

Table 3 Current Compounding Guidelines

National Association of Boards of Pharmacy Model Rules

Model Rules for Pharmaceutical Care

Good Compounding Practices Applicable to State Licensed Pharmacies

Model Rules on Sterile Preparations

Note: A current copy of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* can be obtained from: National Association of Boards of Pharmacy, 700 Busse Highway, Park Ridge, IL 60068; Phone 708/698-6227; or through the NABP internet site at www.nabp.org.

American Society of Health-System Pharmacists Guidelines and Technical Assistance Bulletins

ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals

ASHP Guidelines: Minimum Standard for Pharmaceutical Services in Ambulatory Care.

ASHP Technical Assistance Bulletin on Compounding Nonsterile Products in Pharmacies

ASHP Technical Assistance Bulletin on Quality Assurance for Pharmacy-prepared Sterile Products

ASHP Technical Assistance Bulletin on Handling Cytotoxic Hazardous Drugs

ASHP Technical Assistance Bulletin on Pharmacy-prepared Ophthalmic Products

Note: The complete documents can be accessed on the ASHP web site at www.ashp.org.

United States Pharmacopeia 27 – National Formulary 22

Chapter +795, *Pharmaceutical Compounding—Nonsterile Preparations* (formerly

Chapter +1161, *Pharmacy Compounding Practices*)

Chapter +797, *Pharmaceutical Compounding—Sterile Preparations* (formerly Chapter +1206, *Sterile Drug Products for Home Use*)

Chapter +1075, *Good Compounding Practices*

Chapter +1151, *Pharmaceutical Dosage Forms*

Chapter +1160, *Pharmaceutical Calculations in Prescription Compounding*

Chapter +1191, *Stability Considerations in Dispensing Practice*

Numerous formulation monographs

Note: A current edition of the *USP/NF* is available for purchase by contacting USP at 301-816-8113 or on the internet at www.usp.org. Individual selected chapters on compounding may also be purchased.

References

1. Subramaniam V, Sokol G, Zenger V, Anderson K, Scott G, Brown R, Hoffman R, Cantilena L. Survey of Drug Products Compounded by a Group of Community Pharmacies: Findings from a Food and Drug Administration Study. Rockville, MD: Food and Drug Administration, www.fda.gov/cder/pharmcomp/communityPharmacy/default.htm Accessed December 2002.
2. National Association of Boards of Pharmacy Good Compounding Practices Applicable to State Licensed Pharmacies. National Association of Boards of Pharmacy. Park Ridge, IL, 2001; 151.
3. The 2004 United States Pharmacopeia 27/National Formulary 22. Rockville, MD: The United States Pharmacopeial Convention, Inc., 2003; 2498.
4. Thompson, Secretary of Health and Human Services, et al. v. Western States Medical Center et al. 535 U.S. 2 (2002).
5. Hallissy E, Russell S. Who's mixing your drugs? Bad medicine: Pharmacy mix-ups a recipe for misery; some drugstores operate with very little oversight. San Francisco Chronicle. June 23, 2002: A-1.
6. *Exophiala* infection from contaminated injectable steroids prepared by a compounding pharmacy — United States, July–November 2002. Centers for Disease Control and Prevention. MMWR 2002; 51:1109–1112.
7. Bloom MZ. Compounding in today's practice. Am Pharm 1991;31:31–37.
8. Conlan MF. Compounding versus manufacturing. Where is the line? Drug Topics 1992;136:46–51.

9. FDA Compliance Policy Guide 77132.16. Chapter 32—Drugs General—Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs of Human Use by State-licensed Pharmacies. Rockville, MD: U.S. Department of Commerce, National Technical Information Service, March 1992.
10. Public Law 105-115. Section 127. Application of Federal Law to Practice of Pharmacy Compounding.
11. Guidance for FDA staff and industry, Compliance policy guides manual, Sec. 460.200 Pharmacy compounding. Rockville, MD: Food and Drug Administration Center for Drug Evaluation and Research, May 2002, www.fda.gov/ora/compliance_ref/cpg/default.htm. Accessed December 2002.
12. 2003 Annual Meeting and Compounders on Capitol Hill. International Academy of Compounding Pharmacists. Sugar Land TX., 2003; 4.