Report of the Committee on Law Enforcement/Legislation

NOTE: The NABP Executive Committee accepted all of the Committee's recommendations with the following exception:

- **Recommendation 5, which recommended revising the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act), was accepted by the Executive Committee with the addition of clarifying verbiage in the comments section as denoted by double, waved underline.**

Members Present:

Caroline Juran (VA), *chair*; Kevin Borcher (NE); Lee Ann Bundrick (SC); Gayle Cotchen (PA); Gay Dodson (TX); Lenna Israbian-Jamgochian (MD); James Koppen (MN); Susan Ksiazek (NY); Alice Mendoza (TX); Kevin Mitchell (OH); Tony Moye (GA).

Others Present:

Hal Wand, *Executive Committee Liaison*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Emily Shaffer, Deborah Zak, *NABP staff*.

Introduction:

The Committee on Law Enforcement/Legislation met January 22 and 23, 2013, 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 then reviewed 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 Practice Technology Systems, 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

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Article I

Title, Purpose and Definitions

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Section 105. Definitions.

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~~(o) "Centralized Prescription Filling" means the filling by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order.~~

~~(p) "Centralized Prescription Processing" means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as Dispensing, Drug Utilization Review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.~~

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~~(f2) "Coordinating Pharmacy" is a Pharmacy responsible for the Practice of Telepharmacy performed at Remote Pharmacies and Remote Dispensing Sites.~~

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~~(d6) "Remote Dispensing Site" is a site located within an Institutional Facility or a clinic that utilizes an Automated Pharmacy System and that is electronically linked to the Coordinating Pharmacy via a computer system and/or a video/auditory communication system approved by the Board.~~

~~(e6) "Remote Pharmacy" is a Pharmacy staffed by a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician that is electronically linked to the Coordinating Pharmacy via a computer system and/or a video/auditory communication system approved by the Board.~~

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(l6) "Shared Pharmacy Services" means a system that allows a participating Pharmacist or Pharmacy pursuant to a request from another participating Pharmacist or Pharmacy to process or fill a Prescription Drug Order, which may include preparing, packaging, Labeling, Compounding for specific patients, Dispensing, performing Drug Utilization Reviews, conducting claims adjudication, obtaining refill authorizations, reviewing therapeutic interventions, and/or reviewing institutional facility orders.

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~~Section 105(d6). Comment.~~

~~The Board may want to consider allowing only Institutional Facilities that are licensed by the State to utilize a "Remote Dispensing Site."~~

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Model Rules for Institutional Pharmacy

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Section 6. Shared Pharmacy Services Utilization ~~Centralized Prescription Processing or Filling~~ for Immediate Need.

(a) In accordance with the Model Rules for the Practice of Pharmacy and Shared Pharmacy Services ~~Centralized Prescription Processing and Filling~~, an Institutional Pharmacy may outsource services to another Pharmacy for the 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 ~~Centralized Prescription Processing or Filling s~~Shared Pharmacy Services for its inpatients and residents; and

(2) provides a valid Chart Order to the Pharmacy it has contracted with for the ~~Centralized Prescription Processing or Filling s~~Shared Pharmacy Services.

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Model Rules for the Practice of Pharmacy

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(o) ~~Remote Pharmacy~~ Shared Pharmacy Services

(1) General Requirements

(i) The ~~Pharmacist-in-Charge of the Coordinating~~ Pharmacy must possess ~~shall apply to the Board for~~ a resident or nonresident permit issued by the Board prior to engaging in Shared Pharmacy Services ~~the Practice of Telepharmacy via the Remote Pharmacies and Remote Dispensing Sites.~~

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

(A) Have the same owner; or

(B) 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

(C) 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. ~~A Coordinating Pharmacy shall demonstrate to the Board that there is limited access to pharmacy services in the community prior to engaging in the Practice of Telepharmacy via the Remote Pharmacies and Remote Dispensing Sites.~~

~~(iii) One Pharmacist shall not operate more than three simultaneously open Remote Pharmacies or Remote Dispensing Sites. An exception to this limit may be granted by the Board in situations where the Coordinating Pharmacy has documented a need to supervise additional Remote Pharmacies or Remote Dispensing Sites and has demonstrated that appropriate safeguards are in place to ensure proper supervision of each.~~

~~(iv) Remote Pharmacies that are principally staffed by Certified Pharmacy Technicians or Pharmacy Interns shall be under the continuous supervision of a Pharmacist at the Coordinating Pharmacy at all times that it is open to provide pharmacy services. To qualify as continuous supervision, the Pharmacist is not required to be physically present at the Remote Pharmacy, but shall supervise operations electronically through the use of a video/auditory communication system.~~

~~(v)~~(iii) A ~~Coordinating~~ Pharmacy engaged in Shared Pharmacy Services shall comply with appropriate federal and state controlled substance registrations for each ~~Remote Pharmacy or Remote Dispensing Site~~ Pharmacy if controlled substances are maintained.

