NABP
National Association of Boards of Pharmacy

Report of the Task Force to

REVIEW INSTITUTIONAL PHARMACY AND COMPOUNDING MODEL RULES

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Members Present

Julie Spier (TX), *chair;* Diane Halvorson (ND); William Hayes (WA); Mark Klang (NY); Tyler Laetsch (SD); Brenda McCrady (AR); Mark Mikhael (FL); Karen Ryle (MA); Ashley Schaber (AK); and Donna Yeatman (AL, attended virtually).

Others Present

Stacey Ranucci, *Executive Committee liaison;* Lemrey "Al" Carter, Melissa Becker, Andrew Funk, Eileen Lewalski, Gertrude "Gg" Levine, Maureen Schanck, *NABP staff*.

Introduction

The task force met on September 30 and October 1, 2024, at NABP Headquarters in Mount Prospect, IL. The task force was established based on a recommendation of the Model Act Review Committee, which, in 2022, determined that the Model Rules for Institutional Pharmacy and the Model Rules for Compounded or Repackaged Drugs needed subject matter expert review.

Review of the Task Force Charge

Charge of the task force:

1. Review the Model Rules for Institutional Pharmacy and the Model Rules for Compounded or Repackaged Drugs; and
2. Amend, if necessary, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*) accordingly.

Background and Discussion

The discussion began with a review of the task force charge and the recognition that the task force was established based on a recommendation of the Model Act Review Committee. The committee, which met in 2022, determined that the Model Rules for Institutional Pharmacy and the Model Rules for Compounded or Repackaged Drugs needed subject matter expert review. The task force then reviewed the comments and suggested edits provided by the Alliance for Pharmacy Compounding (APC), the American Society of Consultant Pharmacists (ASCP), and NABP staff for relevant sections of the *Model Act*.

The first comments and suggested revisions reviewed were those of APC regarding the Model Rules for Compounding and Repackaging of Compounded Drugs, along with staff's expert feedback on those comments and suggestions.

The task force first considered the definition of “compounding” and agreed to modify it to include the preparation of drugs or devices in anticipation of regularly observed prescribing “or ordering” patterns. The task force also agreed to supplement the accompanying footnote, adding that anticipatorily compounded drugs may not be dispensed until the receipt of a patient-specific prescription drug order “or pursuant to an order for veterinary office stock.”

In the footnote accompanying subparagraph (c) of the definition of “compounding,” the task force agreed to strike out, “Reconstitution is considered compounding according to USP Standards addressing nonsterile compounding,” as this information is outdated.

The task force agreed to add a definition for “designated person(s),” meaning “one or more individuals identified by the pharmacist-in-charge who is/are responsible and accountable for the performance and operation of the pharmacy and personnel in the preparation of compounded preparations. If the compounding pharmacy has only one person responsible for all compounding in the pharmacy, then that person is the designated person.” Task force members stated that this term is found in the compounding chapters of the United States Pharmacopeia (USP) to identify pharmacy technicians and other personnel in a compounding pharmacy who have been delegated certain responsibilities related to the performance and operation of a compounding pharmacy.

The task force agreed to strike out the definition of the “NABP Information Sharing Network” and the accompanying footnote that was originally added related to the “MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.” Staff explained that, because the memorandum of understanding (MOU) is currently suspended, the information-sharing network is also currently suspended; thus, the term is not relevant at this time.

The task force considered a suggestion to add a definition for “Quality Management System” and decided it was necessary to do so. The task force agreed that this term, used in later sections of the *Model Act*, would be defined as “a formalized system instituted by a pharmacy engaged in compounding that documents processes, procedures, and responsibilities for achieving quality policies and objectives, and coordinates and directs activities to meet patient, customer, and regulatory requirements and improve effectiveness and efficiency on a continuous basis.” This language is adapted from the definition recognized by the American Society for Quality.

In Section 401. Unlawful Practice, the task force agreed to modify the language in paragraph (2) to change “shall” to “may,” giving the boards flexibility in whether to assess a fine under the defined circumstances. The task force also agreed to add the word “sells” to address both the possession and sale of drugs or devices and to change “not licensed” to “not authorized to purchase and possess drugs or devices.”

In Section 402. Licensing (1), the task force agreed with the proposed addition of “drugs, devices, or pharmacist care” services. The task force considered whether to change “pharmacist care services” to “pharmaceutical care services” to include pharmacy technicians or other personnel who may be delegated authority to perform certain tasks. Staff noted that the term “pharmacist care” was adopted recently for consistency with language used by the American Pharmacists Association and is defined

in the *Model Act.* The task force reviewed the definition and acknowledged that, while the pharmacist is still the ultimate responsible party, some of the tasks listed as "pharmacist care" can be delegated to technicians in some states. The task force agreed to leave "pharmacist care" unchanged for now but decided to ask the Committee on Law Enforcement/Legislation (LE/L Committee), scheduled to meet in March 2025, to consider changing the language to be more inclusive.

