



## Report of the Committee on Law Enforcement/Legislation

### Members Present:

Reginald “Reggie” Dilliard (TN), *chair*; Robert Graves (NC); Sebastian Hamilton (MA); Tony King (MT); Debbie Mack (AR); Jeenu Phillip (FL); Shauna White (DC); Jenny Yoakum (TX) Gayle Ziegler (ND).

### Others Present:

Nicole “Nicki” Chopski, *Executive Committee liaison*; Carmen Catizone; Melissa Madigan; Eileen Lewalski; Maureen Schanck; and Romy Schafer, *NABP staff*.

### Introduction:

The committee met on January 14-15, 2020, at NABP Headquarters in Mount Prospect, IL.

### Review of the Committee Charge

Committee members reviewed their charge and accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy.
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

### Background and Discussion:

The committee reviewed and discussed the recommended amendments to the *Model State Pharmacy Act and the Model Rules of the National Association of Boards of Pharmacy (Model Act)* made by the Task Force on Requirements for Pharmacy Technician Education (TFPT Education) together with those made by the Task Force on Pharmacy Technician Competence Assessment (TFPT Comp Assess), as they included many of the same *Model Act* sections. Also taken into consideration during their review of these sections was the publication of the ASHP/ACPE Accreditation Standards for Pharmacy Technician Education and Training Programs.

Members agreed that NABP should recognize a higher level pharmacy technician, an “advanced level certified pharmacy technician” and, based on the discussions of prior task forces, developed a definition to be included in the Model Act, which included an advanced certification or training program requirement. Members agreed that such a designation would

increase technician scope of practice and provide a foundation for technician license portability. Removing language recommended by the TFPT Education that outlined the allowable duties, the committee opined that duties need to be commensurate with education and experience.

The members also recognized the need to add a definition and licensing requirements for “ancillary pharmacy staff person,” which may include cashiers, clerks, bookkeepers, stock persons, and delivery personnel, to give the board authority over support staff not involved in the dispensing process. The committee was mindful not to burden boards with onerous requirements for registering ancillary staff; therefore, members removed the fingerprint-based criminal background check requirement recommended by the TFPT Education.

The committee also reviewed the definitions and licensing language addressing certified pharmacy technicians and certified pharmacy technician candidates. Members agreed with the TFPT Comp Assess to designate the credential/authorization issued by the states as “licensure” rather than “registration” to facilitate portability and to reflect the fact that the credential is one that requires the applicant to meet established standards.

After reviewing the language addressing licensure requirements for certified pharmacy technician candidates, and after much discussion, members found the requirement that a candidate have “successfully completed” a site-specific training program and have “successfully completed” an objective assessment mechanism to be problematic timewise, noting that if these activities have been completed, the candidate would actually be a full-fledged certified pharmacy technician and no longer a candidate. The committee, therefore, recommended that the language be changed to require candidates to be “enrolled” in a site-specific training program or a competency-based pharmacy technician education and training program that includes experiential training approved by the board. The committee also added language requiring certified pharmacy technician applicants to complete a minimum number of practice experience hours approved by the board. The committee also amended a footnote recognizing that ACPE and ASHP standards for pharmacy technician training programs have been developed. The committee also added a footnote contemplating that NABP will develop minimum standards for an entry-level pharmacy technician examination.

In reviewing the sections discussed above, the committee agreed to remove all references to “good moral character” and “gross immorality” throughout the *Model Act* to reflect the fact that references to the terms were removed from the NABP Constitution and Bylaws in 2019.

Pursuant to the reference to “corresponding responsibility” in state laws and rules and federal regulations, the committee approved adding language to the Prescription Drug Order Processing section of the *Model Rules* stating that pharmacists have a corresponding responsibility, but added a footnote to clarify that such responsibility should not impede patients from receiving legitimately prescribed controlled or noncontrolled substances, as patient care should always be the primary consideration.

Members also amended the Pharmacy Care Services Prospective Drug Utilization Review section of the *Model Rules* to note that a prospective drug utilization review may include information obtained from reviewing data found in the state prescription monitoring program.

