NABP
National Association of Boards of Pharmacy

*Task Force to*

# REVIEW MODEL RULES FOR THE PRACTICE OF PHARMACY AND DEVELOP A NEW PHARMACY PRACTICE MODEL

## Members Present

Mark Hardy (ND), *chair,* Debbie Chisolm (CT), Rachael DeBarmore (OR), Timothy "Tim" Fensky (MA), Allison Hill (DC), Richard "Ricky" Indovina, Jr (LA), Jennifer Keonavong (AZ), Mark Klang (NY), Danson Nganga (VI), Eileen Ortega (PR), Richard "Rich" Palombo (NJ), Kevin Robertson (AR), Anastasia Shiamptanis (NB).

## Others Present

Nicole "Nicki" Chopski, *Executive Committee liaison;* Lemrey "Al" Carter, Melissa Becker, William "Bill" Cover, Eileen Lewalski, Maureen Schanck, and Cameron Orr, *NABP staff*.

## Introduction

The task force met on October 18-19, 2022, at NABP Headquarters in Mount Prospect, IL, and virtually on November 9, 2022. This task force was established pursuant to the Report of the *Model Act* Review Committee, which recommended that a task force be convened to review the various sections of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act),* and the presidential initiative of NABP President Reginald B. "Reggie" Dilliard, DPh.

## Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Review the *Model Rules for the Practice of Pharmacy*;
2. Review the recommendations made by the Work Group on Workplace Safety, Well-Being, and Working Conditions; and
3. Amend, if necessary, the *Model Act* accordingly.

## Background and Discussion

The task force members began their discussion with the goal of providing guidance for the development a new pharmacy practice model that allows for more meaningful pharmacist-patient clinical interactions through wider use of shared pharmacy services and expanded scope of practice for pharmacy technicians. The group suggested that broader regulatory language is needed to support innovation in pharmacy practice and agreed that current prescriptive regulatory language hinders innovation and limits pharmacy practice from expanding to meet public health needs and reduce disparity. The members lauded the efforts of the Canadian provinces and state boards of pharmacy that have modified their laws and rules to permit pharmacists and pharmacy technicians to provide patient care services that reflect their extensive education and training. Boards have accomplished this by authorizing such activities as pharmacist prescriptive authority and pharmacy technician product verification. All agreed that pharmacy regulations should be substantial enough to ensure public health protection, while still broad enough to encourage innovation. This concept

aligned with one of the primary goals of the task force, which was to modernize the *Model Act* by removing unnecessary details and overburdensome requirements.

Article I, Section 104. Definitions of the Practice of Pharmacy and Related Terms and Section 105. Definitions

The task force began its review of the recommendations made by the *Model Act* Review Committee, by focusing on Section 104. Practice of Pharmacy, which solely defined the "Practice of Pharmacy." Members agreed that the definition should be clarified and streamlined by incorporating elements of pharmacist care services, which is a defined term that appears the definition of the "Practice of Pharmacy" itself, as well as including other, foundational services including compounding, patient counseling, assessing patients for the purposes of prescribing, administering with respect to medical orders, engaging in collaborative pharmacy practice, and utilizing continuous quality improvement programs. They also agreed that Section 104 should be expanded to include the defined terms found within the new pharmacy practice definition, pharmacist care services and collaborative pharmacy practice, as well as to include medication therapy management, which is a primary responsibility under pharmacist care services. Regarding the definition of medication therapy management, the task force agreed that medication reconciliation should be added as an element. These suggestions were made to bring attention to and encompass the wider scope of pharmacy practice.

As part of their recommendations for Section 104, task force members provided more detail for the definition of "Pharmacist Care Services" to make it more patient-centered and to highlight promoting health and wellness via pharmacist initiatives such as drug utilization review, medication adherence monitoring, medication therapy management, emergency prescribing and dispensing, drug product selection/adaptation, and ordering and interpretation of CLIA waived tests.

Members then deliberated about the difference between emergency dispensing and emergency prescribing and concluded that emergency dispensing occurs when pharmacists authorize additional refills beyond what was prescribed to prevent any disruption in therapy, while emergency prescribing usually occurs without a patient-specific prescription and pursuant to a standing order, statewide protocol, or collaborative practice agreement.

The task force made a few substantive amendments to the remaining definitions in Section 105. These edits involved amending the definition of "Medication Assisted Treatment (MAT)" to "Medication for Treatment of Opioid Use Disorder (MOUD)" to align with the Substance Abuse and Mental Health Services Administration's terminology. The definition of "Patient Counseling" was modified to recognize methods of communication in addition to oral and in person communications, as recommended by the Work Group to Consider Extending Waivers. Furthermore, the definition of "Temporary Pharmacy Facility" was amended so the board could authorize such facilities not only as the result of a public health or state of emergency but also "in the interest of the public by board action." Additionally, the task force deleted the definition of "Prospective Drug Utilization Review" finding the term to be unnecessary as the term "Drug Utilization Review" was sufficiently defined.

*Model Rules for the Practice of Pharmacy*

Task force members moved on to review the *Model Rules for the Practice of Pharmacy.* First, they determined that the licensure section should be abbreviated and thus recommended removing several specific requirements regarding reference materials, formularies, equipment, and physical space. Regarding drug storage, the task force removed detailed requirements and chose instead to require that pharmacies be maintained in compliance with applicable United States Pharmacopeia-National Formulary (USP-NF) standards or manufacturers or distributors product labeling. It was also added that pharmacies should use all equipment and supplies needed to conduct business in a manner that ensures the safety of both patients and pharmacy staff.

In Section 2. Security the task force agreed with the current security requirement to "detect entry" in because it supports current regulatory models of pharmacy technicians working alone without a pharmacist present. However, the group agreed to delete the requirement for board approval of security barriers, as it was deemed unnecessary and burdensome. Members also revised the pharmacy security precautions following separation of employment to be applicable for all causes of separation, not just those related to drug diversion or dishonesty.

The task force then reviewed Section 3. Personnel. Recognizing the increased work demands on pharmacy staff, especially of the pharmacist-in-charge (PIC), since the pandemic began, members reviewed this section with a mindset that essential responsibilities be retained but overly burdensome requirements for the PIC be removed. All agreed that the PIC should retain responsibility for record keeping, quality and safety controls, notifying the board of pharmacy as required by board regulations, verifying that policies and procedures are up to date and address essential pharmacy functions, and ensuring that all staff are licensed and qualified for assigned duties. Members recommended that this section have a more generalized framework and, thus, removed specific details about certain notifications to the board.

The task force also recommended removing personnel requirements that boards do not need to address, such as professional performance evaluations and corporate policies and procedures. Also, although it is a best practice to maintain a CQI program, the task force agreed that specific CQI language should be removed from regulatory requirements and be left for employers to implement and oversee.

