Report of the Committee on Law Enforcement/Legislation

Members Present:

Michael A. Moné (OH), *chair*; Jody Allen (VA); Patricia D'Antonio, (DC); Susan DelMonico (RI); Chris Humberson (WA); Caroline Juran (VA); Dennis McAllister (AZ); Alice Mendoza (TX); Penny Reher (OR).

Others Present:

Susan Ksiazek, *Executive Committee Liaison*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Emily Shaffer, Cameron Orr, *NABP staff.*

Introduction:

The Committee on Law Enforcement/Legislation met January 21 and 22, 2014, at NABP Headquarters.

Review of the Committee Charge

Committee members reviewed their charge and accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists.

2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.

3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Committee members were provided the report of the 2011-2012 Committee on Law Enforcement/Legislation for background information.

LE/L Recommendation 1: The Committee Recommends Approval of the Amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* suggested by the Task Force on Pharmacy Licensure Standards, with Revisions.

The recommended revisions by the task force are denoted by underlines and ~~strikethroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double strikethroughs~~.

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

Article I

Title, Purpose, and Definitions

Introductory Comment to Article I

Article I of the Model State Pharmacy Act and Model Rules of National Association of Boards of Pharmacy (Model Act) *sets forth the foundation upon which the Act is constructed. It clearly declares and acknowledges that safeguarding the public interest is the foremost compelling reason for regulating the Practice of Pharmacy and the Distribution of Drugs and related Devices. It also circumscribes the activities included within the Practice of Pharmacy, as well as the definitions of several other terms used throughout the Act.*

NABP created the Model Act to provide State Boards of Pharmacy with model language that may be used when developing state laws or board rules for the respective States. NABP believes that it is both desirable and necessary to recognize that the public interest must be the central precept in the Model Act, *and its administration, and that State Boards of Pharmacy must constantly strive to achieve the principles enunciated in Article I of the Act.*

An ACT concerning the regulation of the Practice of Pharmacy in this State and related matters.

Be it enacted. . . .

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Section 105. Definitions.

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(a6) "Significant Adverse Drug Reaction" means any Drug-related incident that may result in serious harm, injury, or death to the patient.

(b6) "Significant Loss" means any loss of a Prescription Drug that exceeds a reasonable level established by like persons, which requires that loss to be reported to the Board or as required by Drug Enforcement Administration (DEA) or other state and/or federal agencies for Prescription Drugs and controlled substances.

(c6) "Significant Quality-Related Event" means any Quality-Related Event that results in serious harm, injury, or death to the patient.

(d6) "State of Emergency" means a governmental declaration, usually issued as a result of a Public Health Emergency, that may suspend certain normal functions of government, alert citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.

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Article II

Board of Pharmacy

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Section 213. Powers and Responsibilities.

(a) The Board of Pharmacy shall be responsible for the control and regulation of the Practice of Pharmacy in this State including, but not limited to, the following:

(1) the licensing by examination or by license transfer of applicants who are qualified to engage in the Practice of Pharmacy under the provisions of this Act;

(2) the renewal of licenses to engage in the Practice of Pharmacy;

(3) the establishment and enforcement of compliance with professional standards and rules of conduct of Pharmacists engaged in the Practice of Pharmacy;

(4) the determination and issuance of standards for recognition and approval of degree programs of schools and colleges of Pharmacy whose graduates shall be eligible for licensure in this State, and the specification and enforcement of requirements for practical training, including Pharmacy practice experience;

(5) the enforcement of those provisions of this Act relating to the conduct or competence of Pharmacists practicing in this State; the Revocation, Summary Suspension, Suspension, Probation, Censure, or Reprimand of, or the issuance of Warnings or the assessment of Fines/Civil Penalties or Costs/Administrative Costs against licenses to engage in the Practice of Pharmacy; and the issuance of Cease and Desist orders against any Person or entity;

(6) the licensure and regulation of the training, qualifications, and employment of Pharmacy Interns and Pharmacy Technicians;

(7) the collection of professional demographic data;

(8) the right to seize any such Drugs and Devices found by the Board to constitute an imminent danger to the public health and welfare;

(9) establishing minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, Compounding and/or Dispensing of such Drugs or Devices, ~~and~~ for the monitoring of Drug therapy, and for the Manufacture and Distribution of Drugs and Devices;

(10) establishing minimum standards for the purity and quality of such Drugs, Devices, and other materials within the Practice of Pharmacy;

(11) the issuance and renewal of licenses for pharmacies located within this State, or outside this State if providing services to patients within this State, that Compound or Dispense Drugs or Devices or provide Pharmacist Care.

(12~~1~~) the issuance and renewal of licenses of all ~~Persons engaged in the~~ Manufacturers and Distributors~~ion~~ of Drugs and Devices located within this State, or outside this State if providing such services within this State;

(13~~2~~) inspection at all reasonable hours of the facility and appropriate records of any licensed Person or licensed facility and any Person or facility seeking licensure for the purpose of determining if any provisions of the laws governing licensure, the legal Distribution of Drugs or Devices, or the Practice of Pharmacy are being violated, including the inspection of Protected Health Information. The Board of Pharmacy, its officers, inspectors, and representatives shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this State, and of all other states relating to Drugs, Devices, and the Practice of Pharmacy;

(14~~3~~) establishing minimum standards for maintaining the integrity and confidentiality of prescription information and other patient health care information; and

(15~~4~~) the approval of Pharmacy practice initiatives that improve the quality of or access to Pharmacist Care, but which fall outside the scope of present regulations. This

subsection shall not be construed to expand the definition of the Practice of Pharmacy as defined in this Act.

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Section 213(a). Comment.

The "Practice of Pharmacy in this State" includes shipping Prescription Drugs into this State from another jurisdiction. However, this is not meant to be construed as a licensure requirement for every Pharmacist that is employed at a nonresident Pharmacy unless they are specifically engaged in the Practice of Pharmacy and provide services to residents in this State (see Sections 104 and 501(a) of this Act).

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Article V

Licensing of Facilities

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Section 502. Application.

(a) The Board shall specify by rule the licensure procedures to be followed, including but not limited to, specification of forms for use in applying for such licensure and times, places, and applicable fees.

(b) Applicants for licensure to Distribute, Wholesale Distribute, Manufacture, sell, purchase, transfer, and/or produce Drugs or Devices, and applicants for licensure as a Pharmacy Benefits Manager, shall file with the Board of Pharmacy a verified application containing such information as the Board requires of the applicant relative to the qualifications for a license.

(c) Licenses issued by the Board pursuant to this Act shall not be transferable or assignable.

(d) The Board shall specify by rule minimum standards for responsibility of any Person, Pharmacy, or Pharmacy Benefits Manager that has employees or personnel engaged in the Practice of Pharmacy, or Manufacture, Distribution, Wholesale Distribution, production, sale, or use of Drugs or Devices in the conduct of their business. If the licensed Person is a Pharmacy located in this state, that portion of the facility to which such license applies shall be operated only under the direct supervision of a Pharmacist licensed to practice in this State.

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Section 503. Notifications.

(a) All licensed Persons shall report to the Board of Pharmacy the occurrence of any of the following:
   (1) permanent closing;
   (2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
   (3) any theft or loss of Drugs or Devices;
   (4) any conviction of any employee of any State or Federal Drug laws;
   (5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
   (6) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;

(7) occurrences of Significant Quality-Related Events ~~Adverse Drug Reactions as defined by Rules of the Board~~;
(8) illegal use or disclosure of Protected Health Information; or
(9) any and all other matters and occurrences as the Board may require by rule. ~~or~~
~~(10) report of any inspection conducted by any State or Federal regulatory agency or authorized agent thereof.~~

(b) All licensed Persons shall report to the Board of Pharmacy, or its authorized agent, the occurrence of any Pharmacy or Pharmacy related inspection conducted by any State or Federal regulatory agency or authorized agent thereof and shall provide a copy of the report of such inspection, including applicable documents relating to corrective actions.

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Model Rules for the Practice of Pharmacy

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care, the following rules are essential.

Section 1. Facility.

(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 majority;
(3) be of good moral character; and
(4) 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) Minimum requirements for a Pharmacy:
(1) Each 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) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.
(3) Each Pharmacy shall have ready access to references applicable to the services provided, to include at least one current reference in each of the following categories:
(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) general.
(4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.

(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 shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.
(7) Each 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) Security.
    (i) 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.
    (ii) 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.
    (iii) 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.
(9) Equipment/Supplies.
    The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.
(10) The Pharmacy shall 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 other than as authorized by law or rules of the Board.
(11) The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board.

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Comments

Section 1(a)(3). Comment.

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

Section 1(<u>d</u>~~a~~)(4). Comment.

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

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Section 3. Pharmacy Practice.

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(l) Adverse Drug Reactions
Significant Adverse Drug Reactions shall be reported to the Practitioner ~~and, in writing, to the Board of Pharmacy~~ immediately upon discovery. Appropriate entry on the patient's record shall also be made.

Background:

The committee discussed the task force's recommended revisions to the *Model Act* and while the members agreed with the premise of many of the revisions, they believed that some clarifications were necessary. Specifically, members concurred that the provision bestowing authority for boards of pharmacy to issue and renew pharmacy licenses was necessary, however, decided that the interpretation of this provision as it relates to nonresident pharmacies should be clarified through a comment. The committee agreed that nonresident pharmacies should be licensed by every state in which they provide pharmacy services to residents in those states, but that individual pharmacists need only to obtain licensure in those states in which they are actively engaged in the practice of pharmacy and providing services. Along those lines, the committee believed that a statement should be added to the introductory comment that states the *Model Act* is written in first person point of view for a resident board of pharmacy. Also in that provision, the committee agreed to remove "Persons" from the Manufacturer and/or Distributor licensing authority to avoid confusion of who was required to obtain the license.

The committee also determined that some clarifications were necessary in the notifications section of the *Model Act*, particularly in regard to what is considered a quality-related event versus an adverse drug reaction and in what circumstances should either be reported to the board of pharmacy. Members concurred with the task force's recommendation that significant adverse drug reactions should not be required to be reported to boards of pharmacy and that the intent of the Model Act is to require "significant quality related events" to be reported to boards. With this in mind, the committee clarified this issue by creating a new definition for "Significant Quality Related Event," reasoning that such events are often preventable and therefore should be under the boards' purview.

In addition, the committee addressed the recommendation of the task force that boards be provided with a report of any inspection conducted by any State or Federal agency or their authorized agent. Specifically, the committee clarified the provision that a pharmacy must notify either the board or the board's authorized agent of such inspection and submit the report and applicable documents, including those related to corrective actions.

LE/L Recommendation 2: The Committee Recommends Approval of the Amendments to the *Model Act* Suggested by the Task Force on the Regulation of Pharmacy Benefit Managers.

The recommended revisions by the task force are denoted by underlines and ~~strikethroughs~~.

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

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

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(x4) "Pharmacy Benefits Manager" means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, and that engages in or directs the Practice of Pharmacy.

(y4) "Pharmacy Benefits Processor" means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, but that does not engage in or direct the Practice of Pharmacy.

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Section 105(x4) (and [y4]). Comment.

It is the performance of activities that encompass the Practice of Pharmacy that distinguishes Pharmacy Benefits Managers from Pharmacy Benefits Processors. The activities that may encompass the Practice of Pharmacy by Pharmacy Benefits Managers include, but are not limited to, the following:

- Disease state management
- Disease compliance management
- Drug adherence management
- Drug interaction management
- Drug utilization management
- Formulary management ~~intervention~~
- Generic alternative program management
- Generic incentive program management
- Medical and/or Drug data analysis
- Patient Drug Utilization Review (DUR) services
- Prior authorization services
- Provider profiling and outcomes assessment

- Refill reminder program management
- Therapy guidelines management
- Stop therapy protocol management
- Wellness management
- Maintenance of confidential patient information
- Direction or design of the clinical programs for a pharmacy or a group of pharmacies

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Background:

The committee agreed with the task force's recommendations after minimal discussion and decided that no additional revisions or clarifications were necessary.

LE/L Recommendation 3: The Committee Recommends Approval of Proposed Amendments to the *Model Act* Pursuant to Resolution 109-2-13 to Address Five Percent Rules.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

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

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

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(x2) "Emergency Medical Reasons" include, but are not limited to, transfers of a prescription Drug between a Wholesale Distributor or Pharmacy to alleviate a temporary shortage of a prescription Drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, ie, ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed Practitioners of Prescription Drugs for use in the treatment of acutely ill or injured Persons; provision of minimal emergency supplies of Prescription Drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary Prescription Drugs cannot be obtained; and transfers of Prescription Drugs by a retail Pharmacy to another retail Pharmacy to alleviate a temporary shortage.

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(e6) "Wholesale Distribution" means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer distribution, or sale of Prescription Drugs by a Pharmacy to another Pharmacy or from a Pharmacy to a Practitioner, only for the purpose of dispensing or administration, but not for resale; if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period, providing that such transfers are compliant with federal law. To the extent permitted by the Prescription Drug Marketing Act, Wholesale Distribution does not include:

(1) the sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;
(2) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;
(3) Intracompany Transactions, unless in violation of own use provisions;
(4) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;
(5) the sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;
(7) the transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;
(8) the sale, purchase, or trade of blood and blood components intended for transfusion;
(9) the return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations; or
(10) the sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations.
(11) other transactions excluded from the definition of "wholesale distribution" under 21 CFR 203.3(CC), including any amendments thereto.

