NABP
National Association of Boards of Pharmacy

REPORT OF THE COMMITTEE ON

LAW ENFORCEMENT/LEGISLATION

Members Present

Malcolm J. Broussard (LA), *chair*; Sabrina L. Beck (NE); Alexandra Blasi (KS); Janet Hart (PA); Allison Hill (DC); Tony King (MT); Jeenu Philip (FL); Deena Speights-Napata (MD); and Kim Tanzer (TX).

Others Present

Bradley S. “Brad” Hamilton, *Executive Committee liaison;* Lemrey “Al” Carter; William Cover; Melissa Madigan; Eileen Lewalski; Maureen Schanck; Cameron Orr; and Andrea Busch, *NABP staff*.

Introduction

The committee met on January 19-20, 2022, at NABP Headquarters in Mount Prospect, IL.

Review of the Committee Charge

Charge of the committee:

1. Develop model laws and regulations based on resolutions adopted by the members of the association or on reports of task forces or other committees of the association, or as assigned by the Executive Committee.
2. Review and comment on existing legislation and rules governing the practice of pharmacy and the distribution of prescription medications.
3. Recommend to the Executive Committee model pharmacy practice or prescription drug distribution regulations that are needed to improve the protection of the public health.

Background and Discussion

The committee reviewed and discussed the recommended amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* made by the Work Group to Consider Permanently Extending Certain Waivered Provisions, the United States Pharmacopeial Convention’s (USP) standards for prescription labeling, and recent limitations enacted by states to limit licensure examination attempts. The committee also reviewed recommendations made by the Overview Task Force on Requirements for Pharmacy

Technician Education, Practice Responsibilities, and Competence Assessment (Overview Task Force) and those submitted by Alliance for Pharmacy Compounding for consideration by NABP.

The committee began its discussion by reviewing the work of the Work Group to Consider Permanently Extending Certain Waivered Provisions and its recommendations to make certain emergency allowances permanent, while recommending that other emergency provisions be allowed during a declared emergency or significant public health concern. The committee supported the work group's recognition of pharmacists and pharmacy technicians as being integral in the public health effort during the coronavirus disease 2019 (COVID-19) pandemic and that practice barriers that were lifted during the pandemic should result in expanded scope of practice permanently. The committee agreed with the work group's updated provisions for the definition of the term "pharmacist care services," but also chose to include "devices" in the list of items a pharmacist can prescribe or administer and remove the reference to the Centers for Disease Control and Prevention vaccine language to keep it broad and applicable to state-approved vaccinations. There was also committee consensus for permitting patient counseling to occur electronically and not necessarily in person, by telephone, or via an audiovisual link.

The committee reviewed the work groups recommendations regarding the Model Rules for Institutional Pharmacy and agreed with the recommendation to permanently allow dispensing of previously dispensed outpatient medication for institutional use and vice versa, if labeled appropriately, to avoid potentially wasting such medications and avoid interruption in drug therapy during transition of care. The committee further recommended that controlled substance dispensing by an institutional pharmacy for outpatient use upon discharge should be reported to the state prescription monitoring program. Committee members further noted that the term "inpatient" in this section should be replaced with "institutional" for consistency. The committee also approved the amendment to allow automated pharmacy systems to be utilized wherever the board approves them and their use should not be restricted to institutional settings.

The committee then transitioned to work group recommendations related to significant public health concerns and declared emergencies. Members approved amendments for boards of pharmacy to extend deadlines related to licensure renewal and completion of continuing education requirements during public health emergencies or other significant events. Members also backed suggested amendments to the Model Rules for Public Health Emergencies but recommended that the title be changed to include "Significant Public Health Concerns" rather than "Unusual Public Health Concerns." Recommendations approved for this section included temporary recognition of nonresident state licensure and the activation of the NABP Emergency

Passport for pharmacists, certified pharmacy technicians, certified pharmacy technician candidates, and pharmacy interns. The approved amendments to this section also included temporary recognition of nonresident state licensure for manufacturers, outsourcing facilities, repackagers, third-party logistics providers, and wholesale drug distributors. The committee, however, recommended that applicants should only have to submit the most current Good Manufacturing Practices inspection when applicable, rather than requiring an inspection to have been completed within the previous six months as suggested by the work group.

There was unanimous support among committee members for pharmacists to provide uninterrupted drug therapy through emergency refills and emergency prescribing or dispensing, when necessary, to sustain life or prevent harm or suffering as outlined in Model Rules for the Practice of Pharmacy and the Model Rules for Public Health Emergencies or Significant Public Health Concerns. Although several states already allow for emergency refills when prescribers are unavailable for refill authorization, the need for emergency dispensing was also recognized as necessary during unforeseen emergencies and could be pursuant to statewide protocols, standing orders, or pharmacist prescribing authority. The committee also recommended that a reference to unit-of-use dispensing be included in the regulations for emergency dispensing, as well as the requirement for pharmacists to notify the patient's primary care provider, as soon as possible, when emergency refilling or dispensing occurs. Related to dispensing, the committee also agreed to add a footnote explaining that boards may waive the requirement to transmit prescriptions electronically when it is not feasible to do so during public health emergencies or other significant events, as well as another footnote saying the requirement for the presentation of identification or for a patient signature may be waived.