Also in Section 402(1), the task force agreed to strike out the footnote that accompanied subparagraph (b) that read, "It is contemplated that dispensing practitioners' facilities should only compound nonsterile human drug products and that sterile compounded human drug products should be obtained from outsourcing facilities," because of jurisdictional issues, being that boards of pharmacy do not have the authority to mandate practice models to physicians.

In *Model Rules* Section 13. Repackaging by Pharmacies for Own Use, the task force agreed to change "and" to "and/or" in (1)(c)(iii), stating that repackaged drugs should be labeled with "pharmacy control and/or manufacturer lot number." APC commented that, per its hospital members, it is uncommon to include both. In (1)(d)(i), which lists records of repackaging operations to be maintained, the task force agreed to add the word "drug" in front of "name" and strike out "(nonproprietary and proprietary name)."

In the Model Rules for Compounded or Repackaged Drugs, Section 1. Purpose and Scope, the task force agreed with a staff recommendation to use the word "preparations" instead of "products" to describe compounded drugs throughout the section. It was noted that, because the Drug Supply Chain Security Act (DSCSA) uses the term "products," using it in the context of compounding could be confusing, as compounded preparations are not subject to DSCSA traceability requirements. Members acknowledged that the *Model Act* uses the term "drug product" in reference to both compounded and manufactured products and uses "drug preparation" for compounded veterinary drugs. Thus, the task force agreed to use "drug preparation" when referring to compounded drugs.

The task force also considered whether to strike out the footnote stating, "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." APC commented that the Food and Drug Administration (FDA) guidance is nonbinding, but including it here would effectively make it law.

The task force agreed to strike out the first two provisions in Section 2. Notification, as they pertain to the FDA MOU, which is not currently in effect. The task force discussed the meaning of the word "defect" in the remaining provision and agreed to change it to "deviation from the lot release criteria." They agreed to add the following new language: "The pharmacy shall notify patients and any applicable regulatory authorities of notification of any deviation from the lot release criteria or quality concerns regarding a specific lot/batch. After a deviation is confirmed, the pharmacy shall conduct a recall in accordance with established policies and procedures."

In Section 3. Policy and Procedure Manual, the task force agreed to change "compounded prescription drugs" to "compounded preparations." In paragraph (1), members agreed to change "quality assurance program" to "quality management system," which encompasses both quality assurance and quality control. The use of "quality management system" in this section prompted the new definition mentioned above. Members agreed to add "adverse" in front of "patient care" and to

add the clarifying phrase, “such as adverse events, quality-related events, customer and patient complaints, out-of-specification results, and recalls,” which would be included in quality management. This text was selected to align with the newly defined “quality management system” and the language in Section (8)(1).

Under Section 4. Physical Requirements, the task force agreed to modify the phrase, “Any pharmacy that engages in compounding shall adhere to physical, equipment, and environmental requirements established by USP,” by adding, “as well as to all applicable state and federal laws and rules.” The task force also agreed to replace “sufficient” current reference materials with “adequate and” applicable to “the type of” compounding “being conducted.” The task force considered listing the current reference materials in this section. Staff explained that the section formerly listed references, but the references were removed a few years ago pursuant to a task force recommendation, deferring instead to professional judgment.

In Section 5. Records and Reports, the task force agreed to strike out the language describing the records that shall be maintained and replace it with, “all records related to sterile and nonsterile compounded preparations shall be maintained. This includes but is not limited to all USP and state requirements, batch records, equipment and maintenance records, training and ongoing competency assessment records, testing and release records, and dispensing and distribution records.”

Regarding Section 6. Delivery Service, the task force considered whether the pharmacist-in-charge (PIC) should have full accountability for environmental controls to ensure the stability of the compounded preparations. They determined that this responsibility should be shared with the “pharmacy permit holder” and added this language. They also added “compounded” to modify preparations shipped and added that any compounded preparation shall be “stored appropriately.” They agreed to strike out “(as defined by USP standards)” and replaced it with “following USP requirements.”