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Article V
Licensing of Facilities

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Section 504. Grounds, Penalties, and Reinstatement.

(a) No Person, Pharmacy, or Pharmacy Benefits Manager designated in Section 501 of this Act shall operate until a license has been issued to said Person, Pharmacy, or Pharmacy Benefits Manager by the Board.

(b) Except where otherwise permitted by law, it shall be unlawful for a Manufacturer or a Wholesale Distributor to Distribute or Deliver Drugs or Devices to any Person in this State not licensed under this statute. Any Person who shall Distribute or Deliver Drugs or Devices to a Person not licensed shall be subject to a fine to be imposed by the Board not to exceed one thousand dollars ($1,000) for each offense in addition to such other disciplinary action the Board may take under this Act. Except as otherwise indicated in this Act, each such violation shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this State.

(c) The Board may Suspend, Revoke, deny, or refuse to renew the license of any Person, Wholesale Distributor, Pharmacy, or Pharmacy Benefits Manager on any of the following grounds:

(1) the finding by the Board of violations of any Federal, State, or local laws relating to the Practice of Pharmacy, Drug samples, Wholesale or retail Drug or Device Distribution, or Distribution of controlled substances;

(2) any felony convictions under Federal, State, or local laws;

(3) the furnishing of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Distribution;

(4) suspension or Revocation by Federal, State, or local government of any license currently or previously held by the applicant for the Manufacture or Distribution of any Drugs or Devices, including controlled substances;

(5) obtaining any remuneration by fraud, misrepresentation, or deception;

(6) affiliating with Web sites that may deceive or defraud patients or that violate Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;

(7) dealing with Drugs or Devices that he or she knows or should have known are Counterfeit, Contraband, or stolen Drugs or Devices;

(8) purchasing or receiving of a Drug or Device from a source other than a Person or pharmacy licensed under the laws of the State, except where otherwise provided;

(9) the transfer during any consecutive twelve (12)-month period by a Pharmacy to a Wholesale Distributor or to another Pharmacy of more than five percent (5%) of the total amount of Prescription Drugs or Devices purchased by the Pharmacy in the immediately preceding twelve (12)-month period. The following are not subject to the provisions of this subsection:

(i) Prescription Drugs or Devices that are returned by a pharmacy for credit, in an amount equal to or less than the actual purchase price, to the Wholesale Distributor or Manufacturer from which those products were purchased;

(ii) Intracompany sales;

(iii) The sale, purchase, or trade of a Drug or an offer to sell, purchase, or trade a Drug among hospitals or other health care entities that are under common control;

(iv) The sale, purchase, or trade of a Drug or the offer to sell, purchase, or trade a Drug by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(v) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Drug for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations; and

(vi) The transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing or Filling agreement.

(10) the transfer during any consecutive twelve (12)-month period by a Wholesale Distributor to a Wholesale Distributor of more than five percent (5%) of the total amount of prescription Drugs or Devices purchased by Wholesale Distributor in the immediately preceding twelve (12)-month period;

(11) Wholesale Drug Distributors other than pharmacies Dispensing or Distributing Drugs or Devices directly to patients;

(12) violations of any of the provisions of this Act or of any of the Rules adopted by the Board under this Act; or

(13) illegal use or disclosure of Protected Health Information.

(d) Reinstatement of a license that has been Suspended, Revoked, or restricted by the Board may be granted in accordance with the procedures specified by Section 401 of this Act.

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Model Rules for the Licensure of Wholesale Distributors

Definitions.

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(o) "Distribute" or "Distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include:

(1) to Dispense or Administer;

(2) delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier; or

(3) providing a Drug sample to a patient by a Practitioner licensed to prescribe such Drug; a health care professional acting at the direction and under the supervision of a Practitioner; or the Pharmacy of a hospital or of another health care entity that is acting at the direction of such a Practitioner and that received such sample in accordance with the Act and regulations to administer or dispense.

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(l2) "Wholesale Distribution" means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer <u>distribution, or sale</u> of Prescription Drugs by a Pharmacy to another Pharmacy <u>or from a Pharmacy to a Practitioner, only for the purpose of dispensing or administration, but not for resale;</u> if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period<u>, providing that such transfers are compliant with federal law</u>. To the extent permitted by the Prescription Drug Marketing Act, Wholesale Distribution does not include:

(1) the sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;
(2) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;
(3) Intracompany Transactions, unless in violation of own use provisions;
(4) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;
(5) the sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;
(7) the transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;
(8) the sale, purchase, or trade of blood and blood components intended for transfusion;
(9) the return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations;
(10) the sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations; or
(11) other transactions excluded from the definition of "wholesale distribution" under 21 CFR 203.3(CC), including any amendments thereto.

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Section 12. Prohibited Acts.

It is unlawful for a Person to knowingly and willfully perform or cause the performance of or aid and abet any of the following acts in this State:

(a) the Manufacture, Repackaging, sale, delivery, or holding or offering for sale any Prescription Drug or Device that is Adulterated, Misbranded, Counterfeit, suspected of being Counterfeit, or has otherwise been rendered unfit for Distribution or Wholesale Distribution;
(b) the Adulteration, Misbranding, or Counterfeiting of any Prescription Drug or Device;
(c) the receipt of any Prescription Drug or Device that is Adulterated, Misbranded, stolen, obtained by fraud or deceit, Counterfeit, or suspected of being Counterfeit, or the delivery or proffered delivery of such Prescription Drug or Device for pay or otherwise;
(d) the Alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the Product Labeling of a Prescription Drug or Device or the commission of any

other act with respect to a Prescription Drug or Device that results in the Prescription Drug or Device being Misbranded;

(e) the forging, Counterfeiting, simulating, or falsely representing of any Prescription Drug or Device without the authority of the Manufacturer, or using any mark, stamp, tag, label, or other identification device without the authorization of the Manufacturer;

(f) the purchase or receipt of a Prescription Drug or Device from a Person that is not licensed to Wholesale Distribute Prescription Drugs or Devices to that purchaser or recipient;

(g) the sale or transfer of a Prescription Drug or Device to a Person who is not legally authorized to receive a Prescription Drug or Device;

(h) the sale or transfer of a Prescription Drugs from Pharmacies to Wholesale Distributors for resale;

(~~h~~i) the failure to maintain or provide records as required by this Act and Rules;

(~~i~~j) providing the Board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act and Rules;

(~~j~~k) the Wholesale Distribution of any Prescription Drug or Device that was:
(1) purchased by a public or private hospital or other health care entity;
(2) donated or supplied at a reduced price to a charitable organization; or
(3) stolen or obtained by fraud or deceit.

(~~k~~l) the failure to obtain a license or operating without a valid license when a license is required;

(~~l~~m) the Obtaining of or attempting to obtain a Prescription Drug or Device by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the Distribution or Wholesale Distribution of a Prescription Drug or Device;

(~~m~~n) the Distributing of a Prescription Drug or Device to the patient without a Prescription or Prescription Order from a Practitioner licensed by law to use or prescribe the Prescription Drug or Device;

(~~n~~o) the failure to obtain, Authenticate, or pass on a Pedigree when required under these Rules;

(~~o~~p) the receipt of a Prescription Drug or Device pursuant to a Wholesale Distribution without first receiving a Pedigree, when required, that was attested to as accurate and complete by the Wholesale Distributor;

(~~p~~q) the Distributing or Wholesale Distributing of a Prescription Drug or Device that was previously dispensed by a Pharmacy or distributed by a Practitioner;

(~~q~~r) the failure to report any Prohibited Act as listed in these Rules; or

(~~r~~s) the failure to exercise Due Diligence as provided in Section 9 (Due Diligence) of these regulations.

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Section 12(h). Comment.

Returned purchases from Pharmacies to Wholesale Distributors are not considered to be "transfers, distributions, or sales," and are not affected by this language.

Background:

Members discussed Resolution 109-2-13 Prescription Medication Distribution – The Five Percent Rule for Resale, which reads:

> **WHEREAS**, state and federal safeguards, statutes, and regulations for the United States distribution system for prescription drugs secure against adulterated, misbranded, and counterfeit drugs;
>
> **WHEREAS**, despite the systems in place to secure the drug distribution system from such adulterated, misbranded, and counterfeit drugs there are problems that exist; and
>
> **WHEREAS**, state provisions that allow pharmacies to distribute to other pharmacies and to practitioners a specified quantity of prescription medications based upon determined ratios (often times five percent) have been exploited and resulted in diversion; and
>
> **WHEREAS**, properly constructed laws and regulations allow the distribution of medications between pharmacies in the event of emergency situations and special patient circumstances;
>
> **THEREFORE BE IT RESOLVED** that the National Association of Boards of Pharmacy (NABP) urge its member boards of pharmacy to revise their "five percent" rules to allow the transfer, distribution, or sale of prescription drugs between pharmacies, or from pharmacies to practitioners, only for the purpose of dispensing or administration, but not for resale; and to prohibit the transfer, distribution, or sale of prescription drugs from pharmacies to wholesalers for resale (Note: returned purchases from pharmacies to wholesalers are not "transfers, distributions, or sales," thus they are not affected by this language); and
>
> **BE IT FURTHER RESOLVED** that NABP urge its member boards, when revising their "five percent" rules, to allow pharmacies to transfer, distribute, or sell medications for emergency medical reasons, including public health emergency declarations by federal or state officials, and individual patient needs.

In addition to proposing language that fulfills the mandate of the resolution, the committee discussed the fact that the *Model Act* language currently limits the amount of product that a pharmacy can transfer to another pharmacy to five percent of its total prescription drug sales revenue. It was noted by some members that Drug Enforcement Administration (DEA) controlled substance rules limit the transfer of controlled substances between DEA registrants to five percent of dosage units distributed or dispensed (versus five percent of sales revenue).[1] As such, concern

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[1] 21 CFR §1307.11 Distribution by dispenser to another practitioner or reverse distributor.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to —

(1) Another practitioner for the purpose of general dispensing by the practitioner to patients, provided that—

(i) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with **§1304.22(c)** of this chapter and by the receiving practitioner in accordance with §1304.22(c) of this chapter;

(iii) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter; and

was raised about a potential conflict. The members agreed that verbiage stating "providing that such transfers are compliant with federal law" should be added to the *Model Act* so as to avoid such a conflict.

LE/L Recommendation 4: The Committee Recommends Approval of Proposed Amendments to the *Model Act* Pursuant to Resolution 109-7-13 to Address Performance Metrics and Quotas in the Practice of Pharmacy.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

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

Article I

Title, Purpose, and Definitions

…

Article IV

Discipline

Introductory Comment to Article IV

At the very heart of any Pharmacy Act is the enforcement power of the Board of Pharmacy. The Board must have authority to discipline and/or prohibit Pharmacies, Pharmacists, Pharmacy Interns, Certified Pharmacy Technicians, or Pharmacy Technicians who violate this Act or Rules from continuing to threaten the public if it is to fulfill its responsibilities. The Board must have the ability to stop wrongdoers, either permanently or temporarily, discipline them, and, where appropriate, to guide and assist errant licensees in rehabilitating themselves.

The Model Act *disciplinary provisions are contained in Article IV. They were drafted with the purpose of granting to the Board the widest possible scope within which to perform its disciplinary functions. Standardized disciplinary action terms and definitions were developed to facilitate the accurate reporting of disciplinary actions taken by Boards of Pharmacy and to avoid*

(iv) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and §1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(2) A reverse distributor who is registered to receive such controlled substances.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to paragraph (a)(1) of this section and **§1301.25** of this chapter will exceed 5 percent of this total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

(c) The distributions that a registered retail pharmacy makes to automated dispensing systems at long term care facilities for which the retail pharmacy also holds registrations do not count toward the 5 percent limit in paragraphs (a)(1)(iv) and (b) of this section.

confusion associated with state-to-state variations in terms and definitions. The grounds for disciplinary action were developed to ensure protection of the public, while reserving to the Board the power to expand upon them and adapt them to changing or local conditions as necessary. The penalties permitted under the Model Act *will afford the Board the flexibility to conform and relate discipline to offenses.*

Section 401. Disciplinary Action Terms.

The following is a list of disciplinary actions that may be taken, issued, or assessed by the Board of Pharmacy: Revocation, Summary Suspension, Suspension, Probation, Censure, Reprimand, Warning, Cease and Desist, Fine/Civil Penalty, Costs/Administrative Costs.

Section 402. Grounds, Penalties, and Reinstatement.