The committee members moved on to the topic of standards for prescription labels as outlined in the USP General Chapter <17>. After some thoughtful discussion, the committee agreed to add text indicating that prescription labels should conform with USP General Chapter <17> or the most current chapter addressing labeling of prescription containers, and further agreed to remove all labeling details that are currently outlined in the *Model Act*.
The committee then engaged in a review of a gap analysis, recommended by the Overview Task Force, to compare accreditation standards for pharmacy technician training programs. After analyzing the findings, members determined that the Accrediting Bureau of Health Education Schools (ABHES) and the Pharmacy Technician Accreditation Commission (PTAC) have similar prerequisites and curriculum requirements but differ significantly in their requirements for total minimum hours of training. ABHES requires its accredited programs to provide 160 minimum hours of training, whereas PTAC requires 400 minimum hours for its

accredited providers. The committee agreed that both organizations should be included in a footnote for completeness and to make boards of pharmacy and certified pharmacy technician candidates aware of both options. The committee members also stressed that certified pharmacy technician candidates should verify that an accredited pharmacy technician training program meets state-specific requirements for education, such as minimum hours of training, before enrolling.

NABP staff introduced suggested *Model Act* language submitted by the Alliance for Pharmacy Compounding (APC) to the committee for its consideration. Members welcomed the review of suggested edits and agreed with the APC's suggestion to edit the definition of "significant adverse drug reaction" as it reflected the definition found in the FDA Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products. The committee members also approved all suggested edits by APC related to compounding that are already enumerated in federal law. Furthermore, members approved APC's suggested amendments related to licensure of compounding pharmacies with some additional edits and added a footnote that requires pharmacy applicants to submit responses to a questionnaire regarding compounding operations.

The committee members, however, did not agree with APC's suggestion that the limited distribution of prescription drugs be allowed as part of the practice of pharmacy because it does not align with Section 503A of the Federal Food, Drug, and Cosmetic Act. The committee members also did not approve a suggested amendment to the definition of "drug" due to a concern that it would limit the scope of regulatory authority of the boards of pharmacy. Members of the committee did not approve curtailing pharmacy notification requirements to the boards of pharmacy regarding "significant" theft or loss of drugs or devices, "quality-related events," and reporting of inspectional observations by state or federal agencies but did add a footnote stating that boards of pharmacy should not take disciplinary action based on Food and Drug Administration (FDA) Form 483 Inspectional Observations alone. The committee did not agree to modify current references to USP compounding chapters, nor did it make any changes to current veterinary compounding language as it felt such changes should be considered after FDA issues the final guidance on "Compounding Animal Drugs from Bulk Drug Substances".

The committee members then addressed recent state-enacted limitations on examination attempts for pharmacist licensure by examination. The members unanimously agreed to add a five-attempt limit to safeguard the integrity of the licensure examination and create a pause for further review of the candidate's qualifications by the board of pharmacy.

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

Work Group to Consider Extending Certain Waivered Provisions

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. [1]

Article III
Licensing

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[1] 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 304. Renewal of Licenses.

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

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

(c) 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.

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

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. The Board may extend the date of compliance with continuing pharmacy education provisions in the case of a State of Emergency or ~~Unusual~~ Significant Public Health Concern[2].

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Article V
Licensing of Facilities

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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[3] their license with the Board:[4]

(1) persons engaged in the Practice of Pharmacy (including Telepharmacy);
(2) dispensing Practitioners and Practitioner's facilities including those engaged in nonsterile[5] Compounding;[6]
(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

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

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

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

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

[6] 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.

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

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Section 4. Prescription Drug Order Processing.

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(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.[7]

(1) A Prescription Drug Order must be communicated to a Pharmacist, or when recorded in such a way that the Pharmacist may review the Prescription Drug Order as transmitted, to a Pharmacy Intern or a Certified Pharmacy Technician, in a licensed Pharmacy. This may be accomplished in one of the following ways. A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in 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

[7] 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.

listed in Schedule II, may be communicated orally (including telephone voice communication) [8] or issued electronically.[9, 10]

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Section 5. Record Keeping.

(b) Records of Dispensing/Delivery[11]

(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[12] and shall include, but not be limited to:

(i) quantity Dispensed for original and refills, if different from original;
(ii) date of receipt, Dispensing, Delivery, Distribution, or other disposition;
(iii) serial number (or equivalent if an institution);
(iv) the identification of the Pharmacist, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate responsible for Dispensing;
(v) name and Manufacturer of Drug Dispensed if Drug Product selection occurs; and
(vi) records of refills to date.

(2) Pharmacies that ship 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.[13]

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[8] 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.

[9] If a state requires prescriptions to be electronically transmitted, it may consider waiving such requirement and allow issuance of paper prescriptions during a State of Emergency, in compliance with Federal Law.

[10] 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.

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

[12] 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.

[13] 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

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Section 6. Pharmacist Care Services. ~~14~~

Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Prescribing and Administering Drugs, Devices, ~~Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices~~ vaccines, or biologicals; Prescribing and Dispensing for Emergency Use[15]; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan/practice guidelines; performing therapeutic substitution[16]; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering and performing Clinical Laboratory Improvement Amendments of 1988-waived lab tests and prescribing associated Drugs and Biologicals[17], as provided by State and Federal law, and reporting results and follow up treatment.

