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November 11, 2025

Chief Administrative Officer Peter Ragosta, RPh
Rhode Island Board of Pharmacy
3 Capitol Hill, Room 403
Providence, RI 02908

Dear Mr. Ragosta & Members of the Rhode Island Board of Pharmacy,

Thank you for the opportunity to submit written comments. I am writing to request clarification on whether the Board intends to apply the new USP <795> non-sterile compounding requirements to the longstanding practice of medication flavoring.

Many pharmacists, technicians, and parents in Rhode Island hope this will not be the case. Imposing these standards on simple flavoring will likely push pharmacies to discontinue offering the service altogether, rather than ensure compliance. Flavoring medications with FLAVORx is a safe, well-established, thoroughly tested pharmacy practice that has been offered to parents in Rhode Island for decades, without any reported harm. We currently supply our products to over 100 pharmacies in Rhode Island. Since most of these pharmacies provide flavoring to their customers as a low-cost or even free-of-charge service to boost patient outcomes, the newly added burden of compliance with USP <795> will be a major deterrent to continuing on with the practice.

Most Boards of Pharmacy have found a way to chart a pragmatic path forward for their licensees, one that protects the public while maintaining access. Currently, 48 of 50 State Boards of Pharmacy, plus D.C. and Puerto Rico, provide some form of relief from USP standards when it comes to medication flavoring. Many explicitly carve flavoring out from their compounding standards, while others exercise enforcement discretion. Flavoring continues to be a widely available service in these locales. Conversely, in the two states (California & Washington) that now require full compliance with the new USP <795> standards when flavoring, the number of pharmacies offering the service to their customers has dropped by over 98%. If the same were to happen in Rhode Island, that would leave two pharmacies providing this valuable service to parents across the entire state.

In closing, I invite you to visit www.flavorx.com/regulatory for a complete and up-to-date picture of the current regulatory environment around medication flavoring across the country. I am at your disposal to answer any questions.

Thank you for your time and consideration,

Chad Baker
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November 24, 2025

Eli Lilly and Company

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VIA EMAIL (zachary.garceau@health.ri.gov)

Zachary Garceau
Department of Health
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Re: Proposed Amendments to 216 R.I. Code R. § 216-RICR-40-15-1, Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors

Dear Mr. Garceau:

I write on behalf of Eli Lilly and Company ("Lilly") to comment on the amendments that the Rhode Island Board of Pharmacy ("Board") has proposed to the rule identified above. As a U.S.-based pharmaceutical manufacturer headquartered in Indiana, Lilly has been at the forefront of drug innovation and drug quality for more than 150 years. At Lilly, patient safety is at the heart of everything we do. We believe our commitment to patient safety aligns with the Board's longstanding dedication to public health and the effective regulation of the practice of pharmacy in Rhode Island.

We write to express our support for the inclusion of United States Pharmacopoeia and National Formulary ("USP-NF") requirements in the proposed rule and to respectfully offer suggestions regarding certain other provisions. We aim to partner with the Board in its efforts to protect patient safety.

A. Addition of USP-NF Requirements

We support the Board's proposal to incorporate by reference USP-NF General Chapters <659>, <795>, <797>, <800>, and <825> in new § 1.2, thereby requiring that pharmacies and pharmacists engaged in compounding comply with those chapters. All USP general chapters are developed through a rigorous, science-driven process; reflect robust public participation and public comment; and are intended to be binding industry standards.[1] Requiring compounding pharmacies doing business in Rhode Island to comply with these current industry standards represents a necessary step toward reducing some of the risks posed by compounded products.

These proposed amendments also promote consistency among the states, which is particularly important for drug compounding because state Boards of Pharmacy are primarily responsible for ensuring that pharmacy-compounded drugs are safe for patients. Further, although

[1] *See generally* https://www.usp.org/about.

Congress never intended for compounding pharmacies to engage in significant amounts of interstate commerce, most distribute large amounts of compounded drugs across state lines. As a result, state Boards of Pharmacy must coordinate their oversight and inspection activities, which is facilitated by the current USP-NF standards.

Please note, however, a typographical error in proposed § 1.2(D). That provision refers to "Chapter 797 Pharmaceutical Compounding – Sterile Preparations (2024)." We recommend referring to the official date of Chapter 797, which is "2023."

B. Requirements for Safe, High-Quality Active Pharmaceutical Ingredients

The quality of a medicine is only as good as the quality of its ingredients. We therefore support the Board's effort in proposed § 1.8(A)(10) to strengthen the requirements regarding the quality of ingredients used in compounding. The proposal improves upon existing law by requiring that bulk ingredients be both USP-NF certified ***and*** accompanied by a certificate of analysis ("COA").

While this is a good step, it leaves the door open for the lowest quality bulk active pharmaceutical ingredients ("API") from the cheapest sources to find its way into compounded drugs dispensed to Rhode Islanders. Many of those inferior sources are located abroad, typically in China and India, and operate largely outside of meaningful state and federal oversight. Even when such sources are registered with the U.S. Food and Drug Administration (many are not), many have never been inspected by FDA to ensure that they manufacture APIs according to the appropriate quality, purity, and potency standards. This gap in oversight creates a pathway for foreign API suppliers to import deficient – and potentially dangerous – APIs for use in pharmacy compounded drugs.[2]

These risks are exacerbated by the common practice where API manufacturers sell to wholesalers who then repackage and relabel the product before providing it to compounders. As a result, compounders may be unaware of the API's true provenance and may be forced to rely on COAs of uncertain reliability.[3] Worse still, some unscrupulous compounders may intentionally reduce costs at the expense of patients by substituting substandard ingredients, such as food- or animal-grade materials, in the place of pharmaceutical-grade API.[4]

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[2] *See* FDA, Report on the State of Pharmaceutical Quality FY2024 at 11 (2025), https://www.fda.gov/media/188236/download ("During the past five years, 72% of actions (e.g., warning letters, import alerts, and regulatory meetings) taken against API manufacturers were for sites that only supply compounding pharmacies, even though these sites represent just 18% of API manufacturers in the Site Catalog."); Francis Godwin, API Sourcing, or Buyer Beware, https://www.fda.gov/media/164526/download.

[3] *See* Alliance for Pharmacy Compounding, "FDA's green list: Not our problem?," *available at* https://a4pc.org/news/fdas-green-list-not-our-problem (stating that compounders rely on their wholesalers to vet API manufacturers).

[4] *See, e.g.*, Julian Gill, *Empower Pharmacy says it sells 'quality' compounded drugs. 10 years of FDA violations raise doubts*, Houston Chronicle, May 12, 2025, https://www.houstonchronicle.com/news/investigations/article/empower-pharmacy-compounded-drugs-fda-20281795.php.

To close these gaps and better protect patients, we respectfully recommend further amendments to § 1.8(A)(10) requiring additional information demonstrating that the API is safe and otherwise appropriate for use in compounded medications. We encourage the Board to consider the following revisions to this section:

> Bulk and active ingredients used in the preparation of compounded sterile products (CSPs), and non-sterile compounded products shall be: (a) compliant with the USP or National Formulary (NF) ~~certified and shall be~~; (b) manufactured in an FDA-registered facility that is permitted by the Board; (c) accompanied by a valid certificate of analysis that identifies (i) the name, chemical formulation, potency, and each impurity by chemical name and amount present of the drug substance and (ii) name and FDA Establishment Identifier (FEI) of the API manufacturer and any subsequent repacker or relabeler for the API; and (c) pharmaceutical grade. The certificate of analysis shall be made available for inspection by the Department upon request.

Strengthening the requirements for APIs used in compounded drugs will help to ensure Rhode Islanders only receive medicines with quality ingredients.

C. Clarifying the Meaning of "Essentially Copies of a Commercially Available Product"

We support the current language in § 1.3(A)(31) that excludes drugs "that are essentially copies of a commercially available product" from the definition of compounding. That language plays a critical role in protecting the health of Rhode Islanders. Compounded drugs should never be used when an FDA-approved medicine is available because, unlike approved products, compounded drugs are not reviewed by FDA for safety, effectiveness, or quality before they are marketed. The "essentially copies" language is one of several critical safeguards that prevents manufacturing knockoffs of FDA-approved medicines under the guise of compounding.

However, we urge the Board to expressly define in § 1.3(A) both "essentially copies" and "commercially available" as used in § 1.3(A)(31). Leaving these terms undefined risks creating uncertainty about what may be lawfully compounded under state law. Moreover, the lack of definitions creates a potential ambiguity that bad actors can exploit by making trivial alterations to FDA-approved drugs – alterations that do not yield any clinically meaningful benefit for the patient. Such insignificant changes might include minor dosage adjustments or the addition of unnecessary APIs, such as glycine or niacinamide, solely to avoid the "essentially copies" prohibition while producing large quantities of unreviewed knockoff products.

This concern is underscored by the proposed amendment to § 1.3(A)(31), which adds a statement that the "[a]ddition of vitamins, nutrients, and/or medications to intravenous fluid bags is compounding." Without clarifying what constitutes being "essentially copies of a commercially available product," pharmacies are left to guess whether any addition of a vitamin to an IV fluid bag is permissible regardless of clinical relevance, or whether such a modification is prohibited when it results in a product that lacks any clinically meaningful difference from an available FDA-approved medicine.

