

Report of the Task Force to

REVIEW UNPROFESSIONAL CONDUCT AND DISCIPLINARY ACTIONS



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Members Present

Kimberly Grinston (MO), *chair*; Susan DelMonico (RI); Eric Esterbrook (PA); John C. Kirtley (AR); Tim Koch (AR); Truman Leong (AZ); Troy Menard (LA); Danson Nganga (VI); Julienne Tran (MA); John Weitekamp (WI).

Others Present

Steve Schierholt, *Executive Committee liaison;* Lemrey "Al" Carter, Melissa Becker, Eileen Lewalski, Neal Watson, Gertrude "Gg" Levine, Maureen Schanck, Romy Schafer, *NABP staff*.

Introduction

The task force met on September 18-19, 2023, at NABP Headquarters in Mount Prospect, IL. This task force was established pursuant to a recommendation from the Committee on Law Enforcement/Legislation, which met in February 2023, to review the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* sections pertaining to discipline and unprofessional conduct.

Review of the Task Force Charge

Charge of the task force:

- 1. Review Article V, Discipline, Section 17. Unprofessional Conduct of the *Model Rules for the Practice of Pharmacy,* and Appendix A Guidelines for Disciplinary Sanctions pursuant to the recommendations made by the Committee on Law Enforcement and Legislation; and
- 2. Amend, if necessary, the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy accordingly.

Background and Discussion

Discussion began with a review of the task force charge and the recognition that the task force was established pursuant to a recommendation of the Committee on Law Enforcement/Legislation in February 2023. They also recognized the history of the charge stemming from *Model Act* Review Committee in May 2022 and agreed that this subject needed additional attention and review.

The chairperson then asked the task force to assess the strengths and limitations of the *Model Act* in its current state. Members noted that it is comprehensive, covering a broad scope of issues for



which boards of pharmacy may need to prepare. They also pointed out that it is flexible, enabling the boards to customize the language for use as appropriate for their state. Others appreciated that the *Model Act* addresses pharmacist impairment but noted that a dedicated section on this issue, apart from discipline for drug diversion, which is supportive and includes protection from disciplinary reporting requirements and Freedom of Information Act requests, might be something to consider. Members stated that they are observing an increase in mental health cases but that some rules only allow the boards to address them as disciplinary issues when they might want to take a non-disciplinary approach. Members noted that it is sometimes more appropriate to direct impaired pharmacists to a treatment and recovery plan rather than to impose disciplinary sanctions but that some boards do not have that option.

As far as limitations are concerned, the task force observed that the *Model Act* conflicts with some federal and state laws. Members also took issue with specific wording, such as use of the term "gross unprofessional conduct," which is not distinct from "unprofessional conduct." It was noted that qualifying terms that are not defined distract from, rather than refine, the meaning. Another issue was, in some instances, the term "voluntary surrender" was not included as a disciplinary action. They also talked about eliminating the term "telepharmacy," which they felt is not a practice separate from pharmacy practice as a whole and should not be called out as such.

The task force discussed the goal of *Model Act* Article V. Discipline, noting in the introductory comment to the article that it was drafted to give boards the "widest possible scope" to perform disciplinary functions. It provides an example for states to follow but is not so stringent as to prevent their tailoring the language to their state's needs.

Also discussed was whether the states are experiencing any "pain points." Some noted that a clear definition of "unprofessional conduct" is needed so that states have a delineated framework to identify what does and does not constitute such behavior. Members recognized that as pharmacists move toward more clinical or patient care roles, the *Model Act* does not encompass everything that pharmacists are doing. Also noted was that it is a delicate balancing act to develop regulations that are neither too vague nor too prescriptive to allow pharmacy staff to work at the top of their profession, while maintaining public safeguards. Members stated that if the language is too specific, it brings criticism; if it is too vague, it invites challenges from licensees. With this balance in mind, the task force carefully reviewed the relevant language of the *Model Act* and *Model Rules* and recommended several changes.

In *Model Act* Section 501. Disciplinary Action Terms, the task force recommended supplementing the list of "disciplinary actions that may be taken, issued, or assessed by the board of pharmacy" to include "denial, refusal to issue or renew," and "voluntary surrender" to cover a broader scope of circumstances. The task force recommended adding a footnote to clarify that "costs/administrative costs" can be, but are not necessarily, categorized as disciplinary actions. Members also recommended removing the footnote referencing Appendix A after it was decided to remove the appendix.



The task force considered, but ultimately opted not to include, a suggestion to add wording that allows the board to address issues with a "just culture" mindset, rather than a disciplinary approach. Instead, the task force asked that NABP explore developing a decision tree like the one that the National Council of State Boards of Nursing (NCSBN) developed, consider developing a policy statement on a "just culture" perspective for addressing incidents, and continue educating NABP members about a "just culture" approach.