(a) The Board of Pharmacy may refuse to issue or renew, or may Revoke, Summarily Suspend, Suspend, place on Probation, Censure, Reprimand, issue a Warning against, or issue a Cease and Desist order against, the licenses or the registration of, or assess a Fine/Civil Penalty or Costs/Administrative Costs against any Person Pursuant to the procedures set forth in Section 403 herein below, upon one or more of the following grounds:

(1) unprofessional conduct as that term is defined by the rules of the Board;

(2) incapacity that prevents a licensee from engaging in the Practice of Pharmacy or a registrant from assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public;

(3) being guilty of one (1) or more of the following:

(i) a felony;

(ii) any act involving moral turpitude or gross immorality; or

(iii) violations of the Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;

(4) disciplinary action taken by another state or jurisdiction against a license or other authorization to Practice Pharmacy based upon conduct by the licensee similar to conduct that would constitute grounds for actions as defined in this section;

(5) failure to report to the Board any adverse action taken by another licensing jurisdiction (United States or foreign), government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this section;

(6) failure to report to the Board one's surrender of a license or authorization to Practice Pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this section;

(7) failure to report to the Board any adverse judgment, settlement, or award arising from a malpractice claim arising related to conduct that would constitute grounds for action as defined in this section;

(8) knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Pharmacy Technician is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the Board of Pharmacy;

(9) misrepresentation of a material fact by a licensee in securing the issuance or renewal of a license or registration;
(10) fraud by a licensee in connection with the Practice of Pharmacy;
(11) affiliating with Web sites that may deceive or defraud patients or that violate Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;
(12) engaging, or aiding and abetting an individual to engage in the Practice of Pharmacy without a license; assisting in the Practice of Pharmacy or aiding and abetting an individual to assist in the Practice of Pharmacy without having registered with the Board of Pharmacy; or falsely using the title of Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician;
(13) requiring Pharmacy personnel to meet production and/ or performance metrics and/or quotas that negatively impact patient safety.
~~(13)~~(14) failing to pay the costs assessed in a disciplinary hearing pursuant to Section 213(c)(9);
~~(14)~~ (15) engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of any licensing examination;
~~(15)~~(16) being found by the Board to be in violation of any of the provisions of this Act or rules adopted pursuant to this Act;
~~(16)~~(17) illegal use or disclosure of Protected Health Information;
~~(17)~~(18) failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.

(b)

(1) The Board may defer action with regard to an impaired licensee who voluntarily signs an agreement, in a form satisfactory to the Board, agreeing not to practice Pharmacy and to enter an approved treatment and monitoring program in accordance with this Section, provided that this Section should not apply to a licensee who has been convicted of, pleads guilty to, or enters a plea of nolo contendere to a felonious act prohibited by _____ or a conviction relating to a controlled substance in a court of law of the United States or any other state, territory, or country. A licensee who is physically or mentally impaired due to addiction to Drugs or alcohol may qualify as an impaired Pharmacist and have disciplinary action deferred and ultimately waived only if the Board is satisfied that such action will not endanger the public and the licensee enters into an agreement with the Board for a treatment and monitoring plan approved by the Board, progresses satisfactorily in such treatment and monitoring program, complies with all terms of the agreement and all other applicable terms of subsection (b)(2). Failure to enter such agreement or to comply with the terms and make satisfactory progress in the treatment and monitoring program shall disqualify the licensee from the provisions of this Section and the Board shall activate an immediate investigation and disciplinary proceedings. Upon completion of the rehabilitation program in accordance with the agreement signed by the Board, the licensee may apply for permission to resume the Practice of Pharmacy upon such conditions as the Board determines necessary.

…

Section 402(a)(13). Comment.

This is not intended to include performance metrics that may be related to the ability and competency of pharmacy personnel.

Background:

Members discussed Resolution 109-7-13 Performance Metrics and Quotas in the Practice of Pharmacy, which reads:

> **WHEREAS**, a survey conducted by the Institute for Safe Medication Practices (ISMP) of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors and that 49% felt specific time measurements were a significant contributing factor; and
>
> **WHEREAS**, performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment; and
>
> **WHEREAS**, the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy;
>
> **THEREFORE BE IT RESOLVED** that the National Association of Boards of Pharmacy (NABP) assist the state boards of pharmacy to regulate, restrict, or prohibit the use in pharmacies of performance metrics or quotas that are proven to cause distractions and unsafe environments for pharmacists and technicians; and
>
> **BE IT FURTHER RESOLVED** that NABP review and propose amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* to address the regulation, restriction, or prohibition of the application of performance metrics and quotas that are proven to cause distractions and unsafe environments for pharmacists and technicians.

In proposing language that fulfills the mandate of the resolution, the committee agreed with the concept of prohibiting the type of performance metrics and/or quotas that have been documented to increase the risk of QREs. In order to prevent such language from being interpreted to include metrics related to performance and/or competency evaluations, it was decided to add a comment that clarified that these were not prohibited, as these types of evaluations are important to professional development and patient safety.

LE/L Recommendation 5: The Committee Recommends Amendments to the *Model Act* that Add a Definition for "Medication Synchronization" and that NABP Convene a Task Force to Further Review the Issue.

The revisions are denoted by underlines and ~~strikethroughs~~.

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

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

...

(d4) "Medication Synchronization" refers to a component of Medication Therapy Management that provides authority, at the patient's direction, for the pharmacist to adjust a patient's medication quantity or refill schedule, and the authority to provide the patient with a one-time synchronization refill, in order to manage a patient's maintenance medications and coordinate the dosing schedules to complement the patient's life schedule, unless deemed inappropriate by the prescribing practitioner.

...

(d4e4) "Medication Therapy Management" is a distinct 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.

…

Section 105(h4). Comment.

Medication Synchronization can be effective in improving medication adherence and eliminating gaps in therapy by reducing the number of pharmacy visits for patients on multiple-medication regimens. Patients receive their synchronized refills by appointment with their pharmacist each month, which allows for increased patient-pharmacist interaction and the provision of comprehensive Medication Therapy Management services for chronic illnesses. In addition to facilitating medication adherence and maximizing health benefits, Medication Synchronization may also offer pharmacies a mechanism to improve workload and inventory control. Other possible advantages of medication synchronization include minimization of overall health costs and increased convenience for patients.

"Medication Refill Consolidation," "Medication Schedule Synchronization," and "Medication Refill Synchronization" are other terms used for these types of services.

Medication Synchronization is used in the dispensing of medications for patients with chronic illnesses. Chronic illnesses are those diseases or conditions that are of long duration, require ongoing treatment, and can be controlled but not completely cured. The US National Center for Health Statistics defines a chronic disease as a condition lasting for three or more months. According to the Centers for Medicare and Medicaid Services, the most common chronic conditions among Medicare beneficiaries are hypertension, high cholesterol, heart disease, diabetes, and arthritis. Other common chronic illnesses include heart failure, depression, chronic kidney disease, osteoporosis, Alzheimer's disease, chronic obstructive pulmonary disease, atrial fibrillation, cancer, asthma, and stroke.

Background:

The committee agreed that medication synchronization may benefit the patient and supports the concept, recognizing that it is already being implemented in a number of states and in a number of practices. In order to advance the concept, members recommended that NABP convene a task force to address related issues, including but not limited to:

- Providing authority for the pharmacist to provide medication synchronization services within the legal scope of practice in his/her state;
- Defining which chronic disease states are appropriate for medication synchronization services;
- Identifying circumstances where medication synchronization services should not be offered or provided, such as in the dispensing of certain medications, including controlled substances and psychotherapeutic agents, and where the prescribing practitioner has indicated a specific treatment plan;
- Specifying types of collaborative practice agreements with practitioners that may be necessary in order to provide medication synchronization services; and

- Identifying insurance and/or assistance coverage that may impact access to medication synchronization services.

LE/L Recommendation 6: The Committee Recommends Amendments to the *Model Act* that Require Specified Routine Pharmacy Inspections and Provide for the Submission of NABP e-Profile ID numbers for Pharmacies and Pharmacists-in-Charge Upon Licensure Renewal.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

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

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

…

(i4) "Nonresident Pharmacy" means a Pharmacy located outside this State.

…

Article V

Licensing of Facilities

Introductory Comment to Article V

The fifth and last substantive Article of the Model Act *concerns licensure of Pharmacies, Manufacturers, Wholesale Distributors, and the like. The licensure requirements of this Article will provide a Board with knowledge of all facilities involved in the storage, Distribution, and sale of Drugs or Devices within the state and those located outside the state that are shipping Drugs or Devices into the state. They will permit a Board to better ensure against Drug or Device diversion from the legitimate channels of commerce and provide the necessary data for effective recalls and the dissemination of information.*

Section 501. Licensing.

(a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board:
  (1) persons engaged in the Practice of Pharmacy;
  (2) dispensing Practitioners and Practitioner's facilities;
  (3) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;
  (4) ~~p~~Pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided;
  (5) Pharmacy Benefits Managers; and
  (6) Repository Programs

Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

(b) The Board shall establish by rule, under the powers granted to it under Section 212 and 213 of this Act and as may be required from time to time, under federal law, the Criteria that each Person must meet to qualify for licensure in each classification. The Board shall adopt definitions in addition to those provided in Article I, Section 105, where necessary to carry out the Board's responsibilities. The Board may issue licenses with varying restrictions to such Persons where the Board deems it necessary.

(c) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.

(d) Each licensed Person located outside of this State who ships, mails, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in this State, or Pharmacy located outside of this State who ships, mails, Distributes, or Delivers Drugs or Devices in this State, shall comply with the laws of patients' domicile, and shall designate a registered agent in this state for service of process. Any such licensed Person or Pharmacy who does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such licensed Person growing out of or arising from such Delivery. A copy of any such service of process shall be mailed to such Person or Pharmacy by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Person has designated on its application for licensure in this State. If any such Person is not licensed in this State, service on the Secretary of State only shall be sufficient service.

(e) The Board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the licensure and inspection of entities located in this jurisdiction and those located outside this State.

(f) The Board of Pharmacy may deny or refuse to renew a license if it determines that the granting or renewing of such license would not be in the public interest.

(g) The Board shall establish the standards that a Person must meet for initial and continued licensure under Article V. For facilities that compound sterile pharmaceuticals, an initial or an annual inspection shall be required for purposes of licensure or licensure renewal. For facilities that do not compound sterile pharmaceuticals, an initial inspection or an inspection that takes place not more than every 24 months, shall be required ~~and shall require initial inspections and periodic inspections thereafter~~ for purposes of licensure or licensure renewal. Such inspection shall be performed by the following:

(1) the Board or its duly authorized agent;

(2) a duly authorized agent of a third party approved by the Board; or

(3) for Nonresident Pharmacies, the resident state Board of Pharmacy, if the resident Board's inspection is substantially equivalent to inspection in this State;

~~(h) The Board may enter into an agreement with a third party to undertake inspections of facilities of a Person seeking initial or continued licensure where such third party maintains a program which has standards acceptable to the Board that must be met for any such Person to be accredited or certified by such third party. The Board may rely on~~

~~such accreditation or certification in determining eligibility for initial licensure or licensure renewal.~~

Section 502. Comment.

Boards may want to consider requesting the following information on applications for pharmacy and wholesale distributor licensure:

(a) personal information;
(b) marital information;
(c) family information (parents, siblings, in-laws);
(d) education;
(e) military information;
(f) arrests, detentions, litigations, and arbitrations;
(g) residences (past 25 years);
(h) employment (back to age 18);
(i) character references;
(j) safe deposit box or other depository information;
(k) privileged, occupational, or professional licensure;
(l) out-of-state business, venture, or industry licensure or financial interest in such;
(m) appearances before any licensing agency or similar authority in or outside the state;
(n) denials of a personal license, permit, certificate, or registration for a privileged, occupational, or professional activity;
(o) denials of a business or industry license or related finding of suitability, or participation in a group that has been denied a business or industry license or related finding of suitability;
(p) Administrative actions or proceedings related to the pharmaceutical industry or participation in a group that has been the subject of such administrative actions or proceedings;
(q) guilty findings or pleadings or pleas of nolo contendere to any offense, federal or state, related to prescription Drugs and/or controlled substances or participation in a group that has been found or pled guilty or that has pled nolo contendere to any such offense;
(r) surrender, voluntary or otherwise, of licensure, permit, or certificate of registration relating to the pharmaceutical industry, or participation in a group that has surrendered, voluntary or otherwise, any such licensure, permit, or certificate of registration; and
(s) any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or Drug-related industry.

…

Model Rules for the Practice of Pharmacy

…

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care, the following rules are essential.

Section 1. Facility.

(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 majority;
  (3) be of good moral character; and
  (4) 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; and

(d) Possess the following ~~M~~minimum requirements for a Pharmacy:
  (1) Each 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) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.
  (3) Each Pharmacy shall have ready access to at least one current reference in each of the following categories:
    (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) general.
  (4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.
  (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 shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.
  (7) Each 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) Security.
    (i) 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.
    (ii) 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.

(iii) 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.

(9) Equipment/Supplies.
The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.

(10) The Pharmacy shall 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 other than as authorized by law or rules of the Board.

(11) The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board.

(e) Upon renewal, the licensee shall provide to the Board the NABP e-profile ID of the Pharmacy and Pharmacist-in-Charge.

Background:

While the committee agreed that boards should delineate specific time frames for routine inspections, there were some concerns that requiring annual inspections may be too stringent. After discussing issues such as board staffing levels and the need to ensure public confidence in the boards' ability to protect patient safety, members determined that it would be appropriate to require annual inspections for those pharmacies that compound sterile pharmaceuticals and to require inspections not more than every 24 months for all others. Members also agreed that the NABP e-profile ID of the pharmacy and pharmacist-in-charge should be provided to the board upon licensure renewal to help facilitate inspection processes and communication of information among boards.

