



Report of the Committee on Law Enforcement/Legislation

Members Present:

Larry Pinson (NV), *chair*; Jody Allen (VA); Lemrey “Al” Carter (IL); Debbie Chisolm (CT); Diane Halvorson (ND); Alice Mendoza (TX); Steve Schierholt (OH); Tom Van Hassel (AZ).

Others Present:

Gay Dodson, *Executive Committee Liaison*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Maureen Schanck, Angie Rutkowski, *NABP staff*.

Introduction:

The Committee on Law Enforcement/Legislation met January 24, 2017, at DoubleTree by Hilton O’Hare, Rosemont, 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, including impaired pharmacists.
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.

LE/L Recommendation 1: The Committee Recommends Approving the Amendments to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) Suggested by the Task Force on the Regulation of Telepharmacy Practice, With Revisions.

The recommended revisions by the task force are denoted by underlines and ~~striketroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double striketroughs~~.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

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Section 104. Practice of Pharmacy.

The “Practice of Pharmacy” means, but is not limited to, the interpretation, evaluation, Dispensing, and/or implementation of Medical Orders, and the initiation and provision of Pharmacist Care Services. The Practice of Pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

(See comment list.)

Section 104. Comment.

The definition of the “Practice of Pharmacy” is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Inclusion of or authorization for specific activities, such as the Administration of medications, is purposely not delineated in the definition in order to be empowering and not proscriptive. To assist states in the interpretation of the revised definition of the “Practice of Pharmacy,” the *Model Act* includes the definition of “Pharmacist Care Services” and Model Rules for the Provision of Pharmacist Care Services for those states that need to include specific lists of activities or authorizations due to legislative and/or administrative policies and procedures.

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

Section 105. Definitions.

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- (a4) “Medication Therapy Management” is a distinct Pharmacist Care Service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication Therapy

Management encompasses a broad range of professional activities and responsibilities within the licensed Pharmacist's scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the patient:

- (1) performing or obtaining necessary assessments of the patient's health status;
- (2) formulating a medication treatment plan;
- (3) selecting, initiating, modifying, or administering medication therapy;
- (4) monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- (5) performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- (6) documenting the care delivered and communicating essential information to the patient's other primary care providers;
- (7) providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;
- (8) providing information, support services and resources designed to enhance patient adherence with his or her therapeutic regimens, such as Medication Synchronization;
- (9) coordinating and integrating Medication Therapy Management services within the broader health care management services being provided to the patient; and
- (10) such other patient care services as may be allowed by law.

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- (u4) "Pharmacist Care Services" is the provision by a Pharmacist of patient care activities within this State or into this State, as defined by the Rules of the Board, with or without the Dispensing of Drugs or Devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.¹

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- (c5) "Practice of Telepharmacy" means the Practice of Pharmacy ~~provision of Pharmacist Care Services~~ by registered Pharmacies and Pharmacists located within US jurisdictions through the use of Telepharmacy Technologies ~~between a licensee telecommunications or other technologies to~~ and patients or their agents at distances that are located within US jurisdictions.² The "Practice of Telepharmacy"

¹ Objectives of Pharmacist Care Services include cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or prevention of a disease or symptomatology. Pharmacist Care Services should be provided by all Pharmacists to the extent of their abilities regardless of the practice setting.

~~²The "Practice of Telepharmacy" is deemed to occur within the jurisdiction in which the patient is located and the jurisdiction(s) in which the pharmacist and, if applicable, pharmacy are located; therefore, such practice will be subject to the Pharmacy practice regulations of all jurisdictions' Boards of Pharmacy.~~

is deemed to occur within the jurisdiction in which the patient is located and the jurisdiction(s) in which the pharmacist and, if applicable, pharmacy are located; therefore, such practice will be subject to the Pharmacy practice regulations of all jurisdictions' Boards of Pharmacy.

~~(d5) "Practice of Telepharmacy Across State Lines" means the Practice of Telepharmacy when the patient is located within a US jurisdiction and the pharmacist is located in a different US jurisdiction.~~

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(t1) "Remote Dispensing Site" means a location, other than where a pharmacist is located, where Drugs are maintained and prescriptions are filled by a certified pharmacy technician and dispensed under the direct, remote supervision of a pharmacist.

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(t6) "Telepharmacy Technologies" means secure electronic communications, information exchange, or other methods that ~~shall~~ meet applicable state and federal requirements.

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(bb6) "Valid Patient-Practitioner Relationship" means the following have been established:

- (1) a Patient has a medical complaint;
- (2) a medical history has been taken;
- (3) a face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate Practitioner Board; and
- (4) some logical connection exists between the medical complaint, the medical history, and the physical examination and the Drug prescribed.

(See comment list.)

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Section 105(bb7). Comment.

