



**NABP**

National Association of  
Boards of Pharmacy

*Report of the Overview Task Force on*

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**PHARMACY TECHNICIAN EDUCATION, PRACTICE  
RESPONSIBILITIES, AND COMPETENCE ASSESSMENT**

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### Members Present:

Malcolm Broussard (LA), *chair*; Cindy Fain (AR), Jacqueline “Jackie” Hall (LA), Kristina Jonas (ID), Franklin “Rocky” LaDien (WI), Julie Lanza (MA), Ed McGinley (NJ), Helen Pervanas (NH), Jeenu Philip (FL), Kari Shanard-Koenders (SD), Kristen Snair (AZ), Mitchell “Mitch” Sobel (NJ), Julienne Tran (MA).

### Others Present:

Brad Hamilton, *Executive Committee liaison*; Al Carter, Melissa Madigan, Eileen Lewalski, Maureen Schanck, Cameron Orr, Andrea Busch, *NABP staff*.

### Introduction:

The task force met virtually on December 1, 2020. This is the fifth task force established pursuant to Resolution 115-4-19, Task Force on Requirements for Technician Education, Practice Responsibilities, and Competence Assessment, which was approved by the NABP membership at the Association’s 115<sup>th</sup> Annual Meeting in May 2019.

### Review of the Task Force Charge:

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

1. Review the reports of the Task Force on Requirements for Pharmacy Technician Education, Task Force on Pharmacy Technician Competence Assessment, and Task Force on Pharmacy Technician Practice Responsibilities.
2. Synthesize these task forces’ recommendations into one consolidated set of recommendations.
3. Examine the language in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* addressing all aspects of pharmacy technician regulation and recommend amendments, if necessary, that support technician education, competence assessment, and practice, all in the best interest of patient care.

### Background and Discussion:

The task force members began their discussion by reviewing their charge and reviewing the reports of the first Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment; the Task Force on Pharmacy Technician Education (Education TF); the Task Force on Pharmacy Technician Competence Assessment (Competence TF); the Task Force on Pharmacy Technician Practice Responsibilities (Responsibilities TF); as well as the 2020 Report of the Committee on Law Enforcement/Legislation (LE/L). To accomplish their charge, the members focused on each of the task force’s recommendations, discussing them at length in order to synthesize them into one consolidated set of recommendations, and reviewed the language in the *Model State*



*Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* that addressed all aspects of pharmacy technician regulation, as revised by these groups. As there was a tremendous amount of information that needed to be synthesized, the task force agreed to examine the previous task forces' recommendations independently and then consider all the recommendations in toto to determine whether any duplications, contradictions, or non-actionable items existed prior to making their final recommendations.

The task force reviewed the Education TF and Competence TF recommendations and discussed the career progression and time frame for the levels of pharmacy technicians – from applying as a candidate to becoming certified to earning an advanced certification, including what role education and training played in this progression. Members agreed that it was crucial to require candidates to complete an accredited education and training program to increase standardization across the country and reiterated the previous task forces' conclusions that the training component must be site-specific, as that is essential for a candidate to become competent and to further progress and become certified. Members recognized that the current certification examinations measure knowledge, but not necessarily competence, noting that it is difficult to measure the competence of a certified pharmacy technician candidate, especially if it is being measured through his or her first job. It was further noted that a didactic component is extremely important for these individuals, in addition to site-specific training, for honing their skill sets.

Upon further review of the recommendations of the Education TF, the task force questioned whether it was feasible to encourage state boards of pharmacy to license or register ancillary personnel, including cashiers, clerks, and delivery drivers. Members extensively discussed this issue, noting that it would be a “heavy lift” for boards of pharmacy to implement and could possibly result in Federal Trade Commission challenges for creating barriers to employment. The task force was informed that concern regarding diversion was the main reason for this recommendation and, while members agreed that this is certainly problematic, internal controls in the pharmacy, such as restricting ancillary staff access to drugs, could provide more achievable solutions than requiring registration. As such, the task force agreed that NABP should not encourage boards to register ancillary personnel and that a definition for “ancillary pharmacy staff person” and associated registration requirements should not be added to the *Model Act*. However, members did agree that in furtherance of public protection, NABP should continue to encourage state boards of pharmacy to license all certified pharmacy technician candidates and certified pharmacy technicians and to maintain the definitions of both terms as revised by the previous task forces and LE/L.

