Report of the Committee on Law Enforcement/Legislation

Members Present:

Steven W. Schierholt (OH), *chair*; Allison Vordenbaumen Benz (TX); Lee Ann F. Bundrick (SC); Lemrey "Al" Carter (IL); Debbie Chisolm (CT); Virginia "Giny" Herold (CA); Deborah C. "Debbie" Mack (AR); Lenora Newsome (AR); Jeenu Philip (FL); Gayle D. Ziegler (ND).

Others Present:

Jack W. "Jay" Campbell IV, *Executive Committee Liaison*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Maureen Schanck, Angie Alderton, *NABP staff*.

Introduction:

The Committee on Law Enforcement/Legislation met January 22, 2018, at NABP Headquarters, Mount Prospect, IL.

Review of the Committee Charge

Committee members reviewed their charge and accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, 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 Best Practices for Veterinary Compounding, With Revisions.

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

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

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Section 105. Definitions.

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(x) "Compounding" means the preparation, mixing, assembling, altering, packaging, and 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, ~~are~~ 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[1]; and

(3) ~~reconstitution or~~ manipulation of commercial Products ~~that may require the addition of one or more ingredients~~ for patient-specific needs beyond FDA-approved ~~manufacturer's~~ Labeling.[2]

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(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;[3]

(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 use as a Component of any articles specified in clause (1), (2), or (3) of this definition.

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

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

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

(m4) "Outsourcing Facility"[4] means a facility at one geographic location or address that[5]:
(1) is engaged in the Compounding of sterile drugs for human use;
(2) is registered as an Outsourcing Facility with FDA; and
(3) complies with all of the requirements of Section 503B of the Federal FD&C Act.

(dd6) "Veterinary Dispensing" means the interpretation, evaluation, and implementation of a veterinary Prescription Drug Order, including the preparation, final Verification, and Delivery of a Drug for a veterinary patient in a suitable container appropriately labeled for the client for subsequent Administration.

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National Association of Boards of Pharmacy Model Rules

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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 (e.g., 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.[6]

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[4] Outsourcing Facilities may engage in Compounding for animal use.
[5] Boards may choose to license an Outsourcing Facility as a Pharmacy; however, if a Pharmacy and an Outsourcing Facility are located at the same geographic location or address, or are located adjacent to said location or address, there must be a clear delineation between the two entities and both must comply with current Good Manufacturing Practices as defined by the Federal FD&C Act.
[6] 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.

Section 9. Compounded Drug Preparations for Veterinary Use.[7]

(a) The use of bulk Drug substances for Compounded preparations is prohibited except when:
  (1) there is no marketed approved, conditionally approved, or index listed animal Drug that can be used as labeled to treat the condition;
  (2) there is no marketed approved animal or human Drug that can be used to treat the condition through off-label Drug use;
  (3) the Drug cannot be appropriately Compounded from an approved animal or human Drug;
  (4) immediate treatment with the Compounded drug is necessary to avoid animal suffering or death; and
  (5) 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 office for Administration to clients' animals.

(c) Compounded office use 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 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 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 preparations is prohibited.

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Background:

The committee members were advised that the task force had used Food and Drug Administration's draft guidelines for veterinary compounding as a basis for the majority of the recommended *Model Act* amendments. Members were further advised that the draft guidelines had since been withdrawn. Despite this, the committee, recognizing the substantive value of the guidelines, deferred to the task force's recommended *Model Act* amendments in most instances.

Of significance, the committee agreed with the task force that a new section addressing Compounded Drug Preparations for Veterinary Use be added to the Model Rules for Compounded or Repackaged Pharmaceuticals. The new language was developed using existing California and North Dakota pharmacy regulations addressing veterinary compounding as a foundation. The committee thought that the new language will assist boards and licensees with

[7] This section is intended for non-food-producing animals. For food-producing animals, refer to federal and state laws and rules.

identifying appropriate instances of compounding for office use by veterinarians as well as appropriate dispensing of such compounded products in emergency situations.

In addition, the committee members agreed with the task force that the definition of "Compounding" in Section 105 should clarify that reconstitution per FDA-approved labeling is not compounding, but revised the wording slightly to describe the labeling as "FDA-approved labeling" rather than "manufacturer's Labeling." To clarify further, the committee also agreed that a footnote should be added that states, "Reconstitution of an FDA-approved Drug according to Labeling is not Compounding." In addition, the committee agreed with the addition of a definition for "Veterinary Dispensing" to recognize that this patient population is included as part of the practice of pharmacy.

