CONCISE EXPLANATORY STATEMENT

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement.

AGENCY: Rhode Island Department of Health

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-40-15-1

RULE TITLE: Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors

REASON FOR RULEMAKING:

The Department is amending this rule to include the following:

- A pharmaceutical redistribution program utilizing donated drugs as required by R.I. Gen. Laws Chapter 23-25.6.
- Allowing licensed pharmacists to prescribe, dispense, and administer medications for Human Immunodeficiency Virus (HIV) Pre-exposure (PrEP) and Post-exposure (PEP) Prophylaxis pursuant to R.I. Gen. Laws § 27-18-93.
- Revisions to the Collaborative Practice Agreement policies
- Updates to wording regarding staffing requirements
- Updates to wording regarding compounding to reflect updates to the language in the United States Pharmacopeia

- Revisions to R.I. Gen. Laws § 5-19.1-11, 5-19.1-15, 5-19.1-16, and 5-19.1-20 which implements the following changes:
    - Pharmacist licenses will be valid for a period of two years as R.I. Gen. Laws § 5-19.1-20 states that the renewal fee is to be paid biennially. RIDOH lengthened the licensing period to correspond to the change in the statute.
    - Pharmacy intern licenses will be valid for a minimum of five years.
    - Pharmacy technician licenses will be valid for a minimum of two years.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE: N/A

TESTIMONY AND COMMENTS:

Incorporated References

Comments Received: Noting that the correct date for USP Chapter 797 is 2023, and not 2024 as proposed.
Section involved: § 1.2(D)
Response: *As a result, this date was changed in the regulations.*

Definition of Active Ingredient

Comment Received: Noting a typographical error in §1.3(A)(3) in which the word "cure" was misspelled.
Section Involved: § 1.3(A)(3)
Response: *RIDOH has resolved this error.*

Definition of Beyond-Use-Date

Comment Received: "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."
Section Involved: § 1.3(A)(16)
Response: RIDOH conceptually agrees with this comment and *updated the terminology for BUD and will add "compounded" to the definition.*

Definition of Cancer Drug

Comment Received: "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 nonharmful 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."
Section Involved: § 1.3(A)(24)
Response: RIDOH notes that the term "cancer drug" is defined in R.I. Gen. Laws § 23-25.6-2(1). As a result, this definition will be amended to cite to the statutory definition. The wording will be amended to be a citation to R.I. Gen. Laws § 23-25.6-2(1).

Definition of Compounding

Comments Received: Requesting clarification on the compounding of non-sterile preparations and wording to confirm that medication flavoring does not constitute compounding. RIDOH notes that this subject falls under the USP's list of practices that are not subject to USP standards.
Section involved: § 1.3(A)(32)
Response: *As a result, the following is being added to § 1.3(A)(32): "The flavoring of commercially available oral liquids, tablets, and capsules to facilitate patient dosing is not considered compounding under this Part and exempt from following USP 795 standards." This post comment change simply clarifies that this type of flavoring is exempt from USP 795 standards and is in line with what the current pharmacy regs require.*

Comment Received: "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."
Section involved: § 1.3(A)(32)
Response: RIDOH disagrees with this comment as the USP does not include information covered in medication package inserts and notes that adding anything to an IV bag has always been considered compounding per USP standards. This added language does not represent a substantive change and was only added for clarification. As a result, no changes will be made to the regulations.

Definition of Manufacturing

Comment Received: "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. 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."
Section Involved: § 1.3(A)(88)
Response: RIDOH notes that § 1.3(A)(88) was not proposed for amendments, and therefore comments on this section cannot be accepted at this time.

Definition of Prescriber

Comment Received: "To provide additional clarification, CVS recommend 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~~."
Sections Involved: § 1.3(A)(123)
Response: RIDOH conceptually agrees with this comment and *removed "within this state" from the regulatory definition.*

Proposed Definitions

Comments Received: "…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." And "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:" Proposed definitions were provided.
Section Involved: § 1.3(A)
Response: RIDOH notes that these changes should be directed toward USP and the FDA.

