

# SCOPE OF USP <800>

# 4

## **4.1 WHY IS <800> NECESSARY?**

### **4.1-1 Who has to comply with <800>?**

All healthcare personnel must comply. This includes anyone who handles hazardous drugs (HDs)—personnel involved in receiving, storage, compounding, transporting, administering, disposal, or spill cleanup.

### **4.1-2 What type of compounding does <800> cover?**

Both nonsterile and sterile compounding when HDs are handled.

### **4.1-3 Does <800> replace <797>?**

No. <800> provides the information on handling HDs. It must be used in conjunction with <797> for sterile compounding.

### **4.1-4 Does <800> replace <795>?**

No. <800> provides the information on handling HDs. It must be used in conjunction with <795> for nonsterile compounding.

### **4.1-5 Do community or mail-order pharmacies have to comply with <800>? How about a private physician’s office?**

All healthcare sites must comply with <800>. This includes pharmacies of any type, physician offices and clinics, veterinarian offices, and any other healthcare setting where HDs are handled.

### **4.1-6 Is a nursing station where HDs may be stored considered an “entity”?**

Yes, since a nursing station is part of a healthcare setting.

### **4.1-7 Does a nursing home have to comply with <800>?**

Yes, because a long-term care facility is a healthcare facility.

### **4.1-8 Who doesn’t have to comply with <800>?**

The scope of <800> is healthcare personnel. Manufacturing and supply chain personnel who handle the HDs before they get to a healthcare site are not included in <800>, although their workplaces require safety strategies from different agencies such as Occupational Safety and

Health Administration (OSHA). Patients' homes are not included in <800>, because they are not healthcare settings. However, home health workers are part of the healthcare team; their safety should be addressed with facility policies.

#### **4.1-9 Will USP chapters be enforced at pharmaceutical wholesalers?**

Manufacturers and distributors aren't considered healthcare settings, so <800> is out of scope for those facilities. However, other USP chapters may apply in those sites such as ones on Good Distribution Practices. Additionally, because suppliers respond to customer requests, they may implement changes so their customers are compliant.

#### **4.1-10 Is there any valid science behind <800>? Where can I find more information?**

The medical literature includes worker safety issues since the 1970s. <800> includes a listing of references. Other excellent sources of information are the web site maintained by National Institute for Occupational Safety and Health (NIOSH), which has a frequent update of new literature published (see: <http://www.cdc.gov/niosh/topics/antineoplastic/default.html>) and information on the OSHA Safety and Health Topics web page (see <https://www.osha.gov/SLTC/hazardousdrugs/index.html>).

#### **4.1-11 We have never had anyone injured by handling chemo agents in our facility. Why is <800> needed?**

You are fortunate if that is the case. However, most places don't know this information because it would require extensive medical surveillance to determine it. Harm often isn't identified when only small numbers of personnel are evaluated. Occupational risk is generally determined by large cohorts with controlled conditions. This situation doesn't exist at an individual site.

#### **4.1-12 I've heard <800> referred to as a guideline and a standard. Which is correct? What's the difference?**

<800> is a federally enforceable standard. Healthcare facilities that handle HDs are required to comply with <800>. It's not a guideline; you cannot select certain aspects to consider and not address other elements of it. However, using the Assessment of Risk approach, you can define alternative methods to comply with some of the requirements.

#### **4.1-13 I have heard reference to a letter that The Joint Commission sent to hospital administrators concerning risks of HDs. Where can I get a copy of the letter?**

OSHA, NIOSH, and The Joint Commission sent a letter to all hospital administrators in April 2011 concerning HD exposure and risks to healthcare personnel. It is available at <https://www.osha.gov/ooc/drug-letter.pdf>. Note that the NIOSH list of HDs has been updated since the letter was written.