Staff pointed out that several of the grounds listed in *Model Act* Section 502. Grounds, Penalties, and Reinstatement are also listed in *Model Rules* Section 17. Unprofessional Conduct and asked the taskforce if it is necessary or helpful to include them in both places. The task force ultimately recommended including all the provisions defining unprofessional conduct in the *Model Act* and removing *Model Rules* Section 17 altogether. This was done to better organize the sections, eliminate redundancies, and give the provisions more weight by making them statutory rather than rules-based. Members recognized, however, that many states must still include these in their rules instead. In addition, members recommended modifying the language to remove the reference to the rules and, to provide more flexibility, add the phrase, "which includes but is not limited to the following acts."

Regarding subparagraph 502(1)(c) addressing "incapacity that prevents a licensee from engaging in the practice of pharmacy," the task force recommended deleting "with reasonable skill, competence, and safety to the public" and replacing it with "in a manner that is safe for the public." This language was thought to be more objective and easier to enforce.

To clarify the phrase, "being guilty of one (1) or more of the following," in subparagraph 502(1)(d), the task force recommended adding after "being guilty of," "pleading no contest to, or entering into a pre-trial diversion program for." The task force recommended replacing "a felony," in subparagraph (d)(i), with "any criminal offense, including but not limited to misdemeanors that threaten patient safety." In reference to violations in subparagraph (d)(ii), the members recommended non-substantive revisions to tighten the language.

The task force recommended revising subparagraph 502(1)(j) to be consistent with subparagraph 502(1)(c), deleting "with reasonable skill, competence, and safety to the public" and replacing it with "in a manner that is safe for the public." Also in subparagraph (j), the members decided that suspicion does not constitute grounds and recommended changing "knowing or suspecting" to "failure to report evidence."

In subparagraph 502(1)(k), the members recommended supplementing "misrepresentation of a material fact" with the phrase, "or providing false or fraudulent information." In the same subparagraph, they recommended supplementing "licensee" with "and/or applicant" to make it more widely applicable. They recommended changing 502(I), pertaining to fraud, to include "the



publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy."

The task force recommended moving subparagraph 502(1)(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," to the top of the list because it encompasses the other provisions.

Subparagraph 502(1)(m) pertaining to "affiliating with websites that may deceive or defraud patients or that violate pharmacy drug laws . . ." was struck out because it is inadvertently duplicated in subparagraph (w). Regarding subparagraph 502(1)(w), the task force recommended adding "or other digital platforms," to include social media within the scope, and striking "that may deceive or defraud patients," deciding "that violate pharmacy or drug laws . . ." is more pharmacy-specific.

The task force recommended revising 502(1)(aa), pertaining to the suspension or revocation of any license currently or previously held by the applicant by striking out "for the manufacture or distribution of any drugs or devices, including controlled substances," to broaden the scope. The members recommended striking out subparagraph (bb), "obtaining any remuneration by fraud, misrepresentation, or deception," because members agreed it was duplicative of 502(b)(vii), which was moved from the rules section.

Regarding the phrase in subparagraph 502(1)(cc) that reads, "Dealing with drugs or devices that a person knows or should have known are suspect. . .," the task force recommended changing "dealing with" to "procuring, dispensing, or distributing" for better clarity.

Regarding subparagraph 502(1)(dd) pertaining to "purchasing or receiving of a drug from a source other than an authorized trading partner," it was mentioned that revisions will be needed here and in other relevant sections of the *Model Act* to coincide with the Drug Supply Chain Security Act (DSCSA) when the final regulations are implemented.

In Section 502(2), the task force recommended changing the phrase "would not be in the public interest" to "would not be in the interest of public safety" to make the language more objective. The task force recommended deleting all of paragraph (4), which states that the board shall require complainants to identify themselves, except for the last sentence, which states that unprofessional conduct includes filing a false or fraudulent complaint or report to the board. They recommended moving that last sentence under Unprofessional Conduct.

Regarding subparagraph 502(5)(b)(i), impaired practice licensees, pertaining to the provisions under which a board may require a licensee to enter into an agreement, following the phrase, "Licensee agrees to voluntarily surrender their license," the task force recommended adding "and the board will temporarily suspend such license." In subparagraphs (c), (e), and (f), members



recommended revisions to broaden the language and make it less prescriptive and applicable to other pharmacy licensees in addition to pharmacists.