~~(vi)~~(iv) A ~~Coordinating~~ Pharmacy engaged in Shared Pharmacy Services shall notify the Board in writing within 10 days of a change of location, discontinuance of service, or closure of a ~~Remote Pharmacy or Remote Dispensing Site operated by the Coordinating~~ Pharmacy.

(2) The Pharmacist-in-Charge of a Pharmacy participating in Shared Pharmacy Services must possess a license to practice Pharmacy from the Board(s) prior to engaging in Shared Pharmacy Services.

~~(2) Remote Pharmacy~~

~~A Remote Pharmacy may have a limited Drug inventory consisting of suitable unit-of-use containers Prepackaged by the Coordinating Pharmacy or a registered Repackager or as provided in the original Manufacturer's container. A Remote Pharmacy may utilize an Automated Pharmacy System.~~

~~(3) Remote Dispensing Site~~

~~A Remote Dispensing Site shall utilize an Automated Pharmacy System located in an area accessible only to authorized personnel.~~

~~(4) Personnel~~

~~(i) The Pharmacist-in-Charge of the Coordinating Pharmacy:~~

~~(A) is responsible for the Practice of Telepharmacy performed at Remote Pharmacies and Remote Dispensing Sites, including the supervision of any Automated Pharmacy System and compliance with these Rules;~~

~~(B) is responsible for ensuring that the Coordinating Pharmacy and the Remote Pharmacy and Remote Dispensing Site have entered into a written agreement that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the agreement in compliance with federal and state laws and regulations. Such contract or agreement is not required if the Remote Pharmacy or Remote Dispensing Site are under common control or ownership of the Coordinating Pharmacy;~~

~~(C) shall ensure the Coordinating Pharmacy has sufficient Pharmacists on duty for the safe operation and supervision of all Remote Pharmacies and Remote Dispensing Sites; and~~

~~(D) shall ensure that 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.~~

~~(ii) Pharmacists, Pharmacy Interns, and Certified Pharmacy Technicians at Remote Pharmacies shall be registered with the Board and be trained in the operation of the video/auditory communication system used for Dispensing and Patient Counseling.~~

~~(5)~~(3)Operations

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

(A) maintain records identifying, individually, for each Prescription Drug Order processed, the name of each Pharmacist~~, Certified Pharmacy Technician, Pharmacy Technician,~~ or Pharmacy Intern who took part in the Drug Utilization Review, refill authorization, or therapeutic intervention functions performed at that Pharmacy and any Certified Pharmacy Technician or Pharmacy Technician if they assisted in any of those functions;

(B) maintain records identifying, individually, for each Prescription Drug Order filled or dispensed, the name of each Pharmacist or Pharmacy Intern~~, Certified Pharmacy Technician, Pharmacy Technician, and Pharmacy Intern~~ who took part in the filling, dispensing, and counseling functions performed at that Pharmacy and any Certified Pharmacy Technician or Pharmacy Technician if they assisted in any of those functions;

(C) 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;

(D) maintain a mechanism for tracking the Prescription Drug Order during each step of the processing and filling procedures performed at the Pharmacy;

(E) maintain a mechanism for the patient to identify ~~on the Label~~ all Pharmacies involved in filling the Prescription Drug Order; and

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

~~(B) may receive Prescription Drug Orders or refill requests by the patient or the patient's agent in accordance with the policies and procedures designated by the Pharmacist-in-Charge. The Certified Pharmacy Technician or Pharmacy Intern shall either transmit the Prescription Drug Order or refill request to the Coordinating Pharmacy or process the Prescription Drug Order or refill request so that the Pharmacist at the Coordinating Pharmacy may perform a Prospective Drug Utilization Review prior to Dispensing;~~

~~(C) shall contain an appropriate area for Patient Counseling by the Pharmacist, if required;~~

~~(D) may employ Certified Pharmacy Technicians or Pharmacy Interns, who shall be under the continuous supervision of a Pharmacist at the Coordinating Pharmacy, to assist in the Dispensing process and maintain appropriate video/auditory communication with the Coordinating Pharmacy; and~~

~~(E) may contain an Automated Pharmacy System or a limited Drug inventory for the purposes of preparing medications for Dispensing. The Pharmacist at the Coordinating Pharmacy shall have access to the Remote Pharmacy's automated data processing system to perform a Prospective Drug Utilization Review (DUR) prior to Dispensing. The Pharmacist shall ensure, through the use of the video/auditory communication system, that the Certified Pharmacy Technician or Pharmacy Intern has accurately and correctly prepared the Drug for Dispensing according to the Prescription Drug Order.~~

(ii) Notification to Patients~~Remote Dispensing Sites:~~

(A) 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.