LE/L Recommendation 2: The Committee Recommends Approving the Amendments to the *Model Act* Suggested by the Task Force on Long-Term Care Pharmacy Rules, With Revisions.

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

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

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(y) "Chart Order"[8] means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her ~~designated agent~~ licensed health care designee for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:

(1) the full name of the patient;
(2) date of issuance;
(3) name, strength, and dosage form of the Drug prescribed;
(4) directions for use; and

[8] ~~Chart Orders that are written by the Prescriber's agent shall be countersigned by the prescribing Prescriber within the required time period as required by state law or rule.~~

(5) if written or electronic, the prescribing Practitioner's signature[9] or the signature of the Practitioner's ~~agent~~ licensed health care designee (including the name of the prescribing Practitioner).~~; or if electronically submitted, the prescribing Practitioner's electronic or digital signature.~~

Bidirectional transmission of Chart Orders between the Institutional Pharmacy and the Institutional Facility ~~may occur unless prohibited by state law~~ is allowed. The Pharmacist-in-Charge shall ensure that the Institutional Pharmacy has ~~develop~~ ~~have~~ policies and procedures for a Practitioner to delegate the transmittal of a Chart Order to a licensed nurse employed by, or contracted by, the Institutional Facility and acting within the scope of his or her practice. Renewal of ongoing Chart Orders shall be signed by the prescriber at the appropriate time interval based on facility type and federal regulation, state law or rule. ~~Unless otherwise indicated,~~ Chart Orders shall be ongoing until such time as the Practitioner discontinues the order and such discontinuation is communicated to the Pharmacy~~.~~, including but not limited to, by automatic stop order, unless otherwise indicated.

…

(a3) "Institutional Facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):

(1) hospital;
(2) Long-Term Care Facility;
(3) convalescent home;
(4) nursing home;
(5) extended care facility;
(6) mental health facility;
(7) rehabilitation center;
(8) psychiatric center;
(9) developmental disability center;
(10) drug abuse treatment center;
(11) family planning clinic;
(12) penal institution;
(13) hospice;
(14) public health facility;
(15) athletic facility;~~.~~
(16) assisted living facility; and
(17) intermediate care facility for individuals with intellectual disabilities.

…

[9] A Practitioner's signature for Chart Orders is only required to be maintained at the Institutional Facility unless otherwise required for controlled substances by state and federal law.

(b3) "Institutional Pharmacy"[10] means any place that is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist Care Services to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "Drugs") are Dispensed, Compounded, and Distributed.[11]

(c3) "Therapeutic Interchange" means substitution by the pharmacist of one medication for another medication with a similar therapeutic effect at the time of dispensing.

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National Association of Boards of Pharmacy Model Rules

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Model Rules for Institutional Pharmacy

Section 1. Applicability.

The following Rules are applicable to all Institutional Facilities and Institutional Pharmacies as defined in Section 105 of the Model State Pharmacy Act.~~2 below.~~

~~Section 2. Definitions.~~

~~(a) "Chart Order" means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her licensed health care designee for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:~~

~~(1) the full name of the patient;~~

~~(2) date of issuance;~~

~~(3) name, strength, and dosage form of the Drug prescribed;~~

~~(4) directions for use; and~~

~~(5) if written, the prescribing Practitioner's signature or the signature of the Practitioner's agent (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing Practitioner's electronic or digital signature.~~

[10] Although traditionally characterized as being physically part of an Institutional Facility, the Model Rules recognize that an Institutional Pharmacy may or may not be physically attached to an Institutional Facility.

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

~~(b) "Institutional Facility"[12] means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):~~

~~(1) hospital;~~
~~(2) Long-Term Care Facility;~~
~~(3) convalescent home;~~
~~(4) nursing home;~~
~~(5) extended care facility;~~
~~(6) mental health facility;~~
~~(7) rehabilitation center;~~
~~(8) psychiatric center;~~
~~(9) developmental disability center;~~
~~(10) drug abuse treatment center;~~
~~(11) family planning clinic;~~
~~(12) penal institution;~~
~~(13) hospice;~~
~~(14) public health facility;~~
~~(15) athletic facility.~~

~~(c) "Institutional Pharmacy"[13] means any place which is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist Care Services to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as *Drugs*) are Dispensed, Compounded, and Distributed.[14]~~

~~Section 3~~2. ~~Personnel~~.

