Copyright Alternative in Small-Claims Enforcement Act, the U.S. Copyright Office is adopting as final a May 3, 2023, proposed rule governing the filing of agreement-based counterclaims and related discovery requirements in Copyright Claims Board proceedings.

DATES: Effective August 28, 2023.

FOR FURTHER INFORMATION CONTACT: Rhea Efthimiadis, Assistant to the General Counsel, by email at *meft@copyright.gov* or telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION: The Copyright Alternative in Small-Claims Enforcement Act of 2020 (the ''CASE Act'') [1] directed the Copyright Office to establish the Copyright Claims Board (the ''CCB''), an alternative and voluntary forum for parties seeking to resolve certain copyright-related disputes that have a total monetary value of $30,000 or less. After receiving and considering comments from the public, the Office published final rules addressing various aspects of CCB proceedings.[2] On June 16, 2022, the CCB began receiving claims.

On May 3, 2023, the Office published a notice of proposed rulemaking (''NPRM'') seeking public comment on a proposed rule addressing the filing of agreement-based counterclaims and related discovery requirements in the CCB.[3] The proposed regulations set out the requirements for the content of such counterclaims and any responses to them.[4] The Office also proposed standard interrogatories and standard requests for the production of documents for use in connection with such counterclaims.[5]

The Office received one comment that addressed the proposed rulemaking, but did not recommend any changes to the proposed regulatory text.[6] The Copyright Alliance's comment stated that ''[a]t this time, we have no substantive objections to the Office's proposal to add regulations specifically governing agreement-based counterclaims,'' [7] but requested ''the opportunity to comment further on the rules established in this notice of proposed rulemaking as well as the other regulations governing the CCB once there is more qualitative and quantitative data to consider.'' [8] The Copyright Alliance ''reiterate[d] the importance of ensuring that the rules and regulations do not become so cumbersome and complex such that they make the CCB inaccessible to pro se litigants, who comprise a significant portion of the system's users, and whom the statute was designed to accommodate.'' [9]

The Office appreciates these comments and will take them under advisement. Because the Office did not receive any comments recommending changes to the proposed rule, it adopts the rule as final.

List of Subjects in 37 CFR Parts 222, 225

Claims, Copyright.

Final Regulations

For the reasons stated in the preamble, the U.S. Copyright Office amends 37 CFR parts 222 and 225 as follows:

PART 222—PROCEEDINGS

■ 1. The authority citation for part 222 continues to read as follows:

Authority: 17 U.S.C. 702, 1510.

■ 2. Amend § 222.9 as follows:
■ a. Redesignate paragraphs (c)(6) through (8) as paragraphs (c)(7) through (9), respectively.
■ b. Add paragraph (c)(6) as follows:

§ 222.9 Counterclaim.

* * * * *

(c) * * *

(6) For a counterclaim arising under an agreement asserted under paragraph (c)(2)(iv) of this section—

(i) A description of the agreement that the counterclaim is based upon;

(ii) A brief statement describing how the agreement pertains to the same transaction or occurrence that is the subject of the infringement claim against the counterclaimant; and

(iii) A brief statement describing how the agreement could affect the relief awarded to the claimant;

* * * * *

■ 3. Amend § 222.10 as follows:
■ a. Redesignate paragraph (b)(6) as paragraph (b)(7).
■ b. Add paragraph (b)(6) as follows:

§ 222.10 Response to counterclaim.

* * * * *

(b) * * *

(6) For counterclaims arising under an agreement, as set forth in 37 CFR 222.9(c)(2)(iv), a statement describing in detail the dispute regarding the contractual counterclaim, including any defenses as well as an explanation of why the counterclaim respondent believes the counterclaimant's position regarding the agreement lacks merit; and

* * * * *

PART 225—DISCOVERY

■ 4. The authority citation for part 225 continues to read as follows:

Authority: 17 U.S.C. 702, 1510.