~~(B) If a Shared Pharmacy Services Pharmacy or Pharmacist delivers a Prescription Drug directly to the patient or the patient's agent, the Pharmacy or Pharmacist shall provide, on the Prescription Drug container or on a separate sheet delivered with the Prescription Drug container:~~

~~(-a-) the local telephone number and, if applicable, the toll-free telephone number of the filling Pharmacy or filling Pharmacist; and~~

~~(-b-) a statement that conveys to the patient or patient's agent the following information: "Written information about this prescription has been provided for you; please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at [insert the filling pharmacist or filling pharmacy's telephone numbers]."~~

~~(A) that are located within an Institutional Facility shall utilize an Automated Pharmacy System for the purposes of Dispensing. The Pharmacist at the Coordinating Pharmacy shall have the necessary patient information to perform a Prospective Drug Utilization Review (DUR) prior to Dispensing; and~~

~~(B) that are located in clinics shall utilize an Automated Pharmacy System. Such Automated Pharmacy Systems shall be located in an area that will provide for Patient Counseling and must be installed within the same area utilized by the Practitioner for the provision of clinical services.~~

~~(6)~~(4)Security

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

(ii) Drugs stored at ~~Remote Dispensing Sites~~ Shared Pharmacy Services Pharmacies shall be stored in an area that is:

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

(B) ~~locked by key or combination~~ secured, so as to prevent access by unauthorized personnel.

(iii) Access to the area where Drugs are stored at the ~~Remote Pharmacy or Remote Dispensing Site~~ Shared Pharmacy Services Pharmacies must be limited to:

(A) Pharmacists, Certified Pharmacy Technicians, Pharmacy Technicians, or Pharmacy Interns who are employed by the ~~Coordinating~~ Shared Pharmacy Services Pharmacy; or

(B) Personnel employed at the Institutional Facility or clinic where the ~~Remote Dispensing Site~~ 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 ~~remote~~ Shared Pharmacy Services site.

(iv) ~~Remote~~ Shared Pharmacy Services Pharmacies ~~and Remote Dispensing Sites~~ shall have adequate security to:

(A) comply with federal and state laws and regulations; and

(B) protect the confidentiality and integrity of Protected Health Information;

~~(v) The Coordinating Pharmacy shall have procedures that specify that Drugs may only be Delivered to the Remote Pharmacy or Remote Dispensing Site in accordance with the policies and procedures of the Coordinating Pharmacy.~~

~~(7)~~(5)Policies and Procedures

(i) 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 ~~only~~ those portions of the joint policies and procedures that relate to that participant's operations. The policies and procedures shall:

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

(B) include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in Shared Pharmacy Services; and

(C) 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 that Pharmacy;

(-b-) protecting the confidentiality and integrity of Protected Health Information;

~~(D)~~ (-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;

~~(E)~~ (-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;

~~(F)~~ (-e-)complying with federal and state laws; and

~~(G)~~ (-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.

~~The Coordinating Pharmacy, Remote Pharmacy, and Remote Dispensing Site shall operate in compliance with written policies and procedures that are established by the Coordinating Pharmacy. The policy and procedure manual shall include, but not be limited to, the following:~~

~~(A) a current list containing the name and business address of the Pharmacist-in-Charge and personnel designated by the Pharmacist-in-Charge to have access to the area where Drugs are stored at the Remote Pharmacy or Remote Dispensing Site;~~

~~(B) duties that may only be performed by a Pharmacist;~~

~~(C) a copy of the written agreement between the Coordinating Pharmacy and the Remote Pharmacy or between the Coordinating Pharmacy and the Institutional Facility or clinic where the Remote Dispensing Site is located. Such contract or agreement is not required if the Remote Pharmacy or Remote Dispensing Site are under common control or ownership of the Coordinating Pharmacy;~~

~~(D) date of last review and revision of policy and procedure manual; and~~

~~(E) policies and procedures for:~~

~~(-a-) operation of the video/auditory communication system;~~

~~(-b-) security;~~

~~(-c-) sanitation;~~

~~(-d-) storage of Drugs;~~

~~(-e-) Dispensing;~~

~~(-f-) supervision;~~

~~(-g-) Drug procurement, receipt of Drugs, and Delivery of Drugs.~~

~~1. Drugs may only be Delivered to the Remote Pharmacy or Remote Dispensing Site in a sealed container with a list of Drugs Delivered.~~

2. ~~Drugs Delivered to the Remote Pharmacy or Remote Dispensing Site must be checked by personnel designated by the Pharmacist-in-Charge to verify that the Drugs sent were actually received. The designated Person who checks the order shall document the verification by signing and dating the list of Drugs Delivered.~~

