STATE OF RHODE ISLAND
RHODE ISLAND DEPARTMENT OF HEALTH
CONCISE STATEMENT OF PROPOSED NON-TEHCNICAL AMENDMENTS
(AMENDMENTS TO EXISTING REGULATIONS)

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-1.7(b)(8), the following is a concise statement of proposed non-technical amendments to *Pharmacies, Pharmacists, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1)*

Section and Rationale/Summary of Change

• Throughout – Change from "his/her" to "their"
 	
• § 1.1 – Added "27-18-93(e), and 23-25.6-7 and Chapter 5-19.2" to the authority section.
 	
• §§ 1.2(A) through (H) – Added incorporated references
 	
• § 1.3(A)
  ○ Definitions were added for the following:
  ▪ Cancer drug
  ▪ Compounded non-sterile product
  ▪ Distributor
  ▪ Donation
  ▪ Donor
  ▪ Injectable hormonal contraceptive
  ▪ Most in need
  ▪ Non-controlled substance prescription drugs
  ▪ Out-of-state redistributor
  ▪ Pharmaceutical redistribution program
  ▪ Post-exposure prophylaxis or PEP
  ▪ Pre-exposure prophylaxis or PrEP
  ▪ Prescriber
  ▪ Receiver
  ▪ Redistributor
  ▪ Self-administered hormonal contraceptive
  ▪ Tamper-evident packaging
  ▪ Temperature-sensitive drug
  ▪ Transaction date
  ▪ Trauma informed care
  ▪ Underinsured
  ▪ Value of redistributed drug
  ○ Definitions were removed for the following:
  ▪ Collaborative Practice Committee
  ▪ Complex non-sterile drug preparation
  ▪ Compound Accountability Document
  ▪ Discontinuance
  ▪ Dispense as written
  ▪ Drugs establishment
  ▪ High risk compounded sterile products

Section and Rationale/Summary of Change
▪ Low risk compounded sterile products ▪ Manipulations ▪ Medium risk compounded sterile products ▪ Parenteral pharmacy practice ▪ Perforated unit-dose blister packages ▪ Pharmacist care services ▪ Qualified licensed professional ▪ Radiopharmaceutical quality assurance ▪ Retrospective drug review ▪ Shared pharmacy services ▪ Substance abuse facility • § 1.3(A)(15) – "Administration times (also known as "hang times") shall not exceed twenty-four (24) hours from the established beyond use dating on the dispensed product unless shorter administration times are required by the manufacturer's specifications/literature." was removed from the definition of "Beyond use dating." • § 1.3(A)(18) – "in accordance with section 1.1.7 of this Part" was removed. • § 1.13(A)(27) – Revised definition of "Collaborative pharmacy practice" to signpost to the statutory definition. • § 1.3(A)(28) – Revised definition of "Collaborative practice agreement" to signpost to the statute. • § 1.3(A)(29) – Changed "Compounded sterile preparations" to "Compounded sterile products" and updated definition. • § 1.3(A)(31) – Added "sterile or non-sterile" and "Addition of vitamins, nutrients, and/or medications to intravenous fluid bags is compounding." to the definition of "compounding." • § 1.3(A)(55) – Added "For the purposes of this Part "drug" will mean "medication" and "medication" will mean "drug" • § 1.3(A)(60) – Changed definition of "Drug therapy management" to signpost to the statute. • § 1.3(A)(83) – Changed definition of "Limited function test" to signpost to the statute. • § 1.3(A)(113) – Changed definition of "Pharmacist with advanced training and experience relevant to the scope of collaborative practice" to signpost to the statute. • § 1.3(A)(118) – Revised definition for "Practice of pharmacy" to signpost to the statute and indicate non-statutory language. • § 1.3(A)(129) – Updated RICR citation in definition for "Qualified nuclear pharmacist." • § 1.4(A)(3) – Changed "Current" to "Chapters 795, 797, and 800, incorporated by reference in §§

Section and Rationale/Summary of Change
7.2(D) – (F) of this Part above” • § 1.4.13 – Section deleted as it is redundant with current § 1.5.9. • § 1.5.1(C) – Added "A licensee must provide current contact information to the Department. Furthermore, licensees will have a continuing obligation to inform the Department of any change in their contact information." • § 1.5.1(D) – Added "All licensees subject to provisions of this Part shall conduct themselves in a professional manner and must adhere to conduct mentioned above in § 1.4(A)." • § 1.5.2(C) – Moved text from § 1.19.1. • § 1.5.9(A)(2) – Added language about re-enrollment for a pharmacy intern and updated the length of a license. • § 1.5.9(A)(3) – Added language about notification to the Department upon any changes in the pharmacy intern's status. • § 1.5.9(C)(2) – Changed section to "Has satisfied the Board that they exhibit professional integrity and ethical standards." • § 1.5.10 – Limited License heading was removed and this section was incorporated into 1.5.9. • § 1.5.10(D) – Added “Pharmacy intern licenses are non-transferrable.” This was taken from § 1.4.13. • § 1.5.14 – Updated renewal cycle for Pharmacists • § 1.5.15(A)(4) – Clarifying change to requirement language. • § 1.5.19(B)(1)(f) – Changed “USP Standards” to “USP Chapter 659 incorporated by reference in § 1.2(G) of this Part.” • § 1.6.1(E) – Added: o "including but not limited to, administration of immunizations and medications, prescribing of medications and any future pharmaceutical care functions as allowed by law," and "Should Department deem the pharmacy is inadequately staffed to provide all services they shall be subjected to disciplinary actions by the Board." o “Should the Department deem the pharmacy is inadequately staffed to provide all services, they shall be subjected to disciplinary actions by the Board. Such disciplinary action shall follow the applicable requirements outlined in § 1.16 of this Part. All hearings and reviews required by these Regulations shall be held in accordance with the provisions of R.I. Gen. Laws Chapter 42-35. ▪ 1. Inadequately staffed means an insufficient number of pharmacists and

