NABP
National Association of Boards of Pharmacy

Report of the Task Force to

REVIEW *MODEL ACT* LICENSING AND DISCIPLINARY LANGUAGE

Members Present

Barbara Ellen Vick (NC), *chair,* Michael "Mike" Burleson (KY), Young Chang (GA), Susan DelMonico (RI), Christopher Dembny (TX), Cindy Fain (AR), Laura Forbes (VI), Jerry Moore (AL), Jeenu Philip (FL), Karen Ryle (MA), Julie Spier (TX), Gillian Staikos (FL), Lorri Walmsley (AZ).

Others Present

Traci Collier, *Executive Committee liaison;* Lemrey "Al" Carter, Melissa Becker, William "Bill" Cover, Eileen Lewalski, Maureen Schanck, and Cameron Orr, *NABP staff*.

Introduction

The task force met on October 10-11, 2022, at NABP Headquarters in Mount Prospect, IL, and virtually on November 1 and 11, 2022. This task force was established pursuant to the Report of the *Model Act* Review Committee, which recommended that a task force be convened to review the language in the licensing and disciplinary sections of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*.

Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Review Article III Licensing (of people), Article IV Licensing of Facilities, and Article V Discipline pursuant to the recommendations made by the *Model Act* Review Committee; and
2. Amend, if necessary, *the Model Act* accordingly.

Background and Discussion

The task force reviewed the relevant portions of the *Model Act* that included the suggested amendments and comments submitted by the *Model Act* Review Committee, many of which involved either removing outdated and/or unused provisions or revising definitions to ensure consistency throughout the *Model Act*. With that in mind, the task force reviewed and made the following recommended amendments to Section 105. Definitions and any corresponding references contained therein.

- Revising the definition of "Person" to solely mean an individual and carving out the legal entities previously included in the definition to create a new defined term, "Business Entity."
- Adding a definition for "NABP Verify" to formally recognize the licensure program.
- Removing the following definitions as either being outdated or not adopted and/or used by any states.
    - "Centralized Performance Database"

    - “Contraband Drug”
    - “Practice Accountability Audit”
- Revising the term, as well as the definition of, “Significant Adverse Drug Reaction” to “Serious Adverse Drug Experience” to reflect United States Food and Drug Administration (FDA) language.
- Revising the definition of “Probation” to indicate that this type of disciplinary action does not necessarily include any practice restrictions.
- Revising the definition of “Revocation” to indicate that it is the permanent rescission of a license to practice pharmacy.

Additionally, the task force recommended that all definitions and accompanying provisions related to the wholesale distribution of prescription drugs be reviewed and, if necessary, revised accordingly after FDA publishes the final rule for National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.

The task force then reviewed the board of pharmacy provisions in Article II of the *Model Act* and recommended several amendments to Section 213. Powers and Responsibilities that reflect current language in the NABP Constitution and Bylaws related to licensure transfer, as well as adding provisions for the recognition of the NABP Verify and NABP Emergency Passport programs. Additionally, the members agreed that language pertaining to the competency of individuals authorized to conduct inspections be moved from Article IV to the inspection provision in Article II so as to improve flow and provide guidance to the existing provision. The task force also agreed to recommend removing the “Centralized Performance Database” provisions to reflect the removal of the definition. Lastly, the members recommended revising the language in the “Cost Recovery” provisions to provide the boards with the ability to assess a penalty per violation versus a maximum dollar amount and determine the amount to be assessed.

Members then reviewed Article III. Licensing, which pertains to the licensing of individuals, such as pharmacists and certified pharmacy technicians. In reviewing Section 301. Unlawful Practice, the task force agreed that the practice of telepharmacy does not need to be distinguished from the practice of pharmacy, as it has been fully integrated into the practice of pharmacy since its inception and, as such, recommended removing the related provision. The task force also agreed to add a provision to reflect the use of NABP Verify for nonresident pharmacists. Additionally, members reviewed Sections 302 and 303 pertaining to pharmacy practice experience programs and recommended combining the provisions, so as to streamline the language and keep related provisions in the same section. Under Section 304. Qualifications for Licensure Transfer, the task force agreed to revise the licensure transfer prerequisite of holding an initial license by examination in good standing to simply having an active licence in good standing because a majority of states no longer require that a licensure transfer be based on the original license by examination. The task force also recommended removing language from

Section 307. Renewal of Licenses addressing grounds for denial as it was duplicative of language contained elsewhere. On another matter, members discussed the issue of dispensing practitioners and, while many boards do not have any oversight of dispensing pracitioners, they agreed that there should be licensing provisions and recommended adding a designated section for them.

Regarding Article IV. Licensing of Facilities, the task force made a number of recommendations to either incorporate or remove language that had previously been discussed, such as "Business Entities" versus "Persons," as well as to further streamline and ensure consistency. Members agreed that the first section should mirror Article III and, as such, added a new Section 401. Unlawful Practice, incorporating some of the language pertaining to unlicensed practice from Section 404. Grounds, Penalties, and Reinstatement. The remaining language from Section 404 was more appropriately moved to Article V. Discipline. In addition, members agreed that license renewal frequency should be contained in the rules and, as such, recommended removing it from the statutory provisions. Other issues that the task force addressed within this section included:

- Requiring outsourcing facilities to have a pharmacist-in-charge (PIC), as pharmacies do,and ensure that the facility owner and the PIC have joint responsibility for facility operations;.
- Replacing the term "verified" with "complete and accurate" in Section 403. Application, as this language is more precise;
- Adding a notification requirement regarding temporary pharmacy closures of more than 48 hours.

When the task force reviewed Section 405. Criminal Offense; Forfeiture of Property, it concluded that the classification of criminal offenses, such as what is considered to be a felony, is outside of a board's purview, and as such, should be removed along with the court-ordered forfeiture language.

The task force then reviewed Article V. Discipline, and along with the new and/or revised definitions, recommended amendments throughout for consistency. Additional recommendations included adding as a ground for discipline impeding or subverting an investigation, as well as requiring complainants to identify themselves. Additionally, it was recommended that unprofessional conduct should include the filing by a licensee of a false or fraudulent complaint or report to the board. The task force also made numerous recommended amendments to the impaired licensee provisions, which included the less stigmatizing term "Impaired Practice Licensees" and making the provisions less punitive in nature throughout. Whereas the members decided against recommending prescriptive provisions regarding how treatment programs should be structured, they agreed that it was essential to require such programs to employ substance use disorder professionals.

Turning its attention to the *Model Rules* sections of the *Model Act,* the task force recommended that the *Model Rules for Pharmacy Interns* and the *Model Standards for Pharmacy Practice*

Experience Programs should be combined and unnecessary language deleted, as many of the provisions in the latter, such as the number of experiential hours, are already mandated by the Accreditation Council for Pharmacy Education. Additionally, upon reviewing the notifications section, members recommended that the time frame for pharmacy interns to notify a board regarding changes of name, enrollment status, employment, and/or contact information should be revised from "immediately" to "within 10 days," as members determined that this is a more reasonable period of time for that type of information to be reported.

The task force spent a significant amount of time discussing amendments to the *Model Rules for the Practice of Pharmacy*, particularly in reviewing over-prescriptive, burdensome, and unnecessary language. Members recommended revising the title of Section 1 from "License" to "Pharmacy Licensure" to more aptly describe the section's purpose. Members also recommended removing all the prescriptive pharmacy requirements regarding the space, references, equipment, and storage areas and replacing them with a generalized statement that the pharmacy shall have those types of resources sufficient to allow for the safe and proper storage and compounding and/or preparing of prescription drug orders. Staff informed the members about the .pharmacy accreditation program name change, and they agreed to revise the footnote accordingly. The task force recommended minimal revisions to Section 2. Security to remove outdated language regarding the separation of employment, as well as clarifying language related to reducing internal theft and/or diversion. One significant recommendation made by the members was to allow a pharmacist to serve as a PIC for more than one pharmacy at a time, provided that permission is obtained from the board, as they believed this could be facilitated through technological advances and could help alleviate the pharmacist shortage. Members also removed the requirement for a professional performance evaluation, deeming it outdated, unnecessary, and outside board of pharmacy purview. Along those lines, the task force also recommended removing some of the electronic record-keeping provisions, citing them as being too prescriptive, verbatim of existing federal law, and duplicative of language contained in the policy and procedure section. Additionally, members recommended revising the reporting time frames from a specific number of hours to "as soon as possible" in the System Backup section. Upon review of Section 16. Unprofessional Conduct, the task force recommended that another task force should be convened to specifically review this section, along with Appendix A Guidelines for Disciplinary Sanctions, to ensure that they are current and useful for the boards.

Lastly, the task force reviewed the Community Pharmacy Quality-Related Event (QRE) Data Collection Form, Community Pharmacy Continuous Quality Improvement Program Inspection Form, Community Pharmacy Quality Self-Audit, and the QRE Incidents form in Appendix B, and recommended removing them from the *Model Act*. Regarding this topic, members were informed about the upcoming NABP Medication Safety Academy and the Association's other efforts, such as the presidential initiative of NABP President Reginald B. "Reggie" Dilliard, DPh, "Eliminating Barriers to Enhance Patient Safety," continuing pharmacy education webinars, and other items developed to assist in decreasing prescription errors. Members agreed that the

information shared at the Academy, as well as information from other sources, should be compiled and made available on the NABP website for boards and licensees to reference.

After careful review and deliberation, the task force recommended the following:

1. NABP review all Model Act definitions and accompanying provisions related to the wholesale distribution of prescription drugs be reviewed and, if necessary, revised accordingly after FDA publishes the final rule for National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.

2 NABP convene a task force to review Model Act Section 16. Unprofessional Conduct, along with Appendix A Guidelines for Disciplinary Sanctions, to ensure that they are current and useful for the boards.

3 NABP compile information from the upcoming Medication Safety Academy, as well as from other sources, and make it available on the NABP website for boards and licensees to reference.

4. Amend the Model Act as follows. The amendments recommended by the task force are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I
Title, Purpose, and Definitions

…

Section 105. Definitions.

…

(k) "Business Entity" means an a corporation, subsidiary, partnership, association, organization, affiliate organization, or any other legal entity formed to conduct business.

…

(l) "Cease and Desist" means an order of the Board prohibiting a licensee or other Business Entity or Person ~~or entity~~ from continuing a particular course of conduct that violates the Pharmacy Practice Act or its rules and regulations.[1]

(m) …

~~(n) "Centralized Performance Database" means aggregate data from a large number of pharmacies concerning Quality-Related Events and patients for whom Drug Products and services have been provided at the pharmacies, and from which patient identifiers have been removed.~~

…

(u) "Common Carrier" means any Business Entity or Person ~~entity~~ who undertakes, whether directly or by any other arrangement, to transport property including Prescription Drugs for compensation.[2]

…

~~(e2) "Contraband Drug" means a Drug which is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that Drug, that has inappropriately entered the Drug supply chain Distribution.~~

…

(d2) "Counterfeit Device" means a Device which, or the container, shipping container, seal, or Product Labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a Manufacturer, processor, packer, or Distributor other than the Business Entity, Person or Persons who in fact Manufactured, processed, packed, Distributed, or Wholesale Distributed such Device and which thereby falsely purports or is represented to be the Product of, or to have been packed, Distributed, or Wholesale Distributed by, such other Manufacturer, processor, packer, or Distributor.

(e2) "Counterfeit Drug" means a Drug which, or the container, shipping container, seal, or Product Labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or Device, or any likeness thereof, of a Manufacturer, processor, packer, or Distributor other than the Business Entity, Person or Persons who in fact Manufactured, processed, packed, Distributed, or Wholesale Distributed such Drug and which thereby falsely purports or is represented to be the Product of, or to have been packed, Distributed, or Wholesale Distributed by, such other Manufacturer, processor, packer, or Distributor.

…

[1] No proof of actual damage is required for issuance of a Cease and Desist order.

[2] The definition of "Common Carrier" specifically excludes Wholesale Distributors, which are defined separately.

(g2) "Deliver" or "Delivery" means the actual, constructive, or attempted transfer of a Drug or Device from one Business Entity or Person to another, whether or not for a consideration.

…

(m2) "Dispenser" means a retail Pharmacy, hospital Pharmacy, a group of chain Pharmacies under common ownership and control that do not act as a Wholesale Distributor, or any other Business Entity or Person authorized by law to Dispense or Administer Prescription Drugs, and the affiliated warehouses or Distribution centers of such entities under common ownership and control that do not act as a Wholesale Distributor.

…

(e3) "Health Care Entity" means any Business Entity or Person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care but does not include any retail Pharmacy or Wholesale Distributor.