Lastly, the committee reviewed the Discipline article of the *Model Act* to address the legalization of medical and recreational marijuana in several states (while still classified as a Schedule I federally), as well as the federal legalization of hemp and subsequent growth in the availability of CBD. Members had an extensive discussion regarding the potential consequences of a licensee testing positive for THC, when that licensee had unknowingly ingested a substance that contained THC, or had, under state law, “legally” used medical or recreational marijuana. Also discussed was the potential risk to patient safety in such a situation. Ultimately the committee agreed to add footnotes instructing boards to consider the issue of impairment if a registrant or licensee tests positive for a substance of misuse and/or abuse, as well as to consider state and federal law, including any discrepancies between them, when evaluating a complaint related to a positive result on a cannabinoid drug test. One of the footnotes also noted that complaints of this nature should be assessed on a case-by-case basis.

The revisions recommended by the task forces and identified in other agenda items are denoted by underlines and ~~strikethroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double strikethroughs~~.

## National Association of Boards of Pharmacy Model State Pharmacy Act

### Article I

#### Title, Purpose, and Definitions

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#### Section 105. Definitions.

- (e) “Advanced Level Certified Pharmacy Technician” means personnel who have met the requirements registered for licensure with the Board as a Certified Pharmacy Technician and who have completed an advanced certification or training program approved by the Board. who have completed a nationally accredited education and training program and obtained national certification or have completed educational or training requirements for advanced practice certification and may, under the supervision of a Pharmacist, perform all activities a licensed Pharmacist may legally perform, except the following:
- ~~(1) Drug utilization review (DUR);~~
  - ~~(2) Clinical conflict resolution;~~
  - ~~(3) Prescriber contact concerning prescription drug order clarification or therapy modification; and~~
  - ~~(4) Patient counseling.~~
- (f) “Ancillary Pharmacy Staff Person” means pharmacy support staff person who is not involved in the Dispensing process but may serve as support staff and may enter the licensed dispensing area. This role may include, but is not limited to, cashier, clerk, bookkeeper, stock person, and delivery personnel.

- (g) “Certified Pharmacy Technician”<sup>1</sup> means personnel ~~registered~~ licensed with the Board who have completed a certification program approved by the Board and may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as:
- (1) receiving new written or electronic Prescription Drug Orders;
  - (2) prescription transfer;
  - (3) Compounding; and
  - (4) assisting in the Dispensing process; and
  - (5) performing all functions allowed to be performed by pharmacy technicians
- but excluding:
- (1) Drug Utilization Review (DUR);
  - (2) clinical conflict resolution;
  - (3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
  - (4) Patient Counseling; and
  - (5) Dispensing process validation.
- (h) “Certified Pharmacy Technician Candidate” means personnel ~~registered~~ licensed with the Board who intend to complete a certification program approved by the Board and may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as:
- (1) assisting in the Dispensing process;
  - (2) processing of medical coverage claims;
  - (3) stocking of medications; and
  - (4) cashiering
- but excluding:
- (1) Drug Utilization Review (DUR)
  - (2) clinical conflict resolution;
  - (3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
  - (4) Patient Counseling;
  - (5) Dispensing process validation;
  - (6) prescription transfer; and
  - (7) Receipt of new oral Prescription Drug Orders.

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<sup>1</sup> The *Model Act* defines Certified Pharmacy Technician and Certified Pharmacy Technician Candidate separately to distinguish between the activities that can be performed. A Certified Pharmacy Technician is recognized, because of the completion of a Board-approved certification program, as having knowledge and skills that qualify them to assist the Pharmacist in the Practice of Pharmacy with limited patient care tasks that exceed routine Dispensing or Drug storage activities. Certified Pharmacy Technician Candidates are limited to routine Dispensing activities, Drug storage, medical coverage claims processing, and cashiering.

## Article III

### Licensing

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#### 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) 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.<sup>2</sup>
  - (1) Licensed Pharmacies located outside this State that provide Pharmacist Care Services to individuals in this State must be licensed within this State under Article V of this Act.
  - (2) 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.  
  
(See comment list.)
- (d) It shall be unlawful for any individual to perform the activities of a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate unless currently ~~registered~~ licensed to do so under the provisions of this Act.