The task force agreed to rename Section 8. Quality Assurance to “Quality Management System” and reword, reformat, and expand the provisions in the section to align with the new definition for “Quality Management System” and the revised language in Section 3. Policy and Procedure Manual. The task force agreed with the suggestion to list the items that the quality management system should monitor in paragraph (1). The paragraph referring to the proficiency of all pharmacists who participate in compounding was changed to refer to “pharmacy personnel who participate in compounding” to acknowledge that pharmacy technicians or other personnel may participate in these activities. The new paragraph (3) lists the responsibilities of the pharmacist, while the new paragraph (4) outlines the responsibilities of the “designated person.” In paragraph (5), the task force agreed to change “compounding pharmacy personnel (eg, pharmacy technicians)” to “pharmacy personnel who participate in compounding” and add that they shall be trained and proficient in the particular operations that are performed by that individual, “consistent with USP standards.” The paragraph referring to training was modified to say, “Initial training and ongoing competency assessment evaluation shall be conducted by qualified individuals identified by the designated person(s) in a manner consistent with the USP compounding chapter requirements.” Regarding authorized personnel, the task force agreed to change “authorized by the responsible pharmacist” to “authorized by the designated person.” For consistency, the task force agreed to modify the paragraph referring

to adulterated products by changing “drug” to “preparation.”

In Section 9. Compounded Drug Preparations for Veterinary Use, paragraphs (1)(d) and (1)(e), regarding the use of bulk drug substances for compounded preparations, the task force agreed to add the caveat, “in the pharmacist’s professional judgment,” in terms of appropriateness of compounding, and “in the prescriber’s opinion,” relating to the need for the compounded preparation. Members also recommended adding a footnote stating, “See FDA GFI 256.” In paragraph (2), they agreed to modify the language to include administration “or dispensing” to clients’ animals “from FDA’s list of bulk drug substances for compounding office stock drugs for use in non-food producing animals.” In paragraph (3), they agreed to change “120-hour supply” to “7-day supply.” In paragraph (6), they agreed to replace “on the prescription label” with “in the prescription labeling” to allow for the information to be included in accompanying materials rather than on the product label itself.

The task force then turned its attention to comments and suggested revisions received from ASCP, and staff’s feedback on those comments, for the Model Rules for Institutional Pharmacy. First, the task force agreed to modify the definition of “chart order” to add information that must be included. These items, listed as (b) through (d), include a “second patient identifier such as patient number or date of birth”; “identification of institutional facility name”; and “quantity, if the chart order is for a controlled substance and the chart order may be used as a prescription for the pharmacy to dispense (if the order is in compliance with state and federal law).” For item (h), regarding the signature, the task force agreed to add “or the practitioner’s agent.”

In the definition of “institutional facility,” the task force agreed to change “penal” institution to “correctional” institution. The task force also agreed to modify a footnote accompanying the definition of “institutional pharmacy” to say, “States should recognize that institutional pharmacies, in order to prepare for a disaster or emergency, may be stocking emergency supplies of drugs in emergency kits or automated dispensing machines per state regulations.”

In Section 2. Absence of a Pharmacist at a Pharmacy Located Within an Institutional Facility, paragraph (2)(b), the task force agreed to add the phrase, “or in the smallest quantities available,” to modify the language stating that, in the absence of the pharmacist, it must be ensured that only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements. This added phrase acknowledges that a multi-use container might need to be used in certain circumstances. In paragraph (3), the task force agreed to replace “floor supplies or night cabinets” with “drugs stored in a locked cabinet, automated pharmacy system, or other enclosure constructed and located outside of the pharmacy area.” Also, regarding this section, the task force asked that the LE/L Committee evaluate the need for a pharmacist to verify an order prior to medical staff or other authorized personnel obtaining the drug ordered.

In Section 3. Emergency Kit Use by Institutional Facilities, the task force reviewed paragraph (1)(a), describing emergency kit drugs that must be accessed to prevent the risk of harm to patients, and decided to add the phrase, “or may jeopardize patient care due to a” delay resulting from obtaining such drugs from other sources. The task force agreed to modify paragraph (e) to replace “be labeled so as” with “have a label or list” and add “as defined in 1(a).” Members agreed to move to paragraph (f) the language regarding the expiration date of an emergency kit. They also agreed to add (j), noting that automated pharmacy systems are exempt from certain provisions.

In Section 4. Drug Distribution and Pharmacy Care Services, the task force approved the addition of a new paragraph (2), regarding the repackaging of previously dispensed medications into unit dose or compliance packaging. In paragraph (6), regarding whom the PIC may designate to restock an automated pharmacy system, the task force agreed to add, “or certified pharmacy technician.” In paragraph (7), regarding institutional pharmacies dispensing drugs to patients upon discharge, the task force agreed to add, “with required labeling for outpatient use.”

In Section 6. Relabeling of Previously Dispensed Outpatient Drugs for Institutional Use, paragraph (1), regarding relabeling a drug previously dispensed by an outpatient pharmacy, the task force decided to add the caveat, “as long as relabeling can occur before the next dose is needed.”