LE/L Recommendation 7: The Committee Recommends Amendments to the *Model Act* that Provide a Reference to the National Council for Prescription Drug Programs' Universal Medication Schedule White Paper and for NABP to Take a Leadership Role in the Development of a Standardized Label.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

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

Article I

Title, Purpose, and Definitions

…

Section 3. Pharmacy Practice.

…

(e) Labeling

…

(4) All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall contain a label affixed to the container in which such Drug is Dispensed including:

(i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as "arial"), minimum 12-point size, and in "sentence case." Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated and shall include:

(A) patient name

(-a-) legal name of the patient; or

(-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.

(B) directions for use

(-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order; and

(-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.

…

Section 3(e)(4)(i)(B)(-a-). Comment.

Boards of pharmacy and licensees should recognize that "take as directed" may not provide sufficient information for the appropriate use of the medication. "Take as directed" is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. "Take as directed" should not be used in lieu of patient counseling.

It is understood that prescription drug orders often do not include the indication for use.

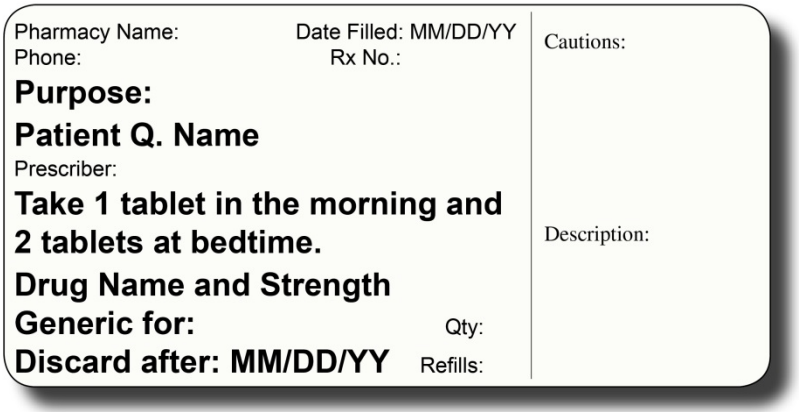
Section 3(e)(4)(i)(B)(-b-). Comment.

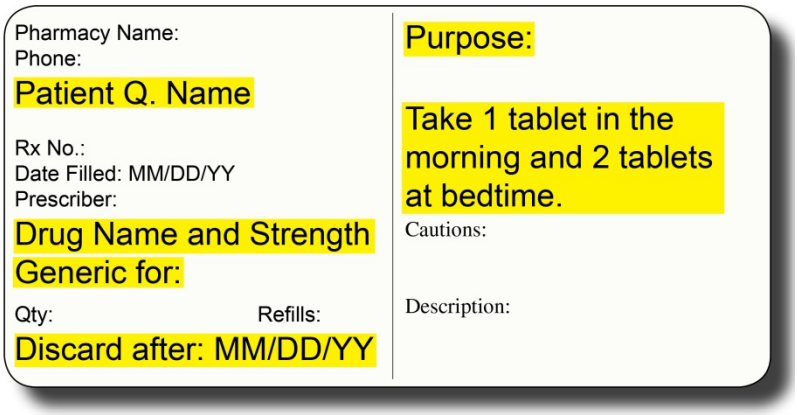
Refer to the National Council for Prescription Drug Programs' Universal Medication Schedule (UMS) White Paper, which provides information on how to convey and simplify dosage and use instructions on prescription labels.

…

Section 3(e)(4)(i), (ii), and (iii). Comment.

Boards of pharmacy may consider utilizing these suggested labeling formats provided below. Note that UMS is used to convey the dosage instructions.





Background:

The committee agreed with adding the reference, however, while discussing the issue and the fact that there are varying labeling standards among the states, the members came to the conclusion that NABP should assist the boards and take a leadership role in developing a standardized label.

LE/L Recommendation 8: The Committee Recommends Amendments to the *Model Act* that Reorganizes the *Model Rules for Institutional Pharmacy and Model Rules for the Practice of Pharmacy* in Order to Consolidate and Increase their Readability.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

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

Article I

Title, Purpose, and Definitions

...

Model Rules for Institutional Pharmacy

Section 1. Applicability.

The following Rules are applicable to all Institutional Facilities and Institutional Pharmacies as defined in Section 2 below.

Section 2. Definitions.

(a) "Chart Order"[2] means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her designated agent for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:
(1) the full name of the patient;
(2) date of issuance;
(3) name, strength, and dosage form of the Drug prescribed;
(4) directions for use; and
(5) if written, the prescribing Practitioner's signature or the signature of the Practitioner's agent (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing Practitioner's electronic or digital signature.

(b) "Institutional Facility"[3] means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):
(1) hospital;
(2) Long-Term Care Facility;
(3) convalescent home;
(4) nursing home;
(5) extended care facility;
(6) mental health facility;
(7) rehabilitation center;
(8) psychiatric center;
(9) developmental disability center;
(10) Drug abuse treatment center;
(11) family planning clinic;
(12) penal institution;
(13) hospice;
(14) public health facility;
(15) athletic facility.

(c) "Institutional Pharmacy"[4] means any place which is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist

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[2] ~~**Section 2(a)**~~ **Comment.**

Chart Orders that are written by the Practitioner's agent shall be countersigned by the prescribing Practitioner within the required time period as required by state law or rule.

[3] ~~**Section 2(b)**~~ **Comment.**

Although the definition of Institutional Facility is broad and may encompass an array of facilities that provide long-term medical care and services for its residents, some states may also recognize residential assisted living facilities or residential group homes as such.

[4] ~~**Section 2(c)**~~ **Comment.**

Although traditionally characterized as being physically part of an Institutional Facility, the Model Rules recognize that an Institutional Pharmacy may or may not be physically attached to an Institutional Facility.

Care to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as *Drugs*) are Dispensed, Compounded, and Distributed.[5]

Section 3. Personnel.

(a) Each Institutional Pharmacy shall be directed by a Pharmacist, hereinafter referred to as the *Pharmacist-in-Charge*, who is licensed to engage in the Practice of Pharmacy in this State.

Section 4. Absence of Pharmacist.

(a) During such times as an Institutional Pharmacy may be unattended by a Pharmacist, arrangements shall be made in advance by the Pharmacist-in-Charge for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of night cabinets and, in emergency circumstances, by access to the Pharmacy. A Pharmacist must be "on call" during all absences.

(b) In the absence of a Pharmacist, Drugs shall be stored in a locked cabinet or other enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Pharmacist-in-Charge shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet(s) and determine who may have access, and shall ensure that:
   (1) Drugs are properly Labeled;
   (2) only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
   (3) whenever access to the cabinet occurs, written Practitioner's orders and proofs-of-use are provided;
   (4) all Drugs therein are inventoried no less than once per week;
   (5) a complete audit of all activity concerning such cabinet is conducted no less than once per month; and
   (6) written policies and procedures are established to implement the requirements of this Section 4.

(c) Whenever any Drug is not available from floor supplies or night cabinets, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of this Section 4. One supervisory nurse in any given eight-hour shift is responsible for obtaining Drugs from the Pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an authorized nurse must be recorded on a suitable form showing the patient name, room number, name of Drug, strength, amount,

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[5] **Comment.**

States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications 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.

date, time, and signature of nurse. The form shall be left with the container from which the Drug was removed.

(d) Emergency kit Drugs may be provided for use by authorized personnel of the Institutional Facility provided, however, such kits meet the following requirements:

(1) Emergency kit Drugs are those Drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such Drugs from such other sources.

(2) All emergency kit Drugs shall be provided and sealed by a Pharmacist;

(3) The supplying Pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits.

(4) Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them.

(5) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency Drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying Pharmacist.

(6) Drugs shall be removed from emergency kits only pursuant to a valid Chart Order.

(7) Whenever an emergency kit is opened, the supplying Pharmacist shall be notified and the Pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.[6]

(8) The expiration date of an emergency kit shall be the earliest date of expiration of any Drug supplied in the kit. Upon the occurrence of the expiration date, the supplying Pharmacist shall replace the expired Drug.

Section 5. Drug Distribution and Control.

(a) The Pharmacist-in-Charge shall establish written procedures for the safe and efficient Distribution of Drugs and for the provision of Pharmacist Care. An annual updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(b) Drugs brought into an Institutional Facility by a patient shall not be Administered unless they can be identified and the quality of the Drug assured. If such Drugs are not to be Administered, then the Pharmacist-in-Charge shall, according to procedures specified in writing, have them turned in to the Pharmacy, which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.

(c) Investigational Drugs shall be stored in and Dispensed from the Pharmacy only. All information with respect to investigational Drugs shall be maintained in the Pharmacy.[7]

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[6] ~~**Section 4(d)(7)**~~ **Comment.**

When the Pharmacist restocks and reseals the emergency kit Drugs, it is recommended that a lock or other similar device be used to assure that unauthorized access to the kit is minimized.

[7] ~~**Section 5(c)**~~ **Comment.**

Regarding the use of investigational Drugs in an institution, it is necessary that the institution ensure that such studies contain adequate safeguards for the patient, the institution, and the scientific integrity of the study. The institution must have written policies and procedures for the approval, management, and control of investigational Drug studies. All patients who participate in investigational Drug studies must freely consent, in

Section 6. Labeling.

(a) All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements:

(1) The label of a single-unit package of an individual-dose or unit-dose system of packaging of Drugs shall include:

(A) the nonproprietary or proprietary name of the Drug;

(B) the route of Administration, if other than oral;

(C) the strength and volume, where appropriate, expressed in the metric system whenever possible;

(D) the control number and expiration date;

(E) identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label; and

(F) special storage conditions, if required.

(2) When a multiple-dose Drug Distribution system is utilized, including Dispensing of single unit packages, the Drugs shall be Dispensed in a container to which is affixed a label containing the following information:

(A) identification of the Dispensing Pharmacy;

(B) the patient's name;

(C) the date of Dispensing;

(D) the nonproprietary and/or proprietary name of the Drug Dispensed; and

(E) the strength, expressed in the metric system whenever possible.

(b) All Drugs Dispensed to inpatients for self-administration shall be Labeled in accordance with Subparagraph 4 of this Section (e).

(c) Whenever any Drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:

(1) name of solution, lot number, and volume of solution;

(2) patient's name;

(3) infusion rate;

(4) bottle sequence number or other system control number;

(5) name and quantity of each additive;

(6) date of preparation;

(7) Beyond-Use Date and time of parenteral admixture; and

(8) ancillary precaution labels.

Section ~~6~~7. Shared Pharmacy Services Utilization for Immediate Need.[8]

(a) In accordance with the Model Rules for the Practice of Pharmacy and Shared Pharmacy Services, an Institutional Pharmacy may outsource services to another Pharmacy for the

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writing, to treatment with these Drugs. The Pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational Drug use are developed and implemented.

[8] ~~**Section 6(a)**~~ **Comment.**

Although Institutional Pharmacies primarily outsource services to another Pharmacy for the purposes of meeting the immediate needs of patients and residents when the Institutional Pharmacy is closed, it is also recognized that other services may be outsourced that the Institutional Pharmacy is not able to provide on an ongoing basis.

limited purpose of ensuring that Drugs or Devices are attainable to meet the immediate needs of patients and residents of the Institutional Facility or when the Institutional Pharmacy cannot provide services on an ongoing basis, provided that the Institutional Pharmacy:

(1) has obtained approval from the Institutional Facility to outsource Shared Pharmacy Services for its inpatients and residents; and

(2) provides a valid Chart Order to the Pharmacy it has contracted with for the Shared Pharmacy Services.

~~Comments~~

~~Section 2(a) Comment.~~

~~Chart Orders that are written by the Practitioner's agent shall be countersigned by the prescribing Practitioner within the required time period as required by state law or rule.~~

~~Section 2(b) Comment.~~

~~Although the definition of Institutional Facility is broad and may encompass an array of facilities that provide long-term medical care and services for its residents, some states may also recognize residential assisted living facilities or residential group homes as such.~~

~~Section 2(c) Comment.~~

~~Although traditionally characterized as being physically part of an Institutional Facility, the Model Rules recognize that an Institutional Pharmacy may or may not be physically attached to an Institutional Facility.~~

~~Section 4(d)(7) Comment.~~

~~When the Pharmacist restocks and reseals the emergency kit Drugs, it is recommended that a lock or other similar device be used to assure that unauthorized access to the kit is minimized.~~

~~Section 5(c) Comment.~~

~~Regarding the use of investigational Drugs in an institution, it is necessary that the institution ensure that such studies contain adequate safeguards for the patient, the institution, and the scientific integrity of the study. The institution must have written policies and procedures for the approval, management, and control of investigational Drug studies. All patients who participate in investigational Drug studies must freely consent, in writing, to treatment with these Drugs. The Pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational Drug use are developed and implemented.~~

~~Section 6(a) Comment.~~

~~Although Institutional Pharmacies primarily outsource services to another Pharmacy for the purposes of meeting the immediate needs of patients and residents when the Institutional Pharmacy is closed, it is also recognized that other services may be outsourced that the Institutional Pharmacy is not able to provide on an ongoing basis.~~

Model Rules for the Practice of Pharmacy

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care, the following rules are essential.

