NABP
National Association of Boards of Pharmacy

REPORT OF THE COMMITTEE ON

LAW ENFORCEMENT/LEGISLATION

Members Present `

Jeenu Philip (FL), *chair*; Sabrina L. Beck (NE); Alexandra Blasi (KS); Janet Getzey Hart (PA); Allison Hill (DC); Tony King (MT); Deena Speights-Napata (MD); and Kim Tanzer (TX).

Others Present

Kamlesh "Kam" Gandhi, *Executive Committee liaison;* Lemrey "Al" Carter; William Cover; Melissa Madigan; Eileen Lewalski; Maureen Schanck; Cameron Orr; and Andrea Busch, *NABP staff*.

Introduction

The committee met virtually on June 14, 2022, and July 21, 2022.

Review of the Committee Charge

Charge of the committee:

1. Develop model laws and regulations based on resolutions adopted by the members of the Association or reports of task forces or other committees of the Association, or as assigned by the Executive Committee.
2. Review and comment on existing legislation and rules governing the practice of pharmacy and the distribution of prescription medications.
3. Recommend to the Executive Committee areas where model pharmacy practice or prescription drug distribution regulations are needed to improve the protection of the public health.

Background and Discussion

The committee reviewed and discussed Resolution 118-1-22 Definition of Pharmacist as a Health Care Provider, as well as the recommended amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* made by the Task Force on Workplace Safety and Well-Being and the *Model Act* Review Committee.

The committee began its discussion by reviewing Resolution 118-1-22,[1] which resolved that NABP convene a task force to examine defining "pharmacist" as a health care provider.

[1] **Resolution 118-1-22 Definition of Pharmacist as a Health Care Provider**

WHEREAS, a pharmacist's evolution of practice has significantly expanded over the years, particularly during the coronavirus disease 2019 pandemic, to include a variety of direct patient care activities; and

Whereas the resolution called for convening a task force, providing the information to this committee allowed for the definition to be revised in a much timelier manner. The brief discussion focused on the goal of ensuring patient access to pharmacist services, as well as keeping the language broad to allow for future changes in practice. In the end, members agreed that adding "health care provider" to the definition of pharmacist and making other corresponding edits to relevant language in that section aligned with the objective of the resolution.

The committee then reviewed the recommendations of the Task Force on Workplace Safety and Well-Being. The first recommendation of the task force was for NABP to amend the *Model Act* definitions pertaining to errors, adverse events, and missed errors to mirror those used by the Centers for Medicare & Medicaid Services (CMS). After reviewing, the committee decided that the current language found in the *Model Act* reflects the desired CMS language and agreed that no amendments were necessary.

The second recommendation of the task force suggested adding a provision to the *Model Act* for mandated break periods for pharmacy staff. The committee supported the task force's recommendation and had a lengthy, spirited discussion about how specific or general the language should be. Ultimately, the committee settled upon wording that they believed provided pharmacy staff with sufficient safeguards from mandated long, continuous working hours, while allowing the pharmacist the discretion to forego rest breaks and work longer hours when necessary. Members also stressed that pharmacy policies and procedures should state that pharmacists must ensure that patients are offered the opportunity for counseling without compromise.

The third recommendation of the task force suggested adding a provision to the *Model Act* for anti-retaliatory (whistleblower) protections for pharmacy staff. As was the case with the prior recommendation, the discussion of the committee focused on whether the language should be specific or general. In the end, the committee settled on wording that they believed provided

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WHEREAS, pharmacists play an integral role as part of a patient's health care team, and as such, many states have amended laws and regulations to recognize pharmacists as health care providers; and

WHEREAS, professional pharmacy organizations have collaborated with legislators to introduce bills that would enable pharmacists, acting as health care providers, to obtain reimbursement for professional pharmacy services rendered; and

WHEREAS, other health care providers are defined by law and such definitions include their scope of practice, but the definition of pharmacist as a health care provider is not clear, standardized, nor universally well recognized; and

WHEREAS, a definition of pharmacist as a health care provider has never been adopted by the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act);*

THEREFORE BE IT RESOLVED that NABP convene a task force that includes appropriate stakeholders to examine this issue and recommend amending, if necessary, the *Model Act* to include a foundational definition of pharmacists as health care providers.

sufficient protections for pharmacy staff, including protection for reporting a "suspected" violation.

Addressing a related issue, the committee referred language intended to prevent the reporting of false complaints to the Task Force to Review *Model Act* Licensing and Disciplinary Language, which is scheduled to meet October 10-11, 2022. The group believed that this language, which had been considered by the Arizona State Legislature, supported due diligence in investigative matters by requiring complainants to disclose their identity for investigative purposes.

Finally, the committee reviewed the work of the *Model Act* Review Committee (MARC). Specifically, MARC has the following recommendations.

