



Report of the Committee on Law Enforcement/Legislation

NOTE: The NABP Executive Committee accepted the report with the exception of Agenda Item #5 *Model Act* amendments that pertain to pharmacy compounding. NABP staff is seeking clarification from Food and Drug Administration (FDA) regarding the standards requirements for 503A and 503B facilities, particularly whether 503A facilities will remain under the jurisdiction of the states and in accordance with United States Pharmacopeial standards. The *Model Act* will be further amended upon that determination and ongoing discussions with FDA regarding the definition of outsourcing facility and related provisions. Additionally the Executive Committee decided that Section 104 Comment required further clarifying revisions to reflect the new definition of “the practice of pharmacy.”

Members Present:

Dave Dryden, (DE), *chair*; Jim Bracewell (GA); Diane Halvorson (ND); Mark Hardy (ND); Pam Reed (LA); Steve Schierholt (OH).

Others Present:

Jay Campbell, *Executive Committee Liaison*; Carmen A. Catizone, Eileen Lewalski, Maureen Schanck, Angie Rutkowski, *NABP staff*.

Introduction:

The Committee on Law Enforcement/Legislation met January 20 and 21, 2016, at Loews Chicago O’Hare Hotel, Rosemont, IL.

Review of the Committee Charge

Committee members reviewed their charge and accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists.
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

LE/L Recommendation 1: The Committee Recommends Approving the Amendments to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) Suggested by the Task Force on Pharmacist Prescriptive Authority, 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 104. Practice of Pharmacy.

~~The “Practice of Pharmacy” means the interpretation, evaluation, and implementation of Medical Orders; the accepting, processing, or Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice, the ordering, conducting, and interpretation of appropriate tests, and the recommendation and Administration of immunizations; and other approved patient care services such as the initiation of Drug therapy; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.~~

(See comment list.) *

Comments

Section 104. Comment.

The definition of the “Practice of Pharmacy” is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Additionally, the definition limits certain activities to performance by Pharmacists only, while allowing qualified personnel to assist Pharmacists in practice. That distinction is noted by listing activities that must be performed by the Pharmacist, such as the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; Patient Counseling; Pharmacist Care; and other tasks that the Pharmacist has responsibility for, such as Compounding and Labeling of Drugs and Devices; the proper and safe storage of Drugs and Devices, and maintenance of proper records. The deliberate distinction between the terms

“must perform” and “is responsible for” intends to allow delegation of tasks to Certified Pharmacy Technicians or Pharmacy Technicians.

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

* Please note a revised definition including background appears on pages 6 and 9.

NABP recognizes that protection of the public health should extend across state borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the “Practice of Pharmacy.”

~~In the interest of public health and patient access to timely, efficient, and quality care, it is warranted to ensure that the definition of the “Practice of Pharmacy” includes pharmacists with the legislative and regulatory authority to initiate medication therapy based upon the following specific parameters. The development of the parameters should include all stakeholders needed to appropriately define and confine the authority within the pharmacist’s education and expertise. (Examples where a pharmacist could potentially initiate medication therapy include public health and preventative medications such as, but not limited to, naloxone, hormonal contraceptives, and travel medications.)~~

~~The following factors should be considered in the development of parameters:~~

- ~~1. No diagnosis required or is easily assessed~~
- ~~2. Formulary or protocol (such as regional, Board, or State established)~~
- ~~3. Communications and feedback is required between pharmacist, patient, and primary care provider where one exists or referral by pharmacist to primary care provider and/or appropriate practitioner, if necessary.~~

Section 105. Definitions.

...

(u) “Collaborative Pharmacy Practice” is that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction and in collaboration with one or more Practitioners ~~under protocol and in collaboration with Practitioner(s)~~ to provide patient care services to achieve optimal medication use and desired patient outcomes.

(v) “Collaborative Pharmacy Practice Agreement” is a written and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice as defined by law and the Rules of the Board.

...

(b4) “Medical Order” means a lawful order of a Practitioner that may or may not include a Prescription Drug Order.

...

- (w4) “Pharmacist’s Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement” means those duties and limitations of duties placed upon one or more Pharmacists by the collaborating Practitioner or Practitioners, the Board, and applicable law, and includes the limitations implied by the scope of practice of the collaborating Practitioner or Practitioners.
- ...
- (f5) “Practitioner” means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.
- ...
- (j5) “Prescription Drug Order” means a lawful order from a Practitioner for a Drug or Device for a specific patient, including orders derived from Collaborative Pharmacy Practice, where a valid Patient-Practitioner relationship exists, that is communicated to a Pharmacist in a licensed Pharmacy.
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Model Rules for the Practice of Pharmacy

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Section 5. Pharmacist Care

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(d) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist’s Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner’s current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

- (i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
- (ii) the types of decisions that the Pharmacist is allowed to make. ~~may include:~~
 - ~~(A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;~~
 - ~~(B) a detailed description of the methods, procedures, decision criteria, and plan the Pharmacist is to follow when conducting allowed activities; and~~
 - ~~(C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made.~~

- (iii) a process for generating any necessary medical orders, including prescription orders, required to initiate allowed activities.
 - (iv) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;
 - (iv) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
 - (vi) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
 - (vii) a provision that allows either party to cancel the Agreement by written notification;
 - (viii) an effective date; ~~and~~
 - (~~viii~~) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing; and
 - (x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.
- (3) Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.
- ~~(34) Initiation of the Collaborative Pharmacy Practice Agreement~~
~~—The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate allowed activities for any particular patient.~~
- (4) Documentation of Pharmacist activities
 Documentation of allowed activities must be kept as part of the patient’s permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered Protected Health Information.
- ~~(5) Review~~
~~—At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.~~

Background:

Although the Executive Committee determined that the Task Force on Pharmacist Prescriptive Authority did not adequately address the task force charge regarding pharmacist prescriptive authority, the committee agreed with the task force members’ reluctance to specifically add pharmacist prescriptive authority language to the Model Act, since this concept is relatively new and warrants further research by NABP and the Executive Committee. The committee members further agreed with the task force members’ decision to amend the definition of collaborative practice agreement to remove restrictions that currently exist. Like the task force members, the committee members determined that collaborative practice laws and rules should be broad in scope to allow varying degrees of collaboration and should not interfere with the extent of collaboration between a pharmacist and other health care providers.

Since the committee members preferred the new definition of the “Practice of Pharmacy” recommended by the Task Force on the Regulation of Pharmacist Care Services, the committee concluded that the “Practice of Pharmacy” definition recommended by the Task Force on Pharmacist Prescriptive Authority should be deleted. Furthermore, the committee members also agreed that, since the new definition of “Practice of Pharmacy” will include the initiation of pharmacist care services, the comment added by the Task Force on Pharmacist Prescriptive Authority in section 104 regarding the initiation of medication therapy should also be deleted.

LE/L Recommendation 2: The Committee Recommends Approving the Amendments to the Model Act Suggested by the Task Force on the Regulation of Pharmacist Care Services, 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 104. Practice of Pharmacy.

The “Practice of Pharmacy” means, but is not limited to, the interpretation, evaluation, Dispensing, and/or implementation of Medical Orders; ~~the accepting, processing, or Dispensing of Prescription Drug Orders;~~ participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; and the initiation and provision of those acts or services necessary to Pharmacist Care Services. ~~in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice, the ordering, conducting, and interpretation of appropriate tests, and the recommendation and Administration of immunizations; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records.~~ The Practice of Pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.
(See comment list.)

Section 104. Comment.

The definition of the “Practice of Pharmacy” is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Additionally, the definition limits certain activities to performance by Pharmacists only, while allowing qualified personnel to assist Pharmacists in practice. That distinction is noted by listing activities that must be performed by the Pharmacist, such as the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; Patient Counseling; Pharmacist Care; and other tasks that the Pharmacist has responsibility for, such as Compounding and Labeling of Drugs and Devices; the proper and safe storage of Drugs and Devices, and maintenance of proper records. The deliberate distinction between the terms “must perform” and “is responsible for” intends to allow delegation of tasks to Certified Pharmacy Technicians or Pharmacy Technicians.

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

NABP recognizes that protection of the public health should extend across state borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the “Practice of Pharmacy.”

...

Section 105. Definitions.

...

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

...

- (x4) “Pharmacy” means any place within this State where Drugs are Dispensed and Pharmacist Care is provided and any place outside of this State where Drugs are Dispensed and Pharmacist Care is provided to residents of this State.
(See comment list.)

- (y4) “Pharmacy Benefits Manager” means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, and that engages in or directs the Practice of Pharmacy.

(See comment list.)

Section 105(x4) (and [y4]). Comment.

It is the performance of activities that encompass the Practice of Pharmacy that distinguishes Pharmacy Benefits Managers from Pharmacy Benefits Processors. The activities that may encompass the Practice of Pharmacy by Pharmacy Benefits Managers include, but are not limited to, the following:

- Disease state management
- Disease compliance management
- Drug adherence management
- Drug interaction management
- Drug utilization management
- Formulary management
- Generic alternative program management

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

- Generic incentive program management
- Medical and/or Drug data analysis
- Patient Drug Utilization Review (DUR) services
- Prior authorization services
- Provider profiling and outcomes assessment
- Refill reminder program management
- Therapy guidelines management
- Stop therapy protocol management
- Wellness management
- Maintenance of confidential patient information
- Direction or design of the clinical programs for a Pharmacy or a group of Pharmacies

...

- (d5) “Practice of Telepharmacy” means the provision of Pharmacist Care by registered Pharmacies and Pharmacists located within US jurisdictions through the use of telecommunications or other technologies to patients or their agents at distances that are located within US jurisdictions.²

...

- (k5) “Primary Care” is the first level of contact of individuals, the family, and the community with the health care delivery system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process. (Areas of Primary Care where Pharmacists provide Pharmacist Care include, but are not limited to, the following: chronic disease management; smoking cessation; maternal and child health; immunizations; family planning; self-care consulting; Drug selection under protocol; treatment of common diseases and injuries; nutrition; and general health education and promotion.)

...

Section 301. Unlawful Practice.

- (a) Except as otherwise provided in this Act, it shall be unlawful for any individual, whether located in or outside this State, to engage in the Practice of Pharmacy in this State unless currently licensed to practice under any facet of the provisions of this Act.
- (b) The provision of Pharmacist Care services to an individual in this State, through the use of telecommunications, the Internet, or other technologies, regardless of the location of the pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.³
- (1) Licensed Pharmacies located outside this State that provide Pharmacist Care services to individuals in this State must be licensed within this State under Article V of this Act.

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

³ NABP recognizes that protection of the public health should extend across State borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the “Practice of Pharmacy” and requires an independently practicing pharmacist located outside this State to register to Practice Telepharmacy Across State Lines, rather than obtain full licensure for providing Pharmacist Care services from outside the State to patients within the State. ~~Pharmacists located outside this State who are providing Pharmacist Care services from a Pharmacy or nonresident Pharmacy licensed in this State need not register with this State to Practice Telepharmacy Across State Lines.~~

- (2) Pharmacists located outside this State who are providing Pharmacist Care services outside of a licensed Pharmacy to individuals located in this State must register with this State to engage in the nonresident Practice of Pharmacy.

...

Model Rules for the Practice of Pharmacy

Section 5. Pharmacist Care Services

- (a) Prospective Drug Utilization Review (DUR)⁴
A Pharmacist shall review the patient record and each Prescription Drug Order for:
 - (1) known allergies;
 - (2) rational therapy contraindications;
 - (3) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
 - (4) reasonable directions for use;
 - (5) potential or actual adverse Drug reactions;
 - (6) Drug-Drug interactions;
 - (7) Drug-food interactions;
 - (8) Drug-disease contraindications;
 - (9) therapeutic duplication;
 - (10) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
 - (11) abuse/misuse.

Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

- (b) Patient Counseling⁵
 - (1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:
 - (i) the name and description of the Drug;
 - (ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
 - (iii) intended use of the Drug and expected action;
 - (iv) special directions and precautions for preparation, Administration, and use by the patient;
 - (v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 - (vi) techniques for self-monitoring Drug therapy;

⁴ Pharmacists should be permitted to use computer software, if available, to accomplish this review.

⁵ The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

- (vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
 - (viii) prescription refill information;
 - (ix) action to be taken in the event of a missed dose; and
 - (x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.
- (2) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.
 - (3) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).
 - (4) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.
- (c) Medication Adherence Monitoring Services and Intervention Programs
Medication Adherence Monitoring Services and Intervention Programs designed to promote improved medication use behaviors, such as compliance and adherence, appropriate monitoring and self-reporting, increased patient knowledge, and improved therapy options, shall comply with established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs. (See Appendix E for Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs.)
- (d) Collaborative Pharmacy Practice
- (1) Collaborative Pharmacy Practice Agreement
A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.
 - (2) Contents
The Collaborative Pharmacy Practice Agreement shall include:
 - (i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
 - (ii) the types of decisions that the Pharmacist is allowed to make may include:
 - (A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;
 - (B) a detailed description of the methods, procedures, decision criteria, and plan the Pharmacist is to follow when conducting allowed activities; and
 - (C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the

prescription record, patient profile, a separate logbook, or in some other appropriate system.

- (iii) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;
- (iv) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
- (v) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
- (vi) a provision that allows either party to cancel the Agreement by written notification;
- (vii) an effective date; and
- (viii) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.

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

(3) **Initiation of the Collaborative Pharmacy Practice Agreement**

The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate allowed activities for any particular patient.

(4) **Documentation of Pharmacist activities**

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

(5) **Review**

At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.

...

Section 14. Provision of Pharmacist Care Services Outside of a Licensed Pharmacy.

(a) ~~A Pharmacist providing Pharmacist Care services outside the premises of a licensed Pharmacy shall maintain the records or other patient specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:~~

(a) In order for a Pharmacist to providing Pharmacist Care Services outside the premises of a licensed Pharmacy an applicant, shall:

- (1) Register/license with the Board(s);
- (2) Have appropriate security and protections in place; similar to or equivalent to ensure for a licensed pharmacy, shall maintain the confidentiality of records or other patient-specific information;
- (3) Maintain such records in such activities shall be maintained in a readily retrievable form; and ~~in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:~~

(4) Follow the patient care process approved by the Board⁶.

- ~~(1) provide accountability and an audit trail;~~
- ~~(2) be provided to the Board upon request;~~
- ~~(3) be preserved for a period of at least five years from the date relied upon or consulted for the purposes of performing any such function; and~~
- ~~(4) secure from unauthorized access and use.~~

Background:

The committee members agreed with the definition of the “practice of pharmacy” that was recommended by the Task Force on the Regulation of Pharmacist Care Services with the hope that the new definition will encompass evolutionary changes to the profession of pharmacy. The committee members further recommended amending the definition to include “the initiation” of pharmacist care services as part of the definition of the “practice of pharmacy.” The committee members concurred with the task force’s recommendation to amend “pharmacist care” to pharmacist care services” throughout the *Model Act*.

The committee members determined that pharmacist care services outside of the premises of a licensed pharmacy should ensure the confidentiality of records and patient-specific information while still being readily retrievable. The committee members determined that each requirement was equally important and should be a separate requirement to stress the distinction. The committee members also concluded that “similar to or equivalent to those in place for a licensed pharmacy” was contradictory and recommended deleting the wording.

LE/L Recommendation 3: The Committee Did Not Recommend Approving the Amendments to the Model Act Suggested by the Federation of Associations of Regulatory Boards (FARB) Following the United States Supreme Court Decision in North Carolina State Board of Dental Examiners v. Federal Trade Commission.

Section 102. Legislative Declaration.

The Practice of Pharmacy in the State of _____ is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest.⁷ It is further declared to be a matter of public interest and concern that the Practice of Pharmacy, as defined in this Act, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the Practice of Pharmacy, and to ensure the quality of Drugs and related Devices Distributed in the State of _____. This Act shall be liberally construed to carry out these objectives and purposes.

~~It is further declared that the intent of this legislation is to regulate the Practice of Pharmacy and will result in displacing competition by restricting licensure to practice Pharmacy, as such practice is defined and interpreted by the Board, to applicants determined by the Board to be qualified under this Act. It is~~

⁶ It is anticipated that Boards use the *Pharmacists’ Patient Care Process* approved in May 2014 by the Joint Commission of Pharmacy Practitioners.

⁷ Pharmacy is a learned profession affecting public health and welfare and should be declared as such by the State Legislature. The Practice of Pharmacy, from time to time, has been erroneously viewed, even by government agencies, as a commercial business rather than a profession. The status of Pharmacy as a profession has been, and will continue to be, of particular importance in litigation.

~~declared that any such restriction on competition is outweighed by the broader interest in protection of the public health, safety and welfare.~~

Background:

The committee members understood that the FARB-suggested language is intended to address *North Carolina State Board of Dental Examiners v. Federal Trade Commission*; however, the members observed that the impact of that decision is yet unknown. Therefore, it would be premature to amend the *Model Act* at this time.

LE/L Recommendation 4: The Committee Agrees That the Current *Model Act* Language Conforms to Resolution 111-7-15 Uniformity of Pre-licensure Experiential Requirements.

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

Article III Licensing

Introductory Comment to Article III

Article III of the Model Act specifies the requirements for initial licensure of Pharmacists, transfer of licensure, and renewal of licenses and registrations. In each of these areas, the Act sets forth basic Criteria and delegates to the Board the authority for implementing those Criteria. The Board does this by utilizing appropriate administrative enforcement mechanisms and by the issuance of specific rules.

Section 301 establishes the basis for this Article by making it unlawful for any unlicensed Person to engage in the Practice of Pharmacy, and by enabling the Board to exact penalties for unlawful practice.

In the area of initial licensure (Section 302), the Board must implement the Act by approving degree programs of Pharmacy, by specifying the examination to be employed (Section 302[b]), by establishing Pharmacy practice experience standards (Section 302[c]), and by ensuring that all other prerequisites are met by each applicant to whom it issues a license.

The Act also reflects the efforts of NABP to continue uniform standards for transfer of licensure (Section 303).

...

Section 302. Qualifications for Licensure by Examination.

- (a) To obtain a license to engage in the Practice of Pharmacy, an applicant for licensure by examination shall:
- (1) have submitted an application in the form prescribed by the Board of Pharmacy;
 - (2) have attained the age of majority;
 - (3) be of good moral character;
 - (4) have graduated and received the first professional degree from a college or school of Pharmacy that has been approved by the Board of Pharmacy;⁸

⁸ It is contemplated that Boards will approve those programs whose standards are at least equivalent to the standards required by the ACPE. This would include college-structured pharmacy practice experience programs and continuing education programs. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

- (5) have graduated from a foreign college of Pharmacy, completed a transcript verification program, taken and passed a college of Pharmacy equivalency examination program, and completed a process of communication-ability testing as defined under Board of Pharmacy regulations so that it is ensured that the applicant meets standards necessary to protect public health and safety;⁹
 - (6) have completed a Pharmacy practice experience program or other program that has been approved by the Board of Pharmacy, or demonstrated to the Board's satisfaction that experience in the Practice of Pharmacy which meets or exceeds the minimum Pharmacy practice experience requirements of the Board;
 - (7) have successfully passed an examination or examinations given by the Board of Pharmacy;
 - (8) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and
 - (9) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the license.
- (b) Examinations.
- (1) The examination for licensure required under Section 302(a)(7) of the Act shall be given by the Board at least two (2) times during each year. The Board shall determine the content and subject matter of each examination and approve the site and date of the Administration of the examination.
 - (2) The examination shall be prepared to measure the competence of the applicant to engage in the Practice of Pharmacy. The Board may employ, cooperate, and contract with any organization or consultant in the preparation and grading of an examination, but shall retain the sole discretion and responsibility for determining which applicants have successfully passed such an examination.
- (c) Pharmacy Practice Experience Programs and Other Training Programs.¹⁰
- (1) All applicants for licensure by examination shall obtain practical experience in the Practice of Pharmacy concurrent with or after college attendance, or both, under such terms and conditions as the Board shall determine.¹¹
 - (2) The Board shall establish such licensure requirements for Pharmacy Interns and standards for Pharmacy practice experiences, or any other experiential program necessary to qualify

⁹ Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Foreign Pharmacy Graduate Equivalency Examination[®] (FPGEE[®]) as part of their assessment of pharmacy education equivalence.

¹⁰ As college-based Pharmacy practice experience programs become uniform under the most recent revision of the ACPE *Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (effective July 1, 2007), and when boards of pharmacy are convinced that schools and colleges of pharmacy are meeting these Accreditation Standards and Guidelines and the competency requirements set out by Boards, Boards should begin to broadly accept and recognize college-based Pharmacy practice experience programs completed by students in other jurisdictions and eliminate requirements that such students obtain additional Pharmacy practice experience hours in addition to those obtained as part of the college of pharmacy curriculum. Because of the potential lack of uniformity among non-college-based Pharmacy practice experience programs, it is recommended that Boards exercise their prerogative to accept only at their discretion non-college based Pharmacy practice experiences completed by Pharmacy Interns in other jurisdictions.

¹¹ Although Boards of Pharmacy mandate a specified number of hours of Pharmacy practice experiences as a prerequisite to licensure, Boards of Pharmacy are also encouraged to deem those requirements met if Boards find that the college-based Pharmacy practice experiences meet or exceed the hourly Pharmacy practice experience requirements.

As indicated in the Model Rules for Pharmacy Interns, applicants for licensure as Pharmacists shall submit evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies as delineated in the ACPE Accreditation Standards and Guidelines and (2) not less than 1,740 hours of Pharmacy practice experience credit under the instruction and supervision of a Preceptor. Boards may consider moving away from requiring a specific number of contact hours should it be determined that the ACPE Accreditation Standards and Guidelines result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

an applicant for the licensure examination, and shall also determine the qualifications of Preceptors used in practical experience programs.¹²

Section 303. Qualifications for Licensure Transfer.¹³

- (a) In order for a Pharmacist currently licensed in another jurisdiction to obtain a license as a Pharmacist by license transfer in this State, an applicant shall:¹⁴
- (1) have submitted an application in the form prescribed by the Board of Pharmacy;
 - (2) have attained the age of majority;
 - (3) have good moral character;
 - (4) have possessed at the time of initial licensure as a Pharmacist all qualifications necessary to have been eligible for licensure at that time in this State;
 - (5) have engaged in the Practice of Pharmacy for a period of at least one (1) year or have met the Pharmacy practice experience requirements of this State within the one (1) year period immediately previous to the date of such application;
 - (6) have presented to the Board proof of initial licensure by examination and proof that such license is in good standing;
 - (7) have presented to the Board proof that any other license granted to the applicant by any other state has not been Suspended, Revoked, or otherwise restricted for any reason, except nonrenewal or for the failure to obtain the required continuing education credits, in any state where the applicant is currently licensed but not engaged in the Practice of Pharmacy; and
 - (8) have paid the fees specified by the Board.
- (b) No applicant shall be eligible for license transfer unless the state in which the applicant was initially licensed as a Pharmacist also grants licensure transfer to Pharmacists duly licensed by examination in this State, under like circumstances and conditions.¹⁵

...

