Report of the Committee on Law Enforcement/Legislation

NOTE: The NABP Executive Committee accepted all of the recommendations of this Committee with the exception of Recommendation 8:

- **Upon review of the information pertaining to the Recommendation, the Executive Committee determined that the language is necessary to address an exemption from non-applicable requirements and therefore the *Model Act* should be amended to include it.**

Members Present:

Patricia Donato, (NY), *chair*; Jeannine Dickerhofe (CO); Dorothy Gourley (OK); Chris Jones (GA); Caroline Juran (VA); Joli Martini (DE); Alice Mendoza (TX); Bradley Miller (TX), Lenora Newsome (AR), Joel Thornbury (KY), Dennis Wiesner (TX).

Others Present:

Susan Ksiazek, *Executive Committee Liaison*; Carmen A. Catizone, Eileen Lewalski, Maureen Schanck, *NABP staff*.

Introduction:

The Committee on Law Enforcement/Legislation met January 20 and 21, 2015, 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.

LE/L Recommendation 1: The Committee Recommends Approving 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 Standards for the Use of PMP Data, 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~~.

Appendix G

Model Prescription Monitoring Program Act

Section 1. Short Title.

This Act shall be known and may be cited as the Model Prescription Monitoring Program Act.

Section 2. Legislative Findings.

(Insert State-appropriate mission/purposes.)

Section 3. Purpose.

(Insert State-appropriate mission/purposes.)

Section 4. Definitions.

(a) "Dispenser" means a Person authorized in this State to distribute to the ultimate user a substance monitored by the Prescription Monitoring Program, but does not include:

(1) a licensed hospital or institutional facility Pharmacy that distributes such substances for the purposes of inpatient care[1];

(2) a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician;

(b) "Drug of Concern" means any prescription or over-the-counter medication that demonstrates a potential for abuse, particularly those identified by Boards of Pharmacy, law enforcement, and addiction treatment professionals.

(c) "Electronic Health Information Systems" means an electronic data intermediary, gateway, or hub that facilitates secure delivery of electronic health information to Practitioners or Dispensers, including:

(1) health information exchanges;

(2) health information networks;

(3) pharmacy software systems;

(4) electronic medical (health) record software applications; or

~~(5) emergency department software applications; or~~

~~(6)~~(5) electronic prescribing software applications.

(d) "Interoperability" means the sharing of Prescription Monitoring Program Information with another PMP, or the integration of Prescription Monitoring Program Information into the Electronic Health Information Systems.

(e~~c~~) "Prescription Monitoring Program Information" means information submitted to and maintained by the Prescription Monitoring Program.

(f~~d~~) "Prescription Monitoring Program (PMP)" means a program established under Section 5 of this Act.

Section 5. Establishment Of A Prescription Monitoring Program.

[1] This reporting exception also applies to situations where a patient, who has been dispensed controlled substance medications during a stay in an institutional facility, is allowed to retain any remaining medication upon discharge.

(a) The Board of Pharmacy shall establish and maintain an electronic system for monitoring all controlled substances in Schedules II through V, all State-specified controlled substances in Schedules II through V, and State-specified Drugs of Concern dispensed to patients in this State.

(b) The Board of Pharmacy may contract with a vendor to establish and maintain the electronic monitoring system pursuant to guidelines, which the Board of Pharmacy shall promulgate

(c) The Board of Pharmacy shall promulgate rules or establish policy to include the following:

(1) using the PMP to improve patient care and to facilitate the goal of reducing misuse, abuse, overdose, addiction to and diversion of controlled substances and drugs of concern;

(2) implementing security and safeguards necessary to ensure information is released only to authorized individuals;

(3) developing criteria for referring prescription monitoring information to a law enforcement agency;~~, professional licensing agency~~

(4) developing criteria for referring Prescription Monitoring Program Information to a licensing board, or other state or federal agency charged with the regulation of prescribing, dispensing, or administering a controlled substance or drug of concern;

(5) designing and implementing training, education, and/or instruction in the appropriate access to and use of the PMP;

(6) adopting the most recent version of the American Society for Automation in Pharmacy (ASAP) technical standards for electronic reporting of Prescription Monitoring Program Information; and

(7) incorporating technological improvements to facilitate the interoperability of the PMP with other state PMPs and Electronic Health Information Systems and to facilitate Prescribers' and Dispensers' access to and use of the PMP.

Section 6. Reporting Of Prescription Monitoring Program Information.

(a) Each Dispenser shall submit to the Board of Pharmacy, by electronic means, or other format specified in a waiver granted by the Board of Pharmacy, ~~at a minimum of every seven days)~~ within 24 hours, information specified by the Board of Pharmacy, including:

(1) ~~Drug Enforcement Administration~~ identification number of the Dispenser;

(2) ~~Drug Enforcement Administration~~ identification number of the Prescriber;[2]

(3) patient name, address, and telephone number ~~of the ultimate user~~;

(4) patient gender;

(5) patient date of birth;

(6) identification of the drug by a national drug code number;

(7) quantity dispensed;

(8) number of days supplied;

(9) number of refills ordered;

(10) whether drug was dispensed as a refill or as a new prescription;

(11) date ~~of dispensing~~ prescription was dispensed;[3]

(12) if a refill, date of the original dispensing; ~~and~~

(13) prescription number;

(14) date the prescription was issued by the Prescriber;

(15) method of payment for the prescription; and

(16) such other information as may be required by State law.

[2] It is recommended that boards of pharmacy consider using practitioners' NPI number for identification purposes

[3] It is recommended that the date prescription was dispensed be clarified to mean the date of delivery to the patient.

(b) Each Dispenser shall ensure that information reported to the PMP is correct and shall submit corrections when necessary.

(c) Each Dispenser shall reverse information for any prescription that was not dispensed.

Section 7. Access To Prescription Monitoring Program Information/Confidentiality.

(a) Except as indicated in paragraphs (b), (c), and (d) of this Section 7, Prescription Monitoring Program Information submitted to the Board of Pharmacy shall be considered Protected Health Information and not subject to public or open records laws.

(b) The Board of Pharmacy shall review the Prescription Monitoring Program Information. If there is reasonable cause to believe a violation of law (or breach of professional or occupational standards) may have occurred, the Board shall notify the appropriate law enforcement, or professional or occupational licensing, certification, or regulatory agency or entity, and provide Prescription Monitoring Program Information required for an investigation.[4]

(c) The Board of Pharmacy may provide Prescription Monitoring Program Information for public research, policy or education purposes, to the extent all information has been De-identified.

(d) The following persons may access the Prescription Monitoring Program Information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar Protected Health Information under federal and State law and regulation

(1) Practitioners (or agents thereof) or Dispensers (or agents thereof) who certify, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient, or verifying PMP information for prescriptions issued by practitioners;

(2) Boards of Pharmacy or vendors/contractors for the purpose of establishing and maintaining the Prescription Monitoring Program;

(3) other state licensing, certification, or regulatory agencies that license, certify, or regulate health care professionals authorized to prescribe, administer, and dispense controlled substances, which certify, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a reportable substance, and such information will further the purpose of the investigation or assist in the proceeding;

(4) local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authorities, which certify, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a reportable substance, and such information will further the purpose of the investigation or assist in the proceeding;

(5) other appropriate entities as determined by the Board of Pharmacy;[5] and

(6) Patients who certify, under the procedures determined by the State, that the requested information is for the purpose of obtaining and reviewing their own records.

(e) The Board of Pharmacy shall be immune from civil liability arising from inaccuracy of any of the information submitted to the Board of Pharmacy pursuant to this Act.

Section 8 Interoperability

[4] This section is intended to allow boards of pharmacy to evaluate Prescription Monitoring Program information and determine appropriate information to provide to law enforcement entities. It is not intended to allow law enforcement officials open access to all data.

[5] It is recommended that appropriate entities include drug courts, district attorneys' offices, addiction treatment professionals, or other similar entities, and only for the purpose of ensuring appropriate patient treatment, as opposed to efforts to search for information without knowledge of whether such information exists.

(a) The Board of Pharmacy shall execute a memorandum of understanding to participate in a single national hub capable of facilitating interoperability among Prescription Monitoring Programs and between Prescription Monitoring Programs and Electronic Health Information Systems.

(b) The Board of Pharmacy shall ensure that access to Prescription Monitoring Program Information by other state Prescription Monitoring Programs is limited to persons described in Section 7(d).

(c) The Board of Pharmacy shall establish the technological connectivity and infrastructure to facilitate the secure delivery of Prescription Monitoring Program Information to authorized users of Prescription Monitoring Programs through other states' Prescription Monitoring Programs or Electronic Health Information Systems.

(d) Any such gateway, hub, or any Electronic Health Information System that facilitates the integration of Prescription Monitoring Program Information into a patient's medical record shall:

(1) verify the identity of the individual requesting the Information;
(2) verify the credential of the individual requesting the Information;
(3) provide the Board of Pharmacy with an audit trail for each request; and
(4) maintain the security and confidentiality of such information.

