NABP
National Association of Boards of Pharmacy

Report of the Committee on

LAW ENFORCEMENT/LEGISLATION

Report of the Committee on Law Enforcement/Legislation

Members Present

Alexandra Blasi (KS), *chair*; Paul Brand (MT); Laura Forbes (VI); Michael Godek (MA); Christopher Hogan (AZ); Tyler Laetsch (SD); Donna Montemayor (TX); John Rocchio (MA); Lucy Shell (TN); Katie Thornell (MA); and Derek Webb (VA).

Others Present

David Bowyer (WV), *Executive Committee liaison*; Lemrey "Al" Carter, Melissa Becker, Andrew Funk, Neal Watson, Gertrude "Gg" Levine, Maureen Schanck, and Ashley Lueder, *NABP staff*.

Introduction

The committee met on March 2-3, 2026, at NABP Headquarters in Mount Prospect, IL.

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 on 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 model pharmacy practice or prescription drug distribution regulations that are needed to improve the protection of public health.

Background and Discussion

The meeting began with a review of the committee charge and agenda items for discussion. Agenda items included recommended amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* stemming from the Task Force to Review Increasing Access to Medications for Opioid Use Disorder; Resolution 121-2-25, Joint Accountability for Pharmacy Compliance, and the resulting decision tree; and several topics that the Executive Committee asked this committee to review. These topics included proposed *Model Act* language addressing medical spa oversight by boards of pharmacy, proposed *Model Act* language outlining a standard of care regulatory model, and several sections of current *Model Act* language, including sections addressing pharmacist scope of practice, oversight of alternative funding programs and prescription drug facilitators or non-dispensing pharmacies, and board policies that allow for pharmacy innovation.

After careful review and deliberation of each agenda item, the committee recommended amendments and additions to the *Model Act,* as described in the sections below. The documents referenced in the discussion are included, with edits shown, at the end of this report.

Recommended *Model Act* Amendments From the Task Force to Review Increasing Access to Medications for Opioid Use Disorder

The committee began its discussion with a review of *Model Act* amendments recommended by the Task Force to Review Increasing Access to Medications for Opioid Use Disorder.

In Article I, Section 105, Definitions, the committee considered the task force's recommended edits to the definition of "drug of concern." The task force recommended adding language describing the term as a drug that is "identified by the board of pharmacy" that demonstrates a potential for abuse "and is not currently scheduled as a controlled substance by state or federal law." The committee, noting that, in some states, it may not be the board of pharmacy making the determination, recommended replacing "identified by the boards of pharmacy" that demonstrates a potential for abuse with "deemed by the state to demonstrate" a potential for abuse.

In Section 8 of the Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors, the committee considered the task force's recommendations to strike references to "third-party logistics providers" and other terms related to the distribution of medication for opioid use disorder (MOUD) and agreed to accept these changes, acknowledging the language was revised to match that of the National Opioid Settlement Final Distributor Settlement Agreement, which establishes requirements for the distribution of controlled substances, including MOUD.

In addition to those recommended by the task force, the committee discussed making other *Model Act* amendments. For instance, in Article I, Section 104, the committee modified the definition of the "practice of pharmacy" by supplementing Subsection (2), "providing patient counseling," with "and education." The committee modified the definition of "pharmacist care services" by changing Subsection (3), "emergency use prescribing and dispensing" to "prescribing, administering, and dispensing drugs or devices."

The committee considered adding a new item, "providing medications for opioid use disorder," to this section. Members weighed this item in light of state and federal efforts to call attention to MOUD versus some states' preference for broader regulations. They noted that some states may oppose pharmacist prescribing. Ultimately, the committee rejected this suggested item in favor of adding the following: "prescribing medications in line with clinical education, training, or experience," to keep the list of services uniformly applicable to any drug or device.

In Article III, Licensing, the committee added a new Section 310, Registration for the Prescribing of Controlled Substances, to encompass pharmacist prescribing, administering, and dispensing MOUD. The new section states, "In order for a pharmacist to prescribe controlled substances, including controlled substances for opioid use disorder, the pharmacist must obtain a DEA registration and, if required, a state controlled substances license and registration." These changes reflect the evolving regulatory landscape on pharmacists' authority regarding MOUD, as well as the move toward a broader regulatory approach.

For consistency with the revised definition of "pharmacist care services" mentioned above, the committee made similar changes to the Model Rules for the Practice of Pharmacy, Section 6, Pharmacist Care Services. In Subsection (1), the committee added "medication adherence monitoring service" to the list of services, revised "emergency use prescribing and dispensing" to "prescribing, administering, and dispensing drugs or devices," struck the footnote

corresponding to emergency use prescribing, and added a new item (g), “prescribing medications in line with clinical education, training, or experience.”

The committee also struck Subsection (7), Emergency Use Prescribing and Dispensing” and the corresponding footnote.

The specific changes recommended by the task force, as well as those of the committee, are shown in Appendix A of this report.

Joint Accountability for Pharmacy Compliance – Resolution and Decision Tree

The committee then examined Resolution 121-2-25, Joint Accountability for Pharmacy Compliance, which the NABP membership passed at the 2025 NABP Annual Meeting. The Resolution calls for NABP to work with member boards and stakeholders to “develop solutions to enhance patient safety through increased compliance” by owners and/or permit holders and designated supervising pharmacists and/or pharmacists-in-charge (PICs).

In response to this resolution, and at the behest of board members at the 2025 NABP Forum, NABP developed a decision tree to assist boards of pharmacy with determining if owners/permit holders and supervising pharmacists/PICs are solely or jointly accountable for regulatory noncompliance. This decision tree is similar to one that NABP developed and the committee approved in 2025 to help boards determine a pharmacist’s or pharmacy technician’s culpability in association with quality-related events. Like that one, the new decision tree is based on a “just culture” disciplinary approach, which examines systemic factors that may contribute to noncompliance rather than just disciplining individuals.

Deeming the new decision tree a useful tool for boards of pharmacy, the committee approved it with no changes.

The resolution and related decision tree are provided in Appendix B of this report.

Proposed *Model Act* Language for Medical Spa Oversight by the Boards of Pharmacy

The committee then reviewed proposed new *model* language for medical spa (med spa) oversight by the boards of pharmacy. Drafted and reviewed by staff subject matter experts, the proposed language gives the boards a path to regulate med spas that are proliferating across the country with little oversight, posing a public health risk. Because states currently may not have the statutory authority to oversee med spas, this section is proposed to be published as an act separate from the actual *Model Act* text.

In discussing the issue, the committee recognized that many med spas possess and administer drugs without appropriate medical supervision, and that the proposed language would authorize boards of pharmacy to enter and inspect med spas, require registration, and implement discipline if the facilities operate in this manner. Under the proposed requirements, a med spa would have to register with the board under the name of the responsible person, enabling the board to take action against that individual if necessary.

The committee appreciated that the proposed language addresses the use of research chemicals, which are not approved for patient use and pose a safety risk.

In its examination of Section 3.1, License and Registration Required, the committee considered the information to be included in a med spa application and recommended that it include the federal employer identification number (FEIN). This discussion led to the decision to add language to a footnote in Section 403 of the *Model Act* advising that boards of pharmacy may want to collect the FEIN from all types of applicant facilities.

Regarding the required physical address of the business where wellness services will be performed, the committee acknowledged that some med spa locations are temporary "pop-up" facilities or may operate out of a van or camper. As such, the committee recommended adding one or two sections on mobile and temporary med spa services, including a notification requirement or readily available report of where services were performed.

The committee also noted that boards in most states issue facility licenses to physical locations. Boards may offer provisions for temporary off-site services, but a permanent address change would require a new application and pre-opening inspection. Members suggested that including model language to this effect may alleviate the need for a temporary license category.

The committee also considered whether boards should require the responsible person to meet educational requirements when applying for a med spa permit. For instance, members noted, if the med spa is administering drugs, the responsible person must know about drugs; most licensed professionals in fields other than pharmacy do not. Ultimately, however, the committee decided that language specifying educational requirements for the responsible person would be too prescriptive.

The proposed language, reflecting the committee's discussion, is provided in Appendix C of this report.

