NABP
National Association of Boards of Pharmacy

Report of the Committee on

LAW ENFORCEMENT/LEGISLATION

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Members Present

David Bowyer (WV), *chair*; Alexandra Blasi (KS); Paul Brand (MT); Young Chang (GA); Cheryl "Cheri" Garvin (VA); Tod J. Grimm (OH); Kevin Morgan (MD); Tiffany O'Hagan (WI); Rodney Richmond (AR); Ian Shaw (TX); Kristen Snair (AZ); Terry Talbott (PA); Cassandra White (ME)

Others Present

Janet Getzey Hart, *Executive Committee liaison;* Lemrey "Al" Carter, Melissa Becker, Eileen Lewalski, Andrew Funk; Gertrude "Gg" Levine, Maureen Schanck, Cameron Orr, *NABP staff*.

Introduction

The committee met on March 5-6, 2024, 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 the public health.

Background and Discussion

After careful review and deliberation, aside from the suggested amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, the committee recommended the following:

(1) NABP should review and reevaluate the definition of Pharmacist-in-Charge (PIC) in light of a movement in some states toward designating a responsible pharmacist but not necessarily a PIC.

(2) NABP should consider performing a comprehensive survey – with a tracking mechanism – to determine the demographic makeup of the boards of pharmacy, given that the 2022-2023 survey yielded an insufficient response rate.

The committee began its discussion with a review of the *Model Act* amendments recommended by three of the four task forces that convened in 2023 to determine whether the committee agreed with, recommended changes to, or rejected the recommendations. One of the four task forces did not recommend any changes to the *Model Act*.

Recommended *Model Act* Amendments from the Task Force to Review Unprofessional Conduct and Disciplinary Actions

The committee first reviewed recommended *Model Act* amendments from the Task Force to Review Unprofessional Conduct and Disciplinary Actions.

In Section 501. Disciplinary Action Terms, the committee agreed with the task force on the addition of "denial, refusal to issue or renew" to the list of disciplinary actions that a board of pharmacy may take, issue, or assess, saying it was helpful to spell out these additional terms. In the same section, the committee then discussed the meaning of "voluntary surrender" of a license and differentiated it from cancelling a license mid-cycle. The committee qualified the term by adding "when under investigation or in lieu of a consent agreement." The committee opted to remove the phrase, "is also considered to be a," in front of "disciplinary action," expressing concern that this would also include someone who placed their license on inactive status, which should not be considered a disciplinary offense.

Regarding Section 502. Grounds, Penalties, and Reinstatement, the committee discussed whether the phrase, "includes but is not limited to," should be kept in subparagraph (1)(b) and whether it holds the force of law. Some members raised the concern that having a list that is intended to be all-inclusive introduces the risk of leaving something out. It was noted that reasonable judges understand the impracticality of attempting to list every possible scenario and accept this language. Others noted that because states are being challenged, there is movement toward exhaustive lists to ensure more direct prosecutorial power and that offenses should fall under some umbrella of a violation. The committee also noted that the language is intended to serve as a model for the states and should not necessarily cover every eventuality.

Also in section 502(1)(b), the committee decided to separate subparagraph (iv) into three distinct provisions to give each more emphasis. Also in this section, the committee changed "selling a drug" to "providing a drug" and added "knowingly" to qualify "filing a false or fraudulent complaint with the board." In addition, within this section, the committee deleted "sexual," from "committing any act of sexual abuse, misconduct, or exploitation related to a licensee's practice of pharmacy," as this verbiage would include sexual abuse.

In subsection (1)(d), the committee changed "being guilty of, pleading no contest to, or entering into a pretrial *diversion program* . . ." to "being guilty of, pleading no contest to, or entering into a pretrial *agreement* . . ." because some areas do not have accessible diversion programs.

In subsection (1)(j), the committee qualified "failure to report evidence" by adding "within ___ days" here and in all other instances of reporting provisions. In the same subsection, in regard to practicing pharmacy, the committee opted to delete reference to "assisting" in the practice, noting that pharmacy technicians, as well as pharmacists, may be considered to be practicing pharmacy. To simplify the issue, the committee opted to remove "pharmacy," changing the wording to "practicing in a manner that is safe for the public."

Regarding subparagraph (1)(l), the committee discussed whether to qualify "fraud by a licensee" by including the word "intentional." The committee decided against the change, however, noting that fraud is inherently intentional. Upon further review, the committee did agree to add the qualifying

phrase, “including the publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy,” to broaden its interpretation.

Regarding the task force’s recommendation to delete subparagraph (4) requiring complainants to identify themselves, the committee ultimately agreed, after much discussion, that the provision should be removed since anonymous complaints can still be extremely valuable, even though anonymity can somewhat inhibit the investigatory process.

The committee spent significant time reviewing subparagraph (5), the impaired practice licensee section, and made several revisions throughout. Regarding board actions involving impaired practice licensees, the committee changed “voluntarily surrender their license” to “voluntarily cease practicing.” The committee also opted to delete the verbiage throughout this section regarding a “treatment and therapeutic monitoring program” to a program that is simply “approved by the board.” Additionally, the committee deleted the requirement that the program includes substance use disorder professionals, realizing recovery specialists are not available in all regions, especially rural areas, where such services may be provided by a general practitioner. Lastly, the committee opted to remove the qualifying term “substantial” from “evidence that a licensee has an impairment . . .” because this term is not defined by United States Drug Enforcement Administration nor is it universally defined by the states or other jurisdictions.

In subparagraph (6), the committee revised the language for grammar and clarity. The committee also removed “at reasonable intervals” regarding the right to petition the board for reinstatement of a license because it is implied within the provision.

In Section 503. Procedure, the committee deleted wording that was considered to be redundant and unnecessarily verbose.

The committee also deleted Section 17. Unprofessional Conduct from the *Model Rules for the Practice of Pharmacy,* as well as Appendix A Guidelines for Disciplinary Sanctions, as these provisions were moved under the various subparagraphs in Section 502 in order to increase conciseness, visibility, and to reduce duplication.

Recommended *Model Act* Amendments from the Task Force on Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy

The committee then turned its attention to the amendments recommended by the Task Force on Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy.

In Section 105 of the *Model Act*, the committee further amended the definition of “practice of telepharmacy” by deleting the phrase, “by pharmacists,” so that the definition reads, “the practice of pharmacy through the use of telepharmacy technologies between a licensee and patients or their agents.” In addition, pertaining to the definitions of “practice of telepharmacy” and “remote dispensing site,” the committee modified the footnotes indicating that states may interpret those definitions to allow certified pharmacy technicians to provide specific services. This was accomplished by adding the phrase, “services such as,” to broaden their applicability. Also, the

committee modified the wording to allow those services to be provided by pharmacy technicians at a remote dispensing site.

The committee then reviewed the relevant sections of the *Model Rules for the Practice of Pharmacy.* Members agreed with all of the task force's recommended deletions in Section 8. Shared Pharmacy Services, as they were either moved to the overall policies and procedures section or removed as being duplicative.

In Section 9. Automated Pharmacy Systems, the committee decided to remove the requirement for the pharmacy to provide a telephone number, replacing it with "method of communication" to reach the pharmacist and to modernize and broaden the language enough to capture other modes.

In subparagraph (1)(g), which delineates the responsibilities of a pharmacist for automated pharmacy systems, the committee replaced "pharmacist-in-charge" with reference to a "designated pharmacist." Committee members suggested using alternate wording, such as "designated pharmacist" or "the policy shall designate the responsible pharmacist." The committee determined that, in the context of this section, a pharmacist, but not necessarily the pharmacist-in-charge, needs to be designated as the party responsible for overseeing the remote pharmacy. Committee members suggested that a future task force examine references to the pharmacist-in-charge as the responsible party.

In Section 14. Telepharmacy, regarding remote dispensing site requirements, the committee amended the wording to state that the pharmacy shall "obtain approval from the board to operate the remote dispensing site" and deleted "submit an application to the board." In addition, the committee recommended that staff modify the language to clarify that a pharmacist must be present in the supervising pharmacy or the remote pharmacy for the remote pharmacy to be accessible to employees and to operate.

Recommended *Model Act* Amendments from the Task Force to Create an Industry Standard for Pharmacy Technician Scope of Practice and Entry-Level Requirements to Support Interstate Portability

The committee then transitioned to reviewing amendments recommended by the Task Force to Create an Industry Standard for Pharmacy Technician Scope of Practice and Entry-Level Requirements to Support Interstate Portability.

The committee agreed with the task force's recommendation to add a provision to the *Model Act* that would facilitate the transfer of licensure for pharmacy technicians. The provision mirrors the qualifications for pharmacist licensure transfer, with slight modifications.

Recommended Amendments to the Model Prescription Monitoring Program Act

The committee then reviewed amendments to the Model Prescription Monitoring Program (PMP) Act that were recommended by subject matter experts.

For the definition of “drug of concern” in Section 4, the committee recommended changing “over-the-counter” to “non-prescription” drug. In Section 6. Reporting of Prescription Monitoring Program Information, the committee recommended deleting “legal” from “patient first and last name.” In the footnote corresponding to this item and pertaining to veterinary prescriptions, the committee advised adding pet “species code.” Additionally, the committee recommended removing the requirement for “patient gender,” noting that this question can be controversial and adds no value to the report. Also, the committee recommended changing the required timeframe to submit information from “within 24 hours” to “by the end of the next business day.”

