NABP
National Association of Boards of Pharmacy

Report of the Task Force on

SHARED PHARMACY SERVICES, AUTOMATED PHARMACY SYSTEMS, REMOTE DISPENSING SITES, AND TELEPHARMACY

Report of the Task Force on Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy

Members Present

John Colaizzi, Jr. (NJ), *chair*; Erick Axcell (KS); Ronda M. Chakolis (MN); Michelle Chan (MA); Debbie Chisolm (CT); Caroline Juran (VA); Yeh "Ling" Yuan Lee (VA); Jerry Moore (AL); Eileen Ortega (PR); Richard "Rich" Palombo (NJ); Carrie Phillips (VT); Genine Pitts (MT); Andy Truong (KS); Lorri Walmsley (AZ); Maria Young (MI).

Others Present

Shane Wendel, *Executive Committee liaison;* Lemrey "Al" Carter, Melissa Becker, Eileen Lewalski, Andrew Funk, Gertrude "Gg" Levine, Maureen Schanck, Cameron Orr, *NABP staff*.

Introduction

The task force met on October 17 and 18, 2023, at NABP Headquarters in Mount Prospect, IL. This task force was established pursuant to a recommendation of the Committee on Law Enforcement/Legislation, which met in February 2023, to review the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*) sections pertaining to shared services, automated pharmacy systems, remote dispensing sites, and telepharmacy.

Review of the Task Force Charge

Charge of the task force:

1. Review *Model Act* sections pertaining to Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy;
2. Amend, if necessary, the *Model Act* accordingly.

Background and Discussion

Discussion began with a review of the task force charge and the recognition that the task force was established pursuant to a recommendation of the Committee on Law Enforcement/Legislation, which met in February 2023. They also recognized the history of the charge stemming from the *Model Act* Review Committee in May 2022 and agreed that these subjects needed additional attention and review.

The task force then studied trends that are putting pressure on the practice of pharmacy to do more with less. The trends that the members discussed included a decline in applications to schools and colleges of pharmacy, a projected increase in prescription volume over time as the number of PharmD graduates continues to decline, and steady growth in pharmacy school graduates taking post-doctoral residency positions rather than entering traditional pharmacy practice. Members also observed a growing number of individuals retiring from pharmacy practice, as well as community pharmacies permanently closing an increasing number of stores.

The task force acknowledged that these trends may pose a public health risk if, in the future, pharmacists are in short supply and patients cannot access a pharmacy to get their medications or immunizations. Members noted that many patients will not get immunizations if they are unable to get them at a pharmacy. Given the risks, the task force recognized that these trends require pharmacies – particularly community pharmacies – to change their practice model to ensure their viability to continue safe dispensing of prescription medications in the years to come. Additionally, they recognized the duty of the boards of pharmacy to ensure that pharmacies have the latitude to implement necessary changes.

The task force identified issues in pharmacy practice that may need to be changed to raise the practice to its full potential. For instance, they observed discordant trends in pharmacy education versus pharmacy practice today. With the advent of the PharmD requirement for pharmacists entering the practice, pharmacy school curricula started moving toward high-level cognitive services. Members observed that the community pharmacy practice model, meanwhile, has yet to evolve to allow the provision of those services. They said this is partially because of a lack of reimbursement for clinical services, as well as the fact that patients remain unaware of all the clinical skills today's pharmacy graduates have. They expressed a need to educate patients and other health care providers on the range of services that pharmacists can provide. Members further noted that the practice model needs to change to allow more time for pharmacists to provide the advanced clinical services in which they have been trained.

Members acknowledged that community pharmacists must often contend with circumstances that may distract from pharmacy practice, such as aspects of retail business that do not factor into other health care practices. The fact that they provide counseling by phone at no charge was recognized by the task force as another significant difference between community pharmacists and other professionals, such as attorneys and physicians, many of whom charge fees to answer calls or emails.

Members observed that health-system pharmacy practice has, in some ways, evolved beyond community pharmacy practice. For instance, they noted that health-system pharmacies often have equipment and systems in place that optimize efficiency, such as centralized fulfillment by robotics and machinery, allowing pharmacists to focus on clinical services, whereas the community pharmacy model has not undergone the same degree of transformation. Members also mentioned that technicians in community pharmacies tend to be paid less than those in hospital settings, and

that hospital pharmacies have an easier time getting reimbursed by benefits management companies than community pharmacies do.