A Valid Patient-Practitioner Relationship includes a relationship with a consulting Practitioner or a Practitioner to which a patient has been referred, or a covering Practitioner, or an appropriate Practitioner-Board-approved telemedicine Practitioner providing that a physical examination had been previously performed by the patient's ~~primary~~ Practitioner.

To best protect the public, the issue of a Valid Patient-Practitioner Relationship should be addressed in each jurisdiction’s Medical Practice Act and the Consumer Fraud Protection Act or their equivalent.

A face-to-face physical examination is not required to establish a Valid Patient-Practitioner relationship if:

- (a) the prescribing Practitioner is issuing a prescription or Dispensing a non-controlled substance legend drug in accordance with the Expedited Partner Therapy in the Management of Sexually Transmitted Diseases Guidance document issued by the United States Centers for Disease Control and Prevention;
- (b) the prescription, Administration, or Dispensing is through a public health clinic or other distribution mechanism approved by the state health authority in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of a biological, chemical, or radiological agent; or
- (c) the prescribing Practitioner is issuing a prescription through a telemedicine practice approved by the appropriate state agency that provides health care delivery, diagnosis, consultation, or treatment by means of audio, video, or data communications. Standard telephone, facsimile transmission, or both, in the absence of other integrated information or data, do not constitute telemedicine practices.
- (d) the state allows third-party prescribing of opioid reversal agents, such as naloxone, or other drugs as allowed by state law to a person other than the patient.

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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 ~~telecommunications, the Internet, or other technologies~~, regardless of the location of the pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.³
 - (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.

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Article V

Licensing of Facilities

Introductory Comment to Article V

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

³ NABP recognizes that protection of the public health should extend across State borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy ~~Across State Lines~~ 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.

Section 501. Licensing.

- (a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board⁴:
- (1) persons engaged in the Practice of Pharmacy (including Telepharmacy);
 - (2) dispensing Practitioners and Practitioner's facilities including those engaged in nonsterile Compounding;⁵
 - (3) persons engaged in the Manufacture or Repackaging of Drugs or Devices;
 - (4) persons engaged in the Wholesale Distribution of Drugs or Devices;
 - (5) persons engaged in Third-Party Logistics Provider activities of Drugs or Devices;
 - (6) pharmacies where Drugs or Devices are Dispensed, or Compounded, or Pharmacist Care Services are provided;
 - (7) Outsourcing Facilities;
 - (8) Pharmacy Benefits Managers; and
 - (9) Repository Programs
- Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

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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 6. Pharmacist Care Services.

- (a) Prospective Drug Utilization Review (DUR).⁶
A Pharmacist shall obtain and review the patient records and medical history ~~and for~~ each Prescription Drug Order ~~and review~~ for:
- (1) known allergies;
 - (2) rational therapy contraindications;

⁴ State may require additional licensing/registration requirements.

⁵ 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, counseling, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

⁶ Pharmacists should be permitted to use computer software, if available, to accomplish this review.

- (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, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(b) Patient Counseling⁷

- (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;
 - (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.

⁷ 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.

- (2) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.
 - (3) 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).
 - (4) 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.)
- (d) Collaborative Pharmacy Practice
- (1) Collaborative Pharmacy Practice Agreement
A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.
 - (2) Contents
The Collaborative Pharmacy Practice Agreement shall include:
 - (i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
 - (ii) the types of decisions that the Pharmacist is allowed to make;
 - (iii) a process for generating any necessary Medical Orders, including prescription orders, required to initiate allowed activities;
 - (iv) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

- (v) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
 - (vi) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
 - (vii) a provision that allows either party to cancel the Agreement by written notification;
 - (viii) an effective date;
 - (ix) signatures of all collaborating Pharmacists and Practitioners who are party to the Agreement, as well as dates of signing; and
 - (x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.
- (3) Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.
- (4) Documentation of Pharmacist Activities
Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals who are providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered Protected Health Information.
- (e) ~~Additional Pharmacist Care Services may include but are not limited to the following:~~
- (1) ~~Patient assessment and evaluation;~~
 - (2) ~~Assessing health plan and medication eligibility and coverage;~~
 - (3) ~~Administering drugs, vaccines, or biologicals;~~
 - (4) ~~Performing Peer Review and peer consultations;~~
 - (5) ~~Reviewing, selecting, and developing formularies or plan /practice guidelines;~~
 - (6) ~~Consulting with other health care professionals;~~
 - (7) ~~Providing patient referrals;~~
 - (8) ~~Performing Medication Therapy Management;~~
 - (9) ~~Ordering lab tests~~
 - (10) ~~Performing lab test as provided by state and federal law.~~

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Section 8. Shared Pharmacy Services.

- (a) General Requirements^{8, 9}

⁸ 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.

⁹ 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.