Accordingly, we recommend that the Board define "essentially copies" to make clear that insignificant changes to a commercially available drug is not permissible compounding. Rather,

a compounded drug should be permitted only when the modification produces a clinically significant difference for an identified patient that is determined and documented by the prescribing practitioner. We suggest the following definition:

> "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as determined and documented in the prescription by the prescribing practitioner and confirmed by the pharmacist, between the compounded drug and the comparable commercially available drug product.

Further, we recommend clarifying "commercially available" by defining what is ***not*** commercially available to provide compounders with clarity about when they may compound "essentially copies" of drugs:

> "Not Commercially Available" means: (a) the drug product has been discontinued and is no longer marketed; or (b) the drug product appears on the FDA drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act.

These standards would appropriately preserve patient access to individualized therapies while preventing unlawful manufacturing of knockoff drugs disguised as compounding.

D. Prohibition of Sales by Section 503B Outsourcing Facilities to Section 503A Compounding Pharmacies

We respectfully request that the Board further amend proposed § 1.8(A)(8) to clarify that FDA Registered Outsourcing Facilities are prohibited from selling compounded drugs to Section 503A Compounding Pharmacies regardless of whether the recipient pharmacy further manipulates the compounded product. This would be consistent with the Federal Food, Drug, and Cosmetic Act's ("FDCA") broad prohibition on the resale of a compounded drug that is labeled "not for resale" in accordance with Section 503B of the FDCA.[5] If the Board chooses not to adopt an outright prohibition, notwithstanding the clear prohibition on resale in Section 503B of the FDCA, then we suggest the following language for consideration at the end of § 1.8(A)(8) to clarify that further manipulation by a pharmacy of a compounded drug received from an outsourcing facility is not permitted:

> A pharmacist shall not add an ingredient to a pharmaceutical product that was compounded at another facility.

* * *

[5] *See* 21 U.S.C. § 331(ccc)(1)

We appreciate the opportunity to comment on these important matters. We applaud the Board's dedication to improving the practice of pharmacy by updating its regulations, which include important measures to protect Rhode Island patients.

Sincerely,

Brad Jordan, Ph.D.
Associate Vice President
Regulatory Policy & Strategy
Eli Lilly and Company

Bill Irvin, RPh
Director, Pharmacy Advocacy & Regulatory Affairs

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November 24, 2025

Peter Ragosta,
Chief Administrative Officer
Rhode Island State Board of Pharmacy
3 Capitol Hill #205
Providence, RI 02908

Re: Request for Public Comment to the proposed amendments to 216-RICR-40-15-1

Dear Mr. Ragosta and Members of the Rhode Island State Board of Pharmacy,

I am writing to you and the members of the Board in my capacity as Director of Pharmacy Advocacy and Regulatory Affairs for CVS Health and its family of pharmacies located across the state of Rhode Island. As the largest pharmacy provider in the state, we are uniquely positioned to deliver a broad range of accessible pharmaceutical care services to Rhode Island residents. CVS Health appreciates the opportunity to comment on the following proposed regulations as noted in 216-RICR-40-15-1.

Section 1.3 – Definitions (A) (30) Compounded Non-Sterile Product:

As proposed, the definition of a "Compounded non-sterile product" or "CNSP" means a product intended to be non-sterile by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.

CVS Health is a strong advocate for ensuring that patients across the state of Rhode Island, especially our most vulnerable patient populations, have easy access to tailored medication adherence solutions that are safe, effective, and often necessary, to ensure positive health outcomes. This includes the addition of a flavoring agent to a medication upon request from a parent, caregiver, patient, or prescriber.

To eliminate confusion and to provide clarity for licensees, prescribers and patients, CVS Health respectfully requests the Board amend the proposed definition to explicitly state that a compounded non-sterile product does not include the flavoring of a conventionally manufactured medication.

"Compounded non-sterile product" or "CNSP" means a product intended to be non-sterile by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation. This definition does not include the flavoring of conventionally manufactured medications provided that the flavors are inert, tested, and do not alter a medication's concentration beyond USP's accepted level of variance.

Section 1.3 – Definitions (A) (122) Prescriber:

As proposed, the definition of "Prescriber" means any person who has occupational licensing by relevant boards to prescribe a medication. Prescribers include, but are not limited to, physicians, or any other person legally permitted to prescribe medication within this state.

To provide additional clarification, CVS Health recommends the Board amend the proposed language to address any potential confusion or challenges for Rhode Island patients receiving medications timely from a properly credentialed out of state prescriber by striking "within the state" as follows:

"Prescriber" means any person who has occupational licensing by relevant boards to prescribe a medication. Prescribers include, but are not limited to, physicians, or any other person legally permitted to prescribe medication ~~within this state~~.

Section 1.6.1 – Licensure Requirements: Pharmacies (E):

CVS Health is committed to fostering a professional work environment that enables pharmacy teams to deliver high-quality care to the citizens of Rhode Island. We recognize that staffing needs vary by location, prescriber habits, and community dynamics.

Our comprehensive and proactive approach to ensuring adequate staffing incorporates all core elements of our pharmacy operational activities, including the administration of immunizations. We advocate for our pharmacists to manage their respective operations in a safe and compliant manner to meet the needs of our patients.

It is the position of CVS Health that the pharmacist in charge should have the authority to assess the staffing level of their respective operation. In the event a pharmacist in charge deems the pharmacy staffing level to be inadequate due the uniqueness of their operation, the concern should be immediately raised to their direct manager for resolution. Should the concern fail to be addressed, and reasonable steps taken by the direct manager, then the Department may consider this factor while assessing whether the pharmacy may have been inadequately staffed as proposed in section 1.6.1 (E).

CVS Health respectfully requests the Board amend section 1.6.1 (E), including (1) "inadequately staffed" as noted below.

"All pharmacies shall maintain an adequate number of pharmacists and pharmacy technicians to meet pharmacy workload demands, including but not limited to, administration of immunizations and medications, prescribing of medications and any future pharmaceutical care functions as allowed by law, provide for adequate rest periods for personnel, and maintain public safety. Pharmacy staffing information shall be provided to the Department upon request, including but not limited to number of pharmacists and pharmacy technicians, prescription volume, pharmacy hours of operation, and staff schedules. Should the pharmacist in charge have concerns that the pharmacy may be inadequately staffed, the pharmacist in charge shall contact their direct manager or permit holder who is responsible for addressing the concern in a reasonable and timely fashion. The State Department may consider pharmacy staffing as a factor when assessing potential disciplinary action by the Board. Such disciplinary action shall follow the applicable

requirements outlined in § 1.19 of this Part. All hearings and reviews required by this Part shall be held in accordance with the provisions of R.I. Gen. Laws Chapter 42-35."

> "Inadequately staffed" means an insufficient number of pharmacists and technicians to safely carry out the practice of pharmacy and meeting workload demands, including but not limited to, administration of medications and immunizations, and all future functions of pharmacy practice as required by laws and regulations. The determination of a pharmacy to be inadequately staffed may be made only after a pharmacist in charge has raised concerns and the direct manager or permit holder has not taken reasonable steps to address the concern raised by the pharmacist in charge. ~~Inadequately staffed may be determined in a number of ways, including but not limited to, on-site observations of current staffing, pharmacy sales/volume reports, pharmacy staffing schedules, and payroll reports.~~

Last, CVS Health recommends the Board strike the last sentence noted above in the definition of "inadequately staffed" as the language is redundant and already within the Department's scope of authority.

Section 1.19.1 (A) – Grounds for Denial or Discontinuation of License

As proposed in section 1.19.1 (A), "The Board, with the approval of the Director, may deny, suspend, revoke the license of, or otherwise discipline the licensee upon proof of the conduct described in R.I. Gen. Laws § 5-19.1-21, including failure of a pharmacy, pharmacy owner, corporation, or anyone acting on behalf of a pharmacy to prevent the loss of controlled substances in accordance with the Controlled Substances Act.

CVS Health respectfully requests the Board strike the proposed language noted above as it is duplicative of the Board's authority already granted by the statute cited, R.I. Gen. Laws § 5-19.1-21. This law permits the Board to take disciplinary action against a licensee, which includes a "pharmacy" and "pharmacy owner," for violations of state and federal controlled substance laws. The addition of the prosed edits in section 1.19.1 (A) and specifically, "anyone acting on behalf of a pharmacy" is confusing at plain read and is duplicative to the language in R.I. Gen. Laws § 5-19.1-21.

In closing, CVS Health appreciates the opportunity to provide feedback and submit comments on these proposed rules. Should you or the Board have any questions, please do not hesitate to contact me.

Sincerely,

Bill Irvin, RPh

Bill Irvin, RPh
Director, Pharmacy Advocacy and Regulatory Affairs

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COMMENTS ON PROPOSED RULES AND REGULATIONS PERTAINING TO PHARMACISTS, PHARMACIES, AND MANUFACTURERS, WHOLESALERS, AND DISTRIBUTORS [216-RICR-40-15-1]
November 2025

The ACLU of Rhode Island appreciates the opportunity to offer comments on these proposed amendments to the Department's regulations relating to pharmacists. We offer comments below on a few particular provisions that deal with the state's new drug redistribution program and expanded access to pharmacist-prescribed medications and contraceptives.