1. Review the following definitions to:
    a. update the definition of "Protected Health Information" to remove references to outdated sections in the federal Health Insurance Portability and Accountability Act;
    b. ensure that the criteria for "Qualified Nuclear Pharmacist" are up to date;
    c. expand the definition of "Quality-Related Event" to include clinical activities, not just dispensing activities;
    d. update the definition of "Suspicious Order" to make it more robust; and
    e. remove the last sentence from the definition of "Practice of Telepharmacy" because it is already in the telepharmacy rules.
2. Ensure that there are adequate references to the state administrative procedures act.
3. Add wording to allow for electronic service of process if permitted by state law.
4. Regarding board composition:
    a. Add technician member to the board of pharmacy composition.
    b. Add a time frame within which a new board member must be appointed in case of a vacancy.
5. Add a "consideration of waiver request" process.
6. For the Model Rules for the Practice of Pharmacy:
    a. Update the wording regarding transfer of a prescription order to accommodate non-paper prescription processes (for example, writing "VOID" or "TRANSFER" on the face of transferred prescriptions).
    b. Update the wording in reference to "sight-readable" data storage and "hard copy printout."

7. For the Model Rules for Nuclear/Radiologic Pharmacy, note that pharmacies shall also adhere to compounding rules if compounding non-radiopharmaceuticals.
8. For the Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors, consider identifying a "Designated Representative" for Manufacturers, Repackagers, and Third-Party Logistics Providers, in addition to Wholesale Distributors.
9. Align with the federal Controlled Substances Act and rules.
    a. Update the wording addressing electronic transmission of controlled substance (CS) prescriptions.
    b. Update the wording addressing oral communication of emergency Schedule II prescription orders.
10. Answer some overarching questions:
    a. Currently, the *Model Act* references various NABP programs and services. Should such references be removed?
    b. The words "pharmaceutical" and "medication" are used interchangeably with "Drug." Should only "Drug" be used?
    c. Currently, the *Model Act* references specific United States Pharmacopeia (USP) chapters. Should specific references be removed and text such as "Current USP chapter addressing…" be used instead?
    d. Currently, the *Model Act* includes templates, resources, and forms as appendices to the document (eg, Sample Pharmacy Automation Policy and Procedure Outline). Should these be removed and used to create separate resources? Are there additional examples of such resources that would be helpful to boards of pharmacy?

The committee recommendations regarding the aforementioned topics are found below. Any revisions to the *Model Act* recommended by the committee are denoted by <u>underlines</u> and ~~strikethroughs~~.

Pursuant to Resolution 118-1-22, Definition of Pharmacist as a Health Care Provider

National Association of Boards of Pharmacy

Model State Pharmacy Act

Article I
Title, Purpose, and Definitions

…

Section 102. Legislative Declaration.

The Practice of Pharmacy in the State of _____ is declared a professional health care practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest.[2] Pharmacy is a learned health care profession affecting public health and welfare and is declared as such by the State Legislature. This Act shall be liberally construed to carry out these objectives and purposes.

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, as well as through access to, health care providers who engage in 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 regulation and control of such other materials as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual.[3]

Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" means the practice of a health care profession that includes, but is not limited to, the interpretation, evaluation, Dispensing, and/or implementation of Medical Orders, and the initiation and provision of Pharmacist Care Services. The Practice of Pharmacy also includes continually

[2] The Practice of Pharmacy, from time to time, has been erroneously viewed, even by government agencies, as a commercial business rather than a profession. The status of Pharmacy as a profession has been, and will continue to be, of particular importance in litigation.

[3] The Statement of Purpose is designed to define the general scope of the Pharmacy Act. It provides for the control and regulation of the Practice of Pharmacy and the licensure of facilities engaged in the Distribution of Drugs and related Devices. A Board will have full knowledge of the whereabouts of Drugs in the legitimate stream of intrastate and interstate commerce, providing it with the ability to better prevent diversion, effectuate recalls, ensure the quality of Drugs Dispensed or Administered to patients, and effectively protect the public.

optimizing patient safety and quality of services through effective use of emerging technologies and competency-based education. [4]

Section 105. Definitions.

…

"Pharmacist" means a health care provider ~~an individual~~ currently licensed by this State to engage in the Practice of Pharmacy, as defined in this chapter, within or outside of a licensed Pharmacy, as defined in the Rules of the Board.

…

"Pharmacist Care Services" means ~~patient~~ health care-related activities provided by a pharmacist within this State or into this State, as defined by the Rules of the Board, with or without the Dispensing of Drugs or Devices, which are intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.[5]

…

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

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

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

NABP

Pursuant to the Report of the Task Force on Workplace Safety and Well-Being

1. *Recommendation to Revise the* Model Act

Model Rules for the Practice of Pharmacy

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Section 3. Personnel.