Members also discussed the addition to the Model Act of an advanced, third tier of pharmacy technicians. They agreed with the addition of a definition and licensing process for “Advanced Level Certified Pharmacy Technician,” recognizing that these were recommended by the



Education TF, subsequently amended by LE/L, and then amended again by the Responsibility TF. In alignment with the recommendations of these groups, the task force further added language to the definition to emphasize that these individuals should be allowed to perform duties within their scope of advanced certification and as assigned by the pharmacist, but should not perform any clinical patient care activities. After further discussion, the task force concurred that the footnote regarding prohibiting any delegation that is directed by a corporate policy or rubric should be removed, as it was deemed to be an employer issue rather than for board of pharmacy oversight. However, because there was a concern that corporate policy could infringe on a pharmacist's professional judgment regarding oversight of any level of pharmacy technician or pharmacy interns, the task force supported the concept that pharmacists should be knowledgeable about an individual's abilities and trust his or her capabilities before delegating tasks.

Regarding the existing technician certification examinations, members questioned whether one of the Competence TF recommendations was requesting that NABP develop a new entry-level examination or conduct a gap analysis of the current examinations. Members echoed the task force's support for NABP developing and/or recognizing minimum standards for an entry-level pharmacy technician examination, and discussed the importance of accreditation standards for educational programs in providing uniformity among states. After in-depth discussion regarding the current certification examinations and the accreditation standards for education and training programs, the task force agreed that it was not necessary for NABP to perform a gap analysis on the examinations or for NABP to develop an additional examination, but that NABP should perform a gap analysis of accreditation standards for pharmacy technician education programs with the goal of recommending accreditation standards that encompass future growth of pharmacist and pharmacy technician scopes of practice, as recommended by the Education TF.

Lastly, the task force discussed the issue of remote practice and shared services, particularly considering the COVID-19 pandemic, and agreed that relevant *Model Act* language that restricts or prohibits these types of practices should be reviewed. Staff informed the members NABP will soon inventory all state board of pharmacy waivers and practice allowances recently implemented during the public health emergency and determine which ones, if any, can safely remain in effect. A corresponding review of the Model Act will also take place to determine if any language needs to be added, removed, or qualified in light of this analysis.

After careful review and deliberation, the task force recommended:

1. NABP encourage state boards of pharmacy to recognize, as a best practice, pharmacy technician education that includes a didactic curriculum from an accredited provider and experiential training for all levels of pharmacy technicians.
2. NABP encourage state boards of pharmacy to license all certified pharmacy technician candidates and certified pharmacy technicians. On the other hand, NABP should not

encourage boards to register other ancillary personnel, such as cashiers, clerks, or delivery drivers.

3. NABP perform a gap analysis of accreditation standards for pharmacy technician educational programs.
4. NABP retain and/or amend *Model Act* language accordingly:
  - a. Retain the definitions and licensure requirements for “Certified Pharmacy Technician” and “Certified Pharmacy Technician Candidate” as amended by the previous technician task forces.
  - b. Include a definition for “Advanced Level Certified Pharmacy Technician” as recommended by the previous technician task forces, as well as the LE/L, to include language that allows these individuals to perform duties within their scope of advanced certification and as assigned by the pharmacist, but that exclude any clinical patient care activities. Additionally, the language should include the caveats that the pharmacist must be knowledgeable of the individual’s abilities and trust his or her capabilities; however, the footnote regarding prohibiting any delegation that is directed by a corporate policy or rubric should be removed.
  - c. Remove the definition and registration requirements for “Ancillary Pharmacy Staff Person.”
5. NABP review *Model Act* language that prohibits remote practice and consider removing or qualifying other provisions that have been recently amended or waived due to the COVID-19 pandemic.

