Alliance for Pharmacy Compounding

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October 29, 2024

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy
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Dear Mr. Briggs,

On behalf of the Alliance for Pharmacy Compounding, I am writing to provide our comments on the proposed sterile compounding rule changes outlined in Texas Pharmacy Rule §291.133. We appreciate the Texas State Board of Pharmacy's efforts to align many of the new rules with the latest U.S. Pharmacopeia (USP) standards, ensuring that Texas pharmacies maintain high standards for patient safety and quality in sterile compounding.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including more than 5,000 compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

We strongly support the Board's authority to tailor USP guidelines to meet the needs of Texas patients and pharmacists. In particular, we endorse increasing the maximum batch size to 500 units and extending beyond-use dates (BUDs) for anhydrous sterile preparations. These provisions ensure patients have timely access to medications, especially during shortages or periods of high demand.

Additionally, we propose some technical clarifications and adjustments:

- **Alternative Testing Methods for Category 2 CSPs**
    - Currently the proposed regulations discuss the potential use of a validated alternative method that is noninferior to Chapter 71 testing for sterility testing of Category 3 CSPs. The language should be clarified to ensure that this is also available to Category 2 CSPs. The use of these alternative sterility testing methods provides CSPs with more usable days for patient care.

- **Component Sourcing**
    - The proposed regulations require that active ingredients be USP/NF grade and if they cannot they have to be CP, AR, ACS, or FCC. There are some active ingredients that are found in FDA approved drugs that do not have a USP/NF monograph and do not come in any of the specified grades. Ketotifen is an example which is available as European Pharmacopeia (EP) grade. The regulations need to account for active ingredients that are allowed by federal law and FDA Guidance.
    - The proposed regulations state that all components must be manufactured in an FDA registered facility. Federal law requires that active ingredients come from FDA registered manufacturers, but does not have this same requirement for excipients. Requiring all excipients to come from FDA registered manufacturers will remove many excipients from sterile compounding in Texas. The requirements for excipients should align with the requirements in Section 503A of the FDCA.
- **Filtration**
    - The proposed regulations require filter integrity testing specifically for Category 3 CSPs. Filter integrity testing should be conducted for all sterilizing filters used independent of the Category of CSP produced.
- **Consistency and Definitions**
    - The language used to describe media-fills varies and uses the terms = “media-fill,” “challenge testing,” and “media-fill challenge testing.” We ask that the Board adopt a single term for clarity.
    - Both the terms “buffer room” and “clean room” are provided in the definitions. For clarity it would be helpful if one term was chosen and used throughout. A buffer room can be used as a part of a cleanroom suite which is also defined.
- **Numerical Formatting**:
    - We note several **numbers that did not come out as expected in the document**, such as using “107” where it should read “10^7” in the definition of sterilizing grade membrane.
    - This also exists in the terminal sterilization definition (e.g., “less than 10^-6”).
- **Definitions**:
    - Including a definition for “cleaning agent,” as provided in USP 797, would ensure consistent understanding of requirements for sterile environments.

- The use of “effluent” in the filtration definition should also be revised to “filtrate” as effluent is defined as waste.

Clarifications

- The Board references USP 71 for sterility testing of batches over 500 units, however, the maximum allowed batch size is 500 units. The language about testing batches over 500 units should be removed to prevent potential confusion.
- Specific CETA documents are referenced in the proposed regulations. Including “or its successor” after each CETA document referenced would reduce the need for future regulatory revisions due to document updates.

These adjustments aim to support patient safety while ensuring practical and consistent regulatory standards. APC remains committed to collaborating with the Texas State Board of Pharmacy to achieve optimal outcomes for patients and compounding pharmacists alike.

Please let us know if further clarification is needed. Thank you for the opportunity to provide feedback.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
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