(a) Pharmacist-in-Charge

…

(b) Professional Performance Evaluation

…

(c) Pharmacy Labor Standards/Shift Lengths and Breaks

(1) A pharmacy licensed under this Act shall not require a pharmacist, pharmacist intern, certified pharmacy technician, or certified pharmacy technician candidate to work longer than 12 continuous hours per day, inclusive of the breaks required under subsection (2).

(2) A pharmacist who works 6 continuous hours or longer per day shall be allowed to take, at a minimum, one 30-minute uninterrupted meal break and one 15-minute break during that 6-hour period. If such pharmacist is required to work 12 continuous hours per day, at a minimum, he or she qualifies for an additional 15-minute break.

(3) A pharmacy may, but is not required to, close when a pharmacist is allowed to take a break under subsection (2). If the pharmacy does not close, the pharmacist shall either remain within the licensed pharmacy or within the establishment in which the licensed pharmacy is located in order to be available for emergencies. In addition, the following applies:

(i) certified pharmacy technicians, certified pharmacy technician candidates, and pharmacist interns authorized by the pharmacist on duty may continue to perform duties as allowed under this Act;

(ii) no duties reserved to pharmacists and pharmacist interns under this Act, or that require the professional judgment of a pharmacist, may be performed by certified pharmacy technicians or certified pharmacy technician candidates;

(iii) only prescriptions that have received final verification by a pharmacist may be dispensed while the pharmacist is on break, except those prescriptions that require counseling by a pharmacist, including all new prescriptions and those refill prescriptions for which a pharmacist has determined that counseling is necessary and/or is conducted pursuant to counseling laws and/or regulations;[6] and

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

(~~e~~d) If any action of the Pharmacy is deemed to contribute to or cause a violation of any provision of this section, the Board may hold the owner and/or Pharmacy permit holder responsible and/or absolve the Pharmacist-in-Charge from the responsibility of that action.

National Association of Boards of Pharmacy Model State Pharmacy Act

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Article V
Licensing of Facilities

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Section 504. Grounds, Penalties, and Reinstatement.

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

(b) Except where otherwise permitted by law, it shall be unlawful for a Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor to Distribute or Deliver Drugs or Devices to any Person in this State not licensed under this statute. Any Person who shall Distribute or Deliver Drugs or Devices to a Person not licensed shall be subject to a fine to be imposed by the Board not to exceed one thousand dollars ($1,000) for each offense in addition to such other disciplinary action the Board may take under this Act. Except as

[6] The pharmacy shall have policies and procedures to ensure that the patient is provided an opportunity to receive counseling.

otherwise indicated in this Act, each such violation shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this State.

(c) The Board may Suspend, Revoke, deny, or refuse to renew the license of any Person, Manufacturer, Repackager, Third-Party Logistics Provider, Wholesale Distributor, Pharmacy, or Pharmacy Benefits Manager on any of the following grounds:[7]

…

(15) Retaliating against or disciplining an employee for filing a complaint with a state board of pharmacy or other licensing body or reporting a suspected violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this paragraph, retaliation or discipline of an employee includes, but is not limited to, the following:
(a) Removing or suspending the employee from employment;
(b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
(c) Transferring or reassigning the employee;
(d) Denying the employee a promotion that otherwise would have been received;
(e) Reducing the employee in pay or position.

…

2. *Referral to the Task Force to Review* Model Act *Licensing and Disciplinary Language*

In addition to recommending the edits to the Model Rules above, committee members reviewed the text of a proposed amendment to Arizona law addressing health professions regulation and the submission of complaints to health regulatory boards (see italicized text below). The committee determined that this text should reviewed by the Task Force to Review *Model Act* Licensing and Disciplinary Language, which is scheduled to meet October 10-11, 2022, for inclusion in the *Model Act*.

32-3229.01. Health profession regulatory boards; complaints; investigations; complainant confidentiality; exceptions; notice

a. Notwithstanding any other provision of this title, a health profession regulatory board shall require complainants to identify themselves in the complaint and make themselves available for

[7] The Prescription Drug Marketing Act of 1987 (PDMA) requires that the state licensing laws provide for the Suspension or Revocation of licenses upon conviction for violation of Federal, State, or local Drug laws or rules pertaining to the unlawful Distribution of Drugs at wholesale. The PDMA defines fines, imprisonment, or civil penalties.

an evidentiary interview. Complainants may request that their identity remain confidential during the preliminary investigatory process. Notwithstanding a complainant's request to remain confidential during the preliminary investigatory process, if the investigatory process results in a determination that a violation of law may have occurred, the respondent is entitled to the complete investigatory file, including the identity of the complainant for purposes of providing a comprehensive response to the complaint. The health profession regulatory board may take action on a complaint if the patient or complainant does not comply with the board's investigation if the board has sufficient evidence of a violation of law. It shall be an act of unprofessional conduct for any licensee or permittee of any health professional regulatory board if that licensee or permittee files a false or fraudulent complaint or report to a health professional regulatory board.

