Position Paper
Rhode Island Board of Medical Licensure and Discipline Sterile Compounding
Approved 5/9/2012

The Rhode Island Board of Pharmacy and Board of Medical Licensure and Discipline have agreed to the following position statement concerning compounding of drugs either in a pharmacy, physician office, or other health care facility. Recent Board inspections of compounding facilities have lead to the conclusion that an absence of recognized sterile compounding guidelines is compromising patient and worker safety. Some of the more Apparent problems include a general lack of appropriate cleanliness in a sterile compounding setting, inadequate procedures for maintaining sterility during the compounding process, inappropriate worker protective apparel which increases the risk of contamination of compounded drug products and a lack of appreciation for the risk to patient and worker safety while compounding sterile products.

In order to provide clarity among compounding professionals the Boards offer this definition from RI law: "Compounding" means the act of combining two (2) or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner, patient, and pharmacist.[i] Any practitioner who lawfully engages in "compounding" of drugs should meet the minimum safety standards for this practice.[ii] USP 797 is the nationally recognized standard for minimum practice and quality for compounded sterile preparations ("CSPs") for drugs and nutrients based on current scientific information.[iii] Evidence shows that by applying USP 797 to practitioners engaging in sterile compounding of drug products, desired patient outcomes could be better effectuated. Promulgation of rules and regulations that increase desired patient outcomes is consistent with the intent of the legislature.[iv]

The objective of USP 797 is to "describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients… (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in CSPs."[v] Patient risk is greatest when there is direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources."[vi] USP 797 is intended not only for pharmacy personnel, but is "intended to apply to all persons who prepare CSPs and all places where CSPs are prepared" including hospitals, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported.[vii]

Under USP 797, qualified licensed health care professionals who supervise compounding are responsible for ensuring compounding personnel are: adequately skilled, educated, instructed, and trained to correctly perform sterile compounding; drug ingredients are correct in quality and amount; opened or partially opened containers are properly stored; sterilization of certain CSPs in order to minimize bacterial endotoxins; proper aseptic technique is used while maintaining labeled strength of ingredients; compounding equipment is clean, accurate, and effective; potential for harm from added substances are evaluated before dispensing and administration; appropriate packaging selection to maintain sterility and strength; maintaining sterility when compounding environment is used; proper labeling of CSPs; procedures conform to sequence and quality established for the specified CSP; and deficiencies in compounding can be rapidly identified and corrected.[viii]

The Rhode Island Board of Medical Licensure and Discipline has established that non-sterile and sterile compounding performed by practitioners must conform to current standards of practice as set forth in USP 795 and 797.

[i] General Laws of Rhode Island §5-19.1-2
[ii] General Laws of Rhode Island §5-19.1-2
[iii] The United States Pharmacopeial Convention, *<797> Pharmaceutical Compounding –Sterile Preparations (2008),* available at www.doh.wa.gov/hsqa/fsl/crs/pdf/USP797summary.pdf (last accessed 2/20/2012)
[iv] General Laws of Rhode Island §5-19.1-1
[v] The United States Pharmacopeial Convention, *<797> Pharmaceutical Compounding –Sterile Preparations (2008),* available at www.doh.wa.gov/hsqa/fsl/crs/pdf/USP797summary.pdf (last accessed 2/20/2012)
[vi] The United States Pharmacopeial Convention, *<797> Pharmaceutical Compounding –Sterile Preparations (2008),* available at www.doh.wa.gov/hsqa/fsl/crs/pdf/USP797summary.pdf (last accessed 2/20/2012)
[vii] The United States Pharmacopeial Convention, *<797> Pharmaceutical Compounding –Sterile Preparations (2008),* available at www.doh.wa.gov/hsqa/fsl/crs/pdf/USP797summary.pdf (last accessed 2/20/2012)
[viii] The United States Pharmacopeial Convention, *<797> Pharmaceutical Compounding –Sterile Preparations (2008),* available at www.doh.wa.gov/hsqa/fsl/crs/pdf/USP797summary.pdf (last accessed 2/20/2012)