Members recommended that controlled substance language related to the manner of issuance of a prescription and record keeping in Sections 4 and 5 should be deleted and, instead, should simply reference compliance with federal laws and rules. The members further recommended that states no longer require patient counseling to be offered by a pharmacist and allow pharmacy technicians to do so. Furthermore, the task force also recommended a provision that pharmacist prescribing and dispensing of emergency prescription drugs under certain circumstances may occur without a maximum 30-day supply limitation and without the need to notify the prescriber of the dispensing.

When reviewing Sections 10 and 11 regarding return and reuse of prescription drugs and drug repository programs, the task force decided that it was important for a pharmacist to inspect and ensure compliance with applicable state and federal requirements before redispensing, and consequently, recommended *Model Act* amendments to convey this need for pharmacist verification. For Section 12. Disposal of Controlled Substances, the task force agreed to delete all requirements for notification and approval by the board and modified the section to simply require compliance with federal law.

The task force engaged in a spirited discussion about whether the *Model Rules for the Practice of Telepharmacy* should be incorporated into the *Model Rules for the Practice of Pharmacy* because of the widespread adoption of virtual communication in health care. The task force ultimately decided to combine the telepharmacy rules into the *Model Rules for the Practice of Pharmacy*, but also recommended that a separate task force on shared pharmacy services be convened to review telepharmacy and automated pharmacy systems in more detail to provide additional guidance. Nevertheless, the task force did recommend that many of the current notification requirements to patients and the board, which are found in the shared pharmacy services and automated pharmacy sections, can be deleted. Finally, the task force recommended adding the NABP Verify credential to the Provision of Pharmacist Care Services Outside of a Licensed Pharmacy section to further the development of a new pharmacy practice model.

New Pharmacy Practice Model

The task force spent considerable time contemplating key features of a new pharmacy practice model and surmised that it should separate drug product processing from the delivery of clinical services and integrate communication technologies. This wider use of technology should also be coupled with advanced automation and shared pharmacy services to allow pharmacists and pharmacy technicians to focus on delivering clinical services to patients in the community pharmacy setting, while transferring responsibilities for product filling, verification, and drug utilization review from the community pharmacy to remote staff.

The members concurred that in order for the practice of pharmacy to evolve and meet future demands, the role of the pharmacy technician will also need to evolve to include product verification, performing diagnostic tests, and administering certain medication as delegated by the pharmacist. Members stressed the importance of uniform standards and minimum competency requirements for all pharmacy technicians and supported more opportunities for pharmacy technician advancement through advanced training and certification programs. The extent of pharmacist supervision of advanced pharmacy technician roles and responsibilities, including independent liability, will also need to be reviewed and defined as the scope of their practice progresses.

Lastly, members agreed that all boards of pharmacy need to adopt regulatory changes in varying degrees to increase uniformity and fully implement an improved pharmacy practice model broadly. Until that occurs, some boards may allow for these changes to be implemented through waivers.

State boards of pharmacy may consider participating in the NABP Verify program to ensure that pharmacists involved in out-of-state remote prescription processing are vetted and that their licenses are monitored by NABP, without requiring nonresident pharmacist licensure to serve these patients. The NABP Verify program also allows pharmacies to efficiently transition workflow out of state whenever the need arises, while providing safeguards for the state where the patient is located. In conclusion, the task force supported a central support model of operations, through the use of shared pharmacy services, to free up community pharmacy staff to engage in more direct patient care.

After careful review and deliberation, the task force agreed on the following recommendations to further its goals of advancing pharmacy practice to meet patients' needs for the future.

1. NABP should support national pharmacy organizations with focusing on key objectives for a new pharmacy practice model and disseminate this information to the state pharmacy boards.
2. NABP should collaborate with pharmacy technician organizations to advance the pharmacy technician role through the development of uniform education and certification standards, including supporting specialty certification, to meet the evolving needs of a new pharmacy practice model.
3. NABP should review the shared pharmacy services and remote automated pharmacy systems sections and any telepharmacy provisions in the *Model Act* in more detail and convene another task force to review this language to address technological advances that have occurred since they were first drafted.
4. Amend the Model Act as follows. The task force's recommended *Model Act* revisions are denoted by underlines and ~~strikethroughs~~.

## Excerpts From the NABP *Model Act* and Rules for the Task Force to Review Model Rules for the Practice of Pharmacy

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**Section 104. Definitions for the Practice of Pharmacy and Related Terms.**

~~The "Practice of Pharmacy" means, but is not limited to, the interpretation, evaluation, Dispensing, and/or implementation of Medical Orders, and the initiation and provision of Pharmacist Care Services. The Practice of Pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based education.~~

The "Practice of Pharmacy" means, but is not limited to:

1. interpretating, evaluating, Compounding, Dispensing, and/or Administering Medical Orders;
2. providing Patient Counseling;
3. assessing the patient for the purposes of prescribing Drugs and Devices;
4. initiating and/or providing Pharmacist Care Services to optimize patient outcomes;

5. using Continuous Quality Improvement Programs, emerging technologies, and competency-based education to improve patient safety and the quality of services provided;
6. engaging in Collaborative Pharmacy Practice. [1]

"Pharmacist Care Services" mean 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:

1. Drug Utilization Review
2. Medication Adherence Monitoring Service
3. emergency use Prescribing and Dispensing[2]
4. Medication therapy management (MTM)
5. reviewing, selecting, and developing formularies and/or practice guidelines
6. performing drug product selection, substitution, Therapeutic Interchange[3], prescription adaptation or continuation of therapy
7. interpreting laboratory tests and performing Clinical Laboratory Improvement Amendments-waived[4] lab tests.

"Collaborative Pharmacy Practice" means that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol and in collaboration with Practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes.

"Medication Therapy Management" includes the following:

1. patient health status assessment and evaluation
2. medication reconciliation
3. formulating medication treatment plan

[1] The definition of the "Practice of Pharmacy" is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Inclusion of or authorization for specific activities, such as the Administration of Drugs, is purposely not delineated in the definition in order to be empowering and not proscriptive. To assist states in the interpretation of the revised definition of the "Practice of Pharmacy," the *Model Act* includes the definition of "Pharmacist Care Services" and Model Rules for the Provision of Pharmacist Care Services for those states that need to include specific lists of activities or authorizations due to legislative and/or administrative policies and procedures.

The definition also acknowledges that pharmacy is a dynamic profession and a broad definition of the practice will permit the Board to make necessary changes from time to time to meet the changing practice. Such changes may be affected by new or amended rules, which would be promulgated pursuant to the requirements of the State Administrative Procedures Act, affording all interested parties an opportunity to review and comment on any proposed rules.