The committee reviewed and agreed to the recommended additions to Section 10. Evaluation, Data Analysis, and Reporting, which delineates what a report should contain to adequately provide trends to show whether the PMP is effective. It was noted that, when the PMP Act was written, the opioid epidemic was still relatively new and that this section addressed the cost benefit, as well as other policy, research, and education issues related to the PMP. The suggested new language reflects the current types of public health benefit information that PMPs can now generate.

Medication for Opioid Use Disorder Prescribing

The committee then discussed issues and documents pertaining to medication for opioid use disorder (OUD) prescribing. Among these documents was a sample collaborative practice agreement for the management of OUD. The committee considered but ultimately opted not to include any sample collaborative practice agreements in the *Model Act* because it would require that they be periodically updated and would also require adding other states’ agreements, resulting in time-consuming maintenance and exponential expansion of the *Model Act*.

The committee also reviewed Section 6. Pharmacy Care Services, subsection (5), pertaining to collaborative pharmacy practice agreements, and observed that the language contained therein covers substantially the same information as the sample practice agreement, although it does not address any specific form of treatment. Committee members considered whether to draft a section on collaborative practice specifically for OUD but ultimately agreed that, while it is an extremely important topic, it is adequately addressed with the current *Model Act* language.

Minority Appointments to Boards of Pharmacy

Turning its attention to the topic of racial/ethnic minority appointments to boards of pharmacy, the committee reviewed laws in Arkansas and Tennessee that mandate or encourage minority appointments to the boards, as well as a lawsuit filed against the Louisiana Board of Medicine claiming racial discrimination in its medical board appointments. The committee also reviewed a document stating NABP’s position supporting racial and ethnic diversity at all levels of health care. Staff explained that this document was created as part of a grant project, “Eliminating Generational Racial Health Disparities,” funded by the Office of Minority Health of the US Department of Health and Human Services.

Committee members noted that racial/ethnic diversification of the boards and the workforce is happening organically. They agreed that boards should be encouraged to represent the

demographics of their state population. It was noted that for many years, the racial/ethnic diversity in cosmetology has been imperative because of differences in hair care requirements.

Questions arose as to the definition of "minority" and whether it should encompass gender and sexual orientation. Some committee members were hesitant to recommend adding language to the *Model Act* until the Louisiana Board of Medicine lawsuit is adjudicated. It was noted, however, that the case could take years to resolve. Committee members observed that the lawsuit was not so much about who was appointed to the board but, rather, how the board went about it. The question was raised as to what would happen if the board required a minority appointment but did not have anyone qualified to fill the role.

Committee members stated that including aspirational language such as "strive to" seems appropriate to encourage movement toward diversity. It was suggested that such language be added to Section 202. Membership. The committee recommended moving the second sentence of the footnote into the section and modifying it to read, "Individual states may wish to consider a board composition that represents the diversity of the population and profession within the state." Committee members raised concerns, however, regarding the reception of such language in states such as Florida, where diversity language is largely prohibited.

Some members suggested that NABP convene a future task force on this topic and others suggested it could be a research topic for one or more schools or colleges of pharmacy, but ultimately the committee decided against any formal recommendation for either issue.

Open Discussion

Finally, the committee chairperson opened the floor for any additional suggestions in response to the committee charge. A few additional revisions to the *Model Act* were suggested. Regarding the definition of "prescription drug order" in Section 105, it was noted that such orders are not only communicated to a pharmacist and that there are other avenues now to receive prescription drug orders. With this in mind, the committee recommended removing the phrase, "that is communicated to a pharmacist in a licensed pharmacy."

Committee members also asked how NABP was addressing artificial intelligence (AI). Staff mentioned that one of the 120th NABP Annual Meeting sessions will focus on AI. Staff noted that, eventually, AI provisions will be added to the *Model Act*, but in what capacity is yet to be determined. It was mentioned that the manner in which states regulate AI will depend considerably on whether and how the federal government regulates it.

LE/L Committee Amendments to the *Model Act*

The revisions to the *Model Act* recommended by the task forces and identified in other LE/L Committee meeting agenda items are denoted by underlines and ~~strikethroughs~~. The recommended revisions by the LE/L Committee are denoted by double underlines and ~~double strikethroughs~~.

Recommended *Model Act* Amendments from the Task Force to Review Unprofessional Conduct and Disciplinary Actions

Model State Pharmacy Act
and Model Rules of the
National Association of Boards of Pharmacy

August 2023

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Article V
Discipline

Introductory Comment to Article V

At the very heart of any Pharmacy Act is the enforcement power of the board of pharmacy. The board must have authority to discipline and/or prohibit pharmacies, pharmacists, pharmacy interns, certified pharmacy technicians, or certified pharmacy technician candidates and business entities and facilities that violate this Act or Rules from continuing to threaten the public if it is to fulfill its responsibilities. The board must have the ability to stop wrongdoers, either permanently or temporarily, discipline them, and, where appropriate, to guide and assist errant licensees in rehabilitating themselves.

The Model Act *disciplinary provisions are contained in Article V. They were drafted with the purpose of granting to the board the widest possible scope within which to perform its disciplinary functions. Standardized disciplinary action terms and definitions were developed to facilitate the accurate reporting of disciplinary actions taken by boards of pharmacy and to avoid confusion associated with state-to-state variations in terms and definitions. The grounds for disciplinary action were developed to ensure protection of the public, while reserving to the board the power to expand upon them and adapt them to changing or local conditions as necessary. The penalties permitted under the* Model Act *will afford the board the flexibility to conform and relate discipline to offenses.*

Section 501. Disciplinary Action Terms.

(1) The following is a list of disciplinary actions that may be taken, issued, or assessed by the board of pharmacy: denial, refusal to issue or renew, revocation, summary suspension, suspension, probation, censure, reprimand, warning, cease and desist, fine/civil penalty, costs/administrative costs,[1] ~~.[2] A~~ or acceptance of a voluntary surrender, when under investigation or in lieu of a consent agreement. ~~is also considered to be a disciplinary action.~~

Section 502. Grounds, Penalties, and Reinstatement.[3]

(1) The board of pharmacy may deny, refuse to issue or renew, or may revoke, summarily suspend, suspend, place on probation, censure, reprimand, issue a warning against, or issue a cease and desist order against, the licenses or the registration of, or assess a fine/civil penalty or costs/administrative costs against any person pursuant to the procedures set forth in Section 503 herein below, upon one or more of the following grounds:

(a) Being found by the board to be in violation of any of the provisions of this Act or rules adopted pursuant to this Act;

(b) Unprofessional conduct, which includes but is not limited to the following acts: ~~as that term is defined by the rules of the board~~;[4]

(i) The illegal use, accessing, or disclosure of protected health information;

(ii) Failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of protected health information;

(iii) Failure to maintain adequate records to account for disclosures of protected health information;

(iv) Engaging in conduct likely to deceive, defraud, or harm the public; ~~or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a licensee with proof of actual injury not having to be established;~~

[1] In some instances, imposition of costs or administrative costs may not be categorized as a disciplinary action.

[2] ~~Guidelines for the imposition of sanctions for certain designated offenses can be found in Appendix A: Guidelines for Disciplinary Sanctions of the *Model Act*.~~

[3] The penalties provided in Section 502 give the board wide latitude to make the disciplinary action fit the offense. The "reasonable intervals" in 502(3) would be determined by the board.

[4] It is particularly important to emphasize the need for specificity in defining the grounds upon which a pharmacist's or pharmacy intern's license to practice pharmacy, or a certified pharmacy technician's or certified pharmacy technician candidate's registration to assist in the practice of pharmacy, may be revoked or suspended. The term "unprofessional conduct" is particularly susceptible to judicial challenge for being unconstitutionally vague. Each offense included within the meaning of this term must be capable of being understood with reasonable precision by the persons regulated so that it can be readily enforced and relied upon during disciplinary proceedings, and so that those regulated by it may easily conform their professional conduct to its meaning(s).

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

This Section must be examined in light of other state laws since some states, for example, restrict the circumstances under which a license may be denied to an individual because of the commission of a felony. In addition, an individual who has been convicted of a felony and who has paid his debt to society has restored constitutional protections that may curtail a strict application of Section 502(1)(c).

(v) Demonstrating a willful or careless disregard for the health, welfare, or safety of a patient;

(vi) Engaging in conduct which substantially departs from the standards of care ordinarily exercised by a licensee with proof of actual injury not having to be established;

(vii) ~~Selling~~ Providing a drug for which a prescription drug order from a practitioner is required, without having received a prescription drug order for the drug;

(viii) Willfully and knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with the federal laws and regulations and state laws and rules;

(ix) Obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's pharmacist care services, absent a clear benefit to the patient, solely in response to promotion or marketing activities;

(x) Willfully and knowingly completing and submitting inaccurate due diligence questionnaires and/or attestation documents regarding the purchase or receipt of drugs from manufacturers, repackagers, third-party logistics providers, and wholesale distributors;

(xi) Knowingly f~~F~~iling a false or fraudulent complaint with the board;

(xii) Participation in any plan, agreement, or arrangement which eliminates or detrimentally affects the traditional relationship of physician, patient, pharmacist, and the patient's freedom of choice of professional services;

(xiii) Committing any act of ~~sexual~~ abuse, misconduct, or exploitation related to a licensee's practice of pharmacy.