Proposed *Model Act* Language for a Standard of Care Regulatory Model

The next item that the committee considered was a proposed Model Pharmacist Practice Act, providing suggested language for boards wanting to establish a standard of care regulatory model. Drafted and reviewed by staff subject matter experts, the proposed language would allow for "a flexible framework for practice expansion over time," as stated in Section 102, Legislative Declaration. To better reflect NABP's public health mission, the committee recommended adding the phrase, "to ensure patient access to clinical services and practice innovation."

The committee discussed whether the proposed language should be identified as a separate option for states. While the members favored incorporating it into the existing practice act, they ultimately decided to defer the decision to the Executive Committee.

It was observed that the proposed language includes a definition for "prescription adaptation" that is not included in the existing *Model Act.* Staff agreed to add it there. The committee considered a section of this proposed definition referring to "the act by which a pharmacist uses their clinical judgment . . . to ensure the therapy is effective and cost-efficient" and agreed to clarify that the therapy should be cost-efficient "for the patient."

In its discussion of the proposed Section 203, Pharmacist Prescribing Authority, the committee agreed that the language should not limit a pharmacist's authority to independently prescribe drugs and devices to specific situations.

Section 401, Grounds for Discipline, prompted discussion about enforcement authority, which, members said, should be descriptive and clear, noting that it would be difficult for a board to implement discipline for a violation that is not specifically defined. On the other hand, the committee considered moral issues that do not concern the practice of pharmacy. Subsequently, the committee agreed that the board's authority to discipline a licensee should not be limited to actions within the practice of pharmacy, noting that some actions outside the practice may speak to a pharmacist's character.

In Section 402, Waiver Authority, regarding the board's authority to grant waivers, the committee recommended that the paragraph refer to "state rules," and indicate that the board may authorize a waiver if the "request is in the best interest of the public."

The proposed language, reflecting the committee's discussion, is included in Appendix D of this report.

Current *Model Act* Language for Discussion About Pharmacist Scope of Practice

The committee then considered the existing *Model Act* language addressing pharmacist scope of practice. In Section 104, Definitions for the Practice of Pharmacy and Related Terms, the committee recommended modifying the definition of "pharmacist care services" to match the edits proposed for documents the committee reviewed earlier. These edits included changing pharmacist care service (3), "emergency use prescribing and dispensing," to "prescribing, administering, and dispensing drugs or devices," striking the footnote on emergency use, and adding a new pharmacist care service (7), "prescribing medications in line with clinical education, training, or experience."

The committee also recommended striking "to provide patient care services" from the definition of "collaborative pharmacy practice," as well as striking "such as medication synchronization" from the list of actions in the definition of "medication therapy management."

In Section 6, Pharmacist Care Services, the committee recommended adding (b) "medication adherence monitoring service" and making other edits to match those included in the definition.

Regarding Subsection (3)(a) Patient Counseling, the committee agreed to strike the caveat that counseling should take place in person "whenever practicable," giving equal weight to counseling conducted via "telephone or other audio/visual means of communication," in consideration of technological advancements and broader acceptance of telehealth. In item (a)(iv), the committee changed "common severe side or adverse effects" to "common side effects, severe side effects . . ." for clarity.

In Subsection (3)(b), establishing who can offer patient counseling, the committee struck language describing specific designees, replacing it with language saying the offer can be made by "the pharmacist or their designee." In Subsection (3)(c), the committee opted to strike examples of alternative forms of patient information, along with the entire Subsection (4) regarding medication adherence monitoring and patient intervention programs, finding the wording unnecessary.

In Subsection (5)(a) regarding a pharmacist planning to engage in collaborative pharmacy practice, the committee agreed to replace specific requirements for documentation, such as having the agreement at their place of practice, with the broader provision that the pharmacist shall have "their collaborative pharmacy practice agreement readily available." The committee

also clarified that the agreement must be within the scope of the "delegating" practitioner's current practice, in light of the recognition that pharmacists are also practitioners.

The committee recommended striking Subsection (6), Emergency Use Prescribing and Dispensing," finding it unnecessary after adding the prescribing language noted above. In addition, the committee simplified Subsection (7)(b) by striking language referencing consideration by disaster or emergency reimbursement programs and leaving, "the pharmacist indicates that it is an 'Emergency Refill Prescription,' and maintains the record."

Regarding Section 15 about pharmacist care services that are external to a pharmacy, the committee recommended changing "outside of a licensed pharmacy" to "unaffiliated with a licensed pharmacy." This change clarifies that pharmacists unaffiliated with a licensed pharmacy may provide such services, especially in the context of digital health.

The relevant *Model Act* excerpts, with the committee's recommended changes shown, are provided in Appendix E of this report.

Current *Model Act* Language for Discussion About Allowing for Pharmacy Innovation

The committee reviewed the current *Model Act* language that allows for pharmacy innovation and discussed revisions that may remove some regulatory barriers and encourage innovation. In Section 213, Powers and Responsibilities, the committee opted to strike the existing language in Subsection (1)(q) regarding approval of "pharmacy practice initiatives that improve the quality of or access to pharmacist care services, but which fall outside the scope of present rules." The committee recommended changing this sentence to "approval of waivers," and added the following language: "The board is authorized to grant waivers from state laws or rules pertaining to the practice of pharmacy if the request is in the best interest of the public," and "The board shall not require express permission for the implementation of new technology or clinical services that are not otherwise prohibited by law, provided that the services are performed in accordance with the standard of care." This language mirrors sections 202 and 402 of the proposed *Model Act* language for a standard of care regulatory model.

Additionally, in the Model Rules for the Practice of Pharmacy, the name of Section 16 was changed from "Approval of Pharmacy Practice Initiatives" to "Approval of Waivers."

The relevant *Model Act* excerpts, with the recommended changes shown, are provided in Appendix F of this report.

Current *Model Act* Language for Discussion About Oversight of Alternative Funding Programs and Prescription Drug Facilitators or Non-Dispensing Pharmacies

An alternative funding program was described as a company accepting prescriptions from prescribers and sending them to pharmacies – sometimes foreign pharmacies – for fulfillment. It was argued that a prescription drug order must be transmitted to a licensed pharmacy of the patient's choice, with no intervening third party having access to the prescription drug order. Language to this effect was included in a former *Model Act* section on electronic prescription transmission but was removed when that section was merged with Section 4(2) of the Model Rules for the Practice of Pharmacy.

The committee considered whether to reinsert the language that was removed, acknowledging that some states may still have this language in their regulations. Some members argued to include the language to stress that the receiving pharmacy must be a licensed pharmacy under the board's jurisdiction and that intermediary third parties could favor one pharmacy over another. On the other hand, members noted that prescriptions are routinely transmitted through intermediaries such as insurance companies, pharmacy benefits managers, and other third parties.

Recognizing the complexity of these considerations, the committee opted not to offer any *Model Act* amendments but, rather, recommended that NABP convene a task force to address this issue.

APPENDIX A
Recommended *Model Act* Amendments From the Task Force to Review Increasing Access to Medications for Opioid Use Disorder

Changes recommended by the task force are identified by underlines and strikethroughs. Recommendations of the committee are shown using double underlines and double strikethroughs.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I
Title, Purpose, and Definitions

…

Section 104. Definitions for the Practice of Pharmacy and Related Terms.

The "practice of pharmacy" means, but is not limited to:

(1) interpreting, evaluating, compounding, dispensing, and/or administering medical orders;
(2) providing patient counseling and education;
(3) assessing the patient for the purposes of prescribing drugs and devices;
(4) initiating and/or providing pharmacist care services;
(5) using continuous quality improvement programs, emerging technologies, and competency-based education to improve patient safety and the quality of services provided;
(6) engaging in collaborative pharmacy practice.[1]

"Pharmacist care services"[2] mean services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination or reduction of symptoms, and promotion of health and wellness. Pharmacist care services include but are not limited to:

(1) drug utilization review;
(2) medication adherence monitoring service;
(3) ~~emergency use~~ prescribing, administering, and dispensing drugs or devices;[3]

[1] 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*. To assist states in the interpretation of the 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.

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.

[2] 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.

[3] Pharmacists may prescribe drugs for emergency use pursuant to specific statewide protocols or standing orders.

(4) medication therapy management;
(5) reviewing, selecting, and developing formularies and/or practice guidelines;
(6) performing drug product selection, substitution, therapeutic interchange,[4] prescription adaptation, or continuation of therapy;
(7) prescribing medications in line with clinical education, training, or experience; and
(8) ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived[5] lab tests.

...

Section 105. Definitions.