- (1) The Pharmacy must possess a resident or nonresident permit issued by the Board prior to engaging in Shared Pharmacy Services.¹⁰
 - (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 Certified Pharmacy Technician or Certified Pharmacy Technician Candidate if they assisted in any of those functions;
 - (ii) maintain records identifying individually, for each Prescription Drug Order filled or dispensed, the name of each Pharmacist or Pharmacy Intern who took part in the filling, dispensing, and counseling functions performed at that Pharmacy and the name of any Certified Pharmacy Technician or Certified Pharmacy Technician Candidate if they assisted in any of those functions;
 - (iii) report to the Board as soon as practical the results of any disciplinary action taken by another state's Board of Pharmacy involving Shared Pharmacy Services;
 - (iv) maintain a mechanism for tracking the Prescription Drug Order during each step of the processing and filling procedures performed at the Pharmacy;

¹⁰ 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.

- (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, 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.
 - (4) Shared Pharmacy Services Pharmacies shall have adequate security to:
 - (i) comply with federal and state laws and regulations; and
 - (ii) Protect the confidentiality and integrity of Protected Health Information.
- (d) Policies and Procedures
- (1) Each participant in Shared Pharmacy Services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for Shared Pharmacy Services. Each participant is required to maintain this portion of the joint policies and procedures that relate to that participant's operations. The policies and procedures shall:
 - (i) outline the responsibilities of each of the pharmacies;

- (ii) include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in Shared Pharmacy Services; and
- (iii) include policies and procedures for:
 - (A) notifying patients that their Prescription Drug Orders may be processed or filled by another Pharmacy and providing the name of the Pharmacy;
 - (B) protecting the confidentiality and integrity of Protected Health Information;
 - (C) dispensing Prescription Drug Orders when the filled Prescription Drug Order is not received or the patient comes in before the Prescription Drug Order is received;
 - (D) maintaining required manual or electronic records to identify the name, initials or identification code and specific activity or activities of each Pharmacist, Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern who performed any Shared Pharmacy Services;
 - (E) complying with federal and state laws; and
 - (F) operating a Continuous Quality Improvement Program for Shared Pharmacy Services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(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 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.

Section 10. 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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~~(b)~~ (f) Practice of Telepharmacy – Remote Dispensing Site Requirements

A Remote Dispensing Site:

- (1) Shall submit an application to the Board.
- (2) The Pharmacist-in-Charge ~~of supervising pharmacy~~ of the Shared Pharmacy Services Pharmacy shall be responsible for all operations of the Remote Dispensing Site.
- (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) Certified Pharmacy Technician. All Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates shall be under the supervision of a Pharmacist at the supervising Pharmacy at all times that the remote site is operational. The Pharmacist shall supervise Telepharmacy operations electronically from the supervising pharmacy.~~
- ~~(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.~~
- (6) ~~(9)~~ A supervising Pharmacy of a remote dispensing site must maintain a functioning video and audio communication system that provides for effective communication between the ~~supervising~~ Shared Pharmacy Services Pharmacy and the Remote Dispensing Site personnel and patients, and their agents or caregivers must be maintained. 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.~~
- ~~(7) (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 Shared Pharmacy Services Pharmacy is closed or during a system outage. 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.~~
- ~~(11) If Drugs are maintained or dispensed from the remote dispensing site, Drug transfers to the remote dispensing site must comply with applicable state and federal requirements.~~
- ~~(12) A remote dispensing site must display a sign, easily visible to the public, that informs patients that:~~
- ~~(i) this is a remote site~~
 - ~~(ii) location of supervising Pharmacy; and~~
 - ~~(iii) informs patients that a Pharmacist will counsel the patient using audio and video communication systems each time a new medication is delivered and on a refill, if necessary, at a remote dispensing site.~~
- ~~(13) The remote dispensing site must use Telepharmacy Technology that confirms that the Drug selected to fill the prescription is the same as indicated on the prescription label and Prescription Drug Order.~~

Background:

The committee members reviewed the *Model Act* amendments suggested by the Task Force on the Regulation of Telepharmacy Practice. The members also reviewed the 2012-2013 Report of the Committee on Law Enforcement/Legislation, specifically *Model Act* language pertaining to the Shared Pharmacy Services section recommended by the 2012 Task Force on Pharmacy Practice Technology Systems. The members agreed that telepharmacy regulations should be left broad to encompass advancements in technology. The members also agreed with some of the edits proposed by the Task Force on the Regulation of Telepharmacy Practice to the definition of "Practice of Telepharmacy" and recommended that it be combined with the associated footnote to emphasize the importance of the information in that footnote – that

telepharmacy is deemed to occur in the jurisdiction where the patient is located and the jurisdiction where the pharmacy or pharmacist is located. The committee members concurred with the task force’s recommendation to add the definition of “Telepharmacy Technologies.”