(a) ~~Each Institutional Pharmacy shall be directed by a Pharmacist, hereinafter referred to as the *Pharmacist-in-Charge*, who is licensed to engage in the Practice of Pharmacy in this State. The Pharmacist-in-Charge shall:~~

~~(1) provide for the sufficient number and type of personnel to assist with the operation of the Institutional Pharmacy.~~

~~(2) oversee the supervision of Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, and delivery personnel while performing duties in the Institutional Pharmacy and Institutional Facility.~~

~~[12] Although the definition of Institutional Facility is broad and may encompass an array of facilities that provide long-term medical care and services for its residents, some states may also recognize residential assisted living facilities or residential group homes as such.~~

~~[13] Although traditionally characterized as being physically part of an Institutional Facility, the Model Rules recognize that an Institutional Pharmacy may or may not be physically attached to an Institutional Facility.~~

~~[14] States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed pharmacy area to accommodate the need to store emergency supplies.~~

~~(3) have policies and procedures for a Practitioner to delegate the transmittal of a Chart Order to a licensed nurse employed by, or contracted by, the Institutional Facility and acting within the scope of his/her practice.~~

Section ~~4~~ ~~3~~ 2. Absence of Pharmacist at a Pharmacy Located Within an Institutional Facility.

(a) During such times as when a~~n Institutional~~ Pharmacy, which is located within an Institutional Facility, may be unattended by a Pharmacist, arrangements shall be made in advance by the Pharmacist-in-Charge for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of night cabinets and, in emergency circumstances, by access to the Pharmacy. A Pharmacist must be "on call" during all absences.

(b) In the absence of a Pharmacist, Drugs shall be stored in a locked cabinet, Automated Pharmacy System, or other enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Pharmacist-in-Charge shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet(s) and determine who may have access, and shall ensure that:

(1) Drugs are properly Labeled;
(2) only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
(3) whenever access to the cabinet occurs, written Practitioner's orders and proofs-of-use are provided;
(4) all Drugs therein are inventoried no less than once per week~~;~~ unless stored in an Automated Pharmacy System;
(5) a complete audit of all activity concerning such cabinet is conducted no less than once per month; and
(6) written policies and procedures are established to implement the requirements of this Section ~~3~~4.

(c) Whenever any Drug is not available from floor supplies or night cabinets, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of this Section 4. One supervisory nurse in any given ~~eight-hour~~ shift is responsible for obtaining Drugs from the Pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an authorized nurse must be recorded on a suitable form showing the patient name, room number, name of Drug, strength, amount, date, time, and signature of nurse. The form shall be left with the container from which the Drug was removed.

Section 3~~4~~. Emergency Kit Use by Institutional Facilities.

(a~~d~~) Emergency kit Drugs may be provided for use by authorized personnel of the Institutional Facility provided, however, such kits meet the following requirements:

(1) Emergency kit Drugs are those Drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such Drugs from such other sources.

(2) All emergency kit Drugs shall be provided and sealed by a Pharmacist~~,~~ or his or her designee in accordance with applicable security and inventory control policies and procedures.

(3) The supplying Pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits.

(4) Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them.

(5) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency Drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying ~~Pharmacist~~Pharmacy.

(6) Drugs shall be removed from emergency kits only pursuant to a valid Chart Order.

(7) Whenever an emergency kit is opened, the supplying ~~Pharmacist~~ Pharmacy shall be notified and the ~~Pharmacist~~ Pharmacy shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.[15]

(8) The expiration date of an emergency kit shall be the earliest date of expiration of any Drug supplied in the kit. Upon the occurrence of the expiration date, the supplying ~~Pharmacist~~ Pharmacy shall replace the expired Drug.

(9) The Pharmacy that supplies controlled substances for emergency kits must comply with applicable state and federal requirements.

Section 4~~5~~. Drug Distribution and Pharmacist Care Services ~~Control~~.

(a) The Pharmacist-in-Charge shall establish written procedures for the safe and efficient acquisition, handling, storage, ~~Distribution~~ and Dispensing of Drugs, including investigational Drugs, and for the provision of Pharmacist Care Services. An annual updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(b) Pharmacist may engage in Therapeutic Interchange or formulary substitution as authorized by the facility's interdisciplinary committee[16] of health care providers,

[15] When the Pharmacy restocks and reseals the emergency kit Drugs, it is recommended that a lock or other similar device be used to assure that unauthorized access to the kit is minimized.

