

# Changes to USP <797>, addition of <800> having enormous impact on hospital pharmacies

*Beginning on December 1, 2019, all hospital pharmacies are expected to comply with USP <797> and USP <800>. For most hospital pharmacies, enforcement of these chapters means big changes to practice, budget, and physical environment. Understanding <797> and <800> is necessary to ensure that hospital pharmacies are compounding safe parenteral products, and that staff involved with procurement, storage, handling, compounding, and administration are safe from potentially harmful exposure.*

USP <797> defines how sterile compounding must occur within a hospital pharmacy. The primary focus is on ensuring sterility and stability of compounded products prepared for parenteral administration. This goal is achieved by defining a plethora of practices and environmental requirements by which hospital pharmacies must abide. These practices can be grouped into two categories: quality assurance and quality practice.

Quality assurance activities specify, among a host of other tasks, how often surface sampling must occur, how often compounding staff technique needs to be audited, and how often the environment must be cleaned. They can also include environmental controls, physical space requirements, and equipment requirements.

This change often costs hundreds of thousands of dollars in capital, with additional tens of thousands each year coming out of the operating budget. In addition, these construction projects are often complicated by the physical constraints of aging hospital buildings.

Quality practice activities include expectations for pharmacy staff on the proper ways to perform all aspects of sterile product compounding. Most of these expectations will be familiar to those who have historically performed sterile compounding. However, additional cleaning requirements from the updated chapters will add time to the duration of the process. As such, it is incumbent upon the pharmacy to create efficient workflows in departments where the timely procurement of compounded parenteral products is a matter of life and death. Often, this means having emergency departments compound their own products in certain situations. Pharmacy managers must work with emergency department managers to ensure that compliance with the updated chapters is maintained.

In addition to adhering to all of <797>, hospital pharmacies that plan to compound hazardous drug products must also adhere to <800>. This chapter focuses primarily on reducing or eliminating exposure of workers to hazardous drugs. It emphasizes the creation of a physical space that maintains a specific set of parameters, including negative pressure. It also defines the handling and storage of hazardous drugs. It is important to remember that compliance with this chapter helps keep our team members safe not only in the pharmacy, but in patient care areas as well.

*For the full article, please visit [www.pharmacytoday.org](http://www.pharmacytoday.org) for the September 2019 issue of Pharmacy Today.*