Section 9~~8~~. Unlawful Acts And Penalties.

(a) A Dispenser who knowingly fails to submit Prescription Monitoring Program Information to the Board of Pharmacy as required by this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(b) A person who knowingly accesses or uses Prescription Monitoring Program Information without authorization in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(c) A person authorized to have Prescription Monitoring Program Information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(d) A person authorized to have Prescription Monitoring Program Information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

Section 10~~9~~. Evaluation, Data Analysis, And Reporting.

(a) The Board of Pharmacy shall design and implement an evaluation component to identify cost benefits of the Prescription Monitoring Program, and other information relevant to policy, research, and education involving substances monitored by the PMP.

(b) The Board of Pharmacy shall report to the (insert appropriate State decision makers, eg, legislature) on a periodic basis, no less than bi-annually, about the cost-benefits and other information noted in paragraph (a).

Section 11~~10~~. Rules And Regulations.

The Board of Pharmacy shall promulgate rules and regulations necessary to implement the provisions of this Act.

Section 12~~11~~. Severability.

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section 13~~12~~. Effective Date.

This Act shall be effective on (insert specific date or reference to normal State method of determination of the effective date).

Background:

The committee discussed and agreed with the task force's recommended definition for "Electronic Health Information Systems" except for having a separate provision for emergency department software applications as members determined this is incorporated into electronic medical (health) record software applications. In regard to the section devoted to the establishing a PMP, the committee decided that the board should establish a separate policy and procedure for referring cases to law enforcement when warranted, but decided to remove "professional licensing agency" as members considered it to be ambiguous and that "licensing board" in the new Section 5(c)(4) was duplicative.

Concerning the task force's recommended additional reporting criteria, the committee agreed with the additions; however, members determined to add a footnote to stress the importance of clarifying that "date prescription was dispensed" means the date of drug delivery to patient. Furthermore, the committee also stressed the need for a uniform identification number for prescribers that will also encompass prescribers such as veterinarians, who are not issued National Provider Identifier (NPI) numbers but decided that the NPI was currently the best option. Lastly, the committee agreed with the task force's recommendation for a definition and new section for "Interoperability" after minimal discussion.

LE/L Recommendation 2: The Committee Recommends Approval of the Amendments to the *Model Act* Suggested by the Task Force on Medication Synchronization, 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

…

Section 105. Definitions.

…

~~(a4)~~ "Medication Synchronization" refers to a component of Medication Therapy Management that ~~provides~~ recognizes the authority of the pharmacist, at the patient's direction, ~~for the pharmacis~~t to proactively adjust the medication quantity or refill schedule and ~~engage in proactive communication and the authority to provide the patient with a one-time synchronization refill~~, to manage a patient's maintenance medications by ~~and~~ coordinating ~~e~~ the ~~dosing~~ refill schedules to improve patient outcomes. ~~unless deemed inappropriate by the prescribing Practitioner.~~

(See comment list.)

(b4) "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(a4). 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. It is recommended that p~~P~~atients receive their synchronized refills by regular 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,~~ and improving patient outcomes, Medication Synchronization may also offer Pharmacies a mechanism to improve workload and inventory control. Other demonstrated ~~possible~~ advantages of medication synchronization include minimization of overall health costs and increased convenience for patients.

Medication Synchronization extends the pharmacist's authority to adjust medication use and quantities, not to exceed the total quantity prescribed or what is otherwise allowed by law.

"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 maintenance medications (excluding controlled substances (Schedules II-V) or those designated "as

needed") 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, but are not limited to, heart failure, depression, chronic kidney disease, osteoporosis, Alzheimer's disease, chronic obstructive pulmonary disease, atrial fibrillation, cancer, asthma, and stroke.

Background:

The committee discussed and ultimately agreed with the task force's recommended revised definition of "Medication Synchronization" and its subsequent revision in the comment section, but suggested that medication synchronization while it involves regular appointments with the pharmacist, they may not necessarily be on a monthly basis. As such, members decided to amend the comment to the definition of medication synchronization by replacing "monthly" with "regular" appointments with the pharmacist. Additionally, the committee preferred to remove "maximizing health benefits" from the medication synchronization comment because members believed this claim, to date, has not been substantiated. Furthermore, the committee suggested that perhaps a comment could possibly be added to clarify that the new definition, while extending the pharmacist's authority to adjust medication use and quantities, should adhere to the medication regimen or what is otherwise allowed by law. Lastly, since some states consider all prescription drugs to be "controlled substances," committee members expressed the importance of delineating that the controlled substance exclusion only applies to controlled substances in Schedules II-V.

LE/L Recommendation 3: The Committee Recommends Approval of the Amendments to the *Model Act* Suggested by the Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts, with Revisions.

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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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) Possess the following 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[6] in each of the following 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.[7]
  (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.~~

[6] Boards may wish to give examples in each of these categories of reference texts.
[7] Patient-oriented reference material can include publications such as Facts and Comparisons' Patient Drug Facts, or the United States Pharmacopoeia Dispensing Information (USPDI).

~~(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)~~(8) 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)~~ (9) 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)~~(10) 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 the Pharmacist-in-Charge.

Section 2. Security.

~~(8) Security.~~

(a) Facility

(~~i~~1) Each Pharmacist, while on duty, shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.

(~~ii~~2) The Pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the Pharmacist is not present. Such barrier shall be approved by the Board of Pharmacy before being put into use. In the event of separation of employment of an employee due to any confirmed Drug-related reason, including diversion, or other acts involving dishonesty, suitable action shall be taken to ensure the security of the pharmacy.

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

(4) The Pharmacy shall implement and maintain technologies that will aid in theft prevention and suspect apprehension, ~~including but not limited to~~ that may include:
(i) Video equipment positioned to identify individuals who may be involved in diversion or theft, if utilized, shall have adequate recording, storage, and retrieval capabilities; and.
(ii) monitored alarm system with backup mechanism.

(b) Internal Theft/Diversion

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

(i) inspection of shipments;
(ii) receipt verification oversight and checking in shipments;
(iii) reconciliation of orders; and
(iv) inventory management including:
(A) determination of 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.

Section 3. 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:[8]

(A) Policies and procedures addressing the following:

(-a-) the provision of Pharmacy services;[9]

(-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[10];

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

[9] 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.

[10] 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.

(-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.

(-i-) actions to be taken to prevent and react to pharmacy robberies and thefts, including but not limited to coordinating with law enforcement, training, mitigation of harm, and protecting the crime scene.

(-j-) the PIC shall have policies and procedures in place that restrict and monitor control over and access to the locks, barriers, and systems used to secure the pharmacy and pharmacy systems in accordance with state laws and regulations.

(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

(C) Quality assurance programs addressing the following:

(-a-) Pharmacy services. The quality assurance program should be designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

(-b-) Automated Pharmacy Systems. The quality assurance program should monitor the performance of the Automated Pharmacy System, ensure the Automated 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.[11]

[11] 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:~~

- ~~inspection of shipments;~~
- ~~receipt verification oversight and checking in shipments;~~
- ~~reconciliation of orders; and~~

(ii) Ensuring that:
  (A) 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[12] 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;
  (E) permanent closing of the Pharmacy;
  (F) Significant Quality-Related Events;
  (G) the installation or removal of Automated Pharmacy Systems. Such notice must include, but is not limited to:
    (-a-) the name and address of the Pharmacy;
    (-b-) the location of the Automated Pharmacy System; and
    (-c-) the identification of the responsible Pharmacist.
    (-d-) Such notice must 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.

- ~~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.~~

~~T~~the Pharmacist-in-Charge, if the practice setting warrants, may also consider implementing diversion prevention and detection policies and procedures that address the following: periodic reviews of employee access to any secure controlled substance storage areas, which may include:

- alarm codes and lock combinations;
- passwords; and
- keys and access badges.
- ~~video surveillance systems.~~

[12] 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.

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

(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.

Background:

The committee unanimously agreed with the task force's conclusion that pharmacy security should be paramount, and therefore a separate security section should be created in the *Model Act* to address it. However, there was significant discussion between members about the requirement to maintain a monitored alarm system with backup mechanism as well as video surveillance. Members noted that, for pharmacies in rural settings, this security requirement can pose an undue burden since such technologies may not be readily available to them. The committee members recommended that, in addition to the policies and procedures already listed, the PIC should also be required to have policies and procedures for monitoring and guarding access to locks, barriers, and other diversion prevention mechanisms in the pharmacy.

The committee also agreed with the task force's recommendation of having a separate policy and procedures requirement for actions to be taken to prevent and react to pharmacy robberies and thefts. However, the committee further recommended that the policy also include "mitigation of harm" as a point of inclusion. Lastly, the committee also discussed that, although the *Model Act* states that the PIC should inform the board within 10 days of any emergency, disaster, or calamity when such an event causes the pharmacy to cease operation, the PIC should make every effort to notify the board as soon as possible.