~~(h) Record keeping.~~

~~(ii) A Coordinating Pharmacy providing pharmacy services at a Remote Pharmacy or Remote Dispensing Site shall, at least annually, review and revise as necessary its written policies and procedures, and document such review.~~

~~(iii) A Coordinating Pharmacy providing pharmacy services at a Remote Pharmacy or Remote Dispensing Site shall maintain a written plan for recovery from an event that interrupts the ability of a Pharmacist to electronically supervise the Dispensing of Drugs at the Remote Pharmacy or Remote Dispensing Site. The written plan for recovery shall include:~~

~~(A) a statement that Drugs shall not be Dispensed at the Remote Pharmacy or Remote Dispensing Site if a Pharmacist is not able to electronically supervise such Dispensing;~~

~~(B) procedures for response when the video/auditory communication system is experiencing downtime; and~~

~~(C) procedures for the maintenance and testing of the written plan for recovery.~~

~~(iv) All policies and procedures must be maintained and made available for inspection by the Board in the Coordinating Pharmacy responsible for the Automated Pharmacy System and at the Remote Pharmacy or Remote Dispensing Site where the Automated Pharmacy System is being used.~~

~~(8) Quality Assurance~~

~~(i) A Coordinating Pharmacy that provides pharmacy services via a Remote Pharmacy or Remote Dispensing Site shall operate according to a written program for quality assurance that:~~

~~(A) requires continuous supervision of the Remote Pharmacy at all times the site is open to provide pharmacy services;~~

~~(B) requires a Pharmacist of the Coordinating Pharmacy to be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Remote Pharmacy or from the Automated Pharmacy System located at the Remote Dispensing Site; and~~

~~(C) establishes procedures to test the operation of all Automated Pharmacy Systems and all video/auditory communication systems at a minimum of every six months and whenever any upgrade or change is made to the system and document the testing of each such system.~~

~~(9)~~(6)Individual Practice

(i) Nothing in this Section shall prohibit an individual Pharmacist licensed in the State, who is an employee of or under contract with a Pharmacy, or a licensed Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern, working under the supervision of the Pharmacist, from accessing that Pharmacy's electronic database from inside or outside the Pharmacy and performing the Prescription Drug Order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:

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

(B) ~~none~~ no part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database. ~~Record Keeping~~

~~(i) Required Records~~

~~(A) A Coordinating Pharmacy shall keep a record of all Drugs received, Dispensed, and Distributed from the Coordinating Pharmacy.~~

~~(B) A Coordinating Pharmacy shall keep a record of all Drugs received, Dispensed, and Distributed from each Remote Pharmacy or Remote Dispensing Site.~~

~~(C) All records of receipt, Dispensing, and Distribution shall be kept at the Coordinating Pharmacy. Coordinating Pharmacy, Remote Pharmacy, and Remote Dispensing Site records must be kept separate from each other.~~

~~(ii) Inventory~~

~~(A) A Coordinating Pharmacy shall keep a perpetual inventory of controlled substances, and other Drugs required to be inventoried according to state and federal law, that are held in the Coordinating Pharmacy, each Remote Pharmacy, and each Remote Dispensing Site.~~

~~(B) A Coordinating Pharmacy shall conduct an annual non-controlled substance Drug inventory at the Coordinating Pharmacy and at each Remote Pharmacy or Remote Dispensing Site.~~

~~(C) All inventory records shall be kept at the Coordinating Pharmacy. The Coordinating Pharmacy, Remote Pharmacy, and Remote Dispensing Site inventory records must be kept separate from each other.~~

(p) Automated Pharmacy Systems

Automated Pharmacy Systems can be utilized in licensed pharmacies~~,~~ and Shared Pharmacy Services ~~Remote~~ Pharmacies~~, and Remote Dispensing Sites~~ located within an Institutional Facility or clinic. A Pharmacist is not required to be physically present at the site of the Automated Pharmacy System if the system is supervised electronically by a Pharmacist. Automated Pharmacy Systems shall comply with the following provisions.

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

(i) name and address of the Pharmacy ~~(or Coordinating Pharmacy)~~ and the Shared Pharmacy Services Pharmacy ~~Remote Pharmacy or Remote Dispensing Site~~ where the Automated Pharmacy System(s) is being used;

(ii) Manufacturer's name and model;

(iii) description of how the Device is used;

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

(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 are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacy practice.
   (i) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.
   (ii) Any Pharmacy ~~(or Coordinating Pharmacy)~~ that maintains an Automated Pharmacy System for the purposes of remote Dispensing to outpatients shall maintain a video/auditory communication system to provide for effective communication between the Shared Pharmacy Services Pharmacy~~Remote Pharmacy or Remote Dispensing Site~~ 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 Shared Pharmacy Services Pharmacy ~~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 ~~(or Coordinating Pharmacy)~~ responsible for the Automated Pharmacy System and at the Shared Pharmacy Services Pharmacy~~Remote Pharmacy or Remote Dispensing Site~~ where the Automated Pharmacy System is being used.