Comment Received: "§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."

Section Involved: § 1.3(A)

Response: RIDOH conceptually agrees with this comment and *has added the proposed definition.*

Pharmacy Staffing

Comment Received: "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."" Proposed language was provided.

Section Involved: § 1.6(E)

Response: RIDOH believes the recommended changes put too much burden on the pharmacist in charge to report to their employer (and places the pharmacist in a difficult situation if their concerns fall on deaf ears), hampering RIDOH's regulatory ability. Therefore, no changes were made in response to this comment.

Compounding of Pharmaceuticals

Comment Received: "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." Consistent with these federal provisions, NNI recommends that the Board delete the exception for outsourcing facilities, as shown below." Proposed revisions to § 1.8(A)(8) were provided.

Section Involved: § 1.8(A)(8)

Response: RIDOH disagrees with the comment, particularly that this language is interpreted as running counter to FDA's regulations. Upon further examination of the language in this section, RIDOH noted, however, that the term "FDA registered" was not necessary. The elimination of this information, while technical in nature, is otherwise clearly set forth in the definition section – see "Outsourcing Facilities" – which makes clear that outsourcing facilities must comply with the FDA Rules.

Comment Received: "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. 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."
Section Involved: § 1.8(A)(8)
Response: RIDOH notes that these changes should be directed toward USP and the FDA. Upon further examination of the language in this section, RIDOH noted, however, that the term "FDA registered" was not necessary. The elimination of this information, while technical in nature, is otherwise clearly set forth in the definition section – see "Outsourcing Facilities" – which makes clear that outsourcing facilities must comply with the FDA Rules.

Comment Received: "We propose updating the language [in § 1.8(A)(9)] to include "CSNPs" (Compounded Sterile Non-Products) in addition to CSPs to ensure completeness and consistency in terminology. This addition clarifies that responsibilities apply to all compounded sterile preparations, ensuring comprehensive coverage of pharmacy operations and alignment with USP standards."
Section Involved: § 1.8(A)(9)
Response: RIDOH conceptually agrees with this comment, *but instead used the accepted, correct term "Compounded Non-Sterile Preparations."*

Comment Received: "Updates to 1.8(A)(10)…leave 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...This gap in oversight creates a pathway for foreign API suppliers to import deficient – and potentially dangerous – APIs for use in pharmacy compounded drugs. 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." Recommended wording was also provided.
Section involved: § 1.8(A)(10)
Response: RIDOH rejects this suggested revision, since the current regulatory language defers to USP 797 standards which are also referenced by the FDA. USP 797 delineates standards for APIs as follows:

- "When APIs are used:
  - Must comply with the criteria in the USP–NF monograph, if one exists
  - Must have a COA that includes the specifications (e.g., compendial requirements for quality) and that test results for the component show that the API meets expected quality
  - In the United States, must be manufactured by an FDA-registered facility

- Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction"

Comment Received: "We recommend that the Board supplement these quality requirements [in § 1.8(A)(10)] 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), 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 § 1.8(A)(10) were provided.
Section involved: § 1.8(A)(10)
Response: RIDOH is rejecting the proposed language changes since the current language defers to USP 797 standards which are also referenced by the FDA. There are citations in USP 797 regarding certificates of analysis (COAs) with respect to APIs. RIDOH continues to defer to the FDA and would leave it to that agency to adopt this proposed language should they choose to do so; below is from USP 797:

- "Must have a COA that includes the specifications (e.g., compendial requirements for quality) and that test results for the component show that the API meets expected quality
- 9.3.3 Component evaluation before use: Compounding personnel must ascertain before use that components for CSPs are of the correct identity, appropriate quality, within expiry date and have been stored under appropriate conditions.
- The following information should be used to make this determination: prescription or medication order, compounding record (CR), master formulation record (if used), vendor label(s), COA(s) of API(s) and other component(s), product labeling of any conventionally manufactured sterile products, labeling of CSP(s), and documentation of the compounding facility's storage conditions and practices."