Background:

Members reviewed Resolution 111-7-15 Uniformity of Pre-licensure Experiential Requirements, which reads:

WHEREAS, pre-licensure experiential requirements vary among states; and

WHEREAS, this variance in pre-licensure experiential requirements may negatively impact new graduates seeking licensure in multiple states;

¹² Boards of Pharmacy are strongly encouraged to utilize the ACPE Accreditation Standards and Guidelines as a basis for establishment and revision of Board standards for Pharmacy practice experiences. These Accreditation Standards and Guidelines also contain additional guidance on the desired behaviors, qualities, and values of preceptors.

¹³ See the NABP Model Rules for Public Health Emergencies for language that addresses the temporary recognition of nonresident pharmacist licensure in the case of a declared State of Emergency issued due to a Public Health Emergency.

¹⁴ It is intended that NABP's National Disciplinary Clearinghouse would be utilized by state Boards for verifying information provided by applicants.

¹⁵ Endorsement states may wish to consider the removal of Subparagraph (b) in this Section.

WHEREAS, a centralized database that contains information regarding completion of pre-licensure experiential programs would be helpful to state boards of pharmacy in their evaluation of new graduate applications for licensure; and

WHEREAS, the use of a centralized NABP database to confirm completion of pre-licensure experiential programs and graduation of applicants for licensure would simplify this process;

THEREFORE BE IT RESOLVED that NABP encourage states to recognize completion of Accreditation Council for Pharmacy Education-accredited pre-licensure experience as fulfillment of all preliminary licensure requirements; and

BE IT FURTHER RESOLVED that NABP encourage states to adopt the use of a centralized NABP database to confirm completion of pre-licensure experiential programs and graduation of new graduates.

(Resolution passed at the NABP 111th Annual Meeting in New Orleans, LA.)

The committee members reviewed existing *Model Act* language, specifically sections related to obtaining pharmacist licensure by examination and licensure transfer. The members determined that the *Model Act* currently articulates that boards should deem completion of Accreditation Council for Pharmacy Education-accredited pre-licensure experience as fulfillment of all preliminary licensure requirements. The committee members noted that the requirement for “having good moral character” may be ambiguous but might be useful to warrant investigation into fitness for practice. Furthermore, the committee members also expressed a desire to assess the need for the “age of majority” in the future to determine if a specific age requirement should be established for licensure.

LE/L Recommendation 5: The Committee Recommends Approval of Proposed Amendments to the *Model Act* Pertaining to Title I and Title II of the Drug Quality and Security Act (DQSA), With Revisions.

Recommended revisions by NABP staff are denoted by underlines and ~~striketroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double striketroughs~~.

**National Association of Boards of Pharmacy
Model State Pharmacy Act
Article I
Title, Purpose, and Definitions**

Section 105. Definitions.

...

- (d) “Adulterated”: A Drug or Device shall be deemed to be Adulterated:
- (1) if:
 - (i) it consists in whole or in part of any filthy, putrid, or decomposed substance; or
 - (ii) it has been produced, prepared, packed, or held under ~~unsanitary~~ insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to ensure that ~~the~~ such Drug or Device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or
 - (iii) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or
 - (iv) it bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the Federal Food, Drug, and Cosmetic Act (Federal Act); or it is a color additive, the intended use of which in or on Drugs or Devices is for purposes of coloring only, and is unsafe within the meaning of the Federal Act;
 - (2) if it purports to be or is represented as a Drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the Federal Act. No Drug defined in an official compendium shall be deemed to be Adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a Drug is recognized in both the United States Pharmacopeia (USP) and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the USP unless it is labeled and offered for sale as a homeopathic Drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not those of the USP;
 - (3) if it is not subject to paragraph (2) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or
 - (4) if it is a Drug and any substance has been mixed or packed therewith so as to reduce its quality or strength; or substituted wholly or in part therefore.
- (e) “Affiliated Entity” means legally separate covered entities that are affiliated and that designate themselves as a single covered entity for the purposes of this section.

- (f) ~~“Authenticate” means to affirmatively verify that each transaction listed in the product’s transaction history has occurred, in accordance with federal requirements and the Rules of the Board.¹⁶~~
- (g) ~~“Authentication of Product History” means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any Component of a radiopharmaceutical.~~
- ...
- (k) ~~“Biological Safety Cabinet” means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.~~
- ...
- (p) “Centralized Prescription Processing” means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as Dispensing, Drug Utilization Review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.
- ...
- (z) ~~“Compounding” means the preparation, of Components into a Drug product (1) as the result of a Practitioner’s Prescription Drug Order or initiative based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (2) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding includes the preparation of Drugs or Devices in anticipation of receiving Prescription Drug Orders based on routine, regularly observed prescribing patterns.¹⁷ mixing, assembling, altering, packaging, and labeling of a Drug, Drug-delivery Device, or Device. Unless performed in an FDA-registered Outsourcing Facility in conformance with federal law, is in accordance with a licensed Practitioner’s Prescription Drug 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 patterns¹⁸, and~~
 - ~~(3) reconstitution or manipulation of commercial products that may require the addition of one or more ingredients for patient-specific needs.~~
- ...

¹⁶ Although Pedigrees record each transaction of a Prescription Drug and are, therefore, primarily used in Authenticating, “other accompanying documents” such as purchase orders and invoices should also be utilized to assist in Authenticating. For example, when such “accompanying documents” seem false or misleading, every attempt should be made to Authenticate the Prescription Drug before it is further wholesale distributed. The Board should also establish standards and procedures for Manufacturers and Wholesale Distributors to complete the Authentication process. These standards should provide consistency among Manufacturers and Wholesale Distributors.

¹⁷ Nothing in these definitions of “Compounding” and “Manufacturing” shall preclude a Pharmacist from informing Practitioners or patients of the ability to Compound or the availability of Compounding services. (See Appendix B, Good Compounding Practices Applicable to State Licensed Pharmacies.)

¹⁸ Anticipatorily Compounded Drugs may not be dispensed until receipt of a patient-specific Prescription Drug Order.

- (s2) “Dispense” or “Dispensing” means the interpretation, evaluation, and implementation of a Prescription Drug Order, including the preparation, final verification, and Delivery of a Drug or Device to a patient or patient’s agent in a suitable container appropriately labeled for subsequent Administration to, or use by, a patient.¹⁹
- (t2) “Dispenser” means:
- (1) a retail Pharmacy, hospital Pharmacy, a group of chain Pharmacies under common ownership and control that do not act as a Wholesale Distributor, or any other Person authorized by law to Dispense or Administer prescription Drugs, and the affiliated warehouses or Distribution centers of such entities under common ownership and control that do not act as a wholesale Distributor.; and
 - (2) does not include a Person who Dispenses only Products to be used in animals pursuant to Federal law.
- (u2) “Distribute” or “Distribution” means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include:
- (1) To Dispense or Administer;
 - (2) Delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier; or
 - (3) Providing a Drug sample to a patient by a Practitioner licensed to prescribe such Drug; a health care professional acting at the direction and under the supervision of a Practitioner; or the Pharmacy of a hospital or of another health care entity that is acting at the direction of such a Practitioner and that received such sample in accordance with the Act and regulations to administer or dispense.
- (v2) ~~“Drop Shipment” means the sale by a Manufacturer, that Manufacturer’s Co-Licensee, that Manufacturer’s Third-Party Logistics Provider, or that Manufacturer’s Exclusive Distributor, of the Manufacturer’s Prescription Drug, to an Authorized Distributor of Record whereby the Authorized Distributor of Record takes title but not possession of such Prescription Drug and the Wholesale Distributor invoices the Pharmacy and the Pharmacy receives Delivery of the Prescription Drug directly from the Manufacturer, that Manufacturer’s Co-Licensee, that Manufacturer’s Third-Party Logistics Provider, or that Manufacturer’s Exclusive Distributor, of such Prescription Drug. Drop Shipments shall be part of the “Normal Distribution Channel.”~~
- ...
- (c3) “Exclusive Distributor” means the Wholesale Distributor that directly purchased the Product from the Manufacturer and is the sole Distributor of that Manufacturer’s Product to a subsequent Repackager, Wholesale Distributor, or Dispenser an entity that:
- (1) ~~contracts with a Manufacturer to provide or coordinate warehousing, Wholesale Distribution, or other services on behalf of a Manufacturer and who takes title to that~~

¹⁹ “Dispensing” includes the Delivery of a Drug or Device to the patient or the patient’s agent by the Pharmacist or the Pharmacist’s agent. Under the statutory definition of “Dispense” in Section 105(u2), Drugs and/or Devices mailed or shipped to a patient are not Dispensed until the Drugs and/or Devices are actually received by the patient or the patient’s agent.

- ~~Manufacturer's Prescription Drug, but who does not have general responsibility to direct the sale or disposition of the Manufacturer's Prescription Drug; and~~
- (2) ~~is licensed as a Wholesale Distributor under this chapter.~~

...

- (n3) "Illegitimate Product" means a Product for which credible evidence shows that the Product:
- (1) is counterfeit, diverted, or stolen;
 - (2) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
 - (3) is the subject of a fraudulent Transaction; or
 - (4) appears otherwise unfit for Distribution such that the Product would be reasonably likely to result in serious adverse health consequences or death to humans.

...

- (y3) "Manufacturer" means a Person engaged in the Manufacture of Drugs or Devices.²⁰
- (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.²¹

...

- (k4) "Normal Distribution Channel" means a chain of custody for a Prescription Drug that goes from a Manufacturer of the Prescription Drug, the Manufacturer's Co-Licensee, the Manufacturer's Third-Party Logistics Provider, or the Manufacturer's Exclusive Distributor to:
- (1) a Wholesale Distributor to a Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or
 - (2) a Wholesale Distributor to a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or
 - (3) a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or
 - (4) as prescribed by the Board's regulations.

...

- (m4) "Outsourcing Facility" means a facility at one geographic location or address that
- (1) is engaged in the Compounding of sterile Drugs for human use;
 - (2) may not compound pursuant to a patient-specific Prescription Drug Order;
 - (3) is registered as an outsourcing facility with the FDA; and

²⁰ "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. An integral component of the licensing of Manufacturers as Wholesale Distributors to prevent or detect Counterfeit or Contraband Drugs or Devices is the requirement for the development, maintenance, and release of the Manufacturer's approved list of Authorized Distributors or Authorized Distributors of Record. Failure to do so would preclude licensure and, if the Manufacturer is licensed, could be grounds for suspension or revocation of the license.

²¹ Manufacturing also includes the Compounding of Drugs for office use of which can only be done by an FDA-registered Outsourcing Facility.

(4) complies with all of the requirements of Section 503B of the FD&C Act.

...

(15) “Product” means a Prescription Drug in a finished dosage form for administration to a patient without substantial further Manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but does not include:

- (1) blood or blood components intended for infusion;
- (2) radioactive Drugs or radioactive biological products;
- (3) imaging Drugs;
- (4) intravenous product that are intended to:
 - (i) replenish fluids and electrolytes;
 - (ii) maintain the equilibrium of water and minerals;
 - (iii) irrigate
- (5) any medical gas;
- (6) homeopathic Drugs marketed in accordance with applicable federal law; or
- (7) a Drug Compounded in compliance with federal law.

(m5) “Product Identifier” means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

...

(a6) “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. 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 further manipulated in any way.

(b6) “Repackager” means a Person who Repackages owns or operates an establishment that repacks and relabels a product or package for:

- (1) further sale; or
- (2) Distribution without a further transaction.²²

(d6) “Return” means providing Product to the authorized immediate Trading Partner from which such Product was purchased or received, or to a returns processor or reverse logistics provider for handling of such Product.

(e6) “Returns Processor or Reverse Logistics Provider ~~Distributor~~” means any Person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable Product received from an authorized Trading Partner such that the Product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further ~~Distribution. receives, takes inventory, and manages the disposition of outdated, expired, or otherwise non-saleable Drugs from Pharmacies, Wholesale Distributors, or other entities.~~

²² Is not intended to include a Pharmacy, Pharmacist, or Outsourcing Facility that Dispenses or Distributes Repackaged Drugs.

...

(k6) “Specific Patient Need” means the transfer of a Product from one Pharmacy to another to fill a Prescription for an identified patient, but does not include the transfer of a Product from one Pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(l6) “Standardized Numerical Identifier” means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific Product, including the particular package configuration, combined with a unique alphanumeric serial number of up to 20 characters.

(m6) “Sterile Pharmaceutical” means any dosage form of a drug, including but not limited to, parenterals (eg, injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.

(n6) “Suspect Product” means a Product for which there is reason to believe that such Product:
(1) is potentially counterfeit, diverted, or stolen;
(2) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(3) is potentially the subject of a fraudulent Transaction; or
(4) appears otherwise unfit for Distribution such that the Product would result in serious adverse health consequences or death to humans.

...

(p6) “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;

...

(q6) “Trading Partner” means:
(1) a Manufacturer, Repackager, Wholesale Distributor, or dispenser from whom a Manufacturer, Repackager, Wholesale Distributor, or dispenser accepts direct ownership of a product or to whom a Manufacturer, Repackager, Wholesale Distributor, or dispenser transfers direct ownership of a product; or
(2) a Third-Party Logistics Provider from whom a Manufacturer, Repackager, Wholesale Distributor, or dispenser accepts direct possession of a product or to whom a Manufacturer, Repackager, Wholesale Distributor, or dispenser transfers direct possession of a product.

(r6) “Transaction” means the transfer of product between Persons in which a change of ownership occurs. Transaction does not include:
(1) intracompany distribution of any product between members of an affiliate or within a Manufacturer;
(2) the Distribution of a Product among hospitals or other health care entities that are under common control;

- (3) the Distribution of a Product for emergency medical reasons including a public health emergency declaration pursuant to State or Federal law, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
- (4) the Dispensing of a Product pursuant to a Prescription;
- (5) the Distribution of Product samples by a Manufacturer or a licensed Wholesale Distributor in accordance with State and Federal law;
- (6) the Distribution of blood or blood components intended for transfusion;
- (7) the Distribution of minimal quantities of Product by a licensed retail Pharmacy to a licensed practitioner for office use;
- (8) the sale, purchase, or trade of a Drug or an offer to sell, purchase, or trade a Drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by State and Federal law;
- (9) the Distribution of a Product pursuant to the sale or merger of a Pharmacy or Pharmacies or a Wholesale Distributor or Wholesale Distributors, except that any records required to be maintained for the Product shall be transferred to the new owner of the Pharmacy or Pharmacies or Wholesale Distributor or Wholesale Distributors;
- (10) the dispensing of a new animal Drug Product approved under Federal Law;
- (11) Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission;
- (12) a combination Product that is:
 - (i) a product comprised of a Device and one or more other regulated components (such as a Drug/Device, biologic/Device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
 - (ii) two or more separate Products packaged together in a single package or as a unit and comprised of a Drug and Device or Device and biological Product; or
 - (iii) two or more finished medical Devices plus one or more Drug or biological Products that are packaged together in what is referred to as a ‘medical convenience kit’ as described in (r6)(13);
- (13) the Distribution of a collection of finished medical Devices, which may include a Product or biological Product, assembled in kit form strictly for the convenience of the purchaser or user if:
 - (i) the medical convenience kit is assembled in an establishment that is registered with the FDA as a Device Manufacturer;
 - (ii) the medical convenience kit does not contain a federally scheduled controlled substance;
 - (iii) in the case of a medical convenience kit that includes a Product, the Person that Manufacturers the kit:
 - (A) purchased such product directly from the pharmaceutical Manufacturer or from a Wholesale Distributor that purchased the Product directly from the pharmaceutical Manufacturer;
 - (B) does not alter the primary container or label of the Product as purchased from the Manufacturer or Wholesale Distributor; and
 - (iv) in the case of a medical convenience kit that includes a Product, the 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;
 - (E) an anticoagulant;
 - (F) a vasopressor; or
 - (G) a sympathomimetic;
 - (14) the Distribution of an intravenous Product 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 Product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
 - (16) the Distribution of a Product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
 - (17) the Distribution of a medical gas;
 - (18) the Distribution or sale of any licensed biologic Product that meets the definition of Device under Federal law.
- (s6) “Transaction History” means a statement in paper or electronic form that includes the transaction information of each prior transaction going back to the Manufacturer of the Product.
- (t6) “Transaction Information means:
- (1) the proprietary or established name or names of the Product;
 - (2) the strength and dosage form of the Product
 - (3) the National Drug Code number of the Product;
 - (4) the container size;
 - (5) the number of containers;
 - (6) the lot number of the Product;
 - (7) the Transaction date
 - (8) the shipment date, if more than 24hours after the Transaction date;
 - (9) the business name and address of the transferring Person; and
 - (10) the business name and address of the transferee Person.
- (u6) “Transaction Statement is a statement, in paper or electronic form, that the entity transferring ownership in a transaction:
- (1) is authorized under federal law;
 - (2) received the Product from a person that is authorized as required under federal law;
 - (3) received Transaction Information and Transaction Statement from the prior owner of the Product, as required by federal law;
 - (4) did not knowingly ship a Suspect or Illegitimate Product;
 - (5) had systems and processes in place to comply with verification requirements outlined in federal law;
 - (6) did not knowingly provide false Transaction Information; and
 - (7) did not knowingly alter the Transaction History.
- (#v6) “USP Standards” means standards published in the current official United States Pharmacopeia or National Formulary.

- (w6) “Verification” means determining whether the Product Identifier of a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the Product by the Manufacturer or Repackager in accordance with Federal law.
- (y6) “Wholesale Distribution” means the Distribution of Prescription a Drugs or Devices 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 by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer, Distribution, or sale of Prescription Drugs by a Pharmacy to another Pharmacy or from a Pharmacy to a Practitioner, only for the purpose of Dispensing or Administration, but not for resale; if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12) month period, providing that such transfers are compliant with federal law. To the extent permitted by the Prescription Drug Marketing Act, Wholesale Distribution does not include²³:
- (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 which 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.
 - (5) the Distribution of minimal quantities of 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 Repacks 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:

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 that 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 that Manufacture and/or Distribute Devices should be licensed with the Board and adhere to the same requirements as those in place for persons that Manufacture and/or Distribute Drugs. In developing laws and rules, states may need to review their current regulations regarding licensure for persons that solely Manufacture and/or Distribute Devices in order to determine the applicability of the Model Rules to persons that Manufacture and/or Distribute Devices.

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

- (i) the medical convenience kit is assembled in an establishment that is registered with the 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 Manufacturers 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;
 - (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.
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- ~~(3) the sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;~~
 - ~~(4) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;~~
 - ~~(5) Intracompany Transactions, unless in violation of own use provisions;~~
 - ~~(6) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;~~
 - ~~(7) the sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;~~

- (8) ~~the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;~~
- (9) ~~the transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;~~
- (10) ~~the sale, purchase, or trade of blood and blood components intended for transfusion;~~
- (11) ~~the return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations;~~
- (12) ~~the sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations; or~~
- (13) ~~other transactions excluded from the definition of "Wholesale Distribution" under 21 CFR 203.3(CC), including any amendments thereto.~~

(z6) "Wholesale Distributor" means any Person (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, including but not limited to Manufacturers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including Distributors' warehouses, Co-licensees, Exclusive Distributors, Chain Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, and retail Pharmacies that conduct Wholesale Distributions.²⁵

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Article V

Licensing of Facilities

Introductory Comment to Article V

The fifth and last substantive Article of the Model Act concerns licensure of Pharmacies, Manufacturers, Wholesale Distributors, 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 better ensure against Drug or Device diversion from the legitimate channels of commerce and provide the necessary data for effective recalls and the dissemination of information.

Section 501. Licensing.

²⁵ "Wholesale Distributor" may be used interchangeably with Wholesaler and, as defined by the Prescription Drug Marketing Act of 1987, includes Manufacturers.

- (a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board²⁶:
- (1) Persons engaged in the Practice of Pharmacy;
 - (2) dispensing Practitioners and Practitioner's facilities including those engaged in non-sterile ~~the Compounding of Sterile Pharmaceuticals;~~²⁷
 - (3) Persons engaged in the Manufacture or Repackaging, ~~production, sale, or Distribution or Wholesale Distribution~~ of Drugs or Devices;
 - (4) Persons engaged in the Wholesale Distribution of Drugs or Devices;
 - (5) Persons engaged in Third-Party Logistic Provider activities of Drugs or Devices;
 - (6) Pharmacies where Drugs or Devices are Dispensed, or Compounded, or where Pharmacist Care Services ~~is~~ are provided;
 - (7) Pharmacies that perform Compounding of Sterile Pharmaceuticals;
 - (8) Outsourcing Facilities;
 - (9) Pharmacy Benefits Managers; and
 - (10) Repository Programs
- Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.
- (b) The Board shall establish by rule, under the powers granted to it under Section 212 and 213 of this Act and as may be required from time to time, under federal law, the Criteria that each Person must meet to qualify for licensure in each classification, as well as the required practice standards applicable to each type of activity and/or facility. The Board shall adopt definitions in addition to those provided in Article I, Section 105, where necessary to carry out the Board's responsibilities. The Board may issue licenses with varying restrictions to such Persons where the Board deems it necessary.²⁸
- (c) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.
- (d) Each licensed Person located outside of this State who ships, mails, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in this State, or Pharmacy located outside of this State who ships, mails, Distributes, or Delivers Drugs or Devices in this State, shall comply with the laws of patients' domicile, and shall designate a registered agent in this state for service of process. Any such licensed Person or Pharmacy who does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such licensed Person growing out of or arising from such Delivery. A copy of any such service of process shall be mailed to such Person or Pharmacy by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Person

²⁶ State may require additional Licensing/Registration requirements.