1. §1.17(C)(2)(b) – Our organization's most significant concern about these proposed regulations involves this subsection, which we find very troubling. It gives pharmacists the option to not participate in the prescribing of hormonal contraceptives, while requiring pharmacy owners to "make every reasonable effort to find a pharmacist to accommodate the patient's needs." We believe that this language has the potential to cause serious and harmful consequences. A pharmacist's refusal to prescribe or assist with contraceptive prescriptions can cause unnecessary and sometimes critical delays in care, especially for those individuals who seek this care from pharmacists because they offer timely and accessible access to reproductive health services. We strongly urge that this subsection be amended.

Specifically, to better protect patients' access to essential care, this provision should be strengthened to mirror the safeguards contained in proposed §1.5.2(C) [and currently codified in §1.16.2(C)]. Under that section, pharmacists may decline to administer a drug or device based on ethical, moral, or religious beliefs, but only after notifying the pharmacy owner who must then

ensure systems are in place so that patients will still receive the medication without interruption. Applying the same standard throughout these regulations is vital to ensure that patients do not suffer from gaps in care or access to contraception use. There is no compelling reason for the regulations to establish different and weaker safeguards for patients in accommodating pharmacists' moral objections when it involves contraceptives. We urge that §1.17(C)(2)(b) be revised to either directly reference §1.5.2(C) or incorporate that subsection's language.

2. §1.16(F) and **§1.17(E) –** Both of these sections concern recordkeeping when a pharmacist prescribes medications for human immunodeficiency virus preexposure and post-exposure prophylaxis, and contraceptives, respectively. While we are pleased that more people will have access to these vital medications through additional pharmacist prescribers, we believe that the recordkeeping requirements should be strengthened by explicitly including references to data protections established by the Health Insurance Portability and Accountability Act of 1996 and, to the extent they stronger, state confidentiality protections. We note that a HIPAA reference is included in the new section of the regulations addressing redistributed drugs. See §1.15.3(F)(3)(h). It seems especially vital to include this language in these sections, considering the attacks on access to these medications from the current presidential administration. Indeed, we believe the Department should consider whether, under the circumstances, additional explicit confidentiality protections for this particular type of prescription information should be included.

3. §1.15.3(C)(17) – Appropriately, R.I.G.L §23-25.6-4(a) establishes that all participation in the drug redistribution program is voluntary. In that vein, this subsection requires a redistributor to notify the recipient that they are receiving a donated drug. We support this notification, but the

regulation does not make clear how a person, upon receiving notice that a drug they are being given is donated, can refuse the donated drug. We believe the process for a patient to decline a donated drug and revoke their participation in the program should be addressed in the regulations.

We appreciate your attention to our views, and trust that you will give them your careful consideration. If the suggestions we have made are not adopted, we request, pursuant to R.I.G.L. §42-35-2.6(1), a statement of the reasons for not accepting them.

Submitted by:

Madalyn McGunagle, Policy Associate
American Civil Liberties Union of Rhode Island

November 25, 2025

Via Email

Zachary Garceau
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RE: Novo Nordisk Inc. Comments to Rhode Island Board of Pharmacy on Proposed Rule: Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1)

Dear Mr. Garceau and Members of the Rhode Island Board of Pharmacy,

I write on behalf of Novo Nordisk Inc. (NNI) to submit comments in response to the Board's proposed rulemaking to amend the pharmacy regulations at 216 R.I. Code R. 40-15-1. NNI appreciates the Board's efforts to align its compounding regulations with USP standards and to clarify other provisions related to compounded drug products in this rulemaking. NNI provides two recommendations to strengthen and clarify the provisions in proposed section 1.8 regarding certificates of analysis and the prohibition on resale for compounded drug products. These recommendations are focused on the provisions in the pharmacy regulations that the Board plans to revise as part of this rulemaking. However, to the extent that the Board plans to revisit its compounding regulations more comprehensively in the future, NNI would be pleased to submit additional specific proposals to help strengthen Rhode Island regulations and ensure that patients are not unnecessarily exposed to risky compounded drugs.

I. Background

Novo Nordisk is a global healthcare company with a 100-year history of innovation, committed to preventing, treating, and ultimately curing diabetes, and to improving the lives of those living with other serious chronic conditions, including hemophilia, growth disorders, and obesity. NNI is the only company in the United States with FDA-approved medicines containing semaglutide. Semaglutide is the foundational molecule that serves as

the primary ingredient for NNI's well-known, prescription only medicines: Rybelsus®, Ozempic®, and Wegovy®.[1]

Patients have long been at the center of NNI's work. NNI believes that patients deserve rigorously tested medicines that are proven to be safe and effective. This principle is the foundation of the "gold standard" U.S. Food and Drug Administration (FDA) drug-approval system, as well as the limited legal framework for compounding. While compounding can play a role for individuals who need customized products, such as patients with allergies to particular ingredients, patients should always receive an FDA-approved drug when appropriate for their care. Compounded drugs are not approved by the FDA and are not subject to the same rigorous requirements as FDA-approved medicines. Accordingly, FDA has warned that compounded drugs "pose a higher risk to patients than FDA-approved drugs" and "should only be used for patients whose medical needs cannot be met by an available FDA-approved drug."[2]

Over the last several years, there has been an overwhelming, opportunistic surge in compounding—far beyond what Congress intended when it enacted the limited federal compounding framework in sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FDCA). The compounding of glucagon-like peptide 1 (GLP-1) drugs such as semaglutide is a prime example.[3] One medical expert has described this situation as "the

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[1] Rybelsus® (semaglutide) tablets are indicated to improve glycemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes who are at high risk for these events. *See* RYBELSUS® Full Prescribing Information (Oct. 2025). Ozempic® (semaglutide) injection is indicated to improve glycemic control in adults with type 2 diabetes, to reduce the risk of major adverse cardiovascular events ("MACE") in adults with type 2 diabetes and established cardiovascular disease, and to reduce the risk of kidney disease worsening, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease. *See* OZEMPIC®, Full Prescribing Information (Oct. 2025). Wegovy® (semaglutide) injection is indicated for chronic weight management in adults and pediatric patients ages 12 years and older with obesity or adults with overweight with at least one weight-related comorbid condition. Wegovy® is also indicated to reduce the risk of MACE in adults with established cardiovascular disease and either obesity or who are overweight and for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis ("MASH"), formerly known as nonalcoholic steatohepatitis ("NASH") with moderate to advanced liver fibrosis in adults. *See* WEGOVY®, Full Prescribing Information (Oct. 2025).

[2] FDA, FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products (Last updated July 26, 2024).

[3] The "semaglutide" bulk drug substance used by compounders is not the same semaglutide used in NNI's FDA-approved medicines. NNI manufactures its semaglutide in yeast using recombinant DNA technology, whereas compounding entities typically use an active pharmaceutical ingredient (API) that is manufactured by chemical synthesis. NNI does not sell semaglutide to any entities for use in compounding. Furthermore, the semaglutide used in NNI's FDA-approved semaglutide medicines is manufactured exclusively by NNI and is not obtained from a third-party supplier. Nevertheless, for the purposes of this letter, we will refer to the compounded products as containing "semaglutide," even though these bulk drug substances are meaningfully different from NNI's semaglutide.

largest uncontrolled, unconsented human experiment of our lifetime."[4] An influx of imports of active pharmaceutical ingredients (API) that are ineligible and unsuitable for use in compounding, as well as unlawful and unsafe compounding and distribution schemes, have contributed to this concerning landscape.

II. Recommendations on Proposed Rulemaking

State Boards of Pharmacy play an essential role in ensuring that compounded drugs meet adequate standards of safety and quality and otherwise comply with all applicable legal parameters. Building upon the Board's updates to section 1.8(A)(10) regarding USP/NF standards and certificates of analysis for active ingredients in compounded drugs, we urge the Board to strengthen the provision by elaborating on necessary components of a valid certificate of analysis. We also ask that the Board make a clarifying edit to section 1.8(A)(8) to make clear that there are no exceptions to the federal prohibition on resale of drugs compounded by 503B outsourcing facilities. These revisions will help to protect the health and welfare of Rhode Island patients.

A. Strengthen Certificate of Analysis Requirement to Promote Safety and Quality

NNI applauds the Board's efforts to enhance section 1.8(A)(10) of its compounding regulations, which provides (as proposed) that "bulk and active ingredients" used in compounded drug products shall be "USP or National Formulary (NF) certified and shall be accompanied by a certificate of analysis" for inspection upon request. We recommend that the Board supplement these quality requirements with language to ensure that certificates of analysis contain information necessary to verify the safety and quality of bulk drug substances, or active pharmaceutical ingredients (API),[5] in compounded drug products. Specifically, we suggest that the Board clarify that valid certificates of analysis should contain information material to ensuring the safety and effectiveness of the API, including the identity and content of the API.

