NABP
National Association of Boards of Pharmacy

Report of the

MODEL ACT REVIEW COMMITTEE

Members Present

Steven W. “Steve” Schierholt (OH), *chair*; Todd Dear (MS); Susan DelMonico (RI); Kristina “Kris” Jonas (ID); Susan “Sue” Mears (IA); Michael Moné (OH); Denise Scarpelli (IL); and Theresa “Terry” Talbott (PA).

Others Present

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

Introduction

The Model Act Review Committee met virtually on July 12, September 22, October 15, and October 29, 2021.

Review of the Task Force Charge

Committee members reviewed their charge and accepted it as follows:

1. Conduct a thorough review of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to ensure the following are updated for relevance and accuracy:
    - dates;
    - footnotes;
    - references to federal law and regulations and standard setting organizations, such as United States Pharmacopeial Convention and Accreditation Council for Pharmacy Education; and
    - overall language to remove outdated provisions.
2. If necessary, make recommendations to the NABP Executive Committee regarding any section of the *Model Act* that should be considered for revision so that current pharmacy practice is accurately reflected.

Background and Discussion

The initial meeting began by reviewing the charge of the Committee and providing an explanation about the process by which the *Model Act* is reviewed and edited each year, which focuses on the work of NABP task forces and the Committee on Law Enforcement/Legislation. It was noted that, due to this process, the *Model Act* is often reviewed and amended in a piecemeal fashion, which results in inconsistencies in language, style, and tone. In addition, references to laws, rules, policies, or guidances may need to also be reviewed and updated.

Staff outlined the process that the Committee would utilize to provide their recommended amendments and topics for discussion and noted that the subsequent meetings would be used to review each recommendation. Members were given a demonstration that instructed them on how they would access an online shared version of the *Model Act* to provide their input.

The Committee was provided 10 weeks to review the document and make suggestions, of which approximately 180 were received. The subsequent meetings were spent reviewing each suggestion for consensus and to determine whether it involved a substantive or non-substantive edit. Non-substantive edits can be made to the *Model Act* without additional review; however, recommendations for substantive amendments must be evaluated by an appropriate task force or committee, or both.

After thoroughly reviewing the Committee's suggestions, all non-substantive edits, other than those that change the order of *Model Act* chapters or sections, were made by staff and documented in the shared *Model Act* document. Those that suggested any changes in the order will be reviewed after substantive amendments are addressed.

All substantive recommendations are compiled below and are categorized by recommended next steps. One set of recommended next steps is to assign the review of the suggestions to various task forces or work groups that will:

- review "*Model Rules for the Practice of Pharmacy*" and other related pharmacy practice sections;
- review "Article III, Licensing" (of people) and applicable rules to update and reorganize;
- review "Article V, Licensing of Facilities" and applicable rules;
- update all disciplinary language;
- update the "*Model Rules for Institutional Pharmacy;*"
- review and update the "*Model Prescription Monitoring Program Act*" and consider developing model rules; and
- add a section addressing medical marijuana.

Once these task forces or work groups review and make their recommendations, as per normal procedure, such recommendations would then be reviewed by the Committee on Law Enforcement/Legislation, and that Committee's recommendations would subsequently be reviewed by the Executive Committee.

For substantive recommendations that do not require an in-depth review, it is recommended that they be assigned directly to the Committee on Law Enforcement/Legislation. They are also complied below.

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Evaluation of the Model Act Review Committee's Substantive Recommendations

Assign to a task force or work group that will do the following:

- Review "*Model Rules for the Practice of Pharmacy*" and other related pharmacy practice chapters.
    - Review definitions of pharmacist, pharmacist care services, pharmacy, and practice of pharmacy.
    - Expand pharmacist prescribing authority and review elements of pharmacist care services and collaborative pharmacy practice and/or statewide protocols.
    - Clarify that the administration of medications and/or immunizations is included in the definition of pharmacist care services. For example, add medication therapy management to the definition of pharmacist care services. Also review technician responsibilities related to this.
    - Add sections on additional pharmacy practice elements, such as veterinary pharmacy, tech-check-tech, point-of-care testing and treatment, provision of drugs to emergency service programs, and delegation to technicians.
    - Consider defining what activities a technician cannot perform in the absence of a pharmacist at a remote dispensing site.
    - Add language about substitution of biologics.
    - For collaborative pharmacy practice, add needed language for pharmacists to collaboratively prescribe controlled substances (CS):
        - Mid-level practitioner registration.
        - Note that collaborating provider must be registered with Drug Enforcement Administration (DEA) and the state CS authority, if needed, and hold a license in good standing in order to prescribe CS. Also, note that practice must be within scope of collaborating practitioner.
    - Add language about conducting retrospective drug utilization review when drugs are removed from an automated pharmacy system prior to a pharmacist's review (emergency use).
    - Add language addressing a review or assessment of handling of hazardous drugs in automated pharmacy systems.
    - Review "Section 12. Disposal of Controlled Substances" as it seems outdated and unnecessary. Refer to DEA regulations.

