



# Rhode Island Pharmacists Association

1643 Warwick Avenue, PMB 113, Warwick, RI 02889

Ph:(401) 684-1874 Fax: (866) 563-9212

info@ripharmacists.org

To whom it may concern,

The Rhode Island Pharmacists Association and the Rhode Island Society of Health-System Pharmacists would like to provide a comment of concern regarding the definition of “Compounding” and “Compounding Sterile Preparations” recently added to the proposed Licensure and Discipline of Physicians Regulations (**216-RICR-40-05-1**).

By adding these definitions to the Physician Regulations, a Physician would be able to prescribe, prepare, and administer the medication. This raises concerns for medication safety since physicians, nurse practitioners, and physician assistant prescribers are not trained in the practice of compounding as it is not part of their college curriculum or post-graduate training. In addition, this introduces unnecessary risks and removes interprofessional checks and balances of the prescribing, compounding, dispensing, and administration process that exist for patient safety.

Compounding is not a benign process even with proper checks and balances as evidenced by the New England Compounding Center (NECC) multi-state meningitis outbreak in September 2012 (<https://www.cdc.gov/hai/outbreaks/meningitis.html>). This event caused **illness in 798 individuals** and resulted in the **death of more than 100 people** which prompted additional training and regulatory requirements to be implemented for the profession of pharmacy.

Additionally, this updated regulation contradicts Rhode Island Statute (**216-RICR-40-15-1.7**) which states that a Pharmacist-in-Charge shall be responsible for meeting the compounding standards (United States Pharmacopeia (USP) 797 and 800) of that facility. 216-RICR-40-15-1.7 reads as follows “Sterile Compounding. The Pharmacist-in-Charge shall ensure the (compounding) activities are accomplished for all sterile compounding as outlined in current USP Standards.” Therefore, prescribers providing and conducting sterile compounding activities would need to have a Pharmacist-in-Charge at their location to ensure compliance to USP Standards.

In conclusion, we are requesting the definitions “Compounding” and “Compounding Sterile Preparations” be removed from the Licensure and Discipline of Physicians Regulations since the added definitions negatively impact patient safety and contradicts current Rhode Island Statute without requirement of a Pharmacist-in-Charge.

The Rhode Island Pharmacists Association and Rhode Island Society of Health Systems Pharmacist are open to providing additional feedback and solutions to improve the language of this Regulation.

Professionally yours,

Rhode Island Pharmacists Association

Chris Federico PharmD, BCACP  
President

Mark Lorson PharmD, BCACP, BCGP  
Legislative Chair

Rhode Island Society of Health Systems Pharmacy

Margaret Charpentier PharmD, BCPS  
President

Raymond Iannuccillo PharmD, BCPS, BCOP  
Legislative Chair