(c) Incapacity that prevents a licensee from engaging in the practice of pharmacy or a registrant from assisting in the practice of pharmacy in a manner that is safe for the public~~, with reasonable skill, competence, and safety to the public~~;[5]

(d) Being guilty of, pleading no contest to, or entering into a pre-trial agreement ~~diversion program~~ for one (1) or more of the following:

(i) ~~a felony;~~ any criminal offense, including but not limited to misdemeanors that threaten patient safety;

(ii) violations of ~~the~~ pharmacy or drug laws or rules ~~of~~ this state, ~~or rules and regulations pertaining thereto; or of laws, rules, and regulations of~~ any other state; or ~~of the~~ federal government;[6]

(e) Disciplinary action taken by another ~~state or~~ jurisdiction against a license or other authorization to practice pharmacy based upon conduct by the licensee similar to conduct that would constitute grounds for actions as defined in this Section, which involves or may result in direct patient impact or harm in states other than that of the initiating board;

[5] Boards need to consider the issue of impairment if a registrant or licensee tests positive for a substance of misuse and/or abuse.

[6] It is contemplated that boards of pharmacy will consider state and federal law, including any discrepancies between state and federal law, when evaluating complaints against a registrant or licensee related to a positive result on a cannabinoid drug test. It is also contemplated that any complaint of this nature will be assessed on a case-by-case basis.

(f) Failure to report to the board any adverse action taken by another licensing jurisdiction (United States or foreign), government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this Section;

(g) Failure to report to the board one's surrender of a license or authorization to practice pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this Section;

(h) Failure to report to the board any adverse judgment, settlement, or award arising from a malpractice claim related to conduct that would constitute grounds for action as defined in this Section;

(i) Failure to report a federal or state settlement or consent agreement related to the practice of pharmacy and/or drug manufacturing or distributing;

(j) ~~Knowing or suspecting~~ Failure to report evidence within _____ days that a pharmacist, pharmacy intern, certified pharmacy technician, or certified pharmacy technician candidate is incapable practicing in a manner that is safe for the public, ~~that a pharmacist or pharmacy intern is incapable of engaging in the practice of pharmacy or that a certified pharmacy technician or certified pharmacy technician candidate is incapable of assisting in the practice of pharmacy in a manner that is safe for the public with reasonable skill, competence, and safety to the public,~~ and failing to report any relevant information to the board of pharmacy;

(k) Misrepresentation of a material fact or providing false or fraudulent information by a licensee and/or applicant in securing the issuance or renewal of a license or registration;

(l) Fraud by a licensee in connection with the practice of pharmacy, including the publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy;

~~(m) Affiliating with websites that may deceive or defraud patients or that violate pharmacy or drug laws of this state or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the federal government;~~

(m) Engaging, or aiding and abetting an individual to engage in the practice of pharmacy without a license~~;~~ or assisting in the practice of pharmacy or aiding and abetting an individual to assist in the practice of pharmacy without a license. ~~being licensed by the board of pharmacy; or~~ ~~f~~

(n) Falsely using the title of pharmacist, pharmacy intern, certified pharmacy technician, or certified pharmacy technician candidate;

(o) Requiring pharmacy personnel to meet production and/or performance metrics and/or quotas that negatively impact patient safety.[7]

(p) Failing to pay the costs assessed in a disciplinary hearing;

(q) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of any licensing examination;[8]

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[7] This is not intended to include performance metrics that may be related to the ability and competency of pharmacy personnel.

[8] It is recommended that the following rule be adopted defining subversion or the attempt to subvert any licensing examination.

(1) Conduct which subverts or attempts to subvert any licensing examination or the administration of any examination shall include, but not be limited to, the following:
   (a) Conduct which violates the security of the examination materials; removing from the examination room any examination materials without authorization; the unauthorized reproduction by any means of any portion of the actual licensing examination;

~~(s) Being found by the board to be in violation of any of the provisions of this Act or rules adopted pursuant to this Act;~~

~~(t) Illegal use, or disclosure of protected health information;~~

(r) Impeding or subverting an investigation or failure to furnish to the board, its investigators, or representatives any information legally requested by the board;

~~(v) Willfully and knowingly submitting false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of drugs from manufacturers, repackagers, third-party logistics providers, and wholesale distributors;~~

(s) Affiliating with websites or other digital platforms ~~that may deceive or defraud patients or~~ that violate pharmacy or drug laws of this state or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the federal government;

~~(x) Illegal use or disclosure of protected health information.~~

(t) Retaliating against or disciplining an employee for filing a complaint with a state board of pharmacy or other licensing body or reporting a suspected violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this paragraph, retaliation or discipline of an employee includes, but is not limited to, the following:

(i) removing or suspending the employee from employment;

(ii) withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;

(iii) transferring or reassigning the employee;

(iv) denying the employee a promotion that otherwise would have been received;

(v) reducing the employee in pay or position.

~~(z)The furnishing of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;~~

(u) ~~(aa)~~Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant. ~~for the manufacture or distribution of any drugs or devices, including controlled substances;~~

~~(bb) Obtaining any remuneration by fraud, misrepresentation, or deception~~;

(v) ~~Dealing~~ Procuring, dispensing, or distributing ~~with~~ drugs or devices that a person knows or should have known are suspect or illegitimate products;[9]

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aiding by any means the unauthorized reproduction of any portion of the actual licensing examination; paying or using professional or paid examination takers for the purpose of reconstructing any portion of the licensing examination; obtaining examination questions or other examination materials, except by specific authorization either before, during, or after an examination; or selling, distributing, buying, receiving, or having unauthorized possession of any portion of a future, current, or previously administered licensing examination.

(b) Unauthorized communication of examination information with any other examinee during the administration of a licensing examination; copying answers from another examinee or permitting one's answers to be copied by another examinee; having in one's possession during the administration of the licensing examination any books, equipment, notes, written or printed materials, or data of any kind other than the examination materials distributed, or otherwise authorized to be in one's possession during the examination; or impersonating any examinee or having an impersonator take the licensing examination on one's behalf.

9 This Section restricts distribution of drugs or devices to licensed entities to help ensure against clandestine distribution to unauthorized and unlicensed persons.

(w) Purchasing or receiving of a drug from a source other than an authorized trading partner or a device from a source other than a person or pharmacy licensed under the laws of the state, except where otherwise provided;

(x) The transfer by a pharmacy to a wholesale distributor or to another pharmacy without being licensed as a wholesale distributor. The following are not subject to the provisions of this subsection:

(i) Prescription drugs or devices that are returned by a pharmacy for credit, in an amount equal to or less than the actual purchase price, to the wholesale distributor or manufacturer from which those products were purchased;

(ii) Intracompany sales;

(iii) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(iv) The sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug by a charitable organization described in 503(c)(3) of the internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(v) The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

(vi) The transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing or filling agreement;

(vii) The transfer of a drug from one pharmacy to another for a specific patient need to fill a prescription drug order for an identified patient;

(viii) The distribution of minimal quantities of product by a pharmacy to a licensed practitioner for office use.

(y) Wholesale drug distributors, other than pharmacies, dispensing or distributing drugs or devices directly to patients;

(z) Violations of any of the provisions of this Act or of any of the rules adopted by the board under this Act.

(2) The board of pharmacy may deny or refuse to issue or renew a license if it determines that the issuing or renewing of such license ~~would not be in the public interest,~~ would <u>not be in the interest of public safety,</u> or as otherwise statutorily provided.

(3) Reinstatement of a license that has been suspended, revoked, or restricted by the board may be granted in accordance with the procedures specified by Section ~~4~~5<u>0</u>1 of this Act.

~~(4)The board of pharmacy shall require complainants to identify themselves in the complaint and make themselves available for an evidentiary interview. Complainants may request that their identity remain confidential during the preliminary investigatory process. The board may take action on a complaint if the patient or complainant does not comply with the board's investigation when the board has probable cause of a violation of law. It shall be an act of unprofessional conduct for any licensee to file a false or fraudulent complaint or report to the board~~.

(4) Impaired practice licensees

(a) The board may defer action with regard to an impaired practice licensee who voluntarily signs an agreement, in a form satisfactory to the board, agreeing not to practice pharmacy and to enter an approved treatment and therapeutic monitoring program in accordance with this Section, provided that this Section should not apply

to a licensee who has been convicted of, pleads guilty to, or enters a plea of nolo contendere to a felonious act prohibited by _____ or a conviction relating to a controlled substance in a court of law of the United States or any other state, territory, or country. A licensee who is physically or behaviorally impaired due to substance use may qualify as an impaired practice licensee and have disciplinary action deferred and ultimately waived only if the board is satisfied that such action will not endanger the public and the licensee enters into an agreement with the board for a treatment and therapeutic monitoring plan approved by the board, progresses satisfactorily in such treatment and monitoring program, complies with all terms of the agreement and all other applicable terms of subsection (2)(b). Failure to enter such agreement or to comply with the terms and make satisfactory progress in the treatment and monitoring program shall disqualify the licensee from the provisions of this Section and the board shall activate an immediate investigation and disciplinary proceedings. Upon successfully meeting the requirements of the treatment and therapeutic monitoring program in accordance with the agreement signed by the board, the licensee may apply for permission to resume the practice of pharmacy upon such conditions as the board determines necessary.