²⁷ Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, counseling, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

²⁸ Section 501(b) contemplates that the Criteria for licensure, beyond minimum requirements for all Persons and Pharmacies, established in an individual entity classification could differ. For example, the Criteria that must be met by a nuclear Pharmacy will certainly differ from that of the community Pharmacy. This type of latitude places the responsibility on the Board to adopt appropriate rules to meet the situation at hand. It also provides a forum for change to meet the changing concepts of professional practice and the Distribution of Drugs and/or Devices.

has designated on its application for licensure in this State. If any such Person is not licensed in this State, service on the Secretary of State only shall be sufficient service.²⁹

- (e) The Board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the licensure and inspection of entities located in this jurisdiction and those located outside this State.
- (f) The Board of Pharmacy may deny or refuse to renew a license if it determines that the granting or renewing of such license would not be in the public interest.
- (g) The Board shall establish the standards that a Person must meet for initial and continued licensure under Article V.
- (h) For facilities that Compound ~~and/or Repackage~~ Sterile Pharmaceuticals, an initial ~~or an annual~~ inspection shall be required ~~for purposes of~~ prior to initial licensure or initiation of sterile compounding activity. Thereafter an annual inspection shall be required for licensure renewal. For facilities that do not Compound Sterile Pharmaceuticals, an initial inspection, and thereafter ~~or~~ an inspection that takes place not ~~more~~ less than every 24 months shall be required for purposes of licensure or licensure renewal³⁰. Such inspection shall be performed by the following:
 - (1) the Board or its duly authorized agent;
 - (2) a duly authorized agent of a third party approved by the Board, such as the NABP Verified Pharmacy Program (VPP) (see Appendix B for the Multistate Pharmacy Inspection Blueprint);
 - (3) for Nonresident Pharmacies, the resident state Board of Pharmacy, if the resident Board's inspection is substantially equivalent to inspection in this State, or a VPP inspection.
- (i) Agents duly authorized to conduct inspections, whether agents of the Board or an approved third party, such as VPP, must be competent to inspect the facilities they are assigned to inspect to include training on any applicable State, Federal, and USP standards.

Section 502. Application.

- (a) The Board shall specify by rule the licensure procedures to be followed, including but not limited to, specification of forms for use in applying for such licensure and times, places, and applicable fees.
- (b) Applicants for licensure to Distribute, Wholesale Distribute, Manufacture, sell, purchase, transfer, and/or produce Drugs or Devices, and applicants for licensure as a Pharmacy Benefits Manager, shall file with the Board of Pharmacy a verified application containing such information as the Board requires of the applicant relative to the qualifications for a license.
- (c) Licenses issued by the Board pursuant to this Act shall not be transferable or assignable.
- (d) The Board shall specify by rule minimum standards for responsibility of any Person, Pharmacy, Pharmacy Benefits Manager that has employees or personnel engaged in the Practice of Pharmacy, or Manufacture, Distribution, Wholesale Distribution, production, sale, or use of Drugs or Devices in the conduct of their business. If the licensed Person is a Pharmacy located in this state, that portion of the facility to which such license applies shall be operated only under the direct supervision of a Pharmacist licensed to practice in this State. If that Person is an Outsourcing Facility, all Compounding at the facility shall be under the direct supervision of a licensed Pharmacist and comply with federal requirements applicable to Outsourcing Facilities.
- (e) A "surety" bond of not less than \$100,000, or other equivalent means of security acceptable to the Board or a third party recognized by the Board such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any

²⁹ This section provides for service of process on any Person who Dispenses, Distributes, or Delivers Drugs or Devices within the State.

³⁰ State resources may have to be considered when evaluating inspection scheduling in combination with risk assessment consideration.

administrative penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their Wholesale Distributor license with the Board. The Board may make a claim against such bond or other equivalent means of security until one year after the Wholesale Distributor's license ceases to be valid or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board that involves the Wholesale Distributor is concluded, including any appeal, whichever occurs later. Manufacturers shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board. The Board may waive the bond requirement, if the wholesale distributor:

- (1) has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesale distributor possesses a valid license in good standing; or
- (2) is a publicly held company.

(See comment list.)

Section 503. Notifications.

- (a) All licensed Persons shall report to the Board of Pharmacy the occurrence of any of the following:
 - (1) permanent closing;
 - (2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
 - (3) any theft or loss of Drugs or Devices;
 - (4) any conviction of any employee of any State or Federal Drug laws;
 - (5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
 - (6) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;
 - (7) occurrences of Significant Quality-Related Events;
 - (8) Significant serious Adverse Drug Reaction events associated with Compounded Drugs;
 - (9) recalls of Compounded drugs;
 - (10) recalls of sterile Repackaged Drugs;
 - (11)8) illegal use or disclosure of Protected Health Information; or
 - (12)9) any and all other matters and occurrences as the Board may require by rule.
- (b) All licensed Persons shall report to the Board of Pharmacy, or its authorized agent, if they are engaging in any sterile Compounding activity conducted at a licensed facility, prior to commencing of any sterile Compounding activity and at least in a manner determined by the Board. The Board may establish by rule additional reporting requirements for sterile and nonsterile Compounding activities.
- (c) All licensed Persons shall report to the Board of Pharmacy, or its authorized agent, the occurrence of any Pharmacy or Pharmacy-related inspection conducted by any state or Federal regulatory agency or authorized agent thereof, and shall provide a copy of the report of such inspection, including applicable documents relating to corrective actions.³¹

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³¹ This includes any report or inspectional observations and any related correspondence with the Federal or State agency.

Model Rules for Sterile Compounded or Repackaged Pharmaceuticals

Section 1. Purpose and Scope.

The purpose of this section is to ensure Positive Patient Outcomes Compounded Pharmaceuticals are prepared and Dispensed according to practice and quality standards through the provision of: ~~standards for~~ (1) Pharmacist Care Services; and (2) the preparation, Labeling, and Distribution of Sterile Compounded or Repackaged Pharmaceuticals by Pharmacies; and (3) Product Quality and Characteristics. These standards are intended to apply to all Sterile and nonsterile Compounded Pharmaceuticals, notwithstanding the location of the patient (eg, home, hospital, nursing home, hospice, doctor's office). All facilities and practitioners engaging in Sterile and nonsterile Compounding or Repackaging shall practice in accordance with Federal Law, these Rules, ~~the Board's Good Compounding Practices Applicable to State Licensed Pharmacies~~, and all the current applicable standards set by the United States Pharmacopeia-National Formulary (USP-NF) ~~chapters on Compounding and sterile pharmaceutical preparations, 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, other applicable referenced general chapters, and federal law. 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.~~

Section 2. Definitions.

- (a) ——— “Beyond Use Date” means a date placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used. ———
- (b) ——— “Bioburden” means the total number of microorganism associated with a specific item prior to sterilization.
- (c) ——— “Biological Safety Cabinet” means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49. ———
- (d) ——— “Critical Areas” means areas designed to maintain sterility of sterile materials. ———
Sterilized product, container/closures, and equipment may be exposed in critical areas.
- (e) ——— “Critical Surfaces” — Surfaces which may come into contact with or directly impact sterilized product or containers/closures.
- (f) ——— “Cytotoxic” means a pharmaceutical that has the capability of killing living cells.
- (g) ——— “Disinfection” means the process by which surface bioburden is reduced to a safe level or eliminated.³²
- (h) ——— “Enteral” means within or by way of the gastrointestinal tract or intestine.
- (i) ——— “ISO Class” means the description of an atmospheric environment characterized by the number of particles within a diameter per cubic foot of air.³³

³²—Some disinfection agents are effective only against vegetative microbes, while others possess additional capability to effectively kill bacterial and fungal spores.

³³—For example, “ISO Class 5” means an atmospheric environment that contains fewer than 100 particles 0.5 microns in diameter per cubic foot of air.

- (j) “Isolator” means a decontaminated unit, supplied with ISO Class 5 or higher air quality that provides uncompromised, continuous isolation of its interior from the external environment (eg, surrounding cleanroom air and Compounding Pharmacy personnel).
- (k) “Outsourcing Facility” means a facility at one geographic location or address that is engaged in the Compounding of human sterile Drugs without a patient specific prescription; has registered as an Outsourcing Facility with the secretary of the US Department of Health and Human Services, Food and Drug Administration; and complies with all applicable state and federal requirements.³⁴ “Parenteral” means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous or intramuscular routes.
- (m) “Positive Patient Outcomes” include the cure or prevention of disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process so as to improve the patient’s quality of life.
- (n) “Product Quality and Characteristics” include sterility, potency, identity, strength, quality, and purity associated with environmental quality, preparation activities, and checks and tests.
- (o) “Risk Level” of the Sterile Pharmaceutical means the level assigned to a Sterile Pharmaceutical by a Pharmacist that represents the probability that the Sterile Pharmaceutical will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals, or other physical matter.³⁵
- (p) “Sterile Pharmaceutical” means any dosage form of a drug, including but not limited to, parenterals (eg, injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.

Section 23. Notification

- (a) All licensed Persons shall report to the Board of Pharmacy, upon request from the Board, the number of Compounded preparations sold or Prescription Drug Orders Dispensed in the State and (for in-State pharmacies) out of the State during a time period specified by the Board in the previous year, including the Drug’s active ingredients, strength and dosage form. Outsourcing Facilities may provide this information by providing the biannual reports they are required to provide to the FDA identifying the drugs compounded in the previous 6 month period, including the drug’s active ingredients, strength and dosage form.
- (b) The Pharmacist shall notify patients if they may have received or be affected by a product found to have a defect or an out-of-specification result and conduct a recall, if the Board deems necessary.

Section 34. Policy and Procedure Manual.

³⁴ If a facility is engaging in the Compounding of human sterile drugs that are pursuant to a prescription, it must register with the Board as a Pharmacy.

³⁵ According to the USP General Chapter 797 (27th revision of the USP), the Risk Levels of operations should guide the health care professional in determining the appropriate procedures necessary to ensure a safe Compounding process. Correspondingly, based upon the Risk Level, health care professionals are responsible for determining the procedural and environmental quality practices and attributes that are necessary for the Risk Level associated with the Sterile Pharmaceutical.

It is recommended that Boards may consider referencing USP General Chapter 797; the revised version went into effect June 1, 2008, after consideration of recommendations received from USP internal expert committees and the professional community.

A policy and procedure manual shall be prepared and maintained for the Compounding, Dispensing, Delivery, Administration, storage, and use of ~~Sterile Pharmaceutical~~ sterile and non-sterile Compounded Prescription Drugs. The policy and procedure manual shall incorporate ~~any~~ all applicable USP requirements, in USP Chapter <797> and; ~~at a minimum should include:~~

- (a) include a quality assurance program for the purpose of monitoring patient care and Pharmacist Care Services outcomes, ~~adverse Drug reactions, personnel qualifications, training and performance, product integrity, equipment, facilities, D~~ disinfection, personnel cleansing and gowning, and guidelines regarding patient education; and
- (b) be current and available for inspection by a Board of Pharmacy-designated agent;
- (c) ~~include a plan designed to prevent microbiological contamination of sterile Drug products and procedures concerning the validation of any sterilization process;~~
- (d) ~~include training and other requirements for Pharmacy Compounding personnel involved in aseptic manipulations to ensure adherence to the basic principles of aseptic technique;~~
- (e) ~~address the management and proper disposal of Cytotoxic hazardous and/or infectious waste, if applicable; and~~
- (f) ~~address how supervisory personnel will monitor the ongoing adherence to procedures and sound practices.~~

4. Physical Requirements.

- (a) Any facility Pharmacy that engages in Sterile Compounding shall adhere to physical, equipment, and environmental requirements established by USP. ~~NF Chapter <797>~~
- (b) ~~Pharmacies shall have sufficient current reference materials applicable related to Compounding. Sterile Pharmaceuticals to meet the needs of the Pharmacy staff to include a current copy of USP standards related to compounding and handling of hazardous materials.~~

Section 5. Records and Reports.

In addition to standard record keeping and reporting requirements, the following records shall be maintained: ~~the following records and reports must be maintained for sterile pharmaceuticals:~~³⁶

- (a) ~~Maintenance schedules, including a system for cleaning and disinfecting the room and equipment;~~
- (b) ~~Compounding records, as described by Good Compounding Practices Applicable to State Licensed Pharmacies, Appendix B, Subpart I;~~
- (c) ~~Records demonstrating that adequate disinfection (or Sterilization) was performed for the laminar flow hood and supplies used in the aseptic Compounding operation; and~~
- (d) ~~Dispensing or Distribution records to document who received the Compounded prescriptions.~~
- (a) All Distributions of non-sterile Compounded preparations or Dispensing of all sterile Compounded preparations.
- (b) Any other records required to conform to USP standards and/or Federal Law.

Section 6. Delivery Service.

³⁶Boards may consider exempting lot number documentation for institutions that have an adequate mechanism in place to recall products. Such mechanisms may include bar coding and other technologies that may contain the necessary information that is effectively needed to recall products.

The Pharmacist-in-Charge shall ensure the environmental control, ~~and stability, and sterility (if applicable)~~ of all ~~products~~ preparations shipped. Therefore, any Compounded ~~preparation,~~ Sterile Pharmaceutical must shall be shipped or Delivered to a patient or patient's agent in appropriate temperature-controlled (as defined by USP Standards) delivery containers and stored appropriately. Information on appropriate storage shall be provided to the patient or patient's agent.

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

The Pharmacist-in-Charge is responsible for ensuring that there is a system for the disposal of ~~Cytotoxic hazardous~~ and/or infectious waste in accordance with applicable State and Federal laws and USP requirements a manner so as not to endanger the public health.

Section 8. Emergency Kit.

When Sterile Pharmaceuticals are provided to home care patients, the Dispensing Pharmacy may supply the nurse or patient with emergency Drugs, if the physician has authorized the use of these Drugs by a protocol, in an emergency situation (eg, anaphylactic shock).

Section 9. ~~Cytotoxic~~ Drugs.

In addition to the minimum requirements for a Pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare ~~Cytotoxic~~ Drugs to ensure the protection of the personnel involved.

- (a) ~~All Cytotoxic Drugs should be Compounded in a vertical flow, Class II, Biological Safety Cabinet. Other products should not be Compounded in this cabinet.~~
- (b) ~~Protective apparel shall be worn by personnel Compounding Cytotoxic Drugs. This shall include disposable masks, gloves, and gowns with tight cuffs.~~
- (c) ~~Appropriate safety and containment techniques for Compounding Cytotoxic Drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.~~
- (d) ~~Disposal of Cytotoxic waste shall comply with all applicable local, State, and Federal requirements.~~
- (e) ~~Written procedures for handling both major and minor spills of Cytotoxic agents must be developed and must be included in the policy and procedure manual.~~
- (f) ~~Prepared doses of Cytotoxic Drugs must be Dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.~~

Section ~~810.~~ 910. Patient Education and Training.

~~If appropriate, the Pharmacist must demonstrate or document the patient's training and competency in managing this type of therapy provided by the Pharmacist to the patient in the home environment. A Pharmacist must be involved in the patient training process in any area that relates to Drug Compounding, Labeling, Administration, storage, stability, compatibility, or disposal. If appropriate, the Pharmacist must be responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.~~

Section 911. Quality Assurance/~~Compounding~~ and Preparation of Compounded ~~Sterile~~ Pharmaceuticals.

- (a) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, component verification and usage, Disinfection, sterilization, equipment, and facilities that are appropriate to the ~~Risk Level of the Sterile Pharmaceutical(s)~~ being prepared. Quality Assurance control programs shall at minimum conform to the requirements of USP. ~~Chapter <797>~~, including but not limited to the following:
- (b) The Pharmacist has the responsibility and authority to inspect and approve or reject all Components, Drug product containers, closures, in-process materials, and/or Labeling. Pharmacist shall have the authority to prepare and review all Compounding records to ensure that no errors have occurred in the Compounding process. If errors have occurred, the Pharmacist is responsible for conducting a full investigation. A written record of the investigation shall be made and shall include conclusions and follow-up. The Pharmacist is also responsible for the proper maintenance, cleanliness, and use of all facilities and equipment used in Compounding.
- (c) All Pharmacists who participate in Compounding, including other Pharmacy personnel who assist the Pharmacist in Compounding, shall be proficient in the science of Compounding and shall acquire the education, training, and/or experience to maintain that proficiency through participation in seminars, studying appropriate literature, and consulting colleagues, or by becoming certified by a Compounding certification program approved by the Board.
- (d) Pharmacists and other Compounding Pharmacy personnel (eg, Pharmacy Technicians) shall be trained and proficient in the particular operations that are performed by that individual.
- (e) Training shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that Compounding Pharmacy personnel remain familiar with applicable operations and policies and procedures.
- (f) Only personnel authorized by the responsible Pharmacist shall be in the immediate vicinity of Compounding operations.

- ~~(a) — All clean rooms and laminar flow hoods shall be certified by an independent contractor according to the International Organization of Standardization Classification of Particulate Matter in Room Air (ISO14644-1) for operational efficiency at least every six months. Appropriate records shall be maintained.~~
- ~~(b) — There shall be written procedures requiring sampling on a frequent basis and special measures taken when microbial contamination is suspected.~~
- ~~(c) — If bulk Compounding of sterile solutions is performed using chemicals that initially are nonsterile, extensive end-product microbial testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter, pyrogens, and microbes.~~
- ~~(d) — There shall be written justification of the chosen Beyond Use Dates for Compounded products.~~
- ~~(e) — There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits. Intervals shall be based on the type of operations performed and shall increase as the Risk Level increases.~~
- ~~(f) — There shall be policies and procedures on the retraining or recertification of trained Pharmacy Compounding personnel in various aspects of aseptic behavior. The training program shall include a demonstration of ongoing competency. Training to ensure skills such as aseptic technique, cleanroom behavior, and knowledge of the hazards posed by contaminated drugs shall be conducted.~~

- ~~(g) Pharmacy Compounding Personnel shall wear sterile garb if conducting one or more aseptic manipulation of sterilized equipment or product.~~
- ~~(h) An effective Disinfection program shall be implemented, including adequate provisions for preventing emergence of unsafe levels of sporeforming organisms.~~
- ~~(i) A system shall be in place for monitoring Pharmacy Compounding personnel and environmental conditions.~~
- ~~(j) A system shall be in place for maintaining any equipment or Devices used to control aseptic conditions.~~

Section 102. Pharmacist Care Services Outcomes.

~~There shall be a documented, ongoing quality assurance control program that monitors patient care and Pharmacist Care outcomes, including but not limited to, the following:~~

- ~~(a) routine performance of Prospective Drug Utilization Review (DUR) and patient monitoring functions by a Pharmacist, as defined in the Rules of the Board;~~
- ~~(b) patient monitoring plans that include written outcome measures and systems for routine patient assessment (examples include infection rates, rehospitalization rates, and the incidence of adverse Drug reactions);~~
- ~~(c) documentation of patient training as specified in Section 10; and~~
- ~~(d) appropriate collaboration with other health care professionals.~~

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Model Rules for Outsourcing Facilities

Section 1. Purpose and Scope.

~~The purpose of this section is to ensure that Outsourcing Facilities are recognized-regulated by this State in a manner harmonized-consistent with Federal law, and to ensure this State has appropriate authority over such facilities. in this jurisdiction. Outsourcing Facilities are FDA-regulated compounding facilities that may compound without prescriptions, but must meet current Good Manufacturing Practices—the quality standard applied to drug manufacturers. They may also be subject to other requirements under Federal law.~~

Section 2. Registration.

- ~~(a) Any Outsourcing Facility located in this State or that distributes Compounded Pharmaceuticals to this State must obtain be inspected and registration registered as an Outsourcing Facility by FDA prior to applying for a license/registration with the Board; and~~
- ~~(b) The facility must be licensed by the Board to practice as an Outsourcing Facility in this State; undergo an inspection by the Board or a third party recognized by the Board such as VAWD³⁷ if the facility is registered with the FDA but has not received an FDA inspection as an Outsourcing Facility.~~

Section 23. Notification

³⁷ States may require authentication and tracking of product, whereby the exchange of information for compounded product is traced.

- (a) All licensed/registered Outsourcing Facilities shall report to the Board the biannual reports they are required to provide to the FDA identifying the Drugs compounded in the previous 6-month period, including:
(a)(b) the drug's active ingredients, strength and dosage form.

Section 34. Requirements

Outsourcing Facilities must:

- (a) Compound Drugs by or under the direct supervision of a licensed Pharmacist;
(b) Compound Drugs in accordance with current Good Manufacturing Practice (cGMP) as required by Federal law;
(c) Ensure that Pharmacists conducting or overseeing Compounding at an Outsourcing Facility must be proficient in the art 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, and/or by becoming certified by a Compounding certification program approved by the Board.

...

Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors

Definitions.

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

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

- (3) ~~if it is not subject to paragraph (2) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or~~
- (4) ~~if it is a Drug and any substance has been mixed or packed therewith so as to reduce its quality or strength; or substituted wholly or in part therefore.~~
- (b) ~~“Authenticate” means to affirmatively verify that each transaction listed in the product’s transaction history has occurred, in accordance with federal requirements and the Rules of the Board.~~
- (c) ~~“Authorized Distributor of Record” means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer’s products. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:~~
 - (1) ~~the wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and~~
 - (2) ~~the wholesale distributor is listed on the manufacturer’s current list of authorized distributors of record, which must be updated by the manufacturer on no less than a monthly basis.~~
- (d) ~~“Centralized Prescription Processing” means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as Dispensing, Drug Utilization Review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.~~
- (e) ~~“Chain Pharmacy Warehouse” means a permanent physical location for Drugs and/or Devices that acts as a central warehouse and performs intracompany sales and transfers of Prescription Drugs or Devices to chain Pharmacies, which are members of the same affiliated group, under common ownership and control. Chain Pharmacy Warehouses must be licensed as Wholesale Distributors.~~
- (f) ~~“Closed Pharmacy” means a Pharmacy that purchases Drugs or Devices for a limited patient population and is not open for dispensing to the general patient population and cannot operate or be licensed as a Wholesale Distributor.~~
- (g) ~~“Co-licensee” means an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a Prescription Drug, consistent with the FDA’s implementation of the Prescription Drug Marketing Act.~~
- (h) ~~“Common Carrier” means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including Prescription Drugs for compensation.³⁸~~
- (i) ~~“Contraband Device” means a Device that is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that Device, or for which the documentation in existence has~~

³⁸ The definition of “Common Carrier” specifically excludes wholesale distributors which are defined separately.

been forged, Counterfeited, falsely created, or contains any altered, false, or misrepresented information.