LE/L Recommendation 4: The Committee Recommends Approval of Proposed Amendments to the *Model Act* Pursuant to Resolution 110-5-14 Regarding Veterinary Pharmacy Education.

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

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) Possess the following 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[13] in each of the following categories, <u>if applicable to the services provided:</u>

(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~~ <u>veterinary drugs[14]; and</u>

(v) <u>general</u>

(4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.[15]

(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.

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

[14] <u>Such as Plumb's Veterinary Drug Handbook</u>

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

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 the Pharmacist-in-Charge.

Background:

Members discussed Resolution 110-5-14 Veterinary Pharmacy Education, which reads:

> **WHEREAS,** pharmacists are recognized as the experts in pharmacology and appropriate drug therapy; and
>
> **WHEREAS,** evolving pharmacist practice includes providing medication therapy for both human and veterinary patients; and
>
> **WHEREAS,** a substantial opportunity exists for increasing veterinary pharmacist care and education in pharmacy practice;
>
> **THEREFORE BE IT RESOLVED** that NABP encourage the development and availability of veterinary pharmacology education at colleges and schools of pharmacy in collaboration with schools of veterinary medicine.
>
> **BE IT FURTHER RESOLVED** that pharmacists dispensing medications for veterinary patients possess the competence and have access to resources necessary to appropriately dispense and provide care.

The committee members agreed that, in order to fulfill the mandate of the resolution, an additional facility requirement for a veterinary drug therapy reference should be required for pharmacies that dispense drugs for veterinary patients. The committee was mindful of the monetary cost of acquiring such reference material. Therefore, the committee wished to clarify that this requirement should only apply to pharmacies that engage in veterinary drug dispensing.

LE/L Recommendation 5: The Committee Recommends Approval of Proposed Amendments to the *Model Act* Pursuant to Footnotes in the *Model Act* Indicating That, by 2015, the *Model Act* Will Be Amended to Require That All Pharmacy Technicians Be Certified.

Recommended revisions by NABP staff 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 Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 103. Statement of Purpose.

It is the purpose of this Act to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the Practice of Pharmacy; the licensure of Pharmacists; the registration of Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates; the licensure, control, and regulation of all sites or Persons, in or out of this State, that Distribute, Manufacture, or sell Drugs (or Devices used in the Dispensing and Administration of Drugs), within this State, and the

Section 105. Definitions.

(p) "Certified Pharmacy Technician"[16] means personnel registered with the Board who have completed a certification program approved by the Board and may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as:

(1) receiving new written or electronic Prescription Drug Orders;
(2) prescription transfer;
(3) Compounding; and
(4) assisting in the Dispensing process; and
(5) performing all functions allowed to be performed by certified pharmacy technician~~s~~ candidates

but excluding:

(1) Drug Utilization Review (DUR);
(2) clinical conflict resolution;
(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
(4) Patient Counseling; and
(5) Dispensing process validation.

(q) "Certified Pharmacy Technician Candidate"[17] ~~-~~means personnel registered with the Board who intend to complete a certification program approved by the Board and ~~who~~ may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as:

(1) assisting in the Dispensing process;
(2) processing of medical coverage claims;
(3) stocking of medications; and

[16] The *Model Act* defines Certified Pharmacy Technician and Certified Pharmacy Technician Candidate separately to distinguish between the activities that can be performed. A Certified Pharmacy Technician is recognized, because of the completion of a Board-approved certification program, as having knowledge and skills that qualify them to assist the Pharmacist in the Practice of Pharmacy with limited patient care tasks that exceed routine Dispensing or Drug storage activities. Certified Pharmacy Technician~~s~~ Candidates are limited to routine Dispensing activities, Drug storage, medical coverage claims processing, and cashiering.

[17] ~~The term Pharmacy Technician will continue to be utilized until 2015. At that time, the Model State Pharmacy Act and Model Rules will be amended to require that all Pharmacy Technicians be certified. The *Model Act* will also be amended at that time to replace the term Pharmacy Technician with the term Candidate for Certified Pharmacy Technician, which will be redefined to provide a path to certification for non-certified pharmacy technicians. A one-time renewal of the Certified Pharmacy Technician Trainee registration will be allowed.~~

(4) cashiering
but excluding:
(1) Drug Utilization Review (DUR);
(2) clinical conflict resolution;
(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
(4) Patient Counseling;
(5) Dispensing process validation;
(6) prescription transfer; and
(7) receipt of new oral Prescription Drug Orders.

…

~~(a5) "Pharmacy Technician" means personnel registered with the Board who may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as:~~
~~(1) assisting in the Dispensing process;~~
~~(2) processing of medical coverage claims;~~
~~(3) stocking of medications; and~~
~~(4) cashiering~~
~~but excluding:~~
~~(1) Drug Utilization Review (DUR);~~
~~(2) clinical conflict resolution;~~
~~(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;~~
~~(4) Patient Counseling;~~
~~(5) Dispensing process validation;~~
~~(6) prescription transfer; and~~
~~(7) receipt of new oral Prescription Drug Orders.~~

…

Comments

Section 104. Comment.

The definition of the "Practice of Pharmacy" is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Additionally, the definition limits certain activities to performance by Pharmacists only, while allowing qualified personnel to assist Pharmacists in practice. That distinction is noted by listing activities that must be performed by the Pharmacist, such as the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; Patient Counseling; Pharmacist Care; and other tasks that the Pharmacist has responsibility for, such as Compounding and Labeling of Drugs and Devices; the proper and safe storage of Drugs and Devices, and maintenance of proper records. The deliberate distinction between the terms "must perform" and "is responsible for" intends to allow delegation of tasks to Certified Pharmacy Technicians or Certified Pharmacy Technician~~s~~ Candidates.

…

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[18]:

(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[19];

(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~~ Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates;

…

Section 301. Unlawful Practice.

…

(b) It shall be unlawful for any individual to perform the activities of a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate unless currently registered to do so

…

Section 304. Renewal of Licenses and Registrations.

(a) Each Pharmacist, Pharmacy Intern, and Certified Pharmacy Technician~~,~~ ~~and Certified Pharmacy Technician Candidate~~ shall apply for renewal of his or her license annually [or at such interval determined by the Board], no later than the first day of _____. A Pharmacist or Pharmacy Intern who desires to continue in the Practice of Pharmacy in this State shall file with the Board an application in such form and containing such data as the Board may require for renewal of the license. If the Board finds that the applicant has been licensed, and that such license has not been Revoked or placed under Suspension, that

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[18] 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).

[19] Great care should be exercised by the Boards with respect to this Section. Many states have statutes or rules which provide that approved or accredited degree programs of schools or colleges of Pharmacy are those approved by the Accreditation council for pharmacy education (ACPE).

It is a well-established rule of administrative law that any delegation of governmental power must carry with it appropriate limitations and procedural safeguards for affected individuals. Thus, a direct, unequivocal grant of the accreditation function to a private organization, such as ACPE, might be deemed an unauthorized, improper, and invalid delegation of Board or legislative authority. An NABP study of this question discovered at least one case where a court overturned a Board action based upon such invalid delegation to a private body. See Garces v Department of Registration and Education, 254 N.E.2d 622 (Ill, 1969).

NABP urges all Boards to adopt, in their Rules, the Standards of Accreditation established from time to time by the ACPE, the nationally recognized accrediting agency for Pharmacy degree programs.

the applicant has attested that he or she has no criminal convictions or arrests, has paid the renewal fee, has continued his or her Pharmacy education in accordance with the rules of the Board, and is entitled to continue in the Practice of Pharmacy, the Board shall issue a license to the applicant.

(b) If a Pharmacist fails to make application to the State Board of Pharmacy for renewal of his or her license within a period of three years from the expiration of his or her license, he or she must pass an examination for license renewal; except that a Person who has been licensed under the laws of this State and after the expiration of his or her license, has continually practiced Pharmacy in another State under a license issued by the authority of such State, may renew his or her license upon payment of the designated fee.

(c) Certified Pharmacy Technician Candidates must complete requirements for Certified Pharmacy Technician licensure/registration within ~~(1) one renewal period~~ 12 months. For good cause shown, the Board may approve one12-month extension.

Section 307. Registration of Certified Pharmacy Technicians.

(a) In order to be registered as a Certified Pharmacy Technician in this State, an applicant shall:[20]
- (1) have submitted an application in the form prescribed by the Board of Pharmacy;
- (2) have attained the age of _____;
- (3) have good moral character;
- (4) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;
- (5) have[21]:
  - (i) graduated from a competency-based ~~certified~~ pharmacy technician education and training program approved by the Board of Pharmacy;[22] ~~or~~
  - (ii) been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific, competency-based education and training program approved by the Board of Pharmacy;[23]
- (6) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;
- (7) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and
- (8) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the registration.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician.[24]

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Certified Pharmacy Technicians.