Recommendations

After careful review and deliberation, the task force made the following recommendations:

1) The LE/L Committee should review the definition of “pharmacist care services” with a focus on inclusivity;
2) The LE/L Committee should review Section 2. Absence of Pharmacist at a Pharmacy Located Within an Institutional Facility to assess whether a pharmacist should verify and order prior to medical staff or other authorized personnel obtaining the drug ordered; and
3) Amend the *Model Act* as denoted by ~~strikethroughs~~ and <u>underlines</u> in the following excerpts.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I
Title, Purpose, and Definitions

Section 105. Definitions.

…

"Compounding" means the preparation, mixing, assembling, altering, packaging, or labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription drug order, medical order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

a) preparation of drug dosage forms for both human and animal patients;
b) preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing or ordering patterns[1]; and
c) manipulation of commercial products for patient-specific needs beyond FDA-approved labeling.[2]

"Designated person(s)" means one or more individuals identified by the pharmacist-in-charge who is/are responsible and accountable for the performance and operation of the pharmacy and personnel in the preparation of compounded preparations. If the compounding pharmacy has only one person responsible for all compounding in the pharmacy, then that person is the designated person.

~~"NABP Information Sharing Network"[3] means the information sharing network developed by NABP that collects, assesses, and allows for review and sharing of compounding pharmacy and physician information as described in the "MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION."~~

"Repackage" means the act of taking a drug product from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.

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[1] Anticipatorily compounded drugs may not be dispensed until receipt of a patient-specific prescription drug order or pursuant to an order for veterinary office stock.

[2] Reconstitution of an FDA-approved drug according to FDA-approved labeling is not considered compounding according to FDA rules. ~~Reconstitution is considered compounding according to USP Standards addressing nonsterile compounding.~~

[3] ~~The information sharing network was built by NABP pursuant to the NABP-FDA "Cooperative Agreement to Develop a System for the Collection, Management, and Sharing of Information on Compounding Pharmacies Distributing Interstate."~~

Repackaging also includes the act of placing the contents of multiple containers, eg, vials, of the same finished drug into one container, providing the container does not include other ingredients or is not further manipulated in any way.
"Repackager" means a person who owns or operates an establishment that repackages and relabels a product or package for:

1. further sale; or
2. distribution without a further transaction.[4]

"Quality Management System" means a formalized system instituted by a pharmacy engaged in compounding that documents processes, procedures, and responsibilities for achieving quality policies and objectives, and coordinates and directs activities to meet patient, customer and regulatory requirements and improve effectiveness and efficiency on a continuous basis.

Article IV
Licensing of Facilities

Introductory Comment to Article IV

The fourth 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 401. Unlawful Practice.

(1) No business entity designated in Section 402 of this Act shall operate until a license has been issued to the business entity by the board.

(2) Except where otherwise permitted by state or federal law, it shall be unlawful for a manufacturer, repackager, third-party logistics provider, or wholesale distributor to distribute or deliver drugs or devices to any person in this state not licensed under this statute. Any manufacturer, repackager, third-party logistics provider, or wholesale distributor who ~~shall~~ distributes, sells, or delivers drugs or devices to a person not ~~licensed shall~~ authorized to purchase and possess drugs or devices may be subject to a fine to be imposed by the board for each offense in addition to such other disciplinary action the board may take under this Act.

[4] Is not intended to include a pharmacy, pharmacist, or outsourcing facility that dispenses or distributes repackaged drugs.

Section 402. Licensing.

(1) The following business entities located within this state, and the following business entities located outside this state that provide drugs, devices or pharmacist care services to other business entities or patients within this state, shall be licensed by the board of pharmacy and shall periodically renew[5] their license with the board:[6]

(a) pharmacies where drugs or devices are dispensed or compounded, or pharmacist care services are provided;[7]

(b) dispensing practitioner's facilities including those engaged in compounding;[8, 9]

(c) manufacturers or repackagers of drugs or devices;

(d) wholesale distributors of drugs or devices;

(e) drug or device third-party logistics providers;

(f) outsourcing facilities;

(g) pharmacy benefits managers; and

(h) repository programs,

Where operations are conducted at more than one location, each such location shall be licensed by the board of pharmacy.

...

(6) Inspections

(a) For facilities that compound and/or repackage sterile drugs, an initial inspection shall be required prior to initial licensure or upon initiation of sterile compounding activity. Thereafter, an annual inspection shall be required for licensure renewal. For facilities that do not compound sterile drugs, an initial inspection, and thereafter an inspection that takes place not less than every 24 months, shall be required for purposes of licensure or licensure renewal[10]. Such inspection shall be performed by the following:

(i) the board or its duly authorized agent; or

(ii) a duly authorized agent of a third party approved by the Board[11].

