100 Daingerfield Road, Suite 401
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Alliance for Pharmacy Compounding

VIA EMAIL

August 6, 2021

Dr. Al Carter
Chief Executive Officer
National Association of Boards of Pharmacy
1600 Freehanville Drive
Mount Prospect, IL 60056

Dear Al,

Thank you sincerely for the opportunity to offer input to NABP's Model Act Committee on the pharmacy compounding provisions in the NABP Model Pharmacy Practice Act. We believe the recommendations that follow here – the first of which references the attached mark-up – can serve to enhance the clarity of state law and regulation related to pharmacy compounding and can improve the information available to state boards of pharmacy related to compounding pharmacies and the medications they prepare.

As you may know, the Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as educators, prescribers, researchers, and suppliers. Compounding exists for patients and animals who are not served by traditional pharmaceutical manufacturers. Every day, APC members play a critical, often life-or-death role in patients' lives, creating essential medications unavailable elsewhere for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.

APC appointed a working group to undertake a review of the compounding provisions of the Model Act you shared with us, and it is their recommendations that we're sharing here. That working group was composed of the following APC members:

Chairman: David Rochefort, RPh, Secretary, New Hampshire Board of Pharmacy
Jennifer Bellis, JD, Georgia
Michael Blaire, RPh, former member, Arizona Board of Pharmacy
Anthony Grzib, RPh, New Jersey
Dave Hill, Colorado
Philip Smyth, CPhT, Ohio
Stephen Snow, JD, Georgia

This letter includes three distinct recommendations, as follows:

1. *Suggested changes to the compounding provisions of the Model Act.* These are presented in the form of a marked-up document in Word, attached.

2. *Request for appointment of a joint NABP-APC working group to make recommendations for improved effectiveness and consistency of state-level adverse event reporting related to compounded preparations.* We have taken the liberty of also drafting a resolution to that end, for presentation to the NABP Board of Directors.
3. *Recommendation for greater standardization state-to-state of license application and renewal processes.*

SUGGESTED CHANGES TO THE COMPOUNDING PROVISIONS OF THE MODEL ACT

The attached document contains APC's suggested edits and comments. Of note:

1. Consistent with our original suggestion to NABP that we move to standardize state-level registration of and data-gathering about general activities of 503A compounding pharmacies, we are recommending inclusion under Article V, 502.c, of a series of standard questions that should be a part of each state's pharmacy licensing and renewal process. The purpose of these questions is to provide the state board of pharmacy basic information about pharmacies in the state that are compounding under Section 503A of the Food, Drug & Cosmetic Act and the nature of that compounding. To be clear, we are not recommending additional licensure – only the inclusion of a set of mandatory questions related to compounding operations to be answered upon application and at each subsequent renewal.
2. We are recommending the addition of several definitions related to compounding in the Model Act. Most of our suggested additions address terms that are used in the current Model Act but are not defined. Defining them – just as many other terms are defined in the Model Act – can create greater clarity for both licensees and regulators. We have also made modest effort to clarify, in a few spots, language that to our thinking was unclear.
3. We have eliminated references to 503B outsourcing facilities in the draft Model Act attached here, mainly because states do not regulate 503Bs and the reference to them in the Model Act may only serve to confuse, in our estimation.

JOINT NABP-APC WORKING GROUP ON STATE-LEVEL ADVERSE EVENT REPORTING FRAMEWORK FOR COMPOUNDED PREPARATIONS

APC acknowledges the need and opportunity to strengthen adverse event reporting in pharmacy compounding and would welcome a good-faith collaboration with NABP and state boards of pharmacy to create an effective and consistent framework for adverse event reporting in the states. Candidly, we believe FDA's ongoing assertion that any unexpected patient reaction to a compounded preparation should be treated as reportable adverse event is practically unworkable, both for regulators and for pharmacy compounders. We have recommended, in the attached Model Act mark-up, some new clarifying language related to what qualifies as an adverse event (Article V, 503.a.8), but even that does not speak to the structure of the reporting framework. While we believe creating a better framework is absolutely possible, we also know the task may be more extensive than the charge given to NABP's Model Act Committee. That's why we recommend the appointment of a joint working group to convene, deliberate, and make recommendations no later than Autumn 2022.