Comment Received: RIDOH received a comment stating: "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." 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."
Section involved: § 1.8(A)(10)
Response: RIDOH is rejecting this change because the language defers to USP 797 and FDA already and refers to bulk drug substances (which are also known as Active Pharmaceutical Ingredients).

Comment Received: "We propose updating the terminology [in §1.8(A)(10)] to replace "active ingredients" with "Active Pharmaceutical Ingredients (APIs)," consistent with the recommended

new definition. This change ensures consistency with defined terminology, promotes clarity, and aligns the regulation with established USP standards and pharmacy practice."
Section involved: § 1.8(A)(10)
Response: *RIDOH agrees with this change and the language was been amended.*

Comment Received: "We recommend deleting this subsection [§1.8(C)(1)] 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."
Section Involved: § 1.8(C)(1)
Response: RIDOH wanted to make a distinction that makes it clear that the PIC is ultimately responsible, but the designated person can perform certain tasks. As a result, no changes were made.

Comment Received: § 1.8(E)(1)(a): "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. This will ensure overall consistency with assignment of BUDs to prior already proposed or existing language.
Section involved: § 1.8(E)(1)(1)
Response: RIDOH does not agree with the proposed changes as the Department intends to continue to defer to USP recommendations for BUDs. The proposed language is not in line with USP 797. As a result, no changes will be made.

Comment Received: "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."
Section Involved: §§ 1.8(F) and (G)
Response: RIDOH rejects this proposed change as it believes the current proposed language is broader and necessary for public health and safety.

Comment Received: "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."
Section Involved: § 1.8(G)(2)
Response: RIDOH rejects this proposed change as it feels public health would be more vulnerable by utilizing less stringent testing.

Comment Received: § 1.8(G)(4) "A written plan and schedule for the environmental monitoring procedures for viable microorganisms 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 Involved: § 1.8(G)(4)
Response: RIDOH rejects this suggestion as it believes in the interest of patient safety, this particular requirement in this section is necessary.

Comment Received: Multiple proposed revisions to § 1.8(G)(6).
Section Involved: § 1.8(G)(6)
Response: RIDOH does not accept these changes as it wishes to maintain the standards set forth in these regulations in the interest of ensuring patient safety.

Pharmaceutical Redistribution

Comment Received: "[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."
Section Involved: § 1.15.3(C)(17)
Response: RIDOH conceptually agrees that the right to refuse redistributed medications can be made clearer. As a result, language has been added to this section.

Comment Received: "This verification requirement [in § 1.15.3(A)(4)(a)] 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." Language changes were proposed.
Section Involved: § 1.15.3(A)(4)(a)
Response: RIDOH disagrees that the requirement would not have a negative impact on patient safety. For this reason, the proposed change is rejected.

Comment Received: "Many facility donors such as pharmacies, wholesalers and manufacturers are licensed in dozens of states. As stated [in § 1.15.3(A)(4)(b)], 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." Language changes were proposed.
Section Involved: § 1.15.3(A)(4)(b)
Response: RIDOH conceptually agrees with this change and *the proposed change has been made.*

Comment Received: "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." Language changes were proposed to § 1.15.3(A)(4)(c).
Section Involved: § 1.15.3(A)(4)(c)
Response: RIDOH does not believe that the newly proposed change provides the same safety measures as the currently proposed language, and therefore this change is rejected.

Comments Received:

- "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." Language changes were proposed to § 1.15.3(A)(4)(d).
- The allowance for the donation of temperature-controlled drugs was also suggested for § 1.15.3(A)(8).

Sections Involved: §§ 1.15.3(A)(4)(d) and 1.15.3(A)(8)
Response: Pursuant to R.I. Gen. Laws § 23-25.6-4, temperature-controlled drugs cannot be donated, and therefore, this change cannot be made.

