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In accordance with the Administrative Procedures Act, R.I. Gen. Laws Section 42-35-3(a)(1), the following is a concise statement regarding this rulemaking for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1).

This amendment to the regulations creates an Authority section, creates definitions for ACPE, actively reports, automated filling system, automated pharmacy system, beyond use dating, biosimilar, complex non-sterile drug preparation, compounding accountability document, consultant pharmacist, dispensing error, dispensing error analysis, DEM, electronic medical record, emergency drug kit, hazardous drug, immunizing pharmacist, interchangeable biological product, limited-function test, medical administration record, NABP, NIOSH, outsourcing facility, patient safety organization, pharmaceutical organization, pharmacist care services, PTCB, restricted pharmacy, shared pharmacy services, and sterile compounding, revises existing definitions, creates a code of professional conduct for pharmacists and pharmacies, provides for a waiver of certain requirements for Block Island, removes statutory reiteration, corrects state/federal statutory and regulatory citations, revises licensure requirements, revises collaborative pharmacy practice training requirements, clarifies requirements for repackaging medication, implements requirements for continuous quality improvement, clarifies requirements regarding biosimilar interchanges, clarifies requirements for medication orders, implements requirements for secure delivery areas, clarifies requirements for compounding pharmacies, clarifies requirements for delegation of immunization, allows for performance of limited function tests, clarifies collaborative practice requirements, clarifies requirements for wholesalers, distributors, and manufacturers, and removes superfluous language.

In response to public comment, §§ 1.8.2 (Automated Medication Filling Systems), 1.8.3 (Use of Automated Pharmacy Systems at Remote Locations, 1.9(H) (regarding contraceptives), 1.11 (Telepharmacy), 1.13(K) (Remote Technician Practice), and 1.13(L) (Technician II Verification Program) of the regulations posted for public comment have been removed from the regulations, in order to allow for further discussion and community review with regulatory stakeholders.

In response to public comment, the definition for ACPE in § 1.2(A)(1) was revised to the correct name for that organization. This revision is reflected throughout the regulations.

In response to public comment, the definition for Beyond Use Dating in § 1.2(A)(13)(b) was revised to account for administration times of dispensed products.

In response to public comment, § 1.4.21(A)(1)(c) has been revised to remove the thirty-four (34) day threshold for labeling of drugs.

In response to public comment, § 1.5.1(E) was created to provide requirements for pharmacies to maintain an adequate number of personnel, and provide evidence thereof to the Department upon request.

In response to public comment, § 1.5.13(F)(3) was revised to remove the requirement for issuance of zero reports if no dispensing errors have occurred within the past thirty (30) days.

In response to public comment, the proposed allowance for patient counseling in written form in § 1.5.14(A) has been removed.

In response to public comment, § 1.5.27(C)(1)(f)(3) was revised to state that nurses in nursing facilities shall be considered authorized designated agents for the purposes of this section.

In response to public comment, § 1.7(A)(8) was revised to state the exception for Outsourcing Facilities, consistent with other provisions of this section.

In response to public comment, § 1.7(D)(3) was revised to require compounding of cytotoxic preparations in accordance with current USP requirements.

In response to public comment, §§ 1.11(B)(8)(a) and (b) were revised to require the authorization of the immunizing pharmacist.

In response to public comment, §§ 1.11.2(B)(1)(i) and (2) were revised to remove references to interns or technicians performing limited function tests, in alignment with statute.

In response to public comment, § 1.13(K) was revised to provide for adequate access by pharmacists to vital signs.

In response to public comment, § 1.15.3 was created to provide requirements for submission of and responses to complaints.

During public comment, it was suggested that the regulations be revised to implement references to the National Healthcarer Association (NHA). RIDOH has determined that these suggested revisions will not be implemented because provisions of the regulations regarding other national certifying organizations as may be approved by the Board are sufficient to allow for use of NHA tests/standards.

During public comment, it was suggested that the fee for pharmacist licensure be reduced, and that the Board of Pharmacy (BOP) and Rhode Island Society of Health-System Pharmacists (RISHP) be included in future discussions regarding pharmacist licensure fees in Rhode Island. RIDOH has determined that this suggested revision will not be implemented because the fee for pharmacist licensure is not contained in these regulations, and inclusion of BOP and RISHP in future discussions of fees will be facilitated through the regulatory process for revisions to the Fee Structure regulations.

During public comment, it was suggested that the regulations be revised to make dispensing errors analysis non-discoverable. RIDOH has determined that this suggested revision will not be implemented because it is already provided for in federal law regarding patient safety organizations.

