dosage forms, such as lozenges, gumdrops, popsicles, and lollipops.
5. Some medications are not very stable and require preparation and dispensing every few days; they are not suitable to be manufactured products.
6. Many physicians desire to deliver products in innovative ways, and pharmacists can work with them to solve medication problems.
7. Most products are not available for veterinary patients and must be compounded.
8. Home health care and the treatment of an increasing number of patients at home have resulted in many community pharmacies and home health care pharmacies preparing sterile products for home use.
9. Hospice care has resulted in new approaches to pain management and higher concentrations and combinations of drugs that are now used.
10. Many drugs are reported in the literature but are not yet manufactured, so pharmacists can compound them for their physicians' and patients' use.

As the extent of compounding increased, many standard-setting agencies and regulatory bodies wanted to ensure quality compounded products; consequently, there was a lot of activity during the mid-1990s to establish guidelines for pharmaceutical compounding.

U.S. Pharmacopeia–National Formulary

In 1990, the U.S. Pharmacopeial Convention initiated a number of activities to bring the compounding provisions of the USP–NF up-to-date. Chapters related to pharmacy compounding were developed and published starting in 1996 (10). In addition, the first of the compounding monographs became official in 1998, and they provide a tested, uniform formulation with valid beyond-use dating.

The USP–NF presently contains the following chapters directly related to pharmaceutical compounding:

<795> Pharmaceutical Compounding-Nonsterile Preparations

<797> Pharmaceutical Compounding-Sterile Preparations

<1160> Pharmaceutical Calculations in Prescription Compounding

<1163> Quality Assurance in Pharmaceutical Compounding

<1176> Prescription Balances and Volumetric Apparatus

In addition, the following are supporting chapters:

<85> Bacterial Endotoxins Test

<1151> Pharmaceutical Dosage Forms

Additional chapters on Compounding for Investigational Studies and Compounding with Hazardous Drugs are being developed. Our present discussion will highlight chapters <795> and <797>. As these chapters are numbered less than <1000>, they are enforceable standards and must be followed.

Chapter <795> Pharmacy Compounding-Nonsterile Preparations contains the following sections: (1) Introduction; (2) Definitions; (3) Categories of Compounding; (4) Responsibilities of the Compounder; (5) Compounding Process; (6) Compounding Facilities; (7) Compounding Equipment; (8) Component Selection, Handling and Storage; (9) Stability Criteria and Beyond-Use Dating; (10) Packaging and Drug Preparation Containers; (11) Compounding Documentation; (12) Quality Control; (13) Patient Counseling; (14) Training; and (15) Compounding for Animal Patients. The purpose of this chapter is to include information to enhance the compounder's ability to extemporaneously compound preparations that are of acceptable strength, quality, and purity.

Chapter <797> Pharmacy Compounding-Sterile Preparations contains the following sections: (1) Definitions; (2) Responsibility of Compounding Personnel; (3) CSP Microbial Contamination Risk Levels; (4) Personnel Training and Evaluation in Aseptic Manipulation Skills; (5) Immediate-Use CSPs; (6) Single-Dose and Multiple-Dose Containers; (7) Hazardous Drugs as CSPs; (8) Radiopharmaceuticals as CSPs; (9) Allergen Extracts as CSPs; (10) Verification of Compounding Accuracy and Sterility; (11) Environmental Quality and Control; (12) Suggested Standard Operating Procedures;