(b) The board may require a licensee to enter into an agreement that includes, but is not limited to, the following provisions:

(i) Licensee agrees to voluntarily cease practicing ~~surrender their license~~, and the board will temporarily suspend such license, for a period of time to be determined by the board following commencement of the ~~treatment and therapeutic monitoring~~ program approved by the board.

(ii) Licensee will enroll in a ~~treatment and monitoring~~ program that ~~includes substance use disorder professionals and~~ is approved by the board.

(iii) Licensee agrees that failure to satisfactorily progress in such ~~treatment and monitoring~~ program shall be reported to the board by the treating professional, who shall be immune from any liability for such reporting made in good faith.

(iv) Licensee consents to the treating physician or professional of the approved ~~treatment and therapeutic monitoring~~ program reporting to the board on the progress of licensee at such intervals as the board deems necessary and such person making such report will not be liable when such reports are made in good faith.

(c) The ability of an impaired practice licensee to practice shall only be restored ~~and charges dismissed~~ when the board is satisfied by the reports it has received from the approved ~~treatment and therapeutic monitoring~~ program that licensee can resume practice under a current approved ~~treatment~~ plan without danger to the public.

(d) Licensee consents, in accordance with applicable law, to the release to the board of any treatment information from the approved ~~treatment~~ program.

(e) Failure to enter into such agreement or to comply with the terms and make satisfactory progress in the ~~treatment and monitoring~~ program shall disqualify the licensee from the provisions of this Section. ~~and the board shall activate an immediate investigation and disciplinary proceedings.~~

(f) Any person who has ~~substantial~~ evidence that a licensee has an impairment due to a substance use disorder ~~for which the licensee is not receiving treatment under a~~

~~program approved by the board pursuant to an agreement entered into under this Section,~~ is diverting a controlled substance, or is mentally or physically incompetent to carry out their duties of licensure, shall make or cause to be made a report to the board. Any person who reports pursuant to this Section in good faith and without malice shall be immune from any civil or criminal liability arising from such reports. Failure to provide such a report within a reasonable time from receipt of knowledge may be considered grounds for disciplinary action against the licensee for failing to report.

~~(6)~~(5) Any person licensed by the board ~~whose license to practice~~ ~~whose license to practice pharmacy~~ in this state whose license has been denied renewal, voluntarily surrendered, summarily suspended, or suspended, ~~or revoked~~ pursuant to this Act~~, whether voluntarily or by action of the board,~~ shall have the right~~, at reasonable intervals,~~ to petition the board for reinstatement of such license.[10] Such petition shall be made as prescribed by the board. Upon investigation and hearing, the board may, at its discretion, grant or deny such petition, or it may modify its original finding to reflect any circumstances that have changed sufficiently to warrant such modifications. The board, also at its discretion, may require such person to pass an examination(s) for reentry into the practice of pharmacy.

~~(7)~~(6) Nothing herein shall be construed as barring criminal prosecutions for violations of this Act.

~~(8)~~(7) All final decisions by the board shall be subject to judicial review pursuant to the Administrative Procedures Act.

Section 503. Procedure.[11]

(1) Notwithstanding any provisions of the state Administrative Procedures Act, the board may, without a hearing, summarily suspend a license ~~for not more than 60 days~~ if the board finds that a pharmacist, pharmacy intern, certified pharmacy technician, certified pharmacy technician candidate, business entity or facility has violated a law or rule that the board is empowered to enforce, and if continued ~~practice by the pharmacist, pharmacy intern, certified pharmacy technician, certified pharmacy technician candidate, business entity or facility~~ would create an imminent risk of harm to the public. The suspension shall take effect upon written notice ~~to the pharmacist, pharmacy intern, certified pharmacy technician, certified pharmacy technician candidate, business entity or facility~~ specifying the statute or rule violated. ~~At the time it issues the suspension notice, the board shall schedule a disciplinary hearing to be held under the Administrative Procedures Act within 20 days thereafter. The pharmacist, pharmacy intern, certified pharmacy technician, certified pharmacy technician candidate, business entity or facility shall be provided with at least 10 days' notice of any hearing held under this subsection.~~

(5) Notwithstanding any provisions of the state Administrative Procedures Act, the board may, in its own name, issue a cease and desist order to stop an individual from engaging in an unauthorized practice of pharmacy or violating or threatening to violate a statute, rule, or

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[10] A pharmacist who is under investigation or who has been charged with a violation of the pharmacy practice act may agree to voluntarily surrender their pharmacist license. When this occurs, the board should formally enter stipulated findings and an order describing the terms and conditions of the surrender including any agreed upon time limitations. This establishes statutory grounds that would support disciplinary action and prevents a pharmacist who has surrendered a license from applying for reinstatement within a time frame unacceptable to the board.

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

order that the board has issued or is empowered to enforce. The cease and desist order must state the reason for its issuance and give notice of the individual's right to request a hearing under applicable procedures as set forth in the Administrative Procedures Act. Nothing herein shall be construed as barring criminal prosecutions for violations of this Act.

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Model Rules for the Practice of Pharmacy

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~~Section 17. Unprofessional Conduct.~~

~~Unprofessional conduct shall include, but is not limited to, the following acts of a pharmacist or pharmacy:~~

~~The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy;~~
~~Unreasonably refusing to compound or dispense prescription drug orders that may be expected to be compounded or dispensed in pharmacies by pharmacists;~~
~~Attempting to circumvent the patient counseling requirements, or discouraging the patient from receiving patient counseling concerning their prescription drug orders;~~
~~The illegal use,~~ accessing, ~~or disclosure of protected health information;~~
~~Failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of protected health information;~~
~~Failure to maintain adequate records to account for disclosures of protected health information;~~
~~Selling, giving away, or otherwise disposing of accessories, chemicals, or drugs or devices found in illegal drug traffic when the pharmacist knows or should have known of their intended use in illegal activities;~~
~~Engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a pharmacist, with proof of actual injury not having to be established;~~
~~Selling a drug for which a prescription drug order from a practitioner is required, without having received a prescription drug order for the drug;~~
~~Willfully and knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with the federal laws and regulations and state laws and rules;~~
~~Obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's pharmacist care services, absent a clear benefit to the patient, solely in response to promotion or marketing activities;~~
~~Willfully and knowingly completing and submitting inaccurate due diligence questionnaires and attestation documents regarding the purchase or receipt of drugs from manufacturers, repackagers, third-party logistics providers, and wholesale distributors.~~

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Appendix A
Guidelines for Disciplinary Sanctions

Improperly Obtaining or Attempting to Obtain a License

Fraud or misrepresentation in applying for or procuring a license issued by the board of pharmacy or in connection with applying for or procuring periodic reregistration of such license.
Range of action: from fine to revocation or denial
Cheating on or attempting to subvert the pharmacist licensure examination(s).
Range of action: revocation or denial

Misdemeanors/Felonies

The commission or conviction of a gross misdemeanor or a felony, whether or not related to the practice of pharmacy, or the entry of a guilty or nolo contendere plea to a gross misdemeanor or a felony charge.
Range of action: from probation to revocation

Deception/Fraud/Misrepresentation

Conduct likely to deceive, defraud, or harm the public.
Range of action: from censure to revocation
Making a false or misleading statement regarding one's skill of the efficacy or value of the medicine, treatment, or remedy dispensed in the treatment of any disease or other condition of the body or mind.
Range of action: from probation to revocation
The use of any false, fraudulent, or deceptive statement in any document connected with the practice of pharmacy.
Range of action: from warning to revocation
Practicing pharmacy under a false or assumed name.
Range of action: from probation to revocation

Patient Confidentiality/Records

Improper management of pharmacy patient records, including illegal use or disclosure of protected health information.
Range of action: from warning to suspension

Negligence/Incompetence/Disability/Malpractice

negligence in the practice of pharmacy as determined by the board.
range of action: from warning to revocation
being found mentally incompetent or insane by any court of competent jurisdiction.
range of action: from suspension to revocation
being physically or mentally unable to engage safely in the practice of pharmacy.
range of action: from probation to revocation

demonstration of incapacity or incompetence to practice pharmacy.
range of action: from probation to revocation
any adverse judgment, award, or settlement against the licensee resulting from a professional malpractice claim related to conduct that would constitute grounds for action as defined in this section.
range of action: from censure to revocation

Sexual Misconduct

Commission of any act of sexual abuse, misconduct, or exploitation related to a licensee's practice of pharmacy.
Range of action: from probation to revocation