**Note: The revisions recommended by the Responsibilities TF are denoted by underlines and strikethroughs. The recommended revisions by this task force are denoted by double underlines and double strikethroughs.**



# National Association of Boards of Pharmacy Model State Pharmacy Act

## Article I

### Title, Purpose, and Definitions

#### Section 105. Definitions.

(e) “Advanced Level Certified Pharmacy Technician” means personnel who have met the requirements for licensure with the Board as a Certified Pharmacy Technician and who have completed an advanced certification or training program approved by the Board, and under the supervision of a Pharmacist, may perform certain activities involved in the Practice of Pharmacy that are within his or her scope of advanced certification and as assigned by the Pharmacist, but excluding clinical patient care activities such as, but not limited to, patient counseling or Drug Utilization Review.<sup>‡</sup>

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~~(g) “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.~~

(n) “Certified Pharmacy Technician”<sup>2</sup> means personnel 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

<sup>‡</sup> ~~It is contemplated that the Pharmacist will make the sole determination based on an individual’s abilities and competence in deciding which responsibilities they feel comfortable delegating to that individual and not based on any type of corporate directive or rubric.~~

<sup>2</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.

but excluding:

- (1) Drug Utilization Review (DUR);
- (2) clinical conflict resolution;
- (3) prescriber contact concerning Prescription Drug Order clarification or therapy modification; and
- (4) Patient Counseling; ~~and~~
- ~~(5) Dispensing process validation.~~

(o) “Certified Pharmacy Technician Candidate means personnel 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:

- a. assisting in the Dispensing process;
- b. processing of medical coverage claims;
- c. stocking of medications; and
- d. cashiering

but excluding:

- (1) Drug Utilization Review (DUR)
- (2) clinical conflict resolution;
- (3) prescriber contact concerning Prescription Drug Order clarification or therapy modification; and
- (4) Patient Counseling;
- ~~(5) Dispensing process validation;~~
- ~~(6) prescription transfer; and~~
- ~~(7) Receipt of new oral Prescription Drug Orders.~~

...

(r) “Remote Dispensing Site” means a location, other than where a pharmacist is located, where Drugs are maintained and prescriptions are filled by an Advanced Level Certified Pharmacy Technician or Certified Pharmacy Technician and dispensed under the direct, remote supervision of a Pharmacist.

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## 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 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 302[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 303).*

#### 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>3</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

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<sup>3</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.



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 an Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate unless currently licensed to do so under the provisions of this Act.

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

- (a) Each Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, 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) Certified Pharmacy Technician Candidates must complete requirements for Certified Pharmacy Technician licensure within 12 months. For good cause shown, the Board may approve one 12-month extension.

#### **Section 305. 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 continued competence.

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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 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>4</sup>~~
- ~~(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Ancillary Pharmacy Staff Persons.~~

**Section 307. Licensure of Certified Pharmacy Technicians.**

- (a) In order to be licensed as a Certified Pharmacy Technician in this State, an applicant shall:<sup>5</sup>
  - (1) have submitted an application in the form prescribed by the Board of Pharmacy;
  - (2) have attained the age of \_\_\_\_\_;
  - (3) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;
  - (4) have<sup>6</sup>:
    - (i) 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>7</sup>

~~<sup>4</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, or Advanced Level Certified Pharmacy Technician under terms and conditions deemed appropriate.~~

<sup>5</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).

<sup>6</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>7</sup> It is recommended that states adopt this requirement, if not currently required, through a process that incorporates provisions for grandfathering.

- (ii) completed a minimum number of pharmacy technician practice experience hours approved by the Board of Pharmacy;<sup>8</sup>
  - (5) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;
  - (6) have undergone a state and federal fingerprint-based criminal background check as specified by 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) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be licensed as a Certified Pharmacy Technician.<sup>9</sup>
- (c) The Board of Pharmacy shall, by rule, establish requirements for licensure of Certified Pharmacy Technicians.

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

- (a) In order to be 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 undergone a state and federal fingerprint-based criminal background check as specified by Board rule;
  - (4) have paid the fees specified by the Board; and
  - (5) 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 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 licensed as a Certified Pharmacy Technician.<sup>10</sup>

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<sup>8</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 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>9</sup> The Board may specifically authorize a pharmacist whose license has been disciplined to ~~register~~ obtain licensure as an Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate under terms and conditions deemed appropriate.

<sup>10</sup> The Board may specifically authorize a pharmacist whose license has been disciplined to ~~register~~ obtain licensure as an Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate, ~~or Ancillary Pharmacy Staff Person~~ under terms and conditions deemed appropriate.

- (c) The Board of Pharmacy shall, by rule, establish requirements for licensure of Certified Pharmacy Technicians.

