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**PHARMACY RULES COMMITTEE  
of the  
PHARMACY EXAMINING BOARD**

**Room 121A, 1400 East Washington Avenue, Madison, WI 53703  
Contact: Dan Williams (608) 266-2112  
October 26, 2017**

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

**AGENDA**

**8:30 A.M.**

**OPEN SESSION – CALL TO ORDER**

- A. Approval of Agenda (1-2)**
- B. Legislation and Rule Matters – Discussion and Consideration**
  - 1) Phar 7 Relating to Practice of Pharmacy
    - a) Previous Topics  
Patient Counseling **(3)**
    - b) New Topics  
Return or Exchange of Health Items **(3-5)**  
Valid Prescriber/Patient Relationship **(6)**  
Remote Dispensing **(6-8)**  
Center Fill **(8-9)**  
Automated Dispensing Systems/Pharmacy Services **(9-13)**
  - 2) Update on Legislation and Pending or Possible Rulemaking Projects
- C. Public Comments**

**ADJOURNMENT**

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 1400 East Washington Avenue, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times

listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

## Patient Counseling

(1) "Patient counseling" means a discussion of matters which will enhance or optimize drug therapy and may include:

- (a) Name and description of the drug.
- (b) Dosage form, dose, route of administration and duration for drug therapy.
- (c) Intended use of the drug and expected action.
- (d) Special directions and precautions for preparation, administration and use by the patient.
- (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) Proper storage and appropriate disposal method of unwanted or unused medication.
- (h) Prescription refill information.
- (i) Action to be taken in the event of a missed dose.
- (j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) A pharmacist shall give the patient or patient's agent appropriate consultation relative to the prescription for all new medication to the patient or change in the patient's therapy. The consultation shall occur before the transfer of medication to the patient. This requirement is not satisfied by only offering to provide consultation.

(3) A pharmacist shall utilize professional judgement in determining whether to give the patient or patient's agent appropriate consultation relative to the prescription for any refill.

(4) Notwithstanding sub. (1), a consultation is not required when a health care provider is administering the medication.

(5) Notwithstanding sub. (1), prescriptions delivered by an agent of the pharmacist to a location of the patient's choice are required to be accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist.

## **NEW TOPICS**

### **Return or exchange of health items**

**Phar 7.04 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, medicines, or items of personal hygiene.
- (b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities.
- (c) "Original container" means the container in which a health item was sold, distributed or dispensed.
- (d) "Resident health care patient" means a patient residing in a community-based residential facility that controls a resident's prescribed and over-the-counter medications as specified by s. DHS 83.37
- (e) "Secured institutional health care patient" means any of the following:

1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under s. DOC 350.17, containing policies and procedures for the control and administration of medications complying with s. DOC 350.20.

2. A juvenile patient who resides in a juvenile correctional facility, as defined in s. 938.02 (10p), Stats.; a secured residential care center for children and youth, as defined in s. 938.02 (15g), Stats.; a juvenile detention facility, as defined in s. 938.02 (10r), Stats.; or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in s. DOC 316.02 (6) and provided to a juvenile patient under the provisions of s. DOC 316.03.

(f) "Tamper-resistant package" means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.

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

(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

(b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their beyond use date.

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

(d) For a secured institutional health care patient or resident health care patient where all of the following apply:

1. The health item was never in the possession and control of the patient.

2. The health item was sold, distributed or dispensed in a tamper-resistant package and, for a drug, includes the beyond use date and manufacturer's lot number.

3. The health item is not commingled with a different health item unless the health item will be repackaged and redispensed to the same patient.

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

(e) A health item that is prepackaged for consumer use and labeled in compliance with all applicable state and federal laws where all of the following apply:

1. The pharmacist determines that the original package is unopened, sealed and intact and that package labeling is unaltered.

2. The pharmacist determines the contents are not adulterated.

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

**(3m)** Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2) (d), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away, or otherwise sold, distributed or redispensed other than to a secured institutional health care patient.