■ 5. Amend § 225.2 as follows:
■ a. Redesignate paragraph (f) as paragraph (h).
■ b. Add paragraphs (f) and (g) as follows:

§ 225.2 Standard interrogatories.

* * * * *

(f) *For a counterclaimant asserting a counterclaim arising under an agreement.* In addition to the information in paragraph (a) of this section, the *standard interrogatories* for

[1] Public Law 116–260, sec. 212, 134 Stat. 1182, 2176 (2020).

[2] 87 FR 20707 (Apr. 8, 2022) (law student representation final rule); 87 FR 12861 (Mar. 8, 2022) (initial proceedings partial final rule); 87 FR 16989 (Mar. 25, 2022) (initial proceedings final rule); 87 FR 24056 (Apr. 22, 2022) (initial proceedings correction); 87 FR 30060 (May 17, 2022) (active proceedings final rule); 87 FR 36060 (June 15, 2022) (active proceedings correction). The Office sought public comments prior to the adoption of these final rules. *See, e.g.,* 86 FR 74394 (Dec. 30, 2021); 86 FR 53897 (Sept. 29, 2021); 86 FR 69890 (Dec. 8, 2021).

[3] 88 FR 27845 (May 3, 2023).

[4] 88 FR 27845, 27846–47.

[5] 88 FR 27845, 27846–48.

[6] *See* Copyright Alliance Comments. The Office received a second comment, which addressed songwriter-related royalty claims that are outside of the scope of this rulemaking. *See* Timothy Gilmore Comments at 1.

[7] Copyright Alliance Comments at 1.

[8] Copyright Alliance Comments at 1–2.

[9] Copyright Alliance Comments at 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-24-05-Hospital/CAH

DATE: February 8, 2024

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Texting of Patient Information and Orders for Hospitals and CAHs

Memorandum Summary

- **Texting patient information and the texting of patient orders among members of the health care team is permissible, if accomplished through a HIPAA compliant secure texting platform (STP) and in compliance with the Conditions of Participation (CoPs).**
- **Computerized Provider Order Entry (CPOE) continues to be the preferred method of order entry by a provider.**

Background:

On January 5, 2018, CMS released QSO-18-10-Hospital, CAHs Revised memorandum, "Texting of Patient Information among Healthcare Providers in Hospitals and Critical Access Hospitals (CAHs)," which acknowledged that the use of texting had become an essential means of communication among hospital and CAH healthcare team members; however, CMS noted the practice of texting patient orders from a provider to a member of the care team would not be compliant with the CoPs, citing concerns with record retention, privacy, confidentiality, security, and the integrity of existing systems at that time.

When CMS developed the 2018 guidance, most hospitals and CAHs did not have the ability to use secure texting platforms to incorporate these messages into the medical record.

Discussion:

The hospital and CAH medical record CoPs at 42 CFR 482.24 and 485.638, respectively, require among other things that inpatient and outpatient medical records be accurately written, promptly completed, properly filed and retained, and accessible. Also, the hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. These requirements do not specify a specific method or system that must be used for author identification and record maintenance.

CPOE continues to be the preferred method of order entry by a provider, but we recognize that alternatives also exist now, as well as significant improvements in the encryption and application interface capabilities of texting platforms to transfer data into electronic health records (EHR).

CMS has held that a physician or advanced practice provider should enter orders into the medical record via a handwritten order or CPOE. An order entered via CPOE, and immediately downloaded into the hospital's or CAH's EHR system, is permitted under the requirements because the order is dated, timed, authenticated, and promptly placed in the medical record.

To comply with the CoPs, all providers must utilize and maintain systems/platforms that are secure and encrypted and must ensure the integrity of author identification as well as minimize the risks to patient privacy and confidentiality, as per the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations. Providers should implement procedures/processes that routinely assess the security and integrity of the texting systems/platforms that are being utilized to avoid negative outcomes that could compromise the care of patients.

CMS expects that providers choosing to incorporate texting of patient information and orders into their EHR will implement a platform that meets the requirements of the HIPAA Security Rule[1] and the HITECH Act Amendment 2021[2] as well as the CoPs.