[16] This is often referred to as the pharmacy and therapeutics committee or the quality assessment and assurance committee.

at a minimum to include a Practitioner and a Pharmacist. Proper record of this authority should be maintained at the Pharmacy.

(c) To ensure continuous patient care, the facility's director of nursing or their documented licensed health care designee ~~shall be considered the legal agent of the Practitioner who is providing care for a patient in the facility and is thereby authorized to~~ may transmit the Chart Order to a Pharmacy.[17]

(d) The Pharmacist shall assess each patient's medication regimen based on a review of the health record, either remotely or on site, in a timely manner that promotes improving patient clinical outcomes, medication safety and education, and appropriate care management.

(e) If the Institutional Pharmacy is not located within an Institutional Facility, the Pharmacist-in-Charge may designate a licensed nurse to ~~can~~ restock an Automated Pharmacy System using verification technology ~~under the supervision of a Pharmacist by~~ such ~~means~~ as bar code scanning, electronic, or other technology.

(f) Institutional Pharmacies either located within or not within Institutional Facilities may Dispense medication to patients upon discharge in order to ensure a transition of care between settings until a new Prescription Drug Order is issued.

~~(b) Drugs brought into an Institutional Facility by a patient shall not be Administered unless they can be identified and the quality of the Drug assured. If such Drugs are not to be Administered, then the Pharmacist-in-Charge shall, according to procedures specified in writing, have them turned in to the Pharmacy, which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.~~

~~(c) Investigational Drugs shall be stored in and Dispensed from the Pharmacy only. All information with respect to investigational Drugs shall be maintained in the Pharmacy.[18]~~

Section 5~~6~~. Shared Pharmacy Services Utilization for Immediate Need.[19]

(a) In accordance with the Model Rules for the Practice of Pharmacy and Shared Pharmacy Services, an Institutional Pharmacy may outsource services to another Pharmacy for the limited purpose of ensuring that Drugs or Devices are attainable to meet the immediate needs of patients and residents of the Institutional Facility or

[17] Federal law may restrict who can transmit a Chart Order for a controlled substance.

[18] ~~Regarding the use of investigational Drugs in an institution, it is necessary that the institution ensure that such studies contain adequate safeguards for the patient, the institution, and the scientific integrity of the study. The institution must have written policies and procedures for the approval, management, and control of investigational Drug studies. All patients who participate in investigational Drug studies must freely consent, in writing, to treatment with these Drugs. The Pharmacist is responsible to the institution and to the principal investigator for seeing that procedures for the control of investigational Drug use are developed and implemented.~~

[19] Although Institutional Pharmacies primarily outsource services to another Pharmacy for the purposes of meeting the immediate needs of patients and residents when the Institutional Pharmacy is closed, it is also recognized that other services may be outsourced that the Institutional Pharmacy is not able to provide on an ongoing basis.

when the Institutional Pharmacy cannot provide services on an ongoing basis, provided that the Institutional Pharmacy:

(1) has obtained approval from the Institutional Facility to outsource Shared Pharmacy Services for its inpatients and residents; and

(2) ~~provides~~ shares a valid Chart Order ~~to~~ with the Pharmacy it has contracted with for the Shared Pharmacy Services without the need to transfer the order.

Section 6~~7~~. Packaging of Previously Dispensed Medication.

(a) At a patient's or patient's caregiver's request, a Pharmacy may change the packaging of a Drug previously Dispensed to the patient.

(b) Any Pharmacy providing packaging 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 Pharmacy that packages a previously Dispensed medication shall retain all original prescription information in accordance with state record-keeping requirements.

Section 7~~8~~. Institutional Pharmacy Delivery Room.

Prescription Drugs, Devices, and other Products restricted to sale or Dispensing by, or under the supervision of, a Pharmacist must be stored in the Pharmacy and must not be sold, Delivered, or otherwise removed from a Pharmacy unless a Pharmacist is present, under the following:

(a) Institutional Pharmacies that are not located within an Institutional Facility may accept Returns or otherwise Deliver fulfilled, verified, and packaged prescription medication in the absence of a Pharmacist or when the Pharmacy is closed for business if the Pharmacy and the Pharmacist-in-Charge maintain written policies and procedures for secured Delivery area storage and removal of prescriptions.