- Review "Article III, Licensing" (of people) and applicable rules to update and better organize.
    - Consider clarifying that this chapter addresses licensure of people, not facilities. With this in mind, some text should be moved to "Article IV, Licensing of Facilities."
    - Ensure text substantively aligns with recommendations of the NABP Work Group to Consider Permanently Extending Certain Waivered Provisions.
    - Consider removing "Section 306. Pharmacy Practice Experience Program Standards; Pharmacy Intern Licensure," as it is similar to language in 302(c).
    - Add requirement for technician experiential hours and add section that addresses technician practice experience program requirements.

- Remove reference to “initial” licensure by examination.
- Add definitions of “license” and “registration” and review use of these words throughout *Model Act*.
- Review “Section 303. Qualifications for Licensure Transfer” to ensure it aligns with current NABP process.
- Remove 303(b) reciprocity text.
    - “No applicant shall be eligible for license transfer unless the state in which the applicant was initially licensed as a Pharmacist also grants license transfer to Pharmacists duly licensed by examination in this State, under like circumstances and conditions.”
- Create a separate section addressing “Grounds for Denial.”
- For “Section 304. Renewal of Licenses,” add consequences for missing the renewal deadline.
- In the “*Model Rules for Pharmacy Interns*” and “*Model Standards for Pharmacy Practice Experience Programs*” chapters:
    - Consider other terms for “pharmacy intern.”
    - Remove text addressing board approval of pharmacy practice experience practice sites, as sites are overseen by schools.
    - Move requirement that intern notify board about location of experience site from “*Model Standards for Pharmacy Practice Experience Programs*” chapter to “*Model Rules for Pharmacy Interns*” chapter.
    - Delete requirement that pharmacy interns report name of preceptor to board within two weeks of starting practice, as it duplicates the section that requires interns to report change of employment.
    - For intern license, add time limit for reporting of change of employment and address (eg, 10 days). Add “name change” to this reporting requirement.
    - Consider having the license expire upon completion of degree, and reconsider need for renewal.
    - Does there need to be an additional process for preceptor approval by the board? Or would this be too prescriptive?

- Review “Article V, Licensing of Facilities” and applicable rules.
    - Align language with the Drug Supply Chain Security Act (DSCSA).
        - Use DSCSA terminology: “Illegitimate,” “Suspect,” and all distribution related terminology.
        - Distribution limits not aligned with DSCSA.
            - Pharmacy distributing to another pharmacy or to wholesaler (5% limit).
            - Wholesaler distributing to another wholesaler (5% limit).
    - In addition to aligning with DSCSA, review for organization.
    - In “Section 501. Licensing,” some items listed are requirements for licensing while others are allowances for the board to carry out their authority. Consider separating.

- Update definition of “temporary pharmacy facility” to allow outside of a declared emergency.
- For the definition of “health care entity,” is the phrase that begins with “but” needed? ““Health Care Entity” means any person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care *but does not include any retail Pharmacy or Wholesale Distributor*.”
- Consider changing the use of “person” to the specific subjects, such as “pharmacist,” “pharmacy,” “wholesaler.”
- Remove reference to “annual” registration.
- Consider moving “pharmacist-in-charge” (PIC) language to rule.
- Review reference to “verified” applications for facility licensure.
- Review reference to competence of agents who inspect facilities for boards. Should this be moved to a section addressing board operations?
- Review reference to surety bond requirements. Are they only for wholesale distributors? Should this be in rule? Since manufacturers are exempt from surety bond requirements (exempt from DSCSA), that text should not be needed.
- For renewal of license, add consequences for missing the renewal deadline.
- Add time limit for reporting and providing copy of inspection by state or federal regulatory agency (for example, 30 days).
- Review references to “dispensing practitioners” in licensing of facilities chapter and labeling and record-keeping rules. Should there be more oversight?
- Consider adding requirement for designated representative for all categories of facility licenses (except pharmacy).
- In “*Model Rules for Outsourcing Facilities*,” consider adding requirement for PIC and responsibilities.