In regard to modernizing the practice of pharmacy, the subject of a hybrid work environment, in which personnel work some days in the pharmacy and some days remotely, was also discussed. The task force recognized that few states currently allow this model but that personnel have come to expect it, especially since the COVID-19 pandemic. Some members stated that they know of no reason not to allow it, and boards of pharmacy in some states, including Kansas, are considering it. Members mentioned that pharmacists could, for example, verify prescription orders from home before sending them to a fulfillment center; meanwhile, a pharmacist in the community could focus on counseling patients.

Overall, the task force agreed on the need to enhance efficiency and productivity through practice models such as shared pharmacy services, automated pharmacy systems, remote dispensing sites, and telepharmacy. Members also acknowledged a need to expand the reach of pharmacy practice to locales that may be physically distant or otherwise difficult to access. Members noted that there are not enough pharmacists available to physically staff 24-hour pharmacies and that these evolving practice models make expanded service hours possible.

Noting that practice models such as telepharmacy are routinely used in hospital pharmacies, members stated that satellite pharmacies operated by a pharmacy technician who is overseen by a pharmacist in another location could be used to extend the resources of community pharmacies. The task force noted that such practice models were instrumental in responding quickly during the COVID-19 pandemic. Members raised concerns, however, that if pharmacists are already busy at the primary pharmacy, they may not have time to supervise another location, and that businesses may be capitalizing on this model to the detriment of pharmacy personnel and patients.

There are multiple factors to consider before pharmacies can implement a shared services or telepharmacy model if the board of pharmacy explicitly allows for it or does not have laws and/or rules preventing it. Others mentioned that there are nuances within those allowances that may create unintended barriers and prevent pharmacies from being able to implement these innovative practice models. The task force considered how to encourage more states to allow it and, within those states that do allow it, how to make it more accessible. In North Dakota, for example, the board allows pharmacies to decide how many telepharmacies, or satellite locations, a pharmacist can safely oversee, noting that it depends partly on the pharmacy's prescription volume.

Turning their attention to the *Model Act,* the members first considered the defined terms and then referred to the relevant section of the act to review it in detail.

The first definition they considered was for "automated pharmacy systems," which led to questions about the types of systems it should encompass. One such question was whether artificial intelligence would be encompassed by this definition. Another question pertained to the use of

technology that can identify active pharmaceutical ingredients in medications to determine whether they are authentic or counterfeit. Members opted to strike the word “mechanical” from the definition, agreeing that the definition should encompass all systems that are automated, including the examples discussed and future advancements.

In Section 9. Automated Pharmacy Systems, the task force considered whether any provisions were missing or too prescriptive. Regarding the locations in which automated pharmacy systems can be used, members discussed whether the term “shared pharmacy services pharmacies,” as used in Paragraph (1), was redundant and confusing and recommended removing this wording. They agreed to supplement “and other locations approved by the board” with the phrase “in accordance with all state and federal laws and rules” to cover all compliant locations.

Members considered whether it is necessary to require a pharmacist to be available at the site of the automated pharmacy system, noting that the necessity may depend on the setting (eg, day surgery center, outpatient center, kiosk). They further discussed requirements for supervision, seeking to keep the language as broad and unrestrictive as possible, allowing boards of pharmacy leeway for interpretation. They agreed to remove the requirement that the system be “supervised electronically,” and replaced that wording with “appropriately secured and monitored.” The rationale was that the word “monitored” is less restrictive than “supervised,” and, noting that monitoring differs depending on the system, they agreed on “appropriately.”

Regarding documentation, as described in Section 9 Subparagraph (1)(a), members recommended revisions to modernize, clarify, and broaden the language and eliminate redundancies. For example, they recommended changing “serial numbers” to “facility-specific unique identifiers.”

Members recommended striking from Subparagraph (1)(b) “[a] pharmacist shall be accessible to respond to inquiries or requests pertaining to drugs dispensed from the automated pharmacy system” and replacing it with the language that was contained in a footnote: “[i]n order to facilitate communication between the pharmacy and the site where the automated pharmacy system is located, a pharmacy should provide a telephone number so that the pharmacist is accessible at all times the automated pharmacy system is operational.” Within this statement, they removed the requirement for the phone number to be “toll-free.” Several additional items within Paragraph (1) were changed or combined for brevity and to eliminate redundancies. Paragraph (2) and its subsections were removed, as they were deemed duplicative.