…

(u3) "Manufacturer" means a Business Entity ~~Person~~ which may include a Virtual Manufacturer, engaged in the Manufacture of Drugs or Devices.

(v3) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a Drug or Device or the labeling or relabeling of the container of a Drug or Device for resale by pharmacies, Practitioners, Business Entities or other Persons.[3]

…

(j4) "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.

…

(b5) "Person" means an individual.~~, corporation, subsidiary, partnership, association, organization, affiliate organization, or any other legal entity, including government.~~

…

(a5) "Pharmacist-in-Charge" means a Pharmacist currently licensed in this state who accepts responsibility for the operation of a Pharmacy or an Outsourcing Facility in conformance with all laws and rules pertinent to the Practice of Pharmacy and the Distribution of Drugs, and who is personally in full and actual charge of such Pharmacy and personnel.

…

(b5) "Pharmacy" means any licensed facility ~~place~~ within or outside this State where Drugs are Dispensed and/or Pharmacist Care Services are provided to residents of this State.

[3] Manufacturing also includes the Compounding of Drugs for office use of which can only be done by an FDA-registered Outsourcing Facility.

(c5) "Pharmacy Benefits Manager" means a Business Entity or Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, and that engages in or directs the Practice of Pharmacy.

~~(d5) "Practice Accountability Audit" means an evaluation of the Centralized Performance Database to determine which pharmacies are consistently in violation of criteria and/or standards.~~

…

(e5) "Probation" means a type of disciplinary action that allows continuation of practice subject to specific conditions established by the Board and that may include a restriction of Pharmacy practice for a specified period of time.[4]

~~(f5) "Professional Performance Evaluation" means a peer review process in which a competency assessment is made of a pharmacist by another pharmacist for the purpose of improving the quality of the evaluated pharmacist's performance.~~

(g5)

…

(a6) "Repackager" means a Business Entity or Person who owns or operates an establishment that Repackages and relabels a Product or package for:

(1) further sale; or

(2) Distribution without a further Transaction.[5]

…

(h6) "Returns Processor" or "Reverse Logistics Provider" means any Business Entity or Person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable Product received from an authorized Trading Partner such that the Product may be processed for credit to the purchaser, Manufacturer, or seller or disposed of for no further Distribution.

(i6) "Revocation" means the ~~withdrawal~~ permanent recission of the license to practice pharmacy

…

(j6) "Serious Adverse Drug Experience" means any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent

[4] Licensee may be placed on Probation for a period of time subject to specific conditions determined by the Board. Probation may result from the Board's decision to stay a license Revocation or Suspension judgment. The licensee may be permitted to continue practice only within conditions established by the Board, and violation of those conditions will end the stay and result in Revocation or Suspension.

[5] Is not intended to include a Pharmacy, Pharmacist, or Outsourcing Facility that Dispenses or Distributes Repackaged Drugs.

or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

…

~~(k6) "Significant Adverse Drug Reaction" means an unexpected adverse drug experience that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. A medical event may also be considered a significant adverse drug reaction when, based on appropriate medical judgment, the medical event places the patient at a significant risk of experiencing any of the outcomes listed above. An adverse drug reaction is unexpected if it has not previously been observed, rather than a reaction that is not anticipated from the pharmacological properties of the pharmaceutical product.~~

…

(k7) "Temporary Pharmacy Facility" means a facility established as a result of a Public Health Emergency or State of Emergency to temporarily provide Pharmacy services within or adjacent to Declared Disaster Areas or as otherwise determined in the interest of the public by Board action.

…

(a8) "Wholesale Distributor" means any Business Entity ~~Person~~, which may include a Virtual Wholesale Distributor, (other than a Manufacturer, a Manufacturer's co-licensed partner, a Third-Party Logistics Provider, or Repackager) engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State.

Article II
Board of Pharmacy

…

NABP

Section 213. Powers and Responsibilities.

(a) The Board of Pharmacy shall be responsible for the control and regulation of the Practice of Pharmacy in this State including, but not limited to, the following[6]:

(1) the licensing by examination or by ~~license~~ licensure transfer of applicants who are qualified to engage in the Practice of Pharmacy under the provisions of this Act;

(2) the issuance and renewal of licenses to engage in the Practice of Pharmacy;

(3) the recognition of the NABP Verify credential for the provision of pharmacy-related services by nonresident Pharmacists;

(~~3~~4) the establishment and enforcement of compliance with professional standards and rules of conduct of Pharmacists engaged in the Practice of Pharmacy;

(~~4~~5) the determination and issuance of standards for recognition and approval of degree programs of schools and colleges of Pharmacy whose graduates shall be eligible for licensure in this State, and the specification and enforcement of requirements for practical training, including Pharmacy practice experience[7];

(~~5~~6) the enforcement of those provisions of this Act relating to the conduct or competence of Pharmacists practicing in this State; the Revocation, Summary Suspension, Suspension, Probation, Censure, or Reprimand of, or the issuance of Warnings or the assessment of Fines/Civil Penalties or Costs/Administrative Costs against licenses to engage in the Practice of Pharmacy; and the issuance of Cease and Desist orders against any Business Entity or Person;

(~~6~~7) the licensure and regulation of the training, qualifications, and employment of Pharmacy Interns, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates;

(~~7~~8) the collection of professional demographic data;

(~~8~~9) the right to seize any such Drugs and Devices found by the Board to constitute an imminent danger to the public health and welfare;

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[6] The "Practice of Pharmacy in this State" includes shipping Prescription Drugs into this State from another jurisdiction. However, this is not meant to be construed as a licensure requirement for every Pharmacist that is employed at a Nonresident Pharmacy unless they are specifically engaged in the Practice of Pharmacy and provide services to residents in this State (see Sections 104 and 401(a) of this Act).

[7] Great care should be exercised by the Boards with respect to this Section. Many states have statutes or rules which provide that approved or accredited degree programs of schools or colleges of Pharmacy are those approved by the Accreditation Council for Pharmacy Education (ACPE).It is a well-established rule of administrative law that any delegation of governmental power must carry with it appropriate limitations and procedural safeguards for affected individuals. Thus, a direct, unequivocal grant of the accreditation function to a private organization, such as ACPE, might be deemed an unauthorized, improper, and invalid delegation of Board or legislative authority. An NABP study of this question discovered at least one case where a court overturned a Board action based upon such invalid delegation to a private body. See *Garces v Department of Registration and Education*, 254 N.E.2d 622 (Ill, 1969). NABP urges all Boards to adopt, in their Rules, the Standards of Accreditation for Doctor of Pharmacy Degree Programs established from time to time by the ACPE, the nationally recognized accrediting agency for Pharmacy degree programs. Of note, ACPE International-Accreditation is awarded based on the ACPE Quality Criteria, which are not equivalent to the ACPE Standards.

(~~9~~10)establishing minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, Compounding and/or Dispensing of such Drugs or Devices, for the monitoring of Drug therapy, and for the Manufacture and Distribution of Drugs and Devices;

(11~~0~~)establishing minimum standards for the purity and quality of such Drugs, Devices, and other materials within the Practice of Pharmacy;

(12~~1~~)the issuance and renewal of licenses for Pharmacies located within this State, or outside this State if providing services to patients within this State, that Compound or Dispense Drugs or Devices or provide Pharmacist Care Services.

(13~~2~~)the issuance and renewal of licenses of all Manufacturers and Distributors of Drugs and Devices located within this State, or outside this State if providing such services within this State;

(14~~3~~)inspection at all reasonable hours of the facility and appropriate records of any licensed Person or licensed facility and any Person or facility seeking licensure for the purpose of determining if any provisions of the laws governing licensure, the legal Distribution of Drugs or Devices, or the Practice of Pharmacy are being violated, including the inspection of Protected Health Information.

(i) Agents duly authorized to conduct inspections, whether agents of the Board or an approved third party, must be competent to inspect the facilities they are assigned to inspect to include training on any applicable State, Federal, and USP standards.

(ii) The Board of Pharmacy, its officers, inspectors, and representatives shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this State, and of all other states relating to Drugs, Devices, and the Practice of Pharmacy;

(15) the recognition of the NABP Emergency Passport for Pharmacists, Pharmacy Interns, Certified Pharmacy Technicians, and businesses to practice on a temporary or emergency basis in accordance with state emergency orders;

(16~~4~~)establishing minimum standards for maintaining the integrity and confidentiality of prescription information and other patient health care information; and[8]

[8] Under this Act, "Protected Health Information" may be used or disclosed without acknowledgement, authorization, or opportunity to agree or object in the situations described in 45 CFR 164.512(a) – (l), and which include:

- As required by law
- For certain public health activities
- For certain health oversight activities
- Pursuant to judicial or administrative proceedings
- For law enforcement purposes
- For military or national security purposes
- As necessary to comply with worker compensation laws
- In situations presenting a serious threat to health or safety

Investigative activities of the Boards of Pharmacy are considered health oversight activities and, therefore, fall under this disclosure exemption.

(17~~5~~) the approval of Pharmacy practice initiatives that improve the quality of or access to Pharmacist Care Services, but which fall outside the scope of present regulations. This subsection shall not be construed to expand the definition of the Practice of Pharmacy as defined in this Act.

~~(b) Centralized Performance Database~~

~~(1) The Board of Pharmacy shall utilize a Centralized Performance Database. The Centralized Performance Database shall be maintained in such a way as to permit an evaluator to apply Criteria and Standards to data from one pharmacy, and determine whether, over time, outcomes from that pharmacy compare favorably with outcomes from other pharmacies.~~

~~(2) The Board of Pharmacy shall conduct a Practice Accountability Audit at least once every six months to identify pharmacies that consistently violate Criteria and/or standards. The Board of Pharmacy shall require that pharmacies so identified provide an explanation of the reason for their consistent violation of Criteria and/or standards.~~

(b~~c~~) The Board of Pharmacy shall have such other duties, powers, and authority as may be necessary to the enforcement of this Act and to the enforcement of Board rules made pursuant thereto, which shall include, but are not limited to, the following:

(1) The Board may join such professional organizations and associations organized exclusively to promote the improvement of the standards of the Practice of Pharmacy for the protection of the health and welfare of the public and/or whose activities assist and facilitate the work of the Board.

(2) The Board may receive and expend funds, in addition to its [annual/biennial] appropriation, from parties other than the State, provided:

(i) such funds are awarded for the pursuit of a specific objective which the Board is authorized to accomplish by this Act, or which the Board is qualified to accomplish by reason of its jurisdiction or professional expertise;

(ii) such funds are expended for the pursuit of the objective for which they are awarded;

(iii) activities connected with or occasioned by the expenditures of such funds do not interfere with the performance of the Board's duties and responsibilities, and do not conflict with the exercise of the Board's powers as specified by this Act;

(iv) such funds are kept in a separate, special account; and

(v) periodic reports are made concerning the Board's receipt and expenditure of such funds.

(3) The Board may establish a Bill of Rights for patients concerning the health care services a patient may expect in regard to Pharmacist Care Services.[9]

[9] A Patient's Bill of Rights establishes the professional services that a patient may expect when obtaining Drugs or Devices from a Pharmacist. The Bill of Rights would normally contain patient expectations that could translate into standards of professional practice and/or codes of conduct for the Pharmacist. Accordingly, if a Board should choose to establish a Patient's Bill of Rights, the Bill should be consistent with standards of practice, codes of ethics, and regulations that the Board has adopted under the Pharmacy Practice Act. If care is not taken, a Board could inadvertently expand the role and the responsibilities of the Pharmacist through the establishment of a Patient's Bill of Rights.

(4) Any investigation, inquiry, or hearing which the State Board of Pharmacy is empowered to hold or undertake may be held or undertaken by or before any member or members of the Board and the finding or order of such member or members shall be deemed to be the order of said Board when approved and confirmed as noted in Section 210(d).

(5) Embargo.[10]

…

(6) The Board may place under seal all Drugs or Devices that are owned by or in the possession, custody, or control of a licensee at the time his or her license is Suspended or Revoked or at the time the Board refuses to renew his license. Except as otherwise provided in this section, Drugs or Devices so sealed shall not be disposed of until appeal rights under the Administrative Procedures Act have expired, or an appeal filed pursuant to that Act has been determined. The court involved in an appeal filed pursuant to the Administrative Procedures Act may order the Board, during the pendency of the appeal, to sell sealed Drugs that are perishable. The proceeds of such a sale shall be deposited with that court.

(7) Except as otherwise provided to the contrary, the Board shall exercise all of its duties, powers, and authority in accordance with the State Administrative Procedures Act.

