

(13) Elements of Quality Control; (14) Verification of Automated Compounding Devices for Parenteral Nutrition Compounding; (15) Finished Preparation Release Checks and Tests; (16) Storage and Beyond-Use Dating; (17) Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs; (18) Patient or Caregiver Training; (19) Patient Monitoring and Adverse Events Reporting; (20) Quality-Assurance Program; (21) Abbreviations and Acronyms; and four appendices. The overall objective of the chapter is to describe conditions and practices to prevent harm, including death, to patients that could possibly result from microbial contamination, excessive bacterial endotoxins, variability in the intended strength and composition, unintended chemical and physical contaminants, and ingredients of inappropriate quality in CSPs (10).

National Association of Boards of Pharmacy

“The Good Compounding Practices Applicable to State-Licensed Pharmacies” (11), developed by the National Association of Boards of Pharmacy, discusses eight recommendations. The subparts include (A) General Provisions and Definitions; (B) Organization and Personnel; (C) Drug Compounding Facilities; (D) Equipment; (E) Control of Components and Drug Product Containers and Closures; (F) Drug Compounding Controls; (G) Continuous Quality Improvement Program; (H) Labeling Control of Excess Products; and (I) Records and Reports.

Subpart (A), General Provisions, provides two important definitions (11):

“Compounding” means the preparation of Components into a Drug product (a) as the result of a Practitioner’s Prescription Drug Order based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (b) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding includes the preparation of limited amounts of Drugs or Devices in anticipation of receiving Prescription Drug Orders based on routine, regularly observed prescribing patterns.

“Manufacturing” means the production, preparation, propagation, conversion, or processing of

a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a Drug or Device or the labeling or relabeling of the container of a Drug or Device for resale by pharmacies, Practitioners, or other Persons.

Subpart (B), Organization and Personnel, discusses the responsibilities of pharmacists and other personnel engaged in compounding. It also stresses that only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation.

Subpart (C), Drug Compounding Facilities, describes the areas that should be set aside for compounding, either sterile or not. Special attention is required for radiopharmaceuticals and for products requiring special precautions to minimize contamination, such as penicillin.

Subpart (D), Equipment, states that equipment used must be of appropriate design, adequate size, and suitably located to facilitate operation for its intended use and for its cleaning and maintenance. If mechanical or electronic equipment is used, controls must be in place to ensure proper performance.

Subpart (E), Control of Components and Drug Product Containers and Closures, describes the packaging requirements for compounded products.

Subpart (F), Drug Compounding Controls, discusses the written procedures to ensure that the finished products are of the proper identity, strength, quality, and purity, as labeled.

Subpart (G), Labeling Control of Excess Products and Records and Reports, describes the various records and reports that are required under these guidelines.

Many individual states have used this model and implemented their own version. All pharmacists and pharmacy students should become familiar with the individual state requirements in the state in which they practice.

It will be important as compounding pharmacy increases to ensure reasonable agreement between the national and state agencies so pharmacists will have a set of guidelines within which they can work to