RECOMMENDATION FOR GREATER STANDARDIZATION STATE-TO-STATE OF LICENSE APPLICATION AND RENEWAL PROCESSES

We continue to hear concerns from our members about the great patchwork that is the pharmacy licensing and renewal process across the country. It is a system beset not only by widely varying requirements and forms state to state but often by inexplicable processing delays. While we understand

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that processing delays my well be beyond NABP's purview, we do want to request that NABP consider pursuing a project to both streamline and standardize the pharmacy licensing application and renewal process across the states. We also understand that states cannot be compelled to participate in such a system, but the very fact of its creation could lead many states to reexamine their processes and – perhaps – opt-in to a standardized process. Clearly, this recommendation is much broader than pharmacy compounding, and we would expect action on it to include engagement with numerous other pharmacy groups.

In closing, thank you again for the opportunity to comment, and for your consideration of our recommendations. Please contact me at scott@a4pc.org if your Model Act Committee has questions or would like APC's working group to present and discuss these recommendations directly.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer

C: APC Board of Directors
Melissa Madigan, NABP

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Alliance for Pharmacy Compounding

DRAFT RESOLUTION FOR NABP BOARD CONSIDERATION

Whereas, pharmacy compounding comprises a significant portion of licensed activity regulated by state boards of pharmacy; and

Whereas, in the interests of the consumers they serve, state boards of pharmacy have an obligation to implement and maintain an effective system of patient reporting of adverse events related to compounded medications; and

Whereas, adverse event reporting frameworks related to compounded medications vary in rigor and effectiveness among states; and

Whereas, among the challenges of adverse event reporting framework related to compounded medications is the absence of a standard, consistent definition of "adverse event" across the states; and

Whereas, patients who experience legitimate adverse events related to a compounded medication – and the compounding pharmacy that prepared that medication – would benefit from a standard reporting framework that is simple, timely, and effective; and

Whereas, the Alliance for Pharmacy Compounding – the pharmacy compounding trade association – recognizes the need and opportunity to strengthen adverse event reporting in pharmacy compounding and has proposed a good-faith collaboration with NABP and state boards of pharmacy to create an effective and consistent framework for adverse event reporting in the states.

Be it therefore resolved that the National Association of Board of Pharmacy supports joining with the Alliance for Pharmacy Compounding to form a joint committee to convene, deliberate, and make recommendations on this important issue no later than Autumn 2022.

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, limited Distribution, and/or implementation of Medical Orders, and the initiation and provision of Pharmacist Care Services. The Practice of Pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training. [1]

Section 105. Definitions.

1. "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.
2. "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 dose of the Compounded Drug Product or alter the composition and effectiveness of the Compounded Drug Product. The term "added substances" is used synonymously with the terms "inactive ingredients," "excipients," "flavoring agents," and "pharmaceutic ingredients."

…

3. "Administer" means the direct application of a Drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

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

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

4. "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.[2]
5. "Bioburden" means the total number of microorganisms associated with a specific item prior to sterilization.

…

6. "Component" means any Active Ingredient or Added Substance intended for use in the Compounding of a Drug, including those that may not appear in such Drug.
7. "Compounding" means the preparation, mixing, assembling, altering, packaging, or Labeling of a Drug, Drug-Delivery Device, or Device, in accordance with a licensed Practitioner's prescription, medication order, or initiative based on the Practitioner/patient/Pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:
    a. preparation of Drug dosage forms for both human and animal patients;
    b. preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns; and
    c. manipulation of commercial Products for patient-specific needs beyond FDA-approved Labeling.[4]

…

8. "Critical Areas" means areas designed to maintain sterility of sterile materials. Sterilized Product, container/closures, and equipment may be exposed in critical areas.

9. "Critical Surfaces" are surfaces that may come into contact with or directly impact sterilized Product or containers/closures.

10. "Cytotoxic" means a pharmaceutical that is identified in Appendix A of the National Institute For Occupational Safety And Health Alert, Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, Publication Number 2016-161.