...
"Drug of concern" means any prescription or over-the-counter drug ~~identified~~ deemed by the state to demonstrate ~~board of pharmacy that demonstrates~~ a potential for abuse and is not currently scheduled as a controlled substance by state or federal law~~, particularly those identified by boards of pharmacy, law enforcement, and addiction treatment professionals~~.

...

Article III
Licensing

...

Section 310. Registration for the Prescribing of Controlled Substances

In order for a pharmacist to prescribe controlled substances, including controlled substances for opioid use disorder, the pharmacist must obtain a DEA registration and, if required, a state controlled substances license and registration.

Model Rules for the Practice of Pharmacy

...

Section 6. Pharmacist Care Services.

(1) Pharmacist care services are services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination or reduction of symptoms, and promotion of health and wellness. Pharmacist care services include, but are not limited to:
  (a) drug utilization review;
  (b) medication adherence monitoring service:
  (c) ~~emergency use~~ prescribing, administering, and dispensing drugs or devices;~~6~~

[4] Providing it is within the same FDA drug class and not prohibited by the prescriber.
[5] Most recent version.
[6] ~~Pharmacist may prescribe drugs for emergency use pursuant to specific statewide protocols or standing orders.~~

(d) medication therapy management;

(e) reviewing, selecting, and developing formularies and/or practice guidelines;

(f) performing drug product selection, substitution, therapeutic interchange[7] prescription adaptation or continuation of therapy; ~~and~~

(g) prescribing medications in line with clinical education, training, or experience; and

(g) ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived[8] lab tests.

...

...

~~(7) Emergency Use Prescribing and Dispensing~~

~~Prescribing and dispensing drugs for emergency use shall be pursuant to a pharmacist-issued prescription drug order and include appropriate patient counseling. Drugs or devices for emergency use include, but are not limited to:~~

~~(a) Opioid overdose reversal agents, such as naloxone;~~

~~(b) Epinephrine;~~

~~(c) Antidote kits;~~

~~(d) Short-acting beta-agonist inhalers. ; and~~

~~(e) Medication for opioid use disorder for the purpose of initiating therapy for opioid use disorder. The pharmacist must:~~

~~(i) obtain a DEA registration and a state controlled substance license or registration, if required; and~~

~~(ii) use professional judgment to assess the clinical appropriateness of the patient's request and the length of time until the patient obtains treatment from an authorized practitioner.[9]~~

...

[7] Provided it is within the same FDA Drug class and not prohibited by the prescriber.

[8] Most recent version.

~~[9] It is contemplated that for long-term treatment, pharmacists should be prescribing under a collaborative practice agreement rather than under an emergency use provision.~~

Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors

...

Section 8. Operations/Reporting Requirements.

(1) Manufacturers, repackagers, ~~third-party logistics providers,~~ and wholesale drug distributors must comply with all reporting requirements and exchange transaction history, transaction information, and transaction statements with authorized trading partners as outlined in federal law.

(2) Manufacturers, repackagers, ~~third-party logistics providers~~, and wholesale distributors shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to a program approved by the board.

(a) Suspicious orders shall be submitted electronically to an approved program within five (5) days of the order being identified as suspicious by the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor, and must include, but not be limited to:

(i) customer name;

~~(ii) NABP e-Profile ID;~~

(iii) customer address;

(iv) customer DEA registration number;

(v) state pharmacy license number(s);

(vi) ~~transaction~~ date of order;

~~(vii) drug name;~~

(viii) NDC number;

(ix) quantity ordered; and

(x) ~~indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply.~~ explanation for why the order is suspicious: details that are order-specific regarding why an order was flagged as a suspicious order, including specific criteria used by the manufacturers, repackagers, and wholesale distributors threshold system (except, phrases such as “order is of unusual size” without any additional detail are not acceptable).

(xi) Name and contact information for a knowledgeable designated point of contact for the suspicious order report.

(b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen (15) days of the end of the calendar month.

(c) Manufacturers, repackagers, ~~third-party logistics providers,~~ and wholesale distributors may apply to the board for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.

(3) Except as described in paragraph 9(4), a manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor shall exercise due diligence to identify customers ordering or seeking to order controlled substances or drugs of concern and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and on a regular basis, as necessary:

(a) questionnaires and affirmative steps by the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor to confirm the accuracy and validity of the information provided;

(b) for a customer who is a prescriber, confirmation of prescriber type, ~~specialty practice area,~~ and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;

(c) review of drug utilization reports; and

(d) obtaining and conducting a review of the following:

~~(i) methods of payment accepted and in what ratios;~~

(ii) the ratio of controlled versus non-controlled drug orders and overall sales; <u>and</u>

(iii) orders for controlled substances or drugs of concern from other manufacturers, repackagers, ~~third-party logistics providers,~~ or wholesale distributors made available by US DEA's Automation of Reports and Consolidated Orders System (ARCOS)<u>.</u> ~~; and~~

~~(iv) the ratio of out-of-state patients served compared to in-state patients.~~

~~(4) A manufacturer, repackager, third-party logistics provider, or wholesale distributor receiving a request for an initial sale of a controlled substance or drug of concern may conduct the sale before complying with paragraph 8(3) if all the following apply:~~

~~(a) the sale is to a new customer;~~

~~(b) the manufacturer, repackager, third-party logistics provider, or wholesale distributor documents that the order is to meet an emergent need;~~

~~(c) the manufacturer, repackager, third-party logistics provider, or wholesale distributor completes the requirements of paragraph 8(3) no later than sixty (60) days from the date of sale.~~

(5) A manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided that the customer submits documentation of an emergent need for a specific patient.

(6) Any customer that is believed to be engaged in potential diversion activities, including those to whom a manufacturer, repackager, ~~third-party logistics provider,~~

or wholesale distributor refuses to sell, shall be electronically reported to a program approved by the board. Such reports shall include:

(a) customer name;
(b) NABP e-Profile ID;
(c) customer address;
(d) DEA number;
(e) state license number(s); and
(f) a detailed explanation of why the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor identified the customer as a possible diversion risk.
(g) Such reports shall be submitted within thirty (30) days of refusal, cessation, or identification by the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor.

(7) Within ninety (90) days of the effective date of this rule, a manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor shall provide to a program approved by the board, information on all customers in the state where the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor has refused to sell or has stopped selling within the past year because the manufacturer, repackager, ~~third-party logistics provider,~~ or wholesale distributor has identified the customer(s) as engaging in potential diversion activity that may cause reported drugs to be diverted from legitimate channels.

(8) All licensed manufacturers, repackagers, ~~third-party logistics providers,~~ and wholesale distributors shall submit all reports to a board-approved program in a DEA ARCOS format.

...

APPENDIX B
Joint Accountability for Pharmacy Compliance – Resolution and Decision Tree

RESOLUTION NO: 121-2-25

TITLE: Joint Accountability for Pharmacy Compliance

ACTION: PASS

WHEREAS, state boards of pharmacy are charged with protecting public health and safety through the regulation of pharmacy practice; and

WHEREAS, pharmacy practice and regulation have increased in complexity to include new and different practice and ownership models; and

WHEREAS, ensuring pharmacy compliance with state and federal requirements and applicable standards of practice is critical to protecting patients and ensuring the appropriate and safe provision of pharmacist care services; and

WHEREAS, proactively ensuring and monitoring pharmacy compliance requires a collaborative effort between pharmacy owners and/or permit holders and the designated supervising pharmacist and/or pharmacist-in-charge (PIC), where applicable; and

WHEREAS, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, Section 402(3), provides: "Each pharmacy and/or outsourcing facility shall have a pharmacist-in-charge. Joint responsibility for compliance with all laws and rules shall be that of the owner and/or permit holder and the pharmacist-in-charge, whether the owner and/or permit holder is a sole proprietor, partnership, association, corporation, or otherwise."[1]

THEREFORE BE IT RESOLVED that NABP develop best practices for member state boards on holding owners and/or permit holders and the designated supervising pharmacists and/or PICs jointly accountable for patient safety and compliance; and

BE IT FURTHER RESOLVED that NABP work with member boards and stakeholders to encourage that owners and/or permit holders and the designated supervising pharmacists and/or PICs collaboratively work with pharmacy staff to gather input on pharmacy compliance, resource needs, workflow processes, and patient safety concerns, and proactively develop solutions to enhance patient safety through increased compliance.