~~(1) the prescription medications are placed in a secured delivery area equipped with adequate security, to prevent unauthorized entry, theft, and diversion. The secured delivery area must be:~~

~~(i) attached or located adjacent to the Pharmacy that fulfilled, verified, and dispensed the prescription medication;~~

~~(ii) have appropriate safeguards to ensure Drug Product integrity in accordance with USP-NF requirements.~~

~~(2) the Pharmacist-in-Charge, or designated Pharmacy staff and the approved delivery personnel have sole access to the secure delivery area.~~

(b) A Pharmacist or a Pharmacy, by means of its Delivery personnel, may accept the Return of the following Drugs or Devices to the secured Delivery area:

(1) emergency kits;

(2) prescription medications that were unsuccessfully Delivered by the Pharmacy personnel or Delivery personnel; and

(3) prescription medications eligible for Return pursuant to applicable state and federal law.

Model Rules for the Practice of Pharmacy

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Section 13. Prepackaging.

(a) A Pharmacy may Prepackage Drugs under the following circumstances:

(1) written policies and procedures have been developed that address the processes of Prepackaging within the Pharmacy;

(2) containers utilized for Prepackaging shall meet, as a minimum requirement, Class B container standards as referenced by USP;

(3) the Prepackaging processes are conducted under conditions that ensure the integrity of the Drug and under the direct supervision of a Pharmacist;

(4) the Prepackaged Drugs are labeled with the following components:

(i) Drug Name;

(ii) Drug Strength;

(iii) Pharmacy Control and Manufacturer lot number;

(iv) Name of the Manufacturer or Distributor of the Drug or National Drug Code; and

(v) Beyond-Use Date~~.~~, which shall be the Manufacturer's expiration date or one that is required under USP standards[20], whichever is earlier;

(5) (~~vi)~~ Records of all Prepackaging operations are maintained and include the following:

(i) the name (nonproprietary and proprietary name), strength, dosage form, quantity per container, and quantity of containers of the Drug being Prepackaged;

(ii) the name of the Manufacturer or Distributor of the Drug;

(iii) Pharmacy Control and Manufacturer lot number;

(iv) expiration date of the Drug according to the original Manufacturer or Distributor container and the Beyond-Use Date;

(v) the name, initials, or identification codes of the Certified Pharmacy Technician or Certified Pharmacy Technician Candidate that Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and

(vi) the date the Drug is Prepackaged.

(6)~~(vii)~~ All Drugs Prepackaged are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Labeling of such Drugs, or with requirements in the current edition of an official compendium.

[20] See USP General Chapter <7> Labeling

(b) Pharmacies that store Drugs within an automated counting device or Automated Pharmacy System may, in place of the required Label, maintain records of lot numbers and Beyond-Use Dates that are required on the Label as long as it is fully traceable and is readily retrievable ~~during an inspection~~.

(c) The Repackaging of Drugs shall follow applicable state and federal law.

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Background:

After discussing several specific topics, the committee concurred for the most part with the *Model Act* amendments proposed by the task force. The committee agreed with the task force that the bidirectional transmission of chart orders between an institutional pharmacy and an institutional facility should be allowed, but recommended that the pharmacist-in-charge (PIC) maintain policies and procedures regarding this activity. The committee also agreed with the task force that chart orders should be ongoing unless discontinued by the prescriber or by means of an automatic stop order in order to decrease the chance that patient drug therapy is interrupted. The committee concurred with the task force that duplicative text found in the Model Rules for Institutional Pharmacy and found in other sections of the *Model Act*, such as in the "Definitions" section, should be removed. The committee members also agreed with the task force's recommendations regarding drug provisions in the absence of a pharmacist and emergency kit use by institutional pharmacies.

The committee members recommended that the Institutional Pharmacy Delivery Room section proposed by the task force be simplified to remove details about the manner of operation of the delivery room and recommended that specific requirements detailing who can have access to the delivery room be removed, as long as there are policies and procedures addressing these topics maintained by the PIC. The committee lauded the task force's recommendation to add a prepackaging section to the Model Rules for Institutional Pharmacy. This section was viewed as necessary to minimize confusion between prepackaging and repackaging, the latter of which requires FDA registration.