(8) In addition to the fees specifically provided for herein, the Board may assess additional reasonable fees for services rendered to carry out its duties and responsibilities as required or authorized by this Act or Rules adopted hereunder. Such services rendered shall include, but not be limited to, the following:
   (i) issuance of duplicate certificates or identification cards;
   (ii) mailing lists or reports of data maintained by the Board;
   (iii) copies of any documents;
   (iv) certification of documents;
   (v) notices of meetings;
   (vi) licensure transfer;
   (vii) examination Administration to a licensure applicant; and
   (viii) examination materials.

(9) Cost Recovery.[11]
   (i) If any order issues in resolution of a disciplinary proceeding before the Board of Pharmacy, the Board may request the _____ to direct any licensee found guilty of a charge involving a violation of any Drug laws or rules, to pay to the Board a sum not to exceed the reasonable costs of the investigation and prosecution of the case and may include a monetary penalty per violation not to exceed _____. a~~and, in any case, not to exceed twenty-five thousand dollars ($25,000).~~

[10] The purpose of this subsection is to ensure quality, purity, and correct Labeling of Drugs, Devices, and other materials.

[11] The "_____" interspersed throughout this section may be filled with the terms: "administrative law judge," "hearing officer," or "presiding officer," as determined by individual states.

(ii) In the case of a Pharmacy or Wholesale Distributor, the order may be made as to the corporate owner, if any, and as to any Pharmacist, officer, owner, or partner of the Pharmacy or Wholesale Distributor who is found to have had knowledge of or have knowingly participated in one or more of the violations set forth in this section.

(iii) The costs to be assessed shall be fixed by the _____ and shall not be increased by the Board; where the Board does not adopt a proposed decision and remands the case to a(n) _____ , the _____ shall not increase any assessed costs.

(iv) Where an order for recovery of costs is made and timely payment is not made as directed in the Board's decision, the Board may enforce the order for payment in the Court in the county where the administrative hearing was held. This right of enforcement shall be in addition to any other rights the Board may have as to any Business Entity or Person directed to pay costs.

(v) In any action for recovery of costs, proof of the Board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

Article III
Licensing

Introductory Comment to Article III

Article III of the Model Act *specifies the requirements for initial licensure of Pharmacists, transfer of licensure, and renewal of licenses and registrations. In each of these areas, the Act sets forth basic Criteria and delegates to the Board the authority for implementing those Criteria. The Board does this by utilizing appropriate administrative enforcement mechanisms and by the issuance of specific rules.*

Section 301 establishes the basis for this Article by making it unlawful for any unlicensed Business Entity or Person to engage in the Practice of Pharmacy, and by enabling the Board to exact penalties for unlawful practice.

In the area of initial licensure (Section 302), the Board must implement the Act by approving degree programs of Pharmacy, by specifying the examination to be employed (Section 302[b]), by establishing Pharmacy practice experience standards (Section 303~~2[c]~~), and by ensuring that all other prerequisites are met by each applicant to whom it issues a license.

The Act also reflects the efforts of NABP to continue uniform standards for transfer of licensure (Section 304).

Section 301. Unlawful Practice.

(a) Except as otherwise provided in this Act, it shall be unlawful for any individual~~, whether~~ located in ~~or outside~~ this State~~,~~ to engage in the Practice of Pharmacy ~~in this State~~ unless currently licensed. ~~to practice under any facet of the provisions of this Act.~~

(b) It shall be unlawful for any individual located outside this state to engage in the Practice of Pharmacy in this state unless currently licensed to practice or credentialed by NABP Verify.[12]

(~~b~~) ~~The provision of Pharmacist Care Services to an individual in this State, through the use of Telepharmacy Technologies, regardless of the location of the Pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.[13] Pharmacists located outside this State who are providing Pharmacist Care Services outside of a licensed Pharmacy to individuals located in this State must register with this State to engage in the nonresident Practice of Pharmacy.~~

(c) Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record-keeping requirements, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.[14]

(d) It shall be unlawful for any individual to perform the activities of a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate unless currently licensed to do so under the provisions of this Act.

(e) (1) 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.

(2) Except as otherwise indicated in this Act, any individual who, after due process, shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy shall be subject to a Fine to be imposed by the Board not to exceed $____ for each offense. Each

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[12] Unless practicing within a licensed nonresident facility or utilizing Shared Services.

[13] ~~NABP recognizes that protection of the public health should extend across State borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy within the scope of the "Practice of Pharmacy" and requires an independently practicing Pharmacist located outside this State to obtain full licensure for providing Pharmacist Care Services from outside the State to patients within the State~~.

[14] Boards of Pharmacy are often confronted with the problem of preventing unlicensed individuals from engaging in one or more facets of the Practice of Pharmacy. The regulation of the Practice of Pharmacy, including the control of unlicensed practice in the profession, has a reasonable and rational relationship to public health, safety, and welfare. See, for example, *State v Wakeen*, 57 N.W.2d 364 (Wis, 1953). cf. *State v VanKeegan*, 113 A.2d 141 (Conn, 1955) and *Williamson v Lee Optical of Oklahoma*, 348 U.S. 483 (1955), concerning prohibitions on the unlicensed practice of ophthalmology. For this reason, vesting the power in the Board to regulate the illicit practice would not appear to violate the constitutional due process requirements. Monetary fines are another enforcement action Boards can utilize to protect the public health. Although monetary fines are not generally considered criminal sanctions, it can be forcibly argued that there are no constitutional barriers impeding the imposition of fines by a Board of Pharmacy. See, for example, *Helvering v Mitchell*, 303 U.S. 376 (1938); *City of Waukegan v Pollution Control Board*, 311 N.E.2d 146 (Ill, 1974); *County Council for Montgomery County v Investors Funding Corp*, 312 A.2d 225 (Md, 1973); and *Rody v Hollis*, 500 P.2d 97 (Wash, 1972).

One area that could present a serious question of law in regard to Section 301(b), however, involves the constitutional limitation on the delegation of authority to administrative agencies. It is likely that the delegation contemplated in Article III of the *Model Act* would be valid in a majority of jurisdictions. See, for example, *Jordan v Board of Insurance*, 334 S.W. 2d 278 (Tex, 1960); *Sutherland v Ferguson*, 397 P. 2d 335 (Kan, 1964); and *Kovack v Licensing Board of City of Waterville*, 173 A. 2d 554 (Me, 1961); see generally L. Davis, Administrative Law Treatise, Section 2.10 (1970 Suppl.). Be cautioned, however, that certain jurisdictions require very specific standards in a delegation of authority that could render Section 301(b) constitutionally suspect. See, for example, *People v Tibbits*, 305 N.E. 2d 152 (Ill, 1973); *Sarasota County v Barg*, 302 So. 2d 737 (Fla, 1974). In these jurisdictions, revisions of Article III may be necessary.

such violation of this Act or the rules promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this State.

(3) Except as otherwise indicated in this Act, any individual who, after due process, shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy that resulted in harm to an individual shall be subject to a Fine to be imposed by the Board not to exceed $____ for each offense. Each such violation of this Act or the rules promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy that resulted in harm to an individual shall also constitute a felony punishable upon conviction as provided in the criminal code of this State.

Section 302. Qualifications for Pharmacist Licensure by Examination.

(a) To obtain a license to engage in the Practice of Pharmacy, an applicant for licensure by examination shall:

(1) have submitted an application in the form prescribed by the Board of Pharmacy;

(2) have attained the age of majority;

(3) have graduated and received the first professional degree from a college or school of Pharmacy that has been approved by the Board of Pharmacy;[15] or have graduated from a foreign college of Pharmacy[16], completed a transcript verification program, taken and passed a college of Pharmacy equivalency examination program, and completed a process of communication-ability testing as defined under Board of Pharmacy regulations so that it is ensured that the applicant meets standards necessary to protect public health and safety;[17]

(4) have completed a Pharmacy practice experience program or other program that has been approved by the Board of Pharmacy, or demonstrated to the Board's satisfaction

[15] It is contemplated that Boards will approve those programs whose standards are at least equivalent to the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs. This would include college-structured pharmacy practice experience programs and continuing education programs. See the footnote to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

[16] Graduates of a professional pharmacy degree program based outside the US and its territories that have been awarded Precertification, Provisional Certification, or Certification by ACPE are not eligible for US pharmacy licensing exams (NAPLEX or MPJE) and must complete the Foreign Pharmacy Graduate Examination Committee (FPGEC) program to be eligible to take the pharmacy licensing exams in the US. Similarly, graduates from an ACPE-accredited post-baccalaureate pharmacy program where the initial pharmacy degree is from a pharmacy program that is not an entry-level, ACPE-accredited pharmacy program, must complete the PFGEC program. [NOTE: ACPE will be changing the terminology that will be used within the ACPE International Services Program. As of January 1, 2023, the ACPE International Services Program will offer "International-Accreditation," "International Pre-Accreditation," and "Provisional International-Accreditation" to qualifying pharmacy degree programs outside the United States of America and its Territories. These will replace ACPE's current "Certification," "Precertification" and "Provisional Certification" statuses.]

[17] Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) as part of their assessment of pharmacy education equivalence.

that experience in the Practice of Pharmacy which meets or exceeds the minimum Pharmacy practice experience requirements of the Board;

(5) have successfully passed an examination or examinations approved by the Board of Pharmacy within five attempts;

(6) have undergone a state and federal fingerprint-based criminal background check as specified by State law or Board rule; and

(7) have paid the fees specified by the Board of Pharmacy for the examination and any related materials and have paid for the issuance of the license.

(b) Examinations.

(1) The examinations for licensure, which include a pharmacy practice examination and a jurisprudence examination, required under Section 302(a)(7) of the Act, shall be provided by a testing provider approved by the Board[18]. If applicable, state-specific compounding examinations shall be administered by the Board.-The content and subject matter of the pharmacy practice examination shall be determined by the examination provider approved by the Board and the Board shall determine the content and subject matter of each state-specific compounding and jurisprudence examination.

(2) The examinations shall be prepared to measure the competence of the applicant to engage in the Practice of Pharmacy. The examination provider may employ, cooperate, and contract with any organization or consultant in the preparation and grading of an examination, but the Board shall retain the sole discretion and responsibility for determining which applicants are eligible for licensure.

(c) ~~Pharmacy Practice Experience Programs and Other Training Programs.[19]~~

~~(1) All applicants for licensure by examination shall obtain practical experience in the Practice of Pharmacy concurrent with or after college attendance, or both, under such terms and conditions as the Board shall determine.[20]~~

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[18] Boards of Pharmacy are strongly encouraged to utilize the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) for this purpose.

~~[19] As college-based Pharmacy practice experience programs become uniform under the most recent revision of the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs, and when boards of pharmacy are convinced that schools and colleges of pharmacy are meeting these Standards of Accreditation and the competency requirements set out by Boards, Boards should begin to broadly accept and recognize college-based Pharmacy practice experience programs completed by students in other jurisdictions and eliminate requirements that such students obtain additional Pharmacy practice experience hours in addition to those obtained as part of the college of pharmacy curriculum.~~

~~Because of the potential lack of uniformity among non-college-based Pharmacy practice experience programs, it is recommended that Boards exercise their prerogative to accept only at their discretion non-college-based Pharmacy practice experiences completed by Pharmacy Interns in other jurisdictions.~~

~~[20] Although Boards of Pharmacy mandate a specified number of hours of Pharmacy practice experiences as a prerequisite to licensure, Boards of Pharmacy are also encouraged to deem those requirements met if Boards find that the college-based Pharmacy practice experiences meet or exceed the hourly Pharmacy practice experience requirements.~~

~~As indicated in the Model Rules for Pharmacy Interns, applicants for licensure as Pharmacists shall submit evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies as delineated in the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs and (2) not less than 1,740 hours of Pharmacy practice experience credit~~

~~(2) The Board shall establish such licensure requirements for Pharmacy Interns and standards for Pharmacy practice experiences, or any other experiential program necessary to qualify an applicant for the licensure examination and shall also determine the qualifications of Preceptors used in practical experience programs.[21]~~

Section 303. Pharmacy Practice Experience Program Standards; Pharmacy Intern Licensure.

(a) The Board of Pharmacy shall establish standards for Pharmacy practice experience programs for the purpose of providing the practice experience necessary for licensure as a Pharmacist.[22]

(b) The Board shall grant a Pharmacy Intern license to Pharmacy students, authorizing those students to engage in the Practice of Pharmacy under the supervision of a Pharmacist.