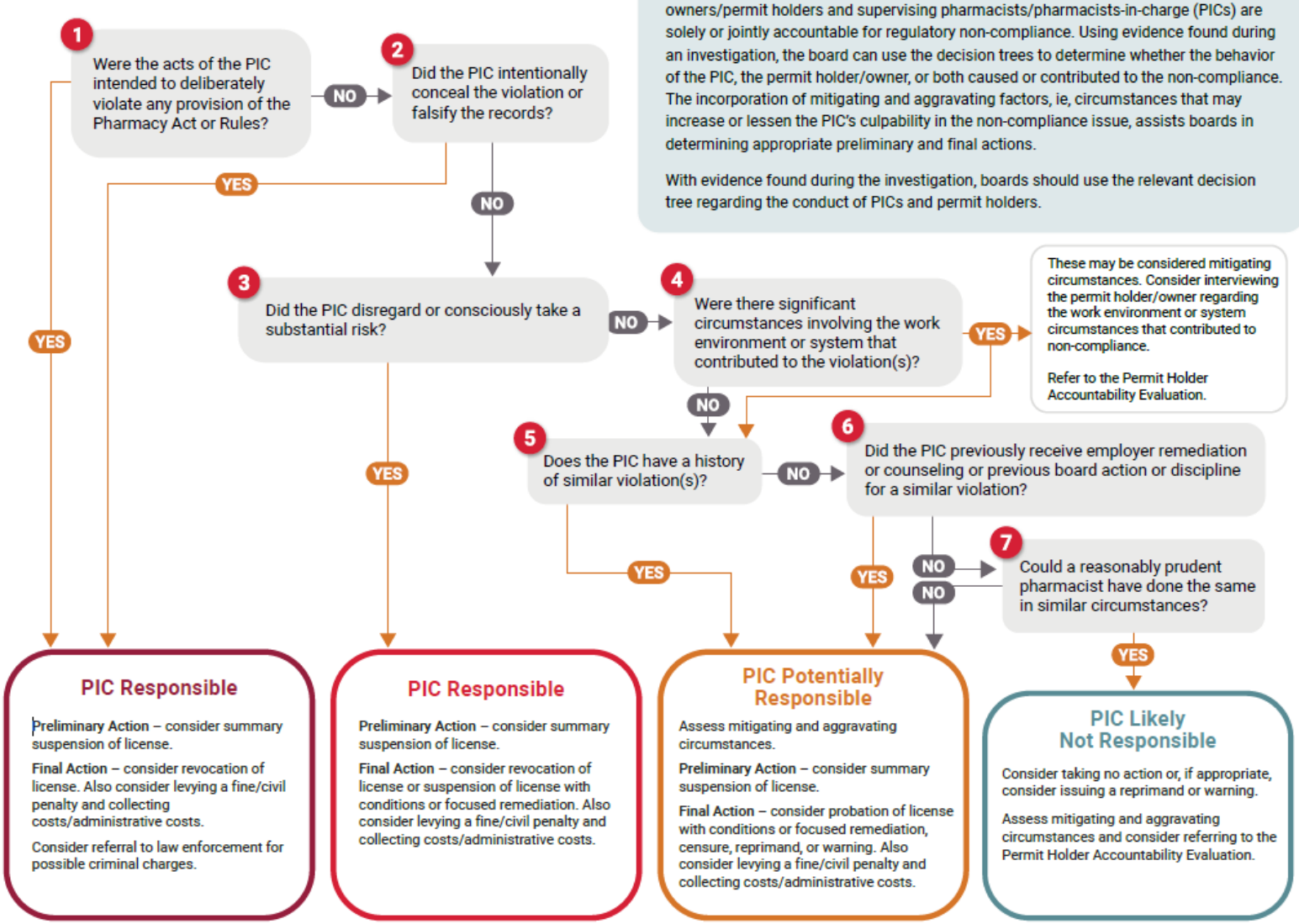
[1] *https://nabp.pharmacy/members/board-resources/model-pharmacy-act-rules/*

NABP
National Association of Boards of Pharmacy

Board of Pharmacy Decision Tree — Pharmacist-in-Charge Accountability Evaluation

These decision trees are intended to assist boards of pharmacy with determining if owners/permit holders and supervising pharmacists/pharmacists-in-charge (PICs) are solely or jointly accountable for regulatory non-compliance. Using evidence found during an investigation, the board can use the decision trees to determine whether the behavior of the PIC, the permit holder/owner, or both caused or contributed to the non-compliance. The incorporation of mitigating and aggravating factors, ie, circumstances that may increase or lessen the PIC's culpability in the non-compliance issue, assists boards in determining appropriate preliminary and final actions.

With evidence found during the investigation, boards should use the relevant decision tree regarding the conduct of PICs and permit holders.

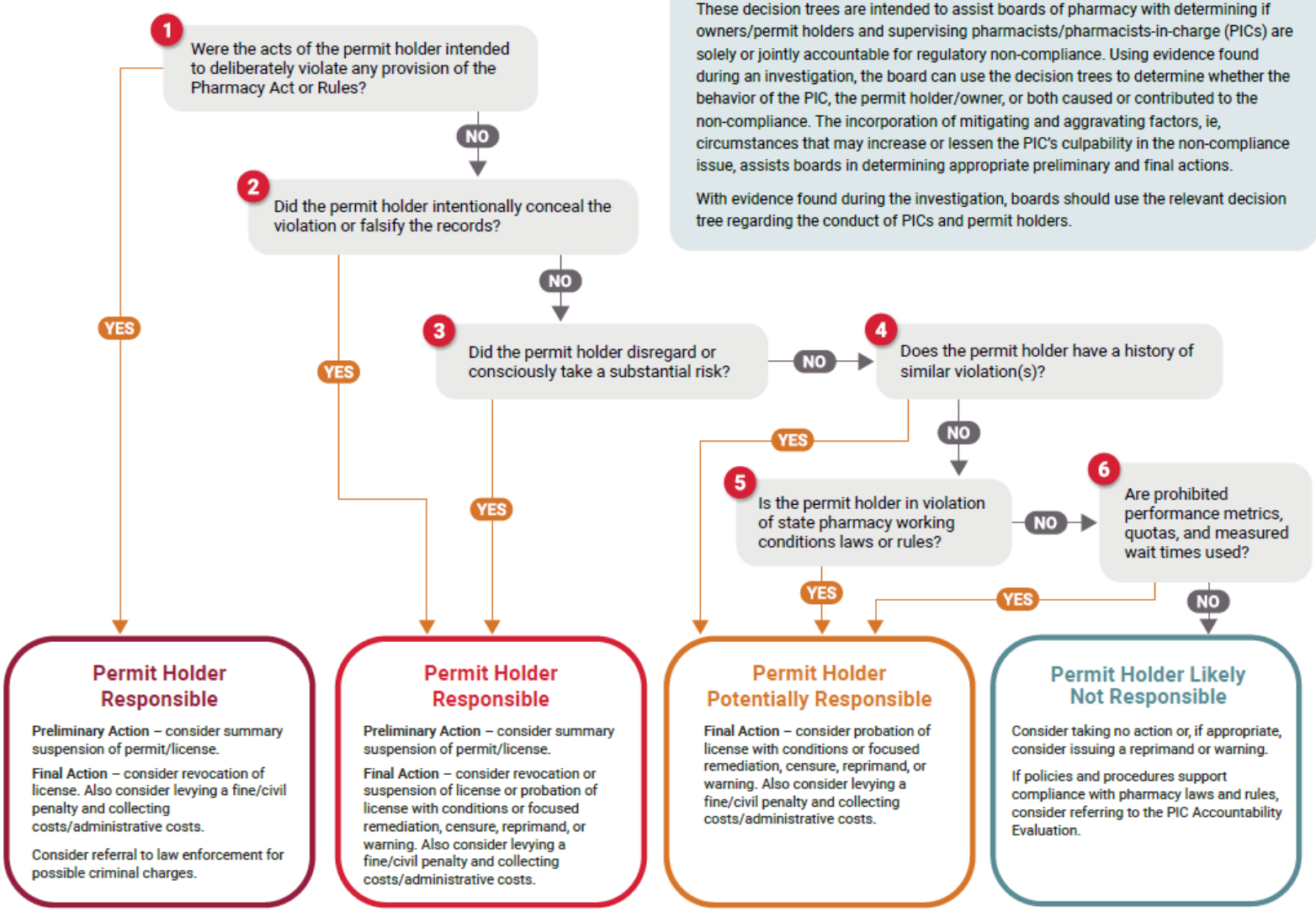


NABP
National Association of Boards of Pharmacy

Board of Pharmacy Decision Tree — Permit Holder Accountability Evaluation

These decision trees are intended to assist boards of pharmacy with determining if owners/permit holders and supervising pharmacists/pharmacists-in-charge (PICs) are solely or jointly accountable for regulatory non-compliance. Using evidence found during an investigation, the board can use the decision trees to determine whether the behavior of the PIC, the permit holder/owner, or both caused or contributed to the non-compliance. The incorporation of mitigating and aggravating factors, ie, circumstances that may increase or lessen the PIC's culpability in the non-compliance issue, assists boards in determining appropriate preliminary and final actions.