(4) It is not a “return” for a patient or agent of a patient to deliver 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 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” for a patient or agent of a patient to deliver 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.

**Note:** Cancer and chronic disease drug returns and redispensing pursuant to ch. DHS 148 are allowed provided the pharmacy follows the requirements in ch. DHS 148.

**Note:** A prescription drug that is returned to a pharmacy that primarily serves patients confined in a state prison is not addressed in this rule. Such a drug may be redispensed to a patient in a state prison provided the requirements of s. 450.09 (7m), Stats., are satisfied.

## NABP Model Rules

### Return and reuse of Prescription Drugs

(1) Prescription Drugs may only be returned and reused providing that the Prescription Drugs:

1. were removed from the Pharmacy for delivery by Pharmacy staff, or a Pharmacy contracted delivery service and returned because the Prescription Drugs were not deliverable or the patient refused delivery, and such Prescription Drugs did not leave the control of the Pharmacy; and
2. Prescription Drugs were packaged in:
  - A. the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging; or
  - B. the dispensing pharmacy's original packaging; and
  - C. returned to the pharmacy immediately after the unsuccessful delivery attempt.
3. If a Pharmacy attempts, but is not able, to deliver Prescription Drugs using an approved common carrier, then such Prescription Drugs may be returned and reused by the Pharmacy if packaged in:
  - A. the manufacturer's original, sealed, and tamper-evident bulk, unit-of- use, or unit-dose packaging; or
  - B. the dispensing pharmacy's original, sealed, and tamper-evident packaging that maintains the product quality as per United States Pharmacopeia (USP) standards.

(2) All returned packaging must indicate that the Prescription Drug's integrity and stability has been maintained.

(3) All returned Prescription Drugs must have been returned on the same day as the attempted delivery and must be evaluated by appropriate Pharmacy staff to ensure such Prescription Drugs are not adulterated or misbranded.

(4) A state-licensed Pharmacist must verify compliance with all of the above elements.

## Valid Prescriber/Patient Relationship

**IOWA 657—8.20(155A) Valid prescriber/patient relationship.** Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of a prescription drug, the order loses its validity and the pharmacist, on becoming aware of the situation, shall cancel the order and any remaining refills. The pharmacist shall, however, exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the prescribed drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new order can be issued.

## Remote Dispensing

**450.01 (7)** "Dispense" means to deliver a prescribed drug or device to an ultimate user or research subject by or pursuant to the prescription order of a practitioner, including the compounding, packaging or labeling necessary to prepare the prescribed drug or device for delivery.

**450.062 Remote dispensing.** Pursuant to rules promulgated by the board, a pharmacist may dispense at the following locations:

- (1) A health care facility under s. [150.84 \(2\)](#) or a facility identified under s. [980.065](#).
- (2) The office or clinic of a practitioner.
- (3) A county jail, rehabilitation facility under s. [59.53 \(8\)](#), state prison under s. [302.01](#), or county house of correction under s. [303.16 \(1\)](#).
- (4) A juvenile correctional facility under s. [938.02 \(10p\)](#), juvenile detention facility under s. [938.02 \(10r\)](#), residential care center for children and youth under s. [938.02 \(15d\)](#), secured residential care center for children and youth under s. [938.02 \(15g\)](#), type 1 juvenile correctional facility under s. [938.02 \(19\)](#), type 2 residential care center for children and youth under s. [938.02 \(19r\)](#), or type 2 juvenile correctional facility under s. [938.02 \(20\)](#).

Phar 7.095 **Operation of remote dispensing sites. (1) DEFINITIONS.** In this section:

(a) "Health care facility" means a facility, as defined in s. 647.01 (4), Stats., or any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health center or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.02, 50.03, 50.35, 51.08 or 51.09, Stats., or a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42 or 252.10, Stats.

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

(c) "Practitioner" means a person licensed in this state to prescribe and administer drugs or licensed in another state and recognized by this state as a person authorized to prescribe and administer drugs.

(d) "Remote dispensing site" means a dispensing site that is not licensed as a pharmacy. Remote does not mean geographical distance or location.

