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USP <800>: Protecting healthcare workers from hazardous drugs

According to the National Institute for Occupational Safety and Health (NIOSH), approximately 8 million American healthcare workers are potentially exposed to hazardous drugs each year. And in May, the Department of Health and Human Services (HHS) released a report critical of CMS surveyors' oversight of hospitals' use of compounded, sterile drugs. The report recommended that surveyors receive proper training on safe compounding practices.

While there have been numerous guidelines and recommendations on how to safely handle, transport, and dispose of potentially harmful chemicals and drugs, none of them have been enforceable. That was until the U.S Pharmacopeial Convention (USP) published its newest chapter on February 1, 2016. With USP General Chapter <800> *Hazardous Drugs; Handling in Healthcare Settings*, the organization hopes to promote worker safety, patient safety, and environmental protection using evidence-based practices and quality standards.

Chapter <800> covers from the moment a hazardous drug is received at the loading dock all the way

through to the medicine's disposal. Its standards apply to anyone who comes into contact with hazardous drugs: nurses, physicians, pharmacists, pharmacy technicians, loading dock personnel, etc.

And on July 1, 2018 the chapter will become fully enforceable by regulators. With 18 months (as of January) until the chapter goes into effect, what do healthcare facilities need to know about USP <800>?

The goal of USP <800>

Rick Schnatz, PharmD, senior manager with the Healthcare Quality & Safety program at USP, says there are many sources that led to the creation of USP <800>, although a big influence was feedback from stakeholders. He recalls an encounter he had with a pharmacist and a veterinarian who represented a compounding pharmaceutical group in Arizona.

"At the end of the first meeting with these folks, I said, 'I have to ask, I've never known a veterinarian to work for a pharmacist, can you tell me why?' " he says. "[The vet] said, 'When I was 35, I had a very active veterinary practice and I developed thyroid cancer. The first question my oncologist asked me was, 'Do you work with hazardous drugs?' "

The veterinarian told his physician that he worked with hazardous drugs regularly at his practice, Schnatz says. When asked if he was using any PPE, the vet had said, "Of course I do, I wear gloves."

Schnatz says this lack of awareness resonated with the compounding expert committee that wrote USP <800>. The committee members had already been thinking along these lines, he says, and the veterinarian's story definitely convinced them to move forward.

Patricia Kienle, RPh, MPA, FASHP, director of accreditation and medication safety at Cardinal Health, says that the new standards should be a boon to worker health and safety.

"I think people need to recognize that hazardous drugs are not limited to chemo," she says. "And that there is an internationally accepted definition of hazardous drugs that includes other agents. Folks absolutely need to look at the latest NIOSH list of hazardous drugs from 2016. And in that NIOSH document, along with what's in USP <800>, there's a listing of why certain drugs are hazardous."

It's also important to note that there's a difference between "hazardous drugs" and the EPA's "hazardous materials." It can be a little bit confusing, she says, because the word "hazardous" appears in both terminologies and there are some drugs that appear on both lists.

"But there is a distinct difference between the drugs that we are talking about and in USP <800> they aren't limited to chemo," she says. "There's a number of other drugs; there's antipsychotics, antibiotics, benzodiazepines. There are all sorts of other drugs that are listed in there. Folks need to understand why they are on that list, and those reasons are provided by NIOSH."

That said, she adds that nothing in USP <800> should really come as a major surprise to anyone.

"Though it's much more detailed in USP <800>, there's been information on hazardous drugs since May 1, 2004 when the first USP <797> chapter was published," she says. "And when USP <797> was revised in 2008, there was a larger section on hazardous drugs included. So this really isn't a surprise to hospitals."

Getting ready

Here are some things hospitals should go over before the July 2018 deadline:

1. **Read and have a copy of the NIOSH hazardous drug list.**

Schnatz say that clinics, hospitals, and pharmacies need to take a close look at the NIOSH *List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*, 2016. The list is updated every two years and facilities need to compare the items in their inventory to the list.