LE/L Recommendation 3: The Committee Recommends the Addition of Definitions for Virtual Manufacturer and Virtual Wholesale Distributor to the *Model Act*.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

(y3) "Manufacturer" means a Person, which may include Virtual Manufacturer, engaged in the Manufacture of Drugs or Devices.~~[21]~~

(z3) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a Drug or Device or the Labeling or relabeling of the container of a Drug or Device for resale by pharmacies, Practitioners, or other Persons.[22]

(a4) "Third-Party Logistics Provider" means an entity that:

(1) Provides or coordinates warehousing, Distribution, or other services on behalf of a Manufacturer, but does not take title to the Prescription Drug or have general responsibility to direct the Prescription Drug's sale or disposition; and

(2) Is licensed as a Third-Party Logistics Provider.

…

(b4) "Wholesale Distribution" means the Distribution of a Drug or Device to a Person other than a consumer or patient, or receipt of a Drug or Device by a Person other than the consumer or patient, but does not include[23]:

(1) intracompany Distribution of any Drug between members of an affiliate or within a Manufacturer;

(2) the Distribution of a Drug or an offer to Distribute a Drug among hospitals or other Health Care Entities that are under common control;

(3) the Distribution of a Drug or an offer to Distribute a Drug for Emergency Medical Reasons, including a Public Health Emergency declaration made by the Secretary of the United States Department of Health and Human Services, except that, for purposes of this paragraph, a Drug shortage not caused by a Public Health Emergency shall not constitute an Emergency Medical Reason;

(4) the Dispensing of a Drug pursuant to a Prescription Drug Order;

~~[21] "Manufacturer" is also defined as a Wholesale Distributor in the *Model Act*. Therefore, all of the conditions, requirements, and prohibited and criminal acts would apply to Manufacturers in states where applicable definitions and sections of the *Model Act* were adopted.~~

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

[23] Although "Devices" is included in both definitions of "Wholesale Distribution" and "Wholesale Distributor," Federal law and some State laws do not define "Wholesale Distribution" as such. Wherever appropriate under the Model Rules, the term is included and recognized that Wholesale Distribution also includes Devices. A disparity could be caused if those Persons who only distribute Devices are not currently licensed by the State and, therefore, not subject to regulation by the Board. Different requirements and standards would exist for these Persons than would apply for Persons who Distribute both Drugs and Devices. It is NABP's position that Persons who Manufacture and/or Distribute Devices should be licensed with the Board and adhere to the same requirements as those in place for Persons who Manufacture and/or Distribute Drugs. In developing laws and rules, States may need to review their current regulations regarding licensure for Persons who solely Manufacture and/or Distribute Devices in order to determine the applicability of the Model Rules to Persons who Manufacture and/or Distribute Devices.

(5) the Distribution of minimal quantities of a Drug by a licensed retail Pharmacy to a licensed Practitioner for office use;[24]
(6) the Distribution of a Drug or an offer to Distribute a Drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(7) the purchase or other acquisition by a Dispenser, hospital, or other Health Care Entity of a Drug for use by such Dispenser, hospital, or other Health Care Entity;
(8) the Distribution of a Drug by the Manufacturer of such Drug;
(9) the receipt or transfer of a Drug by an authorized Third-Party Logistics Provider, provided that such Third-Party Logistics Provider does not take ownership of the Drug;
(10) a Common Carrier that transports a Drug, provided that the Common Carrier does not take ownership of the Drug;
(11) the Distribution of a Drug or an offer to Distribute a Drug by an authorized Repackager that has taken ownership or possession of the Drug and Repackages it in accordance with Federal law;
(12) salable Drug Returns when conducted by a Dispenser;
(13) the Distribution of a collection of finished medical Devices, which may include a Drug Product or biological Product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a "medical convenience kit") if:
    (i) the medical convenience kit is assembled in an establishment that is registered with FDA as a Device Manufacturer;
    (ii) the medical convenience kit does not contain a controlled substance;
    (iii) in the case of a medical convenience kit that includes a Drug Product, the Person that Manufactures the kit:
        (A) purchased such Drug Product directly from the pharmaceutical Manufacturer or from a Wholesale Distributor that purchased the Drug Product directly from the pharmaceutical Manufacturer; and
        (B) does not alter the primary container or Label of the Drug Product as purchased from the Manufacturer or Wholesale Distributor; and
    (iv) in the case of a medical convenience kit that includes a Drug Product, the Drug Product is:
        (A) an intravenous solution intended for the replenishment of fluids and electrolytes;
        (B) a Product intended to maintain the equilibrium of water and minerals in the body;
        (C) a Product intended for irrigation or reconstitution;
        (D) an anesthetic;

[24] Excludes Compounded Drugs unless the Pharmacy is registered under Federal law and Distributing such Compounded Drugs as an Outsourcing Facility.