(4) Automated Pharmacy Systems shall have adequate security systems and procedures, evidenced by written policies and procedures, 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.

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

(8) The filling/stocking of all medications in the Automated Pharmacy System shall be accomplished by qualified personnel under the supervision of a licensed Pharmacist.
(9) A record of medications filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.
(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.
(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.

~~(q) Centralized Prescription Processing and Filling~~

~~(1) A Pharmacy may perform or outsource Centralized Prescription Filling or Centralized Prescription Processing services provided the parties:~~
~~(i) have the same owner; or~~
~~(ii) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and State laws and regulations; and~~
~~(iii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a Prescription Drug Order.~~

~~(2) The parties performing or contracting for Centralized Prescription Processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Board for review upon request and that includes, but is not limited to, the following:~~
~~(i) a description of how the parties will comply with federal and State laws and regulations;~~
~~(ii) the maintenance of appropriate records to identify the responsible Pharmacist(s) in the Dispensing and counseling processes;~~
~~(iii) the maintenance of a mechanism for tracking the Prescription Drug Order during each step in the Dispensing process;~~
~~(iv) the maintenance of a mechanism to identify on the prescription label all Pharmacies involved in Dispensing the Prescription Drug Order;~~
~~(v) the provision of adequate security to protect the integrity and prevent the illegal use or disclosure of Protected Health Information;~~
~~(vi) the maintenance of a Continuous Quality Improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.~~

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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 services until such a time in which provisions for multi-state practice exist.

Background:

The committee discussed and agreed on the vast majority of the task force's recommended revisions regarding replacing technology-specific language with the shared services conceptual language. The committee voiced concern regarding accountability in regard to the practice of multi-jurisdictional shared services and agreed that the best method to ensure this would be to require the pharmacist-in-charge to possess licenses in those states in which services were being performed and recommended to add a comment that this would be required until such time in which provisions for a multi-state licensure system are in place.

LE/L Recommendation 2: The Committee Recommends Approval of the Amendments to the *Model Act* Suggested by the Task Force on Internet Pharmacy Practice, 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~~.

Article III

Licensing of Individuals

Introductory Comment to Article III

Article III of the Model Act *specifies the requirements for initial licensure of Pharmacists, transfer of licensure, and renewal of licenses and registrations. In each of these areas, the Act sets forth basic Criteria and delegates to the Board the authority for implementing those Criteria. The Board does this by utilizing appropriate administrative enforcement mechanisms and by the issuance of specific rules.*

Section 301 establishes the basis for this Article by making it unlawful for any unlicensed Person to engage in the Practice of Pharmacy, and by enabling the Board to exact penalties for unlawful practice.

In the area of initial licensure (Section 302), the Board must implement the Act by approving degree programs of Pharmacy, by specifying the examination to be employed (Section 302[b]), by establishing Pharmacy practice experience standards (Section 302[c]), and by ensuring that all other prerequisites are met by each applicant to whom it issues a license.

The Act also reflects the efforts of NABP to continue uniform standards for transfer of licensure (Section 303).

Section 301. Unlawful Practice.

(a) Except as otherwise provided in this Act, it shall be unlawful for any individual, whether located in or outside this State, to engage in the Practice of Pharmacy in this State unless currently licensed to practice under any facet of the provisions of this Act.

(b) The provision of Pharmacist Care services to an individual in this State, through the use of telecommunications, the Internet, or other technologies, regardless of the location of the pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.

(1) Licensed Pharmacies located outside this State that provide Pharmacist Care services to individuals in this State must be licensed within this State under Article V of this Act.

(2) Pharmacists located outside this State who are providing Pharmacist Care services outside of a licensed Pharmacy to individuals located in this State must register with this State to engage in the nonresident Practice of Pharmacy.

(c) Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

(d) It shall be unlawful for any individual to perform the activities of a Certified Pharmacy Technician or Pharmacy Technician unless currently registered to do so under the provisions of this Act.

(e) (1) The Board may in its own name issue a Cease and Desist order to stop an individual from engaging in an unauthorized Practice of Pharmacy.

(2) Except as otherwise indicated in this Act, any individual who, after due process~~after a hearing~~, shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy shall be subject to a Fine to be imposed by the Board not to exceed $____ for each offense. Each such violation of this Act or the rules promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this State.

(3) Except as otherwise indicated in this Act, any individual who, after due process ~~after a hearing~~, shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy that resulted in harm to an individual shall be subject to a Fine to be imposed by the Board not to exceed $____ for each offense. Each such violation of this Act or the rules promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy that resulted in harm to an individual shall also constitute a felony punishable upon conviction as provided in the criminal code of this State.