(e) "Supervising pharmacy" means a licensed pharmacy that oversees the operations and administration of all aspects of the remote dispensing site.

**(2) LICENSING REQUIREMENTS AND USE OF TITLES RELATING TO THE OPERATION OF REMOTE DISPENSING SITES.** (a) A remote dispensing site shall not be licensed as a pharmacy.

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

**(3) LOCATION OF REMOTE DISPENSING SITES.** A pharmacist may dispense at the following locations:

(a) A health care facility or a facility identified under s. 980.065, Stats.

(b) The office or clinic of a practitioner.

(c) A county jail, rehabilitation facility under s. 59.53 (8), Stats., state prison under s. 302.01, Stats., or county house of correction under s. 303.16 (1), Stats.

(d) A juvenile correctional facility under s. 938.02 (10p), Stats., juvenile detention facility under s. 938.02 (10r), Stats., residential care center for children and youth under s. 938.02 (15d), Stats., secured residential care center for children and youth under s. 938.02 (15g), Stats., type 1 juvenile correctional facility under s. 938.02 (19), Stats., type 2 residential care center for children and youth under s. 938.02 (19r), Stats., or type 2 juvenile correctional facility under s. 938.02 (20), Stats.

**(4) REQUIREMENTS FOR THE OPERATION OF REMOTE DISPENSING SITES.** (a) A remote dispensing site shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.

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

a. Name of store.

b. Address of store.

c. Telephone number of store.

3. The pharmacist is required to talk to you each time you pick up a prescription.

(b) A remote dispensing site shall not open for operation if the supervising pharmacy is closed.

(c) A remote dispensing site shall not dispense a prescribed drug or device in the absence of the ability of a patient to communicate with the pharmacist.

(d) When closed, a remote dispensing site shall have a centrally monitored alarm. For all after hour entries, the personnel entering the site shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for 2 years.

(e) A remote dispensing site shall submit written notification to the board 30 days prior to operating the remote dispensing site.

**(5) DISPENSING REQUIREMENTS.** A remote dispensing site shall meet all of the following:

(a) Comply with the requirements under s. Phar 7.01 and visually inspect prescription orders, labels and dispensed product.

(b) Comply with the labeling requirements under s. Phar 7.12 (2) (g). The prescription label shall contain the name and address of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed.

(c) Comply with federal law if a remote dispensing site dispenses controlled substances.

**(6) RESPONSIBILITIES OF MANAGING PHARMACISTS.** (a) The managing pharmacist of a remote dispensing site shall, in accordance with s. Phar 7.09, do all of the following:

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

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

3. Visit the remote dispensing site at least monthly to conduct controlled substance inventory, to ensure written policies and procedures are being followed, and to ensure that remote dispensing site personnel comply with all federal and state laws regulating the practice of pharmacy.

4. Retain documentation of the monthly inspection visits at the remote dispensing site for 2 years.

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

**(7) REQUIREMENTS FOR PHARMACY TECHNICIANS AND INTERNS.** Pharmacy technicians and interns employed at a remote dispensing site shall satisfy all of the following requirements:

(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 technician within the 3 years prior to the date of employment at the remote dispensing site or completed a training program approved by the

### **Center Fill**

**Phar 7.12 Central fill pharmacy.** (1) In this section:

(a) "Central fill pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

(b) "Originating pharmacy" means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

(2) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:

(a) The central fill 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 in compliance with federal and state law.

(b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the board or its agent.

(c) The central fill pharmacy and originating pharmacy maintain a written filling protocol delineating each pharmacy's assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8.



(d) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8, and which are not assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

(e) The originating pharmacy shall at all times remain solely responsible to perform and comply with the requirements of s. Phar 7.01 (1) (e) and (em).

(f) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review of the patient, drug utilization review, refill authorizations, interventions and drug interactions.

(g) The prescription label attached to the container shall contain the name and address of the originating pharmacy as the licensed facility from which the prescribed drug or device was dispensed for purposes of s. 450.11 (4) (a) 1., Stats. 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 central fill pharmacy filled the prescription order.