11. "Disinfection" means the process by which surface Bioburden is reduced to a safe level or eliminated.

12. "Dispense" 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.

13. "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:
    a. To Dispense or Administer;

Deleted: unless performed in a Food and Drug Administration (FDA)-registered Outsourcing Facility in conformance with Federal law, …

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

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

b. Delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier; or

c. 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.

…

14. "Drug" means:
    a. 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;[5]
    b. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
    c. articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and
    d. articles used as a Component of any articles specified in clause (a), (b), or (c) of this definition.
15. "Home Infusion Pharmacy" means a Pharmacy that Compounds solutions for direct Administration to a patient in a private residence, Long-Term Care Facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

…

16. "ISO Class" means the description of an atmospheric environment characterized by the number of particles within a diameter per cubic foot of air.

17. "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).

…

18. "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.

…

19. "Sterile Pharmaceutical" means any dosage form of a drug, including but not limited to, parenterals (e.g., injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.

20. "Significant Adverse Drug Reaction" means an unexpected adverse drug experience that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. A medical event may also be

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

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Commented [JB1]: We revised this definition because, as originally written, "Added Substances" – including inactive ignredients, additives, and coloring—would be included within the definition of "Drug." (Specifically, the definition of "Components" includes "Added Substances.") We agree that Added Substances, once they are used as Components of (a), (b), or (c), should be included within the definition of "Drug." As written, however, a food coloring sitting on the shelf that is intended to be used in a finished compounded product—but which has not yet been used in the compounding of that product--would fit with the definition of "Drug."

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considered a significant adverse drug reaction when, based on appropriate medical judgment, the medical event places the patient at a significant risk of experiencing any of the outcomes listed above. An adverse drug reaction is unexpected if it has not previously been observed, rather than a reaction that is not anticipated from the pharmacological properties of the pharmaceutical product.

21. "USP Standards" means standards published in the current official United States Pharmacopeia or National Formulary.

Article V
Licensing of Facilities

Introductory Comment to Article V

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

Section 501. Licensing.

(a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board:[6]

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

(2) dispensing Practitioners and Practitioner's facilities including those engaged in nonsterile[7] Compounding;[8]

(3) persons engaged in the Manufacture or Repackaging of Drugs or Devices;

(4) persons engaged in the Wholesale Distribution of Drugs or Devices;

(5) persons engaged in Third-Party Logistics Provider activities of Drugs or Devices;

(6) pharmacies where Drugs or Devices are Dispensed, or Compounded, or Pharmacist Care Services are provided;

(7) Outsourcing Facilities;

(8) Pharmacy Benefits Managers; and

(9) Repository Programs

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

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

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

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

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

out the Board's responsibilities. The Board may issue licenses with varying restrictions to such Persons where the Board deems it necessary.[9]

(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, Dispenses, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in this State, or Pharmacy located outside of this State who ships, mails, Dispenses, Distributes, or Delivers Drugs or Devices in this State, shall comply with the laws of patients' domicile, and shall designate a registered agent in this state for service of process. Any such licensed Person or Pharmacy who does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such licensed Person growing out of or arising from such shipping, mailing, Dispensing, Distribution, Wholesale Distribution, or Delivery of Drugs or Devices. A copy of any such service of process shall be mailed to such Person or Pharmacy by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Person has designated on its application for licensure in this State. If any such Person is not licensed in this State, service on the Secretary of State only shall be sufficient service.[10]

(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 inspection shall be required prior to initial licensure or upon initiation of sterile Compounding activity. Thereafter, an annual inspection shall be required for licensure renewal. For facilities that do not Compound Sterile Pharmaceuticals, an initial inspection, and thereafter an inspection that takes place not less than every 24 months, shall be required for purposes of licensure or licensure renewal[11]. Such inspection shall be performed by the following:

(1) the Board or its duly authorized agent;

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[9] 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.

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

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

(2) a duly authorized agent of a third party approved by the Board, such as the NABP Verified Pharmacy Program (VPP) (see Appendix A for the Multistate Pharmacy Inspection Blueprint); or
(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.