(b) For nonresident pharmacies, the inspection shall be performed by the resident state board of pharmacy, if the resident board's inspection is substantially equivalent to inspection in this state~~,~~ or a duly authorized agent of a third party approved by the board.[12]

…

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

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

[7] Includes remote dispensing machines and/or devices such as kiosks.

[8] ~~It is contemplated that dispensing practitioners' facilities should only compound nonsterile human drug products and that sterile compounded human drug products should be obtained from outsourcing facilities.~~

[9] Licensed Dispensing Practitioners' facilities 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, patient counseling, and all other requirements for the compounding and the dispensing of drugs applicable to pharmacists.

[10] State resources may have to be considered when evaluating inspection scheduling in combination with risk assessment consideration.

[11] Boards of pharmacy are strongly encouraged to utilize the NABP Verified Pharmacy Program for this purpose.

[12] Boards of pharmacy are strongly encouraged to utilize the NABP Verified Pharmacy Program for this purpose.

Section 404. Notifications.

(1) All licensed business entities or persons shall report to the board of pharmacy the occurrence of any of the following:
- (a) permanent closing;
- (b) change of ownership, management, location, or pharmacist-in-charge of a pharmacy;
- (c) any theft or loss of drugs or devices;
- (d) any conviction of any employee of any state or federal drug laws;
- (e) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
- (f) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by state or federal law;
- (g) occurrences of significant quality-related events
- (h) serious adverse drug experience associated with compounded drugs;
- (i) recalls of compounded drugs;
- (j) recalls of sterile repackaged drugs;
- (k) any temporary closing of a pharmacy for more than two (2) consecutive calendar days outside of the pharmacy's regular operating hours shall be reported to the board by the next business day along with contingency plans for accessing patient prescriptions and records;
- (l) illegal use or disclosure of protected health information; or
- (m) any and all other matters and occurrences as the board may require by rule.

…

(2) Prior to commencing any sterile compounding activity, all licensed business entities and/or persons shall report to the board of pharmacy, or its authorized agent, whether the licensed facility will be engaging in any sterile compounding in a manner determined by the board. The board may establish by rule additional reporting requirements for sterile and nonsterile compounding activities.

Model Rules for the Practice of Pharmacy

…

Section 13. Repackaging by Pharmacies For Own Use.

(1) A pharmacy may repackage drugs for its own use under the following circumstances:
- (a) Containers utilized for repackaging shall meet, as a minimum requirement, Class B container standards as referenced by USP;
- (b) The repackaging processes are conducted under conditions that ensure the integrity of the drug and under the direct supervision of a pharmacist;
- (c) The repackaged drugs are labeled with the following components:
  - (i) drug name;
  - (ii) drug strength;
  - (iii) pharmacy control and/or manufacturer lot number;

(iv) name of the manufacturer or distributor of the drug or the national drug code; and
(v) beyond-use date, which shall be the manufacturer's expiration date or one that is required under the most current USP standards, whichever is earlier.

(d) Records of all repackaging operations are maintained and include the following:
(i) the drug name ~~(nonproprietary and proprietary name)~~, strength, dosage form, quantity per container, and quantity of containers of the drug being repackaged;
(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 repackaged the drug and the name or initials of the pharmacist that verified the appropriateness of the repackaged drug; and
(vi) the date the drug is repackaged.

(e) All drugs repackaged 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.

(2) 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 they are fully traceable and are readily retrievable.

(3) The pharmacist-in-charge is responsible for developing or adopting, implementing, and maintaining[13] policies and procedures addressing repackaging processes.

…

Model Rules for Compounded or Repackaged Drugs

Section 1. Purpose and Scope.

The purpose of this Section is to ensure that compounded drugs 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 drugs by pharmacies, including nuclear pharmacies. These standards are intended to apply to all sterile and nonsterile compounded drugs, 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 and these rules, as well as the United States Pharmacopeia–National Formulary (USP-NF) chapters addressing sterile and nonsterile compounding, the handling of hazardous drugs, and other applicable referenced general chapters. The procedures contained herein are considered to be the minimum current good

[13] The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

compounding practices for the compounding of drug preparations ~~products~~ by state-licensed pharmacies for dispensing and/or administration to humans or animals.[14]

Section 2. Notification.

~~(1) On an annual basis, and within 90 days of the beginning of the calendar year, all licensed Persons shall report to an information sharing network approved by the Board[15] the information required by the "Memorandum Of Understanding Addressing Certain Distributions Of Compounded Human Drug Products Between The [Insert State Board Of Pharmacy Or Other Appropriate State Agency] And The U.S. Food And Drug Administration."~~

~~(2) Upon request from the board, all licensed persons shall report to the board of pharmacy the number of compounded prescription drug orders dispensed in the state where the pharmacy is located and out of the state where the pharmacy is located during a specified time period, including the drugs' active ingredients, strength, and dosage form(s).~~

~~(3) The pharmacist shall notify patients if they may have received a product found to have a defect or an out of specification result and conduct a recall if the board deems necessary.~~

The pharmacy shall notify patients and any applicable regulatory authorities of notification of any deviation from the lot release criteria or quality concerns regarding a specific lot/batch. After a deviation is confirmed, the pharmacy shall conduct a recall in accordance with established policies and procedures.