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(b) Patient Counseling[18]

(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 or other

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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.

~~[14] 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.~~

[15] Pharmacist may prescribe pursuant to specific statewide protocols or standing orders.

[16] Providing it is within the same FDA drug class and not prohibited by the prescriber.

[17] Pharmacist may prescribe associated medications pursuant to specific statewide protocols or standing orders

[18] 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.

~~audio/visual~~ means of electronic communication 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.

(2) An offer for Patient Counseling can be made by a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate when it is not required by law or deemed necessary that it be done by the Pharmacist.

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

(4) 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).

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

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(f) Emergency-Use Prescribing and Dispensing ~~for Emergency Use Dispensing~~

Prescribing and Dispensing Drugs for emergency-use shall be pursuant to a Pharmacist-issued Prescription[19] and include appropriate Patient Counseling. Drugs or Devices for emergency use include, but are not limited to:

(1) Opioid overdose reversal agents, such as naloxone;
(2) Epinephrine;
(3) Antidote kits;
(4) Short-acting beta agonist inhalers; and
(5) Medication-assisted Treatment for the purpose of initiating therapy for opioid use disorder. The Pharmacist must:
    (i) obtain a DEA registration and a state controlled substance license or registration, if required; and
    (ii) use professional judgment to assess the clinical appropriateness of the patient's request and the length of time until the patient obtains treatment from an authorized Practitioner.[20]

(g) Emergency Refills

A Pharmacist may Dispense a refill of a Prescription Drug, not to exceed a thirty (30)-day supply, without Practitioner authorization if:[21,22]

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the Patient's life or to the continuation of therapy;
(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Refill Prescription," and maintains the record as required by state and federal law, as well as state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency; and

[19] Pharmacist may prescribe pursuant to specific statewide protocols or standing orders.

[20] It is contemplated that for long-term treatment, Pharmacists should be prescribing under a collaborative practice agreement rather than under an emergency-use provision.

[21] Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure these provisions are applicable to controlled substances.

[22] Boards may consider extending beyond a thirty (30)-day supply.

(3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner's authorization and that authorization of the Practitioner is required for future refills~~.~~ and

(4) the Pharmacist informs the Prescriber of the emergency refill as soon as practicable.

Unit-of-use quantities may be dispensed when appropriate.

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Section 9. Automated Pharmacy Systems.

(a) Automated Pharmacy Systems can be utilized in licensed pharmacies and Shared Pharmacy Services Pharmacies and other locations approved by the Board. ~~located within an Institutional Facility or clinic~~. A Pharmacist is not required to be physically present at the site of the Automated Pharmacy System if the system is supervised electronically by a Pharmacist. Automated Pharmacy Systems shall comply with the following provisions.

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(4) Automated Pharmacy Systems shall have adequate security systems and procedures, evidenced by written policies and procedures[23], to:

(i) prevent unauthorized access;

(ii) comply with federal and state regulations; and

(iii) prevent the illegal use or disclosure of Protected Health Information.

Model Rules for Institutional Pharmacy

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Section 6. ~~Packaging~~ Relabeling of Previously Dispensed Outpatient Medication for Institutional ~~Inpatient~~ Use.

(a) At a patient's or patient's caregiver's request, an Institutional Pharmacy may relabel for ~~inpatient~~ institutional use ~~change the packaging of~~ a Drug previously Dispensed by an outpatient pharmacy to the patient.

[23] The use of Automated Pharmacy Systems requires written policies and procedures in place prior to installation to ensure safety, environmental controls, accuracy, security, and patient confidentiality and to define access and limits to access to equipment and medications.

(b) ~~Any~~ The Institutional Pharmacy providing ~~packaging~~ relabeling services shall have in place policies and procedures to:
(1) assess whether the medication may be Adulterated or Misbranded; and
(2) package and label the medication in compliance with state and federal requirements and USP standards.

(c) The Institutional Pharmacy that ~~packages~~ relabels a previously Dispensed outpatient ~~medication~~ Drug shall retain all original prescription information in accordance with state record-keeping requirements.

Section 7. Relabeling of Previously Dispensed or Administered ~~Inpatient~~ Institutional Multidose Medication for Outpatient Use[24]

(a) At a patient's or patient's caregiver's request, an Institutional Pharmacy may relabel for outpatient use a multidose Drug previously Dispensed ~~to an inpatient~~ for institutional use.

(b) The Institutional Pharmacy providing relabeling services shall have in place policies and procedures to:
1. assess whether the medication may be Adulterated or Misbranded; and
2. package and label the medication in compliance with state and federal requirements and USP standards.

(c) The Institutional Pharmacy that relabels a previously Dispensed multidose Drug shall retain all original Chart Order information in accordance with state record-keeping requirements.

Model Rules for Public Health Emergencies or ~~Unusual~~ Significant Public Health Concerns

Section 1. Purpose and Scope.[25]

[24] Controlled substance dispensing by an Institutional Pharmacy for outpatient use shall be reported to the state's Prescription Monitoring Program.