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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 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 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;
~~(11)~~(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;
~~(12)~~(13) failing to pay the costs assessed in a disciplinary hearing pursuant to Section 213(c)(9);
~~(13)~~(14) engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of any licensing examination;
~~(14)~~(15) being found by the Board to be in violation of any of the provisions of this Act or rules adopted pursuant to this Act;
~~(15)~~(16) illegal use or disclosure of Protected Health Information;
~~(16)~~(17) failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.

…

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) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;
(3) Pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided; and
(4) Pharmacy Benefits Managers.

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.

…

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;
~~(6)~~(7) dealing with Drugs or Devices that he or she knows or should have known are Counterfeit, Contraband, or stolen Drugs or Devices;
~~(7)~~(8) purchasing or receiving a Drug or Device from a source other than a Person or Pharmacy licensed under the laws of the State, except where otherwise provided;
~~(8)~~(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.
~~(9)~~(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;
~~(10)~~(11) Wholesale Drug Distributors other than pharmacies Dispensing or Distributing Drugs or Devices directly to patients;
~~(11)~~(12) violations of any of the provisions of this Act or of any of the Rules adopted by the Board under this Act; or
~~(12)~~(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 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 ~~written~~ 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 ~~maintain on file~~ 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; and
    (iv) general reference.
  (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 the 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. ~~post on its Web site, the Pharmacy owner's name and the type of services offered.~~

…

Background:

The committee agreed with the task force's recommendations with minimal revisions. The members discussed whether Internet pharmacies should be required to be Verified Internet Pharmacy Practice Sites[CM] accredited, but ultimately decided that a board-approved accreditation program would be sufficient to protect the public, thus allowing the boards to make the final determination.

LE/L Recommendation 3: The Committee Recommends Approval of the Amendments to the NABP Position Paper on the Return and Reuse of Prescription Medications and the *Model Act*, Suggested by the Task Force on Drug Return and Reuse Programs, 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~~.

National Association of Boards of Pharmacy Position Statement on the Return and Reuse of Prescription Medications ~~in the Community Pharmacy Setting~~

July 2009, Revised October 2012

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

NABP, in keeping with its mission statement, is addressing the ~~increasingly frequent question~~ issue of whether previously dispensed prescription medications,[1] ~~in the community pharmacy setting,~~ can be safely returned and reused. The position statement separates this issue by addressing the circumstances in both the community setting and in state-mandated repository programs under which previously dispensed medications may be redispensed to patients. Some of NABP's member state boards of pharmacy ~~may approve, and~~ have already enacted regulations ~~approved~~ for return and reuse programs, and NABP strongly encourages those members and members yet to enact regulations to require such programs ~~when it is~~ to demonstrate that the integrity and stability of the medication is maintained, that the medication has not been tampered with, and that the process results in ~~the~~ dispensing ~~of~~ safe medications to patients.

This issue has come to the forefront due to the increase in the quantities of prescription medications that have been prescribed and dispensed and that, ultimately, are not used by patients. As the integrity of previously dispensed prescription medications must always be scrutinized, NABP encourages stakeholders to develop methods that will minimize the amount of unused medications. Collaboration among health care providers and payers is key to this initiative.

[1] At this time, controlled substances may not be included in any return and reuse program in order to comply with existing federal and/or state laws that prohibit the transfer of controlled substances to any person other than for whom it was prescribed.

Equally vital is educating health care providers on the importance of prescribing and dispensing appropriate quantities, particularly limiting quantities for acute therapy and in the initiation of chronic therapy. As today's pharmacists are taking a greater role in their patients' health care regimens, utilizing medication therapy management as a tool to closely monitor and control the use of automatic refills is extremely important. By reviewing the necessity of and quantities dispensed for automatic refills, as well as effectually interacting with patients to determine the appropriateness of whether a prescription should be automatically refilled, pharmacists can play a significant role in decreasing the amount of unused prescription medication that is dispensed.

Community Setting

NABP endorses the return and reuse of medications that have been maintained in a closed system that ensures the integrity of the medication. A closed system is defined as the delivery to and/or the return of prescription medication from a health care or other institutional facility, which is maintained in a controlled environment under the control of a health care practitioner and not the patient.

A closed distribution system enables the pharmacy to ensure that the integrity of the medications dispensed is intact, as they have not left the control of the pharmacy or institutional facility and the control of the medication is under the direction of a health care practitioner.