Moving on to the definition for “practice of telepharmacy,” the task force agreed to strike “registered,” noting it is assumed that the pharmacist is registered or licensed. Members also struck “located within US jurisdictions” and “at distances that are located within US jurisdictions.” The latter strikeouts were made to avoid addressing jurisdiction in a definition, as jurisdiction is already addressed in the statutory sections pertaining to licensing. Recognizing that the practice of

telepharmacy may include technicians providing immunization and test-and-treat services, the task force recommended adding a footnote to this effect.

The meaning of “telepharmacy” and whether it involves dispensing was a matter of some deliberation. Members stated that, traditionally, the term refers to a brick-and-mortar pharmacy remotely supervised by a pharmacist. In some jurisdictions the term encompasses dispensing sites, whereas in Vermont, it encompasses only the tasks that precede dispensing.

Members raised concerns that the terms “telepharmacy,” “remote dispensing site,” and “shared pharmacy services” could be confused. They considered eliminating the term telepharmacy but decided against it because the term is commonly used. Members also expressed the need for pharmacy stakeholders to move away from terms such as “retail” and “store” because it commoditizes the practice of pharmacy and noted that reserving the term “clinical pharmacist” for non-retail pharmacists overlooks the fact that pharmacists in all practice settings must have clinical skills.

In discussing Section 14. Telepharmacy, members agreed that a mileage requirement dictating the distance between a primary pharmacy and its satellite locations is arbitrary and not helpful. Members mentioned that areas in addition to rural communities can experience limited accessibility to a pharmacy, such as in the case of urban “pharmacy deserts,” wherein a community pharmacy may not be available within several city blocks. With this in mind, the members recommended adding a footnote to Subsection (2) Remote Dispensing Site Requirements, stating that “[t]o 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.”

The task force recommended striking Subparagraph (2)(d) and making it a somewhat less prescriptive footnote: “[t]he pharmacist-in-charge shall oversee inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.” An additional footnote was added indicating that “[s]tates may allow pharmacy interns to perform the functions of a certified pharmacy technician at a remote dispensing site.” The task force agreed that a remote dispensing site must maintain contact with “a pharmacist” but not necessarily “at the supervising pharmacy.”

Regarding the communication system, the task force recommended striking “provide an adequate number of views of the entire site” and moving up the language of Subparagraph (n) to bring common subjects together: “[t]he 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.” They agreed to strike Subparagraph (j) and the items beneath it that required the remote dispensing site to retain a recording of facility surveillance. Regarding Subparagraph (m) requiring a remote dispensing site to display a sign, the task force struck the requirements for it to say “this is a remote site” and provide the location of the supervising

pharmacy, requiring it to say only that a pharmacist "is available to counsel" the patient using audio and video communication systems.

Turning to the definition of "shared pharmacy services," the task force agreed to strike "pursuant to a request from another participating pharmacist or pharmacy." Regarding the types of services, they recommended adding, "or provide pharmacist care services" and "product verification, counseling," and removing "reviewing therapeutic interventions."

In Section 8. Shared Pharmacy Services, the task force recommended striking subsections they considered to be too prescriptive and moving some subsections to improve continuity. Members agreed to strike Subsection (3) Drug Storage and Security, as these provisions are addressed in Subsection (2) Operations. In Subsection (4), members qualified "policies and procedures for shared pharmacy services" by adding "that outline the responsibilities of each pharmacy and describe policies reflecting operation requirements," and recommended striking the rest of the section, which they considered to be overly detailed and redundant.

The last definition that the task force considered was for "remote dispensing site." The members recommended keeping the definition as it is and adding a footnote: "[s]tates may interpret 'remote supervision of a pharmacist' to allow certified pharmacy technicians to provide immunizations and 'test and treat' services at a remote dispensing site."

After careful review and deliberation, the task force recommended that NABP amend the *Model Act* as follows. The amendments recommended by the task force are denoted by underlines and ~~strikethroughs~~.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

August 2023

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Section 105. Definitions.

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"Automated pharmacy systems" include, but are not limited to, ~~mechanical~~ systems that perform operations or activities, compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs, and which collect, control, and maintain all transaction information.

"Practice of telepharmacy[1]" means the practice of pharmacy by ~~registered~~ pharmacists ~~located within US jurisdictions~~ through the use of telepharmacy technologies between a licensee and patients or their agents ~~at distances that are located within US jurisdictions~~.

"Remote dispensing site" means a location, other than where a pharmacist is located, where drugs are maintained and prescriptions are filled by a certified pharmacy technician and dispensed under the ~~direct,~~ remote supervision of a pharmacist[2].

"Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy ~~pursuant to a request from another participating pharmacist or pharmacy~~ to process or fill a prescription drug order or provide pharmacist care services, which may include preparing, packaging, labeling, compounding for specific patients, dispensing, product verification, counseling, performing drug utilization reviews, conducting claims adjudication, obtaining refill authorizations, ~~reviewing therapeutic interventions~~, and/or reviewing institutional facility orders.

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Model Rules for the Practice of Pharmacy

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Section 8. Shared Pharmacy Services.

(1) General Requirements[3, 4]

(a) The pharmacy must possess a resident or nonresident permit issued by the board prior to engaging in shared pharmacy services.[5]

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

(i) have the same owner; or

[1] States may interpret the definition of the practice of telepharmacy to allow certified pharmacy technicians to provide immunizations and "test and treat" services.

[2] States may interpret "remote supervision of a pharmacist" to allow certified pharmacy technicians to provide immunizations and "test and treat" services at a remote dispensing site.

[3] 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.

[4] 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.

[5] 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.

(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 records identifying individually, for each prescription drug order filled or dispensed, the name of each pharmacist or pharmacy intern who took part in the filling, dispensing, and patient counseling 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;~~

~~(iii) report to the board as soon as practical the results of any disciplinary action taken by another state's board of pharmacy involving shared pharmacy services;~~

(iv) maintain a mechanism for tracking the prescription drug order during each step of the processing and filling procedures performed at the pharmacy;

(v) maintain a mechanism for the patient, upon request, to identify all pharmacies involved in filling the prescription drug order; and

(vi) be able to obtain for inspection any required record or information ~~within 72 hours~~ of any request by the board or its designee.

(vii) operate a continuous quality improvement program for shared pharmacy services.

~~(3) Drug Storage and Security~~

~~(a) Drugs shall be stored in compliance with state and federal laws and in accordance with these Rules, including those addressing temperature, proper containers, and the handling of outdated drugs.~~

~~(b) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to:~~

~~(i) pharmacists, certified pharmacy technicians, certified pharmacy technician candidates, or pharmacy interns who are employed by the shared pharmacy services pharmacy; or~~

~~(ii) personnel employed at the institutional facility or clinic where the shared pharmacy services pharmacy is located who:~~

~~(A) are licensed health care providers;~~

~~(B) are documented by the pharmacist-in-charge or the person responsible for the supervision and on-site operation of the facility where the shared services pharmacy is located; and~~

~~(C) have completed documented training concerning their duties associated with the shared pharmacy services Pharmacy.~~

~~(d) Shared pharmacy services pharmacies shall have adequate security to:~~

~~(i) comply with federal and state laws and regulations; and~~

~~(ii) protect the confidentiality and integrity of protected health information.~~

(4) 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 operation requirements. ~~Each pharmacy is required to maintain the portion of the joint policies and procedures that relate to that pharmacy's operations. The policies and procedures shall:~~

~~(i) outline the responsibilities of each pharmacy;~~

~~(ii) include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in shared pharmacy services; and~~

~~(iii) include processes for:~~

~~(A) notifying patients that their prescription drug orders may be processed or filled by another pharmacy and providing the name of the pharmacy;~~

~~(B) protecting the confidentiality and integrity of protected health information;~~

~~(C) dispensing prescription drug orders when the filled prescription drug order is not received or the patient comes in before the prescription drug order is received:~~

~~(D) maintaining required manual or electronic records to identify the name, initials or identification code and specific activity or activities of each pharmacist, certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern who performed any shared pharmacy services;~~

~~(E) complying with federal and state laws; and~~

(F) ~~operating a continuous quality improvement program for shared pharmacy services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems~~.

(5) 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~~, shared pharmacy services 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 ~~supervised electronically by a pharmacist~~. Automated pharmacy systems shall comply with the following provisions.

(a) Documentation as to type of equipment, ~~serial numbers,~~ facility-specific unique identifiers, and ~~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~~ name and address of the location where the automated pharmacy system is being used;

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

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

(iv) continuous quality assurance procedures ~~to determine continued appropriate use of the automated pharmacy system~~;

(v) ~~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~~.

(b) ~~A pharmacist shall be accessible to respond to inquiries or requests pertaining to drugs dispensed from the automated pharmacy system.~~[6] In order to facilitate communication between the pharmacy and the site where the automated pharmacy system is located, a pharmacy should provide a telephone number so that the pharmacist is accessible at all times the automated pharmacy system is operational.