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

(i) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law.

(j) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding and dispensing pursuant to a prescription order and track the prescription order during each step in the dispensing process.

(k) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with this section.

(L) The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law.

### **Automated Dispensing Systems/ Pharmacy Services**

Phar 7.09 **Automated dispensing systems. (1)** In this section:

(a) "Automated dispensing system" means a mechanical system that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, or tuberculosis sanatorium, but does not include community-based residential facilities.

**(2)** An automated dispensing system may be used in a community pharmacy, as provided in this section.

(3) An automated dispensing system may be used as provided in this section by an institutional pharmacy serving an inpatient health care facility, that has an established program of receiving prescription orders, and dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. An automated dispensing system used by an institutional pharmacy shall only be located in that institutional pharmacy or within the inpatient health care facility.

(4) The managing pharmacist of a community pharmacy or an institutional pharmacy is responsible for all of the following:

(a) Assuring that the automated dispensing system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed and complying with the recordkeeping and security safeguards pursuant to sub. (5).

(b) Implementing an ongoing quality assurance program that monitors performance of the automated dispensing system, which is evidenced by written policies and procedures.

(c) Providing the board with prior written notice of the installation or removal of an automated dispensing system. The notice provided shall include, but is not limited to the:

1. Name and address of the pharmacy.
2. Initial location of the automated dispensing system. The automated dispensing system may thereafter be relocated within the pharmacy or inpatient health care facility without providing subsequent notification to the board.

3. Identification of the managing pharmacist.

(d) Assigning, discontinuing or changing personnel access to the system.

(e) Assuring that access to the medications comply with state and federal laws.

(f) Assuring that the automated dispensing system is stocked accurately and in accordance with established written policies and procedures.

(5) An automated dispensing system shall comply with the following provisions:

(a) A pharmacy shall maintain on-site the following documentation relating to an automated dispensing system:

1. Name and address of the pharmacy or inpatient health care facility where the system is being used.

2. The system manufacturer's name, model and serial number.

3. Description of how the system is used.

4. Written quality assurance procedures to determine continued appropriate use of the system.

5. Except as required pursuant to par. (b), written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

(b) All written policies and procedures shall be maintained in the pharmacy responsible for the automated dispensing system.

(c) An automated dispensing system shall have adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

(d) Records and data kept by the automated dispensing system shall meet the following requirements:

1. All events involving the contents of the automated dispensing systems must be recorded electronically.

2. Records shall be maintained by the pharmacy and be available to the board. Records shall include:

- a. The time and location of the system accessed.
  - b. Identification of the individual accessing the system.
  - c. Type of transaction.
  - d. Name, strength, dosage form and quantity of the drug accessed.
  - e. Name of the patient for whom the drug was ordered.
  - f. Such additional information as the managing pharmacist may deem necessary.
- (e) The stocking of all medications in the automated dispensing system shall be accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an automated dispensing system is located within a pharmacy the supervision must be direct.
- (f) A record of medications stocked into an automated dispensing system shall be maintained for 5 years and shall include identification of the person stocking and pharmacist checking for accuracy.
- (g) All containers of medications stored in the automated dispensing system shall be packaged and labeled in accordance with state and federal law.
- (h) All aspects of handling controlled substances shall meet the requirements of all state and federal law.
- (i) The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system, in accordance with state and federal law.
- (j) The automated dispensing system shall provide a mechanism for securing and accounting for medication returned to the system and accounting for wasted medications in accordance with state and federal law.