[2] Pharmacists may prescribe Drugs for Emergency Use pursuant to specific statewide protocols or standing orders.
[3] Providing it is within the same FDA Drug class and not prohibited by the prescriber.
[4] Most recent version

4. selecting, prescribing, modifying, or Administering Drugs, Devices, vaccines, or Biologicals
5. monitoring and evaluating the patient's response to therapy, including safety and effectiveness
6. performing a comprehensive Drug Utilization Review to identify, resolve, and prevent medication-related problems, including adverse drug events
7. documenting the care delivered and communicating essential information to the patient's other primary care providers
8. providing education, support services, and resources designed to enhance patient adherence with his or her therapeutic regimens, such as Medication Synchronization
9. coordinating and integrating services within the broader health care management services being provided to the patient; and
10. such other patient care services as may be allowed by law.

**Section 105. Definitions.**

...

(f) ~~"Collaborative Pharmacy Practice" means that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol and in collaboration with Practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes.~~

(g) "Collaborative Pharmacy Practice Agreement" means a written or electronic and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice as defined by law and the Rules of the Board.

…

(b2) "Digital Signature" means an electronic signature based upon cryptographic methods of originator authentication and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

…

(t2) "Drug Utilization Review (DUR)"[5] includes but is not limited to the following activities:

(1) Evaluation of the Prescription Drug Order (s) and patient record(s) for:
   (i) known allergies;
   (ii) rational therapy contraindications;
   (iii) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;[6]
   (iv) reasonable directions for use;
   (v) potential or actual adverse Drug reactions;
   (vi) Drug-Drug interactions;

[5] DUR is also known to mean "Drug Use Review"; however, "Drug Utilization Review" is the preferred term.

[6] A "reasonable" dose, duration of use, and route of administration under "Drug Utilization Review" would be determined by taking into consideration patient-specific factors, including but not limited to, age, gender, and other patient factors, but dependent upon the information about the patient known to the pharmacist.

(vii) Drug-food interactions;
(viii) Drug-disease contraindications;
(ix) therapeutic duplication;
(x) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(xi) abuse/misuse.

(u2) "Electronic Signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a Person with the intent to sign the record.[7]

…

(d4) "~~Medication-assisted Treatment (MAT)~~" "Medication for Treatment of Opioid Use Disorder (MOUD)" means the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of ~~substance use disorders~~ Opioid Use Disorder (OUD).[8]

~~(e4) "Medication Therapy Management" means a distinct Pharmacist Care Service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed Pharmacist's scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the patient:~~

~~(1) performing or obtaining necessary assessments of the patient's health status;~~
~~(2) formulating a medication treatment plan;~~
~~(3) selecting, initiating, modifying, or administering medication therapy;~~
~~(4) monitoring and evaluating the patient's response to therapy, including safety and effectiveness;~~
~~(5) performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;~~
~~(6) documenting the care delivered and communicating essential information to the patient's other primary care providers;~~
~~(7) providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;~~
~~(8) providing information, support services and resources designed to enhance patient adherence with his or her therapeutic regimens, such as Medication Synchronization;~~
~~(9) coordinating and integrating Medication Therapy Management services within the broader health care management services being provided to the patient; and~~
~~(10) such other patient care services as may be allowed by law.~~

…

[7] The term "Electronic Signature" may have different meanings in various State laws and regulations. It is important to distinguish between "Electronic Signatures" and "Digital Signatures," which provide a much higher level of security for electronically transmitted information.

[8] The Substance Abuse and Mental Health Services Administration also refers to MAT as "Medications for Opioid Use Disorder" (MOUD), which are FDA-approved medications for the treatment of opioid use disorders and currently include methadone, naltrexone, and buprenorphine.

(f4) "Patient Counseling" means the ~~oral~~ communication by the Pharmacist of information, as defined in the rules of the applicable Board, to the patient or caregiver in person, whenever practicable, or by telephone or other audio/visual means, in order to ensure proper use of Drugs and Devices.

(a5) ~~"Pharmacist Care Services" means patient health care-related activities provided by a pharmacist within this State or into this State, as defined by the Rules of the Board, with or without the Dispensing of Drugs or Devices, which are intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.[9]~~

…

~~(m5) "Professional Performance Evaluation" means a peer review process in which a competency assessment is made of a pharmacist by another pharmacist for the purpose of improving the quality of the evaluated pharmacist's performance.~~

…

~~(n5) "Prospective Drug Utilization Review (DUR)" means a review of the patient's Drug therapy and Prescription Drug Order as part of a Drug Utilization Review, as defined in the rules of the Board, prior to Dispensing the Drug.~~

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## Model Rules for the Practice of Pharmacy

### Section 1. License.

(a) To obtain a license for a Pharmacy, an applicant shall:
  (1) have submitted an application in the form prescribed by the Board of Pharmacy;
  (2) have attained the age of 18 years ~~majority~~; and
  (3) have paid the fees specified by the Board of Pharmacy for the issuance of the license.

(b) The facility owner, if an individual, shall have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;

(c) The facility shall have undergone a Pharmacy inspection by the Board or authorized agent thereof; and

(d) The Pharmacy shall meet the following minimum requirements:

[9] ~~Objectives of Pharmacist Care Services include cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or prevention of a disease or symptomatology. Pharmacist Care Services should be provided by all Pharmacists within the Standard of Care to the extent of their abilities regardless of the practice setting.~~

(1) The Pharmacy shall be of sufficient size, as determined by the Board, to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.

(2) The Pharmacy shall maintain an area designated for the Practice of Pharmacy ~~provision of Patient Counseling Services~~. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.

(3) The Pharmacy shall have ready access to sufficient references~~, to include at least one current reference[10] in each of the following categories, if~~ applicable to the services provided.~~:~~

~~(i) State and Federal Drug laws relating to the Practice of Pharmacy and the legal Distribution of Drugs and any rules or regulations adopted pursuant thereto;~~

~~(ii) pharmacology;~~

~~(iii) dosage and toxicology;~~

~~(iv) veterinary Drugs[11]; and~~

~~(v) general.~~

(4) The Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.[12]

(5) ~~Each Person involved in the development, maintenance, or use of a Drug formulary shall maintain a currently accepted reference containing guidelines for a sound Drug formulary system.~~

(6) ~~All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas~~ The Pharmacy shall be maintained ~~at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the~~ in compliance with all applicable chapters of United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.

(7) ~~The Pharmacy shall have access to a sink with hot and cold running water that is convenient to the Compounding area for the purpose of hand scrubs prior to Compounding.~~

(8) The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest and safety of the pharmacy staff and patients served and to comply with all State and Federal laws.

(9) The Pharmacy shall protect against ~~provide a means for patients to prevent~~ disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the Delivery of Pharmacist Care Services other than as authorized by law or rules of the Board.

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[10] Boards may wish to give examples in each of these categories of reference texts.

[11] ~~Such as Plumb's Veterinary Drug Handbook.~~

[12] Patient-oriented reference material can include publications such as Facts and Comparisons' Patient Drug Facts, or the United States Pharmacopoeia Dispensing Information (USPDI).