If the task force agrees that this language should be included in the *Model Act*, it should also carefully consider the best placement. Should it be added as a new "ground" for discipline? Should a footnote be added to the "Section 402. Grounds, Penalties, and Reinstatement" heading that simply suggests boards can include this as a ground for discipline? Or should there be a new section drafted that describes procedures related to submission of complaints to the board, which includes this provision?

Pursuant to the 2021 Report of the *Model Act* Review Committee

1. Definitions

a. Update the definition of "Protected Health Information" to remove references to outdated sections in the federal Health Insurance Portability and Accountability Act.

"Protected Health Information" means Individually Identifiable Health Information as defined in the federal Health Insurance Portability and Accountability Act of 1996 and its implementing rules. ~~:~~

~~Except as provided in paragraph (2) of this definition, that is:~~

~~i. transmitted by electronic media;~~

~~ii. maintained in any medium described in the definition of electronic media at §162.103 of the~~ Federal ~~HIPAA privacy rules (45 CFR Part 160);~~

iii. ~~transmitted or maintained in any other form or medium.~~

~~Protected health information excludes individually identifiable health information in:~~

~~iv. education records covered by the Family Educational Right and Privacy Act, as amended 20 USC 1232(g);~~

~~v. records described at 20 USC 1232(g)(4)(B)(iv); and~~

~~vi. employment records held by a licensee in its role as an employer.~~

b. Ensure that the criteria for "Qualified Nuclear Pharmacist" are up to date.

"Qualified Nuclear Pharmacist" means a currently licensed Pharmacist in this State who is certified and/or licensed as a Nuclear Pharmacist by the State Board of Pharmacy or by a certification Board recognized by the State Board of Pharmacy, or who meets the following standards:

(1) Documented successful completion of training for "authorized user status" of radioactive material [cite State Radiation Control Agency or NRC licensure guide].

(2) Completed a minimum of 200 contact hours of instruction in nuclear Pharmacy and the safe handling and the use of radioactive materials from a program approved by the State Board of Pharmacy, with emphasis in the following areas (consisting of didactic and laboratory-based content):
   (i) radiation physics and instrumentation;
   (ii) radiation protection;
   (iii) mathematics of radioactivity;
   (iv) radiation biology; and
   (v) radiopharmaceutical chemistry; and

(3) Attained a minimum of 500 hours of clinical nuclear Pharmacy training under the supervision of a qualified nuclear Pharmacist. This experience should cover the type and quantities of by-product material requested in the application and include the following:
   (i) Ordering, receiving, surveying, and unpackaging radioactive materials safely;
   (ii) Calibration of dose calibrators, scintillation detectors, and survey meters;
   (iii) Calculation, preparation, and calibration of patient doses including the proper use of syringe shield.

c. Expand the definition of "Quality-Related Event" to include clinical activities, not just dispensing activities.

"Quality-Related Event" means any departure from the appropriate Dispensing of a prescribed medication that is or is not corrected prior to the Delivery and/or Administration of the medication.[8] The term "Quality-Related Event" includes:

(1) a variation from the prescriber's prescription drug order, including, but not limited to:
  (i) incorrect Drug;
  (ii) incorrect Drug strength;
  (iii) incorrect dosage form;
  (iv) incorrect patient; or
  (v) inadequate or incorrect packaging, Labeling, or directions;
(2) a failure to identify and manage:
  (i) over-utilization or under-utilization;
  (ii) therapeutic duplication;
  (iii) drug-disease contraindications;
  (iv) drug-drug interactions;
  (v) incorrect drug dosage or duration of drug treatment;
  (vi) drug-allergy interactions; or
  (vii) clinical abuse/misuse~~.~~;
(3) ~~The term also includes~~ packaging or warnings that fail to meet recognized standards~~.~~;
(4) the Delivery of a medication to the wrong patient~~.~~; ~~and~~ or
(5) the failure to meet the professional standard of care in the provision of Pharmacist Care Services. ~~Detect and or appropriately manage a significant actual or potential problem with a patient's drug therapy~~.

d. Update the definition of "Suspicious Order" to make it more robust.

"Suspicious Order" means a request to purchase one or more Products, which includes, but is not limited to, an unsubstantiated order with the following characteristic(s):

(1) unusual size or frequency; or
(2) deviating substantially from a normal pattern.