[25] States may consider adding the following, more detailed language, which specifically addresses Drug Disposal and reporting requirements in the case of an emergency or disaster, to their emergency rules or guidelines:

Disposal of Prescription Drugs in Pharmacies Affected by Certain Disasters

(a) For Pharmacies that sustain flood and/or fire damage in the Prescription department or other damage resulting in an irrevocable loss of the Drug inventory, the entire Drug inventory, including Drugs awaiting pick up by Patients, becomes unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy.

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[26] or ~~similar crisis~~ ~~Unusual~~ Significant Public Health Concerns within the confines of a regulatory framework that serves to protect the welfare and health of the public.

Section 2. Definitions.

(b) For Pharmacies that experience a loss of power for an extended period of time, the Drug inventory must be evaluated for continued Product integrity using USP standards. For example, medications with labeling requiring storage at "controlled room temperature" must be kept at between 68º F and 77º F, with brief deviations of between 56º F and 86ºF. Medication inventories found to have been stored outside of USP standards become unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy. For Pharmacies with questions on USP Product integrity standards, contact USP at 800/227-8772.

Reporting of Theft or Loss of Controlled Substances During an Emergency or Disaster

(a) In circumstances of theft by looting, burglary, etc., where evidence or witnesses indicate the medications were taken by someone, the nearest DEA Diversion Field Office must be notified by telephone, facsimile, or brief written message of the circumstances of the theft immediately upon discovery. In addition, the pharmacy must complete DEA Form 106 – Report of Theft or Loss of Controlled Substances, found at *www.deadiversion.usdoj.gov*, to formally document the actual circumstances of the theft and the quantity of controlled substances involved, once this information has been conclusively determined.

(b) In circumstances of damage or where drugs were irrevocably lost to flooding or other circumstance, such information must be reported on DEA Form 41 – Registrants Inventory of Drugs Surrendered, found at *www.deadiversion.usdoj.gov*.

(c) The amount stolen or lost may need to be calculated by taking the most recent controlled substances inventory, adding the amount purchased since that date, then subtracting the amount dispensed and distributed since that date. Absent a calculated amount, a best estimate should be reported.

Disposal of Prescription Drugs Irrevocably Lost in an Emergency or Disaster

(a) Controlled Substances
Reverse Distributors, either individually or in concert with other contractors, are equipped to dispose of controlled substances. Contact your primary distributor for their recommendations for a reverse Distributor or contact a reverse Distributor directly.

(b) Contaminated Medical Debris
Non-controlled substance Prescription Drugs and Devices contaminated with flood water or other contaminants should be disposed of using a medical waste transportation, processing, and disposal system vendor. Such vendors must be licensed by the state.

(c) Hazardous Debris
Materials are deemed hazardous if they are ignitable, corrosive, toxic, or reactive. Prescription Drugs considered hazardous include, but are not limited to, epinephrine, nicotine, nitroglycerin, physostigmine, reserpine, selenium sulfide, chloral hydrate, and many chemotherapy agents, such as cyclophosphamide, chlorambucil, and daunomycin. Other hazardous items that might be found in a Pharmacy include paints, varnishes and thinners, alcohol, batteries, mercury thermometers, and blood pressure cuffs. It is recommended that Pharmacies handle all contaminated Prescription medications as hazardous debris and dispose of it using a hazardous waste collection and disposal company. These companies must be licensed by the state.

(d) Commercial Waste
Over-the-counter Drugs and other store shelf material may be disposed of in the commercial waste stream.

[26] During a Public Health Emergency, Boards of Pharmacy should issue waivers that mirror waivers issued by Federal and other state entities.

(a) "Declared Disaster Areas" are areas designated by state or federal authorities as those that have been adversely affected by a natural or man-made disaster and require extraordinary measures to provide adequate, safe, and effective health care for the affected population.

(b) "Emergency Dispensing" means Dispensing of a Prescription Drug, including a controlled substance, during a ~~Unusual~~ Significant Public Health Concern or Public Health Emergency , and:

(i) the prescriber cannot be contacted;

(ii) the Pharmacy has no record on file of prior dispensing of the Drug; and

(iii) the immediate needs of the patient must be met until a primary care provider can be seen, so as to prevent unnecessary harm and suffering.

(~~b~~c) "Emergency Standing Prescription Drug Order" means a standing Prescription Drug Order issued by the State Health Officer for Pharmacists to Dispense designated Prescription Drugs during a Public Health Emergency requiring mass Dispensing to expeditiously treat or provide prophylaxis to large numbers of Patients.[27]

(~~c~~d) "Mobile Pharmacy" means a Pharmacy that is self-propelled or movable by another vehicle that is self-propelled.

(e) "NABP Emergency Passport Program" means a program, operated by the National Association of Boards of Pharmacy, that verifies Pharmacists, Pharmacy Technicians, Pharmacy Interns, and Pharmacies meet the standard of licensure and are in good standing in states of licensure in order to practice on a temporary or emergency basis according to state Public Health Emergency orders or as otherwise determined by the state board of pharmacy.

(~~d~~f) "Public Health Emergency" means an imminent threat or occurrence of an illness or health condition caused by terrorism, bioterrorism, epidemic or pandemic disease, novel and highly fatal infectious agent or biological toxin, or natural or man-made disaster, that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability that is beyond the capacity of local government or nongovernmental organizations to resolve.