(c) The Board of Pharmacy shall adopt rules regarding the licensure of Pharmacy Interns and the standards for Pharmacy practice experience programs.[23]

(1) All applicants for licensure by examination shall obtain practical experience in the Practice of Pharmacy concurrent with or after college attendance, or both, under such terms and conditions as the Board shall determine.[24]

~~under the instruction and supervision of a Preceptor. Boards may consider moving away from requiring a specific number of contact hours should it be determined that the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs result in appropriate preparation for students and objective assessment mechanisms demonstrate such.~~

~~[21] Boards of Pharmacy are strongly encouraged to utilize the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs as a basis for establishment and revision of Board standards for Pharmacy practice experiences. These Standards of Accreditation also contain additional guidance on the desired behaviors, qualities, and values of preceptors.~~

[22] As college-based Pharmacy practice experience programs become uniform under the most recent revision of the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs, and when boards of pharmacy are convinced that schools and colleges of pharmacy are meeting these Standards of Accreditation and the competency requirements set out by Boards, Boards should begin to broadly accept and recognize college-based Pharmacy practice experience programs completed by students in other jurisdictions and eliminate requirements that such students obtain additional Pharmacy practice experience hours in addition to those obtained as part of the college of pharmacy curriculum.

Because of the potential lack of uniformity among non-college-based Pharmacy practice experience programs, it is recommended that Boards exercise their prerogative to accept only at their discretion non-college-based Pharmacy practice experiences completed by Pharmacy Interns in other jurisdictions.

[23] Boards of Pharmacy are strongly encouraged to utilize the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs as a basis for establishment and revision of board standards for Pharmacy practice experiences. These Standards of Accreditation also contain additional guidance on the desired behaviors, qualities, and values of preceptors.

[24] Although Boards of Pharmacy mandate a specified number of hours of Pharmacy practice experiences as a prerequisite to licensure, Boards of Pharmacy are also encouraged to deem those requirements met if Boards find that the college-based Pharmacy practice experiences meet or exceed the hourly Pharmacy practice experience requirements.

As indicated in the Model Rules for Pharmacy Interns, applicants for licensure as Pharmacists shall submit evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies as delineated in the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs and (2) not less than 1,740 hours of Pharmacy practice experience credit under the instruction and supervision of a Preceptor. Boards may consider moving away from requiring a specific number of contact hours should it be determined that the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

(2) The Board shall establish such licensure requirements for Pharmacy Interns and standards for Pharmacy practice experiences, or any other experiential program necessary to qualify an applicant for the licensure examination and shall also determine the qualifications of Preceptors used in practical experience programs.[25]

Section 304. Qualifications for Licensure Transfer.[26]

(a) In order for a Pharmacist currently licensed in another jurisdiction to obtain a license as a Pharmacist by ~~license~~ licensure transfer in this State, an applicant shall:[27]

(1) have submitted an application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of majority;
(3) 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;
(4) 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;
(5) have presented to the Board proof of an active ~~initial licensure by examination and proof that such~~ license ~~is~~ in good standing;
(6) 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
(7) have paid the fees specified by the Board.

(b) No applicant shall be eligible for ~~license~~ licensure transfer unless the state in which the applicant was initially licensed as a Pharmacist also grants licensure transfer to Pharmacists duly licensed by examination in this State, under like circumstances and conditions.[28]

...

[25] Boards of Pharmacy are strongly encouraged to utilize the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs as a basis for establishment and revision of Board standards for Pharmacy practice experiences. These Standards of Accreditation also contain additional guidance on the desired behaviors, qualities, and values of preceptors.

[26] See the NABP Model Rules for Public Health Emergencies 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.

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

[28] Endorsement states may wish to consider the removal of Subparagraph (b) in this Section.

Section 307. Licensure of Dispensing Practitioners.

(a) In order to be licensed as Dispensing Practitioner[29] in this State, an applicant shall:

(1) have submitted an application in the form prescribed by the Board of Pharmacy;

(2) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;

(3) submit to an inspection of the Dispensing Practitioner's facility by the Board; and

(4) have paid the fees specified by the Board.

Section 3087. Renewal of Licenses.

(a) Each Pharmacist, Pharmacy Intern, and Certified Pharmacy Technician shall apply for renewal of his or her license annually [or at such interval determined by the Board], no later than the first day of _____. A Pharmacist or Pharmacy Intern who desires to continue in the Practice of Pharmacy in this State shall file with the Board an application in such form and containing such data as the Board may require for renewal of the license. ~~If the Board finds that the applicant has been licensed, and that such license has not been Revoked or placed under Suspension, that the applicant has attested that he or she has no criminal convictions or arrests, has paid the renewal fee, has continued his or her Pharmacy education in accordance with the rules of the Board, and is entitled to continue in the Practice of Pharmacy, the Board shall issue a license to the applicant.~~

(b) If a Pharmacist fails to make application to the State Board of Pharmacy for renewal of his or her license within a period of three years from the expiration of his or her license, he or she must pass an examination for license renewal; except that a Person who has been licensed under the laws of this State and after the expiration of his or her license, has continually practiced Pharmacy in another State under a license issued by the authority of such State, may renew his or her license upon payment of the designated fee.

(c) The Board may extend a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician license renewal date in case of a State of Emergency or Significant Public Health Concern.

Section 3098. Continuing Pharmacy Education.

The Board shall, by rule, establish requirements for continuing education in Pharmacy, including the determination of acceptable program content and fees. The Board shall adopt rules necessary to carry out the stated objectives and purposes, to enforce the provisions of this Section, and to ensure

[29] Licensed Dispensing Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record-keeping requirements, counseling, and all other requirements for the Compounding and the Dispensing of Drugs applicable to Pharmacists.

continued competence. The Board may extend the date of compliance with continuing pharmacy education provisions in the case of a State of Emergency or Significant Public Health Concern[30].

[30] Boards may consider waiving requirements for "live" continuing pharmacy education in the case of a State of Emergency or Significant Public Health Concern.

Article IV
Licensing of Facilities

Introductory Comment to Article IV

The fourth Article of the Model Act *concerns licensure of Pharmacies, Manufacturers, Wholesale Distributors, Repackagers, Third-Party Logistics Providers, and the like. The licensure requirements of this Article will provide a Board with knowledge of all facilities involved in the storage, Distribution, and sale of Drugs or Devices within the state and those located outside the state that are shipping Drugs or Devices into the state. They will permit a Board to verify compliance with federal requirements and better ensure against Drug or Device diversion from the legitimate channels of commerce and provide the necessary data for effective recalls and the dissemination of information.*

Section 401. Unlawful Practice

(a) No Business Entity designated in Section 402 of this Act shall operate until a license has been issued to said Business Entity by the Board.

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

Section ~~401~~402. Licensing.

(a) The following ~~Persons~~ Business Entities located within this State, and the following ~~Persons~~ Business Entities located outside this State that provide services to other Business Entities or patients within this State, shall be licensed by the Board of Pharmacy and shall ~~annually~~ periodically renew[31] their license with the Board:[32]

(1) Pharmacies where Drugs or Devices are Dispensed, or Compounded, or Pharmacist Care Services are provided[33];

[31] The Board may delay a license renewal date in case of a State of Emergency or Significant Public Health Concern.

[32] State may require additional licensing/registration requirements.

[33] Includes remote dispensing machines and/or devices such as kiosks.

(2) Dispensing ~~Practitioners and~~ Practitioner's facilities including those engaged in ~~nonsterile~~[34] Compounding; [35, 36]
(3) Manufacturers or Repackagers of Drugs or Devices;
(4) Wholesale Distributors of Drugs or Devices;
(5) Drug or Device Third-Party Logistics Providers ;
(6) Outsourcing Facilities;
(7) Pharmacy Benefits Managers; and
(8) Repository Programs

Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

(b) The Board shall establish by rule, under the powers granted to it under Section 212 and 213 of this Act and as may be required from time to time, under federal law, the criteria that each ~~Person~~ Business Entity must meet to qualify for licensure in each classification, as well as the required practice standards applicable to each type of activity and/or facility. The Board shall adopt definitions in addition to those provided in Article I, Section 105, where necessary to carry out the Board's responsibilities. The Board may issue licenses with varying conditions to such ~~Persons~~ Business Entity where the Board deems it necessary.[37]

(c) Each Pharmacy and/or Outsourcing Facility shall have a Pharmacist-in-Charge. ~~Whenever an applicable rule requires or prohibits action by a Pharmacy,~~ Joint responsibility for compliance with all laws and rules shall be that of the owner and/or ~~pharmacy~~ permit holder and the Pharmacist-in-Charge ~~of the Pharmacy~~, whether the owner and/or ~~pharmacy~~ permit holder is a sole partnership, association, corporation, or otherwise.

(d) Each licensed Business Entity~~Person~~ located outside of this State which ships, mails, Dispenses, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in this State~~, or Pharmacy located outside of this State which ships, mails, Dispenses, Distributes, or Delivers Drugs or Devices in this State,~~ shall comply with the laws of patients' domicile, and shall designate a registered agent in this state for service of process. Any such licensed Business Entity~~Person or Pharmacy which~~ that does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful

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[34] ~~It is contemplated that dispensing Practitioners and Practitioners' facilities should only compound nonsterile human drug products and that sterile compounded human drug products should be obtained from Outsourcing Facilities.~~

[35] It is contemplated that dispensing ~~Practitioners and~~ Practitioners' facilities should only compound nonsterile human drug products and that sterile compounded human drug products should be obtained from Outsourcing Facilities.

[36] Licensed Dispensing Practitioners' facilities authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record-keeping requirements, counseling, and all other requirements for the Compounding and the Dispensing of Drugs applicable to Pharmacists.

[37] Section 401(b) contemplates that the criteria for licensure, beyond minimum requirements for all Persons and Pharmacies, established in an individual entity classification could differ. For example, the criteria that must be met by a nuclear Pharmacy will certainly differ from that of the community Pharmacy. This type of latitude places the responsibility on the Board to adopt appropriate rules to meet the situation at hand. It also provides a forum for change to meet the changing concepts of professional practice and the Distribution of Drugs and/or Devices.

attorney, upon whom may be served all legal process in any action or proceeding against such licensed Business Entity ~~Person~~ growing out of or arising from such shipping, mailing, Dispensing, Distribution, Wholesale Distribution, or Delivery of Drugs or Devices. A copy of any such service of process shall be mailed to such Business Entity~~Person or Pharmacy~~ by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Business Entity~~Person~~ has designated on its application for licensure in this State, or by electronic means if permitted. If any such Business Entity~~Person~~ is not licensed in this State, service on the Secretary of State only shall be sufficient service.[38]

(e) The Board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the licensure and inspection of Business Entities ~~entities~~ located in this ~~jurisdiction~~ State and those located outside this State.

(f) ~~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.~~

(g) For facilities that Compound and/or Repackage Sterile Drugs, an initial inspection shall be required prior to initial licensure or upon initiation of sterile Compounding activity. Thereafter, an annual inspection shall be required for licensure renewal. For facilities that do not Compound Sterile Drugs, an initial inspection, and thereafter an inspection that takes place not less than every 24 months, shall be required for purposes of licensure or licensure renewal[39]. Such inspection shall be performed by the following:

(1) the Board or its duly authorized agent; or

(2) a duly authorized agent of a third party approved by the Board[40]; or

For Nonresident Pharmacies, the inspection shall be performed by the resident state Board of Pharmacy, if the resident Board's inspection is substantially equivalent to inspection in this State, or a duly authorized agent of a third party approved by the Board[41].

~~(h) Agents duly authorized to conduct inspections, whether agents of the Board or an approved third party, must be competent to inspect the facilities they are assigned to inspect to include training on any applicable State, Federal, and USP standards.~~

...

Section 403~~2~~. Application.[42]

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

[39] State resources may have to be considered when evaluating inspection scheduling in combination with risk assessment consideration.

[40] Boards of Pharmacy are strongly encouraged to utilize the NABP Verified Pharmacy Program for this purpose.

[41] Boards of Pharmacy are strongly encouraged to utilize the NABP Verified Pharmacy Program for this purpose.

[42] Boards may want to consider requesting the following information on applications for Pharmacy and Wholesale Distributor licensure:

(a) personal information;
(b) marital information;
(c) family information (parents, siblings, in-laws);
(d) education;
(e) military information;

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

(b) Applicants for licensure to Dispense, Distribute, Wholesale Distribute, Manufacture, sell, purchase, transfer, and/or produce Drugs or Devices, and applicants for licensure as a Pharmacy Benefits Manager, shall file with the Board of Pharmacy a ~~verified~~ complete and accurate application containing such information as the Board requires of the applicant relative to the qualifications for a license.

(c) The Board of Pharmacy shall require any pharmacy applicant for initial and renewal of licensure to state whether they engage or intend to engage in Compounding as defined in this Act.[43, 44]

(d) Licenses issued by the Board pursuant to this Act shall not be transferable or assignable.