[8] Quality-Related Events may be recorded using the Community Pharmacy Quality-Related Event Data Collection Form found in Appendix D.

e. *Remove the last sentence from the definition of "Practice of Telepharmacy" because it is already in the telepharmacy rules.*

"Practice of Telepharmacy" means the Practice of Pharmacy by registered ~~Pharmacies and~~
Pharmacists located within US jurisdictions through the use of Telepharmacy Technologies between a licensee and patients or their agents at distances that are located within US jurisdictions. ~~The Practice of Telepharmacy is deemed to occur within the jurisdiction in which the patient is located and the jurisdiction(s) in which the pharmacist and, if applicable, pharmacy are located; therefore, such practice will be subject to the Pharmacy practice regulations of all jurisdictions' Boards of Pharmacy.~~

2. *Ensure that there are adequate references to the state administrative procedures act.*

The committee found that there are adequate references to state administrative procedures acts and did not make edits based on this recommendation.

3. *Add wording to allow for electronic service of process if permitted by state law.*

Each licensed Person located outside of this State which ships, mails, Dispenses, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in this State, or Pharmacy located outside of this State which ships, mails, Dispenses, 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 which 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 shipping, mailing, Dispensing, Distribution, Wholesale Distribution, or Delivery of Drugs or Devices. 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, or by electronic means if permitted. If

any such Person is not licensed in this State, service on the Secretary of State only shall be sufficient service.[9]

4. *Regarding board composition:*

a. *Add technician member to the board of pharmacy composition.*

b. *Add a time frame within which a new board member must be appointed in case of a vacancy.*

Section 202. Membership.

The Board of Pharmacy shall consist of _____ members, _____ of whom shall be a representative of the public, one of whom shall be a Certified Pharmacy Technician, and the remainder [each] of whom shall be Pharmacists who possess the qualifications specified in Section 203.[10]

Section 203. Qualifications.

(a) Each Pharmacist member of the Board of Pharmacy shall at the time of appointment[11]:

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

[10] The number of Board members should be determined by each individual state according to its particular requirements. Individual states may wish to consider a Board composition that represents the diversity of practice sites and interests within a state. Variable factors, such as state population, number of Pharmacists, number of pharmacies, and other local considerations, may all be relevant in determining the number of Board members needed to most effectively enforce the Act. In the event a state prefers to limit the Board membership to currently licensed Pharmacists, the bracketed language pertaining to a public member should be deleted, as should Section 203(b). In this event, the alternative "each" should be selected, and Section 203(a) should be renumbered as Section 203.

[11] Section 203(a) of the Act requires that a Pharmacist be engaged in the Practice of Pharmacy at the time of his or her appointment as a Board member and that he or she have at least five (5) years of experience in the Practice of Pharmacy in the state prior thereto. Since the Practice of Pharmacy is defined in Section 104 in broad terms, it renders a Pharmacist actively engaged in almost any phase of the practice eligible for appointment. This provides for candidates who have divergent backgrounds and experiences and who are knowledgeable in the affairs of the profession.

However, it should be noted from the definition of Pharmacy Practice in Section 104 that those persons actively engaged in the Practice of Pharmacy would basically be limited to those individuals who are working within settings where medications/Devices are Dispensed and Pharmacist Care Services is provided. To include persons who are in positions related to the practice but who are not engaged in Dispensing and Pharmacist Care Services functions would wrongfully cause the inclusion of individuals, such as personnel employed by Drug Manufacturers, Wholesale Distributors, and the like, who may be licensed to practice but who do not practice Pharmacy under the terms of the applicable Practice Act. The determination as to whether or not an individual is actively engaged in the Practice of Pharmacy will undoubtedly be rendered on a case-by-case basis. The general Criteria described above, however, would most probably be applicable in making the determination. Under the terms of a Practice Act, which includes a definition of Pharmacy practice, only those persons who are actively engaged in the basic functions set forth in the definition would be individuals "actively engaged in the Practice of Pharmacy."

(1) be a resident of this State for not less than six months;
(2) be currently licensed and in good standing to engage in the Practice of Pharmacy in this State;
(3) be actively engaged in the Practice of Pharmacy in this State;
(4) have five (5) years of experience in the Practice of Pharmacy after licensure.

(b) Each Certified Pharmacy Technician member of the Board of Pharmacy shall at the time of appointment:

(1) be a resident of this State for not less than six months;
(2) be currently licensed and in good standing as a Certified Pharmacy Technician in this State;
(3) be an actively practicing Certified Pharmacy Technician in this State;
(4) have five (5) years of experience as a Certified Pharmacy Technician after licensure.

(c) The public member of the Board of Pharmacy shall be a resident of this State who has attained the age of majority and shall not be, nor shall ever have been, a Pharmacist or a Certified Pharmacy Technician, ~~or the spouse of a Pharmacist,~~ or a Person who has ever had any direct conflict of interest pertaining to the Practice of Pharmacy or material financial interest in the provision of Pharmacy services or who has engaged in any activity directly related to the Practice of Pharmacy.[12]

Section 204. Appointment.