(~~e~~g) "State of Emergency" means a governmental declaration, usually issued as a result of a Public Health Emergency, that may suspend certain normal functions of government, alert

[27] Boards may consider identifying the official who has authority to issue an "Emergency Prescription Drug Order" and reviewing this on a regular basis.

citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.

(~~f~~h) "Temporary Pharmacy Facility" means a facility established as a result of a Public Health Emergency or State of Emergency to temporarily provide Pharmacy services within or adjacent to Declared Disaster Areas.

(i) "~~Unusual~~ Significant Public Health Concern" means a potential threat or occurrence of a circumstance or health condition that poses a risk to the health of a significant number of patients that is beyond the capacity of local government or nongovernmental organizations to immediately resolve.

Section 3. Emergency Standing Prescription Drug Order.

(a) For the duration of a State of Emergency issued due to a Public Health Emergency, a Pharmacist may Dispense a Prescription Drug pursuant to an Emergency Standing Prescription Drug Order if the Pharmacist:

(1) performs, to the extent possible, a Prospective Drug Utilization Review (DUR) and Patient Counseling in accordance with these rules;[28]

(2) reduces the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Standing Prescription Drug Order," and files and maintains the record as required by state and federal law.

Section 4. ~~Public Health~~ Emergency Refills ~~Dispensing~~.

(a) For the duration of the State of Emergency issued due to a Public Health Emergency, or for the duration of a Significant ~~Unusual~~ Public Health Concern, in the affected state and in other states engaged in disaster assistance pursuant to a governmental declaration or rule of the Board, a Pharmacist may Dispense a refill of a Prescription Drug, not to exceed a thirty (30)-day supply, without Practitioner authorization if:[29]

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the Patient's life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Refill

[28] Although these services are important, in times of a disaster or emergency, it may not be possible to perform a Prospective Drug Review or provide counseling on Dispensed Drugs.

[29] Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure these provisions are applicable to controlled substances.

Prescription," and maintains the record as required by state and federal law, as well as state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency; and

(3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner's authorization and that authorization of the Practitioner is required for future refills.

(b) For the duration of the State of Emergency, in an effort to provide patients with the best possible care in light of limited Drug availability and/or limited information on patients' current Drug therapy, a Pharmacist may initiate or modify Drug therapy and Dispense an amount of such Drug to accommodate a patient's health care needs until that patient may be seen by a Practitioner. Pharmacists performing such activities must utilize currently accepted Standards of Care when initiating or modifying Drug therapy. These activities may be undertaken if:

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the Patient's life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates that drug therapy has been initiated or modified due to a disaster or emergency, and maintains the record as required by state and federal law; and[30]

(3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner's authorization and that authorization of the Practitioner is required for future refills.

(c) The Practitioner and Pharmacist shall not incur any liability as a result of the performance of these activities in good faith pursuant to this section.

(d) The Pharmacist shall inform the Prescriber of the emergency refill as soon as practicable.

[30] Boards should be cognizant that state and federal disaster agencies, to ensure continued provision of care during disasters or emergencies, have programs that consider reimbursement requests for medication providers and may request Board assistance in the dispersal of funds. Records of dispensing will likely be needed for possible reimbursement consideration. In addition, records may also be used for post-event evaluation of care.

Section 5. Temporary Recognition of Nonresident State Licensure and NABP Emergency Passport for Pharmacists, Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, and Pharmacy Interns.

~~(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 and registered with the NABP Emergency Passport Program, may Dispense Prescription Drugs in ~~areas affected by the~~ Declared Disaster Areas during the time that the State of Emergency exists if:

(i) an application has been submitted in the form prescribed by the Board of Pharmacy;

(ii) the Board can verify current licensure in good standing of the Pharmacist directly with the state or indirectly via a third-party verification system;[31] ~~and~~

(iii) the fee(s) specified by the Board have been paid; and

(iv) the Pharmacist is engaged in a legitimate relief effort.

If the Board is supplied with proof of an active Emergency Passport, as administered by the National Association of Boards of Pharmacy, and compliance with subsections (i) and (ii) above is demonstrated;

(2) a Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern not licensed in this State, but currently licensed in another state and registered with the NABP Emergency Passport Program, may assist the Pharmacist in Dispensing Prescription Drugs in ~~affected~~ Declared Disaster Areas during the time that the State of Emergency exists if:

(i) an application has been submitted in the form prescribed by the Board of Pharmacy;

(ii) the Board can verify current licensure in good standing of the Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern directly with the state or indirectly via a third-party verification system; ~~and~~

(iii) the fee(s) specified by the Board have been paid; and

[31] 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.

(iv) the Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern is engaged in a legitimate relief effort.

~~If the Board is supplied with proof of an active Emergency Passport, as administered by the National Association of Boards of Pharmacy, compliance with subsections (i) and (ii) above is demonstrated.~~

Section 6. Temporary Recognition of Nonresident State Licensure for Manufacturers, Outsourcing Facilities, Repackagers, Third-Party Logistics Providers, and Wholesale Drug Distributors.