Proposed Revisions to Section 1.8(A)(10)

- Bulk **drug substances ~~and~~ or** active **pharmaceutical** ingredients used in the preparation of compounded sterile products (CSPs), and non-sterile compounded

[4] *See* The Obesity Society, *FDA-Approved vs. Compounded GLP-1s: Comparing Safety, Quality, and Transparency* (Mar. 24, 2025); *see also Restoring Trust in FDA: Rooting Out Illicit Products: Hearing Before the H. Comm. on Oversight & Gov't Reform*, 119th Cong. 11–12 (2025) (statement of David Kessler, former FDA Commissioner) ("In my opinion . . . we have been conducting a reckless national experiment with compounded new weight loss drugs, the GLP-1s.").

[5] *See* 21 CFR § 207.3.

products shall be USP or National Formulary (NF) certified and shall be accompanied by a **valid** certificate of analysis for inspection by the Department upon request. **The certificate of analysis must contain information material to the safety and effectiveness of the drugs compounded using the API, including the identity and content of the API, and identification of each impurity by chemical name and amount present.**

B. Clarify Prohibition on Resale of Compounded Drugs

The Board proposes to make a clarifying edit to the prohibition on offering compounded drugs to "other State-licensed persons or commercial entities for subsequent resale" in section 1.8(A)(8), to refer to "FDA registered" outsourcing facilities. NNI commends the Board for including a resale prohibition in its regulations. However, as currently drafted, the provision appears to exempt outsourcing facilities that are registered with FDA, which is at odds with federal law. The FDCA requires that drugs compounded by 503B outsourcing facilities be labeled as "not for resale," and prohibits resale of such a drug labeled "not for resale."[6] Consistent with these federal provisions, NNI recommends that the Board delete the exception for outsourcing facilities, as shown below.

Proposed Revisions to Section 1.8(A)(8)

- Pharmacists shall not offer pharmaceutically prepared compounded preparations to other State-licensed persons or commercial entities for subsequent resale~~,~~ ~~**except as applied to FDA Registered Outsourcing Facilities**~~.

* * * *

We appreciate the Board's dedication to safeguarding patient health and upholding high standards to protect patients' health and safety. Thank you for the opportunity to provide comments on this proposed rulemaking. We would be pleased to provide further input or clarification of our comments if needed.

[6] 21 USC § 353b(a)(10)(A)(iii)(IX); 21 USC § 331(ccc)(1).

Sincerely,

Gabrielle Cosel
Consultant to Novo Nordisk Inc.

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

hims & hers

November 26, 2025

Via Electronic Mail

Zachary Garceau
Department of Health
3 Capitol Hill
Room 403
Providence, RI 02908

zachary.garceau@health.ri.gov

Re: Comments Related to Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1) Proposed Amendments

Dear Mr. Garceau,

I am writing to you today in my capacity as Director, State Government Affairs for Hims & Hers Health, Inc. Hims & Hers is a digital health platform dedicated to offering millions of people personalized care, regardless of where they live or what hour of the day they're available. We ensure transparent and affordable pricing for all Americans, including those who are uninsured or have high out-of-pocket maximums. Patients are connected with licensed providers who utilize medical expertise, clinical data, patient history, and treatment goals to develop customized treatment plans.

Respectfully, I submit this correspondence regarding the proposed amendments to Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1). We commend the effort put into these amendments, particularly those concerning compounding, as they align regulatory requirements with updates to United States Pharmacopeia (USP) and will help protect the citizens of Rhode Island.

In our review of section 1.8, compounding of pharmaceuticals, we note that the majority of the proposed amendments align with USP, which sets forth the quality standards for preparing compounded medications, including both sterile and non-sterile preparations. These standards are critical for safeguarding patient well-being by providing comprehensive guidance on vital aspects such as ingredient integrity, contamination prevention, precise dosing, and appropriate protocols for training, facility upkeep, and storage. The Food and Drug Administration (FDA) has also adopted USP standards to ensure patient safety and welfare, which is why Hims & Hers advocates for the complete and unreserved adoption of USP standards. Full adherence to USP standards also facilitates the establishment of consistent guidelines across all practice environments. Nonetheless, we have identified sections 1.8 (F) Quality Assurance and

Environmental Monitoring and (G) Environmental Monitoring: Sterile Compounding within the proposed amendments that deviate from USP 797. We respectfully urge the Board to reconsider these amendments to achieve uniformity and consistency with the guidelines embraced by the FDA and the majority of state boards of pharmacy. We have furnished suggested alternative language below, which would necessitate the removal of all current and proposed language in sections 1.8 (F) and (G), and their consolidation into a single new section under (F) Quality Assurance and Environmental Monitoring.

Suggested Language

1.8 Compounding of Pharmaceuticals
(F) Quality Assurance and Environmental Monitoring

1. Pharmacies that compound CSPs shall implement a formal quality assurance program for monitoring, evaluating, correcting, and improving the activities, systems and processes that support the preparation of CSPs in compliance with United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding – Sterile Preparations (2023) incorporated by reference in § 1.2(D) of this Part.
2. Pharmacies that compound CSPs shall implement a formal monitoring program for viable airborne particles to assess microbiological air quality in all classified areas in compliance with United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding – Sterile Preparations (2023) incorporated by reference in § 1.2(D) of this Part.
3. Surface sampling is useful for evaluating facility cleaning and material handling procedures, work surface cleaning and disinfecting procedures, and personnel competency in work practices such as cleaning and disinfecting. All sampling sites and procedures must be described in the facility's SOPs in compliance with United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding – Sterile Preparations (2023) incorporated by reference in § 1.2(D) of this Part.

We appreciate the Board's consideration of these suggested amendments.

Sincerely,

Lauren Paul, PharmD,MS
Director
State Government Affairs
Hims & Hers Health, Inc.

On behalf of the Brown University Health Department of Pharmacy, we appreciate the opportunity to provide comments on the proposed amendments to 216-RICR-40-15-1. We **support many of the proposed updates**, including revisions that improve clarity, modernize pharmacy practice standards, and expand access to pharmacist-provided preventive care.

However, we have several concerns regarding specific proposed revisions within 216 RICR 40 15 1. These include terminology, definitions, and standards that may affect pharmacy practice, patient safety, and compounding processes:

1. **§1.3(A)(3) – Active Ingredient** – **Spelling Correction:** The definition of "active ingredient" contains a typographical error: the phrase "diagnosis, cute, mitigation…" should be corrected to "diagnosis, cure, mitigation…". Correcting this minor error is important to maintain precision and clarity in the regulation, particularly as subsequent definitions and standards build on this terminology.

2. **§1.3(A)(New) – Active Pharmaceutical Ingredient (API) – Proposed Definition:** We propose the addition of a definition for Active Pharmaceutical Ingredient (API) as follows:

   Active Pharmaceutical Ingredient (API) means any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as Bulk Drug Substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).

   Inclusion of this definition will ensure clarity, consistency with USP terminology, and alignment with established pharmacy practice standards.

3. **§1.3(A)(15) – Beyond-Use Dating (BUD):** We propose updating the terminology from "Beyond use Dating" to "Beyond-Use Date (BUD)" to ensure clarity and consistency with standard pharmacy practice. We also recommend revising the definition to specify that it applies to compounded drug preparations. The current definition reads: *"The date or time beyond which a drug preparation is not recommended to be dispensed, administered, stored, or transported."* We propose updating it to: *"The date or time beyond which a compounded drug preparation is not recommended to be dispensed, administered, stored, or transported."* Adopting these changes will strengthen clarity,

reduce potential misinterpretation, and align with USP requirements and established pharmacy practice standards.

4. **§1.3(A)(27) – Compounded Sterile Products:** The proposed omission of the phrase "other than as provided in the manufacturer's labeling" broadens the definition beyond USP <797>/<800> standards. USP <797> defines compounding as the preparation, mixing, assembling, or repackaging of sterile drugs or nutrient preparations for patient-specific use under controlled conditions, explicitly excluding routine activities performed according to manufacturer labeling. Removing this exclusion could impose unnecessary regulatory burdens on pharmacy operations without providing additional patient safety benefits.

   In addition, the proposed revision changes the term "compounded sterile preparations" to "compounded sterile products." In pharmacy practice and under USP standards, *products* refer to manufactured items, whereas *preparations* refer to compounded entities made by pharmacies. Because "products" implies manufacture, this terminology shift introduces potential confusion and is inconsistent with established compounding practices. We recommend reverting the term to "compounded sterile preparations" to maintain alignment with USP language and avoid misclassification of pharmacy-compounded preparations as manufactured products.

5. **§1.3(A)(31) – Compounding:** The proposal to classify "vitamins, nutrients, and medications added to intravenous fluid bags" as compounding extends beyond USP standards and historical hospital practice. These activities have traditionally been performed by nursing staff in accordance with manufacturer instructions. Reclassifying them as compounding could restrict nursing and pharmacy workflows, introduce operational limitations, and potentially impact patient care without providing additional safety benefits.

6. **§1.8(A) – General Requirements: Non-sterile and Sterile Compounding**

   - **§1.8(A)(9)** – We propose updating the language to include "CSNPs" (Compounded Sterile Non-Products) in addition to CSPs to ensure completeness and consistency in terminology. The revised text would read:

     "Proper labeling and supplementary instructions for the clinical administration of CSNPs and CSPs shall be provided by a pharmacist."