(j) The Board may consider exempting facilities engaged solely in the Distribution of dialysate, Drugs, or Devices necessary to perform home renal dialysis to patients with chronic kidney failure from pharmacy licensure, provided that the following criteria are met:
(1) The dialysate, Drugs, or Devices are approved by Food and Drug Administration, as required by federal law.
(2) The dialysate, Drugs, or Devices are lawfully held by a manufacturer (or a manufacturer's agent) that is properly registered with the Board as a Manufacturer and/or Wholesale Drug Distributor
(3) The dialysate, Drugs, or Devices are held and delivered in their original, sealed labeled packaging from the Manufacturing facility.
(4) The dialysate, Drugs, or Devices are delivered only by the Manufacturer (or the Manufacturer's agent) and only upon receipt of a physician's order.
(5) The Manufacturer (or Manufacturer's agent) delivers the dialysate, Drugs, or Devices directly to:
(i) a patient with chronic kidney failure, or his/her designee, for the patient's self-administration of dialysis therapy, or
(ii) a health care provider or institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.
(6) Records of all sales and Distribution of dialysate, Drugs, or Devices to home dialysis patients must be retained and readily available for inspection and copying by the Board for _____ years.

Section 502. Application.[12]

[12] Boards may want to consider requesting the following information on applications for Pharmacy and Wholesale Distributor licensure:
(a) personal information;
(b) marital information;
(c) family information (parents, siblings, in-laws);
(d) education;
(e) military information;
(f) arrests, detentions, litigations, and arbitrations;
(g) residences (past 25 years);
(h) employment (back to age 18);
(i) character references;
(j) safe deposit box or other depository information;
(k) privileged, occupational, or professional licensure;
(l) out-of-state business, venture, or industry licensure or financial interest in such;
(m) appearances before any licensing agency or similar authority in or outside the state;

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

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

(c) The Board of Pharmacy shall require all applicants for initial and renewal licensure to Dispense, Distribute, Wholesale Distribute, Manufacture, sell, purchase, transfer, and/or produce Drugs or Devices to state whether they engage or intend to engage in Compounding as defined in this Act. Applicants who engage or intend to engage in Compounding shall submit concurrently with their application for licensure responses to a questionnaire regarding the applicant's Compounding operations.[13]

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

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

(f) 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

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(n) denials of a personal license, permit, certificate, or registration for a privileged, occupational, or professional activity;

(o) denials of a business or industry license or related finding of suitability, or participation in a group that has been denied a business or industry license or related finding of suitability;

(p) Administrative actions or proceedings related to the pharmaceutical industry or participation in a group that has been the subject of such administrative actions or proceedings;

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

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

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

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

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.

Section 503. Notifications.

(a) All licensed Persons shall report to the Board of Pharmacy the occurrence of any of the following:

(1) permanent closing;

(2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;

(3) any significant theft or loss of Drugs or Devices;

(4) any conviction of any employee of any State or Federal Drug laws;

(5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;

(6) disasters, or any theft, destruction, or loss of records required to be maintained by State or Federal law;

(8) Significant Adverse Drug Reaction associated with Compounded Drugs;

(9) recalls of Compounded Drugs;

(10) recalls of sterile Repackaged Drugs;

(11) illegal use or disclosure of Protected Health Information; or

(12) any and all other matters and occurrences as the Board may require by rule.

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

(c) All licensed Persons shall report to the Board of Pharmacy, or its authorized agent, the occurrence of any Pharmacy or Pharmacy-related inspection conducted by any agency of the Person's home state, or authorized agent thereof, and shall provide a copy of the report of such inspection, including applicable documents relating to corrective actions.

Section 504. Grounds, Penalties, and Reinstatement.