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[20] In 2015, the *Model State Pharmacy Act and Model Rules* ~~will be~~ was amended to require persons seeking to become Certified Pharmacy Technicians to complete each of the requirements outlined in Sections 307(a)(5)(i), 307(a)(5)(ii), and 307(a)(6).

[21] Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Certified Pharmacy Technician Candidate Certification Board examination as part of their assessment of technician competence to assist in the practice of pharmacy.

[22] It is recommended that states adopt this requirement, if not currently required, through a process that incorporates provisions for grandfathering.

[23] It is contemplated that Boards will approve those Certified pharmacy technician Candidate training programs whose standards are at least equivalent to the minimum standards being developed by an accrediting organization recognized by state Boards, such as ACPE. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

[24] The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate under terms and conditions deemed appropriate.

Section 308. Registration of Certified Pharmacy Technicians~~s~~ Candidates.[25]

(a) In order to be registered as a Certified Pharmacy Technician Candidate in this State, an applicant shall:

(1) have submitted an application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of _____;
(3) have good moral character;
(4) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;
(5) have paid the fees specified by the Board; and
(6) have been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific training program and having successfully completed an objective assessment mechanism prepared in accordance with any rules established by the Board.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician Candidate.[26]

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Certified Pharmacy Technician~~s~~ Candidates.

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 Certified Pharmacy Technician~~s~~ Candidates 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.

…

Section 402. Grounds, Penalties, and Reinstatement.[27]

(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;[28]

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[25] ~~In 2015, the Model State Pharmacy Act and Model Rules will be amended to remove the term Pharmacy Technician and incorporate the term Candidate for Certified Pharmacy Technician, which will be redefined to provide a path to certification for non-certified pharmacy technicians. A one-time renewal of the Candidate for Certified Pharmacy Technician will be allowed.~~

[26] The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate under terms and conditions deemed appropriate.

[27] The penalties provided in Section 402 give the Board wide latitude to make the disciplinary action fit the offense. The "reasonable intervals" in 402(c) would be determined by the Board.

[28] It is particularly important to emphasize the need for specificity in defining the grounds upon which a Pharmacist's or Pharmacy Intern's license to practice Pharmacy, or a Certified Pharmacy Technician's or Certified Pharmacy Technician Candidate's registration to assist in the Practice of

…

(8) knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate 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;

…

(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 Certified Pharmacy Technician Candidate;

Section 403. Procedure.[29]

(a) Notwithstanding any provisions of the State Administrative Procedures Act, the Board may, without a hearing, Summarily Suspend a license for not more than 60 days if the Board finds that a Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate has violated a law or rule that the Board is empowered to enforce, and if continued practice by the Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate would create an imminent risk of harm to the public. The Suspension shall take effect upon written notice to the Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate specifying the statute or rule violated. At the time it issues the Suspension notice, the Board shall schedule a disciplinary hearing to be held under the Administrative Procedures Act within 20 days thereafter. The Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate shall be provided with at least 10 days notice of any hearing held under this subsection.

…

Model Rules for the Practice of Pharmacy

…

Section 2. Personnel.

(a) Duties and Responsibilities of the Pharmacist-in-Charge

Pharmacy, may be Revoked or Suspended. The term "unprofessional conduct" is particularly susceptible to judicial challenge for being unconstitutionally vague. Each offense included within the meaning of this term must be capable of being understood with reasonable precision by the Persons regulated so that it can be readily enforced and relied upon during disciplinary proceedings, and so that those regulated by it may easily conform their professional conduct to its meaning(s).

These potential problems make it essential for Boards to issue appropriate rules making the grounds for disciplinary action specific, understandable, and reasonable. In addition, the Boards must ensure that such rules are published for the benefit of all licensees within their jurisdiction. Only by doing so can Boards be assured of authority to take successful and meaningful disciplinary actions that will not later be overturned by the courts.

This section must be examined in light of other state laws since some states, for example, restrict the circumstances under which a license may be denied to an individual because of the commission of a felony. In addition, an individual who has been convicted of a felony or an act involving gross immorality and who has paid his debt to society has restored constitutional protections that may curtail a strict application of Section 402(a)(3).

[29] The procedures which must be followed before disciplinary action can be taken in many of the states are determined by the Administrative Procedures Act. The *Model Act* was drafted on the assumption that such an Act was in effect.

…

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

(i) Developing or adopting, implementing, and maintaining:[30]

(A) Policies and procedures addressing the following:

…

(-h-) the duties to be performed by Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates. The duties and responsibilities of these personnel shall be consistent with their 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 Certified Pharmacy Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

…

(ii) Ensuring that:

(A) all Pharmacists and Pharmacy Interns employed at the Pharmacy are currently licensed and that all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates 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[31] changes:

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

(B) the separation of employment of any Pharmacist, Pharmacy Intern, Certified Pharmacy Technician Candidate, or Certified Pharmacy Technician for any confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination: if it is the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder shall notify the Board of Pharmacy;

…

(3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists, Certified Pharmacy Technicians, and Certified Pharmacy Technician~~s~~ Candidates as may be required to competently and safely provide Pharmacy services.

(i) The Pharmacist-in-Charge shall maintain and file with the Board of Pharmacy, on a form provided by the Board, a current list of all Certified Pharmacy Technicians and Certified Pharmacy Technician~~s~~ Candidates assisting in the provision of Pharmacy services.

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

[31] 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.

(ii) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain written policies and procedures to specify the duties to be performed by Certified Pharmacy Technicians and Certified Pharmacy Technician~~s~~ Candidates. 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 Certified Pharmacy Technician~~s~~ Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technician~~s~~ Candidates shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

(iii) The Pharmacist-in-charge shall develop or adopt, implement, and maintain a Certified Pharmacy Technician ~~Candidate~~ training program that is site-specific to the practice setting of which he or she is in charge for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall utilize a Certified Pharmacy Technician ~~Candidate~~ training manual as part of the training program. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Certified Pharmacy Technician~~s~~ Candidates successfully completing ~~the Pharmacy Technician~~ a site-specific training program and an objective assessment mechanism. The Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board.[32]

…

Section 7. Shared Pharmacy Services.

…

(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 each Pharmacist, or Pharmacy Intern who took part in the Drug Utilization Review, refill authorization, or therapeutic intervention functions performed at that Pharmacy and the name of any Certified Pharmacy Technician or Certified Pharmacy Technician Candidate if they assisted in any of those functions;

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

(c) Drug Storage and Security

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

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

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

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

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

(3) Access to the area where Drugs are stored at the Shared Pharmacy Services Pharmacy must be limited to:

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

…

(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, Certified Pharmacy Technician Candidate, or Pharmacy Intern who performed any Shared Pharmacy Services;

(E) complying with federal and state laws; and

(F) operating a Continuous Quality Improvement Program for Shared Pharmacy Services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(e) Individual Practice

(1) Nothing in this Section shall prohibit an individual Pharmacist licensed in the state, who is an employee of or under contract with a Pharmacy, or a licensed Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern, working under the supervision of the 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:

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

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

…

Section 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.
(vi) 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, initials, or identification codes of the Certified Pharmacy Technician or Certified Pharmacy Technician Candidate that Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and
(F) the date the Drug is Prepackaged.

…

Model Rules for Public Health Emergencies

Section 5. Temporary Recognition of Nonresident Licensure.

(a) When a State of Emergency is declared due to a Public Health Emergency:

…

(2) a Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern not registered or licensed in this State, but currently registered or licensed in another state, may assist the Pharmacist in Dispensing Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:
(i) the Board can verify current registration or licensure in good standing of the Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern directly with the state or indirectly via a third-party verification system; and
(ii) the Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern is engaged in a legitimate relief effort.

…

Appendix A

Model Inspection Form for Nuclear Pharmacies

…

Certified Pharmacy Technicians/Certified Pharmacy Technician Candidates/Supportive Personnel:

Name	Title or Position	Certificate Number	Certificate Posted (Y or N)	Certificate Renewal Current (Y or N)
1. _____	_____	_____	_____	_____
_____				

…

Pharmacy Interns:

Name	Registration Number	Registration Renewal Current (Yes or No)	Registration Posted (Yes or No)
1._____	_____	_____	_____
2._____	_____	_____	_____
3._____	_____	_____	_____
4._____	_____	_____	_____
5._____	_____	_____	_____

(Use additional sheets if necessary.)

Are all pharmacy interns, Certified Pharmacy Technicians, Certified Pharmacy Technician~~s~~ Candidates, and/or supportive personnel performing tasks involving radioactive and associated non-radioactive Drugs under the supervision of a licensed pharmacist in accordance with State pharmacy laws?

Yes _____ No _____ If no, give explanation in the space below:

Appendix B

Good Compounding Practices Applicable to State Licensed Pharmacies

…

Subpart B. Organization and Personnel

…

Training of Pharmacists and other Compounding Pharmacy personnel (eg, Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates) shall be in the particular operations that are performed by that individual.

