RxLegal

USP <800>: Handling Hazardous Drugs

Michael Gabay, PharmD, JD, BCPS*

On March 28, 2014, the United States Pharmacopoeia (USP) proposed a new chapter: USP <800> Hazardous Drugs – Handling in Healthcare Settings, which is available at http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf.^{1,2} The purpose of this proposed chapter is to guide the handling of hazardous drugs and protect health care personnel, patients, and the environment during the transport, storage, preparation, dispensing, and administration of these medications. On an annual basis, more than 8 million health care personnel are potentially exposed to hazardous medications.³ Although the incidence of cancer-related morbidity and mortality due to handling of hazardous drugs among health care personnel has not been definitively quantified, the clinical data on reproductive risks and chromosomal abnormalities are numerous. In fact, the National Institute for Occupational Safety and Health (NIOSH) maintains a comprehensive listing of published data related to the occupational exposure of antineoplastic agents (<http://www.cdc.gov/niosh/topics/antineoplastic/pubs.html>).⁴

USP <800> does not explicitly provide health care personnel with a list of medications deemed hazardous, but it refers facilities to the 2012 National Institute for Occupational Safety and Health (NIOSH) list of antineoplastic and other hazardous drugs in health care settings (<http://www.cdc.gov/niosh/docs/2012-150/>).⁵ The NIOSH list of hazardous medications was compiled in 2004 with updates in 2010 and 2012. Health care facilities need to consistently monitor the NIOSH site for continued updates to the hazardous drug listing.

USP <800> places many responsibilities on organizations that handle hazardous drugs²:

- Having an assigned individual who serves as a “compounding supervisor.” The supervisor is responsible for all aspects related to hazardous medication handling including developing and implementing procedures, overseeing compliance, ensuring personnel competency, and maintaining environmental control of areas where hazardous compounding occurs.
- Maintaining appropriate storage of all hazardous drugs. For the most part, hazardous medications must be stored separately from non-hazardous medications, although exceptions exist.
- Ensuring hazardous drug sterile compounding occurs in an appropriately designed facility. There are 3 possible facility designs for sterile compounding per USP <800>.
- Dispensing oral and topical hazardous medications in an appropriate manner.
- Utilizing closed-system drug transfer devices during preparation and administration of hazardous medications when the dosage form allows.

The goal of all of the recommendations within USP <800> is to minimize or eliminate occupational exposure to hazardous medications.

Although the USP proposes standards for pharmaceutical compounding and handling, including USP <795> Pharmaceutical Compounding – Non-sterile Preparations and USP <797> Pharmaceutical Compounding – Sterile Preparations, the organization has no enforcement authority.⁶ However, various national and state agencies and organizations can either enforce or recommend the adoption of USP standards. The US Food and Drug Administration has the authority to enforce USP standards and may push state agencies to adopt USP <800>. State boards of pharmacy may also adopt USP <800>

*Director, Drug Information Group and Prior Authorization Services, Clinical Associate Professor, Department of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy, Chicago, Illinois

standards and enforce them. In addition, The Joint Commission can reference compliance with USP standards as best practice, which can result in adoption by health care facilities in order to maintain accreditation.

Some states have begun to evaluate the issues surrounding occupational exposure of hazardous medications and have made rules or passed legislation regarding this topic. In October 2013, the California legislature approved a bill that requires the state Occupational Safety and Health Standards Board to adopt a standard for the handling of antineoplastic agents.⁷ The bill stated that the standard “be consistent with and not exceed specific recommendations adopted by NIOSH” for preventing occupational exposure to antineoplastic medications in health care facilities. Other states that have addressed, or are in the process of addressing, handling of hazardous medications include Washington, Maryland, and North Carolina.

In summary, the proposed USP <800> sets standards for the appropriate handling of hazardous medications from transport and storage to preparation and administration. The goal of these standards is to minimize exposure of health care personnel, patients, and the environment to these harmful agents. Although USP cannot enforce the standards, federal and state agencies and organizations may require implementation and adopt enforcement. Some state legislatures have already passed

laws regarding appropriate handling, which impact health care facilities including hospital and community pharmacies.

REFERENCES

1. <800> Hazardous Drugs – Handling in Healthcare Settings. United States Pharmacopoeia Web Site. http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf. Accessed August 8, 2014.
2. Kienle PC. New proposed USP <800>: Hazardous drugs handling. *PharmPurchasingProducts*. 2014;11(5):34.
3. Power LA, Kastango ES, Douglass K, Kienle PC. Understanding the new proposed USP chapter <800>. *Pharm Purchasing Products*. 2014;11(6):6.
4. Occupational exposure to antineoplastic agents. Centers for Disease Control and Prevention Web Site. <http://www.cdc.gov/niosh/topics/antineoplastic/nioshpubs.html>. Accessed August 8, 2014.
5. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2012. Centers for Disease Control and Prevention Web Site. <http://www.cdc.gov/niosh/docs/2012-150/>. Accessed August 8, 2014.
6. Who enforces compliance with USP <797>? Society of Nuclear Medicine and Molecular Imaging Web Site. <http://interactive.snm.org/index.cfm?PageID=7897>. Accessed August 8, 2014.
7. AB-1202 occupational safety and health standards: Hazardous drugs. California legislative information Web Site. http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140AB1202. Accessed August 8, 2014. ■