Drug- and Alcohol-Related Offenses

Being dependent on or habituated to a drug or intoxicant.
Range of action: from probation to revocation
Dispensing, prescribing, selling, administering, distributing, ordering, or giving any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug for any purposes other than medically accepted as therapeutic.
Range of action: from probation to revocation
Except as otherwise permitted by law, dispensing, prescribing, selling, administering, distributing, ordering, or giving to an habitué, addict, or any person previously drug dependent any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug.
Range of action: from probation to revocation
Violating any state or federal law or regulation relating to controlled substances.
Range of action: from warning to revocation

Misuse of License

Aiding or abetting the practice of pharmacy by an unlicensed, incompetent, or impaired person.
Range of action: from reprimand to revocation
Allowing another person to use one's license to practice pharmacy.
Range of action: from reprimand to revocation

Disciplinary Action by Other Jurisdictions

Disciplinary action of another state or jurisdiction against a license or other authorization to practice pharmacy based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this section.
Range of action: same as for similar offense in this state

Failure to Report to and/or Cooperate with Board

Failure to report to the board any adverse action taken by another licensing jurisdiction (united states or foreign), government agency, law enforcement agency, or court for conduct that would

constitute grounds for action as defined in this section.
Range of action: from censure to revocation
Failure to report to the board one's surrender of a license or authorization to practice pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this section.
Range of action: from censure to revocation
Failure to report to the board any adverse judgment, settlement, or award arising from a malpractice claim related to conduct that would constitute grounds for action as defined in this section.
Range of action: from censure to suspension
Failure to cooperate with a lawful investigation conducted by the board.
Range of action: from censure to revocation
Failure to furnish to the board, its investigators, or representatives any information legally requested by the board.
Range of action: from censure to revocation

Other Violations

Violation of any provision(s) of the pharmacy practice act, any rules and regulations of the board, or any action, stipulation, or agreement of the board.
Range of action: corresponds to related actions above

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

August 2023

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Section 105. Definitions.

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"Automated pharmacy systems" include, but are not limited to, ~~mechanical~~ systems that perform operations or activities, compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs, and which collect, control, and maintain all transaction information.

"Practice of telepharmacy[12]" means the practice of pharmacy ~~by registered pharmacists located within US jurisdictions~~ through the use of telepharmacy technologies between a licensee and patients or their agents ~~at distances that are located within US jurisdictions~~.

"Remote dispensing site" means a location, other than where a pharmacist is located, where drugs are maintained and prescriptions are filled by a certified pharmacy technician and dispensed under the ~~direct,~~ remote supervision of a pharmacist[13].

"Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy ~~pursuant to a request from another participating pharmacist or pharmacy~~ to process or fill a prescription drug order or provide pharmacist care services, which may include preparing, packaging, labeling, compounding for specific patients, dispensing, product verification, counseling, performing drug utilization reviews, conducting claims adjudication, obtaining refill authorizations, ~~reviewing therapeutic interventions~~, and/or reviewing institutional facility orders.

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[12] States may interpret the definition of the practice of telepharmacy to allow certified pharmacy technicians to provide services such as, immunizations and "test and treat" services.

[13] States may interpret "remote supervision of a pharmacist" to allow certified pharmacy technicians to provide services such as immunizations and "test and treat" services at a remote dispensing site.

Model Rules for the Practice of Pharmacy

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Section 8. Shared Pharmacy Services.

(1) General Requirements[14, 15]

(a) The pharmacy must possess a resident or nonresident permit issued by the board prior to engaging in shared pharmacy services.[16]

(b) A pharmacy may provide or utilize shared pharmacy services only if the pharmacies involved:

(i) have the same owner; or

(ii) have a written contract or agreement that outlines the services provided and the shared responsibilities of each pharmacy in complying with federal and state pharmacy laws and rules; and

(iii) share a common electronic file or technology that allows access to information necessary or required to perform shared pharmacy services in conformance with the pharmacy act and the board's rules.

(c) A pharmacy engaged in shared pharmacy services shall comply with appropriate federal and state controlled substance registrations for each pharmacy if controlled substances are maintained.

(2) Operations

(a) Pharmacies engaging in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services shall:

(i) maintain records identifying, individually, for each prescription drug order processed, the name of each pharmacist or pharmacy intern who took part in the drug utilization review, refill authorization, or therapeutic intervention functions performed at that pharmacy and the name of any certified pharmacy technician or certified pharmacy technician candidate if they assisted in any of those functions;

~~(ii) maintain records identifying individually, for each prescription drug order filled or dispensed, the name of each pharmacist or pharmacy intern who took part in the filling, dispensing, and patient counseling functions performed at that pharmacy and the name of any certified pharmacy technician or certified pharmacy technician candidate if they assisted in any of those functions;~~

~~(iii) report to the board as soon as practical the results of any disciplinary action taken by another state's board of pharmacy involving shared pharmacy services;~~

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[14] The Board may want to consider the extent to which this General Requirements Section is applicable to institutional-based shared pharmacy services pharmacies, as such application may be subject to interpretation of existing state and federal law governing institutional facilities.

[15] In order to ensure accountability, the pharmacist-in-charge of a pharmacy engaging in shared pharmacy services must possess a license to practice pharmacy in all jurisdictions that they are engaging in such series until such a time in which provisions for multistate practice exist.

[16] Often the terms "licensure," "registration," and "permit" are used interchangeably throughout the *Model Act*. In the case of shared pharmacy services pharmacies that utilize automated pharmacy systems, boards may determine that it is appropriate to issue a permit for the automated pharmacy system but not for the physical site where the automated pharmacy system is located.

(ii) maintain a mechanism for tracking the prescription drug order during each step of the processing and filling procedures performed at the pharmacy

(iii) maintain a mechanism for the patient, upon request, to identify all pharmacies involved in filling the prescription drug order; and

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

(v) operate a continuous quality improvement program for shared pharmacy services.

~~(3) Drug Storage and Security~~

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

~~(b) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to:~~

~~(i) pharmacists, certified pharmacy technicians, certified pharmacy technician candidates, or pharmacy interns who are employed by the shared pharmacy services pharmacy; or~~

~~(ii) personnel employed at the institutional facility or clinic where the shared pharmacy services pharmacy is located who:~~

~~(A) are licensed health care providers;~~

~~(B) are documented by the pharmacist-in-charge or the person responsible for the supervision and on-site operation of the facility where the shared services pharmacy is located; and~~

~~(C) have completed documented training concerning their duties associated with the shared pharmacy services Pharmacy.~~

~~(d) Shared pharmacy services pharmacies shall have adequate security to:~~

~~(i) comply with federal and state laws and regulations; and~~

~~(ii) protect the confidentiality and integrity of protected health information.~~

(3) Policies and Procedures

(a) Each pharmacy in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services that outline the responsibilities of each pharmacy and describe policies reflecting operation requirements. ~~Each pharmacy is required to maintain the portion of the joint policies and procedures that relate to that pharmacy's operations. The policies and procedures shall:~~

~~(i) outline the responsibilities of each pharmacy;~~

~~(ii) include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in shared pharmacy services; and~~

~~(iii) include processes for:~~

~~(A) notifying patients that their prescription drug orders may be processed or filled by another pharmacy and providing the name of the pharmacy;~~

~~(B) protecting the confidentiality and integrity of protected health information;~~

~~(C) dispensing prescription drug orders when the filled prescription drug order is not received or the patient comes in before the prescription drug order is received:~~

~~(D) maintaining required manual or electronic records to identify the name, initials or identification code and specific activity or activities of each pharmacist, certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern who performed any shared pharmacy services;~~

~~(E) complying with federal and state laws; and~~

(F) ~~operating a continuous quality improvement program for shared pharmacy services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems~~.

(4) Individual Practice

(a) Nothing in this Section shall prohibit an individual pharmacist licensed in the state, who is an employee of or under contract with a pharmacy, or a licensed certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the prescription drug order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:

(i) the pharmacy establishes controls to protect the confidentiality and integrity of protected health information; and

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

Section 9. Automated Pharmacy Systems.

(1) Automated pharmacy systems can be utilized in licensed pharmacies~~, shared pharmacy services pharmacies,~~ and other locations approved by the board in accordance with all state and federal laws and rules. A pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is appropriately secured and monitored ~~supervised electronically by a pharmacist~~. Automated pharmacy systems shall comply with the following provisions.

(a) Documentation as to type of equipment, ~~serial numbers,~~ facility-specific unique identifiers, and ~~content,~~ policies and procedures~~, and shared pharmacy services pharmacy location shall be maintained in the pharmacy for review~~. Such documentation shall include, but is not limited to:

(i) name and address of the pharmacy and the ~~shared pharmacy services pharmacy~~ name and address of the location where the automated pharmacy system is being used;

(ii) manufacturer's name and model, if applicable;

(iii) description of how the automated pharmacy system is used;

(iv) continuous quality assurance procedures ~~to determine continued appropriate use of the automated pharmacy system~~;

(v) ~~documentation evidencing that the automated pharmacy system has been tested prior to initial use and on a periodic basis at each location to ensure that the automated pharmacy system is operating properly~~.

(b) ~~A pharmacist shall be accessible to respond to inquiries or requests pertaining to drugs dispensed from the automated pharmacy system.~~[17] In order to facilitate communication between the pharmacy and the site where the automated pharmacy system is located, a pharmacy should provide a method of communication ~~telephone number~~ so that the pharmacist is accessible at all times the automated pharmacy system is operational.