#### Section 302. Qualifications for 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) ~~be of good moral character;~~
  - (4) have graduated and received the first professional degree from a college or school of Pharmacy that has been approved by the Board of Pharmacy;<sup>3</sup>
  - (5) have graduated from a foreign college of Pharmacy, 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

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<sup>2</sup> 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.

<sup>3</sup> It is contemplated that Boards will approve those programs whose standards are at least equivalent to the standards required by the ACPE. This would include college-structured pharmacy practice experience programs and continuing education programs. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

Pharmacy regulations so that it is ensured that the applicant meets standards necessary to protect public health and safety;<sup>4</sup>

- (6) 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 that experience in the Practice of Pharmacy which meets or exceeds the minimum Pharmacy practice experience requirements of the Board;
- (7) have successfully passed an examination or examinations approved by the Board of Pharmacy;
- (8) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and
- (9) 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 administered by an NABP contracted testing provider. If applicable, state-specific compounding examinations shall be administered by the Board. NABP will determine the content and subject matter of the pharmacy practice examination 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. NABP 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.<sup>5</sup>

- (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.<sup>6</sup>

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<sup>4</sup> 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<sup>®</sup> (FPGEE<sup>®</sup>) as part of their assessment of pharmacy education equivalence.

<sup>5</sup> As college-based Pharmacy practice experience programs become uniform under the most recent revision of the ACPE *Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (effective July 1, 2007), and when boards of pharmacy are convinced that schools and colleges of pharmacy are meeting these Accreditation Standards and Guidelines 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.

<sup>6</sup> 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 Accreditation Standards and Guidelines 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

- (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.<sup>7</sup>

### **Section 303. Qualifications for Licensure Transfer.<sup>8</sup>**

- (a) In order for a Pharmacist currently licensed in another jurisdiction to obtain a license as a Pharmacist by license transfer in this State, an applicant shall:<sup>9</sup>
  - (1) have submitted an application in the form prescribed by the Board of Pharmacy;
  - (2) have attained the age of majority;
  - (3) ~~have good moral character;~~
  - (4) 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;
  - (5) 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 previous to the date of such application;
  - (6) have presented to the Board proof of initial licensure by examination and proof that such license is in good standing;
  - (7) 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
  - (8) have paid the fees specified by the Board.
- (b) No applicant shall be eligible for license 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.<sup>10</sup>

### **Section 304. Renewal of Licenses and Registrations.**

- (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

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the ACPE Accreditation Standards and Guidelines result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

<sup>7</sup> Boards of Pharmacy are strongly encouraged to utilize the ACPE Accreditation Standards and Guidelines as a basis for establishment and revision of Board standards for Pharmacy practice experiences. These Accreditation Standards and Guidelines also contain additional guidance on the desired behaviors, qualities, and values of preceptors.

<sup>8</sup> 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.

<sup>9</sup> It is intended that NABP's National Disciplinary Clearinghouse would be utilized by state Boards for verifying information provided by applicants.

<sup>10</sup> Endorsement states may wish to consider the removal of Subparagraph (b) in this Section.

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) Certified Pharmacy Technician Candidates must complete requirements for Certified Pharmacy Technician licensure/~~registration~~ within 12 months. For good cause shown, the Board may approve one 12-month extension.

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### **Section 306. Registration of Ancillary Pharmacy Staff Persons.**

- (a) In order to be registered as an Ancillary Pharmacy Staff Person in this State, an applicant shall:
  - (1) have submitted an application in the form prescribed by the Board of Pharmacy;
  - (2) have attained the age of \_\_\_\_\_;
  - ~~(3) have good moral character;~~
  - ~~(4) have undergone a state and federal fingerprint based criminal background check as specified by Board rule; and~~
  - (5) have paid the fees, if specified, by the Board.
- (b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as an Ancillary Pharmacy Staff Person.<sup>11</sup>
- (c) The Board of Pharmacy shall, by rule, establish requirements for registration of Ancillary Pharmacy Staff Persons.

### **Section 307. ~~Registration~~ Licensure of Certified Pharmacy Technicians.**

- (a) In order to be ~~registered~~ licensed as a Certified Pharmacy Technician in this State, an applicant shall:<sup>12</sup>
  - (1) have submitted an application in the form prescribed by the Board of Pharmacy;
  - (2) have attained the age of \_\_\_\_\_;

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<sup>11</sup> The Board may specifically authorize a pharmacist whose license has been disciplined to register as an Ancillary Pharmacy Staff Person, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate under terms and conditions deemed appropriate.