(E) an anticoagulant;
(F) a vasopressor; or
(G) a sympathomimetic.

(14) the Distribution of an intravenous Drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15) the Distribution of an intravenous Drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the Distribution of a Drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the Distribution of medical gas;

(18) facilitating the Distribution of a Product by providing solely administrative services, including processing of orders and payments; or

(19) the transfer of a Product by a hospital or other Health Care Entity, or by a Wholesale Distributor or Manufacturer operating at the direction of the hospital or other Health Care Entity, to a Repackager and registered with FDA for the purpose of Repackaging the Drug for use by that hospital or other Health Care Entity and other Health Care Entities that are under common control, if ownership of the Drug remains with the hospital or other Health Care Entity at all times.

(c4) "Virtual Manufacturer" means a Manufacturer that sells its own Prescription Drugs and/or Devices but never physically possesses the Product.

(d4) "Virtual Wholesale Distributor" means a Wholesale Distributor that sells a Prescription Drug or Device but never physically possesses the Product.

(e4) "Wholesale Distributor" means any Person, which may include Virtual Wholesale Distributor, (other than a Manufacturer, a Manufacturer's co-licensed partner, a Third-Party Logistics Provider, or Repackager) engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State.

Background:

Pursuant to the addition of definitions for "Virtual Manufacturer" and "Virtual Wholesale Distributor" to the criteria for the Verified-Accredited Wholesale Distributors (VAWD) program, the committee unanimously agreed that the same definitions should be added to the *Model Act*.

LE/L Recommendation 4: The Committee Recommends Amendments to the *Model Act* Pursuant to Resolution 113-3-17, Experiential Learning for Non-US Pharmacists and Students.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 105. Definitions.

…

"Global Exchange Pharmacy Student" means a current student of a non-US professional degree program of a school or college of Pharmacy who is participating in an exchange program administered by an ACPE-accredited or Board-approved US school or college of pharmacy for a limited duration in this state.

…

(a5) "Pharmacy Intern"[25] means an individual who is:

(1) currently licensed by this State to engage in the Practice of Pharmacy while under the supervision of a Pharmacist and is enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and is satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

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

(3) a qualified applicant awaiting examination for licensure or meeting Board requirements for re-licensure; or

(4) an individual participating in a residency or fellowship program.

…

Model Standards for

Pharmacy Practice Experience Programs

Section 1. Preceptor.

[25] Most Pharmacy Interns are either enrolled in a professional degree program or postgraduate program (residency or fellowship), or have graduated from a Board-approved professional degree program and are awaiting examination. In some cases, however, Boards of Pharmacy also designate pharmacists whose licenses have lapsed or been inactive for a significant period of time as "Pharmacy Intern," allowing these pharmacists to obtain practical experience so that their licenses can be reactivated. Additionally, Boards may grant the "Pharmacy Intern" designation to those Pharmacists seeking practical experience following a period of license suspension or revocation.

Boards of Pharmacy may consider limiting the Pharmacy Interns' duration of registration especially if the boards find that Pharmacy Interns are not successfully progressing toward Pharmacist Licensure in an acceptable and reasonable time frame.

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

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

Section 2. Pharmacy Practice Experience Programs.[26]

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

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

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

Section 3. Global Exchange Pharmacy Students.

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

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

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

Background:

After a robust discussion, the committee recommended that a definition for "Global Exchange Pharmacy Student" be added to the *Model Act*. The committee recommended that a Global

[26] Boards of pharmacy are strongly encouraged to utilize the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007) as a basis for the establishment and revision of Board standards for Pharmacy practice experiences.

Exchange Pharmacy Student could participate as an observer in experiential activities as part of a formal educational exchange program without requiring board licensure as a pharmacy technician or pharmacy intern. However, if the Global Exchange Pharmacy Student were involved in clinical, ie, patient care, activities, then the Global Exchange Pharmacy Student would need to be qualified by the ACPE-accredited or Board-approved college or school of pharmacy as exists for IPPE and APPE experiential rotations.

