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Alliance for Pharmacy Compounding

July 7, 2023

Oregon State Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

RE: Rulemaking Policy Discussion Compounding Rules Division 183

Dear Board Members:

The Alliance for Pharmacy Compounding ("APC") 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. Pharmacy compounding is authorized in federal and state law as an appropriate therapeutic option for patients and animals whose needs cannot be met by traditional pharmaceutical manufacturers.

Thank you for the opportunity to comment on the proposed rules for Division 183 pertaining to compounding. We wish to note that although the Proposed Rules are a significant step in the right direction, there are several provisions that cause concern. Accordingly, we offer the following comments to the Proposed Rules:

- **855-183-0050 Personnel:** We recommend adding the word "independently" to the following sentence: *"prior to* **independently** *engaging in compounding,"* would be more in line with the current USP <795> and <797> chapters which state that personnel must be trained before being allowed to perform their job functions independently. This would allow for compounding while being trained.
- **855-183-0200 Requirements: General:** We recommend removing the requirement to adhere to USP chapters above 1000. USP itself states the chapters above 1000 are not intended to be applied to daily practice. While pointing a compounder to the USP chapters referenced to carry out best practices and to learn more about a given subject is encouraged, according to USP General Notices, General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numbered below 1000, a monograph, or these General Notices. To require adherence to those chapters would go well beyond what the standard-setting body itself says is their appropriate function.
- **855-183-0410 Labeling: Compounded Sterile Preparations (CSPs)**:
    - We recommend removing "the include the base solution" from provision (1) that currently states "The strength of each active ingredient, to include the base solution." Bases typically have no strength, as they are inactive ingredients and therefore should not be included in labeling.
    - We recommend removing "Rate of infusion or titration parameters" from provision (3). The rate of infusion can be changed in a medication order for a specific patient and may not be included on the prescription itself. This may lead to errors if changes are made or a rate is not included on the prescription the pharmacy receives.

- **855-183-0520 Recalls:** We recommend extending or removing the time requirement of 12 hours in provision (1) as there are many cases in which this is not feasible due to staffing limitations on weekends or holidays or other times when a pharmacy may be closed.
- **855-183-0710 Service: Copies of a FDA Approved Drug**: We recommend striking. It is stricter than federal law and would create patient access issues. It is not needed as the federal DQSA law states "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product."
- **855-183-7030 (3)(b):** We recommend revising as follows: **"**(b) For in-office use by a licensed veterinarian, and dispensed specifically for a single treatment episode, not to exceed the longer of the length of such single treatment's recommended course of therapy or a 120-hour supply."
    - **Veterinarians must be able to dispense compounded medications from non-patient specific office stock.** As veterinarians often must treat animals in emergent situations where timeliness of medication administration is very essential for patient outcomes. The currently proposed language, Section 855-183-0730 (3)(b) allows "For in-office use [of compounded drugs] by a licensed veterinarian, specifically for a single treatment episode, not to exceed 120-hour supply." The word "dispense" has been removed from the language, thereby introducing vagueness as to the permissibility of the act. While it may be inferred that dispensing from compounded office stock is permissible in light of the 120-hour time frame, the language specifies "in office use." This could also be taken to mean that an animal hospitalized and/or boarded in a veterinary clinic would need to secure a patient specific supply of medication if their stay were to last longer than 120-hours. In the best interest of patient care, it is strongly recommended that the term "dispense" be re-introduced into this provision.
    - **Veterinarians should be able to determine the appropriate amount of medication to dispense to a patient.** In a 2019 survey by the Oregon Veterinary Medical Association, only 26% of respondent veterinarians stated that a 5-day (120-hour) supply would be adequate for optimal patient care. A standard course of antibiotic is 7 to 10 days. However, it is likely that an animal will show signs of recovery by 5 days, and if an owner does not fill the remainder of the medication, incomplete antibiotic therapy can lead to re-infection, superinfection, and antimicrobial resistance. Furthermore, many sterile preparations come in uniform sizes that would exceed a 120-hour supply, and the sterility would be interrupted if a veterinarian had to repackage the medication to adhere to the days' supply limit. Permitting a veterinarian to dispense the full course of therapy would make much more sense.
- **855-183-0730(4):** We recommend revising as follows: "(4) The compounded preparations, other than preparations produced by a 503B outsourcing facility, must not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations."
    - The new USP Chapters 795, 797, and 800 will be effective November 1, 2023, and will severely limit BUDs of sterile and hazardous drugs. If smaller, local pharmacies are allowed to buy products from 503B Outsourcing Facilities that maintain cGMP standards and dispense them to their patients, this will avoid patient access issues created when these local pharmacies are no longer economically able to continue to produce many veterinary drugs.
- **855-080-0021:** We recommend revising as follows: "Xylazine, unless in the form of a FDA-approved product, or compounded for veterinary use."
    - Xylazine is a drug used in veterinary medicine as a sedative with analgesic and muscle relaxant properties. At a Federal level, HR 1839: The Combating Illicit Xylazine Act, allows a specific protection for compounded xylazine, exempting, " the manufacturing,

importation, or use of a xylazine bulk chemical for pharmaceutical compounding by licensed pharmacists or veterinarians;" Unlike the proposed Federal legislation and because compounded preparations are not FDA-approved, compounding xylazine for veterinary use would be prohibited under Oregon law, severely handicapping veterinarians and causing unnecessary animal pain and suffering.

Thank you for this opportunity to comment on the proposed regulation changes. Please direct any questions to APC's Savannah Cunningham at savannah@a4pc.org.

Best,

Scott Brunner, CAE
Chief Executive Officer