Commented [JB2]: We suggest that 503(a)(2) be revised to be consistent with the language used by the Drug Enforcement Agency. (See 21 CFR §1301.76(b))

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;

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

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

(c) The Board may Suspend, Revoke, deny, or refuse to renew the license of any Person, Manufacturer, Repackager, Third-Party Logistics Provider, Wholesale Distributor, Pharmacy, or Pharmacy Benefits Manager on any of the following grounds:[15]

(1) the finding by the Board of violations of any Federal, State, or local laws relating to the Practice of Pharmacy, Drug samples, Wholesale or retail Drug or Device Distribution, or Distribution of controlled substances;
(2) any felony convictions under Federal, State, or local laws;
(3) the furnishing of false or fraudulent material in any application made in connection with Drug or Device Manufacturing or Distribution;
(4) suspension or Revocation by Federal, State, or local government of any license currently or previously held by the applicant for the Manufacture or Distribution of any Drugs or Devices, including controlled substances;
(5) willfully and knowingly submitting false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of Drugs from Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors.
(6) obtaining any remuneration by fraud, misrepresentation, or deception;
(7) affiliating with websites that may deceive or defraud patients or that violate Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;
(8) dealing with Drugs or Devices that he or she knows or should have known are Counterfeit, Contraband, or stolen Drugs or Devices;[16]
(9) purchasing or receiving of a Drug or Device from a source other than a Person or pharmacy licensed under the laws of the State, except where otherwise provided;
(10) the transfer during any consecutive twelve (12)-month period by a Pharmacy to a Wholesale Distributor or to another Pharmacy of more than five percent (5%) of the total amount of Prescription Drugs or Devices purchased by the Pharmacy in the

[15] The Prescription Drug Marketing Act of 1987 (PDMA) requires that the state licensing laws provide for the Suspension or Revocation of licenses upon conviction for violation of Federal, State, or local Drug laws or rules pertaining to the unlawful Distribution of Drugs at wholesale. The PDMA defines fines, imprisonment, or civil penalties.

[16] This section restricts Distribution of Drugs or Devices to licensed entities to help ensure against clandestine Distribution to unauthorized and unlicensed Persons.

immediately preceding twelve (12)-month period. The following are not subject to the provisions of this subsection:

(i) Prescription Drugs or Devices that are Returned by a pharmacy for credit, in an amount equal to or less than the actual purchase price, to the Wholesale Distributor or Manufacturer from which those Products were purchased;

(ii) Intracompany sales;

(iii) The sale, purchase, or trade of a Drug or an offer to sell, purchase, or trade a Drug among hospitals or other health care entities that are under common control;

(iv) The sale, purchase, or trade of a Drug or the offer to sell, purchase, or trade a Drug 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;

(v) 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 Drug for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations; and

(vi) The transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing or Filling agreement.

(11) the transfer during any consecutive twelve (12)-month period by a Wholesale Distributor to a Wholesale Distributor of more than five percent (5%) of the total amount of prescription Drugs or Devices purchased by Wholesale Distributor in the immediately preceding twelve (12)-month period;

(12) Wholesale Drug Distributors other than pharmacies Dispensing or Distributing Drugs or Devices directly to patients;

(13) violations of any of the provisions of this Act or of any of the Rules adopted by the Board under this Act; or

(14) illegal use or disclosure of Protected Health Information.

(d) Reinstatement of a license that has been Suspended, Revoked, or restricted by the Board may be granted in accordance with the procedures specified by Section 401 of this Act.

Section 505. Criminal Offense; Forfeiture of Property.

(a) Violation of any of the provisions of Article V of this Act by any person engaged in the Wholesale Distribution of Drugs and Devices shall constitute a Class three felony, provided that any such violation that results in the death of a Person shall constitute a Class one felony.

(b) A Person engaged in the Wholesale Distribution of Drugs and Devices convicted by a criminal court of this State of violating any of the provisions of Article V may be ordered by the court 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; or

(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 the defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other 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 the 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.

Model Rules for the Practice of Pharmacy

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care Services, the following rules are essential.

Section 1. Facility.

(a) To obtain a license for a Pharmacy, an applicant shall:
  (1) have submitted an application in the form prescribed by the Board of Pharmacy;
  (2) have attained the age of majority; and
  (3) have paid the fees specified by the Board of Pharmacy for the issuance of the license.