LE/L Recommendation 5: The Committee Recommends Amendments to the *Model Act* Pursuant to Resolution 113-5-17, Adjudication of Concurrent Disciplinary Actions.

The recommended revisions by the committee are denoted by underlines and ~~strikethroughs~~.

Article IV
Discipline

…

Section 402. Grounds, Penalties, and Reinstatement.[27]

(a) The Board of Pharmacy may refuse to issue or renew, or may Revoke, Summarily Suspend, Suspend, place on Probation, Censure, Reprimand, issue a Warning against, or issue a Cease and Desist order against, the licenses or the registration of, or assess a Fine/Civil Penalty or Costs/Administrative Costs against any Person Pursuant to the procedures set forth in Section 403 herein below, upon one or more of the following grounds:

(1) unprofessional conduct as that term is defined by the rules of the Board;[28]
(2) incapacity that prevents a licensee from engaging in the Practice of Pharmacy or a registrant from assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public;

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

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

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

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

(3) being guilty of one (1) or more of the following:
    (i) a felony;
    (ii) any act involving moral turpitude or gross immorality; or
    (iii) violations of the Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;
(4) disciplinary action taken by another state or jurisdiction against a license or other authorization to Practice Pharmacy based upon conduct by the licensee similar to conduct that would constitute grounds for actions as defined in this section, which involves or may result in direct patient impact or harm in states other than that of the initiating Board;
(5) failure to report to the Board any adverse action taken by another licensing jurisdiction (United States or foreign), government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this section;
(6) failure to report to the Board one's surrender of a license or authorization to Practice Pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this section;
(7) failure to report to the Board any adverse judgment, settlement, or award arising from a malpractice claim arising related to conduct that would constitute grounds for action as defined in this section;
(8) knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the Board of Pharmacy;
(9) misrepresentation of a material fact by a licensee in securing the issuance or renewal of a license or registration;
(10) fraud by a licensee in connection with the Practice of Pharmacy;
(11) affiliating with websites that may deceive or defraud patients or that violate Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;
(12) engaging, or aiding and abetting an individual to engage in the Practice of Pharmacy without a license; assisting in the Practice of Pharmacy or aiding and abetting an individual to assist in the Practice of Pharmacy without having registered with the Board of Pharmacy; or falsely using the title of Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate;
(13) requiring Pharmacy personnel to meet production and/or performance metrics and/or quotas that negatively impact patient safety.[29]

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

(14) failing to pay the costs assessed in a disciplinary hearing pursuant to Section 213(c)(9);
(15) engaging in any conduct that subverts or attempts to subvert any licensing examination or the Administration of any licensing examination;[30]
(16) being found by the Board to be in violation of any of the provisions of this Act or rules adopted pursuant to this Act;
(17) illegal use or disclosure of Protected Health Information;
(18) failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.

Background:

After reviewing Resolution 113-5-17, Adjudication of Concurrent Disciplinary Actions, which concerns sister-state disciplinary actions, the committee agreed that the *Model Act* should be amended to clarify that jurisdictions should consider taking subsequent, concurrent disciplinary action if the licensee's action "involves or may result in direct patient impact or harm in states other than that of the initiating Board." This committee recommendation is based on the cited resolution that NABP should encourage state boards of pharmacy that are reviewing another board's imposition of a disciplinary action to consider forgoing sister-state disciplinary action absent direct patient impact or harm in their own states.

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

(a) Conduct which subverts or attempts to subvert any licensing examination or the administration of any examination shall include, but not be limited to, the following:
    (1) Conduct which violates the security of the examination materials; removing from the examination room any examination materials without authorization; the unauthorized reproduction by any means of any portion of the actual licensing examination; aiding by any means the unauthorized reproduction of any portion of the actual licensing examination; paying or using professional or paid examination takers for the purpose of reconstructing any portion of the licensing examination; obtaining examination questions or other examination materials, except by specific authorization either before, during, or after an examination; or selling, Distributing, buying, receiving, or having unauthorized possession of any portion of a future, current, or previously administered licensing examination.
    (2) Unauthorized communication of examination information with any other examinee during the administration of a licensing examination; copying answers from another examinee or permitting one's answers to be copied by another examinee; having in one's possession during the administration of the licensing examination any books, equipment, notes, written or printed materials, or data of any kind other than the examination materials Distributed, or otherwise authorized to be in one's possession during the examination; or impersonating any examinee or having an impersonator take the licensing examination on one's behalf.