The committee members recommended that the specific examples of Pharmacist Care Services be deleted to avoid inclusion of what will eventually become outdated examples of services as the pharmacy profession evolves and to allow for emerging practices. The committee members also recommended that the Practice of Telepharmacy rules should be placed under the Shared Pharmacy Services section to align with the recommendations made previously by the 2012 Task Force. The committee members also determined that the General Requirements subsection should be removed, as those requirements apply to all pharmacies and are included in other sections of the *Model Act*. Furthermore, the committee members decided that the wording addressing requirements for remote dispensing site locations should be less specific. Thus, members recommended removing detailed requirements for staffing, record keeping, signage, and technology.

LE/L Recommendation 2: The Committee Recommends Approving the Amendments to the Model Act in Response to a State Request to Define NABP e-Profile ID to Facilitate the Adoption of State Rules That Require the Collection of NABP e-Profile ID Numbers.

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

Article I

Title, Purpose, and Definitions

...

Section 105. Definitions.

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(a4) “National Association of Boards of Pharmacy (NABP)” means the association whose members are the Boards of Pharmacy, which association was established to assist Boards in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

(b4) “NABP e-Profile ID” is a unique identifier for permittees, licensees, and registrants that is provided ~~at no cost~~ by NABP. This unique, unduplicated identifier allows for, but is not limited to, the accurate identification and collection of licensure, disciplinary, and inspection information for permittees, licensees, and registrants, both in-state as well as out-of-state, in a secure electronic profile that can be utilized for applicant submission, review, and/or board action.

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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
 - (4) have paid the fees specified by the Board of Pharmacy for the issuance of the license.

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- (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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Background:

The committee members agreed with the suggested definition of NABP e-Profile ID to further state adoption. Members were also in agreement with its current usage in the *Model Act* for licensure renewal purposes.

LE/L Recommendation 3: The Committee Recommends Approving the Suggested Amendments to the *Model Act* to Align with New NABP Competency Assessment Policies.

National Association of Boards of Pharmacy Model State Pharmacy Act

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).

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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;¹¹
 - (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 Pharmacy regulations so that it is ensured that the applicant meets standards necessary to protect public health and safety;¹²
 - (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

¹¹ 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.

¹² Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Foreign Pharmacy Graduate Equivalency Examination[®] (FPGEE[®]) as part of their assessment of pharmacy education equivalence.

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 ~~given~~ 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. ~~given by the Board~~ If applicable, state-specific compounding exams shall be administered by the Board. ~~at least two (2) times during each year.~~ 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.~~ approve the site and date of the Administration of the examination.
- (2) The examinations shall be prepared to measure the competence of the applicant to engage in the Practice of Pharmacy. ~~The Board~~ 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 ~~have successfully passed such an examination~~ are eligible for licensure.

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Background:

The committee members reviewed the recommended amendments to the *Model Act* and subsequently supported them to align with current NABP competency assessment policies.

LE/L Recommendation 4: The Committee Recommends Approving the Suggested Amendments to the *Model Act* Language in Response to NABP's Initiative to Accredit Specialty Pharmacies.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

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- (f6) “Specialty Drug” means a Drug used to treat a chronic or specific disease or condition that requires frequent communication with other health care providers, extensive patient monitoring and case management, and comprehensive counseling with the patient and/or caregiver.
- (f7) “Specialty Pharmacy” means a Pharmacy that is providing Specialty Pharmacy Practice services and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease are Dispensed and Compounded.
- (f8) “Specialty Pharmacy Practice” means the provision of Pharmacist Care Services, which involves Drugs used to treat chronic or specific diseases and conditions that require frequent communication with other health care providers, extensive patient monitoring and case management, and comprehensive counseling with the patient and/or caregiver. ¹³ Drugs Dispensed by a Specialty Pharmacy may also require instruction and training on complex administration processes and/or handling and storage considerations.

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Background:

The committee members were informed about NABP’s initiative to develop a specialty pharmacy accreditation program. The members determined that the suggested definitions for “Specialty Pharmacy” and “Specialty Pharmacy Practice” were appropriate for inclusion into the *Model Act* and recommended approving both definitions to move the Association’s goal forward.

¹³ It should be noted that the rationale for Dispensing Drugs from a Specialty Pharmacy be based on the Drugs possessing certain characteristics such as a very narrow therapeutic range, life-endangering side effect profile, and/or requiring periodic laboratory or diagnostic testing, and that such characteristics require extensive Pharmacist interaction with both the patient and health care provider(s).

LE/L Recommendation 5: The Committee Recommends Approving the Suggested Amendments to the *Model Act* that Add a Reference to “Insanitary Conditions” in Response to Food and Drug Administration’s “Insanitary Conditions at Compounding Facilities” Guidance Document.