With evidence found during the investigation, boards should use the relevant decision tree regarding the conduct of PICs and permit holders.



APPENDIX C
Proposed *Model Act* Language for Medical Spa Oversight by the Boards of Pharmacy

New language approved by the committee is shown using double underlines.

AN ACT RELATING TO PHARMACY BOARD LICENSURE, ENFORCEMENT, PHARMACEUTICAL SUPPLY CHAIN INTEGRITY, AND REGULATORY ACCOUNTABILITY

NEW ARTICLE: DRUGS, ACTIVE PHARMACEUTICAL INGREDIENTS, AND OVERSIGHT OF COMPOUNDING PRACTICES

SECTION 1. LEGISLATIVE INTENT

a) The legislature finds that the integrity of the pharmaceutical supply chain, which includes the safe compounding of prescription drugs for dispensing or administering to a patient, is a matter of importance to critical public health and safety.
b) It is the intent of the legislature to grant the board of Pharmacy authority to protect the public health and safety from substandard pharmaceuticals being procured, compounded, dispensed, or administered in or into this State.

SECTION 2. DEFINITIONS

a) "Active pharmaceutical ingredient" or "API" means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.[10]
b) "Administer" or "Administration" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.
c) "Adulterated" has the same meaning as 21 U.S.C. § 351.
d) "Adverse event" means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.[11]
e) "Authorized agent" means any individual or entity identified by the board as qualified to conduct inspections, investigations, or seizures on its behalf.
f) "Board" means the state board of pharmacy.
g) "Chemical" means any substance not otherwise defined by the act that is a biologically active substance intended to produce a therapeutic effect in the body to diagnose, cure, mitigate, treat, or prevent disease.
h) "Compounding" or "Compounded" means combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, repackaging, or

[1] This definition is the same as that found in 21 CFR Part 207.
[2] This definition is the same as that found in 21 CFR 312.32.

otherwise altering a drug product or bulk drug substance to create a sterile or nonsterile preparation.

i) "Controlled substance" means a Food and Drug Administration-approved drug or other substance included in the State's Controlled Substances Act listed in Schedule II, III, IV, or V.

j) "Counterfeit" or "Counterfeit Drug" has the same meaning as that found in 21 U.S.C. § 321(g)(2).

k) "Dispense" or "Dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, final verification, and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

l) "Drug" means:

   a. articles recognized as drugs in any official compendium, or supplement thereto, designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
   b. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
   c. articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and
   d. articles intended for use as a component of any articles specified in clause (a), (b), or (c) of this definition.

m) "Facility" means any location not otherwise licensed by the board that receives, stores, compounds, or prepares drugs, APIs, controlled substances, or any other chemicals or peptides.

n) "Licensed healthcare professional" means an individual who has been granted the legal authority by this State to practice a particular healthcare profession.

o) "Medical spa" or "med spa" means any facility licensed by the board that primarily offers or provides wellness services.

p) "Misbranded" has the same meaning as 21 U.S.C. § 352.

q) "National Practitioner Data Bank" means the information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States.

r) "Peptide" means a molecule consisting of two or more amino acids covalently linked together by peptide bonds that are intended to produce a therapeutic effect in the body to diagnose, cure, mitigate, treat, or prevent disease.

s) "Person" means an individual, or a business entity.

t) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

u) "Prescription drug" or "legend drug" means a drug that is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered: (1) "Rx Only"; or (2) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or (3) a drug that is required by any applicable federal or state law or

rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only.

v) "Repack or repackage" has the same meaning as that found in 21 CFR § 207.1.

w) "Responsible person" means a licensed healthcare professional that is registered with the board who has independent authority to procure, prescribe, dispense, or administer prescription drugs and devices and who is responsible for supervising medical spa operations and is registered with the board.

x) "Serious adverse drug experience" means any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse event ~~drug experience~~, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based on appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

y) "Significant violations" include:
   a. substantial deviation from compounding standards established by USP;
   b. procuring, administering, or dispensing unapproved drugs, peptides, or any other chemicals, unless the responsible person
      i. is engaged in systematic research program;
      ii. has obtained the necessary approvals from the Institutional Review board and the FDA; and
      iii. has obtained approval to conduct such research from the board.
   c. other violations identified by rule of the board.

z) "Standard of care" means the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.

aa) "United States Pharmacopeia" or "USP" means the independent, non-profit, scientific organization that establishes public standards for the quality, purity, strength, and consistency of medicines, food ingredients, and dietary supplements.

bb) "Wellness service" means any service that is primarily used in an attempt to enhance an individual's health or physical appearance rather than address an underlying medical condition.

SECTION 3. BOARD AUTHORITY: LICENSURE, INSPECTION, AND INVESTIGATION

3.1 LICENSE AND REGISTRATION REQUIRED

a) A business shall not operate as a medical spa unless licensed by the board under this chapter.

b) The board may issue a medical spa license upon receipt of a completed application and fee and the satisfactory completion of an opening inspection pursuant to 3.3(a)(i) of this act. The application shall include, but not be limited to, the following:
   i. legal and doing business as name;
   ii. Federal Employer Identification Number (FEIN);

iii. physical address of the business where wellness services will be performed[12];
iv. contact information of the business;
v. hours of operation;
vi. Identification of the responsible person, including:
    i. full legal name;
    ii. professional title;
    iii. state professional license number;
    iv. Drug Enforcement Administration registration number, if applicable;
    v. a copy of a valid government-issued identification.
vii. list of all owners with 5% or more ownership interest in the business;
viii. questions related to previous criminal convictions and professional license discipline of the business owners;
ix. intended practices, including whether the medical spa intends to perform compounding.

c) The board may issue a registration to an applicant intending to serve as a responsible person. The application for registration shall include, but not be limited to, the following:
    i. full legal name;
    ii. professional title;
    iii. state healthcare professional license number;
    iv. Drug Enforcement Administration registration number, if applicable;
    v. copy of a valid government-issued identification;
    vi. questions related to previous criminal convictions, professional license discipline, and pending investigations by licensing authorities.
d) A medical spa, by and through the responsible person, that procures, dispenses, furnishes, or administers controlled substances shall obtain a controlled substance registration from the board. The registration shall be issued in the name of the medical spa and shall identify the name of the responsible person on the registration.
e) The board shall establish by rule the licensing and registration fees sufficient to carry out its duties under the act.

3.2 NOTIFICATION TO THE BOARD

a) Medical spas must notify the board within 10 business days of any of the following changes:
    i. ownership;
    ii. legal or doing business as name;
    iii. Federal employer identification number (FEIN);
    iv. physical address of the business where wellness services will be performed;
    v. hours of operation;
    vi. responsible person.
b) As applicable, medical spas shall notify the board, the Drug Enforcement Administration, and law enforcement authorities immediately upon the discovery of theft or significant loss

[3] For businesses operating in a mobile capacity, whether full-time or part-time, the responsible person shall maintain a comprehensive log detailing the specific date, time, GPS coordinates or street address of every location where wellness services are performed. These records must be kept in a readily retrievable manner and be made available to the board upon request.

of any prescription drug, including drugs in transit, or the loss or theft of any DEA Form 222, uncompleted prescription forms, or written prescriptions either dispensed or not yet dispensed.

c) Medical spas must timely notify the board of the occurrence of any of the following:
    i. any criminal conviction of any employee of any state or federal drug laws;
    ii. any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
    iii. serious adverse drug experiences;
    iv. recalls of compounded drug preparations; or
    v. Illegal use or disclosure of protected health information.
d) Unless originally indicated on the initial application for licensure, a medical spa must notify the board of its intent to compound. The board or its authorized agents shall inspect the medical spa prior to the medical spa commencing compounding practices.
e) Medical spas shall provide a 30-day notice to the board of their intent to cease business operations. The board shall make available on its website a prescribed form for such notice.