(a) The Governor shall appoint the members of the Board of Pharmacy in accordance with other provisions of this Section and the State Constitution.

(b) Nominations for appointment to the Board may be made to the Governor by any individual, association, or any other entity. Such nominations shall be recommendations only and shall not be binding in any manner upon the Governor.[13]

[12] Specific qualifying Criteria for the public member have been deliberately omitted from this section. Reliance has been placed in the Governor to determine what attributes an individual should possess in order to meaningfully serve on a Board of Pharmacy. In order to help ensure that such a member would be truly independent in his or her judgments, those persons who have a possible substantial relationship with the profession are rendered ineligible by this Section.

[13] The purpose of Section 204(b) is to provide a mechanism through which any interested Person or group may designate a candidate for the Board. Since nominations are recommendations only, the Governor retains complete discretion in regard to the appointees. As an alternative to appointment of Board of Pharmacy members by the Governor, some state laws call for the election of such members by the states' Pharmacists.

Section 205. Terms of Office.

(a) Except as provided in subsection (b), members of the Board of Pharmacy shall be appointed for a term of _____ years, except that members of the Board who are appointed to fill vacancies that occur prior to the expiration of a former member's full term shall serve the unexpired portion of such term.

(b) The terms of the members of the Board shall be staggered, so that the terms of no more than _____ member(s) shall expire in any year. Each member shall serve until a successor is appointed and qualified.
(1) The present members of the Board shall serve the balance of their terms.
(2) Any present Board member appointed initially for a term of less than _____ years shall be eligible to serve for _____ additional full terms.

(c) No member of the Board shall serve more than _____ consecutive full terms. The completion of the unexpired portion of a full term shall not constitute a full term for purposes of this Section.

Section 206. Vacancies.

Any vacancy that occurs in the membership of the Board for any reason, including expiration of term, removal, resignation, death, disability, or disqualification, shall be expeditiously filled by the Governor in the manner prescribed by Section 204.

5. Add a "consideration of waiver request" process.

Section 15. Approval of Pharmacy Practice Initiatives.[14]

(a) Application.[15]
An application for approval of a Pharmacy practice initiative that improves the quality of or access to Pharmacist Care Services, but which falls outside the scope of present regulations, shall be submitted to the Board and shall contain at least the following information:
(1) the name, address, telephone number, and the license number of the Pharmacist responsible for overseeing the initiative;
(2) the specific location and, if a Pharmacy, the Pharmacy name, address, telephone, and license number where the proposed Pharmacy practice initiative will be conducted; and
(3) a detailed summary of the proposed Pharmacy practice initiative, which includes:

[14] This may also be referred to as Approval of Rule Waiver Requests.

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

(i) the goals and/or objectives of the proposed Pharmacy practice initiative;
(ii) a full explanation of the initiative and how it will be conducted;
(iii) the time frame for the Pharmacy practice initiative, including the proposed start date;
(iv) background information or literature review to support the proposal, if applicable;
(v) the rule(s) that will have to be waived in order to complete the Pharmacy practice initiative and a request to waive the rule(s); and
(vi) procedures to be used during the Pharmacy practice initiative to ensure that the public's health and safety are not compromised as a result of the rule waiver.

(b) Approval by the Board.

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

(1) the Pharmacy practice initiative will improve the quality of or access to Pharmacist Care Services;
(2) the Pharmacy practice initiative will not adversely affect, directly or indirectly, the health, safety, or well-being of the public; and
(3) the alternative measures to be taken, if any, are equivalent or superior to those prescribed in the part for which the rule waiver is requested.

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

(c) Notification.

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

(d) Extension of Approval of Pharmacy Practice Initiatives.

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

6. For the Model Rules for the Practice of Pharmacy:

a. Update the wording regarding transfer of a prescription order to accommodate non-paper prescription processes

(for example, writing "VOID" or "TRANSFER" on the face of transferred prescriptions).

The committee also suggested edits that clarified the prescription drug order process.

Section 4. Prescription Drug Order Processing.

…

Transfer of a Prescription Drug Order

Pharmacies utilizing manual as well as automated data-processing systems shall satisfy all information and documentation requirements ~~of a manual mode~~ for Prescription Drug Order transfer~~al~~ listed below, except as noted below for those Pharmacies accessing a common electronic file. The transfer of original Prescription Drug Order information for the purpose of refill Dispensing is permissible between Pharmacies subject to the following requirements:

(1) The information for a prescription, other than for a controlled substance,[16] must be ~~is~~ communicated directly between Pharmacists, Pharmacy Interns, or Certified Pharmacy Technicians. ~~and the transferring Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician.~~

(2) The following information must be recorded by the transferring pharmacy ~~records the following information~~:

- (i) ~~write the word "VOID" on the face of the invalidated~~ the fact that the original Prescription Drug Order has been deemed void/closed;
- (ii) ~~record on the reverse side of the invalidated Prescription Drug Order~~ the name and address of the Pharmacy to which it was transferred ~~and~~
- (iii) the name of the Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician receiving the Prescription Drug Order;
- (iv) ~~record~~ the date of the transfer; and
- (v) the name of the Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician transferring the information.~~; and~~
- ~~(iv) the computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above~~.