Section 3. Policy and Procedure Manual.

A policy and procedure manual shall be prepared and maintained for the compounding, dispensing, delivery, administration, storage, and use of sterile and nonsterile compounded preparations. ~~prescription drugs~~. The policy and procedure manual shall incorporate all applicable USP requirements and:

(1) include a quality management system established ~~assurance program~~ for the purpose of monitoring adverse patient care and pharmacist care services outcomes, such as adverse events, quality related events, customer and patient complaints, out of specification results, and recalls; and

(2) be current and available for inspection by a board of pharmacy-designated agent.

Section 4. Physical Requirements.

(1) Any pharmacy that engages in compounding shall adhere to physical, equipment, and environmental requirements established by USP, as well as to all applicable state and federal laws and rules.

(2) Pharmacies shall have ~~sufficient~~ current reference materials adequate and applicable to the type of compounding being conducted.

~~[14] 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.~~

~~[15] Boards of pharmacy are encouraged to strongly consider recognizing the NABP Information Sharing Network.~~

Section 5. Records and Reports.

In addition to standard record-keeping and reporting requirements, all records related to sterile and nonsterile compounded preparations shall be maintained. This includes but is not limited to all USP and state requirements, batch records, equipment and maintenance records, training and ongoing competency assessment records, testing and release records, and dispensing and distribution records. ~~the following records shall be maintained:~~

~~(1) All dispensing of sterile compounded and nonsterile compounded preparations.~~

~~(2) Any other records required to conform to and demonstrate compliance with USP standards and federal law.~~

Section 6. Delivery Service.

The pharmacist-in-charge/pharmacy permit holder shall ensure the environmental control, stability, and sterility (if applicable) of all compounded preparations shipped. Therefore, any compounded preparation shall be stored appropriately shipped or delivered to a patient or patient's agent in appropriate temperature-controlled ~~(as defined by USP standards)~~ delivery containers ~~and stored appropriately~~, following USP requirements. Information on appropriate storage shall be provided to the patient or patient's agent.

Section 7. Disposal of Hazardous and/or Infectious Wastes.

The pharmacist-in-charge is responsible for ensuring that there is a system for the disposal of hazardous and/or infectious waste in accordance with applicable state and federal laws and USP requirements.

Section 8. Quality ~~Assurance~~ Management System.

(1) ~~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~~ .

~~(2) 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.~~

~~(3) 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.~~

(1) There shall be a documented, ongoing quality management system established for the purpose of monitoring adverse patient care and pharmacist care services outcomes that monitors:

(a) personnel training and ongoing competency assessment;
(b) hand hygiene and garbing;
(c) environmental monitoring and state of control;
(d) component verification and usage;
(e) cleaning and disinfection of controlled environment;
(f) sterilization and depyrogenation of equipment and supplies;
(g) maintenance of records;
(h) review of policies and procedures;
(i) processes for finished preparation release checks and tests;
(j) evaluation of adverse drug events, quality related events, customer and patient complaints, and out of specification results, and recalls; and
(k) facilities to ensure they are appropriate for the drug being prepared.

Quality management system shall at minimum conform to the requirements of USP.

(2) Pharmacy personnel who participate 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.

(3) The responsibilities of the pharmacist include but are not limited to:
(a) preparing and reviewing all compounding records to ensure that no errors have occurred in the compounding process;
(b) if an error occurs, conducting a full investigation and ensuring a written record, including conclusions and follow up, is made of such investigation; and
(c) ensuring proper maintenance, cleanliness, and use of all facilities and equipment used in compound.

(4) The responsibilities of the designated person include but are not limited to:
(a) overseeing the utilization of the quality management system;
(b) overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing compounded preparations;
(c) maintaining the Master Formulation Records;
(d) monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed;
(e) ensuring that standard operating procedures are fully implemented and ensuring that follow up is carried out if problems, deviations, or errors are identified;
(f) establishing, monitoring, and documenting procedures for the handling and storage of compounded preparations and/or components of compounded preparations; and
(g) inspecting, approving, or rejecting all components, drug product containers, closures, in-process materials, and/or labeling.

(5) Pharmacists and other ~~compounding~~ pharmacy personnel who participate in compounding~~(eg, pharmacy technicians)~~ shall be trained and proficient in the particular operations that are performed by that individual, consistent with USP standards.