3.3 RIGHT OF ENTRY AND INSPECTION OF PREMISES

a) The board or its authorized agents may enter and inspect, during normal business hours, any licensed medical spa or any location that is operating or is suspected of operating as a facility.
    i. Medical spa applicants shall be inspected prior to the commencement of business and will address all aspects of the proposed medical spa's business related to drugs, APIs, or any other chemicals or peptides intended for use in humans.
    ii. Medical spas that compound or repackage drugs, APIs, or any other chemicals or peptides, or that procure, dispense, or administer controlled substances, shall be inspected no less than biennially. medical spas that do not compound or repackage any of the aforementioned substances shall be inspected periodically as determined by the board.
b) Inspections may include areas of the facility or medical spa where drugs, APIs, or any other chemicals or peptides are received, stored, compounded, and prepared for dispensing or administration. The inspection shall include a review of facility or medical spa records, including, but not limited to, ownership information, invoices, purchase orders, certificates of analysis, transaction information, compounding logs, practitioner prescription orders, and dispensing and administration information. If the facility or medical spa is engaged in compounding, the inspection shall evaluate compliance with the most current published version of the United States Pharmacopeia General Chapters <797>, <795>, and <800>, as applicable.
c) The board or its authorized agents may investigate any location, whether licensed or not, that the board has reasonable cause to suspect that drugs, APIs, or any other chemicals or peptides are received, stored, compounded, or prepared for dispensing or administration to humans.
d) The board may contract with an authorized agent to perform inspections.
e) Inspection reports may be made available to the public pursuant to state law or the rules of the board.

3.4 AUTHORITY TO SEIZE, QUARANTINE, AND DUE PROCESS

a) The board or its authorized agents shall have the authority to seize and quarantine drugs, APIs, or any other chemicals or peptides if the board or its agent has probable cause to believe that the drug, API, chemical, or peptide is an unapproved drug, adulterated, misbranded, counterfeit, or is otherwise unauthorized for human use, is labeled in a manner that indicates the substance is for research use only, is not compounded in accordance with USP, or is otherwise in violation of this Chapter.
b) Upon seizure, the board or its agent shall provide the facility or medical spa owner or the responsible person with a detailed, itemized inventory of all seized substances. The board shall conduct an administrative hearing, in accordance with the state's administrative procedures act, which shall be open to the public, to determine the lawful disposition or return of the seized substances. The board shall provide notice of the hearing to the facility owner and the responsible person.

SECTION 4. PRESCRIPTION DRUGS, COMPOUNDING, UNAPPROVED DRUGS OR CHEMICALS, AND SUPPLY CHAIN INTEGRITY

a) It is unlawful for a facility, medical spa, or person to procure, administer, or dispense drugs, peptides, or any other chemicals that are intended for research-use only, unless the responsible person is engaged in a systematic research program, has obtained the necessary approvals from the Institutional Review board and the FDA, and has obtained approval to conduct such research from the board.
b) It is unlawful for a medical spa, facility, or person, other than a licensed veterinarian, to procure, administer, or dispense drugs, peptides, or any other chemicals that are labeled not for use in humans or otherwise indicate they are not suitable for use in humans.
c) A medical spa engaged in compounding under the supervision and direction of the responsible person shall compound in accordance with applicable chapters of the most current version of USP for sterile and nonsterile compounding and shall only procure APIs from an FDA-registered establishment that is licensed with the state, as applicable.

SECTION 5. REPORTING REQUIREMENTS

5.1 REPORTING TO AND RESPONSIBILITIES OF PROFESSIONAL LICENSING BOARDS

a) The board shall provide the professional licensing board that has issued a professional license to the practitioner (e.g., board of medicine, board of nursing), under whose license drugs are procured, prescribed, compounded, dispensed, or administered in a facility, with the following:
    i. Notification of refusal of entry for inspection and investigation purposes;
    ii. Inspection reports that identify any violations of this act;
    iii. Investigative material, including the original complaint, after the board determines through an administrative hearing that the alleged violations were proven by a preponderance of the evidence. If the investigation reveals the culpability of other professionally licensed individuals, the board shall also share the investigative material and the original complaint with the board that issued their license;
    iv. Any fines levied against the facility;

v. Any unpaid fines levied against the facility.

b) The board shall advise the professional licensing board that receives a report from the board whether additional action is needed to protect public health and safety. Any public disciplinary action taken by professional licensing boards pursuant to this act shall be shared with the board and reported to the National Practitioner Data Bank.

5.2 ANNUAL REPORT TO THE GOVERNOR AND LEGISLATURE

a) The board, upon request of the governor or legislature, no later than [insert date] of each year, shall submit a comprehensive report on its inspection and investigation findings conducted under the authority of this act in the preceding fiscal year. The report to the governor and legislature shall include, but is not limited to:
   i. The total number of facility and med spa inspections conducted.
   ii. The total number of consumer complaints received against facilities and med spas.
   iii. A summary of the most significant findings related to violations of compounding, procurement of drugs, and APIs.
   iv. The identity, and country of origin, if known, and the amount of any drugs, APIs, peptides, or any other chemicals seized by the board.
   v. A summary of serious adverse events reported to the board.
   vi. A summary of public disciplinary action taken by professional licensing boards pursuant to this act.
   vii. An estimated cost to the board for inspections and investigation activities conducted pursuant to this act.
   viii. The total amount of penalties levied and collected by the board against facilities, med spas, and responsible persons for violations of this act.
   ix. Specific recommendations for legislative or regulatory changes, including any requests for additional enforcement powers or oversight.

SECTION 6. ENFORCEMENT, LICENSE OR REGISTRATION DENIAL, DISCIPLINE, AND PENALTIES

a) The board may impose a fine of up to $5,000 on the owner of a facility for refusing the board or its authorized agent to enter the facility under the authority of this act. Refusals of entry shall also be reported to the Attorney General for prosecution.
b) The board may deny an application for a medical spa license or the responsible person's registration for any of the following:
   i. Misrepresentation or fraud on the application;
   ii. Criminal convictions of the responsible person or owner(s) relating to fraud, embezzlement, or the possession, distribution, or manufacturing of a drug, or API;
   iii. Prior discipline of the responsible person or owner, if the owner is a licensed healthcare professional;
   iv. Commencing business operations, including procuring, storing, prescribing, dispensing, or administering drugs, APIs, or any other chemicals or peptides prior to licensure;
   v. Failing any component of an opening inspection.

c) The board may discipline the medical spa for violations of this act or rule of the board disciplinary actions may include, but are not limited to, the following:
    i. License Sanctions. Probation, suspension, revocation of the medical spa license, or restricting the license from performing any wellness service;
    ii. Monetary Penalties. Assessment of fines not to exceed $2,500 per violation or $25,000 per significant violation.
d) The board may discipline the responsible person for significant violations of this act, rule of the board, or for failing to meet the standard of care as it relates to procuring, storing, dispensing, or compounding of drugs, APIs, or any other chemicals or peptides. Disciplinary actions may include the following:
    i. Restricting or prohibiting the practitioner from serving as a responsible person;
    ii. Restricting or prohibiting the responsible person from engaging in, supervising, or authorizing any wellness service;
    iii. Imposing a monetary penalty of up to $250 per violation, or up to $2,500 per significant violation, or for failing to meet the standard of care as it relates to procuring, storing, dispensing, or compounding of drugs, APIs, or any other chemicals or peptides.

All disciplinary actions shall be reported to the National Practitioner Data Bank.

All fines levied under the authority of this act shall be payable to the board within 30 calendar days. Fines collected shall be retained by the board and used to carry out its duty under the act.

SECTION 7. IMPLEMENTATION, EFFECTIVE DATE, AND TRANSITION PERIOD

a) The board may adopt rules, consistent with this act, to implement this act.
b) This act shall take effect three months after enactment.
c) Notwithstanding any provision of this act to the contrary, a facility operating as a medical spa prior to the enactment of this act may continue to serve the public subject to the following:
    a. Application deadline: The facility must file a completed license application for a medical spa within 60 days of the effective date of this act.
    b. Temporary authorization: The timely submission of a completed application provides the facility with the temporary authorization to remain operational while the board reviews the application, conducts an opening inspection, and reaches a final licensing decision.