<sup>12</sup> In 2015, the *Model State Pharmacy Act and Model Rules* was amended to require persons seeking to become Certified Pharmacy Technicians to complete each of the requirements outlined in Sections 307(a)(5)(i), 307(a)(5)(ii), and 307(a)(6).



- (3) ~~have good moral character;~~
- (4) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;
- (5) have<sup>13</sup>:
  - (i) ~~passed a nationally recognized, psychometrically validated examination that has been recognized by NABP as an examination that includes testing on NABP's recognized entry-level pharmacy technician practice standards; and graduated from a site-specific training program or a competency-based pharmacy technician education and training program that includes experiential training approved by the Board of Pharmacy;~~<sup>14, 15</sup>
  - (ii) ~~been documented by the Pharmacist in Charge of the Pharmacy where the applicant is employed as having successfully completed a minimum number of pharmacy technician practice experience hours site-specific, competency-based education and training program approved by the Board of Pharmacy; OR completed a nationally accredited, competency-based education and training program approved by the Board of Pharmacy;~~
- (6) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;<sup>16</sup>
- (7) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and
- (8) 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 registration.
- (b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be licensed ~~registered~~ as a Certified Pharmacy Technician.<sup>17</sup>
- (c) The Board of Pharmacy shall, by rule, establish requirements for licensure registration of Certified Pharmacy Technicians.

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<sup>13</sup> 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 Certified Pharmacy Technician Candidate Certification Board examination as part of their assessment of technician competence to assist in the practice of pharmacy.

<sup>14</sup> It is recommended that states adopt this requirement, if not currently required, through a process that incorporates provisions for grandfathering.

<sup>15</sup> It is contemplated that Boards will approve those Certified pharmacy technician Candidate training programs whose standards are at least equivalent to the minimum standards ~~being~~ developed by an accrediting organization recognized by state Boards, such as ACPE and ASHP. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

<sup>16</sup> It is contemplated that NABP will develop minimum standards for an entry-level pharmacy technician examination.

<sup>17</sup> The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician, ~~or~~ Certified Pharmacy Technician Candidate, or Ancillary Pharmacy Staff Person under terms and conditions deemed appropriate.

### **Section 308. ~~Registration~~ Licensure of Certified Pharmacy Technician Candidates.**

- (a) In order to be ~~registered~~ licensed as a Certified Pharmacy Technician Candidate in this State, an applicant shall:
- (1) have submitted an application in the form prescribed by the Board of Pharmacy;
  - (2) have attained the age of \_\_\_\_\_;
  - (3) ~~have good moral character;~~
  - (4) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;
  - (5) have paid the fees specified by the Board; and
  - (6) have enrolled in a site-specific training program or a competency-based pharmacy technician education and training program that includes experiential training approved by the Board of Pharmacy that includes ~~have been documented by the Pharmacist in Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific training program and having successfully completed~~ an objective assessment mechanism prepared in accordance with any rules established by the Board.
- (b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be ~~registered~~ licensed as a Certified Pharmacy Technician Candidate.<sup>18</sup>
- (c) The Board of Pharmacy shall, by rule, establish requirements for ~~registration~~ licensure of Certified Pharmacy Technician Candidates.

### **Section 309. ~~Registration~~ Licensure of Advanced Level Certified Pharmacy Technicians.**

- (a) ~~In order to be registered~~ In order to be licensed as an Advanced Level Certified Pharmacy Technician in this State, an applicant shall:
- (1) have met the requirements ~~be licensed for licensure~~ with the Board of Pharmacy as a Certified Pharmacy Technician; and ~~have submitted an application in the form prescribed by the Board of Pharmacy;~~
  - (2) ~~have attained the age of \_\_\_\_\_;~~
  - (3) ~~have good moral character;~~
  - (4) ~~have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;~~
  - (5) ~~have paid the fees specified by the Board; and~~
  - (6) have completed an advanced certification or training program approved by the Board of Pharmacy. ~~have completed a nationally accredited education and training program and obtained national certification or have completed educational or training requirements for advanced practice certification.~~

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<sup>18</sup> The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate, or Ancillary Pharmacy Staff Person under terms and conditions deemed appropriate.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be ~~registered~~ licensed as an Advanced Level Certified Pharmacy Technician.<sup>19</sup>

(c) The Board of Pharmacy shall, by rule, establish requirements for ~~registered~~ licensure of Advanced Level Certified Pharmacy Technicians.

