Prepare your customers for USP <800>

New standard for handling hazardous drugs goes into effect in December 2019

Beginning December 2019, hospitals, physicians' offices, home care agencies – in short, any healthcare setting in which hazardous drugs are handled – will be expected to comply with a new standard designed to minimize exposure to such drugs. The standard, USP <800>, was developed by the United States Pharmacopeial (USP) with the assistance of the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention, including the National Institute for Occupational Safety and Health, or NIOSH.

Christopher Lomax, Pharm D., senior marketing manager, pharmacy advisor, B. Braun Medical Inc., recently took time to summarize information from "The Chapter <800> Answer Book" by Patricia C. Kienle about the importance of closed system drug-transfer devices. For more information on <800>, go to www.readyfor800.com.

Q: Who will be affected by <800>?
A: <800> applies to all healthcare personnel who handle hazardous-drug (HD) preparations and all entities that store, prepare, transport or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices). Personnel who may potentially be exposed to HDs include, but are not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians.

Q: When must facilities comply with <800>?
A: <800> is official and federally enforceable on December 2019. However, states or other regulatory agencies, accreditation organizations, and entity policy may require compliance before that date. This is all about limiting occupational exposure, so the sooner compliance is achieved, the safer the workplace will be.

Q: What are the major differences between <800> and the 2008 version of USP <795> and <797>, which also addressed hazardous drugs?
A: Two differences:

- Scope: <795> and <797> deal with receipt, compounding, and storage up to the point of administration. <800> includes protection of healthcare workers from the time the HD is received, through and including administration of the HD and disposal of HD waste.
- Requirement for use of closed system drug-transfer devices (CSTDs) when administering antineoplastic agents: CSTDs provide protection for those individuals who administer HDs and are required by <800> when the dosage form allows their use.

Q: What is a closed system drug-transfer device?
A: A CSTD mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drugs or vapor concentration outside of the system.

Q: Does <800> require the use of CSTDs for compounding HDs?
A: <800> recommends the use of CSTDs for compounding, but it is not a requirement.

Q: Does <800> require the use of CSTDs for administering HDs?
A: Antineoplastics must be administered with a CSTD when the dosage form allows.

Q: Can personnel use a CSTD instead of a hood for occasional HD compounding?
A: No, a CSTD cannot be used as a substitute for the appropriate compounding facilities. It is a supplemental engineering control, not a primary engineering control (BioSafety Cabinet or Isolator Glove Box).

Q: How can providers know if the CSTD they want to use actually works?
A: They need to ask the CSTD supplier to provide independent testing results for its device.

Q: Can nursing use a different CSTD for administration than one used in the pharmacy for compounding?
A: That may be possible (depending on the CSTD components used), but it is probably not efficient. Nursing and pharmacy should work together to select the most appropriate product and components, to promote safety and efficiency, and to minimize the potential for removal of the device prior to use.

Q: <800> says, "CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD." Can you elaborate on chemical incompatibility?
A: In some situations, the components of a drug interact with the composition of the material used in certain CSTDs. For information on drug interactions, consult the product Instructions for Use (IFU) or the drug manufacturer's labeling. rep

For more information on USP <800> and hazardous drugs, go to www.readyfor800.com