National Association of Boards of Pharmacy Model State Pharmacy Act

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- (d) “Adulterated”: A Drug or Device shall be deemed to be Adulterated:
- (1) if:
 - (i) it consists in whole or in part of any filthy, putrid, or decomposed substance; or
 - (ii) it has been produced, prepared, packed, or held **under insanitary conditions** whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to ensure that such Drug or Device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or
 - (iii) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or
 - (iv) it bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the Federal Food, Drug, and Cosmetic Act (Federal Act); or it is a color additive, the intended use of which, in or on such Drugs or Devices, is for purposes of coloring only, and is unsafe within the meaning of the Federal Act;
 - (2) if it purports to be or is represented as a Drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or

inadequacy of these tests or methods of assay, those prescribed under authority of the Federal Act. No Drug defined in an official compendium shall be deemed to be Adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a Drug is recognized in both the United States Pharmacopeia (USP) and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the USP unless it is labeled and offered for sale as a homeopathic Drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not those of the USP;

- (3) if it is not subject to paragraph (2) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or
- (4) if it is a Drug and any substance has been mixed or packed therewith so as to reduce its quality or strength; or substituted wholly or in part therefore.

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Model Rules for Compounded or Repackaged Pharmaceuticals

Section 1. Purpose and Scope.

The purpose of this section is to ensure Compounded Pharmaceuticals are prepared and Dispensed according to practice and quality standards through the provision of: (1) Pharmacist Care Services; and (2) the preparation, Labeling, and Distribution of Compounded or Repackaged Pharmaceuticals by Pharmacies. These standards are intended to apply to all Sterile and nonsterile Compounded Pharmaceuticals, notwithstanding the location of the patient (eg, home, hospital, nursing home, hospice, doctor's office). All facilities and Practitioners engaging in Sterile and nonsterile Compounding or Repackaging shall practice in accordance with Federal law, these Rules, and the current United States Pharmacopeia–National Formulary (USP-NF), including but not limited to General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*, General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations*, General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*, and other applicable referenced general chapters. The procedures contained herein are considered to be the minimum current good compounding practices for the Compounding of Drug Products by State-licensed Pharmacies for Dispensing and/or Administration to humans or animals.

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Section 8. Quality Assurance.

- (a) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, Component Verification and usage, Disinfection, sterilization, equipment, and facilities that are appropriate for the Sterile

- Pharmaceutical(s) being prepared. Quality Assurance control programs shall at minimum conform to the requirements of USP.
- (b) The Pharmacist has the responsibility and authority to inspect and approve or reject all Components, Drug Product containers, closures, in-process materials, and/or Labeling. The Pharmacist shall have the authority to prepare and review all Compounding records to ensure that no errors have occurred in the Compounding process. If errors have occurred, the Pharmacist is responsible for conducting a full investigation. A written record of the investigation shall be made and shall include conclusions and follow-up. The Pharmacist is also responsible for the proper maintenance, cleanliness, and use of all facilities and equipment used in Compounding.
 - (c) All Pharmacists who participate in Compounding, including other Pharmacy personnel who assist the Pharmacist in Compounding, shall be proficient in the science of Compounding and shall acquire the education, training, and/or experience to maintain that proficiency through participation in seminars, studying appropriate literature, and consulting colleagues or by becoming certified by a Compounding certification program approved by the Board.
 - (d) Pharmacists and other Compounding Pharmacy personnel (eg, Pharmacy Technicians) shall be trained and proficient in the particular operations that are performed by that individual.
 - (e) Training shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that Compounding Pharmacy personnel remain familiar with applicable operations and policies and procedures.
 - (f) Only personnel authorized by the responsible Pharmacist shall be in the immediate vicinity of Compounding operations.
 - (g) Compounded Drug shall be deemed Adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

Background:

The committee members were provided with a copy of FDA’s definition of “Adulterated Drugs and Devices” and “Insanitary Conditions at Compounding Facilities” Guidance for Industry. After reviewing the material, the committee members determined that the current definition of “Adulterated” in the *Model Act* is consistent with FDA’s definition. Furthermore, they determined that the additional reference to insanitary conditions in the Quality Assurance subsection encompasses the principles elucidated in the guidance document.

LE/L Recommendation 6: The Committee Recommends Approving the Suggested Amendments to the *Model Act* in Response to NABP’s Memo Regarding Allowing Pharmacies to Dispense Epinephrine Auto-Injector Products Through the Manufacturer’s Expiration Date, With Revisions.

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- (g) “Beyond-Use Date” means a date placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.¹⁴

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Model Rules for the Practice of Pharmacy

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Section 4. Prescription Drug Order Processing.

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- (e) Labeling
- (1) All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall have a label affixed to the container in which such Drug is Dispensed. The label shall include the following:¹⁵
- (i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as “arial”), minimum 12-point size, and in “sentence case.” Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated and shall include:
- (A) patient name

¹⁴ In determining a Beyond-Use Date for a specific Drug Product, the Pharmacist may use the recommendations provided in the most recent edition of the United States Pharmacopeia-National Formulary (USP-NF).