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## Article IV Discipline

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### Section 401. 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.<sup>20</sup>

### Section 402. Grounds, Penalties, and Reinstatement.<sup>21</sup>

(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 Person Pursuant to the procedures set forth in Section 403 herein below, upon one or more of the following grounds:

(1) unprofessional conduct as that term is defined by the rules of the Board;<sup>22</sup>

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<sup>19</sup> The Board may specifically authorize a pharmacist whose license has been disciplined to register as an Advanced Level Certified Pharmacy, Technician, Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or an Ancillary Pharmacy Staff Person under terms and conditions deemed appropriate.

<sup>20</sup> Guidelines for the imposition of sanctions for certain designated offenses can be found in Appendix C: Guidelines for Disciplinary Sanctions of the *Model Act*.

<sup>21</sup> 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.

<sup>22</sup> It is particularly important to emphasize the need for specificity in defining the grounds upon which a Pharmacist's or Pharmacy Intern's license to practice Pharmacy, or a Certified Pharmacy Technician's or Certified Pharmacy Technician Candidate's registration to assist in the Practice of Pharmacy, may be Revoked or Suspended. The term "unprofessional conduct" is particularly susceptible to judicial challenge for being unconstitutionally vague. Each offense included within the meaning of this term must be capable of being understood with reasonable precision by the Persons regulated so that it can be readily enforced and relied upon during disciplinary proceedings, and so that those regulated by it may easily conform their professional conduct to its meaning(s).

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

This section must be examined in light of other state laws since some states, for example, restrict the circumstances under which a license may be denied to an individual because of the commission of a felony. In addition, an individual who has been convicted of a felony ~~or an act involving gross immorality~~ and who has paid his debt to society has restored constitutional protections that may curtail a strict application of Section 402(a)(3).

- (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;<sup>23</sup>
- (3) being guilty of one (1) or more of the following:
  - (i) a felony;
  - (ii) ~~any act involving moral turpitude or gross immorality;~~ or
  - (iii) 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;<sup>24</sup>
- (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 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 having registered with the Board of Pharmacy; or falsely using the title of Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate;

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<sup>23</sup> Boards need to consider the issue of impairment if a registrant or licensee tests positive for a substance of misuse and/or abuse.

<sup>24</sup> 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.

- (13) requiring Pharmacy personnel to meet production and/or performance metrics and/or quotas that negatively impact patient safety.<sup>25</sup>
- (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;<sup>26</sup>
- (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) failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.

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## National Association of Boards of Pharmacy Model Rules

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### Model Rules for the Practice of Pharmacy

#### Introductory Comment

*The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care Services, the following rules are essential.*

#### Section 1. Facility.

- (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;
  - (3) ~~be of good moral character;~~ and

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<sup>25</sup> This is not intended to include performance metrics that may be related to the ability and competency of Pharmacy personnel.

<sup>26</sup> 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.

- (4) 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) Possess the following minimum requirements for a Pharmacy:
- (1) Each 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) Each 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) Each Pharmacy shall have ready access to references, to include at least one current reference<sup>27</sup> in each of the following 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<sup>28</sup>; and
    - (v) general.
  - (4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.<sup>29</sup>
  - (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.
  - (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 Pharmacopoeia–National Formulary (USP-NF) and/or the Manufacturer’s or Distributor’s Product Labeling unless otherwise indicated by the Board.
  - (7) Each 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) Equipment/Supplies.  
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.

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<sup>27</sup> Boards may wish to give examples in each of these categories of reference texts.

<sup>28</sup> Such as Plumb’s Veterinary Drug Handbook.

<sup>29</sup> Patient-oriented reference material can include publications such as Facts and Comparisons’ Patient Drug Facts, or the United States Pharmacopoeia Dispensing Information (USPDI).