When a State of Emergency is declared due to a Public Health Emergency, or when there exists an ~~Unusual~~ Significant Public Health Concern:

(1~~3~~) A Manufacturer, Outsourcing Facility, Repackager, Third-Party Logistics Provider, or Wholesale Drug Distributor, not licensed in this State, but currently licensed in another state, may Distribute Prescription Drugs in affected areas ~~Disaster Areas~~ during the time that the State of Emergency or Significant ~~Unusual~~ Public Health Concern exists if ~~(i)~~ the Board can verify ~~:~~ that the entity is engaged in a legitimate relief effort and has ~~(ii)~~ current licensure in good standing in another state.

(2) ~~of the~~ For Wholesale Drug Distributors, verification of state licensure may take place directly with the state or indirectly via a third-party verification system.~~; and~~

~~(iii)the Wholesale Drug Distributor is engaged in a legitimate relief effort.~~

(43)For Wholesale Drug Distributors, the temporary recognition of nonresident licensure or registration shall cease with the termination of the State of Emergency or ~~Unusual~~ Significant Public Health Concern, or after 90 days, whichever comes first.

(4) For Manufacturers, the Board must verify registration with FDA and shall review the most recent ~~that a~~ Current Good Manufacturing Practice (cGMP)[32] inspection. ~~has taken place within the previous six months.~~

Section 7~~6~~. Temporary Pharmacy Facilities or Mobile Pharmacies.

[32] US Food and Drug Administration inspection is preferred.

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Standards Outlined in USP General Chapter <17>

Article I
Title, Purpose, and Definitions

…

Section 105. Definitions.

…

(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 conform with USP General Chapter <17> or the most current chapter addressing prescription container labeling. ~~include the following:~~

~~(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.[33] Critical information text should never be truncated and shall include:~~

~~(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 Order;[34] and~~

~~[33] Alternative access methods may be utilized to address visual impairment in patients or caregivers.~~

~~[34] 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~~

(b) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters;[35]

(C) drug name:

(a) if written for a brand name and a generic Drug is Dispensed, include phrase "Generic for [brand name]" or similar wording;[36] and

(b) include Drug name suffixes, such as CD, SR, XL, XR, etc;

(D) drug strength, expressed in the metric system whenever possible;

(E) oral liquid medication dosage, expressed in milliliters; and

(F) "use by" date:

(a) date after which Drug should not be used; not expiration date of Drug or expiration date of prescription;[37] 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:[38]

(A) Pharmacy name or Dispensing practitioner's entity name;[39]

(B) Pharmacy telephone number;[40]

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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.

[35] 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").

[36] If an Interchangeable Product is Dispensed, include the phrase "interchangeable for [Reference Product]."

[37] Boards of Pharmacy may determine that this "use by" date does not apply to all Drugs (for example epinephrine auto-injectors) and may allow the Manufacturer's expiration date to be used if the Drug is kept in the Manufacturer's original, unopened packaging, provided that the Pharmacist uses professional judgement to assess the continued need for the Drug and counsels the patient on proper storage.

[38] 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.

[39] Boards of Pharmacy should recognize that some pharmacies "do business as" a name other than the corporate name.

[40] 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.

(C) prescriber name:

(a) format as – "Prescriber: [prescriber name]";

(D) "fill date";[41]

(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 information;[42]

(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.[43]

Pursuant to a Gap Analysis Findings as Recommended by Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment

[41] "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.

[42] Auxiliary information, including auxiliary Labels, should be evidence based, standardized, and demonstrated to complement the prescription Label.

[43] Boards of Pharmacy may consider utilizing these suggested Labeling formats provided below.

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 307. Licensure of Certified Pharmacy Technicians.

(a) In order to be licensed as a Certified Pharmacy Technician 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 graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;

(4) have:[44]

(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;[45]

[44] 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.

[45] 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;[46]

(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.[47]

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

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Pursuant to Recommendations by Alliance for Pharmacy Compounding

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National Association of Boards of Pharmacy Model State Pharmacy Act

Article I
Title, Purpose, and Definitions

Introductory Comment to Article I

Article I of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) *sets forth the foundation upon which the Act is constructed. It clearly declares and acknowledges that safeguarding the public interest is the foremost compelling reason for regulating the*

[46] 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 and ABHES. See the footnote to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

[47] The Board may specifically authorize a Pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate under terms and conditions deemed appropriate.

Practice of Pharmacy and the Distribution of Drugs and related Devices. It also circumscribes the activities included within the Practice of Pharmacy, as well as the definitions of several other terms used throughout the Act.

NABP created the Model Act to provide State Boards of Pharmacy with model language that may be used when developing state laws or board rules for the respective States. *NABP believes that it is both desirable and necessary to recognize that the public interest must be the central precept in the* Model Act *and its administration, and that State Boards of Pharmacy must constantly strive to achieve the principles enunciated in Article I of the Act.*

An ACT concerning the regulation of the Practice of Pharmacy in this State and related matters.

Be it enacted. . . .

…

Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" means, but is not limited to, the interpretation, evaluation, Dispensing, ~~limited Distribution~~ 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.[48]

[48] 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.