Comment Received: "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." Language changes were proposed to § 1.15.3(A)(4)(f).
Section Involved: § 1.15.3(A)(4)(f)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "We are concerned that requiring this form [required by § 1.15.3(A)(5)] 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." Language changes were proposed.
Section Involved: § 1.15.3(A)(5)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "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." The comment also proposed adding " No additional record is required beyond the information collected pursuant to this Part and 1.15.3(F) to § 1.15.3(A)(5).
Section Involved: § 1.15.3
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "While this [the content of § 1.15.3(A)(6)] was in older drug donation laws, we have found this language unnecessary and confusing because most donations are made through common carrier." The language is recommended to be removed.
Section Involved: § 1.15.3(A)(6)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "While this [language in § 1.15.3(A)(7)] 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." The commenter proposed to remove "or if the inventory transfer requires prior authorization from the drug manufacturer."
Section Involved: § 1.15.3(A)(7)
Response: RIDOH notes that this change may result in high risk to patient safety associated with REMS drugs. For this reason, this change is rejected.

Comment Received: "We believe this limitation [not allowing the donation of over-the-counter drugs] 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." The commenter proposed to strike OTCs from the list of drugs not allowed to be donated.
Section Involved: § 1.15.3

Response: Pursuant to R.I. Gen. Laws § 23-25.6-4, "(b) The following conditions shall be met for the donation of a prescription drug to occur:…(4) The drugs shall have been prescribed legally by a licensed healthcare professional after having been properly transferred to and processed by an authorized pharmaceutical redistribution program or redistributor." Given that most OTC drugs are not prescribed, they would not meet this qualification, and if these drugs were to be accepted for donation, it would be impossible for redistributors to know which drugs should be accepted. To avoid burdening the system with drugs that will not be prescribed, RIDOH does not accept this proposed change.

Comment Received: "This language [in § 1.15.3(B)(2)] 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." Commenter recommended removing "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."
Section Involved: § 1.15.3(B)(2)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "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." Language changes were proposed to § 1.15.3(B)(2).
Section Involved: § 1.15.3(B)(2)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.
Comment Received: "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."
Section Involved: § 1.15.3
Response: RIDOH notes that these security measures are consistent with those required for other distributors/pharmacies in Rhode Island. For this reason, the proposed change is rejected.

Comment Received: "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." Language changes were proposed to § 1.15.3(B)(12).

Section Involved: § 1.15.3(B)(12)
Response: RIDOH believes the proposed change would negatively impact patient safety by allowing out of state drugs. For this reason, the proposed change is rejected.

Comment Received: Recommending the following change to § 1.15.3(B)(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~~." The commenter stated: "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."
Section Involved: § 1.15.3(B)(13)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "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." Language changes were proposed to § 1.15.3(B)(14).
Section Involved: § 1.15.3(B)(14)
Response: RIDOH believes that it is critical to have the currently proposed language written out, and therefore, the recommendation that this language be replaced with a citation to § 1.15.3(G) is rejected.

Comment Received: "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." Language was proposed to be added as § 1.15.3(B)(16).
Section Involved: § 1.15.3(B)(16)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "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." The commenter recommended that RIDOH change "solely" to "predominantly" in § 1.15.3(C)(10).
Section Involved: § 1.15.3(C)(10)
Response: RIDOH notes that the removal of 'solely' would change the scope of facilities that are allowed to be redistribution facilities, and would conflict with other requirements in the regulation that require that a redistributor cannot be located within a retail pharmacy. For these reasons, the proposed change is rejected.

Comment Received: "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." Language changes were proposed to § 1.15.3(C)(10).
Section Involved: § 1.15.3(C)(10)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "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 [in § 1.15.3(C)(16)] to avoid an arbitrary threshold while still allowing redistributors to focus on patients with need." Language changes were proposed to § 1.15.3(C)(16) and (16)(b).
Sections Involved: §§ 1.15.3(C)(16) and (16)(b).
Response: RIDOH notes that R.I. Gen. Laws § 23-25.6-3 states "Eligibility criteria for the reception of donated drugs shall prioritize individuals who are most in need." Based on the statutory requirement, this proposed change cannot be made.