In accordance with the inclusion of the FEIN in a med spa application, as in paragraph (3.1)(b)(ii) of the proposed Model Act *language above, the committee supplemented a footnote in Article IV, Section 403, of the* Model Act, *as shown below.*

Article IV
Licensing of Facilities

...

Section 403. Application.[13]

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

Applicants for licensure to dispense, distribute, wholesale distribute, manufacture, sell, purchase, transfer, and/or produce drugs or devices, and applicants for licensure as a pharmacy benefits manager, shall file with the board of pharmacy a complete and accurate application containing such information as the board requires of the applicant relative to the qualifications for a license.

The board of pharmacy shall require any pharmacy applicant for initial and renewal of licensure to state whether they engage or intend to engage in compounding as defined in this Act and, if so, complete a questionnaire approved by the board.[14, 15]

Licenses issued by the board pursuant to this Act shall not be transferable or assignable.

...

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

[14] Applicants who engage or intend to engage in compounding shall submit concurrently with their application for licensure responses to a questionnaire regarding the applicant's compounding operations.

[15] The questionnaire contemplated in this paragraph shall request, at a minimum, the following information: 1) the name and address of the location at which compounding occurs or will occur; 2) whether nonsterile compounding occurs or will occur; 3) whether sterile compounding occurs or will occur; 4) whether the applicant compounds or will compound with hazardous drugs; and 5) whether the applicant ships or will ship compounded preparations across state lines.

APPENDIX D
Proposed *Model Act* Language for a Standard of Care Regulatory Model

New language and deletions approved by the committee are shown using double underlines and double strikethroughs.

Model Pharmacist Practice Act

Article I. Title, Purpose, and Definitions

Section 101. Title. This act shall be known as the "Pharmacist Practice Act."

Section 102. Legislative Declaration. The practice of pharmacy is declared a professional health care practice affecting the public health, safety, and welfare, and is subject to regulation in the public interest. To ensure patient access to clinical services and practice innovation, this state adopts a standard of care approach to regulating pharmacists' clinical and non-dispensing practices, allowing a flexible framework for practice expansion over time.

Section 103. Definitions.

"Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, final verification, and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

"Pharmacist care services" mean services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination or reduction of symptoms, and promotion of health and wellness. Pharmacist care services include but are not limited to:

(1) drug utilization review;
(2) medication adherence monitoring service;
(3) ~~emergency use~~ prescribing, administering, and dispensing drugs or devices;[16]
(4) medication therapy management;
(5) reviewing, selecting, and developing formularies and/or practice guidelines;
(6) performing drug product selection, substitution, therapeutic interchange, prescription adaptation, or continuation of therapy;
(7) prescribing medications in line with clinical education, training, or experience; and
(8) ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived lab tests.

The "practice of pharmacy" means, but is not limited to:
(1) interpreting, evaluating, compounding, dispensing, and/or administering medical orders;
(2) providing patient counseling and education;
(3) assessing the patient for the purposes of prescribing drugs and devices;
(4) initiating and/or providing pharmacist care services;
(5) using continuous quality improvement programs, emerging technologies, and competency-based education to improve patient safety and the quality of services provided;
(6) engaging in collaborative pharmacy practice.

[16] ~~Pharmacists may prescribe drugs for emergency use pursuant to specific statewide protocols or standing orders.~~

“Prescription adaptation” means an act by which a pharmacist uses their clinical judgment to modify or substitute a prescription issued by a practitioner to better suit the patient’s specific needs, improve safety, or ensure the therapy is effective and cost-efficient for the patient.

“Standard of care” means the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.

Article II. Professional Practice Standards

Section 201. General Approach to Pharmacist Practice. To evaluate whether a specific action is within the practice of pharmacy, or whether an action can be delegated to other individuals, a licensee or registrant shall independently determine whether:

1. The action is expressly prohibited by this Act, the Pharmacy Practice Act, the Uniform Controlled Substances Act, rules of the Board, or any other applicable state or federal laws.
2. The action is consistent with the individual's education, training, and experience.
3. Performance of the action is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent individual with similar education, training, and experience.

Section 202. Practice Innovation. The Board shall not require express permission for the implementation of new technology or clinical services that are not otherwise prohibited by law, provided that the services are performed in accordance with the standard of care.

Section 203. Pharmacist Prescribing Authority. A pharmacist may independently prescribe drugs and devices if such pharmacist:

1. Obtains adequate information about the patient’s health status to make appropriate decisions based on the standard of care and best available evidence.
2. Maintains adequate documentation which shall become part of the patient's permanent record and be readily available to other healthcare professionals who are providing care to that patient and who are authorized to receive it.

Article III. Delegation and Personnel

Section 301. Delegation of Functions. A pharmacist may delegate any task to any individual under their supervision, provided the pharmacist determines the delegate has the requisite education, training, and experience to perform the task safely and within the standard of care.

Article IV. Discipline and Accountability

Section 401. Grounds for Discipline. The Board may discipline a licensee or registrant for unprofessional conduct, which includes:

1. Standard of Care Violations: Actions or omissions that fail to meet the standard of care provided by other qualified licensees or registrants in the same or similar setting.
2. Incapacity: A lack of fitness for professional practice due to incompetency or impairment that endangers the public.
3. Divergence from Professional Prudence: Engaging in conduct that substantially departs from the standards of care ordinarily exercised by a licensee or registrant, regardless of whether actual injury to a patient is established.

Section 402. Waiver Authority. The Board is authorized to grant waivers from state rules or laws pertaining to the practice of pharmacy if the request is in the best interest of the public.

APPENDIX E
Committee on Law Enforcement/Legislation Amendments to Current *Model Act* Language About Pharmacist Scope of Practice

Recommendations of the committee are shown using double underlines and double strikethroughs.

Article I
Title, Purpose, and Definitions

Section 104. Definitions for the Practice of Pharmacy and Related Terms.

The "practice of pharmacy" means, but is not limited to:

(1) interpreting, evaluating, compounding, dispensing, and/or administering medical orders;
(2) providing patient counseling;
(3) assessing the patient for the purposes of prescribing drugs and devices;
(4) initiating and/or providing pharmacist care services;
(5) using continuous quality improvement programs, emerging technologies, and competency-based education to improve patient safety and the quality of services provided;
(6) engaging in collaborative pharmacy practice.[17]

"Pharmacist care services"[18] mean services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination or reduction of symptoms, and promotion of health and wellness. Pharmacist care services include but are not limited to:

(1) drug utilization review;
(2) medication adherence monitoring service;
(3) ~~emergency use~~ prescribing, administering, and dispensing drugs or devices;[19]
(4) medication therapy management;
(5) reviewing, selecting, and developing formularies and/or practice guidelines;
(6) performing drug product selection, substitution, therapeutic interchange,[20] prescription adaptation, or continuation of therapy;
(7) prescribing medications in line with clinical education, training, or experience, and

[14] 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*. To assist states in the interpretation of the 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.

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.

[15] 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.
[16] Pharmacists may prescribe drugs for emergency use pursuant to specific statewide protocols or standing orders.
[17] Providing it is within the same FDA drug class and not prohibited by the prescriber.

(8) ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived[21] lab tests.

"Collaborative pharmacy practice" means that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol and in collaboration with practitioner(s) ~~to provide patient care services~~ to achieve optimal medication use and desired patient outcomes.

"Medication therapy management" includes the following:

(1) patient health status assessment and evaluation;
(2) medication reconciliation;
(3) formulating medication treatment plan;
(4) selecting, prescribing, modifying, discontinuing, or administering drugs, devices, vaccines, or biologicals;
(5) monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
(6) performing a comprehensive drug utilization review to identify, resolve, and prevent medication-related problems, including adverse ~~drug~~ events;
(7) documenting the care delivered and communicating essential information to the patient's prescribing practitioner(s) and primary care providers;
(8) providing education, support services, and resources designed to enhance patient adherence with therapeutic regimens~~, such as medication synchronization~~;
(9) coordinating and integrating 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.

[21] Most recent version.

Model Rules for the Practice of Pharmacy

…

Section 6. Pharmacist Care Services.