Section 1. Facility.

(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 majority;
  (3) be of good moral character; and
  (4) 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; and

(d) Minimum requirements for a Pharmacy:
  (1) Each 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) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.
  (3) Each Pharmacy shall have ready access to at least one current reference[9] in each of the following categories:
    (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) general.
  (4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.[10]
  (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 shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the United States Pharmacopeia–National

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[9] **Comment.**

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

[10] ~~**Section 1(a)(4).**~~ **Comment.**

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

Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.

(7) Each 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) Security.

(i) 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.

(ii) 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.

(iii) 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.

(9) Equipment/Supplies.
The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.

(10) The Pharmacy shall 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 other than as authorized by law or rules of the Board.

(11) The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board.

Section 2. Personnel.

(a) Duties and Responsibilities of the 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 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:

(A) Policies and procedures addressing the following:

(-a-) the provision of Pharmacy services;[11]

[11] ~~**Section 2(a)(2)(i).**~~ **Comment.**

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 medications, 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

(-b-) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern;
(-c-) computerized recordkeeping 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[12];
(-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 Certified Pharmacy Technicians and Pharmacy Technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Pharmacy Technicians are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Pharmacy Technicians shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

(B) Policies and procedures that address the following activities related to prescription medication shipment by mail or common carrier:
(-a-) properly transferring prescription information to an alternative Pharmacy of the patient's choice in situations where the medication 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 medications;
(-c-) tracking all shipments; and
(-d-) ensuring that drugs do not become adulterated in transit

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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*.

[12] ~~**Section 2(a)(2)(i)(G)**~~. **Comment**.

States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications 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.

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

(C) Qquality assurance programs addressing the following:

(-a-) ~~for~~ 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 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; and;

(-c-) The prevention and detection of Drug diversion.[13]

~~(B) a Pharmacy Technician Training Manual that is site-specific to the practice setting of which he or she is in charge. He or she shall supervise a site-specific training program conducted pursuant to the Pharmacy Technician Training Manual for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Pharmacy Technicians successfully completing the Pharmacy's Technician 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 registration with the Board;~~

~~(C) policies and procedures for the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern. Quality assurance programs shall be designed to prevent and detect Drug diversion;~~

~~(D) policies and procedures for the provision of Pharmacy services;~~

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[13] ~~**Section 2(a)(2)(i)(C).**~~ **Comment.**

As part of a quality assurance program designed to prevent and detect drug diversion, the Pharmacist-in-Charge is expected to ensure policies and procedures are in place that address the following:

1. inspection of shipments;
2. receipt verification oversight and checking in shipments;
3. reconciliation of orders; and
4. inventory management including:
    a. determination of Medications 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.

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:

1. alarm codes and lock combinations;
2. passwords;
3. keys and access badges; and
4. video surveillance systems.

~~(E) an ongoing quality assurance program that monitors performance of the Automated Pharmacy System, which is evidenced by written policies and procedures developed by the Pharmacy;~~

~~(F) policies and procedures for 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 the established policies and procedures;~~

~~(G) procedure for the operation of the Pharmacy, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed, in the event of a fire, flood, pandemic, or other natural or man-made disaster or emergency; and~~

~~(H) policies and procedures for 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.~~

(ii) Ensuring that~~:~~

(A) ~~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; and~~

~~(B)~~ all Pharmacists and Pharmacy Interns employed at the Pharmacy are currently licensed and that all Certified Pharmacy Technicians and Pharmacy Technicians employed at the Pharmacy are currently registered with the Board of Pharmacy.

(iii) Notifying the Board of Pharmacy, immediately and in writing, of any of the following[14] ~~changes~~:

(A) change of employment or responsibility as the Pharmacist-in-Charge;

(B) the separation of employment of any Pharmacist, Pharmacy Intern, Pharmacy Technician, 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; ~~or~~

(E) permanent closing of the Pharmacy; or

(F) Significant Quality-Related Events ~~Adverse Drug Reactions;~~

(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;

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[14] ~~**Section 2(a)(2)(iii).**~~ **Comment.**

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.

(-b-)the location of the Automated Pharmacy System;
(-c-)the identification of the responsible Pharmacist.
Such notice must be 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.

~~(vii) Establishing policies and procedures for 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 the established policies and procedures.~~

~~(viii) Providing the Board with prior written notice of 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 equipment; and~~
~~(C) the identification of the responsible Pharmacist.~~

(3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists, Certified Pharmacy Technicians, and Pharmacy Technicians 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 Pharmacy Technicians assisting in the provision of Pharmacy services.

(ii) The Pharmacist-in-Charge shall ~~develop~~ develop or adopt, ~~and~~ implement, and maintain written policies and procedures to specify the duties to be performed by Certified Pharmacy Technicians and Pharmacy Technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Pharmacy Technicians are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Pharmacy Technicians shall not be assigned duties that may be performed only by Certified Pharmacy Technicians[15];

(iii) The Pharmacist-in-charge shall develop or adopt, implement, and maintain a 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 Pharmacy Technician training manual as part of the

[15] Comment.

The method of and level of Pharmacist supervision over technicians may vary depending on practice site. For example, supervision of technicians in a remote Pharmacy or remote dispensing site will be different than that of technicians in a retail Pharmacy setting.

training program. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Pharmacy Technicians successfully completing the Pharmacy's Technician 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 registration with the Board.[16]

~~(4) The Pharmacist-in-Charge shall develop and implement a procedure for proper management of Drug recalls which may include, where appropriate, contacting patients to whom the recalled Drug product(s) have been Dispensed.~~

~~(5) The owner and/or pharmacy permit holder and the Pharmacist-in-Charge of a Pharmacy that ships medications by mail or common carrier shall be responsible for the development and implementation of policies and procedures to:~~

~~(i) properly transfer prescription information to an alternative Pharmacy of the patient's choice in situations where the medication is not Delivered or Deliverable;~~

~~(ii) verify 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 medications;~~

~~(iii) track all shipments; and~~

~~(iv) ensure that drugs do not become adulterated in transit.~~

(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) 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 3. ~~Pharmacy Practice~~ 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;

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[16] **~~Section 2(a)(2)(ii).~~ Comment.**

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

(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 Prescription Drug Orders shall be applied to paper that utilizes security features[17] 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

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.

(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 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)[18] or issued electronically[19].

(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.

(3) If communicated orally , the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist, the Pharmacy Intern, or 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)

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[17] **Comment.**

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.

[18] ~~**Section 3(b)(5).**~~ **Comment.**

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.

[19] ~~**Section 3(b)(7)(i).**~~ **Comment.**

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.

of this Section ~~3(b)(3)~~. The original, written Prescription Drug Order shall be maintained in accordance with ~~Section 3(g). (Patient Records)~~ State and Federal recordkeeping 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 or Certified Pharmacy Technician, and shall contain the information required by ~~Section 3(a). (Prescription Drug Order)~~state and federal law;

(C) if the prescribing Practitioner is not known to the Pharmacist or Certified Pharmacy Technician, 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. ~~In addition to conforming to the requirements of Section 3(a), t~~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, Pharmacy Intern, or Certified Pharmacy Technician 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 ~~for purposes of this Section 3(b)(3)(ii),~~ and it shall be maintained in

accordance with ~~Section 3(g). (Patient Records)~~state and federal recordkeeping 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 ~~for purposes of this Section 3(b)(3)(iii)~~and it shall be maintained in accordance ~~with Section 3(g). (Patient Records)~~state and federal recordkeeping 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 ~~pursuant to Section 2(a)(2)(xi)~~ shall not have access to Pharmacy records containing Protected Health Information concerning the Pharmacy's patients.

(c) Transfer of a Prescription Drug Order

Pharmacies utilizing automated data-processing systems shall satisfy all information requirements of a manual mode for Prescription Drug Order transferal, except as noted below for those pharmacies accessing a common electronic file~~in subsection (4) below~~. The transfer of original Prescription Drug Order information for the purpose of refill Dispensing is permissible between Pharmacies subject to the following requirements:

(1) The information is communicated directly between Pharmacists or Certified Pharmacy Technicians and the transferring Pharmacist or Certified Pharmacy Technician records the following information:
   (i) write the word "VOID" on the face of the invalidated Prescription Drug Order;
   (ii) record on the reverse side of the invalidated Prescription Drug Order the name and address of the Pharmacy to which it was transferred and the name of the Pharmacist or Certified Pharmacy Technician receiving the Prescription Drug Order;
   (iii) record the date of the transfer and the name of the Pharmacist or Certified Pharmacy Technician transferring the information; and

(iv) the computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above.

(2) The Pharmacist or Certified Pharmacy Technician receiving the transferred Prescription Drug Order information shall reduce to writing the following:
   (i) Write the word "TRANSFER" on the face of the transferred Prescription Drug Order.
   (ii) Provide all information required to be on a Prescription Drug Order pursuant to state and federal laws and rules, and include:
      (A) date of issuance of original Prescription Drug Order;
      (B) original number of refills authorized on original Prescription Drug Order;
      (C) date of original Dispensing;
      (D) number of valid refills remaining and date of last refill;
      (E) Pharmacy's name, address, and original prescription number from which the Prescription Drug Order information was transferred; and
      (F) name of transferring Pharmacist or Certified Pharmacy Technician.
   (iii) Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of Pharmacist Care.

(3) Both the original and transferred Prescription Drug Order shall be maintained for a period of five years from the date of last refill.

(4) Pharmacies accessing a common electronic file or database used to maintain required Dispensing information are not required to transfer Prescription Drug Orders or information for Dispensing purposes between or among Pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each Prescription Drug Order and refill Dispensed, and, further, that a hard copy record of each Prescription Drug Order transferred or accessed for purposes of refilling shall be generated and maintained at the Pharmacy refilling the Prescription Drug Order or to which the Prescription Drug Order is transferred and shall protect against the illegal use or disclosure of Protected Health Information.

(5) In an emergency, a Pharmacy may transfer original Prescription Drug Order information for a non-controlled substance to a second Pharmacy for the purpose of Dispensing up to a 72-hour supply without voiding the original Prescription Drug Order.

(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.

(4) Whenever Drug product selection is performed by a Pharmacist, the Pharmacist shall Dispense the Equivalent Drug Product in a container Labeled in accordance with ~~Section 3(e) (Labeling)~~State Prescription Drug Labeling requirements.

(e) Labeling

~~(1) All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements:~~

~~(i) The label of a single-unit package of an individual-dose or unit-dose system of packaging of Drugs shall include:~~

~~(A) the nonproprietary or proprietary name of the Drug;~~

~~(B) the route of Administration, if other than oral;~~

~~(C) the strength and volume, where appropriate, expressed in the metric system whenever possible;~~

~~(D) the control number and expiration date;~~

~~(E) identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label; and~~

~~(F) special storage conditions, if required.~~

~~(ii) When a multiple-dose Drug Distribution system is utilized, including Dispensing of single unit packages, the Drugs shall be Dispensed in a container to which is affixed a label containing the following information:~~

~~(A) identification of the Dispensing Pharmacy;~~

~~(B) the patient's name;~~

~~(C) the date of Dispensing;~~

~~(D) the nonproprietary and/or proprietary name of the Drug Dispensed; and~~

~~(E) the strength, expressed in the metric system whenever possible.~~

~~(2) All Drugs Dispensed to inpatients for self-administration shall be Labeled in accordance with Subparagraph 4 of this Section (e).~~

~~(3) Whenever any Drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:~~

~~(i) name of solution, lot number, and volume of solution;~~

~~(ii) patient's name;~~

~~(iii) infusion rate;~~

~~(iv) bottle sequence number or other system control number;~~

~~(v) name and quantity of each additive;~~

~~(vi) date of preparation;~~

~~(vii) Beyond-Use Date and time of parenteral admixture; and~~

~~(viii) ancillary precaution labels.~~

(~~4~~1) All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall ~~contain~~ have a label affixed to the container in which such Drug is Dispensed. The label shall include the following~~including~~: [20]

(i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as "arial"), minimum 12-point size, and in "sentence case." Field size and font

[20] ~~**Section 3(e)(4).**~~ **Comment.**

Boards may want to consider supporting legislation which contains this type of language for incorporation into their ~~State~~ state Food and Drug Act, so that it shall apply to all Persons who Dispense Drugs, including Practitioners who prescribe and Administer as well as Dispense Drugs.

size may be increased in the best interest of patient care. Critical information text should never be truncated and shall include:

(A) patient name
  (-a-) legal name of the patient; or
  (-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.

(B) directions for use
  (-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order[21]; and
  (-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.

(C) drug name
  (-a-) if written for a brand name and a generic drug is dispensed, include phrase "Generic for [brand name];"and
  (-b-) include drug name suffixes, such as CD, SR, XL, XR, etc.

(D) drug strength, expressed in the metric system whenever possible

(E) "use by" date
  (-a-) date after which medication should be used; not expiration date of medication or expiration date of prescription; and
  (-b-) format as – "Use by: MM/DD/YY."

(ii) Important information for patients – Must appear on the label but should not supersede critical information for patients and shall include: [22]

(A) pharmacy name or dispensing practitioner's entity name[23];

(B) pharmacy telephone number[24];

(C) prescriber name;
  (-a-) format as – "Prescriber: [prescriber name]."