Comment Received: "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." Language changes were proposed to § 1.15.3(C)(16)(a).
Section Involved: § 1.15.3(C)(16)(a)
Response: RIDOH rejects this change as it would increase the risk of tainting the drug supply chain if drugs were sent out of state. The currently proposed policies would benefit in-state patients.

Comment Received: "Subsection (a) [of § 1.15.3(C)(16)] 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." Language changes were proposed to § 1.15.3(C)(16)(b).
Section Involved: § 1.15.3(C)(16)(b).
Response: RIDOH disagrees that these requirements are redundant. The language prioritizes Rhode Islanders in section (a) and section (b) drills down farther. The documentation requirement is necessary to preserve patient safety and record keeping is required. For these reasons, RIDOH is not accepting the proposed changes.

Comment Received: "We suggest this language [added as § 1.15.3(C)(19)] 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."
Section Involved: § 1.15.3(C)(19)
Response: RIDOH notes that under the currently proposed language, there is no requirement for maintaining a minimum supply and therefore, the suggested wording is unnecessary.

Comment Received: "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." Language changes were proposed to § 1.15.3(F)(2) and "We suggest that redistributors be allowed to have flexibility in their record keeping process to capture the same information in line with regulatory requirements. We believe this will modernize the Rhode Island laws in line with other programs and reduce the paperwork burden while maintaining the same level of safety."
Section Involved: § 1.15.3(F)(2)
Response: RIDOH does not believe the retention of this information to be administratively burdensome and believes that the required information is necessary to maintain patient safety. For these reasons, RIDOH is not accepting the proposed changes.

Comment Received: Included proposed language to be added as § 1.15.3(F)(2)(a).
Section Involved: § 1.15.3(F)(2)(a)
Response: RIDOH was not able to identify the intent of this language and the goal of the addition was not clear. As a result, this change was not made.

Comment Received: "This field [§ 1.15.3(F)(3)(d)] 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." The commenter proposed that RIDOH delete § 1.15.3(F)(3)(d).
Section Involved: § 1.15.3(F)(3)(d)
Response: RIDOH considers this record to be a patient purchase record and such a record is needed to verify that the drugs were legally purchased. Removing this requirement would compromise patient safety. Therefore, this change was not made.

Comment Received: "Adding "upon request" [to §§ 1.15.3(F)(3)(f) and (g)] 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."
Sections Involved: §§ 1.15.3(F)(3)(f) and (g)

Response: RIDOH notes that the currently proposed regulations do not require distributors to submit documentation, and therefore, this change is not necessary.

Comment Received: "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." The commenter suggested adding "No other record of disposal shall be required."
Section Involved: § 1.15.3(G)
Response: RIDOH believes the proposed change would negatively impact patient safety. For this reason, the proposed change is rejected.

Comment Received: "We suggest that the rules [in § 1.15.3(G)(2)] 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." Language changes were proposed to § 1.15.3(G)(2).
Section Involved: § 1.15.3(G)(2)
Response: RIDOH believes all of the included required information is necessary for maintaining safety and traceability of donated drugs.

Record Keeping Requirements

Comments Received: Recommending that recordkeeping requirements in §§ 1.16(F) and 1.17(E) be strengthened by including references to the Health Insurance Portability and Accountability Act of 1996.
Sections Involved: §§ 1.16(F) and 1.17(E)
Response: RIDOH conceptually agrees with these comments. While language related to confidentiality is already included in the Code of Conduct section, *RIDOH opted to include language in both sections that mirrors the added language in § 1.15.3(F)(3)(h).*