**Section 309. Licensure of Advanced Level Certified Pharmacy Technicians.**

- (a) In order to be licensed as an Advanced Level Certified Pharmacy Technician in this State, an applicant shall:
  - (1) have met the requirements for licensure with the Board of Pharmacy as a Certified Pharmacy Technician; and
  - (2) have completed an advanced certification or training program approved by the Board of Pharmacy.
- (b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be licensed as an Advanced Level Certified Pharmacy Technician.<sup>11</sup>
- (c) The Board of Pharmacy shall, by rule, establish requirements for licensure of Advanced Level Certified Pharmacy Technicians

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## Article IV

### Discipline

#### Introductory Comment to Article IV

*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, Advanced Level Certified Pharmacy Technicians, Certified Pharmacy Technicians, or Certified Pharmacy Technician Candidates, ~~or Ancillary Pharmacy Staff Persons~~ who 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 IV. 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-*

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

*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 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>12</sup>

### **Section 402. Grounds, Penalties, and Reinstatement.<sup>13</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>14</sup>
  - (2) incapacity that prevents a licensee from engaging in the Practice of Pharmacy or a ~~registrant~~ registrant from assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public;<sup>15</sup>

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<sup>12</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>13</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>14</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~~ license to assist in the Practice of Pharmacy, may be Revoked or Suspended. The term “unprofessional conduct” is particularly susceptible to judicial challenge for being unconstitutionally vague. Each offense included within the meaning of this term must be capable of being understood with reasonable precision by the Persons regulated so that it can be readily enforced and relied upon during disciplinary proceedings, and so that those regulated by it may easily conform their professional conduct to its meaning(s).

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

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

<sup>15</sup> Boards need to consider the issue of impairment if a registrant or licensee tests positive for a substance of misuse and/or abuse.

- (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;<sup>16</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 an Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate, ~~or Ancillary Pharmacy Staff Person~~, 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;

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<sup>16</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.

- (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 being licensed or registered~~ with the Board of Pharmacy; or falsely using the title of Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, 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.<sup>17</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>18</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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#### **Section 403. Procedure.<sup>19</sup>**

- (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

<sup>17</sup> This is not intended to include performance metrics that may be related to the ability and competency of Pharmacy personnel.

<sup>18</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.

<sup>19</sup> 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.

that a Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate, ~~or Ancillary Pharmacy Staff Person~~ has violated a law or rule that the Board is empowered to enforce, and if continued practice by the Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate, ~~or Ancillary Pharmacy Staff Person~~ would create an imminent risk of harm to the public. The Suspension shall take effect upon written notice to the Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate, ~~or Ancillary Pharmacy Staff Person~~ 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, Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate, ~~or Ancillary Pharmacy Staff Person~~ shall be provided with at least 10 days notice of any hearing held under this subsection.

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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.*

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### Section 3. Personnel.

- (a) Duties and Responsibilities of the Pharmacist-in-Charge
- (1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. 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:<sup>20</sup>
  - (A) Policies and procedures addressing the following:
    - (-a-) the provision of Pharmacy services;<sup>21</sup>
    - (-b-) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and Drugs of Concern;
    - (-c-) computerized recordkeeping systems;
    - (-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;
    - (-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<sup>22</sup>;
    - (-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 Advanced Level Certified Pharmacy Technicians, 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. These policies and procedures

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<sup>20</sup> The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

<sup>21</sup> 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 medications, 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](http://www.fda.gov/cder/drug/shortages).

<sup>22</sup> States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications 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.

shall, at a minimum, specify that Advanced Level Certified Pharmacy Technicians, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Advanced Level Certified Pharmacy Technicians or Certified Pharmacy Technicians.

- (-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-) the PIC shall have policies and procedures in place that restrict and monitor 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.

...

(ii) Ensuring that:

- (A) all Pharmacists, ~~and Pharmacy Interns,~~ Advanced Level Certified Pharmacy Technicians, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates employed at the Pharmacy are currently licensed ~~and that all Ancillary Pharmacy Staff Persons are currently registered~~ with the Board of Pharmacy.

(iii) Notifying the Board of Pharmacy, immediately and in writing, of any of the following<sup>23</sup> changes:

- (A) change of employment or responsibility as the Pharmacist-in-Charge;
- (B) the separation of employment of any Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Certified Pharmacy Technician, ~~or Ancillary Pharmacy Staff Person~~ for any confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, or diversion, and shall include in

<sup>23</sup> 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.