…

Appendix F

Community Pharmacy Continuous Quality Improvement Program Inspection Form

…

P=Present A=Absent N/A= Not applicable		
	P	**A**
Policy and procedures in place		
Periodic CQI meetings held		
Quality-Related Events (QRE) recorded		
Sentinel Events		
Workload compiled		
Staffing needs analyzed/addressed		
Outcome-based certified pharmacy technician ~~and candidate~~ training conducted		
Technology utilized in current/updated		
Pharmacist Care initiatives in place		
Consumer survey policy in place		
Professional performance evaluation policy in place		
Comments: **Recommendations:**		
Report Affirmation		
Additional comments:		
Pharmacist signature: Date:		

Surveyor signature: Date:

Community Pharmacy Quality Self-Audit

Staffing/Workload Date	
Staffing	**Yes/No/Answer**
Number of pharmacist hours allocated per week	
Number of certified pharmacy technician ~~candidate~~ hours allocated per week	
Number of certified pharmacy technician candidate hours allocated per week	
Number of other pharmacy support staff hours allocated per week	
Number of certified pharmacy technicians	
Number of certified pharmacy technician candidates	
~~Number of noncertified Pharmacy Technicians Candidates~~	
Outcome-based certified pharmacy technician training program (If yes, check all applicable)	
❑ Cash register ❑ Prescription intake ❑ Prescription filling	
❑ Inventory ❑ Returning stock bottles to shelf ❑ Clean room	
❑ Computer data entry ❑ Pharmaceutical calculations ❑ Knowledge of practice settings	
❑ Identifying drugs, doses, routes of Administration, dosage forms, etc	
❑ Pharmaceutical and medical terminology ❑ Other	
Workload	**Yes/No/Answer**
Number of hours pharmacy department is open during the week	
Average number of prescriptions filled per week	
Usual ratio of pharmacist to technicians	
Policy is in place that requires increased staffing if workload increases	
Automation	**Yes/No/Answer**
Type	

Background:

The committee members pondered the lack of uniformity among states with respect to pharmacy technician licensure requirements. It was discussed that some states like Texas and Virginia require technicians to obtain certification to maintain licensure, while others states do not require licensure or registration for pharmacy technicians at all. Nevertheless, in order to advance the pharmacy profession, the committee agreed that NABP should set the highest possible standard for pharmacy technician education and training whereby states can model future laws and regulations to conform to it. Thus, the committee unanimously agreed that the *Model Act* should be amended to refer to pharmacy technicians as either Certified Pharmacy Technicians or Certified Pharmacy Technician Candidates as indicated by comments recommended by the 2008-2009 Task Force on Standardized Pharmacy Technician Education and Training. It is the hope of the committee that, as certified pharmacy technician candidates become more skilled and able to assist pharmacists, the pharmacist can delegate more responsibility to certified pharmacy technicians in order to provide better patient care.

LE/L Recommendation 6: The Committee Recommends That the NABP Executive Committee Considers Convening a Task Force to Review the Language in Drug Quality and Security Act (DQSA) Title I as It Pertains to Whether an Outsourcing Facility Can/Should Be Licensed as a Pharmacy by the State and if so, What Specific Requirements Should Exist.

Recommended revisions by NABP staff are denoted by underlines and ~~strikethroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double strikethroughs~~.

Following the enactment of Title I of the DQSA, a definition and requirements section for "outsourcing facility" has been added to the *Model Act*.

Model Rules for Sterile Pharmaceuticals

Section 1. Purpose and Scope.

The purpose of this section is to ensure positive patient outcomes through the provision of standards for (1) Pharmacist Care; (2) the preparation, Labeling, and Distribution of Sterile Pharmaceuticals by Pharmacies; and (3) Product Quality and Characteristics. These standards are intended to apply to all Sterile Pharmaceuticals, notwithstanding the location of the patient (eg, home, hospital, nursing home, hospice, doctor's office). All Compounding Pharmacies and Pharmacists shall practice in accordance with these Rules, the Board's Good Compounding Practices Applicable to State Licensed Pharmacies, ~~and~~ the current United States Pharmacopeia-National Formulary (USP-NF) chapters on Compounding and sterile pharmaceutical preparations, and federal law.

Section 2. Definitions.

…

(k) "Outsourcing Facility" means a facility at one geographic location or address that is

engaged in the compounding of human sterile drugs without a patient specific prescription; has ~~elected to~~ registered as an outsourcing facility with the secretary of the US Department of Health and Human Services, Food and Drug Administration; and complies with all applicable state and federal requirements. [33]

…

Comment regarding patient specific must register as pharmacy.

Section 13. Registration as an Outsourcing Facility.

The facility must meet the following requirements:
(a) Must obtain registration as an outsourcing facility prior to engaging is such practice.
(b) Under the direct supervision of a pharmacist
(c) Must meet current Good Manufacturing Practice (cGMP) requirements.
(d) Must report adverse event and provide FDA with certain information every six months about the products they compound.
(e) Is subject to inspection by FDA according to a risk-based schedule.
(f) Must label with (i) required drug and ingredient information, (ii) facility identification, and (iii) the following or similar statement: "This is a compounded drug. For office use only" or "not for resale."
(g) Must only compound using bulk drug substances that meet specified FDA criteria. May also compound drugs that appear on an FDA shortage list if the bulk drug substances used comply with the aforementioned specified criteria.

LE/L Recommendation 7: The Committee Recommends Approval of Proposed Amendments to the *Model Act* Pertaining to Title II of the DQSA.

Recommended revisions by NABP staff are denoted by underlines and ~~strikethroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double strikethroughs~~.

Following the enactment of Title II of the DQSA, Drug Supply Chain Security Act (DSCSA), references to "Pedigree" have been removed from the *Model Act*. Additionally, Repackagers, Manufacturers, and Third-Party Logistics Providers have been removed from the same category as Wholesalers and must now report state license status to FDA.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

[33] If a facility is engaging in the compounding of human sterile drugs that are pursuant to a prescription, it must register with the Board as a Pharmacy.

Title, Purpose, and Definitions

Section 105. Definitions.

...

(c) "Authenticate" means to affirmatively verify that each transaction listed ~~on the Pedigree and any other accompanying documentation~~ in the product's transaction history has occurred, in accordance with federal requirements and the Rules of the Board.[34]

~~(d)~~ "Contraband Drug" means a Drug which is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that Drug, that has inappropriately entered the drug supply chain distribution. ~~or for which a Pedigree (if required) does not exist, or for which the Pedigree in existence has been forged, Counterfeited, falsely created, or contains any altered, false, or misrepresented information.~~

~~(e) "Pedigree" means a statement or record in a written form or electronic form, approved by the Board, that records each Wholesale Distribution of any given Prescription Drug (excluding Veterinary Prescription Drugs), which leaves the Normal Distribution Channel. Effective December 31, 2007, Pedigrees shall electronically record, for all Prescription Drugs, each Wholesale Distribution starting with the sale by a Manufacturer through acquisition and sale by any Wholesale Distributor, until final sale to a Pharmacy or other authorized Person Administering or Dispensing the Prescription Drug.[35] The Pedigree shall minimally include the following information for each transaction:~~

~~(1) the source of the Prescription Drug(s), including the name and principal address of the seller;~~

~~(2) the proprietary and established name of the Prescription Drug, the amount of the Prescription Drug, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date(s), and lot number(s) or control number(s) of the Prescription Drug;~~

~~(3) the business name and address of each owner of the Prescription Drug and its shipping information, including the name and address of the facility of each Person certifying delivery or receipt of the Prescription Drug;~~

~~[34] Although Pedigrees record each transaction of a Prescription Drug and are, therefore, primarily used in Authenticating, "other accompanying documents" such as purchase orders and invoices should also be utilized to assist in Authenticating. For example, when such "accompanying documents" seem false or misleading, every attempt should be made to Authenticate the Prescription Drug before it is further wholesale distributed. The Board should also establish standards and procedures for Manufacturers and Wholesale Distributors to complete the Authentication process. These standards should provide consistency among Manufacturers and Wholesale Distributors.~~

~~[35] The "Pedigree" should contain the names and addresses of each person certifying delivery or receipt of the Prescription Drug. "Certifying" is to attest and confirm the actual delivery and receipt of the Drug via a signature or other acceptable means as approved by the Board on the Pedigree.~~

~~Feedback from the Wholesale Distributor industry suggests that the sales invoice may not accompany the products when delivered. Customarily, a packaging slip or other similar documentation is provided with the delivery of the product and, therefore, states may consider allowing such documentation to accompany the Pedigree.~~

~~NABP recognizes that technology must be available in order for a Wholesale Distributor to comply with the electronic Pedigree requirements. States should monitor the availability of technology in developing statutes and rules and allow for variances if the technologies needed to comply with the requirements of the Pedigree provisions are not available. In addition, consideration must be given related to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of pharmaceutical product; however, implementation should not be unnecessarily delayed.~~

~~(4) information that states that the Wholesale Distributor has conducted Due Diligence of the Wholesale Distributor(s) from which the Wholesale Distributor purchased; and~~

~~(5) a certification from the Designated Representative of the Wholesale Distributor that the information contained therein is true and accurate under penalty of perjury.~~

…

Model Rules for the Licensure of Wholesale Distributors

Definitions.