- (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) The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board.
- (e) Upon renewal, the licensee shall provide to the Board the NABP e-Profile ID of the Pharmacy and the Pharmacist-in-Charge.

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#### **Section 4. Prescription Drug Order Processing.**

- (a) Prescription Drug Order  
A Prescription Drug Order shall contain the following information at a minimum:
  - (1) full name, date of birth, and street address of the patient;
  - (2) name, prescribing Practitioner's license designation, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;
  - (3) date of issuance;
  - (4) name, strength, dosage form, and quantity of Drug prescribed;
  - (5) directions for use;
  - (6) refills authorized, if any;
  - (7) if a written Prescription Drug Order, prescribing Practitioner's signature;
  - (8) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;
  - (9) if a hard copy Prescription Drug Order generated from electronic media, prescribing Practitioner's electronic or manual signature. For those with electronic signatures, such Prescription Drug Orders shall be applied to paper that utilizes security features<sup>30</sup> that will ensure the Prescription Drug Order is not subject to any form of copying and/or alteration.
- (b) Manner of Issuance of a Prescription Drug Order  
A Prescription Drug Order, to be valid, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice. The responsibility for the proper prescribing and Dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the Pharmacist who fills the Prescription.<sup>31</sup>
  - (1) A Prescription Drug Order must be communicated to a Pharmacist, or when recorded in such a way that the Pharmacist may review the Prescription Drug Order as transmitted, to a Pharmacy Intern or a Certified Pharmacy Technician, in a licensed Pharmacy. This may be accomplished in one of the following ways. A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in

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<sup>30</sup> Examples of security features for prescription paper include those that prevent copying, such as hidden background words or darker-colored areas of the paper (which, when photocopied appear as black), those that prevent adulteration, such as solvent dye and brownstain features, and those that verify authenticity, such as the incorporation of fluorescent threads or watermarks.

<sup>31</sup> While Pharmacists have a corresponding responsibility to ensure that a controlled substance be Dispensed only pursuant to a valid Prescription Drug Order written for a legitimate medical purpose, it should not impede patients from receiving legitimately prescribed controlled substances or noncontrolled substances, as patient care should be the primary consideration.

written form. A Prescription Drug Order, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication)<sup>32</sup> or issued electronically.<sup>33</sup>

- (2) The Pharmacist shall not dispense a Prescription Drug if the Pharmacist knows or reasonably should know that the Prescription Drug Order was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid Patient-Practitioner relationship.
- (3) If communicated orally, the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist, the Pharmacy Intern, or Certified Pharmacy Technician that may be maintained for the time required by laws or rules.

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### **Section 6. Pharmacist Care Services.**<sup>34</sup>

(a) Prospective Drug Utilization Review (DUR)<sup>35</sup>

A Pharmacist shall obtain and review the patient records and medical history for each Prescription Drug Order for:

- (1) known allergies;
- (2) rational therapy contraindications;
- (3) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
- (4) reasonable directions for use;
- (5) potential or actual adverse Drug reactions;
- (6) Drug-Drug interactions;
- (7) Drug-food interactions;
- (8) Drug-disease contraindications;
- (9) therapeutic duplication;
- (10) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
- (11) abuse/misuse.

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<sup>32</sup> Policies and procedures should also provide guidance for properly identifying agents of the prescribing Practitioner who are trained and competent in communicating Prescription Drug Orders.

<sup>33</sup> Electronically transmitted prescriptions should be transmitted from prescriber to Pharmacy with no intervening Persons making illegal alterations that may be considered as engaging in the Practice of Pharmacy without the authority to do so or without being Licensed to do so to such prescriptions. Evolving technologies and systems have alleviated previous concerns regarding the routes by which electronic prescriptions are transmitted, but any attempts to return to illegal prescription altering practices will be halted.

<sup>34</sup> Additional Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Administering Drugs, vaccines, or biologicals; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan /practice guidelines; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering lab tests; and performing lab tests as provided by State and Federal law.

<sup>35</sup> Pharmacists should be permitted to use computer software, if available, to accomplish this review.



Upon recognizing any of the above, which may also include information obtained from reviewing data found in the prescription monitoring program, the Pharmacist shall take appropriate steps to avoid or resolve the problem which ~~shall~~, if necessary, includes consultation with the Practitioner.

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