



PCABTM Principles of Compounding

Compounding is the preparation of components into a drug product either as the result of a practitioner's prescription drug order based on a valid **practitioner/patient/pharmacist relationship** in the course of professional practice, or for the purpose of, or as an incident to, research, teaching, or chemical analysis that are not for sale or dispensing. Compounding is a part of the practice of pharmacy subject to regulation and oversight from the state boards of pharmacy.

Compounded medication may be dispensed to prescribers for office use, where applicable state law permits. Office use does not include prescribers reselling compounded medications.

Compounding may be conducted in anticipation of receiving prescription orders when based on routine, regularly observed prescribing patterns. Anticipatory compounding is limited to reasonable quantities, based on such patterns.

Compounding does not include the preparation of copies of commercially available drug products. Compounded preparations that produce, for the patient, a **significant difference** between the compounded drug and the comparable commercially available drug product or are determined, by the prescriber, as necessary for the medical best interest of the patient are not copies of commercially available products. "Significant" differences may include, for example, the removal of a dye for a medical reason (such as an allergic reaction), changes in strength, and changes in dosage form or delivery mechanism. Price differences are not a "significant" difference to justify compounding.

Both the prescriber (via the prescription) **and the patient** (via the label) should be aware that a compounded preparation is dispensed.

The pharmacy may advertise or otherwise promote that it provides prescription drug compounding services. Such advertising should include only those claims, assertions, or inference of professional superiority in the compounding of drug products that can be independently and scientifically substantiated.