(~~2~~3) ~~The Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician~~ The following information must be recorded by the pharmacy receiving the transferred Prescription Drug Order ~~information shall reduce to writing the following~~:

- (i) ~~Write the word "TRANSFER" on the face of the transferred~~ the fact that the Prescription Drug Order has been received via transfer.

[16] According to 21 CFR §1306.25 (b)(1), the transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill Dispensing must be communicated directly between two licensed Pharmacists.

(ii) ~~Provide all information required to be on a Prescription Drug Order pursuant to state and federal laws and rules, and include:~~

~~(A)~~ the date of issuance of original Prescription Drug Order;

(~~B~~iii) the original number of refills authorized on original Prescription Drug Order;

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

(~~D~~v) the number of valid refills remaining and date of last refill;

(~~E~~vi) the Pharmacy's name, address, and original prescription number from which the Prescription Drug Order information was transferred; and

(~~F~~vii) name of transferring Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician.

(~~iii~~i4) Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of Pharmacist Care Services.

(~~3~~5) Both the original and transferred Prescription Drug Order information shall be maintained for a period of five years from the date of last refill.

(~~4~~6) Pharmacies accessing a common electronic file or database used to maintain required Dispensing information are not required to transfer Prescription Drug Orders or information for Dispensing purposes between or among Pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each Prescription Drug Order and refill Dispensed~~, and, further, that a hard copy record of each Prescription Drug Order transferred or accessed for purposes of refilling shall be generated and maintained at the Pharmacy refilling the Prescription Drug Order or to which the Prescription Drug Order is transferred~~ and shall protect against the illegal use or disclosure of Protected Health Information.

(~~5~~7) In an emergency, a Pharmacy may transfer original Prescription Drug Order information for a non-controlled substance to a second Pharmacy for the purpose of Dispensing up to a 72-hour supply without voiding the original Prescription Drug Order.

b. Update the wording in reference to "sight-readable" data storage and "hard copy printout."

Section 5. Record Keeping.

(c) Electronic Recordkeeping

…

(2) Data Storage and Retrieval.

(i) ~~the system shall have the capability of producing sight-readable information on all original and refill Prescription Drug Orders. The term "sight-readable" means that an authorized individual shall be able to examine the record and read the information from the cathode ray~~

~~tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy; and~~

~~(ii)~~ the system shall provide online retrieval ~~(via CRT display or hard copy printout)~~ of original Prescription Drug Order information. Such information shall include, but not be limited to, the Prescription Drug Order requirements and records of Dispensing as indicated in Section 3 of this Rule; and

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

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

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

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

application for a period of two years after the date of Dispensing the appropriately authorized refill;

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

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

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

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

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

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

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

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

…

7. For the Model Rules for Nuclear/Radiologic Pharmacy, note that pharmacies shall also adhere to compounding rules if compounding non-radiopharmaceuticals.

Model Rules for Compounded or Repackaged Pharmaceuticals

Section 1. Purpose and Scope.

The purpose of this section is to ensure Compounded Pharmaceuticals are prepared and Dispensed according to practice and quality standards through the provision of: (1) Pharmacist Care Services; and (2) the preparation, Labeling, and Distribution of Compounded or Repackaged Pharmaceuticals by Pharmacies, including Nuclear Pharmacies. These standards are

intended to apply to all Sterile and nonsterile Compounded Pharmaceuticals, notwithstanding the location of the patient (eg, home, hospital, nursing home, hospice, doctor's office). All facilities and Practitioners engaging in Sterile and nonsterile Compounding or Repackaging shall practice in accordance with Federal law, these Rules, and the current United States Pharmacopeia–National Formulary (USP-NF), including but not limited to General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations,* General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations,* General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings,* and other applicable referenced general chapters. The procedures contained herein are considered to be the minimum current good compounding practices for the Compounding of Drug Products by State-licensed Pharmacies for Dispensing and/or Administration to humans or animals.[17]

Model Rules for Nuclear/Radiologic Pharmacy

…

Section 4. Other Requirements.

All Nuclear/Radiologic Pharmacies shall: ~~also~~

(a) adhere to the principles outlined in the Rules for Pharmacist Care Services as these pertain to the practice of Nuclear Pharmacy.

