

SOUTH CAROLINA STATE BOARD OF MEDICAL EXAMINERS

ADVISORY OPINION ON THE PRACTICE OF COMPOUNDING DRUGS BY PHYSICIANS

S.C. Code Ann. § 40-47-10(I)(1) provides that the South Carolina State Board of Medical Examiners (“Medical Board”) may publish advisory opinions and position statements relating to practice procedures or policies authorized or acquiesced to by any agency, facility, institution, or other organization that employs persons authorized to practice under this chapter to comply with acceptable standards of practice. Further, S.C. Code Ann. § 40-47-10(I)(5) provides that the Medical Board may use minimum standards as a basis for evaluating safe and effective medical practice.

On August 6, 2018, during its regularly-scheduled meeting, the Medical Board was presented with concerns regarding the practice of compounding medications by physicians. Specifically, the Board was advised that staff with the South Carolina Department of Labor, Licensing and Regulation (“LLR”) received reports that some physicians are compounding medications in an unsafe manner. Additionally, LLR staff indicated that they received questions from physicians about the appropriate standard of care for compounding medications. The Board also heard from a compounding pharmacist, who outlined the potential harm to the citizens of South Carolina that could occur from physicians compounding drugs in an unsafe manner.

The Board viewed this information as an opportunity to educate its licensees on the standard of care for compounding drugs. The compounding of drugs is commonly associated with the practice of pharmacy; however, S.C. Code Ann. § 40-43-60(H) of the South Carolina Pharmacy Practice Act provides that nothing in the Act “shall be construed to require a permit of or to prevent a licensed [physician] from [. . .] compounding drugs used for administration in the regular course of professional practice.”

The Board recognizes that the United States Pharmacopeial Convention (“USP”) is widely recognized as establishing the standard of care for the compounding of drugs. USP is a nonprofit scientific organization founded in 1820 that develops and disseminates public compendial quality standards for medicines and other articles. The compounding of drugs is generally classified into two categories: sterile and nonsterile. USP has published General Chapter 795 (“USP 795”), which establishes standards for compounding quality nonsterile preparations and General Chapter 797 (“USP 797”), which establishes standards for compounding quality sterile preparations.

The Board voted to adopt these standards, USP 795 and USP 797, as the appropriate standards of care by which a physician should abide when compounding nonsterile and sterile drugs, respectively.