(6) ~~Training~~ Initial training and ongoing competency assessment evaluation shall be conducted by qualified individuals identified by the designated person(s) in a manner consistent with the USP compounding chapter requirements. ~~on a continuing basis and with sufficient frequency~~

~~to ensure that compounding pharmacy personnel remain familiar with applicable operations and policies and procedures.~~

(7) Only personnel authorized by the ~~responsible pharmacist~~ designated person shall be in the immediate vicinity of compounding operations.

(8) A compounded preparation ~~drug~~ shall be deemed adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

Section 9. Compounded Drug Preparations for Veterinary Use.

(1) The use of bulk drug substances for compounded drug preparations is prohibited except when:
   (a) 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;
   (b) 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;
   (c) there is no marketed approved animal or human drug that can be used to treat the condition through off-label drug use;
   (d) in the pharmacist's professional judgment, the drug cannot be appropriately compounded from an approved animal or human drug;
   (e) in the prescriber's opinion, immediate treatment with the compounded drug preparation is necessary to avoid animal suffering or death; and
   (f) FDA has not identified a significant veterinary safety concern with the use of the bulk drug substance for compounding.[16]

(2) It is acceptable for any licensed pharmacy to compound veterinary drug preparations to be used by veterinarians in their offices for administration or dispensing to clients' animals from FDA's list of bulk drug substances for compounding office stock drugs for use in non-food producing animals.

(3) 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 7-day supply ~~120-hour supply~~.

(4) The compounded veterinary drug preparations shall 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.

(5) Providing samples of compounded veterinary drug preparations is prohibited.

(6) Upon becoming aware of any adverse event or preparation defect, the pharmacy shall report the event on the designated FDA form[17] within 15 days and include the FDA statement about reporting adverse events in the prescription labeling. ~~on the prescription label.~~

[16] See FDA GFI 256

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

American Society of Consultant Pharmacists Model Rules Comments with NABP Feedback

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I
Title, Purpose, and Definitions

Section 105. Definitions.

"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 their licensed health care designee for a drug or device and shall be considered a prescription drug order provided that it contains:

(a) the full name of the patient;
(b) second patient identifier such as patient number or date of birth;
(c) identification of institutional facility name;
(d) quality, if the chart order is for a controlled substance and the chart order may be used as a prescription for the pharmacy to dispense (if the order is in compliance with state and federal law);
(e) date of issuance;
(f) name, strength, and dosage form of the drug prescribed;
(g) directions for use; and
(h) if written or electronic, the prescribing practitioner's signature[18] or the signature of the practitioner's licensed health care designee (including the name of the prescribing practitioner), or the practitioner's agent.

Bidirectional transmission of chart orders between the institutional pharmacy and the institutional facility is allowed. The pharmacist-in-charge shall ensure that the institutional pharmacy has 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 their 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. 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.

…

[18] 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.

"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):

a. hospital;
b. long-term care facility;
c. convalescent home;
d. nursing home;
e. extended care facility;
f. mental health facility;
g. rehabilitation center;
h. psychiatric center;
i. developmental disability center;
j. drug abuse treatment center;
k. family planning clinic;
l. ~~penal~~ correctional institution;
m. hospice;
n. public health facility;
o. athletic facility;
p. assisted living facility; and
q. intermediate care facility for individuals with intellectual disabilities.

"Institutional pharmacy"[19] means any place that is registered with the state board of pharmacy 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.[20]

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

"Medical order" means a lawful order of a practitioner that may or may not include a prescription drug order.

[19] 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.

[20] States should recognize that institutional pharmacies, in order to prepare for a disaster or emergency, may be stocking emergency supplies of drugs in emergency kits or automated dispensing machines per state regulations. ~~States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of drugs 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.~~

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*.

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

(1) During such times as when a 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.

(2) 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:

- (a) drugs are properly labeled;
- (b) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements <u>or in the smallest quantities available</u>;
- (c) whenever access to the cabinet occurs, written or electronic practitioner's orders and proofs-of-use are provided;
- (d) all drugs therein are inventoried no less than once per week unless stored in an automated pharmacy system;
- (e) a complete audit of all activity concerning such cabinet is conducted no less than once per month; and
- (f) written policies and procedures are established to implement the requirements of this section.

(3) Whenever any drug is not available from <u>drugs stored in a locked cabinet, automated pharmacy system, or other enclosure constructed and located outside of the pharmacy area</u> ~~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. A supervisory nurse in any given 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's 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. Emergency Kit Use by Institutional Facilities.

(1) Emergency kit drugs may be provided for use by authorized personnel of the institutional facility provided, however, such kits meet the following requirements:

(a) 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 or may jeopardize patient care due to a delay resulting from obtaining such drugs from such other sources.