(c) ~~Any pharmacy that maintains an automated pharmacy system for the purposes of remote dispensing to outpatients shall maintain an interactive communication system to provide for effective communication between the patient and the pharmacist; the~~ For remote dispensing to outpatients[18], a ~~the~~ video/auditory communication system shall allow for the appropriate exchange of oral and written communication and patient counseling; if the video/auditory communication system malfunctions, then all operations of the automated pharmacy system shall cease until the system is fully functional.

(d) Automated pharmacy systems shall have adequate security systems to:
  (i) prevent unauthorized access;
  (ii) comply with federal and state regulations; and
  (iii) prevent the illegal use or disclosure of protected health information.

(e) Records and/or electronic data kept by automated pharmacy systems shall meet the following requirements.
  ~~(i) All events involving the contents of the automated pharmacy system must be recorded electronically.~~
  (i) Records must be maintained by the pharmacy and must be readily available to the board. Such records shall include:
    (A) identity of system accessed;
    (B) identification of the individual accessing the system;
    (C) type of transaction;
    (D) name, strength, dosage form, and quantity of the drug accessed;
    (E) name of the patient for whom the drug was ordered; and
    (F) such additional information as the pharmacist-in-charge may deem necessary.

(f) Access to and limits on access (eg, security levels) to the automated pharmacy system shall be defined.[19]

(g) Each automated pharmacy system shall have a designated pharmacist who ~~The pharmacist-in-charge~~ shall have the responsibility to:
  (i) assign, discontinue, or change access to the system;
  (ii) ensure that access to the drugs complies with state and federal regulations;

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[17] ~~In order to facilitate communication between the pharmacy and the site where the automated pharmacy system is located, a pharmacy should provide a toll-free telephone number so that the pharmacist is accessible at all times the automated pharmacy system is operational.~~

[18] Although an "outpatient" generally refers to a person who receives drugs for use outside of an institutional facility, the definition of "outpatient" must be defined by each state. For example, although the *Model Act* classifies penal institutions as a type of institutional facility and therefore its inmates as inpatients, the pharmacist is exempt from providing patient counseling. However, some states may consider inmates of penal institutions as outpatients and therefore should decide if a video/audio communication system is required in such facilities so that the pharmacist is able to provide patient counseling.

[19] This Section anticipates that decisions regarding which health care professionals may access the automated pharmacy system and the level of access allowed (eg, access to drugs, access to patient profiles for viewing only, access to patient profiles for modification) will be left up to the individual(s) responsible for the automated pharmacy system; however, states may decide to take on this responsibility and define those who may have access to the system and the levels of access allowed.

~~(iii) ensure that the automated pharmacy system is filled/stocked accurately.~~

(h) The filling/stocking of all drugs in the automated pharmacy system shall be accomplished by qualified personnel under the supervision of a licensed pharmacist. A record of drugs filled/stocked into an automated pharmacy system shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.[20]

~~(i) A record of drugs filled/stocked into an automated pharmacy system shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.~~

(i) All ~~containers of drugs stored in the automated pharmacy system shall be packaged and labeled~~ prescription fulfillment activities shall take place in accordance with federal and state laws and regulations.

~~(j) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.~~

~~(k) The automated pharmacy system shall provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the automated pharmacy system, all in accordance with existing state and federal law.[21]~~

(i) The automated pharmacy system shall provide a mechanism for securing and accounting for wasted or discarded drugs in accordance with existing state and federal law.

~~(2) Policies and Procedures~~

~~(f) The pharmacist-in-charge is responsible for developing or adopting, implementing, and maintaining automated pharmacy systems policies and procedures that address the following:~~

~~(i) system operation, safety, stocking accuracy, patient confidentiality, access and limits to access, environmental controls, and malfunction;~~

~~(ii) provision of pharmacist care;~~

~~(iii) security, including:~~

~~(A) preventing unauthorized access;~~

~~(B) prevention of the illegal use or disclosure of protected health information.~~

~~(g) All policies and procedures shall be maintained in the pharmacy responsible for the automated pharmacy system and, if the automated pharmacy system is being used at a different location, at that location as well.~~

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Section 14. Telepharmacy

(1) General Requirements

(a) The pharmacy shall:

(i) obtain a resident or nonresident permit issued by the board prior to engaging in the practice of telepharmacy;

(ii) comply with appropriate federal and state controlled substance laws and rules for each pharmacy if controlled substances are maintained;

[20] This Section anticipates that states will allow non-pharmacist personnel to fill/stock automated pharmacy systems under a pharmacist's supervision; however, the state may decide to only allow a pharmacist to perform this function. Should the state allow non-pharmacist personnel to perform this function, it should define the level of pharmacist supervision necessary (eg, immediate, direct, or general).

[21] The state may require that each licensed pharmacy or facility have in place written policies and procedures to address situations in which drugs removed from the system remain unused and must be secured and accounted for.

(iii) maintain additional policies and procedures specific to telepharmacy.

(2) Remote Dispensing Site Requirements[22]

(a) The pharmacy shall obtain approval from the board to operate the remote dispensing site ~~submit an application to the board~~.

(b) The pharmacist-in-charge of the supervising pharmacy shall be responsible for all operations[23].

(c) The pharmacy shall have a written contract or agreement that outlines the services provided and the responsibilities of each party in complying with federal and state pharmacy laws and rules.

~~(d) The pharmacist-in-charge shall oversee monthly inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.~~

~~(e) A pharmacist must be designated to be available within (_) hours, in case of emergency.~~

(d) Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least one (1) certified pharmacy technician[24]. All certified pharmacy technicians and certified pharmacy technician candidates shall be under the supervision of a pharmacist ~~at the supervising pharmacy~~ at all times that the remote site is operational. The pharmacist shall supervise telepharmacy operations electronically ~~from the supervising pharmacy~~.

(e) The remote dispensing site and the supervising pharmacy must utilize a common electronic record-keeping system that must be capable of the following:

(i) Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site at all times of operations; and

(ii) Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed from the supervising pharmacy.

(f) Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, state and federal law.

(g) A supervising pharmacy of a remote dispensing site must maintain a video and audio communication system that provides for effective communication between a pharmacist ~~the supervising pharmacy~~ and the remote dispensing site personnel and patients or caregivers. The system must ~~provide an adequate number of views of the entire site,~~ facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or delivery of drugs The remote dispensing site must use telepharmacy technology that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription drug order.

~~(j) The remote dispensing site must retain a recording of facility surveillance, excluding patient communications, for a minimum of (_) days.~~

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[22] To allow for emerging practice models, states should not impose volume restrictions, milage restrictions, or unnecessary limitations that would limit patient access to remote dispensing sites.

[23] The pharmacist-in-charge shall oversee inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

[24] States may allow pharmacy interns to perform the functions of a certified pharmacy technician at a remote dispensing site.

~~(i) Adequate supervision by the pharmacist in this setting is maintaining uninterrupted visual supervision and auditory communication with the site and full supervisory control of the automated system, if applicable, and must not be delegated to another person.~~

~~(ii) Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed to the public if any component of the communication system is malfunctioning, until system corrections or repairs are completed.~~

~~(iii) The video and audio communication system used to counsel and interact with each patient or patient's caregiver must be secure and compliant with state and federal confidentiality requirements.~~

(h) ~~Unless a pharmacist is present at the remote site, that~~ a remote dispensing site must ~~not be open or its empolyees allowed access to it during times the~~ a supervising ~~pharmacist~~ pharmacy is ~~unavailable.~~ ~~closed.~~ A pharmacist must be present at the supervising site or the remote dispensing site for the remote dispensing site to be open or for employees to be allowed to access it. The security system must allow for tracking of entries into the remote dispensing site, and the pharmacist-in-charge must periodically review the provision of access and record of entries.

~~(l) If drugs are maintained or dispensed from the remote dispensing site, drug transfers to the remote dispensing site must comply with applicable state and federal requirements.~~

(i) A remote dispensing site must display a sign, easily visible to the public, which informs patients~~:~~

~~(i) this is a remote site~~

~~(ii)~~location of supervising pharmacy; ~~and~~

~~(iii)~~that a pharmacist is available to ~~will~~ counsel the patient using audio and video communication systems each time a new drug is dispensed and at the time it is refilled, if necessary, at a remote dispensing site.

~~(n) The remote dispensing site must use telepharmacy technology that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription drug order.~~

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Section 105. Definitions.

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(13) "Certified pharmacy technician" means personnel licensed by the board who have completed a certification program approved by the board and may, under the supervision of a pharmacist, perform certain activities involved in the practice of pharmacy that are within their scope of certification and as delegated by the pharmacist, but excluding clinical patient care activities such as, but not limited to:
- (a) drug utilization review (DUR);
- (b) clinical conflict resolution; and
- (c) patient counseling.

(14) "Certified pharmacy technician candidate" means personnel licensed by the Board who intend to complete a certification program approved by the board and may, under the supervision of a pharmacist, perform certain activities involved in the practice of pharmacy that are within their scope of education and training and as delegated by the pharmacist, but excluding clinical patient care activities such as, but not limited to:
- (a) drug utilization review (DUR);
- (b) clinical conflict resolution; and
- (c) patient counseling.