(10) The Pharmacy, if operating a website ~~conducting the Practice of Pharmacy~~ ~~business over the Internet~~, shall be accredited by a program approved by the Board[13].

(e) 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.**

(a) Facility

(1) 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.

(2) 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. ~~Such barrier shall be approved by the Board of Pharmacy before being put into use.~~ In the event of separation of employment of an employee ~~due to any confirmed Drug-related reason, including diversion, or other acts involving dishonesty~~, suitable action shall be taken to ensure the security of the pharmacy.

(3) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by the rules of the Board.

(4) The Pharmacy shall implement and maintain process and technologies that will aid in theft prevention, detection, and ~~suspect~~ investigation. ~~apprehension that may include:~~

~~(i) video equipment positioned to identify individuals who may be involved in diversion or theft, if utilized, shall have adequate recording, storage, and retrieval capabilities; and~~

~~(ii) monitored alarm system with backup mechanism.~~

~~(b) Internal Theft/Diversion~~

~~(1) the Pharmacist-in-Charge and owner/licensee (facility permit holder) shall ensure policies and procedures are in place that address the following:~~

~~(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~~

[13] ~~Boards of Pharmacy are strongly encouraged to recognize the NABP Digital Merchant Approval Program for this purpose~~ For this purpose, boards of Pharmacy are strongly encouraged to recognize NABP's Healthcare Merchant Accreditation or, if a higher standard is desired, Digital Pharmacy Accreditation .

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~~(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.~~

**Section 3. Personnel.**

(a) Pharmacist-in-Charge

(1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is engaged ~~physically present~~ in the Pharmacy a sufficient amount of time to provide supervision and control. ~~A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.~~

(2) The Pharmacist-in-Charge has the following responsibilities:

~~(i) Developing or adopting, implementing, and maintaining:[14]~~

~~(A) Policies and procedures addressing the following:~~

~~(a) the provision of Pharmacy services;[15]~~

~~(b) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and Drugs of Concern;~~

~~(c) computerized record-keeping systems;~~

~~(d) Automated Pharmacy Systems;~~

~~(e) preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with such established policies and procedures;~~

~~(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 the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence[16];~~

[14] The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

[15] 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, Food and Drug Administration maintains a list of current and resolved Drug shortages, as well as discontinued Drugs on the agency's Drug Shortages Web page at *www.fda.gov/cder/drug/shortages*.

[16] 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.

(-g-) the proper management of Drug recalls which may include, where appropriate, contacting patients to whom the recalled Drug Product(s) have been Dispensed;

(-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-) 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.

(-j-) 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 regulations.

(-k-) The prevention and detection of Drug diversion.[17]

(B) Policies and procedures that address the following activities related to prescription Drug shipment by mail or common carrier:

(-a-) properly transferring prescription information to an alternative Pharmacy of the patient's choice in situations where the Drug is not Delivered or Deliverable;

(-b-) 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;

(-c-) tracking all shipments; and

(-d-) ensuring that Drugs do not become adulterated in transit

(C) Quality assurance programs addressing the following:

(-a-) Pharmacy services. The quality assurance program should be 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;

(-b-) Automated Pharmacy Systems. The quality assurance program should monitor the performance of the Automated Pharmacy System, ensure the Automated

[17]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.

~~Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed, while maintaining appropriate record keeping and security safeguards.~~

(ii) 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.

(iii) Notifying the Board of Pharmacy~~, immediately and in writing,~~ of any of the following[18] 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 Drug Enforcement Administration (DEA) or other State or federal agencies for Prescription Drugs and controlled substances.

(vi) Responding to the Board of Pharmacy regarding any minor violations brought to his or her attention.

[18] 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.

(3) 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 maintain and file with the Board of Pharmacy, on a form provided by the Board, a current list of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates assisting in the provision of Pharmacy services.~~

~~(ii) 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.~~

(iii) The Pharmacist-in-charge shall develop or adopt, implement, and maintain a ~~Certified Pharmacy Technician~~ training program that is site-specific to the practice setting of which he or she is in charge for all individuals employed by the Pharmacy. ~~who will assist in the Practice of Pharmacy~~. ~~The Pharmacist-in-Charge shall utilize a Certified Pharmacy Technician training manual as part of the training program. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates successfully completing a site-specific training program and an objective assessment mechanism. The Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for licensure by the Board.~~[19]

(b) ~~Professional Performance Evaluation~~

~~Each Pharmacist who performs any of the acts described within the definition of "Practice of Pharmacy" is responsible for ensuring that he or she is the subject of a Professional Performance Evaluation at least once each year. Each Pharmacy is responsible for ensuring that every Pharmacist who practices at the Pharmacy for more than 40 hours during any twelve (12)-month period and who performs any of the acts described within the definition of "Practice of Pharmacy" is the subject of a Professional Performance Evaluation at least once each year.~~

(c) Pharmacy Labor Standards/Shift Lengths and Breaks

(1) 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 per day, inclusive of the breaks required under subsection (2).

(2) 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 per day, at a minimum, he or she qualifies for an additional 15-minute break.

(3) A Pharmacy may, but is not required to, close when a Pharmacist is allowed to take a break under subsection (2). If the Pharmacy does not close, the Pharmacist shall either

[19] All training programs should be subject to approval by the Board of Pharmacy.

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 ~~by a Pharmacist~~ may be Dispensed while the Pharmacist is on break, except those Prescription Drug Orders that require 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 regulations;[20] and

(iv) a Pharmacist using his/her professional judgment may waive Subsections (1) and (2).

(d) Policies and Procedures.

The Pharmacist-In-Charge is responsible for developing or adopting, implementing, and maintaining[21] policies and procedures addressing the following:

(1) the ~~provision of~~ Practice of Pharmacy ~~services~~;[22]
(2) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and Drugs of Concern;
(3) ~~computerized~~ record retention~~-keeping~~ systems;
(4) Automated Pharmacy Systems;[23]
(5) Shared Pharmacy Services;[24]
(6) preventing the illegal use or disclosure of Protected Health Information~~, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with such established policies and procedures;~~
(7) 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

[20] The pharmacy shall have policies and procedures to ensure that the patient is provided an opportunity to receive counseling.
[21] The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

[22] 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, Food and Drug Administration maintains a list of current and resolved Drug shortages, as well as discontinued Drugs on the agency's Drug Shortages Web page at *www.fda.gov/cder/drug/shortages*.

[23] See Section 9 Automated Pharmacy Systems.
[24] See Section Shared Pharmacy Services.

and procedures shall include reporting to the Board ~~the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence~~[25];

(8) the proper management of Drug recalls ~~which may include, where appropriate, contacting patients to whom the recalled Drug Product(s) have been Dispensed~~;

(9) 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.