- (j) — “Contraband Drug” means a Drug which is Counterfeit, stolen, Misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that Drug that has inappropriately entered the Drug supply chain Distribution
- (k) — “Counterfeit Device” means a Device which, or the container, shipping container, seal, or Product Labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a Manufacturer, processor, packer, or Distributor other than the Person or Persons who in fact Manufactured, processed, packed, Distributed, or Wholesale Distributed such Device and which thereby falsely purports or is represented to be the product of, or to have been packed, Distributed, or Wholesale Distributed by, such other Manufacturer, processor, packer, or Distributor.
- (l) — “Counterfeit Drug” means a Drug which, or the container, shipping container, seal, or Product Labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or Device, or any likeness thereof, of a Manufacturer, processor, packer, or Distributor other than the Person or Persons who in fact Manufactured, processed, packed, Distributed, or Wholesale Distributed such Drug and which thereby falsely purports or is represented to be the product of, or to have been packed, Distributed, or Wholesale Distributed by, such other Manufacturer, processor, packer, or Distributor.
- (m) — “Designated Representative” means an individual designated by the Wholesale Distributor who will serve as the responsible individual of the Wholesale Distributor with the Board who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.
- (n) — “Device” means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, “Caution: Federal or State law requires Dispensing by or on the order of a physician.”
- (o) — “Distribute” or “Distribution” means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include:
 - (1) to Dispense or Administer;
 - (2) delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier; or
 - (3) providing a Drug sample to a patient by a Practitioner licensed to prescribe such Drug; a health care professional acting at the direction and under the supervision of a Practitioner; or the Pharmacy of a hospital or of another health care entity that is acting at the direction of such a Practitioner and that received such sample in accordance with the Act and regulations to administer or dispense.
- (p) — “Drop Shipment” means the sale by a Manufacturer, that Manufacturer’s Co-Licensee, that Manufacturer’s Third-Party Logistics Provider, or that Manufacturer’s Exclusive Distributor, of the Manufacturer’s Prescription Drug, to an Authorized Distributor of Record whereby the Authorized Distributor of Record takes title but not possession of such Prescription Drug and the Wholesale Distributor invoices the Pharmacy and the Pharmacy receives Delivery of the Prescription Drug directly from the Manufacturer, that Manufacturer’s Co-Licensee, that Manufacturer’s Third-Party Logistics Provider, or that Manufacturer’s Exclusive Distributor, of such Prescription Drug. Drop Shipments shall be part of the “Normal Distribution Channel.”
- (q) — “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;~~
- (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.~~
- (r) ~~“Emergency Medical Reasons” include, but are not limited to, transfers of a Prescription Drug between a Wholesale Distributor or Pharmacy to alleviate a temporary shortage of a Prescription Drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, ie, ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed Practitioners of Prescription Drugs for use in the treatment of acutely ill or injured Persons; provision of minimal emergency supplies of Prescription Drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary Prescription Drugs cannot be obtained; and transfers of Prescription Drugs by a retail Pharmacy to another retail Pharmacy to alleviate a temporary shortage.~~
- (s) ~~“Exclusive Distributor” means an entity that:

 - (1) ~~contracts with a Manufacturer to provide or coordinate warehousing, Wholesale Distribution, or other services on behalf of a Manufacturer and who takes title to that Manufacturer’s Prescription Drug, but who does not have general responsibility to direct the sale or disposition of the Manufacturer’s Prescription Drug; and~~
 - (2) ~~is licensed as a Wholesale Distributor under this chapter; and~~
 - (3) ~~to be considered part of the Normal Distribution Channel, must also be an Authorized Distributor of Record.~~~~
- (t) ~~“FDA” means Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for Drugs, food, cosmetics, and other consumer products.~~
- (u) ~~“Federal Act” means the Federal Food, Drug, and Cosmetic Act.~~
- (v) ~~“Health Care Entity” means any Person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care but does not include any retail Pharmacy or Wholesale Distributor.~~
- (w) ~~“Immediate Container” means a container and does not include package liners.~~
- (x) ~~“Intracompany Transaction” means any transaction between a division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate entity.~~
- (y) ~~“Label” means a display of written, printed, or graphic matter upon the immediate container of any Drug or Device.~~
- (z) ~~“Manufacturer” means a Person engaged in the Manufacture of Drugs or Devices.~~
- (a2) ~~“Misbranded”: A Drug or Device shall be deemed to be misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the Manufacturer, packer, or Distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a Drug; or the label does not show an accurate monograph for Prescription Drugs.~~
- (b2) ~~“Normal Distribution Channel” means a chain of custody for a Prescription Drug that goes, directly or by drop shipment, from a Manufacturer of the Prescription Drug, the Manufacturer’s Co Licensee, the Manufacturer’s Third Party Logistics Provider, or the Manufacturer’s Exclusive Distributor to:~~

- ~~(1) an Authorized Distributor of Record to a Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or~~
- ~~(2) an Authorized Distributor of Record to a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or~~
- ~~(3) a Chain Pharmacy Warehouse to that Chain Pharmacy Warehouse's intracompany Pharmacy to a patient or other designated persons authorized by law to dispense or administer such Prescription Drug to a patient; or~~
- ~~(4) a Pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or~~
- ~~(5) as prescribed by the Board's regulations.~~
- ~~(e2) "Prescription Drug" or "Legend Drug" means a Drug which is required under Federal law to be labeled with either of the following statements prior to being Dispensed or Delivered:~~
 - ~~(1) "Rx Only"; or~~
 - ~~(2) "Caution: Federal law restricts this Drug to use by, or on the order of, a licensed veterinarian"; or~~
 - ~~(3) a Drug which is required by any applicable Federal or State law or rule to be Dispensed pursuant only to a Prescription Drug Order or is restricted to use by Practitioners only.~~
- ~~(d2) "Product Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.~~
- ~~(e2) "Repackage" means changing the container, wrapper, quantity, or Product Labeling of a Drug or Device to further the Distribution of the Drug or Device.~~
- ~~(f2) "Repackager" means a Person who Repackages.~~
- ~~(gh2) "Reverse Distributor" means any Person who receives, takes inventory, and manages the disposition of outdated, expired, or otherwise non-saleable Drugs from Pharmacies, Wholesale Distributors, or other entities.~~
- ~~(h2) "Sales Unit" means the unit of measure the manufacturer uses to invoice its customer for the particular product.~~
- ~~(i2) "Significant Loss" means any loss of a Prescription Drug that exceeds a reasonable level established by like persons which requires that loss to be reported to the Board or as required by Drug Enforcement Administration or other state and/or federal agencies for Prescription Drugs and controlled substances.~~
- ~~(j2) "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 under this chapter; and~~
 - ~~(3) to be considered part of the Normal Distribution Channel, must also be an Authorized Distributor of Record.~~
- ~~(k2) "USP Standards" means standards published in the current official United States Pharmacopeia or National Formulary.~~
- ~~(l2) "Virtual Wholesale Distributor/Broker" means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State which:~~
 - ~~(1) may or may not take title but does not take physical possession of the Prescription Drugs or Devices;~~
 - ~~(2) must be licensed by the state board of pharmacy or other appropriate state agency as a Wholesale Distributor; and~~
 - ~~(3) must be registered as a business entity with the appropriate state or local authority(s) and must operate out of a commercial facility and not out of a residence or personal dwelling.~~

Such location is exempt from the Wholesale Distributor licensure requirements specifically related to possession and storage of Prescription Drugs and Devices.

(m2) — ~~“Wholesale Distribution” means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer, distribution, or sale of Prescription Drugs by a Pharmacy to another Pharmacy or from a Pharmacy to a Practitioner, only for the purpose of dispensing or Administration, but not for resale; if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12) month period, providing that such transfers are compliant with federal law. To the extent permitted by the Prescription Drug Marketing Act, Wholesale Distribution does not include:~~

- ~~(1) the sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;~~
- ~~(2) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;~~
- ~~(3) Intracompany Transactions, unless in violation of own use provisions;~~
- ~~(4) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;~~
- ~~(5) the sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;~~
- ~~(6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;~~
- ~~(7) the transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;~~
- ~~(8) the sale, purchase, or trade of blood and blood components intended for transfusion;~~
- ~~(9) the return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board’s regulations;~~
- ~~(10) the sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board’s regulations; or~~
- ~~(11) other transactions excluded from the definition of “wholesale distribution” under 21 CFR 203.3(CC), including any amendments thereto.~~

(n2) — ~~“Wholesale Distributor” means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State, including but not limited to own label distributors, private label distributors, jobbers, brokers, warehouses, including Distributors’ warehouses, Co Licensees, Exclusive Distributors, Chain Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, Reverse Distributors, and retail Pharmacies that conduct Wholesale Distributions.~~³⁹

³⁹—In their regulation of Wholesale Distributors, many states have decided to license FDA-approved manufacturers separately from Wholesale Distributors, or in some cases exempt them from licensure altogether, because some of the licensing requirements are duplicative of the FDA’s manufacturing licensure processes. Some states have had difficulty in distinguishing who should and who should not be subject to the Wholesale

Section 1. Requirements for Licensure.

Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors that provide services within this State, whether ~~the Wholesale Distributor~~ is located within this State or outside this State, shall be licensed by the Board and shall annually renew their license with the Board using an application provided by the Board. Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors cannot operate from a place of residence. Where ~~Wholesale Distribution~~ operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.⁴⁰

- (a) Every Wholesale Distributor who engages in the Wholesale Distribution of Prescription Drugs or Devices shall license annually with the Board by application and provide information required by the Board on an application approved by the Board, including but not limited to:
- (1) all trade or business names used by the licensee (includes “is doing business as” and “formerly known as”), which cannot be identical to the name used by another unrelated ~~Wholesale Distributor~~ entity licensed to purchase Prescription Drugs or Devices in the State;
 - (2) name(s) of the owner and operator of the licensee (if not the same person), including:
 - (i) if a Person: the name, business address, Social Security number, and date of birth;
 - (ii) if a partnership: the name, business address, and Social Security number and date of birth of each partner, and the name of the partnership and federal employer identification number;
 - (iii) if a corporation: the name, business address, Social Security number and date of birth, and title of each corporate officer and director, the corporate names, the state of incorporation, federal employer identification number, and the name of the parent company, if any; the name, business address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC;
 - (iv) if a sole proprietorship: the full name, business address, Social Security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;
 - (v) if a limited liability company: the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and
 - (vi) any other relevant information that the Board requires.
 - (3) name(s), business address(es), and telephone number(s) of a person(s) to serve as the Designated Representative(s) for each facility of ~~the~~ Wholesale Distributor that engages in the Wholesale Distribution of Prescription Drugs or Devices and additional information as required in Section 10 (Record Keeping);

Distributor licensing requirements. For states that wish to exempt Manufacturers from particular licensing requirements, NABP suggests using the following language:

Subject to the Federal Food, Drug, and Cosmetic Act and all applicable federal law and regulation, an FDA-approved manufacturer, including its affiliates, subsidiaries, agents and other entities under common ownership and control of the manufacturer, that exclusively distributes its own FDA-approved prescription drug and/or biologic product, and that has not left the manufacturer's chain of custody shall be exempt from the requirements of the [this section]...

⁴⁰ The application and screening process for licensing entities engaging in the Distribution of Product ~~Wholesale Distributors~~ represents a critical point in efforts to prevent the introduction of Counterfeit and Contraband products into the medication distribution system. An application that requires detailed information about the applicant and key individuals involved in the operations of the entity ~~Wholesale Distributor~~ is critical.

- (4) a list of all State and Federal licenses, registrations, or permits, including the license, registration, or permit numbers issued to the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor by any other State and Federal authority that authorizes the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor to Manufacture, purchase, possess, Repackage, or Distribute and ~~Wholesale Distribute~~ Prescription Drugs;
 - (5) a list of all disciplinary actions by State and Federal agencies against the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor as well as any such actions against principals, owners, directors, or officers;
 - (6) a full description of each facility and/or warehouse, including all locations utilized for Prescription Drug storage and/or Wholesale Distribution. The description should include the following:
 - (i) square footage;
 - (ii) security and alarm system descriptions;
 - (iii) terms of lease or ownership;
 - (iv) address; and
 - (v) temperature and humidity controls.
 - (7) a copy of the deed for the property on which the Manufacturer's, Repackager's, Third-Party Logistics Provider's, or Wholesale Distributor's establishment is located, if the property is owned by the Manufacturer, Repackager, Third-Party Logistic Provider, or Wholesale Distributor, or a copy of the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor's lease for the property on which the establishment is located that has an original term of not less than one (1) calendar year, if the establishment is not owned by the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor;
 - (8) information regarding general and product liability insurance, including copies of relevant policies;
 - (9) a description of the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor's Drug import and export activities; and
 - (10) a copy of the Manufacturer's, Repackager's, Third-Party Logistics Provider's, or Wholesale Distributor's written policies and procedures as required in Section 11 (Policies and Procedures).
 - (11) the information collected pursuant to Section 1(a)(6) and (a)(10) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The Board shall make provisions for protecting the confidentiality of the information collected under this section.
- (b) A "surety" bond of not less than \$100,000, or other equivalent means of security acceptable to the Board or a third party recognized by the Board such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate "surety" bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their Wholesale Distributor license with the Board. The Board may make a claim against such bond or other equivalent means of security until one year after the Third-Party Logistics Provider's or Wholesale Distributor's license ceases to be valid or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board that involves the Third-Party Logistics Provider or Wholesale Distributor is concluded, including any appeal, whichever occurs later.

Manufacturers and Repackagers shall be exempt from securing a “surety” bond or other equivalent means of security acceptable to the Board or a third party recognized by the Board. The Board may waive the bond requirement, if the Third-Party Logistics Provider or Wholesale Distributor:⁴¹

- (1) has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesale distributor possesses a valid license in good standing; or
 - (2) is a publicly held company.
- (c) Every Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor who engages in Manufacturing, Repackaging, or Wholesale Distribution shall submit a reasonable fee to be determined by the Board.
- (d) Each facility that engages in Wholesale Distribution must undergo an inspection by the Board or a third party recognized by the Board, for the purpose of inspecting the Wholesale Distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board but not less than once every three (3) years. Manufacturing and Repackaging facilities are exempt from inspection by the Board if the Manufacturing or Repackaging facilities are currently registered with FDA in accordance with ~~Section 510 of the Federal Law Act.~~⁴²
- (e) All Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the Board.
- (f) Changes in any information in this Section shall be submitted to the Board, or to a third party recognized by the Board, within 30 days of such change (unless otherwise noted).
- (g) Information submitted by the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor to the Board or a third party recognized by the Board that is considered trade secret or proprietary information, as defined under this State’s privacy and trade secret/proprietary statutes, shall be maintained by the Board or a third party recognized by the Board as private or trade secret/proprietary information and be exempt from public disclosure.
- (h) Per federal requirements, states shall license Third-Party Logistics Providers (those that provide storage and logistical operations related to Drug Distribution) separately from Wholesale Drug Distributors. Minimum requirements for Wholesale Drug Distributor licensure may also apply to Third-Party Logistics Providers if applicable⁴³
- (i) Per federal requirements, states shall license Repackagers and Manufacturers separately from Wholesale Drug Distributors. Minimum requirements for Wholesale Drug Distributor licensure may also apply to Repackagers and Manufacturers if applicable.
- (j) Supply chain trading partners (Wholesale Drug Distributors and Third-Party Logistics Providers) should report state licensure status and other required information to FDA.

Section 2. Minimum Qualifications.

⁴¹ Although Wholesale Distributors may be licensed in multiple states, it is not intended for Wholesale Distributors to procure a separate “surety” bond (or other equivalent means) for each state of licensure. States should consider waiving this requirement if the Wholesale Distributor has procured a “surety” bond (or other equivalent means) for the purposes of licensure in another state, or if the wholesaler is a publicly traded company.

⁴² The Board may designate a third party to conduct inspections and ensure that all requirements for licensure established by the legislature and Board are fulfilled. The NABP Verified-Accredited Wholesale Distributors® (VAWD®) program is available to the states.

⁴³ If a State does not have a licensure category for Third-Party Logistics Providers, facilities that engage in interstate transport of Prescription Drugs must obtain federal registration.

- (a) The Board will consider the following factors in determining the eligibility for, and renewal of, licensure of Persons who engage in the Wholesale Distribution of Drugs or Devices:
- (1) any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state for violating any Federal, State, or local laws relating to Drug or Device Wholesale Distribution;
 - (2) any criminal convictions of the applicant under Federal, State, or local laws;
 - (3) the applicant's past experience in the Manufacture or Wholesale Distribution of Drugs or Devices;
 - (4) the furnishing by the applicant of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Wholesale Distribution;
 - (5) Suspension, sanction, or Revocation by federal, State, or local government against any license currently or previously held by the applicant or any of its owners for violations of State or Federal laws regarding Drugs or Devices;
 - (6) compliance with previously granted licenses of any kind;
 - (7) compliance with the requirements to maintain and/or make available to the Board licensing authority or to Federal, State, or local law enforcement officials those records required to be maintained by Wholesale Distributors; and
 - (8) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.
- (b) The Board shall consider the results of a criminal and financial background check of the applicant, including but not limited to, all key personnel involved in the operations of the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor, including the most senior Person responsible for facility operations, purchasing, and inventory control and the Person or Persons they report to; and all company officers, key management, principals, and owners with ten percent (10%) or greater ownership interest in the company (applying to non-publicly held companies only) to determine if an applicant or others associated with the ownership, management, or operations of the Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor have committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state and federal laws, at the applicant's expense, and will be sufficient to include all states of residence since the Person has been an adult. Manufacturers shall be exempt from criminal and financial background checks.
- (c) The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the State and Federal laws regarding Drugs or Devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

Section 3. Personnel.

Each Person that is issued an initial or renewal license as a Wholesale Distributor, whether in state or out of state, must designate in writing on a form required by the Board, a Person for each facility to serve as the Designated Representative of the Wholesale Distributor.

- (a) To be certified as a Designated Representative, a Person must:
- (1) submit an application on a form furnished by the Board and provide information that includes, but is not limited to:

- (i) information required to complete the criminal and financial background checks required under Section 2(b);⁴⁴
 - (ii) date and place of birth;
 - (iii) occupations, positions of employment, and offices held during the past seven (7) years;
 - (iv) principal business and address of any business corporation, or other organization in which each such office of the Person was held or in which each such occupation or position of employment was carried on;
 - (v) whether the Person, during the past seven (7) years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any Federal or State law regulating the possession, control, or Wholesale Distribution of Prescription Drugs or Devices, together with details of such events;
 - (vi) description of any involvement by the Person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which Manufactured, Administered, Prescribed, Wholesale Distributed, or stored Prescription Drugs and Devices in which such businesses were named as a party in a lawsuit;
 - (vii) description of any criminal offense (not including minor traffic violations) of which the Person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the Person pled guilty or nolo contendere. If the Person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the Board a copy of the final written order of disposition;
 - (viii) photograph of the Person taken within the previous 30 days under procedures as specified by the Board;
 - (ix) name, address, occupation, and date and place of birth for each member of the Person's immediate family, unless the Person is employed by a Wholesale Distributor that is a publicly held company. As used in this subparagraph, the term "member of the immediate family" includes the Person's spouse(s), children, parents, siblings, the spouses of the Person's children, and the spouses of the Person's siblings; and
 - (x) any other information the Board deems relevant.
- (2) have a minimum of two years of verifiable full-time managerial or supervisory experience in a Pharmacy or Wholesale Distributor licensed in this State or another state, where the Person's responsibilities included but were not limited to record keeping, storage, and shipment of Prescription Drugs or Devices;
 - (3) may serve as the Designated Representative for only one Wholesale Distributor at any one time, except where more than one licensed Wholesale Distributor is co-located in the same facility and such Wholesale Distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;
 - (4) be actively involved in and aware of the actual daily operations of the Wholesale Distributor:
 - (i) employed full-time in a managerial position by the Wholesale Distributor;

⁴⁴ Fingerprints represent one of the current means of verifying the identity of the person as well as providing a reliable means to conduct criminal background checks. As technology changes and other means become available to the Board such as retinal scanning or DNA sampling, the Board must stay current with such technologies and amend rules as necessary and appropriate.

- (ii) physically present at the Wholesale Distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and
 - (iii) aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the Wholesale Distributor.
- (b) The information collected pursuant to Section 3(a) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The Board and a third party recognized by the Board shall make provisions for protecting the confidentiality of the information collected under this section.
- (c) Each licensed Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor located outside of this State that Wholesale Distributes Prescription Drugs or Devices in this State shall designate a registered agent in this State for service of process. Any licensed Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor growing out of or arising from such Wholesale Distribution. A copy of any such service of process shall be mailed to such Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor has designated on its application for licensure in this State. If any such Manufacturer, Repackager, Third-Party Logistics Provider, or Wholesale Distributor is not licensed in this State, service on the Secretary of State only shall be sufficient service.
- (d) A Designated Representative must complete.⁴⁵
 - (1) continuing education programs specified by the Board regarding Federal and State laws in regard to the Wholesale Distribution, handling, and storage of Prescription Drugs or Devices; or
 - (2) if no formal continuing education is specified by the Board, training programs that address applicable Federal and State laws and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance.

Section 4. Minimum Requirements for the Storage and Handling of Prescription Drugs and for Establishment and Maintenance of Prescription Drug Records.

The following are required for the storage, handling, transport, and shipment of Prescription Drugs or Devices, and for the establishment and maintenance of Wholesale Distribution records by Wholesale Distributors and their officers, agents, representatives, and employees.

- (a) All facilities at which Prescription Drugs and Devices are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:
 - (1) be of suitable construction to ensure that all Prescription Drugs and Devices in the facilities are maintained in accordance with the Product Labeling of such Prescription Drugs and Devices, or in compliance with official compendium standards such as the United State Pharmacopeia–USP-NF;

⁴⁵ The Board will need to ensure that continuing education programs for the desired content areas are available when considering the implementation of this requirement.

- (2) be of suitable size and construction to facilitate cleaning, maintenance, and proper Wholesale Distribution operations;
 - (3) have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (4) have a quarantine area for storage of Prescription Drugs and Devices that are outdated, damaged, deteriorated, Misbranded, or Adulterated, Counterfeit, or suspected of being Counterfeit, otherwise unfit for Distribution or Wholesale Distribution, or that are in immediate or sealed secondary containers that have been opened;
 - (5) be maintained in a clean and orderly condition;
 - (6) be free from infestation of any kind;
 - (7) be a commercial location and not a personal dwelling or residence;
 - (8) provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information;
 - (9) provide and maintain appropriate inventory controls in order to detect and document any theft, Counterfeiting, or diversion of Prescription Drugs or Devices.
- (b) Wholesale Distributors involved in the Wholesale Distribution of controlled substances shall be duly registered with Drug Enforcement Administration (DEA) and appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment, and Wholesale Distribution of controlled substances.

Section 5. Security and Anti-Counterfeiting.