### NABP Model Rules

#### Section 9. Automated Pharmacy Systems .

- (a) Automated Pharmacy Systems can be utilized in licensed pharmacies and Shared Pharmacy Services Pharmacies located within an Institutional Facility or clinic. A Pharmacist is not required to be physically present at the site of the Automated Pharmacy System if the system is supervised electronically by a Pharmacist. Automated Pharmacy Systems shall comply with the following provisions.
  - (1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and Shared Pharmacy Services Pharmacy location shall be maintained in the Pharmacy for review . Such documentation shall include, but is not limited to:
    - (i) name and address of the Pharmacy and the Shared Pharmacy Services Pharmacy where the Automated Pharmacy System(s) is being used;
    - (ii) Manufacturer's name and model;
    - (iii) description of how the Automated Pharmacy System is used;
    - (iv) quality assurance procedures to determine continued appropriate use of the Automated Pharmacy System;
    - (v) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction; and

- (vi) documentation evidencing that the Automated Pharmacy System has been tested prior to initial use and on a periodic basis at each location to ensure that the Automated Pharmacy System is operating properly.
- (2) Automated Pharmacy Systems should be used only in settings where there is an established program of Pharmacist Care that ensures medication orders or Prescription Drug Orders are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacist Care.<sup>1</sup>
  - (i) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.<sup>2</sup>
  - (ii) Any Pharmacy that maintains an Automated Pharmacy System for the purposes of remote Dispensing to outpatients<sup>3</sup> shall maintain a video/auditory communication system to provide for effective communication between the patient and the Pharmacist; the 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.
- (3) All policies and procedures must be maintained in the Pharmacy responsible for the Automated Pharmacy System and , if the Automated Pharmacy System is being used at a different location, at that location as well.
- (4) Automated Pharmacy Systems shall have adequate security systems and procedures, evidenced by written policies and procedures<sup>4</sup>, to:
  - (i) prevent unauthorized access;
  - (ii) comply with federal and state regulations; and
  - (iii) prevent the illegal use or disclosure of Protected Health Information.
- (5) Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements.
  - (i) All events involving the contents of the Automated Pharmacy System must be recorded electronically.
  - (ii) Records must be maintained by the Pharmacy and must be readily available to the Board. Such records shall include:
    - (A) identity of system accessed;
    - (B) identification of the individual accessing the system;
    - (C) type of transaction;

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<sup>1</sup> Each state should determine whether or not the Dispensing of a “first dose” or an “emergency dose” may take place without prior order review by a Pharmacist but with appropriate security and patient medication management controls in place.

<sup>2</sup> In order to facilitate communication between the Pharmacy and the site where the Automated Pharmacy System is located, a Pharmacy should provide a toll-free telephone number so that the Pharmacist is accessible at all times the Automated Pharmacy System is operational.

<sup>3</sup> 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.

<sup>4</sup> The use of Automated Pharmacy Systems requires written policies and procedures in place prior to installation to ensure safety, accuracy, security, and patient confidentiality and to define access and limits to access to equipment and medications.

- (D) name, strength, dosage form, and quantity of the Drug accessed;
  - (E) name of the patient for whom the Drug was ordered; and
  - (F) such additional information as the Pharmacist-in-Charge may deem necessary.
- (6) Access to and limits on access (eg, security levels) to the Automated Pharmacy System must be defined by policy and procedures and must comply with state and federal regulations.<sup>5</sup>
  - (7) The Pharmacist-in-Charge shall have the responsibility to:
    - (i) assign, discontinue, or change access to the system;
    - (ii) ensure that access to the medications comply with state and federal regulations;
    - (iii) ensure that the Automated Pharmacy System is filled/stocked accurately and in accordance with established, written policies and procedures.
  - (8) The filling/stocking of all medications in the Automated Pharmacy System shall be accomplished by qualified personnel under the supervision of a licensed Pharmacist.
  - (9) A record of medications filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.<sup>6</sup>
  - (10) All containers of medications stored in the Automated Pharmacy System shall be packaged and labeled in accordance with federal and state laws and regulations.
  - (11) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.
  - (12) The Automated Pharmacy System shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the Automated Pharmacy System, all in accordance with existing state and federal law.<sup>7</sup>
  - (13) The Automated Pharmacy System shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

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<sup>5</sup> 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 medications, 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.

<sup>6</sup> 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).

<sup>7</sup> The State may require that each licensed Pharmacy or facility have in place written policies and procedures to address situations in which medications removed from the system remain unused and must be secured and accounted for.