(p) "Compounding" means the preparation, mixing, assembling, altering, packaging, or Labeling of a Drug, Drug-Delivery Device, or Device, ~~unless performed in a Food and Drug Administration (FDA)-registered Outsourcing Facility in conformance with Federal law,~~ in accordance with a licensed Practitioner's prescription, medication order, or initiative based on the Practitioner/patient/Pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

(1) preparation of Drug dosage forms for both human and animal patients;

(2) preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns[49]; and

(3) manipulation of commercial Products for patient-specific needs beyond FDA-approved Labeling.[50]

…

(t2) "Drug" means:

(1) articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;[51]

(2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and

(4) articles ~~intended for~~ used~~d~~ as a Component of any articles specified in clause (1), (2), or (3) of this definition.

…

~~(f6) "Significant Adverse Drug Reaction" means any Drug-related incident that may result in serious harm, injury, or death to the patient.~~

(g6) "Significant Adverse Drug Reaction" means an unexpected adverse drug experience that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or

[49] ~~Anticipatorily Compounded Drugs may not be dispensed until receipt of a patient-specific Prescription Drug Order.~~

[50] Reconstitution of an FDA-approved Drug according to FDA-approved Labeling is not Compounding.

[51] The official compendium recognized by Food and Drug Administration (FDA) and many State Boards of Pharmacy is the USP-NF.

significant disability/incapacity, or a congenital anomaly/birth defect. A medical event may also be considered a significant adverse drug reaction when, based on appropriate medical judgment, the medical event places the patient at a significant risk of experiencing any of the outcomes listed above. An adverse drug reaction is unexpected if it has not previously been observed, rather than a reaction that is not anticipated from the pharmacological properties of the pharmaceutical product.

...

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.*

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 Board:[52]

(1) persons engaged in the Practice of Pharmacy (including Telepharmacy ~~as defined in this Act~~);

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

(2) dispensing Practitioners and Practitioner's facilities including those engaged in nonsterile[53] Compounding;[54]
(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.

(b) The Board shall establish by rule, under the powers granted to it under Section 212 and 213 of this Act and as may be required from time to time, under federal law, the Criteria that each Person must meet to qualify for licensure in each classification, as well as the required practice standards applicable to each type of activity and/or facility. The Board shall adopt definitions in addition to those provided in Article I, Section 105, where necessary to carry out the Board's responsibilities. The Board may issue licenses with varying restrictions to such Persons where the Board deems it necessary.[55]

(c) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.

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

[54] 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 Compounding and the Dispensing of Drugs applicable to Pharmacists.

[55] Section 501(b) contemplates that the Criteria for licensure, beyond minimum requirements for all Persons and Pharmacies, established in an individual entity classification could differ. For example, the Criteria that must be met by a nuclear Pharmacy will certainly differ from that of the community Pharmacy. This type of latitude places the responsibility on the Board to adopt appropriate rules to meet the situation at hand. It also provides a forum for change to meet the changing concepts of professional practice and the Distribution of Drugs and/or Devices.

(d) Each licensed Person located outside of this State who ships, mails, Dispenses, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in this State, or Pharmacy located outside of this State who ships, mails, Dispenses, Distributes, or Delivers Drugs or Devices in this State, shall comply with the laws of patients' domicile, and shall designate a registered agent in this state for service of process. Any such licensed Person or Pharmacy who does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such licensed Person growing out of or arising from such shipping, mailing, Dispensing, Distribution, Wholesale Distribution, or Delivery of Drugs or Devices. ~~Delivery.~~ A copy of any such service of process shall be mailed to such Person or Pharmacy by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Person has designated on its application for licensure in this State. If any such Person is not licensed in this State, service on the Secretary of State only shall be sufficient service.[56]

…

Section 502. Application.[57]

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

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

(a) personal information;
(b) marital information;
(c) family information (parents, siblings, in-laws);
(d) education;
(e) military information;
(f) arrests, detentions, litigations, and arbitrations;
(g) residences (past 25 years);
(h) employment (back to age 18);
(i) character references;
(j) safe deposit box or other depository information;
(k) privileged, occupational, or professional licensure;
(l) out-of-state business, venture, or industry licensure or financial interest in such;
(m) appearances before any licensing agency or similar authority in or outside the state;
(n) denials of a personal license, permit, certificate, or registration for a privileged, occupational, or professional activity;
(o) denials of a business or industry license or related finding of suitability, or participation in a group that has been denied a business or industry license or related finding of suitability;
(p) Administrative actions or proceedings related to the pharmaceutical industry or participation in a group that has been the subject of such administrative actions or proceedings;

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

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

(c) The Board of Pharmacy shall require ~~all~~ any pharmacy applicants~~s~~ for initial and renewal of licensure ~~to Dispense, Distribute, Wholesale Distribute, Manufacture, sell, purchase, transfer, and/or produce Drugs or Devices~~ to state whether they engage or intend to engage in Compounding as defined in this Act.[58, 59] ~~Applicants who engage or intend to engage in Compounding shall submit concurrently with their application for licensure responses to a questionnaire regarding the applicant's Compounding operations.~~

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

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

(q) guilty findings or pleadings or pleas of nolo contendere to any offense, federal or state, related to prescription Drugs and/or controlled substances or participation in a group that has been found or pled guilty or that has pled nolo contendere to any such offense;

(r) surrender, voluntary or otherwise, of licensure, permit, or certificate of registration relating to the pharmaceutical industry, or participation in a group that has surrendered, voluntary or otherwise, any such licensure, permit, or certificate of registration; and

(s) any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or Drug-related industry.