(D) "fill date"[25];

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[21] ~~**Section 3(e)(4)(i)(B)(-a-).**~~ **Comment.**

Boards of pharmacy and licensees should recognize that "take as directed" may not provide sufficient information for the appropriate use of the medication. "Take as directed" is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. "Take as directed" should not be used in lieu of patient counseling.

It is understood that prescription drug orders often do not include the indication for use.

[22] ~~**Section 3(e)(4)(ii).**~~ **Comment.**

Information traditionally included on the patient label must continue to be maintained and safeguarded by the record keeping system. Boards of pharmacy should require that record keeping systems prohibit any alteration or modification of these data unless an appropriate audit trail and justification exists. Record keeping systems should also prohibit any deletion of information except in accordance with state and federal requirements for data management and retention.

[23] ~~**Section 3(e)(4)(ii)(A).**~~ **Comment.**

Boards of pharmacy should recognize that some pharmacies "do business as" a name other than the corporate name.

[24] ~~**Section 3(e)(4)(ii)(B).**~~ **Comment.**

Include ~~P~~phone number of the dispensing pharmacy, recognizing that a pharmacy providing shared services may be involved in the filling process; boards of pharmacy should not require more than one telephone number on the label.

(-a-) format as – "Date filled: MM/DD/YY."
(E) prescription number;
(F) drug quantity;
(-a-) format as – "Qty: [number]."
(G) number of remaining refills;
(-a-) format as – "Refills: [number remaining]" or "No refills," using whole numbers only and managing partial fills through the pharmacy record keeping system;
(H) written or graphic product description;
(I) auxiliary information[26];
(J) any cautions and other provisions which may be required by federal or state law.

(iii) The following additional information for Patients – may appear on the label:
(A) bar codes;
(B) pharmacy address; and
(C) store number. [27]

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[25] ~~**Section 3(e)(4)(ii)(D).**~~ **Comment.**

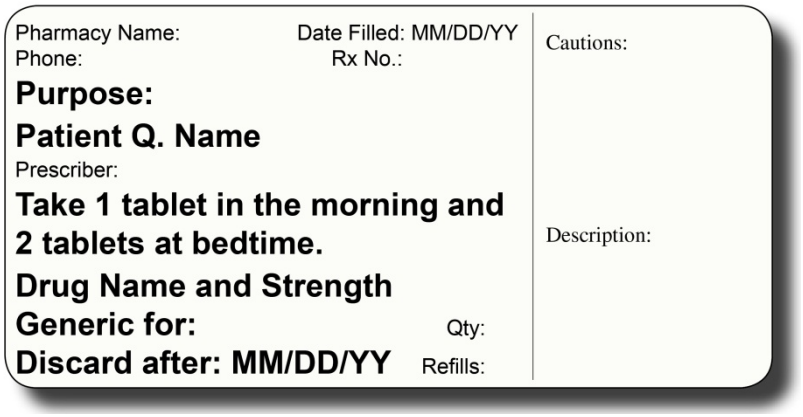
"Fill date" and "use by" date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.

[26] ~~**Section 3(e)(4)(ii)(I).**~~ **Comment.**

Auxiliary information, including auxiliary labels, should be evidence based, standardized, and demonstrated to complement the prescription label.

[27] **Comment.**

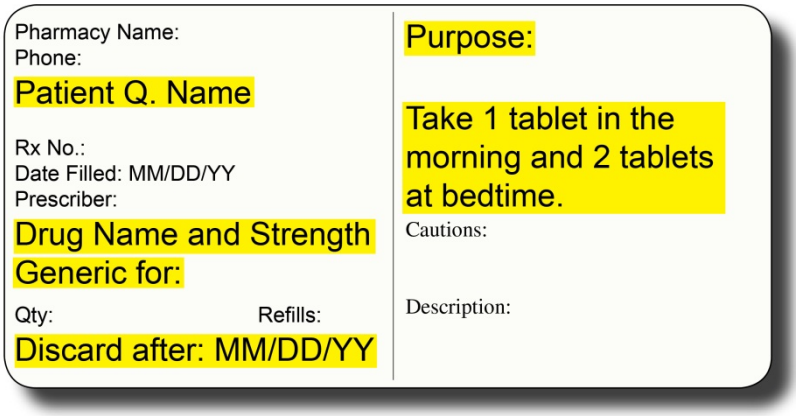
Boards of pharmacy may consider utilizing these suggested labeling formats provided below.



~~(5) No radiopharmaceutical may be Dispensed unless a label is affixed to the immediate container bearing the following information:~~
~~(i) the standard radiation symbol;~~
~~(ii) the words "Caution – Radioactive Material"; and~~
~~(iii) the prescription number.~~
~~(6) No radiopharmaceutical may be Dispensed unless a label is affixed to the outer or Delivery container bearing the following information:~~
~~(i) the standard radiation symbol;~~
~~(ii) the words "Caution – Radioactive Material";~~
~~(iii) the radionuclide and chemical form;~~
~~(iv) the activity and date and time of assay;~~
~~(v) the volume, if in liquid form;~~
~~(vi) the requested activity and the calibrated activity;~~
~~(vii)the prescription number;~~
~~(viii)patient name or space for patient name. Where the patient's name is not available at the time of Dispensing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after Dispensing the radiopharmaceutical, the patient's name shall become a part of the Prescription Drug Order to be retained for a period of three years;~~
~~(ix) the name and address of the nuclear Pharmacy;~~
~~(x) the name of the Practitioner; and~~
~~(xi) the lot number of the prescription.~~

~~(f) Prepackaging~~

~~(1) A Pharmacy may Prepackage Drugs under the following circumstances:~~
~~(i) written policies and procedures have been developed that address the processes of Prepackaging within the Pharmacy;~~
~~(ii) the Prepackaging processes are conducted under conditions that ensure the integrity of the Drug and under the direct supervision of a Pharmacist;~~
~~(iii) the Prepackaged Drugs are labeled with the following components:~~
~~(A) Drug Name;~~
~~(B) Drug Strength;~~
~~(C) Pharmacy Control and Manufacturer lot number;~~
~~(D) Name of the Manufacturer or Distributor of the Drug; and~~



~~(E) Beyond-Use Date.~~

~~(iv) Records of all Prepackaging operations are maintained and include the following:~~

~~(A) the name (nonproprietary and proprietary name), strength, dosage form, quantity per container, and quantity of containers of the Drug being Prepackaged;~~

~~(B) the name of the Manufacturer or Distributor of the Drug;~~

~~(C) Pharmacy Control and Manufacturer lot number;~~

~~(D) expiration date of the Drug according to the original Manufacturer or Distributor container and the Beyond-Use Date;~~

~~(E) the name or initials of the Certified Pharmacy Technician or Pharmacy Technician that Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and~~

~~(F) the date the Drug is Prepackaged.~~

~~(v) 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.~~

Section 4. Recordkeeping

(~~g~~a) Patient Records[28]

(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 patient's medications taken during the preceding 24 months;~~all Prescription Drug Orders obtained by the patient at the Pharmacy maintaining the patient record during the _____ years immediately preceding the most recent entry showing the name of the Drug, prescription number, name and strength of the Drug, the quantity and date received, and the name of the Practitioner;~~ and

[28] ~~**Section 3(g).**~~ **Comment.**

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.

(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 Utilization Review.

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

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

(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

(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[29] 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 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 medications 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 medication.[30]

(c) Electronic Recordkeeping

(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 recordkeeping system and shall:

(i) include examples of all required output documentation provided by the computerized recordkeeping system;

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

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

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[29] ~~**Section 3(m)(1).**~~ **Comment.**

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

[30] ~~**Section 3(m)(2).**~~ **Comment.**

States that require pharmacies that ship medication 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 medication 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.

(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.

(i) the system shall have the capability of producing sight-readable information on all original and refill Prescription Drug Orders. The term "sight-readable" means that an authorized individual shall be able to examine the record and read the information from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy; and

(ii) the system shall provide online retrieval (via CRT display or hard copy printout) 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

(iii) the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV are subject to the following conditions:

(A) the system must provide online retrieval (via computer monitor or hard-copy printout) 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 (via computer monitor or hard-copy printout) of 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 paper, fax, or oral 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 (*e.g.,* 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 log book, 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 and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of years after the date of dispensing the appropriately authorized refill;

(D) the electronic recordkeeping 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.

(iv) 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 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 within 24 hours.

Section 5. Pharmacist Care

(~~h~~a) Prospective Drug Utilization Review (DUR) [31]

A Pharmacist shall review the patient record and 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, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(b~~i~~) Patient Counseling[32]

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[31] ~~**Section 3(h).**~~ **Comment.**

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

[32] ~~**Section 3(i).**~~ **Comment.**

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.

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate 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 and shall include appropriate elements of Patient Counseling. Such elements may include the following:
   (i) the name and description of the Drug;
   (ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
   (iii) intended use of the Drug and expected action;
   (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) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(3) 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).

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

(c) Medication Adherence Monitoring Services and Intervention Programs

Medication Adherence Monitoring Services and 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 established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs. (See Appendix E for Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs.)

(d) 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 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,

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 may include:

(A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;

(B) a detailed description of the methods, procedures, decision Criteria, and plan the Pharmacist is to follow when conducting allowed activities; and

(C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system.

(iii) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(iv) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(v) 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;

(vi) a provision that allows either party to cancel the Agreement by written notification;

(vii) an effective date; and

(viii) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.

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

(3) Initiation of the Collaborative Pharmacy Practice Agreement

The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate allowed activities for any particular patient.

(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 providing care to that patient and who are authorized to received it. Documentation of allowed activities shall be considered Protected Health Information.

(5) Review

At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.

Section 6. Continuous Quality Improvement Program

(~~j~~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;

(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 medications 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 pharmaceutical 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[33]

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

(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.~~

~~(k) 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 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, 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 may include:~~

~~(A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;~~

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[33] ~~**Section 3(j)(7)**~~ **Comment.**

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.

(B) a detailed description of the methods, procedures, decision Criteria, and plan the Pharmacist is to follow when conducting allowed activities; and

(C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system.

(iii) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(iv) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(v) 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;

(vi) a provision that allows either party to cancel the Agreement by written notification;

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(3) Initiation of the Collaborative Pharmacy Practice Agreement

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(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 providing care to that patient and who are authorized to received it. Documentation of allowed activities shall be considered Protected Health Information.

(5) Review

At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.

(l) Adverse Drug Reactions

Significant Adverse Drug Reactions shall be reported to the Practitioner and, in writing, to the Board of Pharmacy immediately upon discovery. Appropriate entry on the patient's record shall also be made.

(m) Records of Dispensing/Delivery

(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 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 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 medications 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 medication.

(n) Computer Records

(1) Systems Manuals

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

(i) include examples of all required output documentation provided by the automated system;

(ii) outline steps to be followed when the automated 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) Automated Data Processing System

(i) Data storage and retrieval. The system shall have the capability of producing sight-readable information on all original and refill Prescription Drug Orders. The term "sight-readable" means that an authorized individual shall be able to examine the record and read the information from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy.

(ii) The system shall provide online retrieval (via CRT display or hard copy printout) 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.

(iii) The Pharmacist-in-Charge shall:

(A) Maintain a log book in which the Pharmacist responsible for Dispensing shall sign a statement each day attesting to the fact that the Prescription Drug Order information entered into the computer that day has been reviewed and is correct as shown. Such a log book shall be maintained at the Pharmacy employing such a system for a period of _____ years after the date of last Dispensing; or

(B) Provide a printout of each day's Prescription Drug Order information. That printout shall be verified, dated, and signed in the same manner as signing a check or legal document (eg, J. H. Smith or John H. Smith) by the individual Pharmacist verifying that the information indicated is correct. Such printout shall be maintained (number) years from the date of last Dispensing.

(iv) The computerized 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.

(v) Any facility maintaining centralized prescription records shall be capable of sending a requested printout to the Pharmacy within 72 hours.

~~(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 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 within 24 hours.~~

Section 7. Shared Pharmacy Services.

~~**(o) Shared Pharmacy Services**~~

(a) General Requirements[34, 35]

(1) The Pharmacy must possess a resident or nonresident permit issued by the Board prior to engaging in Shared Pharmacy Services.[36]

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

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[34] ~~**Section 3(o)(1).**~~ **Comment.**

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~~ state and federal law governing Institutional Facilities.

[35] ~~**Section 3(o)(2).**~~ **Comment.**

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.

[36] ~~**Section 3(o)(1)(i).**~~ **Comment.**

Often the terms "licensure," "registration," and "permit" are used interchangeably throughout the *Model Act*. In the case of Shared Pharmacy Services Pharmacies that utilize Automated Pharmacy Systems, boards may determine that it is appropriate to issue a permit for the Automated Pharmacy System but not for the physical site where the Automated Pharmacy System is located.