- (a) All facilities used for Wholesale Distribution shall be secure from unauthorized entry:
 - (1) access from outside the premises shall be kept to a minimum and be well-controlled;
 - (2) the outside perimeter of the premises shall be well-lighted; and
 - (3) entry into areas where Prescription Drugs or Devices are held shall be limited to authorized personnel; all facilities shall be equipped with an alarm system to detect entry after hours.
- (b) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (c) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or Counterfeiting.
- (d) All common carriers used by a Wholesale Distributor shall ensure security via one of the following:
 - (1) a verifiable security system; or
 - (2) a Board-approved accreditation or certification program.
- (e) At a date at which such technology is required to be maintained, Wholesale Distributors shall possess and maintain in good working order technology and equipment that allows the Wholesale Distributor to Authenticate, track, and trace Prescription Drugs. The technology and equipment shall satisfy standards set by the Board for such technology and equipment. The technology and equipment shall be used, as required by the Board, to conduct tracking, tracing, and Authentication of Prescription Drugs. Wholesale Distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.⁴⁶

⁴⁶ Standards regarding track-and-trace technologies should be developed using a coalition of experts and regulators. In order to implement an effective track-and-trace system that is consistent throughout the entire distribution system, it is suggested that national standards for such technology and equipment be developed.

- (f) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

Section 6. Storage.

All Prescription Drugs and Devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Product Labeling of such Prescription Drugs and Devices, or with requirements in the current edition of an official compendium such as the USP-NF.

- (a) If no storage requirements are established for a Prescription Drug, the Prescription Drug may be held at “controlled” room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.
- (b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of Prescription Drugs and Devices.
- (c) Packaging of the Prescription Drugs and Devices should be in accordance with an official compendium such as USP-NF and identify any compromise in the integrity of the Prescription Drugs or Devices due to tampering or adverse storage conditions.
- (d) Controlled substance Drugs should be isolated from non-controlled substance Drugs and stored in a secure area in accordance with Drug Enforcement Administration security requirements and standards.
- (e) The record keeping requirements in Section 10 (Record Keeping) shall be followed for the Wholesale Distribution of all Prescription Drugs and Devices.

Section 7. Examination of Materials.

- (a) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, Contraband, Counterfeit, suspected of being Counterfeit or Contraband, or damaged Prescription Drugs or Devices, or Prescription Drugs or Devices that are otherwise unfit for Wholesale Distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, Adulteration, Misbranding, Counterfeiting, Contraband, suspected of being Counterfeit or Contraband, or other damage to the contents.
- (b) The Prescription Drugs or Devices found to be unacceptable under paragraph (a) should be quarantined from the rest of stock until the examination and determination that the Prescription Drugs and Devices are not outdated, damaged, deteriorated, Misbranded, Counterfeited, Contraband, or Adulterated and the determination that they are fit for human use.
- (c) Each outgoing shipment shall be carefully inspected for identity of the Prescription Drugs or Devices and to ensure that there is no Delivery of Prescription Drugs or Devices that have been damaged in storage or held under improper conditions.
- (d) Upon receipt, a Wholesale Distributor must review records for the acquisition of Prescription Drugs or Devices for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the Wholesale Distributors involved.
- (e) The record keeping requirements in Section 10 (Record Keeping) shall be followed for all incoming and outgoing Prescription Drugs and Devices.

Section 8. Returned, Damaged, and Outdated Prescription Drugs.

- (a) Appropriate documentation shall be completed if any Prescription Drug that was ordered in excess of need by the Wholesale Distributor, if identified as such, and which the integrity has been maintained, that is returned to the Manufacturer or Wholesale Distributor from which it was acquired.
- (b) Any Prescription Drug or Device that is outdated, damaged, deteriorated, Misbranded, Counterfeited, Contraband, suspected of being Counterfeited or Contraband, Adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other Prescription Drugs and Devices until it is destroyed or returned to either the Manufacturer or Wholesale Distributor from which it was acquired. When Prescription Drugs and Devices are Adulterated, Counterfeited, Contraband, Misbranded, or suspected of being Adulterated, Counterfeit, Contraband, or Misbranded, notice of the Adulteration, Counterfeiting, Contrabandage, Misbranding, or suspected Adulteration, Counterfeiting, Contrabandage, or Misbranding shall be provided within three (3) business days of that determination to the Board, FDA, and Manufacturer or Wholesale Distributor from which they were acquired. Any Prescription Drug or Device returned to a Manufacturer or Wholesale Distributor shall be kept under proper conditions for storage, handling, transport, shipment, and documentation showing that proper conditions were maintained and shall be provided to the Manufacturer or Wholesale Distributor to which the Prescription Drugs or Devices are returned.
- (c) Any Prescription Drug or Device whose immediate or sealed outer or secondary containers or Product Labeling are Adulterated, Misbranded, Counterfeited, Contraband, or suspect of being Counterfeit or Contraband shall be quarantined and physically separated from other Prescription Drugs or Devices until it is destroyed or returned to either the Manufacturer or Wholesale Distributor from which it was acquired. When the immediate or sealed outer or secondary containers or Product Labeling of any Prescription Drug or Device are Adulterated, Misbranded, Counterfeited, Contraband, or suspect of being Counterfeit or Contraband, notice of the Adulteration, Misbranding, Counterfeiting, Contrabandage, or suspected Counterfeiting or Contrabandage shall be provided within three (3) business days of that determination to the Board, FDA, and Manufacturer or Wholesale Distributor from which it was acquired.
- (d) Any Prescription Drug or Device that has been opened or used, but is not Adulterated, Misbranded, Counterfeited, Contraband, or suspect of being Counterfeit or Contraband, shall be identified as such, and shall be quarantined and physically separated from other Prescription Drugs or Devices until it is destroyed or returned to the Manufacturer or Wholesale Distributor from which acquired.
- (e) If the conditions under which a Prescription Drug or Device has been returned cast doubt on the Prescription Drug's or Device's safety, identity, strength, quality, or purity, then the Prescription Drug or Device shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the Prescription Drug or Device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a Prescription Drug or Device has been returned cast doubt on the Prescription Drug's or Device's safety, identity, strength, quality, or purity, the Wholesale Drug Distributor shall consider, among other things, the conditions under which the Prescription Drug or Device has been held, stored, or shipped before or during its return and the condition of the Prescription Drug and its container, carton, or Product Labeling as a result of storage or shipping.
- (f) Contraband, Counterfeit, or suspected to be Counterfeit or Contraband Drugs and Devices, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the Board and FDA.

- (g) The shipping, immediate, or sealed outer or secondary container or Product Labeling, and accompanying documentation, suspected of or determined to be Counterfeit, Contraband, or otherwise fraudulent shall not be destroyed until its disposition is authorized by the Board and FDA.
- (h) The record keeping requirements in Section 10 (Record Keeping) of this rule shall be followed for all outdated, damaged, deteriorated, Counterfeit, Contraband, Misbranded, or Adulterated Prescription Drugs.

Section 9. Due Diligence.

If a Wholesale Distributor is licensed in accordance with these Rules or provides documentation that the Due Diligence procedures are in place and monitored by the Board or a third party recognized by the Board, then the following Due Diligence requirements may be waived by the Board:

- (a) Prior to the initial Wholesale Distribution or acquisition of Prescription Drugs to or from any Wholesale Distributor (or prior to any Wholesale Distribution to a Wholesale Distributor by a Manufacturer), the Distributing Wholesale Distributor (or Manufacturer) shall provide the following information to the acquiring Wholesale Distributor:
 - (1) a list of states in which the Wholesale Distributor is licensed, and into which it ships Prescription Drugs;
 - (2) copies of all State and Federal regulatory licenses and registrations;
 - (3) the Wholesale Distributor's most recent facility inspection reports;
 - (4) information regarding general and product liability insurance, including copies of relevant policies;
 - (5) a list of other names under which the Wholesale Distributor is doing business, or was formerly known;
 - (6) a list of corporate officers;
 - (7) a list of managerial employees directly involved in the day-to-day operations of Wholesale Distribution;
 - (8) a list of all owners of the Wholesale Distributor that own more than ten percent (10%) of the Wholesale Distributor, unless the Wholesale Distributor is publicly traded;
 - (9) a list of all secured common carriers approved by the Wholesale Distributor;
 - (10) a list of all disciplinary actions by State and Federal agencies;
 - (11) a description, including the address, dimensions, and other relevant information, of each facility or warehouse used for Prescription Drug storage and Wholesale Distribution;
 - (12) a description of Prescription Drug import and export activities of the Wholesale Distributor; and
 - (13) a description of the Wholesale Distributor's policies and procedures to comply with this Act.
- (b) Prior to the initial Wholesale Distribution or acquisition of Prescription Drugs to or from any Wholesale Distributor, the Distributing or acquiring Wholesale Distributor shall:
 - (1) conduct a criminal background check of all of the Wholesale Distributor's personnel, shareholders, and owners involved in operations and management as specified in Section 2 (Minimum Qualifications), and require that all Common Carriers contracted with or utilized by the Wholesale Distributor conduct criminal background checks of the employees whose responsibilities include the handling of Prescription Drugs; or
 - (2) verify that the Wholesale Distributor has been accredited by a third party recognized by the Board.
- (c) If a Wholesale Distributor's facility has not been inspected by the Board or a third party recognized by the Board within three (3) years of the contemplated transaction, any Wholesale

Distributor choosing to do business with that facility shall conduct an inspection of the former Wholesale Distributor's facility prior to the first transaction to ensure compliance with applicable laws and regulations relating to the storage and handling of Prescription Drugs or Devices. A third party may be engaged to conduct the site inspection on behalf of the latter Wholesale Distributor. If the Wholesale Distributor's facility has been inspected by the Board or a third party recognized by the Board, within a three (3) year time period, the inspection report is sufficient to meet the requirements of this subsection.

- (d) At least annually, a Wholesale Distributor that Wholesale Distributes or acquires Prescription Drugs to or from another Wholesale Distributor shall update the information set forth in Section 10 (Record Keeping).
- (e) At least once every three (3) years, a Wholesale Distributor that Wholesale Distributes or acquires Prescription Drugs to or from another Wholesale Distributor shall inspect, or engage a third party to inspect, the premises of the facility or facilities of the Wholesale Distributor to or from whom it is Distributing or acquiring Prescription Drugs. If the Distributing or acquiring Wholesale Distributor's facility has been inspected by the Board or a third party recognized by the Board within the three (3)-year time period, the inspection report is sufficient to meet the requirements of this subsection.
- (f) Wholesale Distributors are exempt from inspecting and obtaining the information from Manufacturers of Prescription Drugs as required in Section 9 (Due Diligence) when the Manufacturer is registered with FDA in accordance with ~~Section 510~~ of the Federal Act.
- (g) Supply chain trading partners (Manufacturers, Repackagers, Wholesale Distributors, and dispensers) shall receive and transfer ~~Product~~ Product Transaction Data History to subsequent purchasers per federal guidelines.
- (h) Supply chain trading partners (Manufacturers, Repackagers, Wholesale Distributors, and Dispensers) shall establish a system to:
 - (1) Quarantine and investigate suspect product to determine if it is illegitimate.
 - (2) Notify FDA, the Board, and immediate trading partners if Illegitimate Product is found.

Section 10. Record Keeping.

- (a) Wholesale Distributors shall establish and maintain inventories and records of all transactions regarding the receipt and Wholesale Distribution or other disposition of Prescription Drugs and Devices. These records shall include:
 - (1) dates of receipt and Wholesale Distribution; or
 - (2) other disposition of the Prescription Drugs and Devices
- (b) Such records shall include the Inventories and records and shall be made available for inspection and photocopying by any authorized official of any State, Federal, or local governmental agency for a period of three (3) years following their creation date.
- (c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of any State or Federal governmental agency charged with enforcement of these rules.
- (d) Wholesale Distributors and Manufacturers should maintain an ongoing list of Persons with whom they do business.
- (e) All facilities shall establish and maintain procedures for reporting Counterfeit and Contraband or suspected Counterfeit and Contraband Drugs or Devices or Counterfeiting and Contraband or suspected Counterfeiting and Contraband activities to the Board and FDA.

- (f) Wholesale Distributors shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any Prescription Drug or Device to the Board and FDA, and, where applicable, to DEA.⁴⁷

Section 11. Policies and Procedures.

Wholesale Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and Wholesale Distribution of Prescription Drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale Distributors shall include in their written policies and procedures the following:⁴⁸

- (a) A procedure to be followed for handling recalls and withdrawals of Prescription Drugs and Devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:
- (1) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy; or
 - (2) Any volunteer action by the Manufacturer to remove defective or potentially defective Prescription Drugs or Devices from the market.
- (b) A procedure to ensure that Wholesale Distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.
- (c) A procedure to ensure that any outdated Prescription Drugs shall be segregated from other Prescription Drugs and either returned to the Manufacturer or destroyed in accordance with Federal and State laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated Prescription Drugs. This documentation shall be maintained for two (2) years after disposition of the outdated Prescription Drugs.
- (d) A procedure for the destruction of outdated Prescription Drugs in accordance with Federal and State laws, including all necessary documentation, maintained for a minimum of three (3) years, and the appropriate witnessing of the destruction of outdated Prescription Drugs in accordance with all applicable Federal and State requirements.
- (e) A procedure for the disposing and destruction of containers, Labels, and packaging to ensure that the containers, Labels, and packaging cannot be used in Counterfeiting activities, including all necessary documentation, maintained for a minimum of three (3) years, and the appropriate witnessing of the destruction of any Labels, packaging, Immediate Containers, or containers in accordance with all applicable Federal and State requirements.
- (f) A procedure for identifying, investigating and reporting significant Prescription Drug inventory discrepancies involving Counterfeit, suspect of being Counterfeit, Contraband, or suspect of being Contraband, in the inventory and reporting of such discrepancies within ten (10) business days to the Board and/or appropriate Federal or State agency upon discovery of such discrepancies.
- (g) A procedure for reporting criminal or suspected criminal activities involving the inventory of Prescription Drug(s) and Device(s) to the Board, FDA, and, if applicable, DEA, within the three (3) business days.

⁴⁷ This information should be reported to NABP, if serving as a data collection repository, in addition to the other relevant authorities.

⁴⁸ In developing policies and procedures for the management and quality improvement of the Wholesale Distribution activities of a Wholesale Distributor, the Board may want to refer to the Healthcare Distribution Management Association and the National Association of Chain Drug Stores.

- (h) A procedure for verifying security provisions of Common Carriers.

Section 12. Prohibited Acts.⁴⁹

It is unlawful for a Person to knowingly and willfully perform or cause the performance of or aid and abet any of the following acts in this State:

- (a) the Manufacture, Repackaging, sale, delivery, or holding or offering for sale any Prescription Drug or Device that is Adulterated, Misbranded, Counterfeit, suspected of being Counterfeit, or has otherwise been rendered unfit for Distribution or Wholesale Distribution;
- (b) the Adulteration, Misbranding, or Counterfeiting of any Prescription Drug or Device;
- (c) the receipt of any Prescription Drug or Device that is Adulterated, Misbranded, stolen, obtained by fraud or deceit, Counterfeit, or suspected of being Counterfeit, or the delivery or proffered delivery of such Prescription Drug or Device for pay or otherwise;
- (d) the Alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the Product Labeling of a Prescription Drug or Device or the commission of any other act with respect to a Prescription Drug or Device that results in the Prescription Drug or Device being Misbranded;
- (e) the forging, Counterfeiting, simulating, or falsely representing of any Prescription Drug or Device without the authority of the Manufacturer, or using any mark, stamp, tag, label, or other identification device without the authorization of the Manufacturer;
- (f) the purchase or receipt of a Prescription Drug or Device from a Person that is not licensed to Wholesale Distribute Prescription Drugs or Devices to that purchaser or recipient;
- (g) the sale or transfer of a Prescription Drug or Device to a Person who is not legally authorized to receive a Prescription Drug or Device;
- (h) the sale or transfer of a Prescription Drug or Device from Pharmacies to Wholesale Distributors for resale;⁵⁰
- (i) the failure to maintain or provide records as required by this Act and Rules;
- (j) providing the Board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act and Rules;
- (k) the Wholesale Distribution of any Prescription Drug or Device that was:
 - (1) purchased by a public or private hospital or other health care entity;
 - (2) donated or supplied at a reduced price to a charitable organization; or
 - (3) stolen or obtained by fraud or deceit.
- (l) the failure to obtain a license or operating without a valid license when a license is required;
- (m) the Obtaining of or attempting to obtain a Prescription Drug or Device by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the Distribution or Wholesale Distribution of a Prescription Drug or Device;
- (n) the Distributing of a Prescription Drug or Device to the patient without a Prescription or Prescription Order from a Practitioner licensed by law to use or prescribe the Prescription Drug or Device;
- (o) the Distributing or Wholesale Distributing of a Prescription Drug or Device that was previously dispensed by a Pharmacy or distributed by a Practitioner;

⁴⁹ Boards should be advised that statutory amendments may be necessary in the State practice acts in order to properly integrate the prohibited and criminal acts. It is highly recommended that boards confer with Board Counsel before adopting the Model Rules to make certain that the appropriate statutory language exists in the state pharmacy practice act to support the Model Rules.

⁵⁰ Returned purchases from Pharmacies to Wholesale Distributors are not considered to be “transfers, Distributions, or sales,” and are not affected by this language.

- (p) the failure to report any Prohibited Act as listed in these Rules; or
- (q) the failure to exercise Due Diligence as provided in Section 9 (Due Diligence) of these regulations.

Section 13. Criminal Acts.⁵¹

- (a) A Person who, with intent to defraud or deceive, performs the act of Adulteration, Misbranding, or Counterfeiting of any Prescription Drug or Device commits a felony of the third degree.
- (b) A Person who engages in the Wholesale Distribution of Prescription Drug(s) who, with intent to defraud or deceive, falsely swears or certifies that he or she has Authenticated any documents related to the Wholesale Distribution of Prescription Drugs, commits a felony of the third degree.
- (c) A Person who engages in the Wholesale Distribution of Prescription Drug(s) or Device(s) and knowingly purchases or receives Prescription Drug(s) or Device(s) from a Person, not legally authorized to Wholesale Distribute Prescription Drug(s) or Device(s), in Wholesale Distribution commits a felony of the third degree.
- (d) A Person who engages in the Wholesale Distribution of Prescription Drug(s) or Device(s) and knowingly sells, barter, brokers, or transfers Prescription Drug(s) or Device(s) to a Person not legally authorized to purchase Prescription Drug(s) or Device(s), under the jurisdiction in which the Person receives the Prescription Drug(s) or Device(s) in a Wholesale Distribution, commits a felony of the third degree.
- (e) A Person who knowingly possesses, actually or constructively, any amount of a Contraband Drug(s) or Device(s), who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of a Contraband Drug(s) or Device(s) commits a felony of the third degree.
- (f) A Person who knowingly forges, Counterfeits, or falsely creates any Label for a Prescription Drug(s) or Device(s) or who falsely represents any factual matter contained in any Label of a Prescription Drug(s) or Device(s) commits a felony of the third degree.
- (g) A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the State, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), commits a felony of the third degree.
- (h) A Person who knowingly Manufactures, purchases, sells, delivers, or brings into the State, or who is knowingly in actual or constructive possession of any amount of Contraband Drug(s) or Device(s), and whose acts result in the death of a Person, commits a felony in the first degree.
- (i) A Person found guilty of any offense under this section, under the authority of the Court convicting and sentencing the Person, shall be ordered to forfeit to the State any real or Personal property:
 - (1) used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and
 - (2) constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense. Any property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other

⁵¹ Boards should be advised that statutory amendments may be necessary in the State practice acts in order to properly integrate the prohibited and criminal acts. It is highly recommended that boards confer with Board Counsel before adopting the Model Rules to make certain that the appropriate statutory language exists in the state pharmacy practice act to support the Model Rules.

assets ordered forfeited, shall be equitably divided between the Board and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the Board or the agencies involved in the investigation and prosecution that led to the conviction.

Section 14. Salvaging and Reprocessing.

Wholesale Distributors shall be subject to the provisions of any applicable Federal, State, or local laws or rules that relate to Prescription Drug product salvaging or reprocessing, ~~including Chapter 21, parts 207, 210, and 211k of the Code of Federal Regulations.~~

Section 15. Inspection and Accreditation by a Third Party.

- (a) The Board shall have the authority to recognize a third party to inspect and accredit Wholesale Distributors and Third-Party Logistics Provider.⁵²
- (b) The Board may license by reciprocity, a Wholesale Distributor and Third-Party Logistics Provider that is licensed under the laws of another state, if:
 - (1) the requirements of that State are deemed by the Board to be substantially equivalent; or
 - (2) the applicant is accredited by a third party recognized by the Board. An applicant that is accredited by a third party recognized and approved by the board, shall not be subject to duplicative requirements set by the Board. If an applicant is inspected, but not accredited by a third party, that applicant must comply with the requirements set by the Board through regulation.
- (c) Any applicant that is denied accreditation described under paragraph (a), shall have the right of review of the accreditation body's decision, by:
 - (1) the accreditation body; and
 - (2) the Board.
- (d) The Board recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.
- (e) The Board may waive requirements of this Chapter, by regulation, for Wholesale Distributors and Third-Party Logistics Providers that have obtained and maintain a Board-approved accreditation.

...

~~Appendix B~~

~~Good Compounding Practices Applicable to State Licensed Pharmacies~~

~~The following Good Compounding Practices (GCPs) are meant to apply only to the Compounding of Drugs by State licensed pharmacies.~~

~~Subpart A. General Provisions and Definitions~~

⁵² Such as VAWD.

The procedures contained herein are considered to be the minimum current Good Compounding Practices for the preparation of Drug products by State licensed Pharmacies for Dispensing and/or Administration to humans or animals. Compounding Pharmacists and Pharmacies shall practice in accordance with these Good Compounding Practices, the Board's Rules for Sterile Pharmaceuticals, and the current United States Pharmacopeia National Formulary (USP-NF) chapters on Compounding and sterile product preparation.

The following definitions from the NABP Model State Pharmacy Act apply to these Good Compounding Practices. States may wish to insert their own definitions to comply with State Pharmacy Practice Acts.

- (a) "Compounding" means the preparation of Components into a Drug product (1) as the result of a Practitioner's Prescription Drug Order based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (2) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding includes the preparation of limited amounts of Drugs or Devices in anticipation of receiving Prescription Drug Orders based on routine, regularly observed prescribing patterns.
- (b) "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.
- (c) "Active Ingredients" refer to chemicals, substances, or other Components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.
- (d) "Added Substances" mean the ingredients necessary to prepare the Drug product but are not intended or expected to cause a human pharmacologic response if administered alone in the amount or concentration contained in a single doses of the Compounded Drug product. The term "added substances" is usually used synonymously with the terms "inactive ingredients," "excipients," and "pharmaceutic ingredients."
- (e) "Component" means any Active Ingredient or Added Substance intended for use in the Compounding of a Drug product, including those that may not appear on the product Label.