During public comment, it was suggested that § 1.5.13(F)(2)(a)(3) be revised to require timely notification of the prescriber, instead of the current requirement that pharmacists immediately

assure that the prescriber is notified. RIDOH has determined that this suggested revision will not be implemented because requiring immediate notice is more protective of patient safety.

During public comment, it was suggested that the prohibition on dispensing process validation for pharmacy interns be removed. RIDOH has determined that this suggested revision will not be implemented because it believes that the cited prohibition is necessary to prevent pharmacy interns from operating outside of their appropriate scope of service and without supervision from pharmacists.

During public comment, it was suggested that collaborative pharmacy practice training and continuing education requirements be removed. RIDOH has determined that this suggested revision will not be implemented because it believes that continuing education and training regarding collaborative pharmacy practice is necessary to assure understanding of physician-pharmacist relationships between the respective parties, and assuring continued patient safety in the context of such relationships.

During public comment, it was suggested that the regulations be revised to provide for additional authorities for pharmacists, including direct prescribing for treatments when a CLIA waived test comes back positive (Flu/Strep), for gaps in care (Statin in diabetes), smoking cessation, DME products as well as the ability to expand therapy by one (1) fill under the prescriber's name. RIDOH has determined that these suggested revisions will not be implemented because they go beyond the current statutory authority accorded to RIDOH to create regulations.

During public comment, it was suggested that § 1.3(A)(10) be revised to provide an exception thereof for faxed refill requests and compounding prescriptions. RIDOH has determined that these suggested revisions will not be implemented because the suggested exception would defeat the purpose of this section in preventing undue marketing content being implemented in prescription blanks.

During public comment, it was suggested that the regulations be revised to remove allowance of offering to counsel being delegated by the pharmacist. RIDOH has determined that this suggested revision will not be implemented because it could be an undue burden on pharmacy operations to require pharmacists to provide the offer to counsel to every patient, and such allowance does not abrogate the pharmacist's obligation to actually perform counseling once requested by a patient.

During public comment, it was suggested that the regulations be revised to implement mandatory live verbal counseling for all new medication prescribed to an existing patient and any medications where the dose, strength, route of administration, or directions for use has changed. RIDOH has determined that this suggested revision will not be implemented because mandating such counseling could be prohibitive to patient choice in receiving such information, and could cause undue disruption of pharmacy operations.

During public comment, it was suggested that § 1.5.19(A) be revised to allow prescribers to request that biosimilar interchange not occur. RIDOH has determined that this suggested revision will not be implemented because it believes that control over biosimilar interchange, and the cost considerations thereof, should remain solely within the patient's discretion.

During public comment, it was suggested that § 1.11.1(B)(8) be revised to prohibit delegation of preparation of vaccines or determination of patient eligibility. RIDOH has determined that this

suggested revision will not be implemented because it believes the requirements of § 1.11.1(B)(8)(a) and (b) regarding training of delegates is sufficiently protective to public health.

During public comment, it was suggested that § 1.11.2(B)(2) be revised to require reporting of results within 48 hours of test completion. RIDOH has determined that this suggested revision will not be implemented because the current requirement for reporting within a reasonable timeframe is sufficient to ensure patient safety.

During public comment, opposition was registered regarding removal of language regarding completion of continuing education (CE) as live hours. RIDOH has determined that this suggested revision will not be implemented because the proposed removal will allow more flexibility for technician CE fulfillment.

During public comment, it was suggested that the regulations be revised to reference requirements of USP 795 and 797 and strike language from the regulations that is proposed to be stricken in those standards. RIDOH has determined that this suggested revision will not be implemented because both the USP 795 and 797 are not yet finalized and it would be premature to implement proposed requirements.

During public comment, it was suggested that § 1.5 be revised to require biennial inspection. RIDOH has determined that this suggested revision will not be implemented because limiting inspections to once every two years would not be sufficiently protective for public health, and could hamper RIDOH's efforts to maintain licensee compliance with the regulations.

During public comment, it was suggested that § 1.7(D)(4) be revised to strike demarcation line requirements. RIDOH has determined that this suggested revision will not be implemented because this requirement is necessary to maintain the integrity of compounding operations.

During public comment, it was suggested that continuing education (CE) timeframes be aligned with licensure renewal timeframes. RIDOH has determined that this suggested revision will not be implemented because allowing for CEs between January 1st and December 31st aligns with other states' requirements for such and eases transferability of licenses between states.

During public comment, it was suggested that the regulations be revised to require a one to two (1:2) staffing ratio for pharmacists to verification technicians. RIDOH has determined that this suggested revision will not be implemented because the proposal is addressed with the removal of technician verification provisions and the new requirement for adequate staffing created in § 1.5.1(E).

In the 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 this rule justify its costs.