(i) have the same owner; or
(ii) have a written contract or agreement that outlines the services provided and the shared responsibilities of each party 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 engages 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:
(i) maintain records identifying, individually, for each Prescription Drug Order processed, the name of <u>each</u> Pharmacist, or Pharmacy Intern who took part in the Drug Utilization Review, refill authorization, or therapeutic intervention functions performed at that Pharmacy and <u>the name of</u> any Certified Pharmacy Technician or Pharmacy Technician 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 <u>the name of</u> any Certified Pharmacy Technician or Pharmacy Technician 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) <u>Drug Storage and</u> Security

(1) Drugs shall be stored in compliance with state and federal laws and in accordance with these Rules, including those addressing temperature <u>and</u>~~,~~ proper containers, and <u>those addressing</u> 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, Pharmacy Technicians, 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 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 participant in Shared Pharmacy Services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for Shared Pharmacy Services. Each participant is required to maintain this portion of the joint policies and procedures that relate to that participant's operations. The policies and procedures shall:

(i) outline the responsibilities of each of the pharmacies;

(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 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, Pharmacy Technician, 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~~ state, who is an employee of or under contract with a Pharmacy, or a licensed Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern, working under the supervision of the Pharmacy, 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:

(2) the Pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and

(3) no part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database.

Section 8. Automated Pharmacy Systems.

~~(p) Automated Pharmacy Systems~~

(a) Automated Pharmacy Systems can be utilized in licensed Pharmacies and other approved locations within an Institutional Facility or clinic. A Pharmacist is not required to be physically present at the site of the Automated Pharmacy System if the system is supervised electronically by a Pharmacist. Automated Pharmacy Systems shall comply with the following provisions.

(1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained ~~on site~~ in the Pharmacy ~~for review by the Board of Pharmacy~~. Such documentation shall include, but is not limited to:

(i) name and address if the location where the Automated Pharmacy System (s) is being used;

(ii) Manufacturer's name and model;

(iii) description of how the ~~Device~~ Automated Pharmacy System is used;

(iv) quality assurance procedures to determine continued appropriate use of the ~~automated Device~~ Automated Pharmacy System;

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

(vi) documentation evidencing that the Automated Pharmacy System has been tested prior to initial use and on a periodic basis at each location to ensure that the Automated Pharmacy System is operating properly.

(2) Automated Pharmacy Systems should be used only in settings where there is an established program of Pharmacist Care that ensures medication orders or Prescription Drug Orders are reviewed by a Pharmacist in accordance with established policies and procedures and good ~~Pharmacy practice~~ Pharmacist Care.[37]

(i) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.[38]

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[37] ~~**Section 3(p)(2).**~~ **Comment.**

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

[38] ~~**Section 3(p)(2)(i).**~~ **Comment.**

In order to facilitate communication between the ~~Shared~~ Pharmacy ~~Services 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.

(ii) Any Pharmacy that maintains an Automated Pharmacy System for the purposes of remote Dispensing to outpatients[39] shall maintain a video/auditory communication system to provide for effective communication between the ~~Shared Pharmacy Services Pharmacy~~ 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 ~~at the Remote Pharmacy or Remote Dispensing Site~~ 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 ~~at the Shared Pharmacy Services Pharmacy~~**~~Error! Bookmark not defined.~~**, if ~~where~~ the Automated Pharmacy System is being used at a different Pharmacy location, at that location as well.

(4) Automated Pharmacy Systems shall have adequate security systems and procedures, evidenced by written policies and procedures[40], to:
   (i) prevent unauthorized access;
   (ii) comply with federal and state regulations; and
   (iii) prevent the illegal use or disclosure of Protected Health Information.

(5) Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements.
   (i) All events involving the contents of the Automated Pharmacy System must be recorded electronically.
   (ii) Records must be maintained by the Pharmacy and must be readily available to the Board. Such records shall include:
      (A) identity of system accessed;
      (B) identification of the individual accessing the system;
      (C) type of transaction;
      (D) name, strength, dosage form, and quantity of the Drug accessed;
      (E) name of the patient for whom the Drug was ordered; and
      (F) such additional information as the Pharmacist-in-Charge may deem necessary.

(6) Access to and limits on access (eg, security levels) to the Automated Pharmacy System must be defined by policy and procedures and must comply with state and federal regulations.[41]

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[39] ~~**Section 3(p)(2)(ii).**~~ **Comment.**

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.

[40] ~~**Section 3(p)(4).**~~ **Comment.**

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

[41] ~~**Section 3(p)(6).**~~ **Comment.**

This section anticipates that decisions regarding which health care professionals may access the Automated Pharmacy System and the level of access allowed (eg, access to medications, access to patient profiles for viewing only, access to patient profiles for modification) will be left up to

(7) The Pharmacist-in-Charge shall have the responsibility to:
  (i) assign, discontinue, or change access to the system;
  (ii) ensure that access to the medications comply with ~~State~~ state and ~~Federal~~ federal regulations;
  (iii) ensure that the Automated Pharmacy System is filled/stocked accurately and in accordance with established, written policies and procedures.

(8) The filling/stocking of all medications in the Automated Pharmacy System shall be accomplished by qualified personnel under the supervision of a licensed Pharmacist.

(9) A record of medications filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.[42]

(10) All containers of medications stored in the Automated Pharmacy System shall be packaged and labeled in accordance with federal and state laws and regulations.

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

(12) The Automated Pharmacy System shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the Automated Pharmacy System, all in accordance with existing state and federal law.[43]

(13) The Automated Pharmacy System shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.[44]

Section 9. Return and Reuse of Prescription Drugs.

~~(q) Return and reuse of Prescription Drugs~~

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

(1) were removed from the Pharmacy for delivery by Pharmacy staff, or a Pharmacy contracted delivery service and returned because the Prescription Drugs were not deliverable or the patient refused delivery, and such Prescription Drugs did not leave the control of the Pharmacy; and

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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.

[42] ~~**Section 3(p)(9).**~~ **Comment.**

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~~ state allow non-Pharmacist personnel to perform this function, it should define the level of Pharmacist supervision necessary (eg, immediate, direct, or general).

[43] ~~**Section 3(p)(12).**~~ **Comment.**

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

[44] ~~**Section 3(p)(13).**~~ **Comment.**

The State state may require that each licensed Pharmacy or facility have in place written policies and procedures to address situations in which medications removed from the system are wasted and must be secured and accounted for.

(2) Prescription Drugs were packaged in:
  (i) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging; or
  (ii) the dispensing pharmacy's original packaging; and
  (iii) returned to the pharmacy immediately after the unsuccessful delivery attempt.

(3) If a Pharmacy attempts, but is not able, to deliver Prescription Drugs using an approved common carrier, then such Prescription Drugs may be returned and reused by the Pharmacy if packaged in:
  (i) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use[45], or unit-dose packaging; or
  (ii) the dispensing pharmacy's original, sealed, and tamper-evident packaging that maintains the product quality as per United States Pharmacopeia (USP) standards.

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

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

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

Section 10. Prescription Drug Repository Programs.

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

(11) Qualifications of acceptable medications for reuse. Such qualifications must include the following provisions:
  (i) only non-controlled medications will be accepted
  (ii) all medications will be inspected and determined to be:
    (A) unadulterated;
    (B) unexpired; and
    (C) in unopened unit dose or manufacturer's tamper-resistant original packaging
  (iii) maintenance of a separate physical inventory;
  (iv) completion of a monthly expiration date review for all medications;
  (v) prohibition of charging or accepting compensation for medications 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 medication.

Section 11. Disposal of Controlled Substances.[46]

[45] ~~**Section 3(q)(1)(iii).**~~ **Comment.**

Unit-of-use is not intended to include co-mingled, multi-medication unit-of-use packages also known as compliance packs

[46] ~~**Section 3(r).**~~ **Comment.**

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

~~(r) Disposal of Controlled Substances~~

(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.

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

~~(12) Qualifications of acceptable medications for reuse. Such qualifications must include the following provisions:~~

~~(i) only non-controlled medications will be accepted~~

~~(ii) all medications will be inspected and determined to be:~~

~~(D) unadulterated;~~

~~(E) unexpired; and~~

~~(F) in unopened unit dose or manufacturer's tamper-resistant original packaging~~

~~(iii) maintenance of a separate physical inventory;~~

~~(iv) completion of a monthly expiration date review for all medications;~~

~~(v) prohibition of charging or accepting compensation for medications 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 medication.~~

~~Medication Adherence Monitoring Services and Intervention Programs~~

~~Medication Adherence Monitoring Services and 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 established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs. (See Appendix E for Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs.)~~

Section 12. 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) the Prepackaging processes are conducted under conditions that ensure the integrity of the Drug and under the direct supervision of a Pharmacist;
(3) 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; and
  (v) Beyond-Use Date.
  (iv) Records of all Prepackaging operations are maintained and include the following:
    (A) the name (nonproprietary and proprietary name), strength, dosage form, quantity per container, and quantity of containers of the Drug being Prepackaged;
    (B) the name of the Manufacturer or Distributor of the Drug;
    (C) Pharmacy Control and Manufacturer lot number;
    (D) expiration date of the Drug according to the original Manufacturer or Distributor container and the Beyond-Use Date;
    (E) the name or initials of the Certified Pharmacy Technician or Pharmacy Technician that Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and
    (F) the date the Drug is Prepackaged.
  (v) 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.

Section 413. Provision of Pharmacist Care Outside of a Licensed Pharmacy.

(a) A Pharmacist providing Pharmacist Care services outside the premises of a licensed Pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:
(1) provide accountability and an audit trail;
(2) be provided to the Board upon request;
(3) be preserved for a period of at least five years from the date relied upon or consulted for the purposes of performing any such function; and
(4) secure from unauthorized access and use.

Section 514. Approval of Pharmacy Practice Initiatives.

(a) Application.[47]

[47] **Comment**.

An application for approval of a Pharmacy practice initiative that improves the quality of or access to Pharmacist Care, but which falls outside the scope of present regulations, shall be submitted to the Board and shall contain at least the following information:

(1) the name, address, telephone number, and the license number of the Pharmacist responsible for overseeing the initiative;

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

(3) a detailed summary of the proposed Pharmacy practice initiative, which includes:

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

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

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

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

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

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

(b) Approval by the Board.

The Board shall approve a Pharmacy practice initiative if it determines that:

(1) the Pharmacy practice initiative will improve the quality of or access to Pharmacist Care;

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

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

The Board shall deny, Revoke, or refuse to renew an application for a Pharmacy practice initiative if the Board determines that the above requirements have not been met. In issuing an approval for a Pharmacy practice initiative, the Board may impose such terms and conditions it deems appropriate to carry out the purposes of Section 213(a)(14) of this Act and the rules adopted thereunder.

(c) Notification.

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

(d) Extension of Approval of Pharmacy Practice Initiatives.

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

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

Section ~~6~~15. Unprofessional Conduct.

Unprofessional conduct shall include, but is not limited to, the following acts of a Pharmacist or Pharmacy:

(a) the publication or circulation of false, misleading, or otherwise deceptive statements concerning the Practice of Pharmacy;

(b) unreasonably refusing to Compound or Dispense Prescription Drug Orders that may be expected to be Compounded or Dispensed in Pharmacies by Pharmacists;

(c) attempting to circumvent the Patient Counseling requirements, or discouraging the patient from receiving Patient Counseling concerning their Prescription Drug Orders;

(d) the illegal use or disclosure of Protected Health Information[48];

(e) failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of Protected Health Information;

(f) failure to maintain adequate records to account for disclosures of Protected Health Information;

(g) selling, giving away, or otherwise disposing of accessories, chemicals, or Drugs or Devices found in illegal Drug traffic when the Pharmacist knows or should have known of their intended use in illegal activities;

(h) engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a Pharmacist, with proof of actual injury not having to be established;

(i) selling a Drug for which a Prescription Drug Order from a Practitioner is required, without having received a Prescription Drug Order for the Drug;

(j) willfully and knowingly failing to maintain complete and accurate records of all Drugs received, Dispensed, or disposed of in compliance with the Federal laws and regulations and State laws and rules;

(k) obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's Pharmacist Care, absent a clear benefit to the patient, solely in response to promotion or marketing activities.

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[48] ~~**Section 6(d).**~~ **Comment.**

This Section emphasizes that Pharmacists should not release any data, summary or otherwise, which would reveal any specific identifier or demographic information about patients, prescribers, or providers with regard to the medication Dispensed and which would compromise the patient's or Practitioner's identity or confidentiality of care.