     This addition clarifies that responsibilities apply to all compounded sterile preparations, ensuring comprehensive coverage of pharmacy operations and alignment with USP standards.

   - **§1.8(A)(10)** – We propose updating the terminology to replace "active ingredients" with "Active Pharmaceutical Ingredients (APIs)," consistent with the recommended new definition. The revised text would read:

"Bulk and Active Pharmaceutical Ingredients (APIs) 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."

This change ensures consistency with defined terminology, promotes clarity, and aligns the regulation with established USP standards and pharmacy practice.

7. **§1.8(C)(1) – Responsibilities of Compounding Personnel: Sterile Compounding:** We recommend deleting this subsection due to its repetitive nature. Subsection §1.8(C)(2) already establishes that the pharmacist-in-charge or designated person(s) acting on their behalf shall ensure required responsibilities are achieved. Removing §1.8(C)(1) will streamline the regulation, reduce redundancy, and maintain clarity regarding compounding personnel responsibilities.

We respectfully recommend that the Department consider our comments to ensure that terminology, definitions, and standards within 216 RICR 40 15 1 are consistent with USP guidance and established pharmacy practice. Specifically, maintaining clarity in compounding definitions, preserving the distinction between preparations and products, accurately defining APIs, refining beyond-use dating and IV bag additive practices, ensuring comprehensive responsibilities for CSNPs and CSPs, and reducing redundant regulatory language will support safe, efficient, and effective pharmacy operations. We appreciate the opportunity to provide feedback and trust that these recommendations will assist in developing clear and practicable regulations.

Sincerely,

Julia Vigorito, PharmD

On behalf of the Brown University Health Department of Pharmacy

Outlook

RE: 1.15.3 Drug Redistribution Program Comments

From Julia Gendy <julia@sirum.org>
Date Wed 11/26/2025 4:41 PM
To Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc George Wang <george@sirum.org>

1 attachment (34 KB)
Rhode Island Rulemaking Redlining_Comments 2025-11-26.docx;

Dear Zachary Garceau,

We are writing to comment on the proposed rule regarding the pharmaceutical redistribution program as published on 10/28/2025 in the Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1) filing. Thank you for the opportunity to submit these comments. Please let us know if we can further clarify anything or provide any additional information.

We believe that the Drug Donation Program has an enormous potential to reduce health care costs and reduce needless waste for Rhode Island and Rhode Islanders and we are overall very supportive of the regulation. Based on our experience operating drug donation programs, we have outlined some concerns and considerations attached. We are providing a supplement which incorporates our recommended amendments to the draft rules for your consideration and convenience with our written comments attached to the changes.

About SIRUM

SIRUM is a 501(c)3 nonprofit, founded at Stanford University, that helps implement state-based programs to donate unused medications for patients in need. Donated medication is often the safety-net's last line of defense for vulnerable patients. SIRUM is the national leader in operationalizing donation programs, currently assisting donation programs in eleven states, helping tens of thousands of patients access millions of dollars of donated medication that they would not otherwise have been able to afford or access. SIRUM has provided testimony on over 25 state laws and regulations.

Sincerely,
Julia

--
Julia Gendy (she/her)

Health Policy & Special Projects Fellow
SIRUM | Saving Medicine: Saving Lives

1.15.3 Drug Redistribution Program

A. Drug Donation Conditions

1. All participation in the donation program shall be voluntary pursuant to R.I. Gen. Laws § 23-25.6-4(a).

2. All prescription drugs, excluding controlled substances, that have been approved for medical use in the United States, that are listed in the United States Pharmacopoeia (USP) or National Formulary (USP/NF) and that meet the criteria for donation established in this Part may be accepted for donation under the pharmaceutical redistribution program.

3. Any person who is eighteen (18) years of age or older may donate legally obtained prescription drugs to a redistributor if the drugs meet the requirements of this Part, as determined by a pharmacist who is employed by or under contract with a drug redistributor.

4. For the donation of a prescription drug to occur, the conditions stated in R.I. Gen. Laws § 23-25.6-4(b) must be met. In addition to the conditions stated in R.I. Gen. Laws § 23-25.6-4(b), the following conditions must also be met:

   a. The donor's name, address, and phone contact must be provided to the redistribution program ~~and verified as accurate by the redistribution program prior to accepting donated drug(s)~~.

   b. If the donor is a facility such as a pharmacy, institution, manufacturer, wholesale distributor or any other authorized donor it must provide their resident state and ~~all~~ applicable Rhode Island~~state~~ and federal registrations to the redistribution program in order for donated drug(s) to be accepted.

   c. The donor must sign and date a one-time form provided by the redistributor~~ion program~~ which attests that the donated drug(s) have been stored in temperature-controlled environments, as applicable.

   d. Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or the USP must not be donated or accepted as part of the drug redistribution program unless the drug has a USP-recognized method to detect improper temperature variation during transit;

   e. The donated drug(s) has been stored according to manufacturer or USP storage requirements;

   f. The packaging contains the lot number if available and expiration date of the donated drug(s). If the lot number is not retrievable, all specified medications must be destroyed in the event of a recall;

   g. The drug does not have any signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.

5. All drugs must be inventoried at the redistribution facility. The inventory must include

Commented [1]: This verification requirement is not a standard feature of other state drug donation programs we've seen and we don't believe it would enhance safety benefits. We believe safety is already ensured through proper inspection of the product and compliance with existing storage and handling requirements. In addition, it's not clear what verification means in this context and how this would practically be implemented especially for individual donors. We believe this requirement would add significant administrative burden and discourage participation without improving patient protection.

Commented [2]: Many facility donors such as pharmacies, wholesalers and manufacturers are licensed in dozens of states. As stated, this provision seems to require them to submit every license they hold. We suggest the requirement be for their resident state registration, and if available RI and federal registrations.

Commented [3]: For pharmacies, institutions, manufacturers, and wholesalers that donate regularly, a one-time attestation form that drugs are stored under appropriate temperature conditions provides the same safety measures as repeated signatures while avoiding unnecessary paperwork.

Commented [4]: We acknowledge this is unlikely to change due to the current statute's prohibition on non-room-temperature drugs, but believe it's important to signal support for this flexibility should this be possible or considered in the future. Some of the most valuable and important medications for underserved populations are temperature sensitive such as insulin. We agree that temperature-sensitive drugs need to be handled carefully to ensure their safety and ask that the rules allow for the donation of temperature-sensitive drugs so long as the proper temperature control can be verifiably maintained during transit.

Commented [5]: We have seen in many states this requirement preclude a significant amount of otherwise eligible drugs from the long-term care sector from donation. We suggest allowing medicine to be donated without lot numbers and the addition of instructions to include drugs without a lot number that are subject to a recall along with the affected lot numbers. This is the case for almost all operational donation programs in the country.

the name, strength, and quantity of the drug, and the date of donation if the drug has been continually under the control of a healthcare professional. If the drug has not been continually under the control of a healthcare professional, the redistributor must collect a one-time donation form that is signed by the person making the donation. No additional record is required beyond the information collected pursuant to this Part and 1.15.3(F).

~~6. Drugs must be donated on the premises of the redistributor. A drop box must not be used to deliver or accept donated drugs.~~

7. A drug that is the subject of a U.S. Food and Drug Administration (FDA) managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. § 355-1 must not be donated if the inventory transfer is prohibited by that strategy~~, or if the inventory transfer requires prior authorization from the drug manufacturer~~.

8. The following drugs:

	May be Donated	**May NOT be Donated**
	Cancer drugs	Controlled substances
	Creams	Drugs that are only approved for use in other countries or are from foreign non FDA approved sources
	Drugs donated by a manufacturer	Drugs that the pharmacist deems may not be donated
	Drugs from out-of-state	Empty bottles
	Eye drops	Insulin syringes
	Drugs that have a clear expiration date	Medical supplies and devices
	Drugs that have lot numbers displayed	Non-FDA-approved drugs

Commented [6]: We are concerned that requiring this form every time imposes a form and paperwork burden that may negatively impact access to this program. Limiting the requirement to a one-time form preserves the policy objective without creating redundant paperwork for eligible participants.

Commented [7]: We suggest the rules make clear the information a redistributor must collect in an inventory record to remove ambiguity and to align with other state programs.

Commented [8]: While this was in older drug donation laws, we have found this language unnecessary and confusing because most donations are made through common carrier.

Commented [9]: While this affects a limited number of drugs, if prior authorization could be obtained from a manufacturer, then we believe those drugs should be eligible for donation.

	Drugs within three (3) months of expiration	Open vials, bottles, or packages
	Inhalers (in packaging)	~~Over-the-counter drugs ("OTCs")~~
	FDA-approved drugs from FDA approved sources	~~Temperature-sensitive drugs (cannot be stored at normal room temperature)~~
	Non-controlled substance prescription drugs	Veterinary drugs
	Patches	Compounded drugs
	Samples	
	Sealed liquids	
	Sealed mail order pharmacy bottles	
	Sealed manufacturer bottles	
	Drugs stored in accordance with USP guidelines	
	Surplus products	
	Tamper-proof products (e.g., blister packs)	
	Unopened stock bottles	
	Over-the-counter drugs ("OTCs")	

Commented [10]: We believe this limitation will preclude a substantial number of otherwise eligible drugs from donation. Specifically, OTC drugs are typically a significant component of these programs since many are prescribed to patients in long-term care settings. We want to ensure those prescribed OTCs and other OTCs are eligible for donation.