(e) The Board shall specify by rule minimum standards for responsibility of any Business Entity~~Person~~, Pharmacy, or Pharmacy Benefits Manager that has employees or personnel engaged in the Practice of Pharmacy, or Manufacture, Distribution, Wholesale Distribution, production, sale, or use of Drugs or Devices in the conduct of their business. If the licensed Business Entity~~Person~~ is a Pharmacy located in this State, that portion of the facility to which such license applies shall be operated only under the direct supervision of a Pharmacist licensed to practice in this State. If that Business Entity~~Person~~ is an Outsourcing Facility, all

(f) arrests, detentions, litigations, and arbitrations;
(g) residences (past 25 years);
(h) employment (back to age 18);
(i) character references;
(j) safe deposit box or other depository information;
(k) privileged, occupational, or professional licensure;
(l) out-of-state business, venture, or industry licensure or financial interest in such;
(m) appearances before any licensing agency or similar authority in or outside the state;
(n) denials of a personal license, permit, certificate, or registration for a privileged, occupational, or professional activity;
(o) denials of a business or industry license or related finding of suitability, or participation in a group that has been denied a business or industry license or related finding of suitability;
(p) Administrative actions or proceedings related to the Drug industry or participation in a group that has been the subject of such administrative actions or proceedings;
(q) guilty findings or pleadings or pleas of nolo contendere to any offense, federal or state, related to prescription Drugs and/or controlled substances or participation in a group that has been found or pled guilty or that has pled nolo contendere to any such offense;
(r) surrender, voluntary or otherwise, of licensure, permit, or certificate of registration relating to the Drug industry, or participation in a group that has surrendered, voluntary or otherwise, any such licensure, permit, or certificate of registration; and
(s) any relatives within the fourth degree of consanguinity associated with or employed in the Drug or Drug-related industry.

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

[44] The questionnaire contemplated in 502(c) shall request, at a minimum, the following information: 1) The name and address of the location at which Compounding occurs or will occur; 2) Whether nonsterile Compounding occurs or will occur; 3) Whether sterile Compounding occurs or will occur; 4) Whether the applicant Compounds or will Compound with hazardous drugs; and 5) Whether the applicant ships or will ship compounded preparations across state lines.

Compounding at the facility shall be under the direct supervision of a licensed Pharmacist and comply with Federal requirements applicable to Outsourcing Facilities.

(f) A "surety" bond of not less than $100,000, or other equivalent means of security acceptable to the Board, or a third party recognized by the Board such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution shall be required for all Wholesale Distributor applicants. Such bond will be used to secure payment of any administrative penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when ~~those penalties, fees, or costs are~~ authorized under state law and the licensee fails to pay within thirty (30) days ~~after the penalty, fee, or costs becomes final~~. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their Wholesale Distributor license with the Board. The Board may make a claim against such bond or other equivalent means of security until one year after the Wholesale Distributor's license ceases to be valid or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board that involves the Wholesale Distributor is concluded, including any appeal, whichever occurs later. ~~Manufacturers shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board.~~ The Board may waive the bond requirement~~,~~ if the Wholesale Distributor:

(1) has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the Wholesale Distributor possesses a valid license in good standing; or

(2) is a publicly held company.

Section 404~~3~~. Notifications.

(a) All licensed Business Entities or Persons shall report to the Board of Pharmacy the occurrence of any of the following:

(1) permanent closing;

(2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;

(3) any theft or loss of Drugs or Devices;

(4) any conviction of any employee of any State or Federal Drug laws;

(5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;

(6) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;

(7) occurrences of Significant Quality-Related Events;

(8) ~~Significant Adverse Drug Reaction~~ Serious Adverse Drug Experience associated with Compounded Drugs;

(9) recalls of Compounded Drugs;

(10) recalls of sterile Repackaged Drugs;
(11) any temporary closing of a pharmacy for more than 48 hours shall be reported to the Board by the next business day along with contingency plans for accessing patient prescriptions and records.
(12~~1~~)illegal use or disclosure of Protected Health Information; or
(13~~2~~)any and all other matters and occurrences as the Board may require by rule.

(b) Prior to commending any sterile Compounding activity, a~~A~~ll licensed Business Entities and/or Persons shall report to the Board of Pharmacy, or its authorized agent, whether the licensed facility will be engaging in any sterile Compounding ~~if they are engaging in any sterile Compounding activity conducted at a licensed facility prior to commencing of any sterile Compounding activity~~ in a manner determined by the Board. The Board may establish by rule additional reporting requirements for sterile and nonsterile Compounding activities.

(c) All licensed Business Entities and/or Persons shall report to the Board of Pharmacy, or its authorized agent, the occurrence of any Pharmacy or Pharmacy-related inspection conducted by any State or Federal regulatory agency or authorized agent thereof and shall provide a copy of the report of such inspection, including applicable documents relating to corrective actions within a timeframe determined by the Board.[45]

~~Section 404. Grounds, Penalties, and Reinstatement.~~

~~(a) No Person, Pharmacy, or Pharmacy Benefits Manager designated in Section 401 of this Act shall operate until a license has been issued to said Person, Pharmacy, or Pharmacy Benefits Manager by the Board.~~

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

(c) ~~The Board may Suspend, Revoke, deny, or refuse to renew the license of any Person, Manufacturer, Repackager, Third-Party Logistics Provider, Wholesale Distributor, Pharmacy, or Pharmacy Benefits Manager on any of the following grounds:~~[46]

[45] This includes any report or inspectional observations and any related correspondence with the Federal or State agency. FDA Form 483 Inspectional Observations alone should not be grounds for discipline.

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

~~(1) the finding by the Board of violations of any Federal, State, or local laws relating to the Practice of Pharmacy, Drug samples, Wholesale or retail Drug or Device Distribution, or Distribution of controlled substances;~~

~~(2) any felony convictions under Federal, State, or local laws;~~

~~(3) the furnishing of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Distribution;~~

~~(4) 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;~~

~~(5) 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.~~

~~(6) obtaining any remuneration by fraud, misrepresentation, or deception;~~

~~(7) 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;~~

~~(8) dealing with Drugs or Devices that he or she knows or should have known are or Counterfeit, Contraband, or stolen Drugs or Devices;~~[47]

~~(9) purchasing or receiving of a Drug or a Device from a source other than a Person or pharmacy licensed under the laws of the State, except where otherwise provided;~~

~~(10) the transfer during any consecutive twelve (12)-month period by a Pharmacy to a Wholesale Distributor or to another Pharmacy of more than five percent (5%) of the total amount of Prescription Drugs or Devices purchased by the Pharmacy in the immediately preceding twelve (12)-month period. 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~~

[47] This section restricts Distribution of Drugs or Devices to licensed entities to help ensure against clandestine Distribution to unauthorized and unlicensed Persons.

the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations; and

(vi) The transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing or Filling agreement;

(11) the transfer during any consecutive twelve (12)-month period by a Wholesale Distributor to a Wholesale Distributor of more than five percent (5%) of the total amount of prescription Drugs or Devices purchased by Wholesale Distributor in the immediately preceding twelve (12)-month period;

(12) Wholesale Drug Distributors other than pharmacies Dispensing or Distributing Drugs or Devices directly to patients;

(13) violations of any of the provisions of this Act or of any of the Rules adopted by the Board under this Act; or

(14) illegal use or disclosure of Protected Health Information.

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

(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.

(d) 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 401 of this Act.

Section 405. Criminal Offense; Forfeiture of Property.

(a) Violation of any of the provisions of Article IV of this Act by any person engaged in the Wholesale Distribution of Drugs and Devices shall constitute a Class three felony, provided that any such violation that results in the death of a Person shall constitute a Class one felony.

(b) A Person engaged in the Wholesale Distribution of Drugs and Devices convicted by a criminal court of this State of violating any of the provisions of Article IV may be ordered by the court to forfeit to the State any real or personal property:

(1) used or intended to be used to commit, to facilitate, or to promote the commission of such offense; or

(2) constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense. Any property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the

~~same manner as a search warrant or as otherwise permitted by law, and held until the case against the defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the Board and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered forfeited after conviction of the defendant may, at the discretion of the investigating agencies, be placed into official use by the Board or the agencies involved in the investigation and prosecution that led to the conviction.~~

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 ~~who~~ 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.

The following is a list of disciplinary actions that may be taken, issued, or assessed by the Board of Pharmacy: Revocation, Summary Suspension, Suspension, Probation, Censure, Reprimand, Warning, Cease and Desist, Fine/Civil Penalty, Costs/Administrative Costs.[48]

Section 502. Grounds, Penalties, and Reinstatement.[49]

(a) The Board of Pharmacy may 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 Business Entity or Person pursuant to the procedures set forth in Section 503 herein below, upon one or more of the following grounds:

(1) unprofessional conduct as that term is defined by the rules of the Board;[50]

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

[49] The penalties provided in Section 402 give the Board wide latitude to make the disciplinary action fit the offense. The "reasonable intervals" in 402(c) would be determined by the Board.

[50] 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

(2) incapacity that prevents a licensee from engaging in the Practice of Pharmacy or a registrant from assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public;[51]

(3) being guilty of one (1) or more of the following:
   (i) a felony; or
   (ii) violations of the 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;[52]

(4) 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) 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;

(6) 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;

(7) failure to report to the Board any adverse judgment, settlement, or award arising from a malpractice claim arising related to conduct that would constitute grounds for action as defined in this section;

(8) knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Certified Pharmacy Technician or Certified Pharmacy

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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 402(a)(3).

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

[52] 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.

Technician Candidate is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the Board of Pharmacy;

(9) misrepresentation of a material fact by a licensee in securing the issuance or renewal of a license or registration;

(10) fraud by a licensee in connection with the Practice of Pharmacy;

(11) 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;

(12) engaging, or aiding and abetting an individual to engage in the Practice of Pharmacy without a license; assisting in the Practice of Pharmacy or aiding and abetting an individual to assist in the Practice of Pharmacy without being licensed by the Board of Pharmacy; or falsely using the title of Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate;

(13) requiring Pharmacy personnel to meet production and/or performance metrics and/or quotas that negatively impact patient safety.[53]

(14) failing to pay the costs assessed in a disciplinary hearing ~~pursuant to Section 213(c)(9)~~;

(15) engaging in any conduct that subverts or attempts to subvert any licensing examination or the Administration of any licensing examination;[54]

(16) being found by the Board to be in violation of any of the provisions of this Act or rules adopted pursuant to this Act;

(17) illegal use or disclosure of Protected Health Information;

(18) impeding or subverting an investigation or failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board;

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

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

(a) 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:

(1) 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.

(2) 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.

(19) 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;

(20) 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;

(21) illegal use or disclosure of Protected Health Information.

(22) 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.

(23) the furnishing of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Distribution;

(24) 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;

(25) obtaining any remuneration by fraud, misrepresentation, or deception;

(26) dealing with Drugs or Devices that he or she knows or should have known are Suspect or Illegitimate Product or Counterfeit, Contraband, or stolen Drugs or Devices;[55]

(27) 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;

(28) 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;

[55] This section restricts Distribution of Drugs or Devices to licensed entities to help ensure against clandestine Distribution to unauthorized and unlicensed Persons.

(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;

(viii) The transfer of a Drug from one Pharmacy for to another for a specific patient need to fill a Prescription Drug Order for an identified patient;

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

(29) Wholesale Drug Distributors, other than pharmacies, Dispensing or Distributing Drugs or Devices directly to patients;

(30) violations of any of the provisions of this Act or of any of the Rules adopted by the Board under this Act.

(b) 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, or as otherwise statutorily provided.

(c) 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 401 of this Act..

(~~b~~d) 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 processThe Board may take action on a complaint if the patient or complainant does not comply with the Board's investigation when the Board has sufficient evidence 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.

(~~b~~e) Impaired Practice Licensees

(1) 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 ~~mentally~~ behaviorally impaired due to ~~addiction to Drugs or alcohol~~ substance use may qualify as an impaired practice Pharmacist 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 (b)(2). 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 ~~completion~~ successfully meeting the requirements of the ~~rehabilitation~~ 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.

(2) The Board may require a licensee to enter into an agreement that includes, but is not limited to, the following provisions:
   (i) ~~Licensee agrees that his or her license shall be Suspended or Revoked indefinitely under subsection (b)(1).~~ Licensee agrees to voluntarily surrender his or her 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.

(3) The ability of an impaired practice Pharmacist 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.

(4) Licensee consents, in accordance with applicable law, to the release to the Board of any treatment information from ~~anyone within~~ the approved treatment program.

