

Georgia State Board of Pharmacy

**ADVISORY**

**COMPOUNDING PHARMACIES AND PHARMACISTS**

**October 30, 2012**

The Georgia State Board of Pharmacy reminds pharmacies, pharmacists and medical practitioners who engage in compounding in this state that Board Rule 480-11 requires that all actions be performed in accordance with United States Pharmacopeia (USP) Standards. USP<795> addresses the practice for Non-Sterile Compounding and USP Standard <797> addresses the practice for Sterile Compounding Preparations

Georgia Pharmacies, Pharmacists and Practitioners are also reminded that Georgia law (O.C.G.A. Title 26, Chapter 4, Section 80) and Georgia State Board of Pharmacy Rules and Regulations (Chapter 480) require that medications can only be dispensed pursuant to the receipt of a valid prescription from an authorized practitioner for a specific patient. This prescription must be valid as defined under Georgia laws, rules and regulations.

Additionally, if any pharmacy, pharmacist, or practitioner is in receipt of medication which has been dispensed and labeled for a specific patient, that medication cannot be lawfully utilized, administered, or dispensed to any patient except the one whose name appears on the prescription label (O.C.G.A. 16-13, 26-4)

Further, Georgia laws (O.C.G.A. 26-4-113, 115) and Rules (480-7, -11) prohibit compounding pharmacies from distributing bulk compounded medications to other health care providers without having a drug wholesale permit. These same laws and rules prohibit any pharmacy or medical practitioner in this state from purchasing drugs from any firm except one licensed in Georgia as a Drug Wholesaler and/or Manufacturer.

Board licensees are advised to review USP standards and Board Rule Chapter 480-11 to assure that compounding pharmacy practice is conducted in accordance with state and federal laws and regulations, as required by The Georgia Pharmacy Practice Act (O.C.G.A. 26-4) and Board Rules and Regulations (Chapter 480-5).

The Board advises that all compounding pharmacies and pharmacists should obtain and complete the respective USP Gap Analysis Tool(s) (<sup>®</sup>International Journal of Pharmaceutical Compounding) for USP <795> and <797> as provided below, to determine preliminary compliance with the above-referenced USP standards.

<http://www.ijpc.com/USP/>

The Board appreciates your prompt attention to this important advisory.