¹⁵ 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.

- (-a-) legal name of the patient; or
- (-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.
- (B) directions for use
 - (-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order¹⁶; and
 - (-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.
- (C) drug name
 - (-a-) if written for a brand name and a generic drug is dispensed, include phrase “Generic for [brand name];” and
 - (-b-) include drug name suffixes, such as CD, SR, XL, XR, etc.
- (D) drug strength, expressed in the metric system whenever possible
- (E) “use by” date
 - (-a-) date after which ~~medication~~ Drugs should not be used; not expiration date of ~~medication~~ Drugs or expiration date of prescription;¹⁷ and
 - (-b-) format as – “Use by: MM/DD/YY.”
- (ii) Important information for patients – Must appear on the label but should not supersede critical information for patients and shall include: ¹⁸

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Background:

The committee members were informed about the NABP memo to state boards of pharmacy regarding emergency-use medications, such as epinephrine auto-injector products, which encouraged boards to adopt or modify their position on beyond-use dates and allow pharmacies to dispense such products through the manufacturer’s expiration date. Members agreed that not only does this enhance availability of such drugs in an emergency, but also increases access and decreases the financial burden on patients. The members determined that

¹⁶ Boards of pharmacy and licensees should recognize that “take as directed” may not provide sufficient information for the appropriate use of the medication. “Take as directed” is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. “Take as directed” should not be used in lieu of patient counseling.

It is understood that prescription drug orders often do not include the indication for use.

¹⁷ Boards of Pharmacy may determine that this use by date does not apply to all Drugs emergency use medications (such as for example epinephrine auto-injectors) and may allow the manufacturer’s expiration date to be used if the medication is kept in the manufacturer’s original, unopened packaging, and provided that the pharmacist uses professional judgment to assess the continued need for the medication and counsels the patient on proper storage.

¹⁸ Information traditionally included on the patient label must continue to be maintained and safeguarded by the record-keeping system. Boards of Pharmacy should require that record-keeping systems prohibit any alteration or modification of these data unless an appropriate audit trail and justification exists. Record-keeping systems should also prohibit any deletion of information except in accordance with state and federal requirements for data management and retention.

this should be conveyed by a footnote stating that boards of pharmacy may determine that “use by” dates do not apply to all drugs.

The committee members also suggested that staff replace the term “Medication” with “Drug” throughout the *Model Act*. However, because the term “Medication” is used as a term of art for such practices as Medication Synchronization and Medication Therapy Management, the *Model Act* will have to be closely reviewed in the future for appropriate instances whereby “Medication” can be replaced with “Drug.”

LE/L Recommendation 7: The Committee Recommends Approving the Suggested Amendments to the *Model Act* in Furtherance of Resolution 112-3-16 (Utilization of PMP and Other Data to More Accurately Measure and Report the Scope of Prescription Drug Abuse), With Revisions.

Appendix F

Model Prescription Monitoring Program Act

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Section 6. Reporting Of Prescription Monitoring Program Information.

- (a) Each Dispenser shall submit to the Board of Pharmacy, by electronic means, or other format specified in a waiver granted by the Board of Pharmacy, within 24 hours, information specified by the Board of Pharmacy, including:
- (1) identification Number of Dispenser;
 - (2) identification number of the Prescriber;¹⁹
 - (3) patient name, address, and telephone number;
 - (4) patient gender;
 - (5) patient date of birth;
 - (6) identification of the drug by a national drug code number;
 - (7) quantity dispensed;
 - (8) number of days supplied;
 - (9) number of refills ordered;
 - (10) whether drug was dispensed as a refill or as a new prescription;
 - (11) date prescription was dispensed;²⁰
 - (12) if a refill, date of the original dispensing;
 - (13) prescription number;
 - (14) date the prescription was issued by the Prescriber;
 - (15) method of payment for the prescription; and

¹⁹ It is recommended that Boards of Pharmacy consider using practitioners’ NPI number for identification purposes.

²⁰ It is recommended that the date prescription was dispensed be clarified to mean the date of delivery to the patient.

- (16) such other information as may be required by State law.
- (b) Each Dispenser shall ensure that information reported to the PMP is correct and shall submit corrections when necessary.
- (c) Each Dispenser shall reverse information for any prescription that was not dispensed.

Section 7. Access To Prescription Monitoring Program Information/Confidentiality.