(b) The facility owner, if an individual, shall have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;

(c) The facility shall have undergone a Pharmacy inspection by the Board or authorized agent thereof; and

(d) Possess the following minimum requirements for a Pharmacy:
  (1) 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.
  (2) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.
  (3) Each Pharmacy shall have ready access to references, to include at least one current reference[17] in each of the following categories, if applicable to the services provided:
    (i) State and Federal Drug laws relating to the Practice of Pharmacy and the legal Distribution of Drugs and any rules or regulations adopted pursuant thereto;
    (ii) pharmacology;
    (iii) dosage and toxicology;
    (iv) veterinary Drugs[18]; and
    (v) general.
  (4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.[19]
  (5) Each Person involved in the development, maintenance, or use of a Drug formulary shall maintain a currently accepted reference containing guidelines for a sound Drug formulary system.
  (6) All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as

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Deleted: in each of the following

[17] Boards may wish to give examples in each of these categories of reference texts.

[18] Such as Plumb's Veterinary Drug Handbook.

[19] Patient-oriented reference material can include publications such as Facts and Comparisons' Patient Drug Facts, or the United States Pharmacopoeia Dispensing Information (USPDI).

stipulated by the United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.

(7) Each Pharmacy shall have access to a sink with hot and cold running water that is convenient to the Compounding area for the purpose of hand scrubs prior to Compounding.

(8) Equipment/Supplies.
The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.

(9) The Pharmacy shall provide a means for patients to prevent disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the Delivery of Pharmacist Care Services other than as authorized by law or rules of the Board.

(10) The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board.

(e) Upon renewal, the licensee shall provide to the Board the NABP e-Profile ID of the Pharmacy and the Pharmacist-in-Charge.

…

Model Rules for Compounded or Repackaged Pharmaceuticals

Section 1. Purpose and Scope.

The purpose of this section is to ensure Compounded Pharmaceuticals are prepared and Dispensed according to practice and quality standards through the provision of: (1) Pharmacist Care Services; and (2) the preparation, Labeling, and Distribution of Compounded or Repackaged Pharmaceuticals by Pharmacies. These standards are intended to apply to all Sterile and nonsterile Compounded Pharmaceuticals, notwithstanding the location of the patient (eg, home, hospital, nursing home, hospice, doctor's office). All facilities and Practitioners engaging in Sterile and nonsterile Compounding or Repackaging shall practice in accordance with Federal law, these Rules, and the current United States Pharmacopeia–National Formulary (USP-NF), including but not limited to General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations,* General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations,* General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*, and other applicable referenced general chapters. The procedures contained herein are considered to be the minimum current good compounding practices for the Compounding of Drug Products by State-licensed Pharmacies for Dispensing and/or Administration to humans or animals.[20]

Section 2. Notification.

(a) On an annual basis, and within 90 days of the beginning of the calendar year, all licensed Persons shall report to the NABP Information Sharing Network the information required by the "MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION."

(b) Upon request from the Board, all licensed Persons shall report to the Board of Pharmacy the number of Compounded Prescription Drug Orders Dispensed in the State where the Pharmacy is located and out of the State where the Pharmacy is located during a specified time period, including the Drugs' Active Ingredients, strength, and dosage form(s).

(c) The Pharmacist shall notify patients if they may have received a Product found to have a defect or an out-of-specification result and conduct a recall, if the Board deems necessary.

Section 3. Policy and Procedure Manual.

A policy and procedure manual shall be prepared and maintained for the Compounding, Dispensing, Delivery, Administration, storage, and use of Sterile and nonsterile Compounded Prescription Drugs. The policy and procedure manual shall incorporate all applicable USP requirements and:

(a) include a quality assurance program for the purpose of monitoring patient care and Pharmacist Care Services outcomes; and

(b) be current and available for inspection by a Board of Pharmacy-designated agent.

Section 4. Physical Requirements.

(a) Any Pharmacy that engages in Compounding shall adhere to physical, equipment, and environmental requirements established by USP.