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

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

~~the direct supervision of a licensed Pharmacist and comply with Federal requirements applicable to Outsourcing Facilities.~~

…

Section 503. Notifications.

(a) All licensed Persons shall report to the Board of Pharmacy the occurrence of any of the following:
(1) permanent closing;
(2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
(3) any ~~significant~~ theft or loss of Drugs or Devices;
(4) any conviction of any employee of any State or Federal Drug laws;
(5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
(6) disasters, ~~accidents,~~ or any theft, destruction, or loss of records required to be maintained by State or Federal law;
(7) ~~occurrences of Significant Quality-Related Events;~~
(8) Significant Adverse Drug Reaction associated with Compounded Drugs;
(9) recalls of Compounded Drugs;
(10) recalls of sterile Repackaged Drugs;
(11) illegal use or disclosure of Protected Health Information; or
(12) any and all other matters and occurrences as the Board may require by rule.

(b) All licensed Persons shall report to the Board of Pharmacy, or its authorized agent, if they are engaging in any sterile Compounding activity conducted at a licensed facility prior to commencing of any sterile Compounding activity and at least in a manner determined by the Board. The Board may establish by rule additional reporting requirements for sterile and nonsterile Compounding activities.

(c) All licensed Persons shall report to the Board of Pharmacy, or its authorized agent, the occurrence of any Pharmacy or Pharmacy-related inspection conducted by any ~~State or Federal regulatory agency of the Person's home state, or authorized agent thereof, or~~

~~authorized agent thereof~~ and shall provide a copy of the report of such inspection, including applicable documents relating to corrective actions[60].

Section 504. Grounds, Penalties, and Reinstatement.

(a) No Person, Pharmacy, or Pharmacy Benefits Manager designated in Section 501 of this Act shall operate until a license has been issued to said Person, Pharmacy, or Pharmacy Benefits Manager by the Board.

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

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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*~~

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

~~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.[61]

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Section 8. Quality Assurance.

(a) There shall be a documented, ongoing quality assurance program that monitors personnel performance, Component Verification and usage, Disinfection, sterilization, equipment, and facilities that are appropriate for the Drug being prepared. Quality assurance 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.

[61] ~~The Compounding of Drugs for animals must be done in accordance with the algorithm contained in the Animal Medicinal Drug Use Clarification Act of 1994 and associated FDA Guidance.~~

(g) A Compounded Drug shall be deemed Adulterated if it has been prepared, packed, or held under insanitary conditions whereby ~~after testing,~~ it ~~was determined to~~ ~~may~~ have been contaminated with filth, or whereby it ~~may have~~ ~~has~~ been rendered injurious to health.

~~Section 9. Compounded Drug Preparations for Veterinary Use.~~

(a) ~~The use of bulk Drug substances for Compounded Drug preparations is prohibited except when:~~
~~(1) Compounding is pursuant to a patient-specific prescription for a non-food-producing animal or as an antidote to prevent animal suffering or death in food-producing animals;~~
~~(2) there is no marketed approved, conditionally approved, or indexed (in *The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species*) Drug that can be used as labeled to treat the condition;~~
~~(3) there is no marketed approved animal or human Drug that can be used to treat the condition through off-label Drug use;~~
~~(4) the Drug cannot be appropriately Compounded from an approved animal or human Drug;~~
~~(5) immediate treatment with the Compounded Drug preparation is necessary to avoid animal suffering or death; and~~
~~(6) FDA has not identified a significant veterinary safety concern with the use of the bulk Drug substance for Compounding.~~

(b) ~~It is acceptable for any licensed Pharmacy to Compound veterinary Drug preparations to be used by veterinarians in their offices for Administration to clients' animals.~~

(c) ~~Compounded office use Drug preparations may be Dispensed by a veterinarian to clients only in an urgent or emergency situation for use in a single course of treatment, not to exceed a 120-hour supply.~~

(d) ~~Prohibition on wholesaling~~
~~The Compounded veterinary Drug preparations will not be Distributed by an entity other than the Pharmacy that Compounded such veterinary Drug preparations. This does not prohibit Administration of a Compounded Drug preparation in a veterinary health care setting or Dispensing of a Compounded Drug preparation pursuant to a Prescription Drug Order executed in accordance with federal and state law.~~

(e) ~~Providing samples of Compounded veterinary Drug preparations is prohibited.~~

(f) ~~Upon becoming aware of any adverse event or Product defect, the Pharmacy reports the event on the designated FDA form[62] within 15 days and includes the FDA statement about reporting adverse events on the prescription Label.~~

Pursuant to Recent State Limitations on Examination Attempts

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Article III
Licensing

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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) have graduated and received the first professional degree from a college or school of Pharmacy that has been approved by the Board of Pharmacy;[63]

(4) 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;[64]

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

[62] FDA Form 1932a or most current version.

[63] 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 the footnote to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

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

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

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

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

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

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