(1) Pharmacist care services are services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination or reduction of symptoms, and promotion of health and wellness. Pharmacist care services include, but are not limited to:

(a) drug utilization review;

(b) medication adherence monitoring service:

(c) ~~emergency use~~ prescribing, administering, and dispensing drugs or devices;[22]

(d) medication therapy management;

(e) reviewing, selecting, and developing formularies and/or practice guidelines;

(f) performing drug product selection, substitution, therapeutic interchange[23] prescription adaptation or continuation of therapy; ~~and~~

(g) prescribing medications in line with clinical education, training, or experience; and

(g) ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived[24] lab tests.

…

(3) Patient Counseling[25]

(a) Upon receipt of a prescription drug order and following a review of the patient's record, a pharmacist shall engage in discussion of matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, ~~whenever practicable,~~ or by telephone or other audio/visual means of communication and shall include appropriate elements of patient counseling. Such elements may include the following:

(i) the name and description of the drug;

(ii) the dosage form, dose, route of administration, and duration of drug therapy;

(iii) intended use of the drug and expected action;

(iv) special directions and precautions for preparation, administration, and use by the patient;

(v) common side effects, severe side ~~or adverse~~ effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

---

[22] ~~Pharmacist may prescribe drugs for emergency use pursuant to specific statewide protocols or standing orders.~~

[23] Provided it is within the same FDA Drug class and not prohibited by the prescriber.

[24] Most recent version.

[25] The intent of this Section is to require that the pharmacist personally initiate patient counseling for all new prescription drug orders and exercise their professional judgment for refills.

(vi) techniques for self-monitoring ~~D~~drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) ~~P~~pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(b) An offer for patient counseling can be made by the pharmacist or their designee ~~a certified pharmacy technician or certified pharmacy technician candidate. An offer for patient counseling can be made by a certified pharmacy technician or certified pharmacy technician candidate.~~

(c) Alternative forms of patient information may be used to supplement patient counseling when appropriate. ~~Examples include written information leaflets, pictogram labels, video programs, etc.~~

(d) Patient counseling, as described above and defined in this Act, shall not be required in settings ~~for inpatients of a hospital or institution~~ where ~~other~~ licensed health care professionals are authorized to administer the drug(s).

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

~~(4) Medication Adherence Monitoring Services and Patient Intervention Programs~~
~~Medication adherence monitoring services and patient intervention programs designed to promote improved medication use behaviors, such as compliance and adherence, appropriate monitoring and self-reporting, increased patient knowledge, and improved therapy options, shall comply with federal and state law addressing the privacy of protected health information.~~

(5) Collaborative Pharmacy Practice

(a) Collaborative Pharmacy Practice Agreement
A pharmacist planning to engage in collaborative pharmacy practice shall have their collaborative pharmacy practice agreement readily available ~~on file at their place of practice the collaborative pharmacy practice agreement. Any additional information the board may require concerning the collaborative pharmacy practice agreement, including the agreement itself, shall be made available to the board for review upon request.~~ The agreement may allow the pharmacist, within the pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement, to conduct activities approved by the practitioner in good standing, and as defined by law and by the rules of the board. The collaboration that the practitioner agrees to conduct with the pharmacist must be within the scope of the delegating practitioner's current practice.

(b) Contents
The collaborative pharmacy practice agreement shall include:
(i) identification of the practitioner(s) and pharmacist(s) who are parties to the agreement;
(ii) the types of decisions that the pharmacist is allowed to make;

(iii) a process for generating any necessary medical orders, including prescription drug orders, required to initiate allowed activities;

(iv) a method for the practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary;

(v) a description of the continuous quality improvement program used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(vi) a provision that allows the practitioner to override a collaborative practice decision made by the pharmacist whenever the practitioner deems it necessary or appropriate;

(vii) a provision that allows either party to cancel the agreement by written notification;

(viii) an effective date;

(ix) signatures of all collaborating pharmacists and practitioners who are party to the agreement, as well as dates of signing; and

(x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

(c) Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated.

(d) Documentation of pharmacist activities
Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals who are providing care to that patient and who are authorized to receive it.

~~(6) Emergency Use Prescribing and Dispensing~~

~~Prescribing and dispensing drugs for emergency use shall be pursuant to a pharmacist-issued prescription drug order and include appropriate patient counseling. Drugs or devices for emergency use include, but are not limited to:~~

~~(a) Opioid overdose reversal agents, such as naloxone;~~

~~(b) Epinephrine;~~

~~(c) Antidote kits;~~

~~(d) Short-acting beta-agonist inhalers; and~~

~~(e) Medication for opioid use disorder for the purpose of initiating therapy for opioid use disorder. The pharmacist must:~~

~~(i) obtain a DEA registration and a state controlled substance license or registration, if required; and~~

~~(ii) use professional judgment to assess the clinical appropriateness of the patient's request and the length of time until the patient obtains treatment from an authorized practitioner.~~[26]

(7) Emergency Refills

[26] It is contemplated that for long-term treatment, pharmacists should be prescribing under a collaborative practice agreement rather than under an emergency use provision.

A pharmacist may authorize and dispense a refill of a prescription drug without practitioner authorization if:[27]

(a) in the pharmacist's professional judgment, the prescription drug is essential to the maintenance of the patient's life or to the continuation of therapy;

(b) the pharmacist ~~makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule,~~ indicates that it is an "Emergency Refill Prescription," and maintains the record, ~~as required by state and federal law, as well as state and federal disaster agencies, for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency~~;

(c) the pharmacist informs the patient or the patient's agent at the time of dispensing that the prescription drug is being provided without the practitioner's authorization and that authorization of the practitioner is required for future refills; and

(d) the pharmacist informs the prescriber of the emergency refill as soon as practicable.

Unit-of-use quantities may be dispensed when appropriate.

…

Section 15. Provision of Pharmacist Care Services Unaffiliated with ~~Outside of~~ a Licensed Pharmacy.

In order for a pharmacist to provide pharmacist care services unaffiliated with a ~~outside the premises of a~~ licensed pharmacy, an applicant shall:

(1) register/license with the board(s) or; if located out of state, have an active NABP Verify credential;

(2) have appropriate security and protections in place to ensure the confidentiality of records or other patient-specific information;

(3) maintain such records in readily retrievable form; and

(4) follow the patient care process approved by the board.[28]

[27] Boards may consider contacting US DEA ahead of time to ensure that these provisions are applicable to controlled substances.

[28] It is anticipated that boards use the current *Pharmacists' Patient Care Process* approved by the Joint Commission of Pharmacy Practitioners.

APPENDIX F
Committee on Law Enforcement/Legislation Amendments to Current *Model Act* Language About Allowing for Pharmacy Innovation

Recommendations of the committee are shown using double underlines and double strikethroughs.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article II
Board of Pharmacy

...

Section 213. Powers and Responsibilities.

(1) 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:[29]

...

(q) approval of <u>waivers. The board is authorized to grant waivers from state laws or rules pertaining to the practice of pharmacy if the request is in the best interest of the public.</u> ~~pharmacy practice initiatives that improve the quality of or access to pharmacist care services, but which fall outside the scope of present rules. This subsection shall not be construed to expand the definition of the practice of pharmacy as defined in this Act.~~

<u>The board shall not require express permission for the implementation of new technology or clinical services that are not otherwise prohibited by law, provided that the services are performed in accordance with the standard of care.</u>

...

[29] The "practice of pharmacy in this state" includes shipping prescription drugs into this state from another jurisdiction.

...

Section 16. Approval of Waivers ~~Pharmacy Practice Initiatives~~.[30]

(1) Application[31]

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:

(a) The name, address, telephone number, and the license number of the pharmacist responsible for overseeing the initiative;

(b) 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

(c) A detailed summary of the proposed pharmacy practice initiative, which includes:

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

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

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

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

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

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

(2) Approval by the Board

The board shall approve a pharmacy practice initiative if it determines that:

(a) the pharmacy practice initiative will improve the quality of or access to pharmacist care services;

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

(c) 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

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

[31] 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.

such terms and conditions it deems appropriate to carry out the purposes of Section 213(1)(q) of this Act and the rules adopted thereunder.

(3) Notification

The board shall notify the applicant in writing within sixty (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.

(4) 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 (1). An approval of a pharmacy practice initiative shall be renewed by the board if the applicant continues to satisfy the criteria contained in subsection (2) and demonstrates compliance with the alternative measures or conditions imposed at the time the original pharmacy practice initiative was approved.