Based on the existence of a Pharmacist/patient/Practitioner relationship and the presentation of a valid Prescription Drug Order or Medical Order, Pharmacists may Compound, in reasonable and justified quantities, Drug products that are commercially available in the marketplace when they are different from the FDA approved product and there is a specific, documented medical need for this variation for a particular patient.

Pharmacists shall receive, store, or use Drug substances for Compounding that are Components of FDA-approved drugs and that have been made in an FDA-registered facility. If this requirement cannot be met, Pharmacists shall procure a Certificate of Analysis for each lot purchased. Pharmacists shall also receive, store, or use Drug Components in Compounding prescriptions that meet official compendia requirements.

The Pharmacist shall notify patients if they may be affected by a product found to have a defect or an out-of-specification result.

Compounding includes the preparation of Drugs or Devices in anticipation of receiving Prescription Drug Orders or Medical Orders based on routine, regularly observed prescribing patterns. Pharmacists may Compound Drugs in limited quantities, prior to receiving a valid Prescription Drug Order or Medical Order based on a history of receiving valid Prescription Drug Orders or Medical Orders that have been generated solely within an established Pharmacist/patient/Practitioner relationship, and provided that they maintain the prescriptions on file for all such products Compounded at the Pharmacy (as required by State and Federal law). The Compounding of inordinate amounts of Drugs in anticipation of receiving prescriptions without any historical basis is considered Manufacturing.

~~A Pharmacist may not Compound a Drug that appears on the FDA List of Drugs Withdrawn or Removed from the Market for Safety Reasons or on the FDA List of Drug Products that Present Demonstrable Difficulties in Compounding unless approved by the Board.~~

~~Pharmacists shall not offer Compounded Drug products to other State-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a Practitioner to Administer to an individual patient, in limited quantities. Compounding pharmacies/Pharmacists may advertise or otherwise promote the fact that they provide prescription Compounding services, in accordance with State law, as well as applicable federal laws.~~

~~Pharmacists engaged in the Compounding of Drugs shall operate in conformance with applicable State law regulating the Practice of Pharmacy.~~

Subpart B. Organization and Personnel

~~As in the Dispensing of all prescriptions, the Pharmacist has the responsibility and authority to inspect and approve or reject all Components, Drug product containers, closures, in-process materials, Labeling, and 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 prescription Compounding practice.~~

~~All Pharmacists who participate in the Compounding of Drugs, including other Compounding Pharmacy personnel who assist the Pharmacist in Compounding, shall be proficient in the art 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. Also, all Compounding Pharmacy personnel who participate in Drug Compounding must be aware of and familiar with all details of the Good Compounding Practices.~~

~~Training of Pharmacists and other Compounding Pharmacy personnel (eg, Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates) shall be in the particular operations that are performed by that individual. Training shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that Compounding Pharmacy personnel remain familiar with applicable operations.~~

~~Personnel engaged in the Compounding of Drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as a coat/jacket, apron, or hand or arm coverings, shall be worn as necessary to protect Drug products from contamination. For a sterile Compounding operation involving one or more aseptic manipulations, sterile gowning components are necessary. See the Model Rules for Sterile Pharmaceuticals.~~

~~Only personnel authorized by the responsible Pharmacist shall be in the immediate vicinity of the Drug Compounding operation. Any Person shown at any time (either by medical examination or Pharmacist determination) to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a Drug product being Compounded shall be excluded from direct contact with Components, Drug product containers, closures, in-process materials, and Drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products(s) being Compounded. All personnel who normally assist the Pharmacist in Compounding procedures shall be instructed to report to the Pharmacist any health conditions that may have an adverse effect on Drug products.~~

Subpart C. Drug Compounding Facilities

Pharmacies engaging in Compounding shall have a specifically designated and adequate area (space) for the orderly placement of equipment and materials to be used to Compound medications and to prevent mix-ups or contamination between Components, containers, labels, in-process materials, and finished Drug products. The Drug Compounding area for sterile products shall be separate and distinct from the area used for the Compounding or Dispensing of nonsterile Drug products. The area(s) used for the Compounding of Drugs shall be maintained in a good state of repair and be of suitable construction and location to facilitate cleaning, maintenance, and proper operation. Adequate space and appropriate material flow shall be provided.

Bulk Drugs and other materials used in the Compounding of Drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration as specified on the label.

Adequate lighting, heating, ventilation, and air conditioning shall be provided in all Drug Compounding areas to prevent contamination or decomposition of Components. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any Compounded Drug product. Adequate washing facilities, easily accessible to the Compounding area(s) of the Pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-use towels.

The area(s) used for the Compounding of Drugs shall be maintained in a clean and sanitary condition. Sewage, trash, and other refuse in and from the Pharmacy and immediate Drug Compounding area(s) shall be held and disposed of in a safe, sanitary, and timely manner.

Sterile Products/Radiopharmaceuticals

If sterile (aseptic) products are being Compounded, conditions set forth in the NABP Model Rules for Sterile Pharmaceuticals must be followed.

If radiopharmaceuticals are being Compounded, conditions set forth in the NABP Model Rules for Nuclear/Radiologic Pharmacy must be followed.

Special Precaution Products

The Compounding area should be designed, arranged, used, and maintained to prevent cross-contamination. Equipment and Compounding areas should be thoroughly cleaned promptly after use, and special precautions should be taken to meticulously clean equipment and Compounding areas after Compounding Drug products that contain allergenic Components (eg, sulfonamides or penicillins).

Subpart D. Equipment

Equipment used in the Compounding of Drug products shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. The types and sizes of equipment will depend on the dosage forms and the quantities Compounded. Equipment used in the Compounding of Drug products shall be of suitable composition so that surfaces that contact Components, in-process materials, or Drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the Drug products beyond that which they purport or are represented to possess.

Equipment and utensils used for Compounding shall be cleaned and disinfected immediately prior to use to prevent contamination of the Drug product. In the case of equipment, utensils, and containers/closures used in the Compounding of sterile Drug products, cleaning, sterilization, and maintenance procedures as set forth in the NABP Model Rules for Sterile Pharmaceuticals must be followed.

Previously cleaned equipment and utensils used for Compounding Drugs must be protected from contamination prior to use. Immediately prior to the initiation of Compounding operations, they must be inspected by the Pharmacist and determined to be suitable for use.

Equipment shall be properly maintained to prevent malfunctions that would alter the drug product's safety, identity, strength, quality, or purity. Equipment shall be subject to maintenance and there shall be cleaning schedules and descriptions of the methods, equipment, and materials used in cleaning and maintenance operations. There shall be methods of reassembling equipment to ensure proper cleaning and maintenance.

Automatic, mechanical, or electronic equipment, or other types of equipment or related systems shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance, as per manufacturer instructions.

Subpart E. Control of Components and Drug Product Containers and Closures

Components, Drug product containers, and closures, used in the Compounding of Drugs shall be handled and stored in a manner to prevent contamination. Bagged or boxed Components of Drug product containers and closures used in the Compounding of Drugs shall be stored off the floor in such a manner as to permit cleaning and inspection.

Compounded Drug products should be packaged in containers meeting USP standards. The container used depends on the physical and chemical properties of the Compounded Drug products. Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the Compounded Drug beyond that which it purports or is represented to possess. Container Drug interaction should be considered with substances such as phenolic Compounds and sorptive materials (eg, polypeptides and proteins).

Changes to these procedures shall be reviewed and approved by the appropriate organizational units and by a representative from the Continuous Quality Improvement Program.

Components, Drug product containers, and closures for use in the Compounding of Drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the Compounded Drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the Drug, sterilized and processed to remove pyrogenic properties to ensure that they are suitable for their intended use.

Drug product containers and closures intended for the Compounding of sterile products must be handled, sterilized, stored, etc, in keeping with the NABP Model Rules for Sterile Pharmaceuticals. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for Drug product containers and closures used in the preparation of sterile pharmaceuticals, if these processes are performed by the Pharmacist, or under the Pharmacist's supervision following the NABP Model Rules for Sterile Pharmaceuticals.

Components, Drug product containers, and closures shall not be used for Compounding operations for which they are unsuitable.

Subpart F. Drug Compounding Controls

There shall be written procedures for the Compounding of Drug products to ensure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the Components, their amounts (in weight or volume), the order of Component addition, and a description of the Compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the Drug, shall be listed. These written procedures shall be followed in the execution of the Drug Compounding procedure.

Components for Drug product Compounding shall be accurately weighed, measured, or subdivided as appropriate to ensure that the Compounded Drug product will be formulated with the intent to provide 100% of the Labeled or established amount of active ingredient. The Compounding Pharmacist should:

- (a) ~~check and recheck these operations at each stage of the process to ensure that each weight or measure is correct as stated in the written Compounding procedures;~~
- (b) ~~observe the finished Drug product to ensure that it appears as expected;~~
- (c) ~~record the various compounding steps completed at the time of performance; and~~
- (d) ~~investigate any discrepancies and take appropriate corrective action before the Drug product is dispensed to the patient.~~

If a Component is removed from the original container to another (eg, a powder is taken from the original container, weighed, placed in a container, and stored in another container) the new container shall be identified with the:

- (a) ~~Component name;~~
- (b) ~~weight or measure;~~
- (c) ~~lot number; and~~
- (d) ~~expiration date or Beyond Use Date.~~

To ensure the reasonable uniformity and integrity of Compounded Drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product being Compounded (eg, Compounding of capsules). Such control procedures shall be established to monitor the output and to validate the performance of those Compounding processes that may be responsible for causing variability in the final Drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

- (a) ~~tablet or capsule weight variation;~~
- (b) ~~adequacy of mixing to assure uniformity and homogeneity; or~~
- (c) ~~clarity, completeness, or pH of solutions.~~

Rejected in process and finished materials shall not be used for Compounding operations for which they are unsuitable.

Assurance of sterility in a Compounded sterile Drug product is mandatory. Appropriate written procedures designed to prevent microbiological contamination of Compounded Drug products shall be established and followed. Such procedures shall include validation of any sterilization process.

Subpart G. Continuous Quality Improvement Program

Each Compounding Pharmacy shall implement a Continuous Quality Improvement (CQI) Program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this document. Emphasis on the CQI Program should be placed on maintaining and improving the quality of systems and the provision of patient care. The CQI Program should ensure that any plan aimed at correcting identified problems also includes appropriate follow up to make certain that effective corrective actions are performed. The CQI Program should adhere to the provisions set out in the NABP Model Rules for the Practice of Pharmacy.

A CQI Program shall be documented through written policies and procedures and shall include the following:

- (a) ~~consideration of all aspects of the preparation and dispensing of products as described in the NABP Model Rules for Sterile Pharmaceuticals and the USP Chapter 797 “Pharmaceutical Compounding—Sterile Preparations;”~~
- (b) ~~description of specific monitoring and evaluation activities;~~
- (c) ~~specification of how results are to be reported and evaluated;~~
- (d) ~~collection of complaints, returns, or recalls that are the result of issues concerning the identity, strength, quality, and/or purity of Compounded Drug products;~~
- (e) ~~identification of appropriate follow up mechanisms when action levels or thresholds are exceeded; and~~

~~(f) ——— delineation of the individuals responsible for each aspect of the CQI Program.~~

~~In developing a specific plan, focus should be on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone, provided that Compounding of Drug products with these attributes are appropriate. Proper evaluation of environmental monitoring might include, for example, the trending of an indicator such as settling plate counts.~~

~~The selection of indicators and the effectiveness of the overall CQI Program plan should be reassessed as needed or on an annual basis.~~

Subpart H. Labeling Control of Excess Products

~~In the case where a limited quantity of a Compounded Drug product in excess of that to be initially Dispensed in accordance with Subpart A is prepared, the excess product shall be labeled or documentation referenced with the complete list of Components, the preparation date, and the assigned Beyond Use Date based upon appropriate testing, published data, and/or USP Guidelines. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (eg, in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity.~~

~~At the completion of the Drug finishing operation, the product shall be examined for correct Labeling.~~

Subpart I. Records and Reports

~~Compounding Pharmacies shall maintain a Formulation Record and a Compounding Record.~~

~~Formulation Record— A formulation record lists individually Compounded Drug products, and includes, but is not limited to, the following information:~~

- ~~(a) ——— name, strength, and dosage form of the Drug product Compounded;~~
- ~~(b) ——— all Components and an accurate statement of the weight or measure of each component;~~
- ~~(c) ——— equipment needed to prepare the Drug product, when appropriate;~~
- ~~(d) ——— mixing instructions, including:
 - ~~(1) — mixing temperatures;~~
 - ~~(2) — other environmental controls, such as the duration of mixing;~~~~
- ~~(e) ——— other factors pertinent to the replication of the Drug product as Compounded;~~
- ~~(f) ——— Beyond use Date;~~
- ~~(g) ——— container, closures, and packaging materials used in dispensing;~~
- ~~(h) ——— storage requirements;~~
- ~~(i) ——— Labels and Labeling with appropriate Beyond use Date and instructions for storage and use; and~~
- ~~(j) ——— quality control procedures to include identification of the Person(s) performing and directly supervising or checking each significant step in the Compounding operations.~~

~~Compounding Record— A Compounding record contains:~~

- ~~(a) ——— documentation of the name and strength of the Compounded Drug product;~~
- ~~(b) ——— the formulation record reference for the Drug product;~~
- ~~(c) ——— the sources and lot numbers of the Components;~~
- ~~(d) ——— the total number of dosage units Compounded;~~
- ~~(e) ——— the name of the Person who prepared the Drug product;~~
- ~~(f) ——— the name of the Pharmacist who approved the Drug product;~~
- ~~(g) ——— the name of the Practitioner and the name of the patient who received the Compounded Drug product;~~
- ~~(h) ——— the date of preparation;~~
- ~~(i) ——— the prescription number or assigned internal identification number;~~

- ~~(j) the Dispensing or Distribution records to document who received the Compounded Prescriptions, if different than the Patient; and~~
- ~~(k) the results of quality control procedures (eg, weight range of filled capsules) as described within the pharmacy's CQI Program.~~

~~Records required under these Good Compounding Practices may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.~~

~~Any records required to be maintained in compliance with these Good Compounding Practices shall be retained for the same period of time as each State requires for the retention of prescription files. All records required to be retained under these Good Compounding Practices, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection.~~

Comments

Subpart A. Comment.

~~Boards of Pharmacy should continually monitor compliance with these Good Compounding Practices to distinguish Compounding from Manufacturing, including consideration of the following factors:~~

- ~~(a) Compounded prescription volume;~~
- ~~(b) the existence of a Practitioner/patient/Pharmacist relationship;~~
- ~~(c) use of commercial scale equipment;~~
- ~~(d) availability of the product (commercially available);~~
- ~~(e) whether or not the pharmacy Compounds, in anticipation of receiving Prescription Drug Orders, an inordinate supply of product;~~
- ~~(f) whether the Pharmacy Compounds Drugs for third parties who resell to individual patients; or~~
- ~~(g) any such other indicators as may be necessary to monitor from time to time to determine compliance and distinguish Compounding from Manufacturing, such as Compounding Drugs that were withdrawn or removed from the market for safety reasons, or Compounding finished drugs from bulk active ingredients that are not components of FDA approved Drugs.~~

~~Additionally, Boards of Pharmacy, in extreme situations as defined by the Board, may permit the Compounding of Products contained on the FDA List of Drugs Withdrawn or Removed from the Market for Safety Reasons or on the FDA List of Drug products that Present Demonstrable Difficulties in Compounding. For example, if a determination has been made and documented that other FDA approved Drug Products have not been able to successfully treat the patient, the Pharmacist can Compound a product that appears on the FDA lists only if documentation of, for example, clinical assessments, benefit to risk analysis, etc, can be provided and the Patient and Practitioner are informed and aware of the benefits to risks.~~

Subpart D. Comment.

~~Boards of Pharmacy may consider referencing USP NF Chapter 41 (Weights and Balances), Chapter 1176 (Prescription Balances and Volumetric Apparatus), and equipment manufacturers' instruction manuals.~~

Subpart E. Comment.

~~Boards of Pharmacy may consider referencing USP NF Chapter 661 (Containers) and Chapter 671 (Containers Permeation).~~

Subpart F. Comment.

Boards may consider referencing USP Chapter 797 “Pharmaceutical Compounding—Sterile Preparations” and requiring adherence by all Compounding Pharmacists to the Compounding and packaging of sterile product guidelines found within that chapter. The revised version of USP Chapter 797 went into effect June 1, 2008, after consideration of recommendations received from USP internal expert committees and the professional community.

Boards may consider referencing the following checklist, found in the USP Chapter 795 “Pharmaceutical Compounding—Nonsterile Preparations” and requiring its use by the Compounding Pharmacist to ensure the appropriate strength, quality, and purity of the Compounded product:

- (a) — Have the physical and chemical properties and medicinal, dietary, and pharmacological uses of the Drug products been reviewed?
- (b) — Is the quantity and quality of each Active Ingredient identifiable?
- (c) — Will the Active Ingredients be effectively absorbed, locally or systemically according to the prescribed purpose, from the Drug product and route of Administration?
- (d) — Are there Added Substances (confirmed or potentially present) from manufactured products that may be expected to cause an allergic reaction, irritation, toxicity, or undesirable organoleptic response from the patient? Are there Added Substances (confirmed or potentially present) that may be unfavorable (eg, unsuitable pH or inadequate solubility)?
- (e) — Were all calculations and measurements confirmed to ensure that the Drug product will be Compounded accurately?

Subpart I. Comment.

The objective of documentation is to allow another pharmacist to reproduce the identical prescription at a future date. The formulation record provides a consistent source document for preparing the Drug product (recipe), and the Compounding record documents the actual Components in the Drug product and the person responsible for the Compounding activity.

Normally, the patient’s name and the name of the Practitioner Prescribing the Compounded Drug product are recorded in the Compounding Record at the time of compounding and dispensing. If, however, the Compounded Drug Product is prepared in anticipation of a Prescription Drug Order, a mechanism should be implemented that identifies to whom the previously Compounding Drug Products have been dispensed.

Background:

The committee members reviewed the recommended amendments to the *Model Act* that align with federal requirements outlined in DQSA. The members agreed to add and revise definitions to mirror those in the Drug Supply Chain Security Act (DSCSA), but also recommended deleting “Drop Shipment” from the *Model Act* to stay current. The committee members also reasoned that the facility licensing section should not include a separate licensure requirement for pharmacies that compound sterile pharmaceuticals. However, the committee members also recommended that a comment be added to clarify that some states may have additional licensing requirements.

The members expressed satisfaction with the amendments to the Model Rules for Compounded Pharmaceuticals and the Model Rules for Outsourcing Facilities sections. The members noted that state laws and rules should reference USP General Chapters whenever possible, especially in regard to policies and procedures and quality assurance control programs. The members also recommended that the Patient Education and Training section, as well as the Pharmacist Care

Outcomes section, should be deleted since the material is covered in other sections in the *Model Act*. Furthermore, the members also recommended deleting Appendix B, Good Compounding Practices Applicable to State licensed Pharmacies, and its corresponding Comments section due to being outdated.

For the Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistic Providers, and Wholesale Distributors, the committee members recommended removing or updating definitions associated with the Prescription Drug Marketing Act and replacing them with definitions outlined in DSCSA instead. The committee members were very supportive of the recommended reference to the Verified-Accredited Wholesale Distributors (VAWD) program as a Board designated third party to conduct inspections for initial licensure and/or verification of regulatory compliance. The members further recommended that third party logistics providers should also be included as a separate category for VAWD inspection and accreditation.

LE/L Recommendation 6: The Committee Recommends Removing the Model Inspection Form for Nuclear Pharmacies Located in Appendix A of the *Model Act* and Recommends the Multistate Pharmacy Inspection Blueprint as a Replacement.

Appendix A

Model Inspection Form for Nuclear Pharmacies

I. General Information

Type of Inspection _____

Announced _____ Unannounced _____ Investigational _____

Date: _____ Time Inspection Started: _____

Time Inspection Completed: _____

A. Inspector's Name

Name _____

Position/Title _____

Address _____

City _____ State _____ Zip Code _____

Telephone _____ Ext _____

B. Nuclear Pharmacy

Pharmacy Name _____

Address _____

City _____ State _____ Zip Code _____

Telephone _____ Ext _____

C. Facility Hours

Time Open _____ Time Closed _____

Days Open _____ Total Hours _____

D. Prescription Department Hours

Time Open _____ Time Closed _____

Days Open _____ Total Hours _____

E. Is a nuclear pharmacist present in the facility at all times that the pharmacy is open for business?

Yes _____ No _____

If no, give explanation in the space below:

F. Name of Facility

Facility Name _____

Manager _____

Pharmacy License/Permit Number _____

Expiration Date _____

Renewal of Pharmacy License/Permit Number Current: Yes _____ No _____

Pharmacy License/Permit Number Posted: Yes _____ No _____

G. Facility Staff Information

Pharmacists:

Name	Title or Position	Certificate Number	Certificate Posted (Y or N)	Certificate Renewal Current (Y or N)
1. _____	_____	_____	_____	_____

2.	_____	_____	_____	_____	_____
3.	_____	_____	_____	_____	_____
4.	_____	_____	_____	_____	_____
5.	_____	_____	_____	_____	_____
6.	_____	_____	_____	_____	_____
7.	_____	_____	_____	_____	_____
8.	_____	_____	_____	_____	_____
9.	_____	_____	_____	_____	_____
10.	_____	_____	_____	_____	_____

(Use additional sheets if necessary.)

Have all pharmacists notified the Board of Pharmacy of any changes in mailing address and place of employment?

Yes _____ No _____ If no, give explanation in the space below:

Pharmacists' Education and Training:

Name	Training BPS Board Certified (Yes or No)	Documentation Available (Yes or No)
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____

(Use additional sheets if necessary.)

Qualifications of pharmacists are in accordance with State Board of Pharmacy standards for education and experience in the safe handling and use of radioactive pharmaceuticals and other related materials?

Yes _____ No _____ If no, give explanation in the space below:

**Certified Pharmacy Technicians/Certified Pharmacy Technician
Candidates/Supportive Personnel:**

Name	Title or Position	Certificate	Certificate	Certificate
------	-------------------	-------------	-------------	-------------

		Number	Posted (Y or N)	Renewal Current (Y or N)
1.	_____	_____	_____	_____
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____
7.	_____	_____	_____	_____
8.	_____	_____	_____	_____
9.	_____	_____	_____	_____
10.	_____	_____	_____	_____

(Use additional sheets if necessary.)

Pharmacy Interns:

Name	Registration Number	Registration Renewal Current (Yes or No)	Registration Posted (Yes or No)
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____

(Use additional sheets if necessary.)

Are all pharmacy interns, Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, and/or supportive personnel performing tasks involving radioactive and associated non-radioactive Drugs under the supervision of a licensed pharmacist in accordance with State pharmacy laws?