- (a) Except as indicated in paragraphs (b), (c), and (d) of this Section 7, Prescription Monitoring Program Information submitted to the Board of Pharmacy shall be considered Protected Health Information and not subject to public or open records laws.
- (b) The Board of Pharmacy shall review the Prescription Monitoring Program Information. If there is reasonable cause to believe a violation of law (or breach of professional or occupational standards) may have occurred, the Board shall notify the appropriate law enforcement, or professional or occupational licensing, certification, or regulatory agency or entity, and provide Prescription Monitoring Program Information required for an investigation.²¹
- (c) The Board of Pharmacy may provide Prescription Monitoring Program Information for public research, policy or education purposes, to the extent all information has been De-identified.²²
- (d) The following persons may access the Prescription Monitoring Program Information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar Protected Health Information under federal and State law and regulation:
 - (1) Practitioners (or agents thereof) or Dispensers (or agents thereof) who certify, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient, or verifying PMP information for prescriptions issued by practitioners;
 - (2) Boards of Pharmacy or vendors/contractors for the purpose of establishing and maintaining the Prescription Monitoring Program;
 - (3) other state licensing, certification, or regulatory agencies that license, certify, or regulate health care professionals authorized to prescribe, administer, and dispense controlled substances, which certify, under the procedures determined by the State, that the requested information is related to an

²¹ This section is intended to allow boards of pharmacy to evaluate Prescription Monitoring Program information and determine appropriate information to provide to law enforcement entities. It is not intended to allow law enforcement officials open access to all data.

~~²² NABP encourages PMPs to provide reports and other analytical information to appropriate prescribers, pharmacists, and entities that serve as sources of data impacting the identification and reporting of prescription drug injuries and deaths, such as, but not limited to, coroners' offices, to help address the prescription drug epidemic and improve patient care.~~

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

- (4) local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authorities, which certify, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a reportable substance, and such information will further the purpose of the investigation or assist in the proceeding;
- (5) entities that serve as sources of data impacting the identification and reporting of prescription drug injuries and deaths, such as, but not limited to, coroners' offices, to help address the prescription drug epidemic and improve patient care;
- (6) other appropriate entities ~~as determined by the Board of Pharmacy~~^{23 22}; and
- (7) Patients who certify, under the procedures determined by the State, that the requested information is for the purpose of obtaining and reviewing their own records.

- (e) The Board of Pharmacy shall be immune from civil liability arising from inaccuracy of any of the information submitted to the Board of Pharmacy pursuant to this Act.

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Background:

In response to Resolution 112-3-16, Utilization of PMP and Other Data to More Accurately Measure and Report the Scope of Prescription Drug Abuse, members reviewed suggested *Model Act* amendments to support providing prescription monitoring program data to appropriate entities to evaluate data impacting the identification and reporting of prescription drug injuries and deaths. The committee determined that the suggested language in the footnote granting PMP data access to entities that study the reporting of drug injuries and deaths be edited and moved within the body of the Model Prescription Monitoring Program Act. Furthermore, the committee also recommended that other appropriate entities include agencies listed in the footnote such as drug courts, district attorneys' offices, addiction treatment professionals, etc. The committee members recommended removing "as determined by the Board of Pharmacy" following other appropriate entities in order to be more encompassing.

^{23 22} It is recommended that other appropriate entities include drug courts, district attorneys' offices, addiction treatment professionals, or other similar entities, and only for the purpose of ensuring appropriate patient treatment, as opposed to efforts to search for information without knowledge of whether such information exists.

LE/L Recommendation 8: The Committee Recommends Approving the Suggested Amendments to the *Model Act* in Response to Resolution 112-2-16 (Increasing Patient Access to Naloxone Rescue Kits).

Model Rules for the Practice of Pharmacy

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Section 6. Pharmacist Care Services.

- (a) Prospective Drug Utilization Review (DUR).²⁴
A Pharmacist shall review the patient record and 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, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

- (b) Patient Counseling.²⁵
- (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;

²⁴ Pharmacists should be permitted to use computer software, if available, to accomplish this review.

²⁵ 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) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.
 - (3) 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).
 - (4) 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.)
- (d) Collaborative Pharmacy Practice
- (1) Collaborative Pharmacy Practice Agreement
A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of

Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

- (i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
- (ii) the types of decisions that the Pharmacist is allowed to make;
- (iii) a process for generating any necessary Medical Orders, including prescription orders, required to initiate allowed activities;
- (iv) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;
- (v) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
- (vi) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
- (vii) a provision that allows either party to cancel the Agreement by written notification;
- (viii) an effective date;
- (ix) signatures of all collaborating Pharmacists and Practitioners who are party to the Agreement, as well as dates of signing; and
- (x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

(3) Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(4) Documentation of Pharmacist Activities

Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals who are providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered Protected Health Information.

(e) Emergency-Use Dispensing

Prescribing and Dispensing Drugs for emergency-use pursuant to a Pharmacist-issued Prescription²⁶ and appropriate patient counseling, including but not limited to:

- (1) Opioid overdose reversal agents (naloxone);

²⁶ Pharmacist may prescribe pursuant to specific statewide protocols or standing order.

- (2) Epinephrine;
- (3) Antidote kits; and
- (4) Short-acting beta agonist inhalers.