(10) activities related to prescription Drug shipment by mail or common carrier:

(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) ~~ensuring~~ taking measures to prevent that Drugs do not become Adulterated in transit

(11) quality assurance programs addressing Pharmacy services and equipment.:

(i) ~~Pharmacy services. The quality assurance program should be 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;~~

(ii) ~~Automated Pharmacy Systems. The quality assurance program should monitor the performance of the Automated Pharmacy System, ensure the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed, while maintaining appropriate record keeping and security safeguards.~~

(12) 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.

(i) 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 regulations.

[25] 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.

(ii) 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.

(iii) the prevention and detection of Drug diversion.[26]

(13) operational aspects of the computerized record-keeping system ~~including:~~

~~(i) examples of all required output documentation provided by the computerized record-keeping system;~~

~~(ii) steps to be followed when the computerized record-keeping system is not operational due to scheduled or unscheduled system interruption;~~

~~(iii) regular and routine backup file procedures and file maintenance;~~

~~(iv) audit procedures, personnel code assignments, and personnel responsibilities; and~~

~~(v) a quality assurance mechanism for data entry validation.~~

(14) the pharmacy Continuous Quality Improvement Program;

~~(15) compliance with all applicable federal and state law.~~

(d) 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.**

(a) Prescription Drug Order

A Prescription Drug Order shall contain the following information at a minimum:

(1) full name, date of birth, and street address of the patient
(2) name, prescribing Practitioner's license designation, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;
(3) date of issuance;
(4) name, strength, dosage form, and quantity of Drug prescribed;
(5) directions for use;
(6) refills authorized, if any;
(7) if a written Prescription Drug Order, prescribing Practitioner's signature;
(8) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;
(9) if a hard copy Prescription Drug Order generated from electronic media, prescribing Practitioner's electronic or manual signature. For those with electronic signatures, such

[26]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.

Prescription Drug Orders shall be applied to paper that utilizes security features[27] that will ensure the Prescription Drug Order is not subject to any form of copying and/or alteration.

(b) Manner of Issuance of a Prescription Drug Order for a controlled substance should comply with federal regulations[28]

~~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.[29]~~

~~(1) A Prescription Drug Order must be communicated to a Pharmacist, or when recorded in such a way that the Pharmacist may review the Prescription Drug Order as transmitted, to a Pharmacy Intern or a Certified Pharmacy Technician, in a licensed Pharmacy. This may be accomplished in one of the following ways. A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in written or electronic form. A Prescription Drug Order, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication)[30] or issued electronically.[31, 32]~~

~~(2) The Pharmacist shall not dispense a Prescription Drug if the Pharmacist knows or reasonably should know that the Prescription Drug Order was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid Patient-Practitioner relationship.~~

[27] 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.

[28] 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.

[29] 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.

[30] Policies and procedures should also provide guidance for properly identifying agents of the prescribing Practitioner who are trained and competent in communicating Prescription Drug Orders.

[31] If a state requires prescriptions to be electronically transmitted, it may consider waiving such requirement and allow issuance of paper prescriptions during a State of Emergency, in compliance with Federal Law.

[32] 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.

~~(3) If communicated orally, the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist, the Pharmacy Intern, or the Certified Pharmacy Technician that may be maintained for the time required by laws or rules.~~

~~(4) A Prescription Drug Order for a Schedule II controlled substance may be communicated orally only in the following situations and/or with the following restrictions. Otherwise, a Prescription Drug Order for a Schedule II controlled substance must be communicated in written form or issued electronically.~~

~~(i) A Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner or the Practitioner's agent by way of Electronic Transmission, provided the original written, signed Prescription Drug Order is presented to the Pharmacist for review prior to the actual Dispensing of the controlled substance, except as noted in paragraph (ii) or (iii) of this Section 3(b)(3). The original Prescription Drug Order shall be maintained in accordance with state and federal record-keeping requirements.~~

~~(ii) In the case of an Emergency Situation, a Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner orally, provided that:~~

~~(A) the quantity prescribed and Dispensed is limited to the amount adequate to treat the patient during the emergency period (Dispensing beyond the emergency period must be pursuant to a Prescription Drug Order either written and signed or electronically issued by the prescribing Practitioner);~~

~~(B) the orally communicated Prescription Drug Order shall be immediately reduced to writing by the Pharmacist if necessary, and shall contain the information required by state and federal law;~~

~~(C) if the prescribing Practitioner is not known to the Pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered Practitioner, which may include a callback to the Practitioner using the Practitioner's phone number as listed in the telephone directory and/or other good faith efforts to ensure his or her identity; and~~

~~(D) within seven days after authorizing an emergency oral Prescription Drug Order, the Practitioner shall cause a written Prescription Drug Order for the emergency quantity prescribed to be delivered to the Dispensing Pharmacist. The Prescription Drug Order shall have written on its face "Authorization for Emergency Dispensing," and the date of the orally transmitted Prescription Drug Order. The written Prescription Drug Order may be delivered to the Pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the Dispensing Pharmacist shall attach this written Prescription Drug Order to the emergency oral Prescription Drug Order, which had earlier been reduced to writing. The Pharmacist shall notify the nearest office of the DEA if the prescribing Practitioner fails to deliver a written Prescription Drug Order.~~

~~(iii) The prescribing Practitioner may authorize his or her agent to communicate~~

~~a Prescription Drug Order orally or by way of Electronic Transmission via facsimile to a Pharmacist in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order. In an Institutional Facility, the prescribing Practitioner's agent must be authorized by and in accordance with written policies and procedures of the Facility and applicable state and federal laws.~~

~~(5) A Prescription Drug Order for a Schedule II narcotic substance to be Compounded for the direct Administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be communicated by the Practitioner or the Practitioner's agent to the Home Infusion Pharmacy via facsimile. The hard copy of such faxed prescription serves as the original, written Prescription Drug Order and it shall be maintained in accordance with state and federal record-keeping requirements.~~

~~(6) A Prescription Drug Order for a Schedule II controlled substance for a resident of a Long-Term Care Facility may be communicated by the Practitioner or the Practitioner's agent via facsimile. The hard copy of such faxed prescription serves as the original, written Prescription Drug Order and it shall be maintained in accordance with state and federal record-keeping requirements.~~

~~(7) All Prescription Drug Orders for a Schedule III-V controlled substance communicated by way of Electronic Transmission via facsimile shall:~~

~~(i) be transmitted to a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician in a licensed Pharmacy of the patient's choice;~~

~~(ii) identify the transmitter's phone number or any other suitable means to contact the transmitter for verbal and/or written confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law;~~

~~(iii) be transmitted by an authorized Practitioner or his or her designated agent; and~~

~~(iv) be deemed the original Prescription Drug Order, provided it meets the requirements of this subsection.~~

~~(8) All Prescription Drug Orders for a Schedule II-V controlled substance issued and processed electronically shall be in compliance with existing federal or state laws and rules.~~

~~(9) The Pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the Prescription Drug Order issued electronically or by facsimile to ensure it is consistent with existing federal or state laws and rules.~~

~~(10) All electronic equipment for receipt of Prescription Drug Orders issued electronically or by facsimile shall be maintained so as to ensure against unauthorized access.~~

~~(11) Persons other than those bound by a confidentiality agreement shall not have access to Pharmacy records containing Protected Health Information concerning the Pharmacy's patients.~~

…

(d) Drug Product Selection by the Pharmacist

(1) 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 Federal Food and Drug Administration is required.