~~Comments~~

~~Section 1(a)(3). Comment.~~

~~Boards may wish to give examples in each of these categories of reference texts.~~

~~Section 1(a)(4). Comment.~~

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

~~Section 2(a)(2)(i). Comment.~~

~~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 medications, 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*.~~

~~Section 2(a)(2)(i)(C). Comment.~~

~~As part of a quality assurance program designed to prevent and detect drug diversion, the Pharmacist-in-Charge is expected to ensure policies and procedures are in place that address the following:~~

1. ~~inspection of shipments;~~
2. ~~receipt verification oversight and checking in shipments;~~
3. ~~reconciliation of orders; and~~
4. ~~inventory management including:~~
    a. ~~determination of Medications 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.~~

~~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:~~

1. ~~alarm codes and lock combinations;~~
2. ~~passwords;~~
3. ~~keys and access badges; and~~
4. ~~video surveillance systems.~~

~~Section 2(a)(2)(i)(G) Comment.~~

~~States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications 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.~~

~~Section 2(a)(2)(ii). Comment.~~

~~All training programs should be subject to approval by the Board of Pharmacy.~~

~~Section 2(a)(2)(iii). Comment.~~

~~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.~~

~~Section 2(a)(3)(ii). Comment.~~

~~The method of and level of Pharmacist supervision over technicians may vary depending on practice site. For example, supervision of technicians in a Remote Pharmacy or Remote Dispensing Site will be different than that of technicians in a retail Pharmacy setting.~~

~~Section 3(a)(9). Comment.~~

~~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.~~

~~Section 3(b)(7)(i). Comment.~~

~~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.~~

~~Section 3(b)(5). Comment.~~

~~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.~~

~~Section 3(e)(4). Comment.~~

~~Boards may want to consider supporting legislation which contains this type of language for incorporation into their State Food and Drug Act, so that it shall apply to all Persons who Dispense Drugs, including Practitioners who prescribe and Administer as well as Dispense Drugs.~~

~~Section 3(e)(4)(i)(B)(-a-). Comment.~~

~~Boards of pharmacy and licensees should recognize that "take as directed" may not provide sufficient information for the appropriate use of the medication. "Take as directed" is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. "Take as directed" should not be used in lieu of patient counseling.~~

~~It is understood that prescription drug orders often do not include the indication for use.~~

~~Section 3(e)(4)(ii). Comment.~~

~~Information traditionally included on the patient label must continue to be maintained and safeguarded by the record keeping system. Boards of pharmacy should require that record keeping systems prohibit any alteration or modification of these data unless an appropriate audit trail and justification exists. Record keeping systems should also prohibit any deletion of information except in accordance with state and federal requirements for data management and retention.~~

~~Section 3(e)(4)(ii)(A). Comment.~~

~~Boards of pharmacy should recognize that some pharmacies "do business as" a name other than the corporate name.~~

~~Section 3(e)(4)(ii)(B). Comment.~~

~~Phone number of the dispensing pharmacy recognizing that a central fill pharmacy may be involved in the filling process; boards of pharmacy should not require more than one telephone number on the label.~~

~~Section 3(e)(4)(ii)(D). Comment.~~

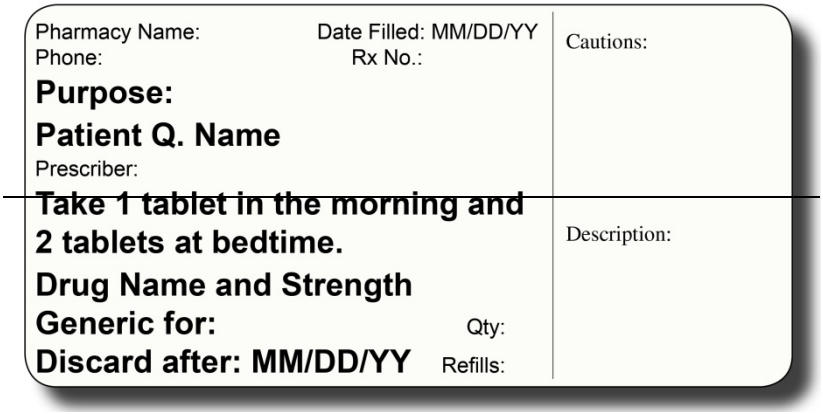
~~"Fill date" and "use by" date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.~~

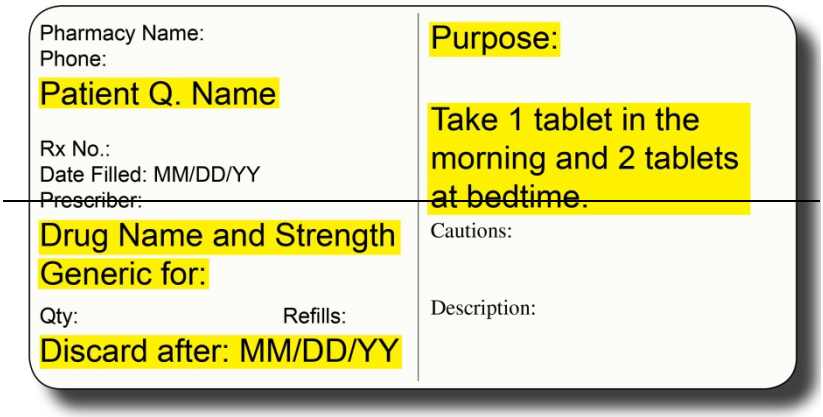
~~Section 3(e)(4)(ii)(I). Comment.~~

~~Auxiliary information, including auxiliary labels, should be evidence based, standardized, and demonstrated to complement the prescription label.~~

~~Section 3(e)(4)(i), (ii), and (iii). Comment.~~

~~Boards of pharmacy may consider utilizing these suggested labeling formats provided below.~~





~~Section 3(g). Comment.~~

~~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.~~

~~Section 3(h). Comment.~~

~~Pharmacists should be permitted to use computer software, if available, to accomplish this review.~~

~~Section 3(i). Comment.~~

~~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.~~

~~Section 3(j)(7) Comment.~~

~~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.~~

~~Section 3(m)(1). Comment.~~

~~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.~~

~~Section 3(m)(2). Comment.~~

~~States that require pharmacies that ship medication 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 medication 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.~~

~~Section 3(o)(1). Comment.~~

~~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.~~

~~Section 3(o)(1)(i). Comment.~~

~~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.~~

~~Section 3(o)(2). Comment.~~

~~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.~~

~~Section 3(p)(2). Comment.~~

~~Each state should determine whether or not the Dispensing of a "first dose" or an "emergency dose" may take place without prior order review by a Pharmacist but with appropriate security and patient medication management controls in place.~~

~~Section 3(p)(2)(i). Comment.~~

~~In order to facilitate communication between the Shared Pharmacy Services 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.~~

~~Section 3(p)(2)(ii). Comment.~~

~~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.~~

~~Section 3(p)(4). Comment.~~

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

~~Section 3(p)(6). Comment.~~

~~This section anticipates that decisions regarding which health care professionals may access the Automated Pharmacy System and the level of access allowed (eg, access to medications, access to patient profiles for viewing only, access to patient profiles for modification) will be left up to the individual(s) responsible for the Automated Pharmacy System; however, states may decide to take on this responsibility and define those who may have access to the system and the levels of access allowed.~~

~~Section 3(p)(9). Comment.~~

~~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).~~

~~Section 3(p)(12). Comment.~~

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

~~Section 3(p)(13). Comment.~~

~~The State may require that each licensed Pharmacy or facility have in place written policies and procedures to address situations in which medications removed from the system are wasted and must be secured and accounted for.~~

~~**Section 3(q)(1)(iii). Comment.**~~

~~Unit-of-use is not intended to include co-mingled, multi-medication unit-of-use packages also known as compliance packs.~~

~~**Section 3(r). Comment.**~~

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

~~**Section 5. Comment.**~~

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

~~**Section 6(d). Comment.**~~

~~This Section emphasizes that Pharmacists should not release any data, summary or otherwise, which would reveal any specific identifier or demographic information about patients, prescribers, or providers with regard to the medication Dispensed and which would compromise the patient's or Practitioner's identity or confidentiality of care.~~

Model Rules for Nuclear/Radiologic Pharmacy

Section 1. Purpose and Scope.

The Practice of Nuclear/Radiologic Pharmacy is hereby recognized as a specialty of Pharmacy practice, regulated by State Boards of Pharmacy. As such, the following model rules are included to address those areas specific or unique to this specialty practice. Nuclear/Radiologic Pharmacy Practice refers to a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other Drugs.

Section 2. Definitions.

(a) "Authentication of Product History" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any Component of a radiopharmaceutical.

(b) "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(c) "Nuclear Pharmacy" means a Pharmacy providing radiopharmaceutical services or, as provided in Section 3 of these Rules, an appropriate area of any Institutional Facility.

(d) "Qualified Licensed Professional" means a non-Pharmacist individual (such as a physician, nurse, or technologist) who possesses a current state license, if applicable, and who has sufficient training and experience to safely handle and Dispense radiopharmaceuticals as defined by the respective requirements of [cite appropriate Nuclear Regulatory Commission (NRC) or Agreement State and State Board of Pharmacy law(s)].

(e) "Qualified Nuclear Pharmacist" means a currently licensed Pharmacist in the State of practice, who is certified as a Nuclear Pharmacist by the State Board of Pharmacy or by a certification Board recognized by the State Board of Pharmacy, or who meets the following standards:

(1) Minimum standards of training for "authorized user status" of radioactive material [cite State Radiation Control Agency or NRC licensure guide].
(2) Completed a minimum of 200 contact hours of instruction in nuclear Pharmacy and the safe handling and the use of radioactive materials from a program approved by the State Board of Pharmacy, with emphasis in the following areas:
    (i) radiation physics and instrumentation;
    (ii) radiation protection;
    (iii) mathematics of radioactivity;
    (iv) radiation biology; and
    (v) radiopharmaceutical chemistry.
(3) Attained a minimum of 500 hours of clinical nuclear Pharmacy training under the supervision of a qualified nuclear Pharmacist.

(f) "Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

(g) "Radiopharmaceutical Service" means, but shall not be limited to, the procurement, storage, handling, preparation, Labeling, quality assurance testing, Dispensing, Delivery, record keeping, and disposal of radiopharmaceuticals and other Drugs.

(h) "Radiopharmaceuticals" are radioactive Drugs as defined by Food and Drug Administration and the _____ State Board of Pharmacy [cite appropriate law(s)].

Section 3. General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) Nuclear Pharmacy License. A license to operate a Pharmacy providing radiopharmaceutical services shall only be issued to a Qualified Nuclear Pharmacist. All personnel performing tasks in the preparation and Distribution of radioactive Drugs shall be under the direct supervision of a Qualified Nuclear Pharmacist. A Qualified Nuclear Pharmacist shall be responsible for all operations of the Pharmacy and shall be in personal attendance at all times that the Pharmacy is open for business. In emergency situations when a Qualified Nuclear Pharmacist is not present, designated Qualified Licensed Professionals may have access to the licensed area. These individuals may prepare single doses of radiopharmaceuticals for the immediate emergency, and must document such activities.

(b) Nuclear Pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the State or as otherwise defined by the _____ State Board of Pharmacy.

(c) The Nuclear Pharmacy area shall be secured from unauthorized personnel.

(d) Nuclear Pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive Drugs and other radioactive materials in accordance with [cite appropriate Pharmacy and radiological control agency or NRC Statute(s)].

(e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Radiation Control Agency or NRC before approval of the license.

(f) Radiopharmaceuticals are to be Dispensed only upon a Prescription Drug Order from a Practitioner authorized to possess, use, and Administer radiopharmaceuticals.

(g) The permit to operate a Nuclear Pharmacy is conditioned upon an approved State Radiation Control Agency (RCA) or NRC license. Copies of the RCA or NRC inspection reports shall be made available upon request for Board inspection.

(h) Labeling

(1) No radiopharmaceutical may be Dispensed unless a label is affixed to the immediate container bearing the following information:

a. the standard radiation symbol;
b. the words "Caution – Radioactive Material"; and
c. the prescription number.

(2) No radiopharmaceutical may be Dispensed unless a label is affixed to the outer or Delivery container bearing the following information:

a. the standard radiation symbol;
b. the words "Caution – Radioactive Material";
c. the radionuclide and chemical form;
d. the activity and date and time of assay;
e. the volume, if in liquid form;
f. the requested activity and the calibrated activity;
g. the prescription number;
h. patient name or space for patient name. Where the patient's name is not available at the time of Dispensing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after Dispensing the radiopharmaceutical, the patient's name shall become a part of the Prescription Drug Order to be retained for a period of three years;
i. the name and address of the nuclear Pharmacy;
j. the name of the Practitioner; and
k. the lot number of the prescription.

Section 4. Other Requirements.

All Nuclear/Radiologic Pharmacies shall also adhere to the principles outlined in the Rules for Pharmacist Care as these pertain to the practice of Nuclear Pharmacy. (See Appendix A for Model Inspection Form for Nuclear Pharmacies.)

Background:

After reviewing the proposed amendments for changing the lay-out of the *Model Rules,* the committee agreed that this would increase readability and serve the boards needs by consolidating various sections. Members also approved removing the comments sections and placing that text as footnotes for ease of reference.

Additionally, while reviewing the lay-out, staff called attention to several provisions in need of possible revisions. One of such was contained in the recordkeeping section regarding the time frame for a patient's medication history. Members decided that the pharmacist should make a reasonable effort to obtain a list of medication that a patient had taken in the preceding 24 months. Along those lines, the committee agreed that patient records should be maintained for a period of ten years to coincide with Centers of Medicare & Medicaid Services provisions. Members also determined that "in compliance with federal law" should be added to the section regarding disposal of controlled substances to avoid any potential conflicts.

LE/L Recommendation 9: The Committee Recommends that the Definition and Usage of the Word "Person" in the *Model Act* Should Be Reviewed.

The committee recommends that the definition of the word "Person" as it is used in the *Model Act* be clarified.

Background:

While discussing other recommended amendments to the *Model Act*, the committee agreed that the definition of the word "Person" should be clarified, as it is likely to be perceived inconsistently by *Model Act* users. As this term is used extensively throughout the *Model Act*, the committee decided that a separate review of the entire *Model Act* should be conducted to ensure that all of the necessary revisions are made.