"Some of these [drugs] aren't marked as hazardous," he says. "For example, hormones. Hormones are used in compounding quite frequently in the outpatient world, bioidentical hormones. And they aren't marked as hazardous drugs, but they are on the [NIOSH] list and they can cause reproductive problems."

2. Have a compliant clean room

"Most hospitals should at this point because it's been a requirement since 2004," Kienle says. "So if they have a compliant clean room that meets the requirements that are in USP <797> for chemo, they will be compliant with <800>. With a couple of little exceptions. If they've chosen to use some of the not-optimal but possible design characteristics that are in <797>. But if they have an anteroom and a negative pressure buffer-room that meets <797> requirements, that's the same as what's in <800>."

3. Do a risk assessment

This is new for USP <800>, Kienle says, because the chapter defines specific containment properties and work practices that have to be used when dealing with hazardous drugs.

"USP <800> also allows organizations to carve out some of those specific dosage forms of the drugs that aren't antineoplastic agents and deal with them differently if they can identify strategies that they take to protect their employees," she says. "That's all wrapped up in this assessment of risk and folks need to be doing that. They certainly need to do it before July 1, 2018 when USP <800> goes into effect. But I would recommend that they start that quickly; I think it will put their mind at ease on how they are going to handle some of these other drugs that aren't antineoplastic agents."

4. Examine your closed system drug transfer devices

These devices are already required in limited circumstances under USP 797, Kienle says. The difference is that USP <800> now requires the use of closed system drug transfer devices (CSTD) for the administration of agents.

"They need to look at this from a hospitalwide perspective, it can't just be done by pharmacy alone or nursing alone," she says. "It has to be done as part of a coordinated effort because the pieces that are used in these devices certainly need to match between pharmacy and administration of the drug."

Finding resources

Schnatz doesn't expect facilities to have trouble finding the resources to help meet USP <800> standards. There are a lot of good training resources out there from national pharmacy organizations as well as USP itself.

"We do training, we've already conducted classes on USP <800>," he adds. "It's didactic, folks can attend in person, and live over the web, things of that sort. And there are many equipment manufacturers that make the hoods and devices that these folks will need in order to safely protect their workers and their environment when they are compounding these preparations."

Kienle says a few things come to mind when she thinks of the resources needed. There's the cost of upgrading facilities and equipment, meeting new requirements like CSTDs, and training of personnel.

However, she points out a lot of what's in USP <800> was already required under previous USP chapters. If a facility already has a clean room for chemotherapy medication compounding that meets USP <797> standards, it may need only minimal changes to be USP <800> compliant.

"There are plenty of places that will say, 'Oh, it's going to cost me X number of dollars to do this for my system,' " she says. "But it really should have been done more than 10 years ago. I don't mean to be callous about that, but people need to remember this isn't entirely new."

Training staff

UPS <800> requires that every organization have a designated person who's trained and qualified to:

- Develop and implement appropriate hazardous drug and compounding procedures
- Ensuring compliance with USP <800> as well as all applicable laws, regulations, and standards
- Ensuring personnel are properly trained and educated
- Ensures environmental control of the storage and compounding areas
- Maintaining reports of testing/sampling performed in facilities

However, the chapter doesn't specify how many hours or what types of training the designated person needs. Schnatz says this is partly because the standards apply to so many different types and sizes of settings, it would be difficult to come up with a set of training requirements that would apply equally to all of them. It's also because they can't guess at the training the designated person has already received, he adds.

"If you've got someone who just graduated school or just became a technician, they'll need more training than someone who has been in this field for a number of years," Schnatz says. "It also depends on the environment that they're in. If they're doing sterile, they might need more training than if they're doing nonsterile because of complexities unto itself of making a sterile product at the end of the time you're compounding."

Schnatz notes that no matter what level of education the designated person receives, USP <800> requires that the person refresh training every 12 months.

Kienle says that typically it's up to state enforcement agencies (e.g., Boards of Pharmacy) to determine specific amounts and types of training hours. Certain states (e.g., Texas) are very specific about how much training the designated person needs, she says. Facilities and clinics need to be aware of their state requirements.