(5) ~~The impaired licensee who has enrolled in an approved treatment and monitoring program and entered into an agreement with the Board in accordance with subsection (b)(1) hereof shall have his license Suspended or Revoked, but enforcement of this Suspension or Revocation shall be stayed by the length of time the licensee remains in~~

~~the program and makes satisfactory progress, and complies with the terms of the agreement and adheres to any limitations on his practice imposed by the Board to protect the public.~~ 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.

(6) Any Pharmacist who has substantial evidence that a licensee has an impairment due to a substance use disorder ~~active addictive disease~~ 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 the duties of his or her license, 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 ~~so~~ for failing to report.

(~~e~~f) Any Person whose license to practice Pharmacy in this State has been denied renewal, voluntarily surrendered, ~~Revoked~~, Summarily Suspended, Suspended, or Revoked ~~placed on Probation, Censured, Reprimanded, issued a Warning against, or issued a Cease and Desist order against, the licenses or the registration of, or assessed a Fine/Civil Penalty or Costs/Administrative Costs against~~ 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.[56] Such petition shall be made ~~in writing and in the form~~ 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.

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

(~~e~~h) All final decisions by the Board shall be subject to judicial review pursuant to the Administrative Procedures Act.

~~(fi) Any individual or entity whose license to practice Pharmacy, or registration to assist in the Practice of Pharmacy, is Revoked, Suspended, or not renewed shall return his or her license or registration certificate to the offices of the State Board of Pharmacy within 10 days after receipt of notice of such action~~.

[56] A Pharmacist who is under investigation or who has been charged with a violation of the Pharmacy Practice Act may agree to voluntarily surrender his or her 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.

Section 503. Procedure.[57]

(a) 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, ~~or~~ 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, ~~or~~ 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, ~~or~~ 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, ~~or~~ Certified Pharmacy Technician Candidate, Business Entity or Facility shall be provided with at least 10 days notice of any hearing held under this subsection.

(b) 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.

[57] 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.

National Association of Boards of Pharmacy
Model Rules

Model Rules for Pharmacy Interns and Pharmacy Practice Experience Programs[58]

Section 1. Licensure.

Every individual shall be licensed by the Board of Pharmacy before beginning Pharmacy practice experiences in this State.[59] A license to practice Pharmacy as a Pharmacy Intern shall be granted only to those individuals who:

(a) are enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

(b) are graduates of an approved professional degree program of a school or college of Pharmacy or are graduates who have established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, who are currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or

(c) are qualified applicants awaiting examination for licensure or meeting Board requirements for re-licensure; or

(d) are participating in a residency or fellowship program; and

(e) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule.

Section 2. Identification.

The Pharmacy Intern shall be so designated in his or her professional relationships, and shall in no manner falsely assume, directly or by inference, to be a Pharmacist. The Board shall issue to the Pharmacy Intern a license for purposes of identification and verification of his or her role as a Pharmacy Intern~~, which license shall be surrendered to the Board upon discontinuance of Pharmacy practice experiences for any reason including licensure as a Pharmacist~~. No individual not ~~properly~~ licensed by

[58] Boards of pharmacy are strongly encouraged to utilize the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs as a basis for the establishment and revision of Board standards for Pharmacy practice experiences.

[59] See the most recent ACPE standards for professional degree programs leading to a Doctor of Pharmacy degree for Pre-Advanced Pharmacy Practice Experience (Pre-APPE) and Advanced Pharmacy Practice Experience (APPE) Curricula.

It is also encouraged that Boards of Pharmacy allow Pharmacy students to be registered as Pharmacy Interns as early as initial enrollment in a Board-approved professional program as long as the Pharmacy student has begun to take professional degree courses.

the Board as a Pharmacy Intern shall take, use, or exhibit the title of Pharmacy Intern, or any other term of similar like or import.

Section 3. Supervision.

A Pharmacy Intern shall be allowed to engage in the Practice of Pharmacy provided that such activities are under the supervision of a Pharmacist. A Pharmacist shall be actively engaged in the supervision and instruction of the Pharmacy Intern during all professional activities throughout the entire Pharmacy practice experience period. The Pharmacist is responsible for supervising all the Practice of Pharmacy activities performed by the Pharmacy Intern, including but not limited to the accurate Dispensing of the Drug.[60]

Section 4. Notification required.

(a) All Pharmacy Interns shall notify the Board within 10 days ~~immediately~~ upon change of name, enrollment status, employment, and required contact information such as residential address and/or email address.

(b) The Pharmacy Intern, excluding those who are currently enrolled in a professional degree program of a school or college of pharmacy approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist, shall notify the Board of Pharmacy within two weeks of beginning practice as a Pharmacy Intern, in a manner designated by the Board, of the identity of the Pharmacy practice experience site and of the Preceptor.

Section 5. Evidence of Completion.

Applicants for licensure as Pharmacists shall submit, or cause to be submitted, evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies; and (2) not less than 1,740 hours of Pharmacy practice experience credit under the instruction and supervision of a Preceptor.[61]

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[60] According to the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs, most Pharmacy practice experiences must be under the supervision of a qualified Pharmacist Preceptor licensed in the United States. Realizing that in some cases non-Pharmacist Preceptors can also provide valuable learning opportunities, it is hoped that Boards of Pharmacy recognize these experiences and that schools and colleges of pharmacy ensure, in most cases through faculty, that the desired competencies are being met.

Supervision includes an actual review of the Prescription Drug Order and the dispensed Drug or Product to ensure public protection.

[61] These requirements coincide with the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs. Boards of pharmacy are strongly encouraged to utilize these Standards of Accreditation as a basis for the establishment and revision of Board standards for Pharmacy practice experiences.

Introductory Pharmacy practice experiences, which are not less than 300 contact hours, are in addition to the advanced practice experiences taken during the final professional year, which account for not less than 25 % of the curricular length or 1,440 contact hours. The total Pharmacy practice experience hour requirement, therefore, is not less than 1,740 hours. Boards may consider moving away from requiring a

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~~Model Standards for~~
~~Pharmacy Practice Experience Programs~~

~~Section 1. Preceptor.~~

(a) ~~The Pharmacy Intern, excluding those who are currently enrolled in a professional degree program of a school or college of pharmacy approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist, shall notify the Board of Pharmacy within two weeks of beginning practice as a Pharmacy Intern, in a manner designated by the Board, of the identity of the Pharmacy practice experience site and of the Preceptor.~~

(b) ~~A Preceptor may be responsible for the training of more than one Pharmacy Intern. The number of Pharmacy Interns engaged in the Practice of Pharmacy at any time is limited to the number of Pharmacy Interns the Pharmacist can appropriately precept as approved by the Board.~~

~~Section 2. Pharmacy Practice Experience Programs.~~[62]

~~(a) The Pharmacy at which a Pharmacy Intern is being trained shall provide an environment that is conducive to the learning of the Practice of Pharmacy by a Pharmacy Intern. Pharmacy practice experience sites shall meet the standards approved by the Board.~~

~~(b) Pharmacy practice experience in non-traditional practice sites (eg, industry-sponsored programs) must be approved by the Board of Pharmacy prior to granting of credit.~~

~~(c) When a Pharmacy Intern desires to obtain credit for training received in a state other than this State, the Pharmacy Intern shall abide by all the provisions of the Pharmacy practice experience rules in that state, and shall provide evidence from that state's Board of Pharmacy of the number of clock hours of experience achieved by the Pharmacy Intern.~~

~~Section 3. Global Exchange Pharmacy Students.~~

~~A Global Exchange Pharmacy Student may participate in observation-only clinical learning experiences, not to exceed _____, provided:~~

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specific number of contact hours should it be determined that the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

[62] ~~Boards of pharmacy are strongly encouraged to utilize the ACPE Standards of Accreditation for Doctor of Pharmacy Degree Programs as a basis for the establishment and revision of Board standards for Pharmacy practice experiences.~~

~~(a) the Global Exchange Pharmacy Student has been reviewed and qualified by the ACPE-accredited or Board-approved school or college of pharmacy as exists for Introductory Pharmacy Practice Experience (IPPE) and Advanced Pharmacy Practice Experience (APPE) experiential rotations; and~~

~~(b) he or she is under the direct in-person supervision of a Pharmacist.~~

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Model Rules for the Practice of Pharmacy

Section 1. Pharmacy Licensure.

(a) To obtain a license for a Pharmacy, an applicant shall:
  (1) have submitted an application in the form prescribed by the Board of Pharmacy;
  (2) have attained the age of majority; and
  (3) have paid the fees specified by the Board of Pharmacy for the issuance of the license.

(b) The facility owner, if an individual, shall have undergone a state and federal fingerprint-based criminal background check ~~as specified by Board rule;~~.

(c) The facility shall have undergone a Pharmacy inspection by the Board or authorized agent thereof.~~; and~~

(d) The Pharmacy shall have sufficient space, references, equipment, and storage to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparing Prescription Drug Orders. ~~meet the following minimum requirements:~~
  ~~(1) The Pharmacy shall be of sufficient size, as determined by the Board, to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.~~
  ~~(2) The Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.~~
  ~~(3) The Pharmacy shall have ready access to references, to include at least one current reference[63] in each of the following categories, if~~ applicable to the services provided.~~:~~
    ~~(i) State and Federal Drug laws relating to the Practice of Pharmacy and the legal Distribution of Drugs and any rules or regulations adopted pursuant thereto;~~
    ~~(ii) pharmacology;~~
    ~~(iii) dosage and toxicology;~~
    ~~(iv) veterinary Drugs[64]; and~~
    ~~(v) general.~~
  ~~(4) The Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.[65]~~
  (5) ~~Each Person involved in the development, maintenance, or use of a Drug formulary shall maintain a currently accepted reference containing guidelines for a sound Drug formulary system.~~

[63] Boards may wish to give examples in each of these categories of reference texts.

[64] Such as Plumb's Veterinary Drug Handbook.

[65] Patient-oriented reference material can include publications such as Facts and Comparisons' Patient Drug Facts, or the United States Pharmacopoeia Dispensing Information (USPDI).

~~(6) All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.~~

~~(7) The Pharmacy shall have access to a sink with hot and cold running water that is convenient to the Compounding area for the purpose of hand scrubs prior to Compounding.~~

~~(8) The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.~~

(9) ~~The Pharmacy shall provide a means for patients to prevent disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the Delivery of Pharmacist Care Services. other than as authorized by law or rules of the Board.~~

~~(10)~~

(e) The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board[66].

(f~~e~~) Upon renewal, the licensee shall provide to the Board the NABP e-Profile ID of the Pharmacy and the Pharmacist-in-Charge.

Section 2. Security.

(a) ~~Facility~~ Basic Provisions

(1) Each Pharmacist, while on duty, shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.

(2) The Pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the Pharmacist is not present. Such barrier shall be approved by the Board of Pharmacy before being put into use. In the event of separation of employment of an employee for cause, ~~due to any confirmed Drug-related reason, including diversion, or other acts involving dishonesty,~~ suitable action shall be taken to ensure the security of the pharmacy.

(3) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information ~~as provided by the rules of the Board~~.

(4) The Pharmacy shall implement and maintain technologies that will aid in theft prevention and suspect apprehension that may include:

[66] Boards of Pharmacy are strongly encouraged to recognize the NABP ~~Digital~~ Healthcare Merchant Accreditation or, if a higher standard is desired, Digital Pharmacy Accreditation ~~Approval Program~~ for this purpose.

(i) video equipment positioned to identify individuals who may be involved in diversion or theft, if utilized, shall have adequate recording, storage, and retrieval capabilities; and

(ii) monitored alarm system with backup mechanism.

(b) Internal Theft/Diversion Prevention

(1) the Pharmacist-in-Charge and owner/licensee (facility permit holder) shall ensure policies and procedures ~~are in place~~ that address the following are adopted, implemented, and maintained:

(i) inspection of shipments;

(ii) receipt verification oversight and checking in shipments;

(iii) reconciliation of orders; and

(iv) inventory management including:

(A) determination of Drugs that need to be monitored and controlled beyond existing systems such as controlled substances and Drugs of Concern; and

(B) conducting quarterly reconciliations at a minimum, but which shall be more frequent, up to perpetual, depending on the potential for or incidence of diversion for a particular Drug.

Section 3. Personnel.

(a) Pharmacist-in-Charge

(1) No Business Entity or Person shall operate a Pharmacy without a Pharmacist-in-Charge. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may ~~not~~ serve as Pharmacist-in-Charge for more than one Pharmacy at any one time ~~except~~ upon obtaining ~~written~~ permission from the Board.