Contact:
For questions or concerns relating to this memorandum, please contact QSOG_Hospital@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to specific provider types and intended to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.
Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.

[1] The HIPAA Security Rule establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information. The Security Rule is located at 45 CFR Part 160 and Subparts A and C of Part 164.
[2] HITECH Act Amendment 2021 requires that the Department of Health and Human Services (HHS) consider whether a covered entity or business associate has "adequately demonstrated" it had, for not less than the previous 12 months, "recognized security practices" in place when making certain determinations under the HIPAA Security Rule.

Model Rules for the Practice of Pharmacy

Section 1. Pharmacy Licensure.

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

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

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

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

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

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

Section 2. Security.

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

Section 3. Personnel.

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

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

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

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

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

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

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

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

(C) change of ownership of the pharmacy;

(D) change of address of the pharmacy;

(E) permanent closing of the pharmacy;

(F) significant quality-related events;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Policies and Procedures

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

(a) the practice of pharmacy;[108]

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

(c) record retention systems;

(d) automated pharmacy systems;[109]

(e) shared pharmacy services;[110]

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

(g) the proper management of drug recalls;

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

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

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

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

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

[109] See Section 9. Automated Pharmacy Systems.

[110] See Section 8. Shared Pharmacy Services.

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

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

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

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

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

(m) the pharmacy continuous quality improvement program.

(2) Pharmacy Labor Standards/Shift Lengths and Breaks

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

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

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

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

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

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

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

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

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

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

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

Section 4. Prescription Drug Order Processing.

(1) Prescription Drug Order

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

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

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

(c) date of issuance;

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

(e) directions for use;

(f) refills authorized, if any;

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

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

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

(2) Manner of Issuance of a Prescription Drug Order

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

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

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

(3) Transfer of a Prescription Drug Order

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

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

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

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

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

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

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

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

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

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

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

(4) Drug Product Selection by the Pharmacist

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

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

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

(5) Labeling

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

Section 5. Record Keeping.

(1) Patient Records[118]

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

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

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

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

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

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

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

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

(2) Records of Dispensing/Delivery[119]

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

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

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

(3) Electronic Record Keeping

(a) Data Storage and Retrieval

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

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

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

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

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

(b) Security

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

(c) System Backup (Auxiliary Records Maintenance)

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

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

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

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

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

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

Section 6. Pharmacist Care Services.

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

(a) drug utilization review;

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

(c) medication therapy management;

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

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

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

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

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

(3) Patient Counseling[126]

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

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

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

[124] Most recent version.

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

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

(iv) special directions and precautions for preparation, administration, and use by the patient;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

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

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

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

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

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

(5) Collaborative Pharmacy Practice

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 7. Continuous Quality Improvement Program.

(1) Continuous Quality Improvement Program

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

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

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

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

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

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

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

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

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

(e) Quality Self-Audit

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

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

(f) Protection from Discovery[129]

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

(g) Compliance with Subpoena

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

Section 8. Shared Pharmacy Services.

(1) General Requirements[131, 132]

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

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

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

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

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

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

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

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

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

(2) Operations

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

(3) Policies and Procedures

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

(4) Individual Practice

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

Section 9. Automated Pharmacy Systems.

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

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

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

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

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

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

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

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

(i) prevent unauthorized access;

(ii) comply with federal and state rules; and

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

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

(i) identification of the system accessed;

(ii) identification of the individual accessing the system:

(iii) type of transaction;

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

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

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

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

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

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

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

Section 10. Return and Reuse of Prescription Drugs.

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

Section 11. Prescription Drug Repository Programs.

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

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

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

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

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

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

Section 12. Disposal of Controlled Substances.[139]

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

Section 13. Repackaging by Pharmacies for Own Use.