…

(b) "Authenticate" means to affirmatively verify that each transaction listed ~~on the Pedigree and any other accompanying documentation~~ in the product's transaction history has occurred, in accordance with federal requirements and the Rules of the Board.~~[36]~~

(j) "Contraband Drug" means a Drug which is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that Drug, that has inappropriately entered the drug supply chain distribution ~~or for which a Pedigree (if required) does not exist, or for which the Pedigree in existence has been forged, Counterfeited, falsely created, or contains any altered, false, or misrepresented information.~~

~~(c2) "Pedigree" means a statement or record in a written form or electronic form, approved by the Board, that records each Wholesale Distribution of any given Prescription Drug (excluding Veterinary Prescription Drugs). The Pedigree shall minimally include the following information for each transaction:~~

~~(1) the source of the Prescription Drug(s), including the name and principal address of the seller;~~

~~(2) the proprietary and established name of the Prescription Drug, the amount of the Prescription Drug, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date(s), and lot number(s) or control number(s) of the Prescription Drug;~~

~~(3) the business name and address of each owner of the Prescription Drug and its shipping information, including the name and address of the facility of each Person certifying delivery or receipt of the Prescription Drug;~~

~~(4) information that states that the Wholesale Distributor has conducted Due Diligence of the Wholesale Distributor(s) from which the Wholesale Distributor purchased; and~~

~~(5) a certification from the Designated Representative of the Wholesale Distributor that the information contained therein is true and accurate under penalty of perjury.~~

…

~~[36] Although Pedigrees record each transaction of a Prescription Drug and are, therefore, primarily used in Authenticating, "other accompanying documents" such as purchase orders and invoices should also be utilized to assist in Authenticating. For example, when such "accompanying documents" seem false or misleading, every attempt should be made to Authenticate the Prescription Drug before it is further Wholesale Distributed. The Board should also establish standards and procedures for Manufacturers and Wholesale Distributors to complete the Authentication process. These standards should provide consistency among Manufacturers and Wholesale Distributors.~~

Section 5. Security and Anti-Counterfeiting.

…

~~(g) Authentication of Pedigrees:~~[37]
~~(1) Wholesale Distributors that acquire Prescription Drugs from other Wholesale Distributors outside the Normal Distribution Channel shall Authenticate the Pedigrees of at least ten percent (10%) of all such Prescription Drugs, unless an electronic pedigree and track and trace system, which documents each transaction, is in place.~~
~~(2) Wholesale Distributors and Manufacturers from whom Wholesale Distributors have acquired Prescription Drugs shall cooperate with Pedigree Authentication efforts and provide the requested information in a timely manner. The Board shall provide Authentication standards and procedures.~~
~~(3) Each Wholesale Distributor that has Distributed a Prescription Drug for which an acquiring Wholesale Distributor is conducting a Pedigree Authentication, shall provide to the acquiring Wholesale Distributor, upon request, detailed information regarding its acquisition of the Prescription Drug, including:~~
~~(i) Date of acquisition;~~
~~(ii) Lot number or control number;~~
~~(iii) Acquisition invoice number; and~~
~~(iv) Name, address, telephone number, and e-mail address (if available) of the Manufacturer or Wholesale Distributor from which the Prescription Drug was acquired.~~
~~(4) If the Wholesale Distributor attempting to Authenticate the Pedigree of the Prescription Drug is unable to Authenticate the Pedigree, the Wholesale Distributor shall quarantine the Prescription Drug and file a report with the Board and FDA within three (3) business days after completing the attempted Authentication; and~~
~~(5) If the Wholesale Distributor attempting to Authenticate the Pedigree of the Prescription Drug is able to Authenticate the Pedigree, the Wholesale Distributor shall maintain records of the Authentication for three (3) years, and shall produce them to the Board upon request.~~
…

Section 8. Returned, Damaged, and Outdated Prescription Drugs.

(a) Appropriate documentation shall be completed~~ and any necessary notations made to the Pedigree~~ if any Prescription Drug that was ordered in excess of need by the Wholesale Distributor, if identified as such, and which the integrity has been maintained, that is returned to the Manufacturer or Wholesale Distributor from which it was acquired

…

Section 10. Record Keeping.

~~[37] The Board may want to consider specifying that Authentications should not include only one product, but involve a spectrum of products and sources.~~

(a) Wholesale Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and Wholesale Distribution or other disposition of Prescription Drugs and Devices. These records shall include:
(1) dates of receipt and Wholesale Distribution or other disposition of the Prescription Drugs and Devices;
~~(2) pedigrees for all Prescription Drugs that are Wholesale Distributed outside the Normal Distribution Channel; and~~[38]
~~(3) effective at a date set by the Board no sooner than July 1, 2009, Pedigrees shall be maintained for each wholesale distribution of a prescription drug starting with the sale by a Manufacturer through acquisition and sale by any Wholesale Distributor, until final sale to a Pharmacy or other authorized Person Administering or Dispensing the Prescription Drug. Pedigrees may be implemented through an approved, uniform, and universally available system that electronically tracks and traces the prescription drug. This electronic tracking system will be deemed to be readily available only upon there being available a standardized system originating at the Manufacturer and capable of being used on a wide scale across the entire health care industry, which includes manufacturers, wholesale distributors, and pharmacies. Also, consideration must be given to:~~[39]
~~(i) the large-scale implementation of this technology across the supply chain;~~
~~(ii) the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product; and~~
~~(iii) the findings and recommendations from FDA regarding the use of track-and-trace technology and a standardized numerical identifier.~~
~~Nevertheless, implementation should not be unnecessarily delayed. Implementation of this subsection shall satisfy the requirements under Section 10 (a)(2).~~
(b) Such records shall include the Inventories and records and shall be made available for inspection and photocopying by any authorized official of any State, Federal, or local governmental agency for a period of three (3) years following their creation date.
(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of any State or Federal governmental agency charged with enforcement of these rules.
(d) Wholesale Distributors and Manufacturers should maintain an ongoing list of Persons with whom they do business.
(e) All facilities shall establish and maintain procedures for reporting Counterfeit and Contraband or suspected Counterfeit and Contraband Drugs or Devices or Counterfeiting and Contraband or suspected Counterfeiting and Contraband activities to the Board and FDA.

~~[38] The utilization of the "Normal Distribution Channel" is not meant to be a permanent solution for a pedigree system. Its purpose is to provide state boards of pharmacy with an interim solution, until the technology for an electronic pedigree system for all prescription drugs is available on a large scale and across the supply chain.~~

~~[39] NABP recognizes that technology must be available in order for a Wholesale Distributor to comply with these requirements. Information received by NABP indicates that the June 1, 2009 implementation date is a realistic goal for enacting the requirements of this section. However, states should monitor the availability of technology in developing statutes and rules and allow for variances if the technologies needed to comply with the requirements of the Pedigree provisions are not available. Consideration must be given, however, to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. Nevertheless, implementation should not be unnecessarily delayed.~~

(f) Wholesale Distributors shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any Prescription Drug or Device to the Board and FDA, and, where applicable, to DEA.[40]

Section 11. Policies and Procedures.

…

~~(h) A procedure for conducting Authentication of Pedigrees in accordance with Section 5 (Security and Anti-Counterfeiting) and standards adopted by the Board.~~

…

Section 12. Prohibited Acts.[41]

…

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

…

Section 13. Criminal Acts.[42]

…

~~(b) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, fails to deliver to another Person a complete and accurate Pedigree, when required, concerning a Prescription Drug prior to transferring the Prescription Drug to another Person commits a felony of the third degree.~~
~~(c) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, fails to acquire a complete and accurate Pedigree, when required, concerning a Prescription Drug prior to obtaining the Prescription Drug from another Person commits a felony of the third degree.~~
~~(d) A Person who engages in the Wholesale Distribution of Prescription Drug(s) and knowingly destroys, alters, conceals, or fails to maintain a complete and accurate Pedigree concerning any Prescription Drug in his possession commits a felony of the third degree.~~
~~(e) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who is in possession of a Pedigree, as required by the Board, and who knowingly fails to Authenticate the Pedigree as required, and who nevertheless Wholesale Distributes or attempts to further Wholesale Distribute Prescription Drug(s) commits a felony of the third degree.~~

[40] This information should be reported to NABP, if serving as a data collection repository, in addition to the other relevant authorities.