(b) If compounding non-radiopharmaceutical products, adhere to all sterile/nonsterile compounding requirements.

8. For the Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors, consider identifying a "Designated Representative" for Manufacturers, Repackagers, and Third-Party Logistics Providers, in addition to Wholesale Distributors.

Section 1. Requirements for Licensure.

Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors that provide services within this State, whether located within this State or outside this State, shall

[17] The Compounding of Drugs for animals must be done in accordance with the algorithm contained in the Animal Medicinal Drug Use Clarification Act of 1994 and associated FDA Guidance.

be licensed by the Board and shall annually renew their license with the Board using an application provided by the Board. Third-Party Logistics Providers and Wholesale Drug Distributors must report license status to FDA as outlined in Federal law. Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors cannot operate from a place of residence. Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

(a) Every Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor who engages in the Manufacturing, Repackaging, or 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 entity 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, their Social Security numbers or unique identifiers and their dates of birth, 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
(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 licensee ~~facility of a Wholesale Distributor that engages in the Wholesale Distribution of Prescription Drugs or Devices and additional information as required in Section 9 (Record Keeping)~~;

…

9. Align with the federal Controlled Substances Act and rules.

a. Update the wording addressing electronic transmission of CS prescriptions.

b. Update the wording addressing oral communication of emergency Schedule II prescription orders.

Manner of Issuance of a Prescription Drug Order[18]

A Prescription Drug Order, to be valid, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice. The responsibility for the proper prescribing and Dispensing of controlled substances is upon the prescribing Practitioner, but a corresponding responsibility rests with the Pharmacist who fills the prescription.[19]

(1) A Prescription Drug Order must be communicated to a Pharmacist, or when recorded in such a way that the Pharmacist may review the Prescription Drug Order as transmitted, to a Pharmacy Intern or a Certified Pharmacy Technician, in a licensed Pharmacy. This may be accomplished in one of the following ways. A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in written or electronic form. A Prescription Drug Order, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) [20] or issued electronically.[21, 22]

(2) The Pharmacist shall not dispense a Prescription Drug if the Pharmacist knows or reasonably should know that the Prescription Drug Order was issued solely on the basis of an

[18] Electronically transmitted prescriptions should be transmitted from prescriber to Pharmacy with no intervening Persons making illegal alterations that may be considered as engaging in the Practice of Pharmacy without the authority to do so or without being licensed to do so to such prescriptions. Evolving technologies and systems have alleviated previous concerns regarding the routes by which electronic prescriptions are transmitted, but any attempts to return to illegal prescription altering practices will be halted.

[19] While Pharmacists have a corresponding responsibility to ensure that a controlled substance is Dispensed only pursuant to a valid Prescription Drug Order written for a legitimate medical purpose, this should not impede patients from receiving legitimately prescribed controlled substances or non-controlled substances, as patient care should be the primary consideration.

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

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

[22] Electronically transmitted prescriptions should be transmitted from prescriber to Pharmacy with no intervening Persons making illegal alterations that may be considered as engaging in the Practice of Pharmacy without the authority to do so or without being Licensed to do so to such prescriptions. Evolving technologies and systems have alleviated previous concerns regarding the routes by which electronic prescriptions are transmitted, but any attempts to return to illegal prescription altering practices will be halted.

Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid Patient-Practitioner relationship.

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

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

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

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

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

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

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

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

10. *General questions:*

a. *Currently, the* Model Act *references various NABP programs and services. Should such references be removed?*

The committee recommended that such references should be removed from model language text, but that footnotes should be used to identify corresponding NABP programs.

b. *The words "pharmaceutical" and "medication" are used interchangeably with "Drug." Should only "Drug" be used?*

The committee recommended that the words "drug" and "medication" should be used throughout, with the word "medication" used in reference to clinical activities and the word "drug" used in reference to pharmacy management activities, such as managing inventory. If the word "pharmaceutical" is being used in these instances, it should be changed.

c. *Currently, the* Model Act *references specific USP chapters. Should specific references be removed and text such as "Current USP chapter addressing…" be used instead?*

The committee recommended removing numerical references to USP chapters, and instead use "USP chapter addressing [insert topic]."

d. *Currently, the* Model Act *includes templates, resources, and forms as appendices to the document (eg, Sample Pharmacy Automation Policy and Procedure Outline). Should these be removed and used to create separate resources? Are there additional examples of such resources that would be helpful to boards of pharmacy?*

The committee recommended removing templates, resources, and forms from the appendices section of the *Model Act* and having staff determine the appropriate web page(s) to display them. Text should be added to the *Model Act*

introduction and footnotes should be added, where appropriate, to note that these resources exist and where they can be found. In addition, any “Acts” should be moved to the *Model Act* itself.