(2) The Pharmacist shall not select an Equivalent Drug Product if the Practitioner instructs otherwise, either orally or in writing, on the Prescription Drug Order.

(3) The Pharmacist shall notify the patient or patient's agent if a Drug other than the brand name Drug prescribed is Dispensed.

(e) Labeling

(1) 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.**

(a) Patient Records[33]

(1) 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 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.

(2) 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, ~~idiosyncrasies,~~ 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.

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

[33] The Pharmacist should have access to clinical and laboratory data concerning each patient, and should monitor each patient's response to his or her 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.

(4) Protected Health Information may be used or disclosed as allowed under state and federal privacy rules.

(5) Significant Adverse Drug Reactions shall be reported to the Practitioner and an appropriate entry shall be made in the patient's record.

(b) Records of Dispensing/Delivery[34]

(1) Records of receipt, Dispensing, Delivery, Distribution, or other disposition of all Drugs or Devices are to be made and kept by Pharmacies for five years[35] 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.

(2) 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.[36]

(c) Electronic Record Keeping

(1) ~~Systems Policies and Procedures~~

~~An up-to-date policy and procedure manual shall be developed by the Pharmacist-in-Charge that explains the operational aspects of the computerized record-keeping system and shall:~~

~~(i) include examples of all required output documentation provided by the computerized record-keeping system;~~

~~(ii) outline steps to be followed when the computerized record-keeping system is not operational due to scheduled or unscheduled system interruption;~~

~~(iii) outline regular and routine backup file procedure and file maintenance;~~

~~(iv) outline audit procedures, personnel code assignments, and personnel responsibilities; and~~

~~(v) provide a quality assurance mechanism for data entry validation.~~

(2) Data Storage and Retrieval.

[34] 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.

[35] States should check federal laws and ensure that the number of years the state requires Dispensing records to be maintained are at least as many as federal requirements.

[36] 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.

(i) The system shall provide online retrieval of original Prescription Drug Order information. Such information shall include, but not be limited to, the Prescription Drug Order requirements and records of Dispensing as indicated in Section 3 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. ~~the following conditions:~~

~~(A) The system must provide online retrieval of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the Practitioner; full name and address of the patient; name, address, and DEA registration number of the Practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing Practitioner;~~

~~(B) The system must also provide online retrieval the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity Dispensed, the identification code, or name or initials of the Dispensing Pharmacist for each refill and the total number of refills Dispensed to date for that prescription order;~~

~~(C) Documentation of the fact that the refill information entered into the computer each time a Pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual Pharmacist who refilled such a prescription order. The individual Pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document ( eg, J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that Pharmacy for a period of two years from the Dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each Pharmacy using such a computerized application within 72 hours of the date on which the refill was Dispensed. It must be verified and signed by each Pharmacist who is involved with such dispensing. In lieu of such a printout, the Pharmacy shall maintain a bound logbook, or separate file, in which each individual Pharmacist involved in such Dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him or her and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of Dispensing the appropriately authorized refill;~~

(D) The electronic record-keeping system shall have the capability of producing a printout of any Prescription Drug Order data. The system shall provide a refill-by-refill audit trail for any specified strength and dosage form of any Drug. Such an audit trail shall be by printout, and include the name of the prescribing Practitioner, name and location of the patient, quantity Dispensed on each refill, date of Dispensing of each refill, name or identification code of the Dispensing Pharmacist, and unique identifier of the Prescription Drug Order; and

(E) Any facility maintaining centralized prescription records shall be capable of sending a requested printout to the Pharmacy within 48 hours.

(iii) if a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically and are subject to the following:

(A) records must be maintained electronically for _____ years from the date of their creation or receipt;

(B) records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read;

(C) records required by this section part must be made available to the state and federal agencies upon request;

(D) if the Pharmacy discontinues or changes the electronic prescription service provider or transfers the electronic Prescription Drug Order records to another Pharmacy, the Pharmacy must ensure that the records are stored in a format that can be retrieved, displayed, and printed in a readable format; and

(E) digitally signed prescription records must be transferred or migrated with the digital signature.

(3) 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.

(4) 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 ~~within a two-hour time period~~ 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 ~~within 96 hours~~.

(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 ~~within 24 hours~~.

**Section 6. Pharmacist Care Services.**

~~Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and Drug eligibility and coverage; Prescribing and Administering Drugs, Devices, vaccines, or biologicals; Prescribing and Dispensing for emergency use[37]; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan/practice guidelines; performing therapeutic substitution[38]; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering and performing Clinical Laboratory Improvement Amendments of 1988 waived lab tests and prescribing associated Drugs and Biologicals[39], as provided by State and Federal law, and reporting results and follow up treatment.~~

(a) Pharmacist Care Services are services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination of reduction of symptoms, and promotion of health and wellness.[40] Pharmacist Care Services include but are not limited to:

(1) Drug Utilization Review

(2) Medication Adherence Monitoring Service

(3) emergency use Prescribing and Dispensing[41]

(4) Medication therapy management (MTM)

(5) reviewing, selecting, and developing formularies and/or practice guidelines

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

[38] Providing it is within the same FDA drug class and not prohibited by the prescriber.

[39] Pharmacist may prescribe associated Drugs pursuant to specific statewide protocols or standing orders.

[40] Pharmacist Care Services should be provided by all Pharmacists within the Standard of Care to the extent of their abilities regardless of the practice setting.

[41] Pharmacist may prescribe Drugs for Emergency Use pursuant to specific statewide protocols or standing orders.

(6) performing drug product selection, substitution, Therapeutic Interchange[42] prescription adaptation or continuation of therapy,

(7) interpreting laboratory tests and performing Clinical Laboratory Improvement Amendments-waived[43] lab tests.

(~~a~~b) ~~Prospective~~ Drug Utilization Review (DUR)[44]

A Pharmacist shall obtain and review the patient records and medical history for each Prescription Drug Order for:

(1) known allergies;
(2) rational therapy contraindications;
(3) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
(4) reasonable directions for use;
(5) potential or actual adverse Drug reactions;
(6) Drug-Drug interactions;
(7) Drug-food interactions;
(8) Drug-disease contraindications;
(9) therapeutic duplication;
(10) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(11) 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.

(~~b~~c) Patient Counseling[45]

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall ~~personally initiate~~ 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 ~~electronic~~ 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;

[42] Providing it is within the same FDA Drug class and not prohibited by the prescriber.
[43] Most recent version
[44] Pharmacists should be permitted to use computer software, if available, to accomplish this review.