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(58) "NABP Emergency Passport Program" means a program, operated by NABP, that verifies pharmacists, certified pharmacy technicians, pharmacy interns, and pharmacies meet the standard of licensure and are in good standing in states of licensure in order to practice on a temporary or emergency basis according to state public health emergency orders or as otherwise determined by the state board of pharmacy.

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(60) "NABP Verify" means an ongoing credentialing and license monitoring service, operated by NABP, that verifies pharmacists and applicable business entities are licensed in good standing and provides proof of that status

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Section 304. Qualifications for Licensure Transfer.[25]

(1) In order for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist by licensure transfer in this state, an applicant shall:[26]
- (a) have submitted an application in the form prescribed by the board of pharmacy;
- (b) have attained the age of 18 years;
- (c) have possessed at the time of initial licensure as a pharmacist all qualifications necessary to have been eligible for licensure at that time in this state;
- (d) have engaged in the practice of pharmacy for a period of at least one (1) year or have met the pharmacy practice experience requirements of this state within the one (1) year period immediately preceding the date of such application;
- (e) have presented to the board proof of an active license in good standing;
- (f) have presented to the board proof that any other license granted to the applicant by any other state has not been suspended, revoked, or otherwise restricted for any reason, except nonrenewal or for the failure to obtain the required continuing education credits, in any state where the applicant is currently licensed but not engaged in the practice of pharmacy; and
- (g) have paid the fees specified by the board.

(2) In order for a certified pharmacy technician currently licensed in another jurisdiction to obtain a license as a certified pharmacy technician by licensure transfer in this state, an applicant shall:
- (a) have submitted an application in the form prescribed by the board of pharmacy;
- (b) have attained the age of ___ years;
- (c) have possessed at the time of transfer all qualifications necessary to be eligible for licensure in this state;
- (d) have assisted in the practice of pharmacy for a period of at least ___ or have met the experience requirements of this state;
- (e) have presented to the board proof of an active license in good standing;
- (f) have presented to the board proof that any other license granted to the applicant by any other state has not been suspended, revoked, or otherwise restricted for any reason, except nonrenewal or for the failure to obtain the required continuing education credits, in any state where the applicant is currently licensed but not assisted in the practice of pharmacy; and
- (g) have paid the fees specified by the board.

[25] See the NABP Model Rules for Public Health Emergencies or Significant Public Health Concerns for language that addresses the temporary recognition of nonresident pharmacist licensure in the case of a declared state of emergency issued due to a public health emergency.

[26] It is intended that NABP's National Disciplinary Clearinghouse would be utilized by state boards for verifying information provided by applicants.

Model Prescription Monitoring Program Act

Section 1. Short Title

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

Section 2. Legislative Findings

(Insert state-appropriate mission/purposes.)

Section 3. Purpose

(Insert state-appropriate mission/purposes.)

Section 4. Definitions

For the purposes of this Act:

(1) "Dispenser" means a person authorized in this state to ~~distribute~~ dispense to the ultimate user a substance monitored by the prescription monitoring program, but does not include~~:~~
   ~~(a)~~ a licensed hospital or institutional facility pharmacy that ~~distributes~~ dispenses such substances for the purposes of inpatient care;
   ~~(a) a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician;~~

(2) "Drug of Concern" means any prescription or ~~over-the-counter~~ non-prescription drug that has been identified for additional scrutiny and is required to be reported to the PMP. ~~demonstrates a potential for abuse, particularly those identified by boards of pharmacy, law enforcement, and addiction treatment professionals.~~

(3) "Electronic Health Information Systems" means an electronic data intermediary, gateway, or hub that facilitates secure delivery of electronic health information to practitioners or dispensers, including:
   (a) health information exchanges;
   (b) health information networks;
   (c) pharmacy software systems;
   (d) electronic medical (health) record software applications; or
   (e) electronic prescribing software applications.

(4) "Interoperability" means the sharing of prescription monitoring program information with another prescription monitoring program, or the integration of prescription monitoring program information into the electronic health information systems.

(5) "Prescription Monitoring Program Information" means information submitted to and maintained by the prescription monitoring program.[27]

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

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

Section 5. Establishment of a Prescription Monitoring Program

(1) The board of pharmacy[28] shall establish and maintain an electronic system for monitoring all federal controlled substances in Schedules II through V, ~~all~~ state-specified controlled substances in Schedules II through V, and state-specified drugs of concern dispensed ~~to~~ patients in this state.

(2) The board of pharmacy may contract with a vendor to establish and maintain the electronic monitoring system pursuant to guidelines, which the board of pharmacy shall promulgate.

(3) The board of pharmacy shall promulgate rules or establish policy to include the following:

- (a) using the PMP to improve patient care and to facilitate the goal of reducing misuse, abuse, overdose, addiction to and diversion of controlled substances and drugs of concern;
- (b) implementing security and safeguards necessary to ensure that information is released only to authorized individuals;
- (c) developing criteria for ~~referring~~ providing PMP information to a law enforcement agency;
- (d) developing criteria for ~~referring~~ providing PMP information to a licensing board, or other state or federal agency charged with the regulation of prescribing, dispensing, or administering a controlled substance or drug of concern;
- (e) designing and implementing training, education, and/or instruction in the appropriate access to and use of the PMP;
- (f) adopting ~~the most recent version of~~ the American Society for Automation in Pharmacy (ASAP) technical standards for electronic reporting of PMP information; and
- (g) incorporating technological improvement to facilitate the interoperability of the PMP with other state PMPs and electronic health information systems and to facilitate prescribers' and dispensers' access to and use of the PMP.

Section 6. Reporting of Prescription Monitoring Program Information[29]

(1) Each dispenser shall submit to the PMP the following information: ~~board of pharmacy, by electronic means, or other format specified in a waiver granted by the board of pharmacy, within 24 hours, information specified by the board of pharmacy, including:~~

- (a) identification number of dispenser;
- (b) identification number of the prescriber;[30]
- (c) patient ~~legal~~ first and last name, address, and telephone number;[31]
- (d) ~~patient gender~~;
- (e) patient date of birth;
- (f) identification of the drug by a national drug code number;
- (g) quantity dispensed;
- (h) number of days supplied;

[28] Some states may assign this responsibility to an agency other than the board of pharmacy, such as the department of health.
[29] States may consider including this information in rules rather than in statute.

[30] It is recommended that boards of pharmacy consider using practitioner's NPI number for identification purposes when applicable. Consider using state license numbers for veterinarians.

[31] For veterinary prescriptions, use the pet owner's name, address, telephone number, gender, ~~and~~ date of birth, and species code.

(i) number of refills ordered;
(j) whether drug was dispensed as a refill or as a new prescription;
(k) date prescription was dispensed;[32]
~~(l) if a refill, date of the original dispensing;~~
(m) prescription number;
(n) date the prescription was issued by the prescriber;
(o) method of payment for the prescription; and
(p) such other information as may be required by state law or rule.

(2) Such information shall be submitted by electronic means ~~within 24 hours~~ by the end of the next business day after ~~of~~ dispensing.

(3) A PMP may grant a waiver to the electronic submission of data requirement in unique circumstances.

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

~~(5) Each dispenser shall reverse information for any prescription that was not dispensed.~~

Section 7. Access to Prescription Monitoring Program Information/Confidentiality

(1) Except as indicated in paragraphs (2), (3), and (4) of this Section 7, PMP information submitted to the ~~board of pharmacy~~ PMP shall be considered protected health information and not subject to public or open records laws.

(2) The board of pharmacy shall review the PMP information. If there is reasonable cause to believe a violation of law or rule (or breach of professional or occupational standards) may have occurred, the board shall notify the appropriate law enforcement, or professional or occupational licensing, certification, or regulatory agency or entity, and provide PMP information required for an investigation.[33]

(3) The board of pharmacy may provide PMP information for public research, policy or education purposes, to the extent that all information has been de-identified and as permitted under state law or rule.

(4) The following persons may access the PMP information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar protected health information under federal and state law and regulation:
(a) practitioners (or agents thereof) or dispensers (or agents thereof) who certify, under the procedures determined by the state, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient, or verifying PMP information for prescriptions issued by practitioners;
(b) boards of pharmacy or vendors/contractors for the purpose of establishing and maintaining the PMP;
(c) agents of other state licensing, certification, or regulatory agencies that license, certify, or regulate health care professionals authorized to prescribe, administer, and dispense controlled substances, ~~which~~ who certify, under the procedures determined by the state, that the requested information is related to an individual

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

[33] This Section is intended to allow boards of pharmacy to evaluate prescription monitoring program information and determine appropriate information to provide to law enforcement entities. It is not intended to allow law enforcement officials open access to all data.

investigation or proceeding involving the unlawful diversion or misuse of a reportable substance, and such information will further the purpose of the investigation or assist in the proceeding;

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

(e) entities that serve as sources of data impacting the identification and reporting of prescription drug injuries and deaths, such as, but not limited to, medical examiners or coroners (or agents thereof)~~coroners' offices~~, to help address the prescription drug epidemic and improve patient care;

(f) other appropriate entities;[34] and

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

(5) The board of pharmacy shall be immune from civil liability arising from inaccuracy of any of the information submitted to the ~~board of pharmacy~~ PMP pursuant to this Act.