Commented [JB4]: We suggest additional consideration regarding whether to codify these USP chapters. We do not intend to argue against states requiring pharmacies to adhere to USP; our concern is whether incorporating the chapters by reference as they are written is the best practice for drafting legislation. The USP chapters were not drafted to be used as legislation. Accordingly, they contain language that is not necessarily appropriate or reflective of the Board's intent. For example, USP uses "should" or other permissive language rather than "shall" in instances where the Board might wish to make a requirement mandatory. In such cases, "shall" would be appropriate.

Commented [JB5]: We suggest this footnote be deleted for two reasons. First, AMDUCA is already binding federal law. Second, the FDA's Guidance For Industry is not binding on either pharmacies, manufacturers, outsourcing facilities or the agency, but this footnote would make the Guidance binding under state law. There is also potential for ambiguity; for example, does this apply to draft Guidance as well as final Guidance?

Deleted: [20] The Compounding of Drugs for animals must be done in accordance with the algorithm contained in the Animal Medicinal Drug Use Clarification Act of 1994 and associated FDA Guidance.

(b) Pharmacies shall have sufficient current reference materials applicable to Compounding.

Section 5. Records and Reports.

In addition to standard record-keeping and reporting requirements, the following records shall be maintained:

(a) All Dispensing of sterile Compounded and nonsterile Compounded preparations.
(b) Any other records required to conform to and demonstrate compliance with USP standards and Federal law.

Section 6. Delivery Service.

The Pharmacist-in-Charge shall ensure the environmental control, stability, and sterility (if applicable) of all preparations shipped. Therefore, any Compounded preparation 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 Hazardous and/or Infectious Wastes.

The Pharmacist-in-Charge is responsible for ensuring that there is a system for the disposal of hazardous and/or infectious waste in accordance with applicable State and Federal laws and USP requirements.

Section 8. Quality Assurance.

(a) There shall be a documented, ongoing quality assurance program that monitors personnel performance, Component Verification and usage, Disinfection, sterilization, equipment, and facilities that are appropriate for the Drug being prepared. Quality assurance programs shall at minimum conform to the requirements of USP.
(b) The Pharmacist has the responsibility and authority to inspect and approve or reject all Components, Drug Product containers, closures, in-process materials, and/or Labeling. The Pharmacist shall have the authority to prepare and review all Compounding records to ensure that no errors have occurred in the Compounding process. If errors have occurred, the Pharmacist is responsible for conducting a full investigation. A written record of the investigation shall be made and shall include conclusions and follow-up. The Pharmacist is also responsible for the proper maintenance, cleanliness, and use of all facilities and equipment used in Compounding.
(c) All Pharmacists who participate in Compounding, including other Pharmacy personnel who assist the Pharmacist in Compounding, shall be proficient in the science of Compounding and shall acquire the education, training, and/or experience to maintain that proficiency through participation in seminars, studying appropriate literature, and consulting colleagues or by becoming certified by a Compounding certification program approved by the Board.
(d) Pharmacists and other Compounding Pharmacy personnel (eg, Pharmacy Technicians) shall be trained and proficient in the particular operations that are performed by that individual.
(e) Training shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that Compounding Pharmacy personnel remain familiar with applicable operations and policies and procedures.

(f) Only personnel authorized by the responsible Pharmacist shall be in the immediate vicinity of Compounding operations.

(g) A Compounded Drug shall be deemed Adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, unless such Compounded Drug can affirmatively be shown not to be Adulterated.

Commented [JB6]: We support the principles behind this provision. However, we are concerned that, as written, this provision could result in entire lots of drugs prepared over a broad timeframe being deemed adulterated due to the observance of an "insanitary condition" without regard to whether the drugs were actually impacted. For example, 6 months' worth of compounded preparations could be deemed adulterated because a spot of rust is found in the corner of the clean room, or if an investigang agency deems a surface "difficult to clean." There should merely be a rebuttable presumption of adulteration that can be disproven by testing.

Section 9. Compounded Drug Preparations for Veterinary Use.