[45] The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her 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.

(iii) intended use of the Drug and expected action;
(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.

(2) An offer for Patient Counseling can be made by a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate ~~when it is not required by law or deemed necessary that it be done by the Pharmacist~~.

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

(4) 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).

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

(~~c~~d) 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.

(~~d~~e) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the ~~written~~ Collaborative Pharmacy Practice Agreement. ~~The initial existence and subsequent termination of any such agreement and a~~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. ~~Patients or caregivers shall be advised of such agreement.~~

(2) 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 he or she 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.

(3) Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(4) 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. ~~Documentation of allowed activities shall be considered Protected Health Information~~.

(e) Emergency use Prescribing and Dispensing
Prescribing and Dispensing Drugs for emergency use shall be pursuant to a Pharmacist-issued Prescription and include appropriate Patient Counseling. Drugs or Devices for emergency use include, but are not limited to:
(1) Opioid overdose reversal agents, such as naloxone;
(2) Epinephrine;
(3) Antidote kits;
(4) Short-acting beta agonist inhalers; and
(5) Medication-assisted Treatment 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.[46]

(f) Emergency Refills

A Pharmacist may Prescribe and Dispense a refill of a Prescription Drug~~, not to exceed a thirty (30) day supply,~~ without Practitioner authorization if:[47,~~48~~]

(1) 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;

(2) 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 it is an "Emergency Refill Prescription," and maintains the record as 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;

(3) 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

~~(4) 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.

(a) Continuous Quality Improvement Program

(1) 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).

(2) 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, ~~which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;~~

(ii) initiate documentation of QREs as soon as possible, but no more than three 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;

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

[47] Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure these provisions are applicable to controlled substances.

~~[48] Boards may consider extending beyond a thirty (30) day supply.~~

(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;

~~(v) provide ongoing CQI education at least annually to all pharmacy personnel;~~

(vi) 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.

(3) 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 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.

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

(5) 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.

~~(6) Consumer Survey~~

~~As a component of its CQI Program, each Pharmacy should conduct a Consumer Survey of patients who receive Drug Products and services at the Pharmacy. A Consumer Survey should be conducted at least once per year. A statistically valid sampling technique may be used in lieu of surveying every patient. Each Pharmacy should use the results of its Consumer Survey to evaluate its own performance at a particular time and over a period of time.~~

(7) Protection from Discovery[49]

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[50]. 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

[49] 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.

[50] 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.

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.

(8) 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.**

(a) General Requirements[51, 52]

(1) The Pharmacy must possess a resident or nonresident permit issued by the Board prior to engaging in Shared Pharmacy Services.[53]

(2) A Pharmacy may provide or utilize Shared Pharmacy Services only if the Pharmacies involved:

(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.

(3) 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.

(4) ~~A Pharmacy engaged in Shared Pharmacy Services shall notify the Board in writing within 10 days of a change of location, discontinuance of service, or closure of a Pharmacy.~~

(b) Operations

(1) Pharmacies engaging in Shared Pharmacy Services, or a Pharmacist acting independently of a Pharmacy and participating in Shared Pharmacy Services shall:

[51] 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.

[52] 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 he/she is engaging in such series until such a time in which provisions for multistate practice exist.

[53] 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) 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 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 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.

~~(2) Notification to Patients~~

~~(i) Pharmacies engaging in Shared Pharmacy Services shall notify patients that their Prescription Drug Orders may be processed or filled by another Pharmacy unless the Prescription Drug is delivered to patients in Institutional Facilities where a licensed health care professional is responsible for administering the Prescription Drug to the patient.~~

(c) Drug Storage and Security

(1) 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.

~~(2) Drugs stored at Shared Pharmacy Services Pharmacies shall be stored in an area that is:~~

~~(i) separate from any other Drugs used by the health care facility; and~~

~~(ii) secured, so as to prevent access by unauthorized personnel.~~

(3) 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 designated in writing by the Pharmacist-in-Charge or the Person responsible for the supervision and on-site operation of the facility where the ~~Automated Pharmacy System~~ Shared Services Pharmacy is located; and

(C) have completed documented training concerning their duties associated with the Shared Pharmacy Services Pharmacy.

(4) 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.

(d) Policies and Procedures

(1) Each Pharmacy in Shared Pharmacy Services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for Shared Pharmacy Services. 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 ~~policies and procedures~~ 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.

(e) Individual Practice

(1) 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.

(g) ~~Practice of Telepharmacy –~~ Remote Dispensing Site Requirements [54]

A Remote Dispensing Site:

(1) Shall submit an Application to the Board.

(2) The Pharmacist-in-Charge of the Shared Pharmacy Services Pharmacy shall be responsible for all operations of the Remote Dispensing Site.

(3) Shall have a written contract or agreement that outlines the services provided and the responsibilities of each Pharmacy in complying with Federal and State pharmacy laws and rules.

(4) 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.

(5) A Pharmacist must be designated to be available within ( ) hours, in case of emergency.

(6) A functioning video and audio communication system that provides for effective communication between the Shared Pharmacy Services Pharmacy and the Remote Dispensing Site personnel and patients, and their agents or caregivers, must be maintained. 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 other matters involved in the lawful transaction or Delivery of Drugs. The Remote Dispensing Site must retain a recording of the facility surveillance, excluding patient communications, for a minimum of ( ) days.

(7) Unless a Pharmacist is present, a Remote Dispensing Site must not be open or its employees allowed access during times the Shared Pharmacy Services Pharmacy is closed or during a system outage.

## Section 9. Automated Pharmacy Systems.

(a) Automated Pharmacy Systems can be utilized in licensed pharmacies and Shared Pharmacy Services Pharmacies and other locations approved by the Board. 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 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;

[54] For Boards of Pharmacy that have yet to add rules for the Practice of Telepharmacy and/or require more specificity, see Appendix F Model Rules for the Practice of Telepharmacy.

~~(v) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction; and~~

(v~~i~~) 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 Services that ensures Medical Orders or Prescription Drug Orders are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacist Care Services.~~[55]

(2~~i~~) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.[56]

(3~~ii~~) Any Pharmacy that maintains an Automated Pharmacy System for the purposes of remote Dispensing to outpatients[57] shall maintain an interactive ~~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~~[58]~~,~~ 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.

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[55] 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 Therapy Management controls in place.

[56] 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.

[57] 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.

~~[58] The use of Automated Pharmacy Systems requires written policies and procedures in place prior to installation to ensure safety, environmental controls, accuracy, security, and patient confidentiality and to define access and limits to access to equipment and Drugs.~~

(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.

(6) Defined a~~A~~ccess 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~~. [59]

(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 Drugs complies 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 Drugs in the Automated Pharmacy System shall be accomplished by qualified personnel under the supervision of a licensed Pharmacist.