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

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

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

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

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

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

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

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

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

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

Section 14. Telepharmacy

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Application[146]

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Approval by the Board

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

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

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

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

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

(3) Notification

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

(4) Extension of Approval of Pharmacy Practice Initiatives

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

STATE OF WISCONSIN
Department of Health Services
Division of Public Health

1 West Wilson Street
PO Box 2659
Madison WI 53701-2659

Telephone: 608-266-1568
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TTY: 888-701-1253

Date: January 6, 2023 DPH Numbered Memo EMS 23-01

To: Pharmacies licensed in Wisconsin

From: Wisconsin Department of Health Services (DHS)

Statewide Epinephrine Standing Order for Pharmacists

Background
Under Wisconsin law (Wis. Stat. § 255.07), a health care provider with prescribing authority who is employed by or under contract with the department may issue a statewide standing order for the dispensing of epinephrine auto-injectors or prefilled syringes for use under sub. (4) by authorized individuals or by employees or agents of authorized entities who have completed the training required by sub. (5).

Definition
A standing order is defined in Wis. Stat. § 450.01(21p) as an order transmitted electronically or in writing by a practitioner for a drug or device for multiple patients or for one or more groups of patients. A centralized, statewide epinephrine standing order for pharmacists outlines predetermined conditions and criteria that, when met, enables pharmacists across Wisconsin to dispense epinephrine without a patient-specific prescription order. A health care provider with prescribing authority who is licensed in Wisconsin and employed by or under contract with the Department of Health Services (DHS) may issue standing orders for epinephrine that delegate authority to pharmacists practicing and licensed in Wisconsin to dispense epinephrine to those authorized in the standing order.

Subject
Statewide Standing Order for Pharmacies—Epinephrine Dispensing for Anaphylaxis Treatment

Effective date
01/19/2023 (supersedes all previous versions)

Expiration of standing order
This order is effective as of the date signed and shall remain effective until withdrawn by Dr. Colella, DHS Secretary, or either's designee. Dr. Colella retains the right to modify or supplement this order as needed.

Approved for use as a population-based standing order by
Wisconsin Department of Health Services (DHS)

Purpose
This statewide epinephrine standing order delegates authority to pharmacists and outlines the policies and procedures necessary for dispensing epinephrine without a patient-specific prescription to authorized individuals or to employees or agents of authorized entities who have completed the

Policy

This standing order authorizes pharmacists located, and licensed in Wisconsin, to maintain supplies of epinephrine for the purposes stated herein and does not prevent the use of patient-specific or third-party prescriptions for epinephrine written by prescribers.

Authority

This standing order is issued pursuant to Wis. Stat. § 255.07, which permits a physician with prescribing authority who is employed by or under contract with DHS to issue a statewide standing order to one or more persons authorizing the dispensing of epinephrine.

Procedures

This standing order authorizes pharmacists to dispense epinephrine pursuant to the following procedures outlined herein. Unlimited refills are authorized.

1. Standing order compliance requirements

a. **Participant training**: Before dispensing epinephrine under the standing order to an authorized employee, agent, or individual, the pharmacy must verify completion of an anaphylaxis training program conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or an organization approved by DHS. The authorized employee, agent, or individual shall provide the pharmacy a certificate of training from a nationally recognized organization or an organization approved by DHS that must be current within four years of completion.

b. **Public posting**: The standing order signed by a health care provider with prescribing authority who is licensed in Wisconsin and employed by or under contract with DHS, can be found at the following DHS website: https://dhs.wisconsin.gov/dph/memos/ems/index.htm.

c. **Order copy maintenance**: A copy of the standing order signed by a DHS State EMS Medical Director, who is also a licensed physician in Wisconsin, must be maintained on file and be readily retrievable at each participating pharmacy site.

d. **Participant authority**: All registered pharmacists at the pharmacy must be familiar with epinephrine and the patient education materials.

e. **Patient education**: The pharmacist must educate the patient and distribute the patient education materials at the time of dispensing.

f. **Record maintenance**: Pharmacists must maintain dispensing records according to Wis. Admin. Code § Phar 7.11 requirements (pharmacy records).