- Update all discipline language.
  - Consider removing all reference to criminal penalties.
  - Separate “impaired pharmacist” section from discipline. Focus on voluntary participation.
  - Update definition of “probation,” “suspension,” “summary suspension,” and “revocation.”
    - Update “revocation” to clarify “withdrawal” and that revocation is not the same as a voluntary surrender, which is also a withdrawal. Change “withdrawal” to “permanent recission” and remove text after first sentence.
  - Add “subverting an investigation” as a prohibited act for licensees.
  - Review cost recovery language to update. Increase limit and consider providing penalties per violation.
  - Add section on disqualifying criminal convictions.
  - Reconsider term “costs/administrative costs” and consider using only “costs.”
  - Review conditions for “reinstatement.”

- Update "*Model Rules for Institutional Pharmacy*."
    - Address non-disaster emergent issues, such as leaking pipes or out-of-range temperature in pharmacy or refrigerator.
    - Add wording about the periodic inspection of emergency kits and be sure it complies with DEA if CS are included in kit.
    - Consider removing section on night supplies and simply require a policy and procedure.
        - If not removed, update outdated terminology and sections:
            - Night cabinet, floor supplies
            - Supervisory, authorized, responsible nurse
    - Consider changing language about nurses transmitting chart orders to the pharmacy to language that describes the pharmacist's responsibility when a nurse transmits such an order.
    - Address federal laws and/or rules regarding CS and shared services use – need for prescription rather than a chart order.
    - Consider allowing central fill and/or shared services for all pharmacy operations in some facilities.
    - Move this text from definition of "chart order" to rules:
        - "Bidirectional transmission of Chart Orders between the Institutional Pharmacy and the Institutional Facility is allowed. The Pharmacist-in-Charge shall ensure that the Institutional Pharmacy has policies and procedures for a Practitioner to delegate the transmittal of a Chart Order to a licensed nurse employed by, or contracted by, the Institutional Facility and acting within the scope of his or her practice. Renewal of ongoing Chart Orders shall be signed by the prescriber at the appropriate time interval based on facility type and federal regulation, state law, or rule. Chart Orders shall be ongoing until such time as the Practitioner discontinues the order and such discontinuation is communicated to the Pharmacy, including but not limited to, by automatic stop order, unless otherwise indicated."

- Review and update "*Appendix E, Model Prescription Monitoring Program Act*" and consider developing model rules.

- Add a chapter on regulation of medical marijuana.

Assign to the Committee on Law Enforcement/Legislation

- Remove references to NABP programs and services.
- Review for consistency the use of words "pharmaceutical" and "drug."
- Expand definition of "quality related event" to include clinical activities, not just dispensing activities.
- In the "*Model Rules for the Practice of Pharmacy*," for the labeling of prescription containers, do we need to address patients who need text in foreign languages? This may be moot as

the 2021-2022 Committee on Law Enforcement/Legislation addressed it, and the report is pending approval.

- Regarding board composition.
    - Add technician member to board of pharmacy composition.
    - Add time frame within which new board member must be appointed in case of a vacancy.
- Add a "consideration of waiver request" process.
- Align wording of entire document to updated federal laws and/or rules.
    - Update wording regarding electronic transmission of CS prescriptions.
    - Update wording regarding oral communication of emergency Schedule II prescription orders.
- Update wording regarding transfer or prescription order to accommodate non-paper prescription processes (for example, writing "VOID" or "TRANSFER" on face of transferred prescriptions).
- Update wording in reference to "sight readable" data storage.
- Add reference to a state's Administrative Procedures Act to ensure board follows such act.
- Update definition of "protected health information" to remove references to Health Insurance Portability and Accountability Act sections.
- Update definition of "suspicious order" to make it more robust.
- Add wording to allow electronic service of process if permitted by state law.
- Add DSCSA descriptive wording ("illegitimate, suspect") regarding counterfeit drugs.
- In "*Model Rules for Nuclear/Radiologic Pharmacy*," note that pharmacies shall also adhere to compounding rules if compounding non-radiopharmaceuticals.
- Ensure criteria for "Qualified Nuclear Pharmacist" is up to date.
- Remove references to specific US Pharmacopeia (USP) chapters, noting only: "Current USP chapter on…."
- Remove last sentence from telepharmacy practice definition. It is already in rules, so is it needed in definition? This was included in the definition due to much confusion at the time of the development of this language:
    - "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."
- Remove all templates, resources, and forms from the *Model Act* document (eg, Sample Pharmacy Automation Policy and Procedure Outline) and create a separate resource of these items and additional examples that would be helpful to boards of pharmacy.