(2) The Pharmacist-in-Charge has the following responsibilities:

(i) Developing or adopting, implementing, and maintaining:[67]

(A) Policies and procedures addressing the following:

(-a-) the provision of Pharmacy services;[68]

(-b-) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and Drugs of Concern;

(-c-) computerized record-keeping systems;

[67] The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

[68] The Pharmacist-in-Charge, as part of the responsibilities to manage as effectively as possible a patient's therapy to avoid a harmful interruption of therapy because of a shortage or limited Distribution of Drugs, can proactively improve Pharmacy operations by developing a systematic approach to address such circumstances. References such as the American Society of Health-System Pharmacists (ASHP) Guidelines in Managing Drug Product Shortages could be used as resources for developing policies and procedures if appropriate. Additionally, Food and Drug Administration maintains a list of current and resolved Drug shortages, as well as discontinued Drugs on the agency's Drug Shortages Web page at www.fda.gov/cder/drug/shortages.

(-d-) Automated Pharmacy Systems;

~~(-e-) preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with such established policies and procedures;~~

(-e~~f~~-) operation of the Pharmacy in the event of a fire, flood, pandemic, or other natural or man-made disaster or emergency, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed. Such policies and procedures shall include reporting to the Board the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence[69];

(-g-) the proper management of Drug recalls which may include, where appropriate, contacting patients to whom the recalled Drug Product(s) have been Dispensed;

(-h-) the duties to be performed by pharmacy personnel. The duties and responsibilities of these personnel shall be consistent with their education, training, experience, and license and shall address the method and level of necessary supervision specific to the practice site.

(-i-) actions to be taken to prevent and react to pharmacy robberies and thefts, including but not limited to coordinating with law enforcement, training, mitigation of harm, and protecting the crime scene.

(-j-) restrictions and control over and access to the locks, barriers, and systems used to secure the pharmacy and pharmacy systems in accordance with state laws and regulations.

(-k-) The prevention and detection of Drug diversion.[70]

(B) Policies and procedures that address the following activities related to prescription Drug shipment by mail or common carrier:

[69] States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of Drugs in areas outside the licensed pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed pharmacy area to accommodate the need to store emergency supplies.

[70]The Pharmacist-in-Charge, if the practice setting warrants, may also consider implementing diversion prevention and detection policies and procedures that address the following: periodic reviews of employee access to any secure controlled substance storage areas, which may include:

- alarm codes and lock combinations;
- passwords; and
- keys and access badges.

(-a-) properly transferring prescription information to an alternative Pharmacy of the patient's choice in situations where the Drug is not Delivered or Deliverable;
(-b-) verifying that common carriers have in place security provisions, such as criminal background checks and random drug screens on its employees who have access to prescription Drugs;
(-c-) tracking all shipments; and
(-d-) ensuring that Drugs do not become adulterated in transit.

(C) Quality assurance programs addressing the following:
(-a-) Pharmacy services. The quality assurance program should be 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;
(-b-) Automated Pharmacy Systems. The quality assurance program should monitor the performance of the Automated Pharmacy System, ensure the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed, while maintaining appropriate record keeping and security safeguards.

(ii) Ensuring that all Pharmacists, Pharmacy Interns, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates employed at the Pharmacy are currently licensed by the Board of Pharmacy. [71]

(iii) Notifying the Board of Pharmacy <u>as required</u>~~,~~ ~~immediately and in writing,~~ of any of the following[72] changes:
(A) change of employment or responsibility as the Pharmacist-in-Charge;
(B) the separation of employment of any Pharmacist, Pharmacy Intern, Certified Pharmacy Technician Candidate, or Certified Pharmacy Technician for any confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination: if it is the employment of the Pharmacist-in-Charge that is

[71] <u>While it is strongly encouraged that all Pharmacy personnel should be licensed, there may still be jurisdictions that allow non-licensed individuals, such as cashiers, to work in a Pharmacy, and in such instances the Pharmacist-in-Charge is responsible for their supervision.</u>

[72] If states require the Pharmacist-in-Charge or other Person in charge of the Pharmacy to submit information regarding the separation of employment of licensees, especially in circumstances of suspected or confirmed abuse, theft, or diversion of Drugs, states should also be aware of confidentiality and employment laws that may restrict the release of information and be cautioned that the release of such information may create a liability for the reporting Pharmacy.

In instances where the Pharmacist-in-Charge and the owner and/or pharmacy permit holder are the same person and that person is no longer employed or designated as the Person in charge, then the Board must take action to cease operation of the Pharmacy.

terminated, the owner and/or pharmacy permit holder shall notify the Board of Pharmacy;

(C) change of ownership of the Pharmacy;

(D) change of address of the Pharmacy;

(E) permanent closing of the Pharmacy;

(F) Significant Quality-Related Events;

(G) the installation or removal of Automated Pharmacy Systems. Such notice must include, but is not limited to:

(-a-) the name and address of the Pharmacy;

(-b-) the location of the Automated Pharmacy System; and

(-c-) the identification of the responsible Pharmacist.

(-d-) Such notice must occur prior to the installation ~~or removal~~ of the system.

(iv) Making or filing any reports required by state or federal laws and rules.

(v) Reporting any theft, suspected theft, diversion, or other Significant Loss of any Prescription Drug within one business day of discovery to the Board of Pharmacy and as required by Drug Enforcement Administration (DEA) or other State or federal agencies for Prescription Drugs and controlled substances.

(vi) Responding to the Board of Pharmacy regarding any minor violations brought to his or her attention.

(3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates as may be required to competently and safely provide Pharmacy services.

~~(i) The Pharmacist-in-Charge shall maintain and file with the Board of Pharmacy, on a form provided by the Board, a current list of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates assisting in the provision of Pharmacy services.~~

(i~~i~~) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain ~~written~~ policies and procedures to specify the duties to be performed by Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates. The duties and responsibilities of these personnel shall be consistent with their education, training, and experience and shall address the method and level of necessary supervision specific to the practice site.

(ii~~i~~) The Pharmacist-in-charge shall develop or adopt, implement, and maintain a Certified Pharmacy Technician training program that is site-specific to the practice setting of which he or she is in charge for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall utilize a Certified Pharmacy Technician training manual as part of the training program. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates successfully completing a site-specific training program and an objective assessment

mechanism. ~~The Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for licensure by the Board~~.[73]

~~(b) Professional Performance Evaluation~~

~~Each Pharmacist who performs any of the acts described within the definition of "Practice of Pharmacy" is responsible for ensuring that he or she is the subject of a Professional Performance Evaluation at least once each year. Each Pharmacy is responsible for ensuring that every Pharmacist who practices at the Pharmacy for more than 40 hours during any twelve (12) month period and who performs any of the acts described within the definition of "Practice of Pharmacy" is the subject of a Professional Performance Evaluation at least once each year.~~

(b~~c~~) Pharmacy Labor Standards/Shift Lengths and Breaks

(1) A pharmacy licensed under this Act shall not require a Pharmacist, Pharmacist Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate to work longer than 12 continuous hours per day, inclusive of the breaks required under subsection (2).

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

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

(i) Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, and Pharmacist Interns authorized by the Pharmacist on duty may continue to perform duties as allowed under this Act;

(ii) no duties reserved to Pharmacists and Pharmacist Interns under this Act, or that require the professional judgment of a Pharmacist, may be performed by Certified Pharmacy Technicians or Certified Pharmacy Technician Candidates;

(iii) only Prescription Drug Orders that have received final verification by a Pharmacist may be Dispensed while the Pharmacist is on break, except those Prescription Drug Orders that require counseling by a Pharmacist, including all new Prescription Drug Orders and those refilled Prescription Drug Orders for which a Pharmacist has determined that counseling is necessary and/or is conducted pursuant to counseling laws and/or regulations;[74] and

[73] All training programs should be subject to approval by the Board of Pharmacy.

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

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

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

Section 5. Record Keeping.

(a) Patient Records[75]

(1) A patient record system shall be maintained by all Pharmacies and Dispensing Practitioners for patients for whom Prescription Drug Orders are Dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously Dispensed Drugs at the time a Prescription Drug Order is presented for Dispensing, and be created and stored in a manner to protect against illegal use or disclosure of Protected Health Information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

(i) full name of the patient for whom the Drug is intended;
(ii) street address and telephone number of the patient;
(iii) patient's age or date of birth;
(iv) patient's gender;
(v) a list of the Drugs taken by the patient during the preceding 24 months; and
(vi) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, Drug reactions, ~~idiosyncrasies~~, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs or Devices currently being used by the patient which may relate to Prospective Drug Review.

(3) A patient record shall be maintained for a period of not less than ten years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

~~(4) Protected Health Information may be used or disclosed as allowed under state and federal privacy rules.~~

[75] The Pharmacist should have access to clinical and laboratory data concerning each patient, and should monitor each patient's response to his or her Drug therapy. Any unexpected or untoward response should be reported to the prescribing physician. If the Pharmacist is not doing this monitoring, the identity of the health care provider that has assumed this responsibility should be documented in the patient's profile.

It is acceptable for new Prescription Drug Order data to be added to the patient profile, but original entries may not be altered.

(4~~5~~) ~~Significant Adverse Drug Reactions~~ Serious Adverse Drug Experiences shall be reported to the Practitioner and an appropriate entry shall be made in the patient's record.

(b) Records of Dispensing/Delivery[76]

(1) Records of receipt, Dispensing, Delivery, Distribution, or other disposition of all Drugs or Devices are to be made in accordance with Federal law and kept by Pharmacies for five years[77] and shall include, but not be limited to:

(i) quantity Dispensed for original and refills, if different from original;

(ii) date of receipt, Dispensing, Delivery, Distribution, or other disposition;

(iii) serial number (or equivalent if an institution);

(iv) the identification of the Pharmacist, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate responsible for Dispensing;

(v) name and Manufacturer of Drug Dispensed if Drug Product selection occurs; and

(vi) records of refills to date.

(2) Pharmacies that ship Drugs by mail, common carrier, or other type of Delivery service shall implement a mechanism to verify that a patient or caregiver has actually received the Delivered Drug.[78]

~~(c) Electronic Record Keeping~~

~~(1) Systems Policies and Procedures~~

~~An up-to-date policy and procedure manual shall be developed by the Pharmacist-in-Charge that explains the operational aspects of the computerized record-keeping system and shall:~~

~~(i) include examples of all required output documentation provided by the computerized record-keeping system;~~

~~(ii) outline steps to be followed when the computerized record-keeping system is not operational due to scheduled or unscheduled system interruption;~~

~~(iii) outline regular and routine backup file procedure and file maintenance;~~

~~(iv) outline audit procedures, personnel code assignments, and personnel responsibilities; and~~

~~(v) provide a quality assurance mechanism for data entry validation.~~

~~(2) Data Storage and Retrieval.~~

~~(i) The system shall provide online retrieval of original Prescription Drug Order information. Such information shall include, but not be limited to, the Prescription~~

[76] If a Board requires the presentation of identification or patient signature in order for a patient to receive prescribed Drugs, it may consider waiving such requirements during a State of Emergency, in compliance with Federal Law.

[77] States should check federal laws and ensure that the number of years the state requires Dispensing records to be maintained are at least as many as federal requirements.

[78] States that require pharmacies that ship Drugs by mail, common carrier, or other type of Delivery service to implement a mechanism to verify that the patient or caregiver has actually received the Delivered Drug may want to consider allowing the mechanism to include a waiver provision that allows the patient or caregiver to request Delivery without verification and advises the patient or caregiver of the possible consequences of receiving Delivery without verification.

~~Drug Order requirements and records of Dispensing as indicated in Section 3 of this Rule; and~~

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

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

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

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

~~Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of Dispensing the appropriately authorized refill;~~

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

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

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

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

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

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

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

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

(13) Security

To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the Drug has been Dispensed, any alterations in Prescription Drug Order data shall be documented, including the identification of the Pharmacist responsible for the alteration.

(24) System Backup (Auxiliary Records Maintenance)

(i) In the event of an unscheduled system interruption, sufficient patient data and Prescription Drug Order data should be available to permit reconstruction of such data as soon as possible ~~within a two-hour time period~~ for the Pharmacist to Dispense Drugs with sound professional judgment.

(ii) An auxiliary system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason and to ensure that all refills are authorized by the original Prescription Drug Order and that the maximum number of refills is not exceeded.

(iii) The auxiliary system shall be in place to provide for the maintenance of all necessary patient Drug information (as outlined in this rule) until the automated system becomes operational. However, nothing in this section shall preclude the Pharmacist from using professional judgment for the benefit of a patient's health and safety.