2. Consultation with patient

a. **Offer education** on:
- Anaphylaxis recognition and epinephrine administration.
- The importance of establishing an anaphylaxis response plan.
- The importance of others in their residence learning this plan in case of emergency.

b. **Provide client with information** about the epinephrine **delivery options** and **insurance coverage**.

c. **Review questions** about anaphylaxis and epinephrine administration.

d. **Provide overview** of:
- How to recognize anaphylaxis.
- Proper procedure to respond to anaphylaxis with the use of epinephrine.
- Contraindications

- Side effects

e. **Discuss** how to **safely dispose** of epinephrine.

f. After Epinephrine administration
   - **Call 911.** Tell emergency dispatcher the person is having anaphylaxis and may need epinephrine when emergency responders arrive.
   - Lay the person flat, raise legs and keep warm. If breathing is difficult or they are vomiting, let them sit up or lie on their side.
   - If symptoms do not improve, or symptoms return, more doses of epinephrine can be given about 5 minutes or more after the last dose.
   - Alert emergency contacts.
   - Encourage transport to ER, even if symptoms resolve; symptoms may reoccur.

Epinephrine Pharmacist Dispensing Protocol

Clinical Pharmacology Description

Epinephrine is indicated for the treatment of anaphylaxis induced by an allergen. Anaphylaxis is highly likely when **any one** of the following two criteria are fulfilled[1]:

1. Acute onset of an illness (minutes to several hours) with simultaneous involvement of the skin, mucosal tissue, or
both (e.g., generalized hives, pruritus or flushing, swollen lips-tongue-uvula) *AND AT LEAST ONE OF THE FOLLOWING:*

- Respiratory compromise (e.g., dyspnea, wheeze-bronchospasm, stridor, reduced PEF*, hypoxemia)
- Reduced BP** or associated symptoms of end-organ dysfunction (e.g., hypotonia [collapse], syncope, incontinence)
- Severe gastrointestinal symptoms (e.g., severe crampy abdominal pain, repetitive vomiting), especially after exposure to non-food allergens

Acute onset of hypotension, or bronchospasm, or laryngeal involvement, after exposure to a known or highly probable allergen for that patient (minutes to several hours), even in the absence of typical skin involvement (https://www.worldallergyorganizationjournal.org/article/S1939-4551(20)30375-6/fulltext#secsectitle0030).

Eligible Candidates

An employee or agent of an authorized entity* who has completed the training required by sub. (5) or an authorized individual** may use an epinephrine auto-injector or prefilled syringe prescribed under sub. (2) to do any of the following:

(a) Provide one or more epinephrine auto-injectors or prefilled syringes to any individual who the employee, agent, or authorized individual believes in good faith is experiencing anaphylaxis, or to the parent, guardian, or caregiver of that individual for immediate administration, regardless of whether the individual has a prescription for an epinephrine auto- injector or prefilled syringe or has previously been diagnosed with an allergy.

(b) Administer an epinephrine auto-injector or prefilled syringe to any individual who the employee, agent, or authorized individual believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for an epinephrine auto-injector or prefilled syringe or has previously been diagnosed with an allergy.

*"Authorized entity" means any entity or organization, other than a school described in s. 118.2925, operating or participating in a business, activity, or event at which allergens capable of causing anaphylaxis may be present, including a recreational and educational camp, college, university, day care facility, youth sports league, amusement park, restaurant, place of employment, and sports arena.

** "Authorized individual" means an individual who has successfully completed the training program under sub. (5).

[1] Cardona V, Ansotegui IJ, Ebisawa M, El-Gamal Y, Fernandez Rivas M, Fineman S, Geller M, Gonzalez-Estrada A, Greenberger PA, Sanchez Borges M, Senna G, Sheikh A, Tanno LK, Thong BY, Turner PJ, Worm M. World allergy organization anaphylaxis guidance 2020. World Allergy Organ J. 2020 Oct 30;13(10):100472. doi: 10.1016/j.waojou.2020.100472. PMID: 33204386; PMCID: PMC7607509.