(a) The use of bulk Drug substances for Compounded veterinary Drug preparations is permitted except when:

(1) The compounded veterinary drug preparation is Essentially a Copy of a Commercially Available marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA approved human drug, and the prescribing veterinarian has not provided the pharmacy with medical rationale for the need of such compounded veterinary drug preparation based on the clinical needs of the animal patient; or

(2) The compounded veterinary drug preparation is intended as an antidote to prevent animal suffering or death in food-producing animals, and the veterinarian has not specified a scientifically-based withdrawal time that ensures residues of the antidote and the underlying toxin are not present in the animal at the time of slaughter; or

(3) FDA has identified a significant veterinary safety concern with the use of the bulk Drug substance in compounded veterinary drug preparations.

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

(c) Prohibition on wholesaling

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

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

(e) Comply with the Notification requirements set forth in Section 503.

Deleted: **Section 9. Compounded Drug Preparations for Veterinary Use.**¶
The use of bulk Drug substances for Compounded Drug preparations is prohibited except when:¶
Compounding is pursuant to a patient-specific prescription for a non-food-producing animal or as an antidote to prevent animal suffering or death in food-producing animals;¶
there is no marketed approved or conditionally approved Drug that can be used as labeled to treat the condition;¶
there is no marketed approved animal or human Drug that can be used to treat the condition through off-label Drug use; ¶
the Drug cannot be appropriately Compounded from an approved animal or human Drug;¶
immediate treatment with the Compounded Drug preparation is necessary to avoid animal suffering or death; and¶
FDA has not identified a significant veterinary safety concern with the use of the bulk Drug substance for Compounding.¶
It is acceptable for any licensed Pharmacy to Compound veterinary Drug preparations to be used by veterinarians in their offices for Administration to clients' animals. ¶
Compounded office use Drug preparations may be Dispensed by a veterinarian to clients only in an urgent or emergency situation for use in a single course of treatment, not to exceed a 120-hour supply.¶
Prohibition on wholesaling ¶
The Compounded veterinary Drug preparations will not be Distributed by an entity other than the Pharmacy that Compounded such veterinary Drug preparations. This does not prohibit Administration of a Compounded Drug preparation in a veterinary health care setting or Dispensing of a Compounded Drug preparation pursuant to a Prescription Drug Order executed in accordance with federal and state law.¶
Providing samples of Compounded veterinary Drug preparations is prohibited.¶
Upon becoming aware of any adverse event or Product defect, the Pharmacy reports the event on the designated FDA form[21] within 15 days and includes the FDA statement about reporting adverse events on the prescription Label.

Commented [JB7]: The existing language would cause state regulations to become more restrictive than what FDA is currently proposing in its draft guidance. The existing language all but prohibits use of bulk compounds. We believe our suggested language strikes an appropriate balance between permitting compounding from bulk substances while preventing the inappropriate use of bulk drug substances when providing compounds to veterinarians.

Commented [a8]: See attached proposed definition

Commented [a9]: See attached proposed definition

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Commercially Available Drug Product

A drug product is Commercially Available if it is an FDA-approved, marketed drug product. A drug product is not Commercially Available if

- the drug product has been discontinued and is no longer marketed;
- the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act. A drug "appears on the drug shortage list in effect under section 506E" if the drug is in "currently in shortage" status (and not in "resolved" status) in FDA's drug shortage database; or
- the drug product is not available to veterinarians or pharmacies through wholesale distribution channels or otherwise without undue restriction and in amounts necessary to meet supply needs; the drug product is on allocation or back order and excludes veterinarians and/or pharmacies; or the manufacturer of the drug product prohibits distribution of the drug product to veterinarians and/or pharmacies.

Essentially a Copy of a Commercially Available Drug Product

A drug product is Essentially a Copy of a Commercially Available drug product if:

- the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the Commercially Available drug product;

- the dosage strength of the compounded drug is the same or similar (as defined below) to the dosage strength of the Commercially Available drug product; and

- the Commercially Available drug product is the same dosage form as prescribed for the compounded drug, unless a prescriber determines that there is a change required which produces, for that patient or patient population, a significant difference from the commercially available drug product, which determination shall be deemed to exist if a veterinarian prescribes or orders such compounded drug product.