- the notice the reason for the termination: if it is the employment of the Pharmacist-in-Charge that is 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 be 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, Advanced Level Certified Pharmacy Technicians, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates, ~~and Ancillary Pharmacy Staff Persons~~ 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 Advanced Level Certified Pharmacy Technicians, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates, ~~and Ancillary Pharmacy Staff Persons~~ assisting in the provision of Pharmacy services.
  - (ii) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain written policies and procedures to specify the duties to be performed by Advanced Level Certified Pharmacy Technicians, 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. These policies and procedures shall, at a minimum, specify that Advanced Level Certified Pharmacy Technicians, Certified Pharmacy Technicians, and Certified Pharmacy

Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technicians or Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Advanced Level Certified Pharmacy Technicians and that Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

- (iii) 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 registration with the Board.<sup>24</sup>

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

- (a) Prescription Drug Order

...

- (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>25</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,

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<sup>24</sup>All training programs should be subject to approval by the Board of Pharmacy.

<sup>25</sup> While Pharmacists have a corresponding responsibility to ensure that a controlled substance is Dispensed only pursuant to a valid Prescription Drug Order written for a legitimate medical purpose, this should not impede patients from receiving legitimately prescribed controlled substances or non-controlled substances, as patient care should be the primary consideration.

to a Pharmacy Intern, Advanced Level Certified Pharmacy Technician 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 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>26</sup> or issued electronically.<sup>27</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, Advanced Level Certified Pharmacy Technician, or Certified Pharmacy Technician that may be maintained for the time required by laws or rules.
- (4) A Prescription Drug Order for a Schedule II controlled substance may be communicated orally only in the following situations and/or with the following restrictions. Otherwise, a Prescription Drug Order for a Schedule II controlled substance must be communicated in written form or issued electronically.
  - (i) A Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner or the Practitioner's agent by way of Electronic Transmission, provided the original written, signed Prescription Drug Order is presented to the Pharmacist for review prior to the actual Dispensing of the controlled substance, except as noted in paragraph (ii) or (iii) of this Section 3(b)(3). The original, written Prescription Drug Order shall be maintained in accordance with state and federal recordkeeping requirements.
  - (ii) In the case of an Emergency Situation, a Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner orally, provided that:
    - (A) the quantity prescribed and Dispensed is limited to the amount adequate to treat the patient during the emergency period (Dispensing beyond the

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<sup>26</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>27</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.

- emergency period must be pursuant to a Prescription Drug Order either written and signed or electronically issued by the prescribing Practitioner);
- (B) the orally communicated Prescription Drug Order shall be immediately reduced to writing by the Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, or Certified Pharmacy Technician, if necessary, and shall contain the information required by state and federal law;
  - (C) if the prescribing Practitioner is not known to the Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, or Certified Pharmacy Technician, he or she must make a reasonable effort to determine that the oral authorization came from a registered Practitioner, which may include a callback to the Practitioner using the Practitioner's phone number as listed in the telephone directory and/or other good faith efforts to ensure his or her identity; and

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- (iii) The prescribing Practitioner may authorize his or her agent to communicate a Prescription Drug Order orally or by way of Electronic Transmission via facsimile to a Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, or Certified Pharmacy Technician in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order. In an Institutional Facility, the prescribing Practitioner's agent must be authorized by and in accordance with written policies and procedures of the Facility and applicable state and federal laws.

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- (7) All Prescription Drug Orders for a Schedule III-V controlled substance communicated by way of Electronic Transmission via facsimile shall:
  - (i) be transmitted to a Pharmacist, Pharmacy Intern, Advanced Level Certified Pharmacy Technician, or Certified Pharmacy Technician in a licensed Pharmacy of the patient's choice;
  - (ii) identify the transmitter's phone number or any other suitable means to contact the transmitter for verbal and/or written confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law;
  - (iii) be transmitted by an authorized Practitioner or his or her designated agent; and
  - (iv) be deemed the original Prescription Drug Order, provided it meets the requirements of this subsection.

...