Section 8. Interoperability

(1) The board of pharmacy or applicable state agency shall execute a memorandum of understanding[35] to participate in a single national hub capable of facilitating interoperability among PMPs and between PMPs and electronic health information systems.

(2) The board of pharmacy or applicable state agency shall ensure that access to PMP information by other state PMPs is done in compliance with the memorandum of understanding ~~limited to persons described in Section 7(4)~~.

(3) The board of pharmacy or applicable state agency shall establish the technological connectivity and infrastructure to facilitate the secure delivery of PMP information to authorized users of PMPs through other states' PMPs or electronic health information systems.[36]

(4) Any ~~such gateway, hub, or any~~ electronic health information system that facilitates the integration of PMP information into a patient's medical record shall:

(a) verify the identity of the individual requesting the information;

(b) verify the credential of the individual requesting the information;

(c) provide the board of pharmacy with an audit trail for each request; and

(d) maintain the security and confidentiality of such information.

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

[35] States are encouraged to utilize the model Memorandum of Understanding between NABP and [State} Relating to Its PMP.

[36] It is contemplated that the acceptable use of PMP data is for a single instance review of a patient's dispensation history and with consistency of information being delivered or presented.

Section 9. Unlawful Acts and Penalties

(1) A dispenser who knowingly fails to submit PMP information to the PMP ~~board of pharmacy~~ as required by this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(2) A person who knowingly accesses or uses PMP information without authorization in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

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

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

Section 10. Evaluation, Data Analysis, and Reporting

~~(1) The board of pharmacy shall design and implement an evaluation component to identify cost benefits of the PMP, and other information relevant to policy, research, and education involving substances monitored by the PMP.~~

(1) The board of pharmacy shall provide a report to the (insert appropriate state decision makers, eg, legislature) on a periodic basis, ~~no less than annually, about the cost-benefits and other information noted in paragraph (1)~~ that contains, at a minimum, the following information:

(a) costs associated with operating and maintaining the program;
(b) funding sources;
(c) prescribing and dispensing trends for each type of controlled substance;
(d) total number of queries made to the program and the percentage of queries made through an integrated solution; and
(e) any other information the board of pharmacy deems relevant to support public health policy.

Section 11. Rules and Regulations

The board of pharmacy shall promulgate rules and regulations necessary to implement the provisions of this Act.

Section 12. Severability

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

Section 13. Effective Date

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

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

August 2023

. . .

Article II
Board of Pharmacy

. . .

Section 202. Membership.

The board of pharmacy shall consist of _____ members, _____ of whom shall be a representative of the public, one of whom shall be a certified pharmacy technician, and the remainder of whom shall be pharmacists who possess the qualifications specified in Section 203.[37] Individual states may wish to consider a board composition that represents the diversity of the population and the profession within the state.

Section 203. Qualifications.

(1) Each pharmacist member of the board of pharmacy shall at the time of appointment[38]:
- (a) be a resident of this state for not less than six months;
- (b) be currently licensed and in good standing to engage in the practice of pharmacy in this state;
- (c) be actively engaged in the practice of pharmacy in this state; and
- (d) have five (5) years of experience in the practice of pharmacy after licensure.

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[37] The number of board members should be determined by each individual state according to its particular requirements. ~~Individual states may wish to consider a board composition that represents the diversity of practice sites and interests within a state.~~ Variable factors, such as state population, number of pharmacists, number of pharmacies, and other local considerations, may all be relevant in determining the number of board members needed to most effectively enforce the Act.

[38] Section 203(1) of the Act requires that a pharmacist be engaged in the practice of pharmacy at the time of their appointment as a board member and that they have at least five (5) years of experience in the practice of pharmacy in the state prior thereto. Since the practice of pharmacy is defined in Section 104 in broad terms, it renders a pharmacist actively engaged in almost any phase of the practice eligible for appointment. This provides for candidates who have divergent backgrounds and experiences and who are knowledgeable in the affairs of the profession.

However, it should be noted from the definition of pharmacy practice in Section 104 that those persons actively engaged in the practice of pharmacy would basically be limited to those individuals who are working within settings where drugs/devices are dispensed and pharmacist care services is provided. To include persons who are in positions related to the practice but who are not engaged in dispensing and pharmacist care services functions would wrongfully cause the inclusion of individuals, such as personnel employed by drug manufacturers, wholesale distributors, and the like, who may be licensed to practice but who do not practice pharmacy under the terms of the applicable Practice Act. The determination as to whether or not an individual is actively engaged in the practice of pharmacy will undoubtedly be rendered on a case-by-case basis. The general criteria described above, however, would most probably be applicable in making the determination. Under the terms of a Practice Act, which includes a definition of pharmacy practice, only those persons who are actively engaged in the basic functions set forth in the definition would be individuals "actively engaged in the practice of pharmacy."

(2) Each certified pharmacy technician member of the board of pharmacy shall at the time of appointment:
   (a) be a resident of this state for not less than six months;
   (b) be currently licensed and in good standing as a certified pharmacy technician in this state;
   (c) be an actively practicing certified pharmacy technician in this state; and
   (d) have five (5) years of experience as a certified pharmacy technician after licensure.

(3) The public member of the board of pharmacy shall be a resident of this state who has attained the age of 18 years and shall not be, nor shall ever have been, a pharmacist, a certified pharmacy technician, or a person who has ever had any direct conflict of interest pertaining to the practice of pharmacy or material financial interest in the provision of pharmacy services or who has engaged in any activity directly related to the practice of pharmacy.[39]

Section 204. Appointment.

(1) The Governor shall appoint the members of the board of pharmacy in accordance with other provisions of this Section and the state constitution.

(2) Nominations for appointment to the board may be made to the Governor by any individual, association, or any other entity. Such nominations shall be recommendations only and shall not be binding in any manner upon the Governor.[40]

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

[40] The purpose of Section 204(2) is to provide a mechanism through which any interested person or group may designate a candidate for the board. Since nominations are recommendations only, the Governor retains complete discretion in regard to the appointees. As an alternative to appointment of board of pharmacy members by the Governor, some state laws call for the election of such members by the states' pharmacists.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I
Title, Purpose, and Definitions

Introductory Comment to Article I

Article I of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) *sets forth the foundation upon which the Act is constructed. It clearly declares and acknowledges that safeguarding the public interest is the foremost compelling reason for regulating the practice of pharmacy and the distribution of drugs and related devices. It also circumscribes the activities included within the practice of pharmacy, as well as the definitions of several other terms used throughout the Act.*

NABP created the Model Act *to provide state boards of pharmacy with model language that may be used when developing state laws or board rules for the respective states. NABP believes that it is both desirable and necessary to recognize that the public interest must be the central precept in the* Model Act *and its administration, and that state boards of pharmacy must constantly strive to achieve the principles enunciated in Article I of the Act.*

An Act concerning the regulation of the practice of pharmacy in this state and related matters.

Be it enacted. . . .

Section 101. Title of Act.

This Act shall be known as the "_____ Pharmacy Practice Act."

Section 102. Legislative Declaration.

The practice of pharmacy in the state of _____ is declared a professional health care practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest.[41] Pharmacy is a learned health care profession affecting public health and welfare and is declared as such by the state legislature. This Act shall be liberally construed to carry out these objectives and purposes.

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

Section 103. Statement of Purpose.

It is the purpose of this Act to promote, preserve, and protect the public health, safety, and welfare through the effective control and regulation of, as well as through access to, health care providers who engage in the practice of pharmacy; the licensure of pharmacists; the registration of certified pharmacy technicians and certified pharmacy technician candidates; the licensure, control, and regulation of all sites or persons, in or out of this state, that distribute, manufacture, or sell drugs (or devices used in the dispensing and administration of drugs), within this state, and the regulation and control of such other materials as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual.[42]

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**.** [43]

"Pharmacist care services"[44] 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 and dispensing;[45]
(4) medication therapy management (MTM);
(5) reviewing, selecting, and developing formularies and/or practice guidelines;

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[42] The Statement of Purpose is designed to define the general scope of the Pharmacy Act. It provides for the control and regulation of the practice of pharmacy and the licensure of facilities engaged in the distribution of drugs and related devices. A board will have full knowledge of the whereabouts of drugs in the legitimate stream of intrastate and interstate commerce, providing it with the ability to better prevent diversion, effectuate recalls, ensure the quality of drugs dispensed or administered to patients, and effectively protect the public.

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

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

[44] 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.

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

(6) performing drug product selection, substitution, therapeutic interchange[46], prescription adaptation or continuation of therapy;
ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived[47] 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" ~~(MTM)~~ 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.

…

Section 105. Definitions.

…

(15) "Prescription drug order" means a lawful order from a practitioner for a drug or device for a specific patient, including orders derived from collaborative pharmacy practice, where a valid patient-practitioner relationship exists~~, that is communicated to a pharmacist in a licensed pharmacy.~~

[46] Providing it is within the same FDA drug class and not prohibited by the prescriber.
[47] Most recent version.