Commented [11]: See comment above.

	Temperature sensitive drugs with a USP-recognized method to detect improper temperature variation during transit.	

B. Handling of Drugs to be Redistributed

1. A pharmacist must adhere to standard pharmacy practices, as required by State and Federal law, when dispensing all drugs.

2. A licensed pharmacist employed by or under contract with the redistributor must inspect donated prescription drugs to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs. ~~The pharmacist who inspects the drugs must sign an inspection record stating this inspection has been completed and attach it to the copy of the inventory or donor record provided with the drugs.~~

3. The redistributor must be responsible for drug recalls and must have an established mechanism to notify recipients in the event of a drug recall.

4. Donated drugs may be dispensed only if the drugs are prescribed by a healthcare prescriber for use by an eligible person and are dispensed by a pharmacist or other person permitted to dispense.

5. Donated drugs must be physically distinguishable or electronically separated from ~~shall not be stored with~~ non-donated inventory.

6. The drug redistribution facility must have a quarantine area for drugs that are expired, adulterated, recalled, misbranded, or deteriorated such that these drugs are separated from drugs to be dispensed or redistributed.

7. If any one of the conditions contained in § 1.15.3(A) of this Part is not satisfied, the donated drugs shall not be distributed pursuant to R.I. Gen. Laws § 23-25.6-4(c).

8. The redistributor must remove the original donor's identification and the name of the dispensing pharmacy from the package prior to dispensing the drugs.

9. The drugs must be labeled properly with a serial number or other effective label in accordance with § 1.6.17(A) of this Part.

10. Drug diversion and theft prevention measures ~~plan~~ must be in place at the drug redistribution location.

11. Security measures, including but not limited to, an alarm system monitored 24/7, security cameras, and motion detectors must be in place at the redistribution location. Entry to areas where drugs are stored must be limited to authorized personnel only.

12. Drugs donated under the drug redistribution program may ~~must not~~ be transferred by any participating entity to other in-state participants or out-of-state participants in

Commented [13]: This language as is, does not heighten safety, but rather adds an additional administrative burden. We have seen many redistribution programs fail due to overly burdensome inventory requirements. These changes maintain the same verification requirements but streamline processes and removes paperwork burdens without jeopardizing patient safety.

Commented [14]: We understand the need to differentiate between donated medicine and other inventory. However, we have seen adoption hindered in states because repositories do not have the extra space necessary to have a completely separated area for donated medications. Workflow also suffers if staff must check two separate places for each drug. This change allows the medications to be clearly labeled as donated and/or non-donated, rather than physically segregated, which would provide differentiation without additional space.

Commented [15]: We believe that the facilities operating under this program should have similar requirements to standard pharmacies/distributors and ask that the requirements in this paragraph match.

Commented [16]: Standard non-donated drugs can be transferred more than once indicating there's no safety concerns with additional transfers. We believe donated drugs should not be treated differently. Most active state repository programs - even very successful ones - have a significant amount of donated drugs that they cannot use. Rather than allowing these drugs to expire and go to waste, it would be beneficial to supply these drugs to repository programs in other states and help others in need.

a drug donation or repository program operated by another state to the extent permitted by the laws of this state and the other jurisdiction ~~more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or waste hauler~~.

13. Drugs donated to a Receiver may be further donated to another eligible receiver in the program when one has the need for a drug and another has it available ~~cannot be re-donated~~.

14. When donated drugs are destroyed, records of their destruction must be retained by the drug redistribution program and readily retrievable upon request of any state board of pharmacy or federal regulatory agency.

a. Documentation must be in accordance with § 1.15.3(G) of this Part ~~include, and not be limited to, a record of the drug(s) destroyed, drug dosage, drug quantity, the name of the person or reverse~~

~~distributor destroying the drug(s), and the names of donors of the drug(s) destroyed~~.

15. Drug redistributors must maintain compliance with all applicable requirements of the DQSA (Drug Quality & Security Act) and DSCSA (Drug Supply Chain Security Act) 21 U.S.C. § 301.

16. Notwithstanding any other law or rule, a redistributor may substitute a prescribed drug for:

a. A drug that is in stock and which is a therapeutically equivalent drug or
b. A biological product with an interchangeable biological product.

Substitutions as provided in subsection (16) of this section may include but are not limited to:

a. splitting a combination drug into two or more drugs;
b. combining two or more drugs into a combination drug; and
c. a different form of the prescribed drug, including but not limited to, an oral tablet or capsule.

If a redistributor dispenses or administers a substitute for a donated drug, communication of such substitution to the patient and the provider shall be required unless the donation program substitution policy is readily available on the program's website.

C. Redistributor Requirements

1. Conditions of redistribution of donated medications are pursuant to R.I. Gen. Laws § 23-25.6-5.

2. Redistributors must be licensed by the Department as distributors in accordance with the provisions of R.I. Gen. Laws Chapter 21-28, as amended and this Part.

3. A separate distributor license is required for each redistribution location. 4. A

name change of a licensed drug redistributor shall require a new license.

Commented [17]: As stated above, most active state repository programs - even very successful ones - have a significant amount of donated drugs that they cannot use. This would minimize the amount of medicine wasted.

Commented [18]: We recommend simplifying this provision to require documentation "in accordance with § 1.15.3(G)" so that all disposal requirements are consolidated. This avoids the risk of conflicting or duplicative lists of requirements in different sections and provides clearer guidance to redistributors about which documentation standard applies.

Commented [19]: Repositories are limited often to dispensing donated drugs based on available inventory stock and may not have a specific drug available. However, this does not mean they do not have access to an effective, equivalent solution. Allowing substitutions for equivalent drugs or interchangeable biological products will increase the number of eligible patients receiving the health care they are dependent upon.

5. A pharmacist licensed in Rhode Island must be responsible for ensuring donated drugs meet the criteria for redistribution. If in the licensed pharmacist's professional judgment, the safety, identity, strength, quality, or purity of the donated drug makes it unsuitable for redistribution, the drug must not be redistributed and may be destroyed.

6. A pharmacist licensed in Rhode Island must be responsible for developing a formulary of drugs appropriate for the redistribution program.

7. The Board shall have the right to deny an application for a drug redistribution program license if it determines that approving the application would not be consistent with public health and safety. Appeals may be made in accordance with § 1.19.5 of this Part.

8. Pursuant to R.I. Gen. Laws § 23-25.6-3(b), the donation and redistribution of drugs is not categorized as wholesale distribution and does not warrant licensing as a drug wholesale distributor.

9. A drug redistributor must employ a sufficient number of personnel who are educated and experienced to safely and lawfully engage in the operation of a drug redistribution facility.

10. A pharmacy that predominantly ~~solely~~ operates a drug redistribution program may repackage a reasonable quantity of donated drugs in anticipation of dispensing the drugs to its patient population or as necessary for storage, dispensing, administration, or transfers in accordance with this Part. The pharmacy must have repackaging policies and protocols in place for identifying and recalling drugs.

11. A pharmaceutical redistribution program must not be operated from a person's residence.

12. The cost to any person for a redistributed drug must not exceed the current established Rhode Island Medicaid dispensing fee that is paid to retail pharmacies for a non-redistributed prescription drug dispensed to a Medicaid recipient; this fee is a separate fee and does not include the usual and customary cost, acquisition cost or any similar industry standard drug acquisition costs that Rhode Island Medicaid would reimburse to a licensed retail pharmacy for a covered prescription.

13. A designated facility manager responsible for the operation of the redistribution program must be employed by the redistributor.

14. Written policies and procedures that address no less than the following items must be documented and implemented:

    a. Receipt of drugs;

    b. Security;

    c. Storage;

    d. Inventory management;

    e. Redistribution of drugs;

Commented [20]: It is rare that a pharmacy only operates under a drug donation program and will typically supplement with other supply or purchased stock. We want to make sure these entities are eligible to participate.

Commented [21]: We recommend amending the rules to permit participating pharmacies to repackage a donated drug or medical supply, as necessary. Medication in these programs are often donated in unit-dose packaging from long-term care facilities. Allowing the repackaging of these donations provides patients with a more uniform and standard packaging, saves space for participating pharmacies, and will ease workflow burdens for participating pharmacy staff.

f. Reporting of drug loss or theft;

g. Handling drugs that have been recalled;

h. Pharmacist methodology for accepting drugs that will be redistributed; i.

Handling drug recalls;

j. Emergency/disaster plan for facility; and,

k. Segregation of outdated drugs from working inventory.

15. A drug redistributor must dispense donated prescription drugs in compliance with all applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements related to packaging, labeling, record-keeping, drug utilization review, and patient counseling.