(iv) When the automated system is restored to operation, the information regarding Prescription Drug Orders Dispensed and refilled during the inoperative period shall be entered into the automated system as soon as possible. ~~within 96 hours.~~

(v) Routine backup systems and procedures (hard copy, copy, disk, etc) shall be in place and operational to ensure against loss of patient data.

(vi) In the event that permanent Dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy shall be notified as soon as possible.~~within 24 hours~~.

…

…

Section 16. Unprofessional Conduct.

Unprofessional conduct shall include, but is not limited to, the following acts of a Pharmacist or Pharmacy:

(a) the publication or circulation of false, misleading, or otherwise deceptive statements concerning the Practice of Pharmacy;

(b) unreasonably refusing to Compound or Dispense Prescription Drug Orders that may be expected to be Compounded or Dispensed in Pharmacies by Pharmacists;

(c) attempting to circumvent the Patient Counseling requirements, or discouraging the patient from receiving Patient Counseling concerning their Prescription Drug Orders;

(d) the illegal use or disclosure of Protected Health Information;

(e) failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of Protected Health Information;

(f) failure to maintain adequate records to account for disclosures of Protected Health Information;

(g) 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;

(h) 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;

(i) selling a Drug for which a Prescription Drug Order from a Practitioner is required, without having received a Prescription Drug Order for the Drug;

(j) 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;

(k) 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;

(l) 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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Model Rules for Outsourcing Facilities

Section 1. Purpose and Scope.
The purpose of this section is to ensure that Outsourcing Facilities are regulated by this State in a manner consistent with Federal law and to ensure this State has appropriate authority over such facilities.

Section 2. Registration.
(a) Any Outsourcing Facility located in this State or that Distributes Compounded Drugs to this State must be inspected and registered as an Outsourcing Facility by FDA prior to applying for a license/registration with the Board; and
(b) The facility must undergo an inspection by the Board or a third party recognized by the Board such as Drug Distributor Accreditation[79] if the facility is registered with FDA but has not received an FDA inspection as an Outsourcing Facility.

Section 3. Notification.
(a) All licensed/registered Outsourcing Facilities shall report to the Board the biannual reports they are required to provide to FDA identifying the Drugs Compounded in the previous six (6)-month period, including the Drug's Active Ingredients, strength, and dosage form.

Section 4. Requirements.
Outsourcing Facilities must:
(a) Designate a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or permit holder and the Pharmacist-in-Charge, whether the owner and/or permit holder is a sole proprietor, partnership, association, corporation, or otherwise.
(~~a~~b) Compound Drugs by or under the direct supervision of a licensed Pharmacist;
(~~b~~c) Compound Drugs in accordance with current Good Manufacturing Practice (cGMP) as required by Federal law;
(~~c~~d) Ensure that Pharmacists conducting or overseeing Compounding at an Outsourcing Facility must be proficient in the art of Compounding and shall acquire the education, training, and/or experience to maintain that proficiency through participation in seminars, studying

[79] States may require authentication and tracking of Product, whereby the exchange of information for Compounded Product is traced.

appropriate literature, and consulting colleagues, and/or by becoming certified by a Compounding certification program approved by the Board.

(~~d~~e) Label Compounded Drugs with:
(i) required Drug and ingredient information,
(ii) facility identification, and
(iii) the following or similar statement: “This is a compounded drug. For office use only” or “Not for resale”; and

(e<u>f</u>) Only Compound using bulk Drug substances that meet specified FDA criteria. May also compound Drugs that appear on an FDA shortage list if the bulk drug substances used comply with the aforementioned specified criteria.

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Appendix C
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.
   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

9. Negligence in the Practice of Pharmacy as determined by the Board.
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

16. 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

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 or organization 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.

~~Appendix D~~
~~Community Pharmacy Quality-Related Event (QRE)~~
~~Data Collection Form~~

~~QRE Prescription Data~~
~~Attach copy of: ☐ prescription ☐ label ☐ photo of vial~~ ~~(mark all available)~~
~~Original Rx date:~~ ~~Refill date:~~ ~~Date/time reported:~~
~~Drug Prescribed (name, strength, and dosage form):~~ ~~Directions:~~ ~~Drug indication:~~
~~Prescription was received by the pharmacy via:~~ ~~☐ telephone, by whom:~~ ~~☐ written~~ ~~☐ computer~~ ~~☐ fax~~

~~QRE Data~~	
~~QRE Type: (select all that apply)~~ ~~A. Prescription processing error:~~ ~~☐ Incorrect drug (1)~~ ~~☐ Incorrect strength (2)~~ ~~☐ Incorrect dosage form (3)~~ ~~☐ Incorrect patient (4)~~	~~B. A failure to identify and manage~~ ~~☐ Over/under utilization (1)~~ ~~☐ Therapeutic duplication (2)~~ ~~☐ Drug-disease contraindications (3)~~ ~~☐ Drug-drug interactions (4)~~ ~~☐ Incorrect duration of treatment (5)~~

❑ Inaccurate or incorrect packaging, labeling, or directions (5) ❑ Other (6):	❑ Incorrect dosage (6) ❑ Drug-allergy interaction (7) ❑ Clinical abuse/misuse (8)

QRE Contributing Factors
Day of the week and time of QRE: No. of new prescriptions: No. of refill prescriptions: RPh to tech ratio:
RPh staff status: ❑ regular staff ❑ part-time/substitute staff length of employment: No. of hours RPh on duty: Average No. of prescriptions filled per hour: No. of other RPhs on duty: No. of support staff on duty:
Automation ❑ yes ❑ no Type:
❑ Computer software ❑ Environmental (lighting/noise/distractions/workspace ❑ Equipment failure ❑ Failure to supervise ❑ Legibility ❑ Increased Rx volume as compared to normal ❑ Shift change ❑ Policies and/or procedure not followed ❑ Staff shortage ❑ Sound alike/look alike Drugs ❑ Other, explain
Describe factors checked above and/or other preliminary root contributors:
Counseling was offered: ❑ yes ❑ no Counseling was given: ❑ yes ❑ no Documentation of offer: ❑ yes ❑ no Documentation of counseling: ❑ yes ❑ no

Pharmacist Information
Name of verifying pharmacist:

Name(s) of other person(s) and title(s) involved in processing the prescription:
Describe remedial action taken:

If patient received Drug, complete Patient and Prescriber Information sections.

Patient Information
Patient's name: Prescription was dispensed to:
Address: Telephone No.:
Patient DOB: Sex: M or F If minor, name of parent(s)/guardian(s):
Who discovered the error/relationship to patient?:
Did patient ingest Drug? ❑ yes ❑ no If yes, how many doses?:
❑ Not harmed ❑ Received treatment and or increased monitoring ❑ Seriously harmed, explain ❑ Did not survive, explain

Prescriber Information

Was the prescriber informed: ☐ yes ☐ no If yes, provide date:
Prescriber's name: Telephone No.:
Prescriber's instructions/comments:

Report Affirmation
Additional comments:
Name and title of preparer of this report:
Signature: Date:

Community Pharmacy Continuous Quality Improvement Program Inspection Form

General Information	
Pharmacy name:	License No.:
Address:	Phone No.:
Pharmacist-in-charge (PIC):	PIC License No.:
Date/time:	Date of previous inspection: Attach copy of previous inspection
Purpose of inspection	

❑ Complaint ❑ Routine ❑ Follow-up ❑ New pharmacy ❑ Change in owner ❑ Other Comment:

Pharmacy Staff (Include pharmacist, intern, certified pharmacy technician, certified pharmacy technician candidate, and cashier)			
Name	**Title**	**License No.**	**Present**

P=Present A=Absent N/A= Not applicable				
CQI Program		**P**	**A**	**N/A**
	Policy and procedures in place			
	Periodic CQI meetings held			
	Quality-Related Events (QRE) recorded			
	Sentinel Events			

	~~Workload compiled~~			
	~~Staffing needs analyzed/addressed~~			
	~~Outcome-based certified pharmacy technician training conducted~~			
	~~Technology utilized in current/updated~~			
	~~Pharmacist Care Services initiatives in place~~			
	~~Consumer survey policy in place~~			
	~~Professional performance evaluation policy in place~~			
~~**Comments:**~~ ~~**Recommendations:**~~				
~~**Report Affirmation**~~				
~~**Additional comments:**~~				
~~Pharmacist signature: Date:~~				
~~Surveyor signature: Date:~~				

~~Community Pharmacy Quality Self-Audit~~

Each pharmacy shall conduct a quality self-audit at least quarterly and upon change of pharmacist-in-charge. The goals of the quality self-audit are to monitor changes in the number of quality-related events (QRE) over time, to evaluate compliance with CQI procedures, and to develop a plan for improved adherence with the CQI Program.

General Information	
Date:	Quarterly ☐ Change of pharmacist-in-charge
Pharmacy name:	Address:
Telephone:	License No.:
Pharmacist-in-charge:	Date of previous self-audit:

Pharmacy Staff

(Include pharmacist, intern, certified pharmacy technician and certified pharmacy technician candidate, cashier)

Name	**Title**	**License No.**	**Start Date**

Staffing/Workload Date	
Staffing	**Yes/No/Answer**

Number of pharmacist hours allocated per week	
Number of certified pharmacy technician hours allocated per week	
Number of certified pharmacy technician candidate hours allocated per week	
Number of other pharmacy support staff hours allocated per week	
Number of certified pharmacy technicians	
Number of certified pharmacy technician candidates	
Outcome-based certified pharmacy technician training program (If yes, check all applicable)	
❑ Cash register ❑ Prescription intake ❑ Prescription filling	
❑ Inventory ❑ Returning stock bottles to shelf ❑ Clean room	
❑ Computer data entry ❑ Pharmaceutical calculations ❑ Knowledge of practice settings	
❑ Identifying drugs, doses, routes of Administration, dosage forms, etc	
❑ Pharmaceutical and medical terminology ❑ Other	
Workload	**Yes/No/Answer**
Number of hours pharmacy department is open during the week	
Average number of prescriptions filled per week	
Usual ratio of pharmacist to technicians	
Policy is in place that requires increased staffing if workload increases	
Automation	**Yes/No/Answer**
Type	

CQI Program Data	
General	**Yes/No/Answer**
Pharmacy has a CQI policy and procedure manual	
Employees must verify review of policy and procedure manual	
Periodic CQI Meetings	**Yes/No/Answer**
Pharmacy holds CQI meetings (if yes, indicate frequency)	
Average length of CQI meetings in minutes	
Staff attending CQI meetings ❑ Pharmacists ❑ Technicians ❑ Manager ❑ Pharmacy supervisor ❑ Owner ❑ Other	
Program Documentation Methods	**Yes/No/Answer**
QRE forms utilized	
Method used to document interaction in relation to CQI program ❑ Computer database ❑ On prescription ❑ Custom-made form ❑ Standard form ❑ Other	
Method used to verify drug product with prescription label ❑ Bar code ❑ NDC code ❑ Name of product ❑ Other	
First time refills are checked against hardcopy	
Consumer Surveys	**Yes/No/Answer**
Consumer survey policy in place, if yes, indicate frequency	
Other technique in place to evaluate performance, if yes, describe	

~~Method of conducting consumer survey~~ ~~❑ Distributed at time of dispensing ❑ Mail ❑ Telephone ❑ Other~~	
~~Consumer survey feedback utilized to improve delivery of pharmacy services~~	
~~Outcome-Based Professional Performance Evaluation~~	
~~Frequency~~ ~~❑ Annually ❑ Biannually ❑ Quarterly ❑ Other~~	
~~Staff required to have outcome-based professional performance evaluations~~ ~~❑ All employees ❑ Full-time pharmacists ❑ Part-time pharmacists ❑ Other~~	
~~Self-audit includes:~~	
~~❑ Number of overridden drug-drug interaction warnings~~	
~~❑ Number of patients that received duplicative drug therapy~~	
~~❑ Number of patients that received extensive counseling~~	
~~❑ Number of QREs tracked over time. Indicate time period~~	

~~QRE Incidents~~

~~Utilizing QRE Data Collection Sheets, compile the data below.~~

~~Date~~								
~~QRE type (eg, A(1) = incorrect drug dispensed)~~								
~~Drug name and strength~~								

~~Rx received via:~~								
~~New or refill~~								
~~Day of week/time~~								
~~RPh to tech ratio~~								
~~RPh staff status~~								
~~No. of hrs RPh on duty~~								
~~No. of other pharmacists on duty~~								
~~No. of other support staff~~								
~~Average No. of prescriptions/hour~~								
~~Responsible pharmacist's name~~								
~~Patient received Drug~~								
~~Prescriber notified~~								
~~Counseling offered~~								
~~Counseling accepted~~								