The task force recommended the following changes to Section 503. Procedure, pertaining to the conditions in which the board may summarily suspend a license: The phrase "for not more than 60 days" was removed to make subparagraph 503(1) less prescriptive. Also struck out were the sentences in this subparagraph dictating that "the board shall schedule a disciplinary hearing. . ." as it was agreed that that specific information is contained in a state's administrative procedure act.

Finally, after reviewing Appendix A. Guidelines for Disciplinary Sanctions, the task force recommended removing it because they determined that it is outdated and redundant.

After reviewing the *Model Act*, the task force directed their attention to the subject of having a just culture approach to quality-related events and the Missouri guidelines on this subject. The task force recognized that this approach focuses first on fixing the systems in which medication errors occur, rather than on punishing the individuals who made the errors. Members noted that the incentive for this approach is to encourage personnel to report errors so that others can learn from them and address systemic issues to reduce the likelihood of the errors recurring. Members stated that this approach requires separating the error from the root cause.

They also noted that it is a misconception that a just culture approach is nonpunitive. Rather, this approach involves ranking a behavior to determine the type of action to take. It starts by looking at how the system contributed to the error. If the system is determined not to be a contributing factor, the next step is to look at the individual. In some cases, members stated, punitive action is appropriate. For instance, it was stated that if a licensee demonstrates a pattern of behavior that is determined to be reckless, the individual should be held accountable.

Members noted that a just culture approach would be useful to implement at the pharmacy or entity level, as well as the individual level. Others noted that it is not as effective for assessing entities as it is for pharmacists. Members stated that boards regulate businesses and individuals, and that this approach includes the human component. They added that businesses need to give licensees the tools they need to implement safer practices. Members further noted that various entities and chains respond to situations differently.

The task force determined that a decision tree would be helpful as a tool for use by boards as a basis for consistency in assessing the role of individuals and entities when errors occur. The task force reviewed a just culture rubric developed by NCSBN that was discussed during the Medication Safety Academy held at NABP in March 2023. The task force considered the rubric as an example of a tool that can assist in determining whether an error resulted from reckless behavior or a systemic problem and asked if NABP could develop such a tool for use by the boards for assessing both individuals and entities.



The task force determined that it is premature to write the just culture approach into a regulation, as many regulators have yet to become familiar with it. To inspire the profession to adopt a new just culture mindset, members asked if NABP can help to facilitate this change by developing a policy statement encouraging the use of a just culture approach by the boards of pharmacy. They also suggested that NABP develop continuing education for state regulators and inspectors about just culture and how to implement it.

After careful review and deliberation, the task force made the following recommendations:

- 1. Explore developing a decision tree for boards of pharmacy to use in evaluating qualityrelated events using a just culture perspective focusing on human behavior for individuals and for entities.
- 2. Consider developing a policy statement on a "just culture" perspective for addressing incidents.
- 3. Continue educating boards of pharmacy on just culture perspectives and concepts.
- 4. Continue monitoring and editing the *Model Act* to align with the DSCSA.
- 5. Amend the *Model Act* as follows. The amendments recommended by the task force are denoted by <u>underlines</u> and strikethroughs.



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

August 2023

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Article V Discipline

I. 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.

II. 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: <u>denial</u>, <u>refusal</u> to <u>issue or renew</u>, <u>revocation</u>, summary suspension, suspension, probation, censure, reprimand, warning, cease and desist, fine/civil penalty,



costs/administrative costs^{1,2} <u>A voluntary surrender is also considered to be a disciplinary action.</u>

- III. Section 502. Grounds, Penalties, and Reinstatement.³
- (1) The board of pharmacy may <u>deny</u>, 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 costs⁴ against any person pursuant to the procedures set forth in Section 503 herein below, upon one or more of the following grounds:
 - (a) <u>Being found by the board to be in violation of any of the provisions of this Act or</u> 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;⁵
 - (i) <u>The illegal use, accessing, or disclosure of protected health information;</u>
 - (ii) <u>Failure to maintain adequate records, systems, and security to protect</u> 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 In some instances, imposition of costs or administrative costs may not be categorized as a disciplinary action.

⁵ 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) <u>Selling a drug for which a prescription drug order from a practitioner is</u> required, without having received a prescription drug order for the drug;
- (vi) <u>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;</u>
- (vii) 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;
- (viii) Willfully and knowingly completing and submitting inaccurate due diligence guestionnaires and/or attestation documents regarding the purchase or receipt of drugs from manufacturers, repackagers, third-party logistics providers, and wholesale distributors;
- (ix) Filing a false or fraudulent complaint with the board;
- (x) 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;
- (xi) 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;⁶
- (d) Being guilty of, pleading no contest to, or entering into a pre-trial 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 <u>or rules</u> of this state, or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the federal government;⁷
- (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;
- (f) Failure to report to the board any adverse action taken by another licensing jurisdiction (united states or foreign), government agency, law enforcement agency,

⁶ Boards need to consider the issue of impairment if a registrant or licensee tests positive for a substance of misuse and/or abuse.