Order to dispense

Upon satisfactory assessment that the following requirements have been met:

(a) An employee or agent described in sub. (3) or (4) or an individual seeking to be an authorized individual completed an anaphylaxis training program and at least every 4 years thereafter conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or an organization approved by the department.

(b) The organization that conducts the training under par. (a) shall issue a certificate, on a form approved by the department, to each person who successfully completes the anaphylaxis training program.

and upon providing consultation to that individual regarding recognizing and responding to suspected anaphylaxis, deliver one epinephrine kit. The specific epinephrine formulation shall be selected from the list below in accordance with the recipient's preference and training to administer a particular formulation:

Product, quantity and instructions for epinephrine to be dispensed

	Auto-injector	Pre-filled syringe
Adult 66 pounds or more/30 kilograms or more	Dispense Two single-use auto-injectors of epinephrine 1:1,000; 0.3 to 0.5 mg/ml depending on manufacturer availability. Sig: Place one auto-injector against the middle of the outer thigh (through clothing, if needed), then push firmly until you hear a click sound, and hold in place for 3 seconds to allow drug administration. If there is no improvement after 5 minutes, repeat the injection.	Dispense Two single-use pre-filled syringes of epinephrine 1:1,000; 0.5 mg/ml Sig: 1) Uncap the epinephrine syringe. 2) Insert the needle into the muscle of the middle of the outer thigh of the patient, through clothing if needed, and push on the plunger to inject the epinephrine. If there is no improvement after 5 minutes, repeat the injection.
Pediatric 33 to 66 pounds/15 to 30 kilograms for prefilled syringes or as specified by auto-injector manufacturer. Do not dispense pediatric epinephrine for patients below 33 pounds/15 kg or as specified by autoinjector manufacturer.	Dispense Two single-use auto-injectors of epinephrine 1:1,000; 0.15 mg/ml. Sig: Place one auto-injector against the middle of the outer thigh (through clothing, if needed), then push firmly until you hear a click sound, and hold in place for 3 seconds to allow drug administration. If there is no improvement after 5 minutes, repeat the injection.	Dispense Two single-use pre-filled syringes of epinephrine 1:1,000; 0.15 mg/ml. Sig: 1) Uncap the epinephrine syringe. 2) Insert the needle into the muscle of the middle of the outer thigh of the patient, through clothing if needed, and push on the plunger to inject the epinephrine. If there is no improvement after 5 minutes, repeat the injection.

Prescription label

Should include the following:

- Name of the recipient or patient (prescribed or using)
- Prescriber name on the standing order
- Epinephrine formulation and concentration
- Date dispensed
- Refills: PRN, as needed for a year
- Patient instructions
  - Dispensed per standing order; and
  - Use as directed.

Patient Education

- Review common questions about anaphylaxis and epinephrine administration.
- Provide an overview of how to recognize anaphylaxis and proper procedure to respond with epinephrine.
- Discuss how to administer epinephrine and when.
- Discuss how to safely dispose of epinephrine.

Additional information and resources are available on https://www.foodallergy.org/resources.

Contraindications

Patients know to be hypersensitive to epinephrine or any components of the preparation.

Precautions

Common side effects of epinephrine include:

- Fast, irregular or "pounding" heartbeat.
- Sweating.
- Shakiness.
- Headache.
- Feeling nervous.
- Weakness.
- Dizziness.
- Nausea and vomiting.
- Breathing problems.

Statewide Epinephrine Standing Order Signature:

M. Riccardo Colella DO, MPH

__1.6.2023

SIGNATURE: **DATE**

Dr. Mario Riccardo Colella, DHS EMS Medical Director Wisconsin Medical License: 50358-21

NPI #: 1336106277

By dispensing epinephrine under this Statewide Epinephrine Standing Order for Pharmacists, the managing pharmacist attests that all registered pharmacists at this location have received

one hour of training on epinephrine and have read and understand both the epinephrine standing order and the epinephrine patient education materials.