Hormonal Contraceptives

Comment Received: Related to the provision in § 1.17(C)(2)(b) which allows pharmacists the option to not participate in the prescribing of hormonal contraceptives. Commenters provided proposed language to address these concerns.
Section Involved: § 1.17(C)(2)(b)
Response: RIDOH notes that R.I. Gen. Laws § 5-19.1-36(a) states: "a pharmacist *may* prescribe and dispense all short-term, FDA-approved hormonal contraceptives." The use of "may" makes the whole concept optional for pharmacists to participate. RIDOH added the language around finding another pharmacist as a safety measure for the patient should a pharmacist who does not want to participate turn down the patient. This keeps them from being left on their own to find another provider. RIDOH has opted to change the language from "and shall" to "but must."

Disciplinary Action

Comment Received: "CVS Health respectfully requests the Board strike the proposed language [in § 1.19.1(A)] 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."
Section Involved: § 1.19.1(A)
Response: RIDOH does not agree with this proposed change as it would hamper the Department's regulatory ability to hold responsible individuals accountable for the loss of controlled substances. Therefore, no changes were made in response to this comment.

Preparations vs. Products

Comment Received: "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."
Section Involved: Throughout regulations
Response: RIDOH conceptually agrees with the comment and *standardized to "compounded sterile preparations (CSPs)" and "compounded nonsterile preparations (CNSPs)" throughout the regulations.*

Comment Received: "The proposed omission of the phrase "other than as provided in the manufacturer's labeling" broadens the definition [of Compounded Sterile Preparations] 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."
Section Involved: Throughout regulations
Response: RIDOH conceptually agrees with this comment. As noted above, *the terminology for CSP has been changed to use "preparations." Additionally, the phrase "other than as provided in the manufacturer's labeling" has been added to the definition of CSP.*

CHANGES TO THE TEXT OF THE RULE:

- Changed the date of "United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding – Sterile Preparations" in § 1.2(D) to 2023.
- Typographical error in § 1.3(A)(4) was corrected.
- A definition for "Active Pharmaceutical Ingredient (API)" was added as § 1.3(A)(4).
- Removed "within this state" from the definition of "Prescriber"
- Changed "Beyond Use Dating" to "Beyond Use Date" and added "compounded" to § 1.3(A)(16)(a).
- Revised the definition of "Cancer drug" to cite to the definition in statute (R.I. Gen. Laws § 23-25.6-2(1)).
- Changed "Compounded Sterile Products" to "Compounded Sterile Preparations" and changed "products" to "preparations" where appropriate throughout the regulations
- Changed "product" to "preparation" in § 1.3(A)(30) and § 1.8(A)(10).
- Added "The flavoring of commercially available oral liquids, tablets, and capsules to facilitate patient dosing is not considered compounding under these regulations and exempt from following USP 795 standards." To the definition of Compounding (§ 1.3(A)(32)).
- The phrase "other than as provided in the manufacturer's labeling" was added to the definition of CSP (§ 1.3(A)(30)).
- Removed "FDA Registered" from § 1.8(A)(8).
- Added "and CNSPs" to § 1.8(A)(9).
- Changed "active ingredients" to "Active Pharmaceutical Ingredients (APIs)" in § 1.8(A)(10).
- Language was updated in § 1.15.3(A)(4)(b) to state "If the donor is a facility such as a pharmacy, institution, manufacturer, wholesale distributor or any other authorized donor it must provide ~~all~~ their resident state and applicable Rhode Island and federal registrations to the redistribution program in order for donated drug(s) to be accepted."
- Added "While acceptance of a redistributed drug is voluntary, the patient shall always have the option to refuse this type of medication." To § 1.15.3(C)(17).
- Revised § 1.17(C)(2)(b) to change "and shall" to "but must"
- Added the following to §§ 1.16(F) and 1.17(E): "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)."

REGULATORY ANALYSIS:

In development of this rule, consideration was given to:

1) Alternative approaches;

2) Overlap or duplication with other statutory and regulatory provisions; and

3) Significant economic impact on small business

No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.