The components of a closed distribution system in a community pharmacy setting for the return and reuse of medications include ~~A safe return and reuse protocol in the community pharmacy setting may include,~~ but are not limited to, the following elements:

- Returned and reused medications refer to those medications that have been removed from the pharmacy for delivery by pharmacy staff, a pharmacy contracted delivery service, or an approved common carrier, and returned because the product is not deliverable or the patient refuses delivery, and such medications have not left the control of the pharmacy staff, pharmacy contracted delivery service, or approved common carrier. ~~Medications that have been delivered to the patient cannot be returned and reused.~~
- If a pharmacy attempts, but is not able, to deliver prescription medications using its own staff or its own local delivery service, then such prescription medications may be returned and reused by the pharmacy if:

- packaged in:
  - (A) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use*, or unit dose packaging; or
  - (B) the dispensing pharmacy's original packaging; and
- returned to the pharmacy ~~immediately~~ on the same day after the unsuccessful delivery attempt.

- If a pharmacy attempts, but is not able, to deliver prescription medications using an approved common carrier, then such prescription medications may be returned and reused by the pharmacy if:
  - packaged in:
    - (A) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use*, or unit dose packaging; or
    - (B) the dispensing pharmacy's original, sealed, and tamper-evident packaging, ~~if the pharmacy demonstrated to the board of pharmacy~~ that ~~such packaging~~ maintains the product quality as per United States Pharmacopeia (USP) standards.~~; and~~
  - ~~returned to the pharmacy within 14 days of the unsuccessful delivery attempt.~~ returned to the pharmacy on the same day after the unsuccessful delivery attempt.
- All returned packaging must indicate ~~demonstrate~~ that the product's integrity and stability has been maintained. ~~(the pharmacy must furnish data from studies affirming the integrity and stability).~~
- ~~All returned prescription medications must have an expiration of at least six months from the date of return.~~
- All returned prescription medications must be evaluated by appropriate pharmacy staff to ensure such medications are not adulterated or misbranded. A state-licensed pharmacist must verify compliance with all of the above elements. ~~prior to re~~dispensing.~~.~~

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

Repository Programs

NABP does not endorse the reuse of medications that have left the closed distribution system as there is an inability to ensure the integrity of such drugs, which may place the public at risk. Repository program, for the purposes of this position statement, is defined as a program that is

established to receive previously dispensed medications and redispense such to qualified individuals and/or to facilitate the proper disposal of unacceptable medications in compliance with state and federal ~~environmental~~ regulations. NABP strongly encourages all repository programs ~~currently operated, state- mandated repository programs and repository programs yet to be implemented~~ to require the following:

- Repository programs should be registered with and under the jurisdiction of the board of pharmacy and should be subject to inspection;
- Repository programs must have written policies and procedures, which include at a minimum:
    - Qualifications of acceptable medications for reuse, which must include:
        - only non-controlled medications; and
        - were inspected and determined to be:
            - unadulterated;
            - unexpired; and
            - in unopened unit-dose or manufacturer's tamper-resistant original packaging;
    - Maintenance of a separate physical inventory;
    - Completion of a monthly expiration date review for all medications;
    - Prohibition of charging or accepting compensation for medications except for administrative or minimal dispensing fees;
    - Dispensing by a pharmacist or a practitioner within the practitioner's scope of practice; and
    - Record keeping, including the source and dispensation of all medication.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 105. Definitions.

…

(c6) "Repository Program" means a program that is established to receive previously dispensed medications and redispense such to qualified individuals and/or to facilitate the proper disposal of unacceptable medications in compliance with state and environmental regulations.

…

Article V
Licensing of Facilities

…

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) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;
(3) pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided; ~~and~~
(4) Pharmacy Benefits Managers~~.~~; and
(5) Repository Programs.
Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

…

Model Rules for the Practice of Pharmacy

…

Section 3. Pharmacy Practice.

…

(r) Return and reuse of Prescription Drugs
(1) Prescriptions Drugs may only be returned and reused providing that the Prescription Drugs:
(i) 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
(ii) Prescriptions Drugs were packaged in:
(A) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging; or
(B) the dispensing pharmacy's original packaging; and
(C) returned to the pharmacy immediately after the unsuccessful delivery attempt.
(iii) If a Pharmacy attempts, but is not able, to deliver Prescription Drugs using an approved common carrier, then such Prescription Drugs may be returned and reused by the Pharmacy if packaged in:

(A) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging; or

(B) the dispensing pharmacy's original, sealed, and tamper-evident packaging that maintains the product quality as per United States Pharmacopeia (USP) standards.

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

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

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

(s) Disposal of Controlled Substances

…

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

(1) 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.

(u) Medication Adherence Monitoring Services and Intervention Programs

…

Section 3(r)(1)(iii)(A). Comment.

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

Background:

The committee agreed with the revisions to the Position Paper as suggested by the Task Force on the Return and Reuse of Prescription Medications; however, the committee added some verbiage to clarify certain elements. Members discussed the length of time in which medications should be returned to the pharmacy after an unsuccessful delivery attempt and determined that in order to

ensure the integrity of any undelivered medications they should be returned to the pharmacy on the same day. Members also determined that it was necessary to clarify that the term "unit-of-use" did not include co-mingled, multi-medication compliance packs. Additionally, the committee agreed to clarify that the required monthly review was to ensure that all medications are not expired.