16. A drug redistributor licensed in Rhode Island must prioritize the dispensing of redistributed drugs to citizens of Rhode Island ("Rhode Islanders") in ~~most~~ need and other eligible Rhode Islanders under the following conditions:

a. Rhode Island patients must receive no less than ninety-five percent (95%) of the redistributed drugs, by value. Licensed drug redistributors must retain readily producible documents demonstrating this prioritization. Rhode Island patients may receive less than ninety-five percent (95%) of the redistributed drugs, by value if no eligible Rhode Island patient in need of specific drugs are identified after reasonable efforts.

b. Prior to redistributing drugs to any institution, the drug redistributor must prioritize individual Rhode Islanders who are ~~most~~ in need, do not have health insurance, are underinsured, would face enormous financial hardship to pay the full price or co-pay for a non-redistributed prescription drug, or are reliant on public health programs ~~and must retain readily producible documents demonstrating this prioritization~~.

17. A redistributor must notify a patient if the patient is receiving a drug that has been donated.

19. A redistributor operating primarily for the purpose of participating in this program shall not be required to possess a comprehensive or minimum supply of medicine.

D. Physical Plant

1. The drug redistribution facility must be of suitable size and construction to facilitate operations, cleaning, maintenance, and storage of drugs. Additionally, the drug redistribution program must maintain:

a. An appropriate HVAC system to control the facility's temperature and humidity;

b. Appropriate temperature conditions as specified by the USP as follows:

(1) Room temperature drugs must be stored at a temperature range of sixty-eighty to seventy-seven degrees Fahrenheit (68° to 77° F);

Commented [22]: The phrase "in most need" creates an ambiguous standard that is difficult to define and implement consistently. As stated this could require case-by-case determinations that go beyond what the statute requires. We suggest simplifying this language to avoid an arbitrary threshold while still allowing redistributors to focus on patients with need.

Commented [23]: We have experienced in all drug donation programs around the country that there are some drugs in high surplus that will go to waste if the eligible patients are only a specific population within one state. We support the use of these drugs rather than their destruction and suggest that if an in-need, uninsured, underinsured, or patient facing financial hardship is unavailable, then another patient can receive these donated drugs.

Commented [24]: The phrase "in most need" creates an ambiguous standard that is difficult to define and implement consistently. As stated this could require case-by-case determinations that go beyond what the statute requires. We suggest simplifying this language to avoid an arbitrary threshold while still allowing redistributors to focus on patients with need.

Commented [25]: Subsection (a) already requires readily producible documents demonstrating Rhode Islander prioritization. We believe this is redundant and adds unnecessary administrative burden when a single, clear record keeping requirement in (a) is sufficient for accountability.

Commented [26]: We suggest this language to make sure for example that a charitable pharmacy that is primarily operating under this drug donation program wouldn't be required to have a comprehensive formulary that other standard retail pharmacies may be required to have. A comprehensive formulary would be near impossible to maintain because of the episodic nature of donated supply.

(2) An automated temperature monitoring system that records temperatures and provides continuous readings 24/7;

c. Appropriate lighting and adequate space with shelving for drug products so that no products are stored on floors.

d. The drug redistribution facility must be free of infestation of birds, rodents, insects, and vermin of any kind.

E. Drug Storage

1. Storage of donated drugs shall be in accordance with R.I. Gen. Laws § 23-25.6-5(e).

F. Record Keeping

1. A paper or electronic log for tracking redistributed drugs must be maintained at the redistribution facility.

2. The log must document the transaction date, drug name, strength, and quantity, ~~date the drug left the donor,~~ date the drug was received at the redistribution facility, and name ~~and contact information of~~ the donor, ~~and location of the drug's origin, expiration date of the drug, date pharmacist approved the drug to be redistributed, date the drug was released to Receiver, and the pharmacist's initials~~.

a. A donor or drug redistributor may contract with another party to create and/or maintain the records required under this Part on its behalf. An identifier, such as a serial number or barcode, may be used in place of any or all information required by this Part if it allows such information to be readily retrievable. Upon request by a state or federal regulator, the identifier used for requested records shall be replaced with the original information. An identifier shall not be used on patient labels when dispensing or administering a drug.

3. The drug redistributor must retain readily producible records in paper or electronic form for every drug that is redistributed with no less than the following information:

a. Name of person that received a redistributed drug;

b. Name, strength, and quantity of redistributed drug;

c. Name of State where the redistributed drug was dispensed;

~~d. Price paid for each drug that was sold by the drug redistributor pursuant to R.I. Gen. Laws § 23-25.6-5(c) and §§ 1.15.3(C)(13) and 1.15.3 (H)(4) of this Part;~~

e. Proof of prioritization of Rhode Island patients in need, in accordance with §§ 1.15.3(C)(16) and 1.15.3(H) of this Part ~~need for person who received the redistributed drug~~;

Commented [27]: We propose limiting the redistribution log to core product and transaction details, rather than requiring donor identity and multiple date fields on a line-by-line basis. Redistributors already maintain donor information in other required records and systems. A more focused log still allows regulators to follow the movement of donated drugs, while any additional information can be obtained from existing donor and dispensing records as needed.

Commented [28]: We suggest that redistributors be allowed to have flexibility in their record keeping process to capture the same information inline with regulatory requirements. We believe this will modernize the Rhode Island laws inline with other programs and reduce the paperwork burden while maintaining the same level of safety.

Commented [29]: This field does no seem well-suited for a donation program. "Price paid" is not applicable to donated drugs, and any handling/dispensing fee charged to patients is already governed by R.I. Gen. Laws § 23-25.6-5(c). If the intent is instead to capture what would have been paid outside the program, that amount is highly variable (insurance status, network pharmacy, discount programs) and often unknown to charitable pharmacies that do not bill insurance, so the value would be speculative.

f. Upon request, readily ~~Readily~~ producible data breakdowns which demonstrate the locations where redistributed drugs were dispensed; and,

g. Upon request, readily ~~Readily~~ producible data breakdowns which demonstrate the persons in need and other populations where redistributed drugs were dispensed.

h. Patient records that contain Protected Health Information (PHI) must be stored and maintained following all requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

4. All records required pursuant to the provisions of R.I. Gen. Laws Chapter 23-25.6 and this Part must be retained in hard copy or electronic format for a period of no less than two (2) years.

G. Drug Destruction/Disposal

1. Donated drugs that cannot be utilized by the redistributor must be destroyed in accordance with the requirements of R.I. Gen. Laws § 23-25.6-5(d).

2. A drug disposal log must be maintained in hard-copy or electronic form at the facility that consists of drug name, strength, quantity, and the date and method of disposal ~~date the drug left the donor, date the drug was received at the redistribution facility, the name and contact information of the donor, location of the drug's origin, expiration date of the drug, reason the drug was disposed and the pharmacist's initials~~. No other record of disposal shall be required.

3. A hazardous drug disposal service must be in place for the safe disposal of any such drugs.

H. Patient Eligibility Criteria shall be in accordance with the provisions of R.I. Gen. Laws § 23-25.6-3(a).

Commented [30]: Adding "upon request" makes clear that redistributors must be able to generate these breakdowns, but are not required to maintain or submit them on a continuous basis. This keeps the same requirement while avoiding an ongoing reporting obligation that would be burdensome without providing additional safety or compliance benefits.

Commented [31]: See above.

Commented [32]: We suggest that the rules simplify the required disposal record contents to align with other state programs. This information is already required under general record-keeping and is not necessary in a drug disposal log.

Commented [33]: We suggest this addition to make clear the information a facility must include in a disposal record to remove ambiguity and to align Rhode Island with other state programs.

Planned Parenthood
Care. No matter what.
Planned Parenthood of Southern New England

November 26, 2025

Zachary Garceau
Department of Health
3 Capitol Hill Room 403
Providence, RI 02908
Submitted electronically via rules.sos.ri.gov

RE: Rules and Regulations Pertaining to Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1)

Dear Mr. Garceau,

Planned Parenthood of Southern New England (PPSNE) is pleased to submit these comments in response to the proposed rule, "Rules and Regulations Pertaining to Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1)" released by the Department of Health (the Department) on October 28, 2025. As a trusted sexual and reproductive health (SRH) care provider, educator, and advocate, we appreciate the opportunity to provide input on this proposed rule.

Planned Parenthood is a safety net provider for the people in Rhode Island most in need of health services and serves as a leading health care provider, educator, and advocate of high-quality, affordable health care. Every year, our Providence health center provides affordable birth control, lifesaving cancer screenings, testing and treatment for STIs, abortion, and other essential care to over 9,600 Rhode Island patients through in person or telehealth visits.

The enactment of R.I. Gen. Laws § 5-19.1-36 was a critical step to reducing barriers for patients' access to essential reproductive health care, including contraception. Pharmacist-prescribed contraception is a necessary intermediate step to increase access to contraception, but access to and coverage of over-the-counter hormonal contraception should be the ultimate goal. Planned Parenthood along with the American College of Obstetricians and Gynecologists supports over-the-counter access to hormonal contraception without age restrictions and celebrated the Food and Drug Administration (FDA) approval of Opill (norgestrel0.075mg), a progestin-only birth control pill, for over-the-counter (OTC) use for people of all ages. Pharmacist prescribing of contraceptives has been proven to be safe and effective means of increasing contraceptive access.[1] Research indicates that one in three adult women[2]—and more transgender men and nonbinary people—who have ever tried to get a prescription for birth control said they faced obstacles. These barriers fall harder on people of color and Indigenous communities, young people, immigrants, LGBTQ+ folks, people working to make ends meet, people in rural communities, and people with disabilities.