⁷ 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.



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) <u>Failure to report a federal or state settlement or consent agreement related to the practice of pharmacy and/or drug manufacturing or distributing;</u>
- (j) Knowing or suspecting Failure to report evidence 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, <u>in a manner that is safe for the public</u>, 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;
- (I) 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;
- (n) Engaging, or aiding and abetting an individual to engage in the practice of pharmacy without a license; <u>or</u> assisting in the practice of pharmacy or aiding and abetting an individual to assist in the practice of pharmacy without <u>a license</u>. being licensed by the board of pharmacy; or <u>f</u>
- (o) <u>Falsely using the title of pharmacist</u>, pharmacy intern, certified pharmacy technician, or certified pharmacy technician candidate;
- (p) Requiring pharmacy personnel to meet production and/or performance metrics and/or quotas that negatively impact patient safety.⁸
- (q) Failing to pay the costs assessed in a disciplinary hearing;
- (r) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of any licensing examination;⁹

⁸ This is not intended to include performance metrics that may be related to the ability and competency of pharmacy personnel.

⁹ 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:



- (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;
- (u) 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;
- (w) 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.
- (y) 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;
- (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;

⁽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; 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.



- (cc) <u>Dealing-Procuring, dispensing, or distributing with drugs or devices that a person</u> knows or should have known are suspect or illegitimate products;¹⁰
- (dd) 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;
- (ee) 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.
- (ff) Wholesale drug distributors, other than pharmacies, dispensing or distributing drugs or devices directly to patients;
- (gg) 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 not be in the interest of public safety, 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<u>5</u>01 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

¹⁰ This Section restricts distribution of drugs or devices to licensed entities to help ensure against clandestine distribution to unauthorized and unlicensed persons.



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.

(5) Impaired practice licensees

- The board may defer action with regard to an impaired practice licensee who (a) 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 disgualify 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 necessarv.
- (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 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.
 - (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) Any person licensed by the board whose license to practice whose license to practice pharmacy in this state 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.¹¹ 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) Nothing herein shall be construed as barring criminal prosecutions for violations of this Act.
- (8) All final decisions by the board shall be subject to judicial review pursuant to the Administrative Procedures Act.

¹¹ 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.



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IV. Section 503. Procedure.¹²

- (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 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, certified pharmacy technician candidate, business entity or facility shall be provided with at least 10 days' notice of any hearing held under this subsection.
- (2) 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 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.

¹² 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.



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:

- (1) The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy;
- (2) Unreasonably refusing to compound or dispense prescription drug orders that may be expected to be compounded or dispensed in pharmacies by pharmacists;
- (3) Attempting to circumvent the patient counseling requirements, or discouraging the patient from receiving patient counseling concerning their prescription drug orders;
- (4) The illegal use, <u>accessing</u>, or disclosure of protected health information;
- (5) Failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of protected health information;
- (6) Failure to maintain adequate records to account for disclosures of protected health information;
- (7) 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;
- (8) 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;
- (9) Selling a drug for which a prescription drug order from a practitioner is required, without having received a prescription drug order for the drug;
- (10) 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;
- (11) 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;
- (12) 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

- (1) 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
- (2) Cheating on or attempting to subvert the pharmacist licensure examination(s). Range of action: revocation or denial

Misdemeanors/Felonies

(3) 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

- (4) Conduct likely to deceive, defraud, or harm the public. Range of action: from censure to revocation
- (5) 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.
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 - Range of action: from probation to revocation
- (6) 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
- (7) Practicing pharmacy under a false or assumed name. Range of action: from probation to revocation

Patient Confidentiality/Records

(8) 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. (9) range of action: from warning to revocation
- (10) being found mentally incompetent or insane by any court of competent jurisdiction. range of action: from suspension to revocation
- (11) being physically or mentally unable to engage safely in the practice of pharmacy. range of action: from probation to revocation
- (12) demonstration of incapacity or incompetence to practice pharmacy. range of action: from probation to revocation
- (13) 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

(14) 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

- (15) 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 (16)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
- (17) 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
- (18) Violating any state or federal law or regulation relating to controlled substances. Range of action: from warning to revocation

Misuse of License

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



Disciplinary Action by Other Jurisdictions

(21) 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

- (22) 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
- (23) 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

(24) 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

- (25) Failure to cooperate with a lawful investigation conducted by the board. Range of action: from censure to revocation
- (26) 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

(27) 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