LE/L Recommendation 4: The Committee Recommends Amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* Pursuant to Resolution 108-7-12 to Address Appropriate Regulation for Prescriber Dispensing or Prescriber Drug Outlets.

The revisions pursuant to the Resolution are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

…

(u2) "Dispense" or "Dispensing" means the interpretation, evaluation, and implementation of a Prescription Drug Order, including the preparation, final verification, and Delivery of a Drug or Device to a patient or patient's agent in a suitable container appropriately labeled for subsequent Administration to, or use by, a patient.

…

Article V

Licensing of Facilities

...

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;

~~(2)~~(3)persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;

~~(3)~~(4)Pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided; and
~~(4)~~(5) Pharmacy Benefits Managers.
Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

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Model Rules for the Practice of Pharmacy

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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.
(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
(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:
(A) pharmacy name or dispensing practitioner's entity name;

(B) pharmacy telephone number;
(C) prescriber name;
(-a-) format as – "Prescriber: [prescriber name]."
(D) "fill date;"
(-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;
(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.
(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.

…

(g) Patient Records

(1) A patient record system shall be maintained by all Pharmacies <u>and dispensing Practitioners</u> 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 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
(vi) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

…

Section 501 (a)(2). Licensing. Comment.

Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, counseling, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

Background:

The committee discussed at length the prevalence of dispensing practitioners and the fact that, in some instances, a complete drug utilization review is not conducted and the patient may not be provided with adequate counseling. As some states have enacted laws and regulations that require dispensing physicians to register with the board of pharmacy, members agreed that all boards should enact licensing provisions for dispensing physicians in order for the boards to have enforcement oversight of these practices.

LE/L Recommendation 5: The Committee Recommends Amendments to the *Model Act* to Clarify Telemedicine Practices.

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

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 105. Definitions.

…

(u6) "Valid Patient-Practitioner Relationship" means the following have been established:

(1) a Patient has a medical complaint;
(2) a medical history has been taken;
(3) a face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate Practitioner Board; and
(4) some logical connection exists between the medical complaint, the medical history, and the physical examination and the Drug prescribed.

…

Section 105(u6). Comment.

A valid Patient-Practitioner Relationship includes a relationship with a consulting Practitioner or a practitioner to which a patient has been referred, or a covering Practitioner, or an appropriate Practitioner-Board-approved telemedicine Practitioner providing that a physical examination had been previously performed by the patient's primary Practitioner.

To best protect the public, the issue of a Valid Patient-Practitioner Relationship should be addressed in each jurisdiction's Medical Practice Act and the Consumer Fraud Protection Act or their equivalent.

A face-to-face physical examination is not required to establish a Valid Patient-Practitioner Relationship if:

(a) the prescribing practitioner is issuing a prescription or dispensing a non-controlled substance legend drug in accordance with the Expedited Partner Therapy in the Management of Sexually Transmitted Diseases Guidance document issued by the United States Centers for Disease Control and Prevention; or

(b) the prescription, administration, or dispensing is through a public health clinic or other distribution mechanism approved by the state health authority in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of a biological, chemical, or radiological agent; or

(c) the prescribing practitioner is issuing a prescription through a telemedicine practice approved by the appropriate state agency that provides health care delivery, diagnosis, consultation, or treatment by means of audio, video, or data communications. Standard telephone, facsimile transmission, or both, in the absence of other integrated information or data, do not constitute telemedicine practices.

Background:

Upon review by NABP staff, it was determined that the definition of "Valid Patient-Practitioner Relationship" should provide additional guidance on telemedicine practices. The committee agreed to the revisions, but determined that it should be clarified that only non-controlled substance legend drugs can be prescribed without a face-to-face physical examination to comply with the federal regulations pursuant to the Ryan Haight Act for Internet pharmacies.

LE/L Recommendation 6: The Committee Recommends that NABP Comment on the Drug Enforcement Administration (DEA) Notice of Proposed Rulemaking for the Disposal of Controlled Substances.

The LE/L Committee recommends that NABP should provide comments to DEA on the Notice of Proposed Rulemaking for the Disposal of Controlled Substances.

Background:

The committee reviewed the *Federal Register* notice containing DEA's Proposed Rulemaking for the Disposal of Controlled Substances drafted in accordance with the Secure and Responsible Drug Disposal Act. Members agreed that NABP should comment favorably on the proposed rulemaking as it fully addresses the issues surrounding the need for ultimate users to dispose of unwanted, unused controlled substances so as to prevent diversion, abuse, and accidental ingestion.