Yes _____ No _____ If no, give explanation in the space below:

H. Compliance Posture of the Facility and Staff Personnel

1. Are there any current citations or other disciplinary actions against the facility's pharmacy license/permit?

— Yes _____ No _____ If yes, give explanation in the space below:

~~2. Are there any current citations or other disciplinary actions against any existing staff personnel at the facility? Yes _____ No _____ If yes, give explanation in the space below:~~

~~3. If there are any current citations or other disciplinary actions against either the facility or the staff personnel, are the communications regarding these events properly posted (eg, initial complaint letter along with written reply for corrective actions to be taken, etc)? Yes _____ No _____ If no, give explanation in the space below:~~

~~I. Radioactive materials (RAM) license for the facility:~~

~~RAM license: _____~~

~~Date of Issuance: _____ Expiration Date: _____~~

~~If there is no current RAM license for the facility, give explanation in the space below:~~

~~1. Are there any current citations or other disciplinary actions against the facility's RAM license?
— Yes _____ No _____ If yes, give explanation in the space below:~~

~~J. Does the facility store or use any controlled substances?~~

~~— Yes _____ No _____ If no, give explanation in the space below:~~

~~1. If yes, is all necessary documentation and registration available?
— Yes _____ No _____ If no, give explanation in the space below:~~

~~2. If yes, is the DEA permit properly posted?
— Yes _____ No _____ If no, give explanation in the space below:~~

~~3. DEA Permit Number: _____ Permit Renewal Current: Yes _____ No _____
— Permit Expiration Date: _____
— If the permit is not current, give explanation in the space below:~~

~~4. Are authorized signatures and/or power of attorney documentation maintained and appropriate for the current DEA permit, and is this documentation available?
— Yes _____ No _____ If no, give explanation in the space below:~~

~~K. Are facility operational policies and procedures written, maintained, and followed for the purchase/receipt/storage/manipulation/Compounding/ distribution/quality assurance/disposal of radioactive and non-radioactive Drugs?~~

~~— Yes _____ No _____ If no, give explanation in the space below:~~

L. Have any documented events of the following nature taken place since the last inspection?

1. ~~MisAdministration of radioactive or non-radioactive Drugs?~~

~~— Yes _____ No _____ If yes, give explanation in the space below:~~

~~a. — Is documentation available describing corrective actions to be taken to prevent the reoccurrence of these events? Yes _____ No _____ If no, give explanation in the space below:~~

~~b. — Were any of these events reported to the State Board of Pharmacy and/or other appropriate State or Federal agencies? Yes _____ No _____ If no, give explanation in the space below:~~

2. ~~Product mislabeling of radioactive or non-radioactive Drugs?~~

~~— Yes _____ No _____ If yes, give explanation in the space below:~~

3. ~~Lost radioactive or non-radioactive Drugs?~~

~~— Yes _____ No _____ If yes, give explanation in the space below:~~

~~a. — Is documentation available describing corrective actions to be taken to prevent the reoccurrence of these events? Yes _____ No _____ If no, give explanation in the space below:~~

~~b. — Were any of these events reported to the State Board of Pharmacy and/or other appropriate State or Federal agencies? Yes _____ No _____ If no, give explanation in the space below:~~

M. Inspection History

1. ~~Date of last State Board of Pharmacy inspection: _____~~

2. ~~List of non-compliance item(s) noted during last inspection:~~

~~Non-Compliant Item — Corrective Action Taken~~

~~a. _____ a.~~

~~b. _____ b.~~

~~c. _____ c.~~

~~d. _____ d.~~

e. _____ e.

f. _____ f.

g. _____ g.

_____ h. _____ h.

(Use additional sheets if necessary.)

Facility, Equipment, and Instrumentation

For the following sections, the key appearing below can be used as a guide for completing the “Source of Information” category as it appears for each statement. Items that do not apply to the operational perspectives of a given practice site can be indicated as such by writing “Not Applicable” or “N/A” in the space provided for that statement.

IO = Inspector’s Observations

LS = Licensee Statement

RR = Records Review

WI = Worker Interview

A. Facility

	Yes	No	Source of Information	N/A or Comment Number
1. _____ Restricted areas are well defined and physically segregated by barriers from unrestricted areas. _____	=====	=====	=====	=====
2. _____ Access to restricted areas is secure from entry by unauthorized personnel. _____	=====	=====	=====	=====
3. _____ Access to the pharmacy is kept locked at all times when the pharmacist is not available. _____	=====	=====	=====	=====
4. _____ Pharmacy floor plans and layout design comply with all State Board of Pharmacy requirements. _____	=====	=====	=====	=====
5. _____ Shielding is present to prevent radiation exposure in unrestricted areas of the facility. _____	=====	=====	=====	=====
6. _____ Documentation that ventilation systems from fume hoods and biological cabinets are adequate to prevent the accidental release of airborne radioactive _____	=====	=====	=====	=====

	Yes	No	Source of Information	N/A or Comment Number
7. materials inside the facility. Pharmacy library contains current editions (as opposed to "copies") of all reference texts and other documents, as stipulated by State Board of Pharmacy requirements.	=====	=====	=====	=====
a. United States Pharmacopeia National Formulary (with supplements).	=====	=====	=====	=====
b. United States Pharmacopeia Dispensing Information (USPDI)	=====	=====	=====	=====
c. Radiological Health Handbook (or equivalent).	=====	=====	=====	=====
d. State laws and regulations pertaining to Pharmacy practice.	=====	=====	=====	=====
e. State and/or federal laws and regulations pertaining to the safe handling, use, storage, Dispensing, transport, and disposal of radioactive and non-radioactive Drugs.	=====	=====	=====	=====
f. Other reference texts as required by State Pharmacy laws.	=====	=====	=====	=====

Equipment

	Yes	No	Source of Information	N/A or Comment Number
1. Equipment and supplies comply with applicable State and Federal laws/regulations governing the safe handling, use, storage, preparation, Dispensing, distribution, and disposal of radioactive and non-radioactive Drugs. Including but not limited to:	=====	=====	=====	=====
a. Laminar air flow hood and/or biological safety cabinet	=====	=====	=====	=====
b. Fume hood	=====	=====	=====	=====

e. Dose calibrator	=====	=====
d. Analytical balance	=====	=====
e. Lead shielded drawing station	=====	=====
f. Well scintillation counter	=====	=====
g. Assorted glassware	=====	=====
h. Microscope	=====	=====
i. Hemocytometer	=====	=====
j. Chromatographic apparatus	=====	=====
k. Thermometers	=====	=====
l. Refrigerator	=====	=====
m. Radiation monitoring equipment	=====	=====
n. Syringe and vial shields	=====	=====
o. Decontamination supplies	=====	=====
p. Transport containers/boxes	=====	=====
q. DOT shipping labels	=====	=====
r. Other supplies as necessary	=====	=====

B. Instruments

	Yes	No	Source of Information	N/A or Comment Number
1. Instruments (eg, Geiger-Mueller survey meters, area ratemeters, Cutie Pie survey meter, etc) comply with applicable State and Federal regulations governing radioactive and non-radioactive Drugs.	=====	=====	=====	=====
2. Instrument maintenance and repair logs are maintained and documentation is available.	=====	=====	=====	=====
3. Instruments are calibrated at intervals specified in the facility's radioactive materials license.	=====	=====	=====	=====
4. Dose calibrator	=====	=====	=====	=====
 a. Constancy checks are performed in accordance with State and/or Federal regulations and documentation is available.	=====	=====	=====	=====

b. Accuracy checks are performed in accordance with State and/or Federal regulations and documentation is available.	_____	_____	_____	_____
c. Linearity checks are performed in accordance with State and/or Federal regulations and documentation is available.	_____	_____	_____	_____
d. Geometry checks are performed in accordance with State and/or Federal regulations and documentation is available.	_____	_____	_____	_____

Nuclear Pharmacy Procedure

A. Protective Clothing/Safety

	Yes	No	Source of Information	N/A or Comment Number
1. Safety principles and practices are adhered to as described in the facility's policy and procedure manual.	_____	_____	_____	_____
a. Disposable gloves are readily accessible and worn when handling radioactive and/or biohazard material.	_____	_____	_____	_____
b. Lab coats are readily accessible and worn by staff personnel when in restricted areas of the facility.	_____	_____	_____	_____
c. Used needles and other biohazardous materials are disposed of properly.	_____	_____	_____	_____
d. Facility employees have received training on infectious disease prevention. Documentation of such training is available.	_____	_____	_____	_____

e. ~~Dosimetry Badges readily accessible and worn appropriately?~~

~~=====~~ ~~=====~~ ~~=====~~ ~~=====~~

B. Posting and Labeling

	Yes	No	Source of Information	N/A or Comment Number
1. Radiation caution signs are properly used and posted throughout the restricted areas of the facility.	=====	=====	=====	=====
2. Biohazard caution signs are properly used and posted throughout the facility.	=====	=====	=====	=====
3. Appropriate notices to employees are posted.	=====	=====	=====	=====

C. Visitors

	Yes	No	Source of Information	N/A or Comment Number
1. Cleaning and maintenance personnel are escorted when entering and leaving the facility.	=====	=====	=====	=====
2. Custodial and maintenance personnel have been given training as to the proper procedures for entering and leaving the facility, and such training is documented.	=====	=====	=====	=====

D. Receipt of Incoming Shipments of Radioactive and Non-Radioactive Drugs

	Yes	No	Source of Information	N/A or Comment Number
1. Documentation is maintained for the receipt of Drugs (radioactive, non-radioactive, and controlled substances) in accordance with State and Federal	=====	=====	=====	=====

regulations.				
2. Procedures are established for the receipt of Drugs by the facility during times other than normal working hours.	=====	=====	=====	=====
3. Procedures are established for the handling of incoming shipments of radioactive and non-radioactive Drugs that are damaged, or for accidents (eg, spills) that occur while attempting delivery within the facility.	=====	=====	=====	=====
4. Both radioactive and non-radioactive Drugs are stored under appropriate conditions.	=====	=====	=====	=====

E. Traceability and Inventory of Radioactive and Non-radioactive Drugs

	Yes	No	Source of Information	N/A or Comment Number
1. Radioactive and non-radioactive Drugs and/or chemicals can be traced to Manufacturer's lot number.	=====	=====	=====	=====
2. Incoming shipment records for radioactive and non-radioactive Drugs and/or chemicals indicate date of receipt, source or Manufacturer, lot number, amount or quantity, Drug expiration date, calibration (if applicable), and documentation is available.	=====	=====	=====	=====
3. Outgoing shipment records for radioactive and non-radioactive Drugs contain all required information as specified by State pharmacy laws for legend Drugs.	=====	=====	=====	=====
4. Inventory for radioactive and non-radioactive Drugs (including controlled	=====	=====	=====	=====

<p>substances and chemicals) matches physical inventory, and documentation is available.</p> <p>5. Receipt of expired radioactive Drugs and radioactive waste is documented and the records indicate the type, nature, and quantity of item(s), the date of placement into waste storage, the date of removal (disposal) from storage, and the method of disposal, along with other information as specified by State and Federal regulations.</p>	=====	=====	=====	=====
<p>6. Records of Drug destruction and/or return (including shipments to Manufacturers, DEA, etc) are maintained and documentation is available.</p>	=====	=====	=====	=====
<p>7. Outdated and deteriorated Drugs are removed from active inventory.</p>	=====	=====	=====	=====
<p>8. Outdated and deteriorated Drugs are disposed of in accordance with State and Federal regulations.</p>	=====	=====	=====	=====
<p>9. Drug product recalls.</p> <p style="padding-left: 20px;">a. Policies and procedures exist for responding to events involving Drug product recalls.</p> <p style="padding-left: 20px;">b. Events of Drug product recalls and action taken in response thereto is documented and available.</p>	=====	=====	=====	=====

F. Dispensing

	Yes	No	Source of Information	N/A or Comment Number
<p>1. Work area is neat and clean in appearance.</p>	=====	=====	=====	=====
<p>2. Proper aseptic technique is used in the preparation and</p>	=====	=====	=====	=====

Dispensing of all parenteral Drug products.				
a. Adequate space and equipment is available for aseptic preparation and Dispensing of parenteral Drug products.	=====	=====	=====	=====
b. Personnel are adequately trained in aseptic technique and documentation of such training is available.	=====	=====	=====	=====
3. Syringe shields and other appropriate shielding are used during the preparation and Dispensing of radioactive Drugs.	=====	=====	=====	=====
4. Records are maintained for the Compounding, preparation, Dispensing, and distribution of both radioactive and non-radioactive Drugs in accordance with State and Federal regulations.	=====	=====	=====	=====
5. Radioactive and non-radioactive Drugs are dispensed upon a prescription order from a licensed (authorized user) medical Practitioner.	=====	=====	=====	=====
a. Radioactive and non-radioactive Drugs intended only for in vitro or animal research are dispensed to a non medical Practitioner authorized by the Nuclear Regulatory Commission or an agreement State agency, or other regulatory agency, to possess such Drugs, and documentation recognizing such is available.	=====	=====	=====	=====
6. A registered nuclear pharmacy, upon receiving an oral prescription for a radioactive or non radioactive Drug, immediately reduces the prescription to writing in accordance with State pharmacy law.	=====	=====	=====	=====
7. Each radiopharmaceutical dosage is assayed in the dose	=====	=====	=====	=====

~~calibrator and dispensed within ±10% of the prescribed patient dose.~~

~~8. Labeling for radioactive and non-radioactive Drugs is done prior to Dispensing in accordance with State and Federal regulations.~~

~~a. Accuracy of the information content on all product Labeling is verified by the licensed pharmacist on duty prior to Drug Dispensing.~~

~~9. The outer container of each radioactive Drug dispensed has a label which contains the following information:~~

~~a. The standard radiation symbol~~

~~b. The words "Caution—Radioactive"~~

~~c. The radionuclide~~

~~d. The chemical form~~

~~e. The amount of radioactivity~~

~~f. The calibration date and time~~

~~g. The expiration date and time~~

~~h. If a liquid, the volume~~

~~i. If a solid, the number of dosage forms or weight~~

~~j. If a gas, the number of vials or ampules~~

~~k. The Drug prescription or lot number~~

~~l. The name, address, and phone number of the pharmacy~~

~~m. If a Drug is to be used for diagnostic imaging and does not require a patient name, then the words "For Physician Use Only" appear on the prescription label~~

~~(See Section III.G.7. for situations when a patient's name shall appear on the prescription label.)~~

~~10. The immediate inner container of each radioactive Drug dispensed has a label, which contains the following information:~~

~~a. The standard radiation symbol.~~

b. The words “Caution— Radioactive Materials.”	=====	=====	=====	=====
c. The radiopharmaceutical name.	=====	=====	=====	=====
d. The Drug prescription or lot number.	=====	=====	=====	=====
e. The patient’s name if the Drug is intended for therapy; involves a radio-labeled blood cell Component or monoclonal antibody or is investigational in nature.	=====	=====	=====	=====

G. Special Radiopharmaceutical Preparation and Labeling Procedures

	Yes	No	Source of Information	N/A or Comment Number
1. Procedures for the Radio Labeling of red blood cells are performed as stated in the facility’s policy and procedures manual and/or Drug insert.	=====	=====	=====	=====
2. Procedures for the Radio Labeling of white blood cells are performed as stated in the facility’s policy and procedures manual and/or Drug insert.	=====	=====	=====	=====
3. Procedures for the Radio Labeling of platelets (or other blood cell Components) are performed as stated in the facility’s policy and procedures manual and/or Drug insert.	=====	=====	=====	=====
4. Procedures for the Radio Labeling of monoclonal antibodies are performed as stated in the facility’s policy and procedure manual, Drug package insert or investigational new Drug (IND) protocol.	=====	=====	=====	=====
5. Procedures for the Radio Labeling and Dispensing of radiopharmaceuticals for patient therapy are performed as stated in the facility’s policy and procedure manual and/or	=====	=====	=====	=====

<p>Drug package insert.</p> <p>6. Procedures for the Compounding of Drugs labeled with positron-emitting radio-nuclides are performed as stated in the facility's policy and procedure manual.</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>
<p>7. The outer container Labeling for and radioactive Drug involving radio-labeled blood-cell Components, monoclonal antibodies, or whose use is intended for patient therapy, or is investigational in nature (under an IND protocol), shall list the patient's name.</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>

H. Quality Control of Radiopharmaceuticals

	Yes	No	Source of Information	N/A or Comment Number
<p>1. Sterility testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>
<p>2. Pyrogen testing is performed, when appropriate, as stated in the facility's policy and procedure manual or USP-NF, and documentation is available.</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>
<p>3. Breakthrough testing for the presence of the parent radionuclide in a generator eluate (eg, Molybdenum Mo99 from a Mo99/Tc99m generator) is performed, when appropriate, as stated in the facility's policy and procedure manual and/or Drug package insert, and documentation is available.</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>
<p>4. Breakthrough testing for the presence of column packing</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>	<p>=====</p>

material in a generator eluate is performed, when appropriate, as stated in the facility's policy and procedure manual, or Drug package insert and/or USP-NF, and documentation is available.				
5. Radionuclidic purity testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.	=====	=====	=====	=====
6. Radiochemical purity testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.	=====	=====	=====	=====
7. Microscopic inspection is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.	=====	=====	=====	=====
8. pH testing is performed, when appropriate, as stated in the facility's policy, and procedure manual and/or USP-NF, and documentation is available.	=====	=====	=====	=====
9. Other types of quality control testing procedures are performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP-NF, and documentation is available.	=====	=====	=====	=====
a. Chemical purity testing, and documentation is available.	=====	=====	=====	=====
b. Specific activity determinations, and documentation is available.	=====	=====	=====	=====
10. Facility employees have	=====	=====	=====	=====

been properly trained to perform quality control testing procedures and documentation of such training is available.

11. Documentation available that leak testing of all sealed radioactive sources is performed, as stated in the facility's policy and procedure manual, and/or its radioactive materials license.

=====

I. Pharmacy Law

	Yes	No	Source of Information	N/A or Comment Number
1. Phone prescriptions are received only by authorized personnel in accordance with State pharmacy law.	=====	=====	=====	=====
2. Phone prescriptions are immediately reduced to writing and shall record information in accordance with State pharmacy law, including but not limited to:	=====	=====	=====	=====
a. The name of the Practitioner and the institution he or she represents	=====	=====	=====	=====
b. The date of the prescription	=====	=====	=====	=====
c. The name and dose of the radio pharmaceutical or non-radioactive Drug	=====	=====	=====	=====
d. The serial number assigned to the prescription by the Dispensing nuclear pharmacy	=====	=====	=====	=====
e. The patient's name	=====	=====	=====	=====
f. Any specific instructions, if required	=====	=====	=====	=====
3. All prescriptions are reviewed by the pharmacist on duty and are initialed before Dispensing.	=====	=====	=====	=====
4. Prescription orders and Dispensing records for	=====	=====	=====	=====

~~radioactive Drugs contain all information stipulated by State and Federal regulations:~~

- ~~a. Name and address of the pharmacy~~ _____
- ~~b. Drug prescription or lot number~~ _____
- ~~c. Date Drug is dispensed~~ _____
- ~~d. Name and address of the clinic, hospital, or office to which the Drug(s) is dispensed~~ _____
- ~~e. Name of the licensed medical Practitioner authorized to prescribe, receive, and use the Drug(s)[Note: See III.F.5a. pertaining to non medical individuals who may also order, receive, and use the dispensed Drug(s)].~~ _____
- ~~f. The name of the dispensed Drug~~ _____
- ~~g. Prescribed amount and/or activity of the dispensed Drug~~ _____
- ~~h. Drug concentration at the requested time/date of calibration~~ _____
- ~~i. Drug calibration date and time~~ _____
- ~~j. Drug expiration date and time~~ _____
- ~~k. Initials of the Dispensing pharmacist appear on all records pertaining to the Compounding, preparation, and Dispensing of the Drug~~ _____
- ~~5. A copy of the clinic, hospital, or office's current radioactive material license, along with the names of individuals from these locals who can phone or transmit orders to the nuclear pharmacy, are kept on file and such documentation is available.~~ _____
- ~~6. The facility's policy and procedure manual defines the roles and responsibilities of pharmacy interns and supportive personnel with respect to the acquisition,~~ _____

handling, use, preparation, Dispensing, quality assurance testing, distribution, inventory control, and disposal, etc., of radioactive and non-radioactive Drugs.

7. Transfer of Drug products are limited to unopened containers with Manufacturer's instructions attached (except in emergency situations).	=====	=====	=====	=====
8. Copies of any IND protocols, and patient consent forms, etc, for which the pharmacy may prepare and dispense the Drug are maintained on file, and such documentation is available.	=====	=====	=====	=====
a. Copy of the Institutional Review Board approval form (or letter).	=====	=====	=====	=====
b. Copy of the Radiation Safety Committee approval form (or letter).	=====	=====	=====	=====
c. Letter from the Manufacturer (sponsor) indicating that the physician requesting the IND Drug is a qualified investigator.	=====	=====	=====	=====

J. Regulatory (Miscellaneous)

	Yes	No	Source of Information	N/A or Comment Number
1. Documentation for any requests for facility remodeling (if appropriate) from either the city, county, or state is maintained.	=====	=====	=====	=====
2. Drugs and other materials are appropriately segregated and stored within the facility, such as:	=====	=====	=====	=====
a. Radioactive vs non-radioactive Drugs	=====	=====	=====	=====
b. Reagents/germicides/disinfectants vs Drugs.	=====	=====	=====	=====
c. Irrigation and topical solutions	=====	=====	=====	=====

- ~~vs injectable Drugs.~~
- ~~d. Flammable vs nonflammable
Drugs.~~ ~~=====~~ ~~=====~~ ~~=====~~ ~~=====~~
- ~~e. Drugs vs food.~~ ~~=====~~ ~~=====~~ ~~=====~~ ~~=====~~
- ~~f. Drugs vs specimens.~~ ~~=====~~ ~~=====~~ ~~=====~~ ~~=====~~
- ~~g. Controlled substances.~~ ~~=====~~ ~~=====~~ ~~=====~~ ~~=====~~

~~3. DEA Schedule II Drugs are stored in a locked area, and keys are possessed only by authorized staff personnel.~~ ~~=====~~ ~~=====~~ ~~=====~~ ~~=====~~

~~4. Access to current copies of all applicable Department of Transportation (DOT), Nuclear Regulatory Commission (NRC), Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), State Board of Pharmacy, and other local, State, or Federal regulations pertaining to radioactive and non-radioactive Drugs are available.~~ ~~=====~~ ~~=====~~ ~~=====~~ ~~=====~~

~~5. All previous State Board of Pharmacy inspection reports and other related correspondence are available and readily retrievable.~~ ~~=====~~ ~~=====~~ ~~=====~~ ~~=====~~

III. Comments Section

_____ List all comments in the space below, referencing section/item number. Use additional sheets if necessary.

V. Evaluation

_____ Provide in the space below a brief evaluation of the facility's compliance posture and program effectiveness overall. Use additional sheets if necessary.