(9) 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.[60]

(10) All containers of Drugs 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 Drugs removed from and subsequently returned to the Automated Pharmacy System, all in accordance with existing state and federal law.[61]

(13) 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.

(b) Policies and Procedures

[59] 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.

[60] 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).

[61] 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.

(1) The Pharmacist in Charge is responsible for developing or adopting, implementing, and maintaining Automated Pharmacy Systems policies and procedures that address the following:

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

(v) provision of Pharmacist Care;

(vi) security, including:

a. preventing unauthorized access;

b. prevention of the illegal use or disclosure of Protected Health Information.

(2) 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.

**Section 10. Return and Reuse of Prescription Drugs.**

(a) Prescription Drugs may only be returned and reused providing that the Prescription Drugs were packaged in:

(1) the original, sealed, and tamper-evident bulk, unit-of-use,[62] or unit dose packaging; or

(2) the Dispensing Pharmacy's original packaging that maintains the Product quality.

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

(c) All returned Prescription Drugs must be evaluated by appropriate Pharmacy staff to ensure such Prescription Drugs are not adulterated or misbranded.

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

**Section 11. Prescription Drug Repository Programs.**

(a) Repository Programs must have written policies and procedures, which include at a minimum:

(1) Qualifications of acceptable Drugs for reuse. Such qualifications must include the following provisions:

(i) only non-controlled Drugs will be accepted;[63]

(ii) all Drugs will be inspected by a Pharmacist 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;

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

[63] Except for federally scheduled controlled substance Drugs that may be prescribed for substance use disorders and as allowed by federal and state laws and regulations.

(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.

(2) A requirement that the patient receives notification that the Drug is being Dispensed by a Repository Program.

**Section 12. Disposal of Controlled Substances.**[64]

(a) 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 ~~by the following procedures and~~ in compliance with federal law:

(1) ~~The responsible individual shall send the Board of Pharmacy a list of the controlled substances to be disposed of, including the name(s) and quantity of the Drug(s) .~~

(2) ~~The Board shall authorize and instruct the applicant to dispose of the controlled substances in one of the following manners:~~

~~(i) by Delivery to an agent of the Board of Pharmacy or the Board of Pharmacy office;~~
~~(ii) by destruction of the Drugs in the presence of a Board of Pharmacy officer, agent, inspector, or other authorized individual; or~~
~~(iii) by such other means as the Board of Pharmacy may determine to ensure that the Drugs do not become available to unauthorized Persons.~~

**Section 13. Prepackaging.**

(a) A Pharmacy may Prepackage Drugs under the following circumstances:

~~(1) written policies and procedures have been developed that address the processes of Prepackaging within the Pharmacy;~~

(2) containers utilized for Prepackaging shall meet, as a minimum requirement, Class B container standards as referenced by USP;

(3) the Prepackaging processes are conducted under conditions that ensure the integrity of the Drug and under the direct supervision of a Pharmacist;

(4) the Prepackaged 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 must current USP standards, whichever is earlier;

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

(5) Records of all Prepackaging 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 Prepackaged;
  (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 Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and
  (vi) the date the Drug is Prepackaged.

(6) All Drugs Prepackaged are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such Drugs, or with requirements in the current edition of an official compendium.

(b) 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 is readily retrievable.

(c) The Pharmacist in Charge is responsible for developing or adopting, implementing, and maintaining[65] policies and procedures addressing Prepackaging processes.

(d) The Repackaging of Drugs shall follow applicable state and federal law.

## Section 14. Telepharmacy

(a) General Requirements

(1) 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.

(b) Remote Dispensing Site Requirements

(1) The Pharmacy shall submit an application to the Board.

(2) The Pharmacist-in-Charge of supervising pharmacy shall be responsible for all operations.

(3) 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.

(4) 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.

[65] The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

(5) A Pharmacist must be designated to be available within (_) hours, in case of emergency.

(6) Unless staffed by a Pharmacist, a Remote Dispensing Site must be staffed by at least one (1) Certified Pharmacy Technician. 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.

(7) 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.

(8) 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.

(9) A supervising Pharmacy of a Remote Dispensing Site must maintain a video and audio communication system that provides for effective communication between 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 other matters involved in the lawful transaction or Delivery of Drugs. 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 or entity.

(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.

(10) Unless a Pharmacist is present, a Remote Dispensing Site must not be open or its employees allowed access to it during times the supervising Pharmacy is 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.

(11) 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.

(12) A Remote Dispensing Site must display a sign, easily visible to the public, that informs patients:

(i) this is a remote site

(ii) location of supervising Pharmacy; and

(iii) that a Pharmacist will counsel the patient using audio and video communication systems each time a new Drug is Dispensed, and on a refill, if necessary, at a Remote Dispensing Site.

(13) 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.

**Section 154. Provision of Pharmacist Care Services Outside of a Licensed Pharmacy.**

(a) 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.[66]

…

## ~~Model Rules for the Practice of Telepharmacy~~

(a) ~~General Requirements~~

~~(1) 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.~~

~~(b) Remote Dispensing Site Requirements~~

[66] It is anticipated that Boards use the *Pharmacists' Patient Care Process* approved in May 2014 by the Joint Commission of Pharmacy Practitioners.

(10) ~~The Pharmacy Sshall submit an application to the Board.~~

(11) ~~The Pharmacist-in-Charge of supervising pharmacy shall be responsible for all operations.~~

(12) ~~The Pharmacy Sshall 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.~~

(13) ~~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.~~

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

(15) ~~Unless staffed by a Pharmacist, a Remote Dispensing Site must be staffed by at least one (1) Certified Pharmacy Technician. 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.~~

(16) ~~The Remote Dispensing Site and the supervising Pharmacy must utilize a common electronic record-keeping system that must be capable of the following:~~

~~(iii) Electronic records must be available to, and accessible from, both the supervising pharmacy and the Remote Dispensing Site at all times of operations; and~~

~~(iv) Prescriptions dispensed at the Remote Dispensing Site must be distinguishable from those dispensed from the supervising Pharmacy.~~

(17) ~~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.~~

(18) ~~A supervising Pharmacy of a Remote Dispensing Site must maintain a video and audio communication system that provides for effective communication between 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 other matters involved in the lawful transaction or Delivery of Drugs. The Remote Dispensing Site must retain a recording of facility surveillance, excluding patient communications, for a minimum of (_) days.~~

~~(iv) 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 or entity.~~

~~(v) 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.~~

~~(vi) 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.

(10) Unless a Pharmacist is present, a Remote Dispensing Site must not be open or its employees allowed access to it during times the supervising Pharmacy is 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.

(11) 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.

(12) A Remote Dispensing Site must display a sign, easily visible to the public, that informs patients:

(iv) this is a remote site

(v) location of supervising Pharmacy; and

(vi) that a Pharmacist will counsel the patient using audio and video communication systems each time a new Drug is Dispensed, and on a refill, if necessary, at a Remote Dispensing Site.

(13) 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.