[6] ~~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.~~

(c) ~~Any pharmacy that maintains an automated pharmacy system for the purposes of remote dispensing to outpatients shall maintain an interactive communication system to provide for effective communication between the patient and the pharmacist; the~~ For remote dispensing to outpatients[7], a ~~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.

(d) Automated pharmacy systems shall have adequate security systems to:
- (i) prevent unauthorized access;
- (ii) comply with federal and state regulations; and
- (iii) prevent the illegal use or disclosure of protected health information.

(e) 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;
  - (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.

(f) Access to and limits on access (eg, security levels) to the automated pharmacy system shall be defined.[8]

(g) The pharmacist-in-charge shall have the responsibility to:
- (i) assign, discontinue, or change access to the system;
- (ii) ensure that access to the drugs complies with state and federal regulations;
- ~~(iii) ensure that the automated pharmacy system is filled/stocked accurately.~~

(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

[7] 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.

[8] 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.

maintained and shall include identification of the persons filling/stocking and checking for accuracy.[9]

~~(i) 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.~~

(j) All ~~containers of drugs stored in the automated pharmacy system shall be packaged and labeled~~ prescription fulfillment activities shall take place in accordance with federal and state laws and regulations.

~~(k) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.~~

~~(l) The automated pharmacy system shall provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the automated pharmacy system, all in accordance with existing state and federal law.[10]~~

(m) 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.

~~(2) Policies and Procedures~~

~~(a) The pharmacist-in-charge is responsible for developing or adopting, implementing, and maintaining automated pharmacy systems policies and procedures that address the following:~~

~~(i) system operation, safety, stocking accuracy, patient confidentiality, access and limits to access, environmental controls, and malfunction;~~

~~(ii) provision of pharmacist care;~~

~~(iii) security, including:~~

~~(A) preventing unauthorized access;~~

~~(A) prevention of the illegal use or disclosure of protected health information.~~

~~(b) All policies and procedures shall 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.~~

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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;

[9] 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).

[10] The state may require that each licensed pharmacy or facility have in place written policies and procedures to address situations in which drugs removed from the system remain unused and must be secured and accounted for.

(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[11]

(a) The pharmacy shall submit an application to the board.

(b) The pharmacist-in-charge of the supervising pharmacy shall be responsible for all operations[12].

(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) The pharmacist-in-charge shall oversee monthly inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.~~

~~(e) A pharmacist must be designated to be available within (_) hours, in case of emergency.~~

(f) Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least one (1) certified pharmacy technician[13]. All certified pharmacy technicians and certified pharmacy technician candidates shall be under the supervision of a pharmacist ~~at the supervising pharmacy~~ at all times that the remote site is operational. The pharmacist shall supervise telepharmacy operations electronically ~~from the supervising pharmacy~~.

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

(h) 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.

(i) A supervising pharmacy of a remote dispensing site must maintain a video and audio communication system that provides for effective communication between a pharmacist ~~the supervising pharmacy~~ and the remote dispensing site personnel and patients or caregivers. The system must ~~provide an adequate number of views of the entire site,~~ facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and

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

[12] 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.

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

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.

(j) ~~The remote dispensing site must retain a recording of facility surveillance, excluding patient communications, for a minimum of (_) days.~~

~~(i) Adequate supervision by the pharmacist in this setting is maintaining uninterrupted visual supervision and auditory communication with the site and full supervisory control of the automated system, if applicable, and must not be delegated to another person.~~

~~(ii) Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed to the public if any component of the communication system is malfunctioning, until system corrections or repairs are completed.~~

~~(iii) The video and audio communication system used to counsel and interact with each patient or patient's caregiver must be secure and compliant with state and federal confidentiality requirements.~~

(k) Unless a pharmacist is present at the remote site, that ~~a remote dispensing~~ site must not be open or its employees allowed access to it during times ~~the~~ a supervising pharmacist ~~pharmacy~~ is unavailable. ~~closed.~~ 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.

(l) ~~If drugs are maintained or dispensed from the remote dispensing site, drug transfers to the remote dispensing site must comply with applicable state and federal requirements.~~

(m) A remote dispensing site must display a sign, easily visible to the public, which informs patients~~:~~

~~(i) this is a remote site~~

~~(ii) location of supervising pharmacy; and~~

(iii) that a pharmacist is available to ~~will~~ 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.

~~(n) 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.~~