VI. Follow-up Recommendations

Provide in the space below a brief statement of actions required in order to bring the facility's operation into full compliance. Use additional sheets if necessary.

Signature of Inspector _____

Printed Name of the Inspector _____

Date _____ Time _____

Signature of Pharmacy Manager _____

Printed Name of Pharmacy Manager _____

Date _____ Time _____

Background:

The committee members reviewed the Model Inspection Form for Nuclear Pharmacies currently found in Appendix A of the *Model Act*. The committee members agreed that the form was outdated since the Verified Pharmacy Program (VPP) surveyors use an updated nuclear pharmacy inspection form instead. In the interest of achieving universal inspection forms among state boards and VPP, the committee decided to recommend removing the old nuclear pharmacy inspection form currently available in the *Model Act*.

Members then pondered the possibility of including the Multistate Pharmacy Inspection Blueprint in the *Model Act* for public viewing. The committee agreed that doing so would be in the best interest of the public for the pharmacy community to have full access to such standards. The committee members then also concluded that a link should be established in the *Model Act* after the blueprint that will direct interested individuals to the most current VPP inspection forms. This is particularly important since the VPP inspection forms are continually being updated over time.

Appendix B

Multistate Pharmacy Inspection Blueprint

Section 1.0.0 Practice

1.1.0 Classification*

- Traditional Community
- Mail Order
- Manufacturer
- Compounding
 - Nonsterile Compounding
 - Sterile Compounding
 - Nonsterile HD Compounding
 - Sterile HD Compounding
- Institutional
- Closed Door
 - Long-Term Care
- HMO/PBM only
- Internet Pharmacy
- Telepharmacy
- Central Fill/Processing/Workload Balancing/Shared Services
- Outsourcing Facility
- Wholesale Distributor
- Clinical Trials/Research
 - Medical Marijuana
- Nuclear
- Veterinary
- Specialty
- Specify for any of the classifications above
 - Mail/Deliver (in-state)
 - Mail/Deliver (out of state, please list below)

1.2.0 Other Practices to note

- 1.2.1 Provide products for "Office Use"
 - 1.2.1.1 Patient specific for administration
 - 1.2.1.2 Any non-patient specific for administration
- 1.2.2 Wholesale distribution (less than 5%)

1.3.0 Business Information

- 1.3.1 Business Name
 - 1.3.1.1 DBA
 - 1.3.1.2 Street Address
 - 1.3.1.3 City, State, Zip
 - 1.3.1.4 Telephone Number
 - 1.3.1.5 Toll-free Number

- 1.3.1.6 Fax Number
- 1.3.1.7 Email Address

1.4.0 Website*

- 1.4.1 Operational Website
- 1.4.2 Affiliated Websites

1.5.0 Personnel

- 1.5.1 Pharmacists
 - 1.5.1.1 PIC/Supervising Pharmacist
 - 1.5.1.2 PIC email
 - 1.5.1.3 Nonresident PIC (if applicable)
 - 1.5.1.4 Compounding Pharmacists
 - 1.5.1.5 Total Pharmacists
 - 1.5.1.6 Total Pharmacist Hours Per Week
- 1.5.2 Technicians
 - 1.5.2.1 Technicians in Training
 - 1.5.2.2 Registered/Licensed Technicians
 - 1.5.2.3 Nationally Certified Technicians
 - 1.5.2.4 Compounding Technicians
 - 1.5.2.5 Total Technicians
 - 1.5.2.6 Total Technician Hours Per Week
 - 1.5.2.7 Ratio at time of inspection
- 1.5.3 Interns/Students
 - 1.5.3.1 Total Student Interns
 - 1.5.3.2 Total Graduate Interns
- 1.5.4 Other Personnel
 - 1.5.4.1 Nonsterile Compounding Manager
 - 1.5.4.2 Sterile Compounding Manager
 - 1.5.4.3 Hazardous Compounding Supervisor
 - 1.5.4.4 Total Other Personnel

Section 2.0.0 State and Federal Licensure/Registration Information of State of Residence

2.1.0 Types of Licensure and/or Registration

- 2.1.1 State permits, registrations, and licenses
 - 2.1.1.1 Business Name on License/Registration
 - 2.1.1.2 License/Registration Agency
 - 2.1.1.3 License/Registration Number
 - 2.1.1.4 Expiration Date

- 2.1.1.5 Frequency of renewal (annual/bi/tri)
- 2.1.2 Federal permits, registration, and licenses
 - 2.1.2.1 DEA
 - 2.1.2.1.1 Business Name on License/Registration
 - 2.1.2.1.2 License/Registration Agency
 - 2.1.2.1.3 License/Registration Number
 - 2.1.2.1.4 Expiration Date
 - 2.1.2.1.5 Restrictions/limitations/waivers
 - 2.1.2.2 FDA
 - 2.1.2.2.1 Business Name on License/Registration
 - 2.1.2.2.2 License/Registration Agency
 - 2.1.2.2.3 License/Registration Number
 - 2.1.2.2.4 Expiration Date
 - 2.1.2.3 Other businesses at that address
 - 2.1.2.3.1 Type of business

2.2.0 Inspections

- 2.2.1 State
 - 2.2.1.1 Inspection/Response (dates)
 - 2.2.1.2 Frequency of inspection
 - 2.2.1.3 Warning Letters/Response
 - 2.2.1.4 Consent/Response
- 2.2.2 Federal
 - 2.2.2.1 DEA
 - 2.2.2.1.1 Inspection/Response (dates)
 - 2.2.2.1.2 Frequency
 - 2.2.2.1.3 Warning Letters / Response
 - 2.2.2.1.4 Consent/Response
 - 2.2.2.2 FDA
 - 2.2.2.2.1 483 Inspection/Response (dates)
 - 2.2.2.2.2 Frequency
 - 2.2.2.2.3 Warning Letters/Response
 - 2.2.2.2.4 Consent/Response
- 2.2.3 Other
 - 2.2.3.1 Inspection/Response
 - 2.2.3.2 Warning Letters/Response
 - 2.2.3.3 Consent/Response

2.3.0 Accreditations/Certifications*

- 2.3.1 Pharmacy Accreditations

2.3.2 Pharmacy Accreditations or Certifications that have been rescinded or suspended

Section 3.0.0 Physical Description of Facility

Each Pharmacy shall be of sufficient size, as determined by the Board, to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.

3.1.0 Policies and Procedures

3.1.1 Confirmation of P&Ps in place and readily available

3.2.0 Size

3.2.1 Pharmacy Size

3.2.1.1 Size of dedicated space within the Pharmacy where prescription processing activities occur

3.3.0 Appearance

3.3.1 Cleanliness

3.4.0 Records Storage

3.4.1 On-site storage of required paper records

3.4.2 Off-site storage, if allowed of records

3.4.3 Ready retrieval of electronic records

3.4.4 Record retention length of time

3.5.0 Equipment

3.5.1 Equipment to maintain and monitor temperature and humidity control of environment

3.5.2 Drug storage equipment (eg, refrigerators and freezers and appropriate equipment to monitor storage temperatures)

3.5.3 Necessary reference materials in accordance with scope of practice at pharmacy

3.6.0 Security

3.6.1 Physical Security

3.6.1.1 Entry detection and access

3.6.1.2 Alarm system(s)

3.6.1.3 Controlled substances secured

3.6.2 Pharmacist Responsibility

- 3.6.2.1 Effective control against theft or diversion of Drugs and/or Devices
- 3.6.2.2 Resignation or termination of staff for cause
- 3.6.2.3 Proper reporting to law enforcement for diversion/termination for cause
- 3.6.3 Patient Confidentiality
 - 3.6.3.1 System security
 - 3.6.3.2 Personnel access, monitoring, and revocation
 - 3.6.3.3 Disposal
 - 3.6.3.3.1 Prescription information (PHI)
 - 3.6.3.3.2 Prescription packaging (vials, etc)
 - 3.6.3.3.3 Hazardous waste
 - 3.6.3.3.4 Drugs
- 3.6.4 Systems Backup
 - 3.6.4.1 Facility
 - 3.6.4.2 Prescription processing
- 3.6.5 Equipment
 - 3.6.5.1 General
 - 3.6.5.2 Automated
 - 3.6.5.2.1 Dispensing
 - 3.6.5.2.2 Packaging
 - 3.6.5.3 System Backup

3.7.0 Compounding Area

- 3.7.1 General Condition
 - 3.7.1.1 Cleanliness
 - 3.7.1.2 Risk level
- 3.7.2 Nonsterile
 - 3.7.2.1 Compounding area size
 - 3.7.2.2 Compounding powder hoods number
- 3.7.3 Sterile Compounding
 - 3.7.3.1 Ante Room size
 - 3.7.3.2 Clean/Buffer Room size
 - 3.7.3.3 LAFW hoods/areas
 - 3.7.3.4 Number BSC hoods
 - 3.7.3.5 Number CAI/CACI hoods
- 3.7.4 Nonsterile HD Compounding Area size
 - 3.7.4.1 Designated HD Compounding hoods number (in addition to 3.7.2.2)
- 3.7.5 Sterile HD Compounding

- 3.7.5.1 Negative Pressure
- 3.7.5.2 Sterile HD Room size
- 3.7.5.3 Number of BSC hoods
- 3.7.5.4 Number of CACI hoods

3.8.0 Hours of Operation

3.9.0 Drive-through window

Section 4.0.0 Description of Dispensing and/or Distribution Information

4.1.0 Policies and Procedures

- 4.1.1 Confirmation of P&Ps in place and readily available

4.2.0 Prescription Volume Dispensed (DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription.)

- 4.2.1 Average Prescriptions Dispensed/day/week/month
- 4.2.2 State-specific breakdown

4.3.0 Volume Distributed (DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific – is not labeled with the patient name at the pharmacy.)

- 4.3.1 Average Orders Distributed/day/week/month
- 4.3.2 State-specific breakdown

Section 5.0.0 Prescription Processing

5.1.0 Policies and Procedures

- 5.1.1 Confirmation of P&Ps in place and readily available

5.2.0 Processing at Pharmacy

- 5.2.1 Processes in place to assure the integrity, legitimacy, and authenticity of prescription orders
- 5.2.2 Staff Training
- 5.2.3 Red Flags
- 5.2.4 Procedure to follow when a prescription is suspected of (or actually is) fraudulent
 - 5.2.4.1 Action Steps
 - 5.2.4.2 Reporting
- 5.2.5 Electronic prescription capability and Processing
 - 5.2.5.1 Non-controlled substances
 - 5.2.5.2 Controlled substances

- 5.2.6 Processes in place for ensuring that prescriptions are verified for accuracy prior to dispensing
- 5.2.7 Processes in place to ensure integrity, stability, and purity of prescription medications in transport, if applicable
- 5.2.8 Brand of prescription processing system
- 5.2.9 Veterinary prescriptions
 - 5.2.9.1 Records and labeling include species and name of the animal/owner as required by resident state law.
 - 5.2.9.2 Identification as a veterinary prescription in pharmacy records/system?
- 5.2.10 Labeling of prescriptions
- 5.2.11 Records of dispensing
 - 5.2.11.1 Written and verbal (reduced to writing) prescriptions
 - 5.2.11.2 Electronic prescriptions
 - 5.2.11.3 Dispensing records
 - 5.2.11.4 On-site or readily retrievable for required retention time

5.3.0 Shared Services /Central Fill/Central Processing

- 5.3.1 P&Ps for shared services
- 5.3.2 Appropriate records showing identification of person performing and accountability for each separate process, and appropriate labeling
- 5.3.3 Portions of the prescription processing performed at a different location
 - 5.3.3.1 Prescriptions received by another location (including written, telephone, fax, electronic)
 - 5.3.3.2 Patient information (demographics and contact information) and profile information (allergies, disease states, etc) entered into the computer at another location
 - 5.3.3.3 Prescription information entered into the computer system at another location
 - 5.3.3.4 Accuracy of the prescription information entered into the computer verified at another location
 - 5.3.3.5 Prescriptions dispensed or sold pursuant to shared services agreement
 - 5.3.3.6 DUR process (including assessing and acting on DUR alerts and warnings) performed at another location (prospective review)
- 5.3.4 Ownership/Organization
 - 5.3.4.1 Common ownership
 - 5.3.4.2 Central fill
 - 5.3.4.3 Other agreement

5.4.0 Drug Utilization Review

- 5.4.1 Prospective DUR prior to the dispensing of a medication or product
 - 5.4.1.1 Drug-drug interaction (prescription and OTC)
 - 5.4.1.2 Drug-allergy interaction
 - 5.4.1.3 Therapeutic duplication
 - 5.4.1.4 Under- or over-utilization (including clinical abuse/misuse)
 - 5.4.1.5 Disease state or condition contraindication
 - 5.4.1.6 Incorrect dosage or duration of therapy
 - 5.4.1.7 Gender or age-related contraindications
 - 5.4.1.8 Additional information in the DUR process
 - 5.4.1.9 DUR overrides/bypasses documented (documented via a password/biometric override or by computer logs)
 - 5.4.1.10 Manual or electronic process
 - 5.4.1.10.1 Name of vendor and system

5.5.0 Prescription Monitoring Program

- 5.5.1 Access by pharmacists to the state PMP/PDMP program data for specific patients?
- 5.5.2 Verification of a policy regarding access and follow-up or reporting
- 5.5.3 Pharmacist utilization of the PMP data
- 5.5.4 Required reporting to PMPs by the pharmacy.

5.6.0 Off-site

- 5.6.1 Emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)
- 5.6.2 Maintain any automated prescription dispensing devices outside the pharmacy, such as Pyxis in a nursing home, secure mailbox device patients access after hours, etc
 - 5.6.2.1 Licenses
- 5.6.3 Do emergency kits and automated prescription dispensing devices contain any compounded sterile products?

Section 6.0.0 Patient Care

6.1.0 Policies and Procedures

- 6.1.1 Confirmation of P&Ps in place and readily available

6.2.0 Patient Records and Profile Data

- 6.2.1 Organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver.

6.3.0 Patient Counseling and Communication

- 6.3.1 Pharmacists provide counseling for all new prescriptions/changes in therapy, prescriptions picked up at the pharmacy (proactively, no “offer”)
 - 6.3.1.1 Documentation
- 6.3.2 An ”offer” to counsel is made for all new prescriptions/changes in therapy, prescriptions picked up at the pharmacy
 - 6.3.2.1 Personnel making offer
 - 6.3.2.2 Documentation of offer for counseling
- 6.3.3 Patient counseling provided for delivered prescriptions
- 6.3.4 Patient counseling provided for mailed prescriptions
- 6.3.5 Patient Information
 - 6.3.5.1 PPIs provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)
 - 6.3.5.2 MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)
- 6.3.6 REMS implementation programs performed
 - 6.3.6.1 Programs (such as iPledge for isotretinoin, or Tikosyn)
- 6.3.7 Patient counseling documented
 - 6.3.7.1 Pharmacist notes in the profile of the patient during counseling
 - 6.3.7.2 Refusal of counseling documented
- 6.3.8 Patients have 24-hour access to a pharmacist
- 6.3.9 Process for drug recalls
- 6.3.10 Drug take-back program
 - 6.3.10.1 DEA registration modification for controlled substances take back
- 6.3.11 Private area for patient counseling and providing patient counseling service
- 6.3.12 Face-to-face/remote

6.4.0 Other Patient Services

- 6.4.1 Collaborative Drug Therapy Management, Medication Therapy Management
- 6.4.2 Immunizations
- 6.4.3 Patient lab testing such as blood glucose tests, cholesterol tests, etc?
 - 6.4.3.1 CLIA waiver expiration date
 - 6.4.3.2 Name of lab director listed. Verify that the lab director is current (usually the PIC is the lab director named)
- 6.4.4 Training for additional services
- 6.4.5 P&Ps for other patient services

Section 7.0.0 Product Receipt and Inventory

7.1.0 Policies and Procedures

7.1.1 Confirmation of P&Ps in place and readily available

7.2.0 Pharmacy drug ordering

7.2.1 Received product from authorized trading partners

7.2.1.1 List trading partners

7.2.2 Receive transaction data (transaction history, transaction information, transaction statement)

7.2.3 Verification-suspect and illegitimate product

7.3.0 Controlled Substances (all C-I through C-V)

7.3.1 Records of receipt/invoices

7.3.2 Procurement of C-II controlled substances

7.3.2.1 DEA-222 forms to procure C-II substances

7.3.2.2 CSOS utilization (electronic procurement) to order and receive C-II controlled substances

7.3.2.3 Power of Attorney

7.3.3 Inventories

7.3.3.1 Biennial (or more frequent if required by state)

7.3.3.2 Other required inventories (eg, change of PIC, theft/loss)

7.3.3.3 Perpetual inventory log of all C-II controlled substances (including APIs, if applicable)

7.3.3.3.1 Perpetual inventory log reconciliation

7.4.0 Pseudoephedrine

7.4.1 Record of sales

7.5.0 Other restricted products (such as exempt C-V controlled substances, paraphernalia, dextromethorphan, Plan B, etc)

7.5.1 Record of sales

7.6.0 Outdated, damaged, or recalled products segregated

7.6.1 P&Ps on reverse distribution

7.7.0 Repackage prescription medications

7.7.1 Pre-pack bulk containers of prescription medications

7.3.3.4 Unit-of-use quantities

7.3.3.5 Blister packaging for subsequent dispensing; eg, long-term care system

- 7.3.3.6 Patient compliance packaging
- 7.3.3.7 Other
- 7.7.2 Repackaging record/log
- 7.7.3 Appropriate labeling of repackaged products
- 7.7.4 Repackaging and shipping interstate or intrastate
 - 7.3.3.8 Registered as a repackager with FDA, if applicable
- 7.7.5 Return to Stock P&Ps for dispensed prescriptions not picked up

Section 8.0.0 Compounding

8.1.0 Nonsterile Compounding

- 8.1.1 Policies and Procedures
 - 8.1.1.1 Confirmation of P&Ps in place and readily available
- 8.1.2 USP Chapter <795> and other referenced chapters
- 8.1.3 Veterinary Compounding

8.2.0 Sterile Compounding

- 8.2.1 Policies and Procedures
 - 8.2.1.1 Confirmation of P&Ps in place and readily available
- 8.2.2 USP Chapter <797> and other referenced chapters
- 8.2.3 Veterinary Compounding

8.3.0 Nuclear Compounding

- 8.3.1 Policies and Procedures
 - 8.3.1.1 Confirmation of P&Ps in place and readily available
- 8.3.2 USP Chapters <795> and <797> and other referenced chapters (with nuclear exemptions noted in the chapter)
- 8.3.3 US Nuclear Regulatory Commission portions of CFR Title 10

Section 9.0.0 Quality Assurance/Quality Improvement Program

9.1.0 Documented formalized QA/QI program

- 9.1.1 Oversight of the program
- 9.1.2 Formal performance program and written P&Ps
- 9.1.3 QA data readily retrievable

9.2.0 ORE defined

- 9.2.1 Recording
- 9.2.2 Reporting
 - 9.2.2.1 Internal
 - 9.2.2.2 Outside peer review committee or patient safety organization

9.3.0 Errors

9.3.1 External errors

9.3.1.1 Documented and tracked

9.3.1.2 Reached the patient

9.3.2 Internal errors

9.3.2.1 Documented and tracked

9.3.2.2 Reporting

9.3.3 Root cause analysis implemented

9.4.0 Reporting adverse events to appropriate entities (eg, board of pharmacy, FDA MedWatch, VAERS)

9.4.1 Prescription medications

9.4.2 Compounded products

9.4.3 Vaccinations

9.5.0 Incidents involving malfunctioning or defective medical equipment or devices (glucose meters, DME, injection devices, etc) documented and reported to the manufacturer or distributor

9.6.0 Patient complaints

9.6.1 Documented and tracked

9.7.0 Data

9.7.1 Evaluated

9.7.2 Summary QA/QI

9.7.2.1 Report

9.7.2.2 Shared with staff

9.7.3 Process or policy changes or improvements made based upon other data collected in the QA/QI program

9.7.4 Improvements or changes evaluated for performance as a way to measure the effectiveness of the QA/QI program

Pharmacy Interstate Inspection Blueprint Key

<u>API:</u>	<u>Active pharmaceutical ingredient</u>
<u>BSC:</u>	<u>Biological safety cabinet</u>
<u>CAI:</u>	<u>Compounding Aseptic Isolator</u>
<u>CACI:</u>	<u>Compounding Aseptic Containment Isolator</u>
<u>CLIA:</u>	<u>Clinical Laboratory Improvement Amendment</u>
<u>CSOS:</u>	<u>Controlled Substances Ordering System</u>
<u>DBA:</u>	<u>Doing business as</u>
<u>DEA:</u>	<u>Drug Enforcement Administration</u>
<u>DME:</u>	<u>Durable medical equipment</u>
<u>DMEPOS:</u>	<u>Durable medical equipment, prosthetics, orthotics, and supplies</u>
<u>DUR:</u>	<u>Drug Use Review</u>
<u>EMT:</u>	<u>Emergency medical technician</u>
<u>FDA:</u>	<u>Food and Drug Administration</u>
<u>HD:</u>	<u>Hazardous drug</u>
<u>HMO:</u>	<u>Health maintenance organization</u>
<u>LAFW:</u>	<u>Laminar airflow workbench</u>
<u>NSAID:</u>	<u>Non-steroidal anti-inflammatory drug</u>
<u>OTC:</u>	<u>Over-the-counter</u>
<u>P&P:</u>	<u>Policy and procedure</u>
<u>PBM:</u>	<u>Pharmacy benefits manager</u>
<u>PDMP:</u>	<u>Prescription drug monitoring program</u>
<u>PHI:</u>	<u>Protected health information</u>
<u>PIC:</u>	<u>Pharmacist-in-charge</u>

PMP: Prescription monitoring program

PPI: Patient package insert

QA: Quality assurance

QI: Quality Improvement

QRE: Quality-related event

REMS: Risk evaluation mitigation strategy

USP: United States Pharmacopeia

VAERS: Vaccine Adverse Event Reporting System

VAWD[®]: Verified-Accredited Wholesale Distributors[®]

Vet-VIPPS[®]: Veterinary-Verified Internet Pharmacy Practice Sites[®]

VIPPS[®]: Verified Internet Pharmacy Practice Sites[®]