[41] Boards should be advised that statutory amendments may be necessary in the State practice acts in order to properly integrate the prohibited and criminal acts. It is highly recommended that boards confer with Board Counsel before adopting the Model Rules to make certain that the appropriate statutory language exists in the state pharmacy practice act to support the Model Rules.

[42] Boards should be advised that statutory amendments may be necessary in the State practice acts in order to properly integrate the prohibited and criminal acts. It is highly recommended that boards confer with Board Counsel before adopting the Model Rules to make certain that the appropriate statutory language exists in the state pharmacy practice act to support the Model Rules.

(f) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, falsely swears or certifies that he or she has Authenticated any documents related to the Wholesale Distribution of Prescription Drugs, commits a felony of the third degree.

~~(g) A Person who engages in the Wholesale Distribution of Prescription Drug(s) and knowingly forges, Counterfeits, or falsely creates any Pedigree, who falsely represents any factual matter contained on any Pedigree, or who knowingly omits to record material information required to be recorded in a Pedigree, commits a felony of the third degree.~~

…

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Introductory Comment to Article I

Section 105. Definitions.

…

(a6) Manufacturer, but does not take title to the Prescription Drug or have general "Repackager" means a Person who Repackages

(b6) "Third-Party Logistics Provider" means an entity that:

(1) Provides or coordinates warehousing, Distribution, or other services on behalf of a responsibility to direct the Prescription Drug's sale or disposition; and

(2) ~~Is licensed as a Wholesale Distributor~~ under this chapter. Is licensed as a Third-Party Logistics Provider

(c6) "Wholesale Distributor" means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State, including but not limited to ~~Manufacturers~~, ~~Repackagers,~~ own-label distributors, private-label distributors, jobbers, brokers, warehouses, ~~including Manufacturers'~~ and Distributors' warehouses, Co-licensees, Exclusive Distributors, ~~Third-Party Logistics Providers~~, Chain Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, and retail Pharmacies that conduct Wholesale Distributions.[43]

…

Model Rules for the Licensure of Wholesale Distributors

Definitions.

[43] "Wholesale Distributor" may be used interchangeably with Wholesaler and, as defined by the Prescription Drug Marketing Act of 1987, includes Manufacturers.

…

(g2) "Repackager" means a Person who Repackages.

(k2) "Third-Party Logistics Provider" means an entity that:
(1) provides or coordinates warehousing, Distribution, or other services on behalf of a Manufacturer, but does not take title to the Prescription Drug or have general responsibility to direct the Prescription Drug's sale or disposition; and
(2) is licensed as a Third-Party Logistics Provider ~~Wholesale Distributor under this chapter~~ and
(3) to be considered part of the Normal Distribution Channel, must also be an Authorized Distributor of Record.

(o2) "Wholesale Distributor" means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State, including but not limited to ~~Manufacturers~~, ~~Repackagers,~~ own-label distributors, private-label distributors, jobbers, brokers, warehouses~~, including Manufacturers'~~ and Distributors' warehouses, Co-Licensees, Exclusive Distributors, ~~Third-Party Logistics Providers~~, Chain Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, Reverse Distributors, and retail Pharmacies that conduct Wholesale Distributions. [44]

…

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, Repackagers, Third-Party Logistics Providers, 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 verify compliance with federal requirements and 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;

[44] In their regulation of Wholesale Distributors, many states have decided to license FDA-approved manufacturers separately from Wholesale Distributors, or in some cases exempt them from licensure altogether, because some of the licensing requirements are duplicative of the FDA's manufacturing licensure processes. Some states have had difficulty in distinguishing who should and who should not be subject to the Wholesale Distributor licensing requirements. For states that wish to exempt Manufacturers from particular licensing requirements, NABP suggests using the following language:
Subject to the Federal Food, Drug, and Cosmetic Act and all applicable federal law and regulation, an FDA-approved manufacturer, including its affiliates, subsidiaries, agents and other entities under common ownership and control of the manufacturer, that exclusively distributes its own FDA-approved prescription drug and/or biologic product, and that has not left the manufacturer's chain of custody shall be exempt from the requirements of the [this section]…

(2) dispensing Practitioners and Practitioner's facilities;[45]
(3) persons engaged in the Manufacture, production, sale, repackaging, or Distribution (including Third-Party Logistics Providers) or Wholesale Distribution of Drugs or Devices;
(4) pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided;
(5) Outsourcing Facilities:
(6) Pharmacy Benefits Managers; and
(7) 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 Licensure of Wholesale Distributors

…

Section 1. Requirements for Licensure.

Wholesale Distributors that provide services within this State, whether the Wholesale Distributor is located within this State or outside this State, shall be licensed by the Board and shall annually renew their license with the Board using an application provided by the Board. Wholesale Distributors cannot operate from a place of residence. Where Wholesale Distribution operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy. [46]

(a) Every Wholesale Distributor who engages in the Wholesale Distribution of Prescription Drugs or Devices shall license annually with the Board by application and provide information required by the Board on an application approved by the Board, including but not limited to:

(1) all trade or business names used by the licensee (includes "is doing business as" and "formerly known as"), which cannot be identical to the name used by another unrelated Wholesale Distributor licensed to purchase Prescription Drugs or Devices in the State;

(2) name(s) of the owner and operator of the licensee (if not the same person), including:

(i) if a Person: the name, business address, Social Security number, and date of birth;

(ii) if a partnership: the name, business address, and Social Security number and date of birth of each partner, and the name of the partnership and federal employer identification number;

(iii) if a corporation: the name, business address, Social Security number and date of birth, and title of each corporate officer and director, the corporate names, the state of incorporation, federal employer identification number, and the name of the parent company, if any; the name, business address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC;

(iv) if a sole proprietorship: the full name, business address, Social Security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;

(v) if a limited liability company: the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

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[45] 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.

[46] The application and screening process for licensing Wholesale Distributors represents a critical point in efforts to prevent the introduction of Counterfeit and Contraband products into the medication distribution system. An application that requires detailed information about the applicant and key individuals involved in the operations of the Wholesale Distributor is critical.

(vi) any other relevant information that the Board requires.

(3) name(s), business address(es), and telephone number(s) of a person(s) to serve as the Designated Representative(s) for each facility of the Wholesale Distributor that engages in the Wholesale Distribution of Prescription Drugs or Devices and additional information as required in Section 10 (Record Keeping);

(4) a list of all State and Federal licenses, registrations, or permits, including the license, registration, or permit numbers issued to the Wholesale Distributor by any other state and federal authority that authorizes the Wholesale Distributor to purchase, possess, and Wholesale Distribute Prescription Drugs;

(5) a list of all disciplinary actions by State and Federal agencies against the Wholesale Distributor as well as any such actions against principals, owners, directors, or officers;

(6) a full description of each facility and warehouse, including all locations utilized for Prescription Drug storage and/or Wholesale Distribution. The description should include the following:

(i) square footage;
(ii) security and alarm system descriptions;
(iii) terms of lease or ownership;
(iv) address; and
(v) temperature and humidity controls.

(7) a copy of the deed for the property on which the Wholesale Distributor's establishment is located, if the property is owned by the Wholesale Distributor, or a copy of the Wholesale Distributor's lease for the property on which the establishment is located that has an original term of not less than one (1) calendar year, if the establishment is not owned by the Wholesale Distributor;

(8) information regarding general and product liability insurance, including copies of relevant policies;

(9) a description of the Wholesale Distributor's Drug import and export activities; and

(10) a copy of the Wholesale Distributor's written policies and procedures as required in Section 11 (Policies and Procedures).

(11) the information collected pursuant to Section 1(a)(6) and (a)(10) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The Board shall make provisions for protecting the confidentiality of the information collected under this section.

(b) A "surety" bond of not less than $100,000, or other equivalent means of security acceptable to the Board or a third party recognized by the Board such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate "surety" bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their Wholesale Distributor license with the Board. The Board may make a claim against such bond or other equivalent means of security until one year after the Wholesale Distributor's license ceases to be valid or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board that involves the Wholesale Distributor is concluded, including any appeal, whichever occurs later. Manufacturers shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board. The Board may waive the bond requirement, if the Wholesale Distributor:[47]

(1) has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesale distributor possesses a valid license in good standing; or

(2) is a publicly held company.

[47] Although Wholesale Distributors may be licensed in multiple states, it is not intended for Wholesale Distributors to procure a separate "surety" bond (or other equivalent means) for each state of licensure. States should consider waiving this requirement if the Wholesale Distributor has procured a "surety" bond (or other equivalent means) for the purposes of licensure in another state, or if the wholesaler is a publicly traded company.

