100 Daingerfield Road, Suite 100
Alexandria, VA 22314

www.a4pc.org

Alliance for Pharmacy Compounding

November 25, 2025

Rhode Island Board of Pharmacy
c/o Rhode Island Department of Health
3 Capitol Hill St
Providence, RI 02908

Re: Proposed Amendments to Chapter 40, Subchapter 15 – Pharmacy Regulations (216 RICR-40-15-1)

Members of the Board:

Thank you for the opportunity to comment on the proposed draft regulations published October 28, 2025. The Alliance for Pharmacy Compounding represents compounding pharmacists and pharmacies nationwide, and we appreciate the Board's effort to modernize and clarify Rhode Island's compounding framework.

Definitions

We first want to address the definitions of "Manufacture" and "Manufacturer."

- Definition 88: "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or packaging or repackaging.
- Definition 89: "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or poisons.

We recognize that the inclusion of "compounding" within these definitions likely stems from the federal Controlled Substances Act and Food, Drug, and Cosmetic Act, both of which use similar wording. However, the federal definition of *manufacture* also explicitly excludes compounding performed in conformity with state law and incident to a practitioner's professional practice. Specifically, 21 U.S.C. § 802(15) states:

> "...such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice."

This important exclusion recognizes that traditional pharmacy compounding, when performed pursuant to a valid patient-specific prescription, is part of the practice of pharmacy, not manufacturing.

To reflect this distinction and avoid unintended overlap, we recommend the Board revise the definition of "Manufacture" to include similar language, such as:

> *"Manufacture" does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a pharmacist as an incident to the dispensing of such drug or substance in the course of professional practice.*

This simple clarification would align Rhode Island's rule with both federal statute and section 503A of the FD&C Act, ensuring that licensed compounding pharmacies are appropriately regulated as healthcare providers rather than manufacturers.

Additionally, the proposed text alternates between "products" and "preparations" when describing compounded drugs. In USP terminology, *"preparation"* refers to a compounded medication, while *"product"* refers to a manufactured drug. For example, the draft defines:

> "Compounded sterile products" means a preparation intended to be sterile…
> "Compounded non-sterile product" means a product intended to be non-sterile…

We recommend standardizing to "compounded sterile preparations (CSPs)" and "compounded nonsterile preparations (CNSPs)" throughout to maintain alignment with USP <795> and <797> and prevent misinterpretation during inspections.

Finally, the definition of "cancer drug" in the proposed rule appears problematic:

> "Cancer drug" means a prescription drug that is used to treat cancer, the side effects of cancer, or the side effects from a cancer medication. A cancer drug must be deemed a non-harmful substance by the FDA and shall only be administered by a licensed professional.

This definition is inconsistent with federal terminology and could have unintended consequences. FDA does not classify drugs as "non-harmful," and requiring *all* cancer-related medications, including oral chemotherapy drugs and supportive or symptom-management drugs like ondansetron, to be administered only by a licensed professional could restrict patient access to common take-home therapies. We recommend revising this section to align with federal labeling and usage parameters rather than creating new categories or administration restrictions.

USP Chapters

The draft references USP <797> (2024) and USP <795> (2023). However, both chapters became official in November 2023, with enforcement beginning in November 2023 across most jurisdictions. For consistency and accuracy, we recommend citing both as *USP 2023 versions* to match national reference and implementation dates.

API Selection Criteria

We also wish to comment on section 1.8(A)(10), which states:

> "Bulk and active ingredients used in the preparation of compounded sterile products (CSPs) and non-sterile compounded products shall be USP or National Formulary (NF) certified and shall be accompanied by a certificate of analysis for inspection by the Department upon request."

While we fully support the goal of ensuring ingredient quality and traceability, the current language could unintentionally exclude many bulk substances legitimately used in pharmacy compounding that lack an official USP or NF monograph.

To maintain both quality and access, we recommend aligning this section with section 503A(b)(1)(A) of the FD&C Act, which allows bulk substances that:

1. Comply with an applicable USP/NF monograph, if one exists; or
2. Are components of FDA-approved drugs; or
3. Appear on the FDA's interim or final published list of bulk substances that may be used in compounding.

Adopting this standard would preserve consistency with federal law and avoid restricting substances that are commonly compounded for clinical need.

Essentially a Copy Definition

We also recommend refining the draft section addressing "essentially a copy" of a commercially available drug. As written, the proposed language is overly broad and could create confusion about when a prescriber-documented clinical difference allows compounding.

We suggest the Board mirror FDA's guidance on this topic, which defines "essentially a copy" in a way that protects innovation while still allowing legitimate compounding when a prescriber determines and documents a clinical difference for an individual patient. Incorporating that federal standard would ensure alignment with the 503A framework, provide clear direction for inspectors and licensees, and protect patient access to individualized therapies without permitting duplicative products.

Environmental Monitoring Frequency

The proposed environmental monitoring (EM) section states that all viable sampling for Category I and II CSPs must occur monthly, and Category III weekly, noting that "minimum frequencies shall exceed the USP standards."

Under USP <797> (2023), EM frequency requirements differ by sample type (air vs. surface) and are based on risk category and performance of the cleanroom. By requiring *all* EM, air and surface, for Category III weekly and Category I/II monthly, the draft exceeds USP without clear justification. We recommend adopting USP <797> frequencies directly or clarifying which sampling type (air or surface) the rule is addressing. Overly frequent EM mandates can create unnecessary cost and testing burden without proven quality benefit, particularly for Category I environments.

Conclusion

With these clarifications, the Board can strengthen regulatory consistency, avoid unintended restrictions on legitimate compounding, and continue supporting patient-specific care in Rhode Island.

Thank you for your consideration and for the opportunity to comment. APC welcomes further discussion and would be glad to participate in any stakeholder sessions as this rulemaking advances.

Respectfully submitted,

Scott Brunner, CAE
Chief Executive Officer