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[1] Over-the-Counter Access to Hormonal Contraception https://www.acog.org/en/Clinical/Clinical%20Guidance/Committee%20Opinion/Articles/2019/10/Over-the-Counter%20Access%20to%20Hormonal%20Contraception

[2]Pharmacy2020,8,176;doi:10.3390/pharmacy8040176 *Opposition to Pharmacist Contraception Services: Evidence for Rebuttal* https://doi.org/10.1089/jwh.2015.5312

Enacted legislation increasing access to PrEP (pre-exposure prophylaxis) and PEP (post-exposure prophylaxis) also provides a critical layer of protection for Rhode Islanders by dramatically reducing the risk of HIV transmission. PrEP is over 99% effective in preventing HIV through sexual transmission and PEP is essential for preventing infection after a potential exposure.[3] Although these medications are highly effective, PrEP remains significantly underutilized.[4] As is the case with contraceptive access, barriers to care disproportionately impact people of color and Indigenous communities, young people, immigrants, LGBTQ+ folks, people working to make ends meet, people in rural communities, and people with disabilities. Pharmacist prescribing is an essential step to increase access to PrEP/PEP and decrease the risk of HIV transmission in our state.

We appreciate DOH's commitment to expanding access to birth control and PrEP/PEP and offer the following proposed amendments to the proposed regulation.

I. §1.17(C)(2)(b)

PPSNE suggests removal of the language in §1.17(C)(2)(b) stating pharmacists' option not to participate in pharmacist prescribing of contraceptives. This language is unnecessary and may confuse a pharmacy owner's obligations to adequately ensure individual access to requested or prescribed contraceptives.

It is crucial that the regulation be consistent throughout that individual access to contraceptive care is essential and patient requests for medication or care should be fulfilled when at all possible. For example, the proposed language in §1.5.2(C) (which mirrors existing language in the current regulation at §1.16.2(C)) clearly lays out both pharmacist and pharmacy owner obligations regarding individual pharmacist refusal to dispense a drug and centers patient access to prescribed medications. A similar approach to patient access could be mirrored here. If §1.17(C)(2)(b) does not reference or duplicate the approach in §1.5.2(C), then we suggest amended language below:

> A pharmacist <u>that does not meet the requirements of subsection (C)(1)</u>~~shall have the option to not participate in the prescribing of injectable hormonal contraceptives and self-administered hormonal contraceptives and~~ shall make every reasonable effort to find a pharmacist to accommodate the patient's ~~needs~~ <u>request for prescription of injectable hormonal contraceptives or self-administered hormonal contraceptives.</u>

This more patient-centered approach should also be incorporated into §1.16, regarding pharmacist prescription of PrEP/PEP.

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[3] *Pre-Exposure Prophylaxis*, HHS (Sept. 18, 2025), https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis; *Post-Exposure Prophylaxis*. HHS (Nov. 12, 2025), https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/post-exposure-prophylaxis.

[4] Amanda Hempel et al., *Pre-exposure prophylaxis for HIV: effective and underused*, CMAJ (Sept. 6, 2022), https://www.cmaj.ca/content/194/34/E1164.

II. Confidentiality Protections

PPSNE also recommends heightened privacy protections for records regarding pharmacist prescription of contraceptive and PrEP/PEP required under §1.16(F) and §1.17(E). At minimum, these sections should mirror the language in proposed §1.15.3(F)(3)(h), reiterating that PHI must be stored and maintained in compliance with HIPAA standards. However, given the particularly sensitive nature of these records, the Department should consider more stringent protections for this type of prescription information.

PPSNE appreciates the Department's careful consideration of how our state can improve and expand access to contraceptives as well as PrEP/PEP. Should you have any questions about the issues discussed in this comment, please contact Gretchen Raffa at gretchen.raffa@ppsne.org.

Thank you for your consideration,

Gretchen Raffa
Chief Policy and Advocacy Officer
Planned Parenthood of Southern New England

November 26th, 2025

Zachary Garceau
Rhode Island Department of Health
3 Capitol Hill, Room 403
Providence, RI 02908

Dear Mr. Garceau,

Empower Pharmacy's core belief is to provide access to personalized, affordable medication through innovation with a commitment to quality, service, and people. Since 2009 we have grown into the nation's largest, most advanced compounding pharmacy and outsourcing facility serving healthcare markets across the country. We proudly serve patients across the state of Rhode Island and play a pivotal role in supporting critical access to medications. I am writing to you as Director of Government Affairs to work collaboratively with the Board and to help continue our efforts to drive safe and quality access to medications for patients in Rhode Island.

We thank the Board for its efforts to update regulations to keep pace with industry advancements while protecting patient safety. Our request is for clarification on several items within the Proposed Rules: 216-RICR-40-15-1 relating to Pharmacists, Pharmacies, Manufacturers, Wholesalers, and Distributors. Our goal is to work collaboratively with the Board to ensure the proposed language is strengthened, clear, and data driven. We have included our requests for clarification below.

Section 40-15-1.8 (E)(1)(a.) Compounding of Pharmaceuticals
Recommendation Amendments:

1. SCAs shall be designed and used following United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding – Sterile Preparations (2023) incorporated by reference in § 1.2(D) of this Part. PECs or barriers isolator systems shall be located following the USP standards incorporated in § 1.2(D) of this Part.

a. BUDs will be assigned using the USP standards incorporated in § 1.2(D) of this Part, documented testing or literature and professional judgment.

Comment/Rationale: To maintain consistency with proposed amendments to section 1.8 (A)(9), we recommend adding the language above in green font. This will ensure overall consistency with assignment of BUDs to prior already proposed or existing language.

Section 40-15-1.8 (G)(4) Environmental Monitoring: Sterile Compounding
Recommendation Amendments:

A written plan and schedule for the environmental monitoring procedures for viable micro-organisms shall be established and followed. The plan shall be adequate to evaluate the various PEC and SECs classified controlled air environment areas (LAFW, barrier isolators, biological safety cabinets, buffer or clean room, and anteroom) of the designated sterile compounding area(s). Minimum frequencies for sampling shall ~~exceed~~ meet the USP standards incorporated in § 1.2(D) of this Part~~. as follows: Category I and Category II CSPs shall occur monthly and Category III CSPs shall occur weekly. For sterile compounding areas used for low and medium-risk preparations, a minimum monthly evaluation shall be required.~~

~~*For sterile compounding areas used for high-risk preparations, a weekly evaluation shall be required.*~~

Comment/Rationale: If the board has taken the stance to adopt USP Standards, it should be consistent in expectations of that standard. If minimum frequencies for sampling are to exceed USP, we ask the Board to provide burden of proof with published studies and evidence to support why exceeding USP standards is warranted. What published evidence or data are the board utilizing to showcase exceeding USP standards is superior?

Section 40-15-1.8 (G)(6) Environmental Monitoring: Sterile Compounding
Recommendation Amendments:

6. In the event of sample results being above the USP action levels in a PEC or SEC stated in the USP standards incorporated in § 1.2(D) of this Part the following shall occur:
    a. The pharmacy shall conduct a risk assessment to continue safe sterile compounding activities which may include but not be limited to the following:
        (1) Thorough terminal cleaning of all impacted compounding spaces.
        (2) Documentation and maintenance of the result that is to remain in the facilities records for at least 2 years and can be requested for review via inspection.
        ~~(2) Reducing BUD~~
        (3) Consideration of alternate locations for sterile compounding.
        ~~(4) Notification of the Board of Pharmacy for all instances of repeat actionable growth consisting of more than two (2) consecutive tests and shall provide the Board of Pharmacy with a corrective action plan.~~
        (5) The Department of Health shall have the authority to order a clean room to cease operations if it determines there is significant risk to public health. A proper notice must be given of at least 15 days by the Department of Health alongside a thorough report that details facts and objective evidence of why the determination has been made deemed "significant risk". The facility has the right to appeal the decision.

Comment/Rationale: We would ask for burden of proof as to how reducing BUDs for all products would be considered an evidence-based solution. We support the concept of conducting a risk assessment to protect patient safety and product integrity. Instead of requiring notifications to the Board with corrective action plans, we support facilities being required to document and maintain results for a span of time. This documentation can be requested at any time via inspection by the Board or Department. This would ensure accountability and long-term record keeping of risk assessments and corrections rather than one off reporting. In addition, while we support and understand the proposal to provide the Department with authority to order cease of operations, we do believe proper notice shall be given. As written, the rule is subjective and does not place accountability on the Department to provide a report or detail/evidence of why this determination could be made, which is unfair to facilities and patients. In addition, we believe in allowing for a fair process and appealing to a decision as facilities should also be granted the ability of due process.

Empower Pharmacy fully supports the Board's mission to protect the public through the advancement of quality and safety in compounding practice. We believe that regulations grounded in validated data and science-based risk assessment best serve this mission. We stand ready to collaborate with the Board,

compounding experts, and other stakeholders to design a framework that promotes both innovation and patient safety as the Board develops compounding regulations.

Sincerely,

Derek Webb

Derek H. Webb, Pharm.D., RPh
Director of Government Affairs
Empower Pharmacy
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