(c) Transfer of a Prescription Drug Order

Pharmacies utilizing automated data-processing systems shall satisfy all information requirements of a manual mode for Prescription Drug Order transferal, except as noted below for those pharmacies accessing a common electronic file. The transfer of original Prescription Drug Order information for the purpose of refill Dispensing is permissible between Pharmacies subject to the following requirements:

- (1) The information for a prescription, other than for a controlled substance<sup>28</sup>, is communicated directly between Pharmacists, Advanced Level Certified Pharmacy Technicians, or Certified Pharmacy Technicians and the transferring Pharmacist, Advanced Level Certified Pharmacy Technician, or Certified Pharmacy Technician records the following information:
  - (i) write the word “VOID” on the face of the invalidated Prescription Drug Order;
  - (ii) record on the reverse side of the invalidated Prescription Drug Order the name and address of the Pharmacy to which it was transferred and the name of the Pharmacist or Certified Pharmacy Technician receiving the Prescription Drug Order;
  - (iii) record the date of the transfer and the name of the Pharmacist or Certified Pharmacy Technician transferring the information; and
  - (iv) the computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above.
- (2) The Pharmacist, Advanced Level Certified Pharmacy Technician, or Certified Pharmacy Technician receiving the transferred Prescription Drug Order information shall reduce to writing the following:
  - (i) Write the word “TRANSFER” on the face of the transferred Prescription Drug Order.
  - (ii) Provide all information required to be on a Prescription Drug Order pursuant to state and federal laws and rules, and include:
    - (A) date of issuance of original Prescription Drug Order;
    - (B) original number of refills authorized on original Prescription Drug Order;
    - (C) date of original Dispensing;
    - (D) number of valid refills remaining and date of last refill;
    - (E) Pharmacy’s name, address, and original prescription number from which the Prescription Drug Order information was transferred; and
    - (F) name of transferring Pharmacist or Certified Pharmacy Technician.
  - (iii) Systems providing for the electronic transfer of information shall not infringe on a patient’s freedom of choice as to the provider of Pharmacist Care Services.

<sup>28</sup> According to 21 CFR §1306.25 (b)(1), the transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing must be communicated directly between two licensed pharmacists.

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### **Section 5. Recordkeeping.**

(a) Patient Records<sup>29</sup>

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(b) Records of Dispensing/Delivery

(1) Records of receipt, Dispensing, Delivery, Distribution, or other disposition of all Drugs or Devices are to be made and kept by Pharmacies for five years<sup>30</sup> 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, Advanced Level Certified Pharmacy Technician, 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 medications 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 medication.<sup>31</sup>

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<sup>29</sup> 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.

<sup>30</sup> 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.

<sup>31</sup> States that require pharmacies that ship medication 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 medication 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.



**Section 6. Pharmacist Care Services.** <sup>32</sup>

- (a) **Prospective Drug Utilization Review (DUR)**<sup>33</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.

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, if necessary, includes consultation with the Practitioner.

- (b) **Patient Counseling**<sup>34</sup>
- (1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:
    - (i) the name and description of the Drug;

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<sup>32</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>33</sup> Pharmacists should be permitted to use computer software, if available, to accomplish this review.

<sup>34</sup> The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

- (ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
- (iii) intended use of the Drug and expected action;
- (iv) special directions and precautions for preparation, Administration, and use by the patient;
- (v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (vi) techniques for self-monitoring Drug therapy;
- (vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
- (viii) prescription refill information;
- (ix) action to be taken in the event of a missed dose; and
- (x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) An offer for Patient Counseling can be made by an Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate when not required by law or deemed necessary by the Pharmacist.

(2 3) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(34) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).

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

(c) Medication Adherence Monitoring Services and Intervention Programs

Medication Adherence Monitoring Services and Intervention Programs designed to promote improved medication use behaviors, such as compliance and adherence, appropriate monitoring and self-reporting, increased patient knowledge, and improved therapy options, shall comply with established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs. (See Appendix D for Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs.)

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## Section 8. Shared Pharmacy Services.

- (a) General Requirements<sup>35, 36</sup>
- (1) The Pharmacy must possess a resident or nonresident permit issued by the Board prior to engaging in Shared Pharmacy Services.<sup>37</sup>
  - (2) A Pharmacy may provide or utilize Shared Pharmacy Services only if the Pharmacies involved:
    - (i) have the same owner; or
    - (ii) have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy laws and rules; and
    - (iii) share a common electronic file or technology that allows access to information necessary or required to perform Shared Pharmacy Services in conformance with the pharmacy act and the Board’s rules.
  - (3) A Pharmacy engaged in Shared Pharmacy Services shall comply with appropriate federal and state controlled substance registrations for each Pharmacy if controlled substances are maintained.
  - (4) A Pharmacy engages in Shared Pharmacy Services shall notify the Board in writing within 10 days of a change of location, discontinuance of service, or closure of a Pharmacy.
- (b) Operations
- (1) Pharmacies engaging in Shared Pharmacy Services, or a Pharmacist acting independently of a Pharmacy and participating in Shared Pharmacy Services shall:
    - (i) maintain records identifying, individually, for each Prescription Drug Order processed, the name of each Pharmacist, or Pharmacy Intern who took part in the Drug Utilization Review, refill authorization, or therapeutic intervention functions performed at that Pharmacy and the name of any Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate if they assisted in any of those functions;