Background:

The committee members reviewed the proposed amendments to the *Model Act* to grant pharmacists individual prescriptive authority to prescribe and dispense naloxone to expand access and protect public health. The members agreed that such recommendations are necessary in light of the current opioid epidemic gripping many states across the country. Furthermore, the committee agreed that pharmacists should be able to facilitate the delivery of medication needed in an emergency to prevent injury or death. Therefore, the committee also concluded that boards may wish to grant pharmacists authority to dispense other emergency medication based on the potential for harm reduction and confounding factors such as geography.

LE/L Recommendation 9: The Committee Recommends Approving the Suggested *Model Act* Amendments to Correspond With the Updated United States Pharmacopeia (USP) General Chapter <17> Prescription Container Labeling.

Model Rules for the Practice of Pharmacy

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Section 4. Prescription Drug Order Processing.

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(e) Labeling

- (1) All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall have a label affixed to the container in which such Drug is Dispensed. The label shall include the following:²⁷
 - (i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as “arial”), minimum 12-point size, and in “sentence case.” Field size and font size may be increased in the best interest of patient care²⁸. Critical information text should never be truncated and shall include:

²⁷ 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.

²⁸ Alternative-access methods may be utilized to address visual impairment in patients or caregivers.

- (A) patient name
 - (-a-) legal name of the patient; or
 - (-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.
- (B) directions for use
 - (-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order²⁹; and
 - (-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters³⁰.
- (C) drug name
 - (-a-) if written for a brand name and a generic drug is dispensed, include phrase “Generic for [brand name];” and
 - (-b-) include drug name suffixes, such as CD, SR, XL, XR, etc.
- (D) drug strength, expressed in the metric system whenever possible
- (E) “use by” date
 - (-a-) date after which medication should be used; not expiration date of medication or expiration date of prescription; and
 - (-b-) format as – “Use by: MM/DD/YY.”
- (ii) Important information for patients – Must appear on the label but should not supersede critical information for patients and shall include: ³¹
 - (A) pharmacy name or dispensing practitioner’s entity name³²;
 - (B) pharmacy telephone number³³;
 - (C) prescriber name;
 - (-a-) format as – “Prescriber: [prescriber name].”

²⁹ Boards of pharmacy and licensees should recognize that “take as directed” may not provide sufficient information for the appropriate use of the medication. “Take as directed” is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. “Take as directed” should not be used in lieu of patient counseling.

It is understood that prescription drug orders often do not include the indication for use.

³⁰ Consider adhering to the universal medication schedule (UMS). The UMS shifts medication-taking into four standardized time periods (morning, noon, evening, bedtime) and uses simplified language and formatting to promote understanding (eg, “take 1 tablet in the morning and 1 tablet at bedtime”).

³¹ Information traditionally included on the patient label must continue to be maintained and safeguarded by the record-keeping system. Boards of Pharmacy should require that record-keeping systems prohibit any alteration or modification of these data unless an appropriate audit trail and justification exists. Record-keeping systems should also prohibit any deletion of information except in accordance with state and federal requirements for data management and retention.

³² Boards of Pharmacy should recognize that some pharmacies “do business as” a name other than the corporate name.

³³ Include phone number of the dispensing pharmacy, recognizing that a pharmacy providing shared services may be involved in the filling process; Boards of Pharmacy should not require more than one telephone number on the label.

- (D) “fill date”³⁴;
 - (-a-) format as – “Date filled: MM/DD/YY.”
 - (E) prescription number;
 - (F) drug quantity;
 - (-a-) format as – “Qty: [number].”
 - (G) number of remaining refills;
 - (-a-) format as – “Refills: [number remaining]” or “No refills,” using whole numbers only and managing partial fills through the pharmacy record keeping system;
 - (H) written or graphic product description;
 - (I) auxiliary information³⁵;
 - (J) any cautions and other provisions which may be required by federal or state law.
- (iii) The following additional information for Patients – may appear on the label:
- (A) bar codes;
 - (B) pharmacy address; and
 - (C) store number.³⁶

Background:

After the committee members reviewed the revised USP General Chapter <17> Prescription Container Labeling, they determined that the new chapter is timely and relevant to state pharmacy board regulations. The committee concurred that a footnote should be added to indicate that alternative-access methods may be utilized to convey critical information to patients or caregivers with visual impairment. Furthermore, the committee agreed with the USP recommendation that directions for use should be simplified. Therefore, members agreed to add an additional footnote to the labeling subsection to encourage using the universal medication schedule and standardized time periods.

³⁴ “Fill date” and “use by” date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.

³⁵ Auxiliary information, including auxiliary labels, should be evidence based, standardized, and demonstrated to complement the prescription label.

³⁶ Boards of pharmacy may consider utilizing these suggested labeling formats provided below.