(c) Every Wholesale Distributor who engages in Wholesale Distribution shall submit a reasonable fee to be determined by the Board.
(d) Each facility that engages in Wholesale Distribution must undergo an inspection by the Board or a third party recognized by the Board for the purpose of inspecting the Wholesale Distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board but not less than once every three (3) years. Manufacturing facilities are exempt from inspection by the Board if the Manufacturing facilities are currently registered with FDA in accordance with Section 510 of the Federal Act.
(e) All Wholesale Distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the Board.
(f) Changes in any information in this Section shall be submitted to the Board, or to a third party recognized by the Board, within 30 days of such change (unless otherwise noted).
(g) Information submitted by the Wholesale Distributor to the Board or a third party recognized by the Board that is considered trade secret or proprietary information, as defined under this State's privacy and trade secret/proprietary statutes, shall be maintained by the Board or a third party recognized by the Board as private or trade secret/proprietary information and be exempt from public disclosure.[48]
(h) Per federal requirements, states shall license Third-Party Logistics Providers (those that provide storage and logistical operations related to drug distribution) separately from wholesale drug distributors. Minimum requirements for wholesale drug distributor licensure may also apply to Third-Party Logistics Providers if applicable. [49]
(i) Per federal requirements, states shall license repackagers and manufacturers separately from wholesale drug distributors. Minimum requirements for wholesale drug distributor licensure may also apply to repackagers and manufacturers if applicable.
(j) Supply chain trading partners (wholesale drug distributors and Third-Party Logistics Providers) should report state licensure status and other required information to FDA.

New Requirements for Track and Trace per DSCSA section 581 and section 582 of the Food Drug and Cosmetic Act Have Been Added.

Model Rules for the Licensure of Wholesale Distributors

Section 9. Due Diligence.

If a Wholesale Distributor is licensed in accordance with these Rules or provides documentation that the Due Diligence procedures are in place and monitored by the Board or a third party recognized by the Board, then the following Due Diligence requirements may be waived by the Board:

(a) Prior to the initial Wholesale Distribution or acquisition of Prescription Drugs to or from any Wholesale Distributor (or prior to any Wholesale Distribution to a Wholesale Distributor by a Manufacturer), the Distributing Wholesale Distributor (or Manufacturer) shall provide the following information to the acquiring Wholesale Distributor:

(1) a list of states in which the Wholesale Distributor is licensed, and into which it ships Prescription Drugs;

[48] The Board may designate a third party to conduct inspections and ensure that all requirements for licensure established by the legislature and Board are fulfilled. The NABP Verified-Accredited Wholesale Distributors® (VAWD®) program is available to the states.

[49] If a state does not have a licensure category for Third-Party Logistics Providers, facilities that engage in interstate transport of prescription drugs must obtain federal registration.

(2) copies of all State and Federal regulatory licenses and registrations;
(3) the Wholesale Distributor's most recent facility inspection reports;
(4) information regarding general and product liability insurance, including copies of relevant policies;
(5) a list of other names under which the Wholesale Distributor is doing business, or was formerly known;
(6) a list of corporate officers;
(7) a list of managerial employees directly involved in the day-to-day operations of Wholesale Distribution;
(8) a list of all owners of the Wholesale Distributor that own more than ten percent (10%) of the Wholesale Distributor, unless the Wholesale Distributor is publicly traded;
(9) a list of all secured common carriers approved by the Wholesale Distributor;
(10) a list of all disciplinary actions by State and Federal agencies;
(11) a description, including the address, dimensions, and other relevant information, of each facility or warehouse used for Prescription Drug storage and Wholesale Distribution;
(12) a description of Prescription Drug import and export activities of the Wholesale Distributor; and
(13) a description of the Wholesale Distributor's policies and procedures to comply with this Act.

(b) Prior to the initial Wholesale Distribution or acquisition of Prescription Drugs to or from any Wholesale Distributor, the Distributing or acquiring Wholesale Distributor shall:

(1) conduct a criminal background check of all of the Wholesale Distributor's personnel, shareholders, and owners involved in operations and management as specified in Section 2 (Minimum Qualifications), and require that all Common Carriers contracted with or utilized by the Wholesale Distributor conduct criminal background checks of the employees whose responsibilities include the handling of Prescription Drugs; or
(2) verify that the Wholesale Distributor has been accredited by a third party recognized by the Board.

(c) If a Wholesale Distributor's facility has not been inspected by the Board or a third party recognized by the Board within three (3) years of the contemplated transaction, any Wholesale Distributor choosing to do business with that facility shall conduct an inspection of the former Wholesale Distributor's facility prior to the first transaction to ensure compliance with applicable laws and regulations relating to the storage and handling of Prescription Drugs or Devices. A third party may be engaged to conduct the site inspection on behalf of the latter Wholesale Distributor. If the Wholesale Distributor's facility has been inspected by the Board or a third party recognized by the Board, within a three (3) year time period, the inspection report is sufficient to meet the requirements of this subsection.

(d) At least annually, a Wholesale Distributor that Wholesale Distributes or acquires Prescription Drugs to or from another Wholesale Distributor shall update the information set forth in Section 10 (Record Keeping).

(e) At least once every three (3) years, a Wholesale Distributor that Wholesale Distributes or acquires Prescription Drugs to or from another Wholesale Distributor shall inspect, or engage a third party to inspect, the premises of the facility or facilities of the Wholesale Distributor to or from whom it is Distributing or acquiring Prescription Drugs. If the Distributing or acquiring Wholesale Distributor's facility has been inspected by the Board or a third party recognized by the Board within the three (3)-year time period, the inspection report is sufficient to meet the requirements of this subsection.

(f) Wholesale Distributors are exempt from inspecting and obtaining the information from Manufacturers of Prescription Drugs as required in Section 9 (Due Diligence) when the Manufacturer is registered with FDA in accordance with Section 510 of the Federal Act.
(g) Supply chain trading partners (Manufacturers, Repackagers, Wholesale Distributors, and dispensers) shall receive and transfer product transaction data history to subsequent purchasers per federal guidelines.
(h) Supply chain trading partners (Manufacturers, Repackagers, Wholesale Distributors, and dispensers) shall establish a system to:

(1) Quarantine and investigate suspect product to determine if it is illegitimate.
(2) Notify FDA, the Board, and immediate trading partners, if illegitimate product is found.

Background:

The committee deferred to NABP staff to draft revisions to the *Model Act* in order to reflect the provisions contained in Title I and II of the DQSA. Additionally, members determined that these issues required further scrutiny of which could be better facilitated by convening a separate task force.

LE/L Recommendation 8: NABP Should Not Amend the *Model Act to* Allow for a Licensure Exemption for Manufacturers That Dispense Dialysate, Drugs, and Devices to Home Dialysis Patients.

The committee does not recommend that NABP amend the *Model Act* to provide for a licensure exemption for manufacturers that dispense dialysate, drugs, and devices to home dialysis patients.

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;[50]
(3) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;
(4) 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.[51]

(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.[52]

(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

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[50] 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.

[51] Section 501(b) contemplates that the Criteria for licensure, beyond minimum requirements for all Persons and Pharmacies, established in an individual entity classification could differ. For example, the Criteria that must be met by a nuclear Pharmacy will certainly differ from that of the community Pharmacy. This type of latitude places the responsibility on the Board to adopt appropriate rules to meet the situation at hand. It also provides a forum for change to meet the changing concepts of professional practice and the Distribution of Drugs and/or Devices.

[52] This section provides for service of process on any Person who Dispenses, Distributes, or Delivers Drugs or Devices within the State.

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 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 consider exempting facilities engaged solely in the distribution of dialysate, drugs, or devices necessary to perform home renal dialysis to patients with chronic kidney from pharmacy licensure, provided that the following criteria are met:

(1) The dialysate, drugs, or devices are approved by Food and Drug Administration, as required by federal law.
(2) The dialysate, drugs, or devices are lawfully held by a manufacturer (or a manufacturer's (agent) that is properly registered with the Board as a manufacturer and/or wholesale drug distributor
(3) The dialysate, drugs, or devices are held and delivered in their original, sealed labeled packaging from the manufacturing facility.
(4) The dialysate, drugs, or devices are delivered only by the manufacturer (or the manufacturer's agent) and only upon receipt of a physician's order.
(5) The manufacturer (or manufacturer's agent) delivers the dialysate, drugs, or devices directly to:
    (i) a patient with chronic kidney failure, or his/her designee, for the patient's self-administration of dialysis therapy, or
    (ii) a health care provider or institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.
(6) Records of all sales and distribution of dialysate, drugs, or devices to home dialysis patients must be retained and readily available for inspection and copying by the Board for _____ years.

Background:

The committee members recommended that the *Model Act* not be amended to allow manufacturers to dispense prescription drugs directly to patients since such delivery methods could lead to interpretations that circumvent the pharmacy regulatory frame work and could negatively impact patient safety. The committee members stressed that, by eliminating the verification by a pharmacist, the dialysis patient is void of the benefit of having a pharmacist review the prescription for appropriateness before it is dispensed directly to the patient. The committee members further recommended that manufacturers that wish to seek licensure exemptions should petition the state boards directly for waivers or variances. The committee did not endorse this licensure exemption and concluded that it should be reviewed on a state-by-state basis.