Section and Rationale/Summary of Change
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. 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." • § 1.6.9(A) – Added "and" after (4) to indicate all procedures are required. • § 1.6.12(A)(2) – Added "and" after (d) to indicate all procedures are required. • § 1.6.15(A)(5) – Added Schedule II to section, updated C.F.R. citation and added additional citation. • § 1.7.3(D) – Updated renewal cycle and fee for nonresident pharmacies • § 1.8(A)(6) – Changed requirements for labeling to refer to USP 797 guidelines • § 1.8(A)(8) – Added "FDA Registered" • § 1.8(A)(9) – Changed "current USP standards" to "USP Chapters 795 and 797 incorporated by reference in §§ 1.2(D) and (E) of this Part." • § 1.8(A)(10) – Changed "or" to "and" to clarify that all provisions are required • § 1.8(B) – Added "or designated person(s) acting on behalf of the pharmacist-in-charge" and changed "current USP standards" to "USP Chapter 797 incorporated by reference in §§ 1.2(D) of this Part." • §§ 1.8(B)(2), (3), and (4) and 1.8(C)(1)(a), (2), and (3) – Removed sections • § 1.8(C)(2) – Added "or designated person(s) acting on behalf of the pharmacist-in-charge" • § 1.8(C)(2)(a) – Revised section to read "Compounding personnel shall have demonstrated competencies (including but not limited to media-fill) on file following United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding – Sterile Preparations (2023) incorporated by reference in § 1.2(D) of this Part." • §§ 1.8(C)(2)(a)(1) through (6), (b), (c), (d), and (e) – Removed sections • § 1.8(D) – Added "Clean Room Suite (Secondary engineering control (SEC))" to the section header • § 1.8(D)(1) – Clarifying change to language

Section and Rationale/Summary of Change
• § 1.8(D)(2) – Revised wording to read "Pharmacies shall employ the use of Primary Engineering Controls (PECs) or a barrier isolator system to prepare CSPs as defined by current USP standards. These devices shall be located in accordance with current USP standards." • § 1.8(D)(3) – Changed "cytotoxic" to "hazardous" and “current USP standards” to “USP Chapter 800, incorporated by reference in § 1.2(F) of this Part.” • §§ 1.8(D)(4) and (5) – Removed sections • § 1.8(D)(4) – Added "Sinks or water sources shall be located in compliance with current USP standards." • § 1.8(E) – Added section for "Facility Requirements – Sterile Compounding Segregated Compounding Area (SCA)" • § 1.8(F) – Added section for "Quality Assurance and Environmental Monitoring" • §§ 1.8(G)(1) through (4) – Multiple updates made to section regarding "Environmental Monitoring: Sterile Compounding" • §§ 1.8(G)(6) through (8) – Removed sections • §§ 1.8(F)(1) and (2) – Removed sections • § 1.8(F)(6) – Added section discussing "In the event of sample results being above current applicable USP action levels in a PEC or SEC the following shall occur:" • § 1.8.2(B) – Removed "microfilm, microfiche" • § 1.8.3(A) – Changed section to read “Compounding of radiopharmaceuticals for Positron Emission Tomography (PET) shall be performed in accordance with USP Chapter 825, incorporated by reference in § 1.2(H) of this Part.” • § 1.8.3(B) through (E) – Sections removed • § 1.13.1(A)(5) – License renewal updates • §§ 1.13.1(E)(1)(a) and 1.13.1(E)(2)(a) – Changed section to "Has satisfied the Board that he/she exhibits professional integrity and ethical standards." • § 1.13.1(I)(1) – Replaced wording to match statutory language. • § 1.13.1(I)(1) – (3) – Language updated to reflect statute. • § 1.14 – Section was removed and replaced with signpost to statute.

Section and Rationale/Summary of Change

• § 1.15
  ○ The name of this section was changed to “Wholesale Distributors, Redistributors, and Manufacturers”
  ○ Added “or redistributor” throughout the section.
 	
• § 1.15.1(A)(1) was revised to add a reference to R.I. Gen. Laws § 23-25.6-1 *et seq.*
 	
• 15.1.1(C)(1)(a) – Updated internal reference.
 	
• § 1.15.1(C)(1)(g) was revised to add the phrase “or of redistributions in programs established under R.I. Gen. Laws § 23-25.6-1.”
 	
• § 1.15.3 – Added as a new section regarding the Medication Redistribution Program.
 	
• § 1.16 – Added section for "Medications for Human Immunodeficiency Virus (HIV) Preexposure (PrEP) and Post-exposure (PEP) Prophylaxis"
 	
• § 1.17 – Added section for "Contraceptives"
 	
• § 1.19.1(A) – Added "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."
 	
• § 1.19.1(A)(1) – Section deleted to remove statutory duplication.
 	
• § 1.19.1(B) – Section added to address compliance during an investigation.
 	
• § 1.19.1(B)(i) – Section deleted as it was redundant with 1.19.1(B).
 	
• § 1.19.2(A) – Removed section.