<sup>35</sup> The Board may want to consider the extent to which this General Requirements Section is applicable to institutional-based Shared Pharmacy Services Pharmacies, as such application may be subject to interpretation of existing state and federal law governing Institutional Facilities.

<sup>36</sup> In order to ensure accountability, the Pharmacist-in-Charge of a Pharmacy engaging in Shared Pharmacy Services must possess a license to practice Pharmacy in all jurisdictions that he/she is engaging in such series until such a time in which provisions for multistate practice exist.

<sup>37</sup> Often the terms “licensure,” “registration,” and “permit” are used interchangeably throughout the *Model Act*. In the case of Shared Pharmacy Services Pharmacies that utilize Automated Pharmacy Systems, Boards may determine that it is appropriate to issue a permit for the Automated Pharmacy System but not for the physical site where the Automated Pharmacy System is located.

- (ii) maintain records identifying individually, for each Prescription Drug Order filled or dispensed, the name of each Pharmacist or Pharmacy Intern who took part in the filling, dispensing, and counseling functions performed at that Pharmacy and the name of any Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate if they assisted in any of those functions;
    - (iii) report to the Board as soon as practical the results of any disciplinary action taken by another state's Board of Pharmacy involving Shared Pharmacy Services;
    - (iv) maintain a mechanism for tracking the Prescription Drug Order during each step of the processing and filling procedures performed at the Pharmacy;
    - (v) maintain a mechanism for the patient to identify all Pharmacies involved in filling the Prescription Drug Order; and
    - (vi) be able to obtain for inspection any required record or information within 72 hours of any request by the Board or its designee.
  - (2) Notification to Patients
    - (i) Pharmacies engaging in Shared Pharmacy Services shall notify patients that their Prescription Drug Orders may be processed or filled by another Pharmacy unless the Prescription Drug is delivered to patients in Institutional Facilities where a licensed health care professional is responsible for administering the Prescription Drug to the patient.
- (c) Drug Storage and Security
  - (1) Drugs shall be stored in compliance with state and federal laws and in accordance with these Rules, including those addressing temperature, proper containers, and the handling of outdated drugs.
  - (2) Drugs stored at Shared Pharmacy Services Pharmacies shall be stored in an area that is:
    - (i) separate from any other Drugs used by the health care facility; and
    - (ii) secured, so as to prevent access by unauthorized personnel.
  - (3) Access to the area where Drugs are stored at the Shared Pharmacy Services Pharmacy must be limited to:
    - (i) Pharmacists, Advanced Level Certified Pharmacy Technicians, Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, or Pharmacy Interns who are employed by the Shared Pharmacy Services Pharmacy; or
    - (ii) Personnel employed at the Institutional Facility or clinic where the Shared Pharmacy Services Pharmacy is located who:
      - (A) are licensed health care providers;

- (B) are designated in writing by the Pharmacist-in-Charge or the Person responsible for the supervision and on-site operation of the facility where the Automated Pharmacy System is located; and
- (C) have completed documented training concerning their duties associated with the Shared Pharmacy Services Pharmacy.

...

(e) Individual Practice

- (1) Nothing in this Section shall prohibit an individual Pharmacist licensed in the state, who is an employee of or under contract with a Pharmacy, or a licensed Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern, working under the supervision of the Pharmacy, from accessing that Pharmacy's electronic database from inside or outside the Pharmacy and performing the Prescription Drug Order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:
  - (i) the Pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and
  - (ii) no part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database.

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## **Model Rules for Public Health Emergencies**

### **Section 1. Purpose and Scope.**

By the provision of these rules by the Board, the primary purpose of the section is to enable Pharmacists and Pharmacies to assist in the management and containment of a Public Health Emergency or similar crisis within the confines of a regulatory framework that serves to protect the welfare and health of the public.