(b) All emergency kit drugs shall be provided and sealed by a pharmacist or their designee in accordance with applicable security and inventory control policies and procedures.

(c) 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.

(d) 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.

(e) The exterior of each emergency kit shall ~~be labeled so as~~ have a label or list to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only, as defined in 1 (a). 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 pharmacy.

(f) 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 pharmacy shall replace the expired drug.

(g) Drugs shall be removed from emergency kits only pursuant to a valid chart order.

(h) Whenever an emergency kit is opened, the supplying pharmacy shall be notified, and the pharmacy shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.[21]

~~(i) 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 pharmacy shall replace the expired drug.~~

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

(j) Automated pharmacy systems are exempt from paragraphs (1)(b), (e), (f), and (h).

Section 4. Drug Distribution and Pharmacist Care Services.

(1) The pharmacist-in-charge shall establish written procedures for the safe and efficient acquisition, handling, storage, and dispensing of drugs, including investigational drugs, patient-supplied drugs, and for the provision of pharmacist care services. An annual updated copy of such procedures shall be available for inspection by the board of pharmacy.

(2) The pharmacy may re-package previously dispensed medications into unit dose or compliance packaging following established policies and procedures adopted by the pharmacy and in compliance with state and federal regulations.

[21] When the pharmacist 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.

(3) A pharmacist may engage in therapeutic interchange or formulary substitution as authorized by the facility's interdisciplinary committee[22] of health care providers, at a minimum to include a practitioner and a pharmacist.

(4) To ensure continuous patient care, the facility's director of nursing or their documented licensed health care designee or practitioner agent may transmit the chart order to a pharmacy.[23]

(5) 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.

(6) If the institutional pharmacy is not located within an institutional facility, the pharmacist-in-charge may designate a licensed nurse or certified pharmacy technician to restock an automated pharmacy system using verification technology such as bar code scanning, electronic, or other ~~technology~~ systems in accordance with established policies and procedures.

(7) Institutional pharmacies either located within or not within institutional facilities may dispense drugs to patients upon discharge with required labeling for outpatient use in order to ensure a transition of care between settings until a new prescription drug order is issued.

Section 5. Shared Pharmacy Services Utilization for Immediate Need.[24]

(1) In accordance with the Section addressing shared pharmacy services in the Model Rules for the Practice of Pharmacy, an institutional pharmacy may outsource services to another pharmacy for the limited purpose of ensuring that drugs or devices are available to meet the immediate needs of patients of the institutional facility or when the institutional pharmacy cannot provide services on an ongoing basis, provided that the institutional pharmacy:

(a) has obtained approval from the institutional facility to outsource shared pharmacy services for its inpatients; and

(b) shares a valid chart order with the pharmacy it has contracted with for the shared pharmacy services without the need to transfer the order.

Section 6. Relabeling of Previously Dispensed Outpatient Drugs for Institutional Use.

(1) At a patient's or patient's caregiver's request, an institutional pharmacy may relabel for institutional use a drug previously dispensed by an outpatient pharmacy to the patient as long as relabeling can occur before the next dose is needed.

(2) The institutional pharmacy providing relabeling services shall have established policies and procedures to:

(a) assess whether the drug may be adulterated or misbranded; and

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

[23] Federal law may restrict who can transmit a chart order for a controlled substance.

[24] 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.

(b) package and label the drug in compliance with state and federal requirements and USP standards.

(3) An institutional pharmacy that relabels a previously dispensed outpatient drug shall retain all original prescription information in accordance with state record-keeping requirements.

Section 7. Relabeling of Previously Dispensed or Administered Institutional Multidose Drugs for Outpatient Use.[25]

(1) At a patient's or patient's caregiver's request, an institutional pharmacy may relabel for outpatient use a multidose drug previously dispensed for institutional use.

(2) The institutional pharmacy providing relabeling services shall have in place policies and procedures to:
   (a) assess whether the drug may be adulterated or misbranded; and
   (b) package and label the drug in compliance with state and federal requirements and USP standards.

(3) The institutional pharmacy that relabels a previously dispensed multidose drug shall retain all original chart order information in accordance with state record-keeping requirements.

Section 8. Institutional Pharmacy Delivery Room.

Prescription drugs, devices, and other products 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:

(1) Institutional pharmacies that are not located within an institutional facility may accept returns or otherwise deliver fulfilled, verified, and packaged prescription drugs 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.

(2) 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:
   (a) emergency kits;
   (b) prescription drugs that were unsuccessfully delivered by the pharmacy personnel or delivery personnel; and
   (c) prescription drugs eligible for return pursuant to applicable state and federal law.

[25] Controlled substance dispensing by an institutional pharmacy for outpatient use shall be reported to the state's prescription monitoring program.