USP Compliance Consulting

Overview
Intravenous compounding errors have been frequently documented in the literature, including several cases of patient contamination from compounded products. Traces of hazardous drugs have been found in the urine of workers and on surfaces in the pharmacy and elsewhere in facilities.

Many organizations have weighed in on these issues. The United States Pharmacopeia (USP) has set standards for compounding (2004) to prevent contaminated products and to protect the worker and environment (2019). The Food and Drug Administration (FDA), State Boards of Pharmacy, and Centers for Medicare and Medicaid Services (CMS) via The Joint Commission are the primary enforcers of these regulations.

USP Chapter <800> and the revised USP Chapter <797> take effect Dec. 1, 2019. These regulations have stringent requirements for facilities and personnel in the management of hazardous drugs. Many facilities will have to fund new equipment and/or construction projects to meet these standards as well as change practices.

For more information, contact consulting@vizientinc.com or visit www.vizientinc.com.

What’s needed to be in compliance with USP standards?
- Standard operating procedures
- A designated compounding coordinator
- Significant physical plant capabilities
- Proper use of appropriate equipment and supplies
- Extensive cleaning and decontamination
- Maintaining State of Control of the working environment through testing and oversight
- Involvement of many disciplines
- Highly trained personnel

Pharmacy compliance trends
- Three-quarters of those surveyed regarding Chapter <800> indicate they are ready and will be in compliance; others feel they are not even in compliance with USP Chapter <797>
- Hospitals need to work through planning and preparation for construction and equipment funding to comply with USP Chapter <800>
- The FDA has taken a more aggressive stance in inspections and follow-up
- State Boards of Pharmacy may require more stringent standards of practice than the USP

The Vizient® approach—expert pharmacy services
Vizient Pharmacy Advisory Solutions provides a customized assessment to assist members with USP compliance.

Our consulting team of highly skilled experts will:
- Conduct an on-site assessment of your facilities
- Assess the current Standard Operating Procedures
- Review pertinent state laws for specific issues related to your site
- Provide a gap analysis between what is found, what the standard requires and what we recommend
- Provide didactic training and/or implementation support as needed to realize approved business plans as determined in the proposal and/or Statement of Work
- Present a summary of findings to affected and interested personnel

As the nation’s largest member-driven health care performance improvement company, Vizient provides network-powered insights in the critical areas of clinical, operational, and supply chain performance and empowers members to deliver exceptional, cost-effective care.