(See comment list.)

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**Section 5. Temporary Recognition of Nonresident Licensure.**

- (a) When a State of Emergency is declared due to a Public Health Emergency:
  - (1) a Pharmacist not licensed in this State, but currently licensed in another state, may Dispense Prescription Drugs in areas affected by the Declared Disaster during the time that the State of Emergency exists if:
    - (i) the Board can verify current licensure in good standing of the Pharmacist directly with the state or indirectly via a third-party verification system; and<sup>38</sup>
    - (ii) the Pharmacist is engaged in a legitimate relief effort.
  - (2) an Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern not ~~registered or~~ licensed in this State, but currently ~~registered or~~ licensed in another state, may assist the Pharmacist in Dispensing Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:
    - (i) the Board can verify current ~~registration or~~ licensure in good standing of the Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern directly with the state or indirectly via a third-party verification system; and
    - (ii) the Advanced Level Certified Pharmacy Technician, Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern is engaged in a legitimate relief effort.

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**Appendix G**

**Model Rules for the Practice of Telepharmacy**

- (a) General Requirements
  - (1) The Pharmacy shall:
    - (i) obtain a resident or nonresident permit issued by the Board prior to engaging in the Practice of Telepharmacy;
    - (ii) comply with appropriate federal and state controlled substance laws and rules for each Pharmacy if controlled substances are maintained;
    - (iii) maintain additional policies and procedures specific to Telepharmacy.

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<sup>38</sup> If the information cannot be verified directly by the state Board of Pharmacy in which the nonresident pharmacist is licensed, the NABP Disciplinary Clearinghouse may be utilized to verify that a nonresident pharmacist has not had disciplinary action taken against his or her license.

(b) Remote Dispensing Site Requirements

- (1) Shall submit an application to the Board.
- (2) The Pharmacist-in-Charge of supervising pharmacy shall be responsible for all operations.
- (3) Shall have a written contract or agreement that outlines the services provided and the responsibilities of each party in complying with federal and state pharmacy laws and rules.
- (4) The Pharmacist-in-Charge shall oversee monthly inspections, maintenance and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.
- (5) A Pharmacist must be designated to be available within ( \_ ) hours, in case of emergency.
- (6) Unless staffed by a Pharmacist, a Remote Dispensing Site must be staffed by at least one (1) Advanced Level Certified Pharmacy Technician or Certified Pharmacy Technician. All Advanced Level Certified Pharmacy Technicians, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates shall be under the supervision of a Pharmacist at the supervising Pharmacy at all times that the remote site is operational. The Pharmacist shall supervise Telepharmacy operations electronically from the supervising pharmacy.
- (7) The Remote Dispensing Site and the supervising Pharmacy must utilize a common electronic recordkeeping system that must be capable of the following:
  - (i) Electronic records must be available to, and accessible from, both the supervising pharmacy and the Remote Dispensing Site at all times of operations; and
  - (ii) Prescriptions dispensed at the Remote Dispensing Site must be distinguishable from those dispensed from the supervising pharmacy.
- (8) Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, state and federal law.
- (9) A supervising Pharmacy of a Remote Dispensing Site must maintain a video and audio communication system that provides for effective communication between the supervising Pharmacy and the Remote Dispensing Site personnel and patients or caregivers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or Delivery of Drugs. The Remote Dispensing Site must retain a recording of facility surveillance, excluding patient communications, for a minimum of ( \_ ) days.
  - (i) Adequate supervision by the pharmacist in this setting is maintaining uninterrupted visual supervision and auditory communication with the site and full supervisory control of the automated system, if applicable, and must

- not be delegated to another person or entity.
- (ii) Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the Remote Dispensing Site must be, or remain, closed to the public if any component of the communication system is malfunctioning, until system corrections or repairs are completed.
  - (iii) The video and audio communication system used to counsel and interact with each patient or patient's caregiver must be secure and compliant with state and federal confidentiality requirements.
- (10) Unless a Pharmacist is present, a Remote Dispensing Site must not be open or its employees allowed access to it during times the supervising Pharmacy is closed. The security system must allow for tracking of entries into the Remote Dispensing Site, and the Pharmacist-in-Charge must periodically review the provision of access and record of entries.