"But [training] really depends on the scope of services that are being provided," Kienle says. "There are a number of hospitals that limit their IV preparation to fairly simple compounds. There are others that have automated compounding devices that do a lot of total parenteral nutrition, neonates, respiratory mixtures, ophthalmic mixtures. It really depends on the scope of services provided."

But there's a growing number of training courses that are out there.

"Particularly if people are not comfortable that they know all that they need to, I would really encourage them to go to one of the courses that includes hands-on training, not just video or didactic training," she says.

Enforcement

In Schnatz's view, the biggest change that USP <800> makes is the fact that it will be enforceable by a number of government and private agencies.

"The first [hazardous drugs] guidance was by the Oncology Nursing Society (ONS) in 1984," he says. "And in 1986 OSHA also came out with guidance, and then the American Society of Hospital Pharmacists (ASHP) Technical Advisory Bulletin on Cytotoxic Agents in 1985 was published. But these were guidances. They weren't standards and they weren't enforceable. And that's how we got into it."

However, while USP sets the standards that hospitals will be expected to follow, the organization itself won't be the one to enforce the chapter, says Kienle.

Enforcement will be left up to various regulators such as CMS, and many different state boards including pharmaceutical, nursing, and veterinary boards. This also includes the various accreditation organizations, such as The Joint Commission, DNV Healthcare, and HFAP. Many of these organizations already require compliance with USP chapters and guidelines.

"We've seen CMS, for example, in the last year and a half or so put in almost everything that's in USP <797> and add that into the *Conditions of Participation*," she says. "There are pieces of hazardous drugs [standards] in that language right now, so we'll have to see how CMS approaches that. Certainly, most state boards of pharmacy implement Chapter <797>, or even a much broader perspective of USP chapters, in their pharmacy regulations."

Patient safety is the most important thing, she says, and USP <800> will certainly make improvements in that area. What makes USP <800> unique is that it's the first required standard whose main goal is to protect healthcare workers and the environment from hazardous drug effects.

"We've known there have been issues for decades," she says. "In fact, in 1985 ASHP put out its first technical assistance bulletin on cytotoxic agents. And we've known well before that [the dangers], but that was the

first one put out for the pharmacy and the medical community specifically. But none of these were enforceable because they were only guidelines from professional organizations, even the NIOSH's alert from 2004. NIOSH is an advisory group so it wasn't a requirement."

Loredana Jinga, BSN, MPH, USP's marketing director, says USP <800> brings value across the organization. Often, hazardous drugs aren't clearly labelled as such, she says. Without the proper procedures healthcare workers might not necessarily know they are in contact with a potentially hazardous drug. "For example, nurses may not know that non-chemotherapeutic drugs are on the NIOSH hazardous drug list or the type of risk these may pose in the short and long term," she says. "I think it's really important to bring awareness to some of these blind spots to protect all healthcare workers—nurses, physicians, environment of services, everyone."

PPE

It should go without saying that PPE compliance has a major role in USP <800>. One of the chapter's requirements is that proper gowns, gloves, masks, hair covers, goggles, and respirators be worn when administering injectable antineoplastic hazardous drugs. When it comes to getting staff to follow USP PPE best practices, Schnatz says, hospitals and clinics should vw compliant by this point. There have been PPE requirements for hazardous drugs and compounding for decades, going back to the Oncology Nursing Society's PPE document in 1984, and OSHA's document in 1986.

"Hospitals are already ahead of the game in a big way," Schnatz says. "Because they've lived with <797> since 2004, and they lived with <795> since 1995. So they're already using protective equipment: the gloves, the guards, the shoe covers, facial covers, those types of things. We're pretty far down the road with that."

While hospitals should be ready for USP <800>'s PPE requirement, he says, other types of facilities or organizations such as smaller clinics, veterinary offices, and pharmacies might need more education on PPE.

Kienle says that she almost thinks there needs to be two different terms. One term for the protective garb worn to protect the sterility of the products one is making, (e.g., IVs) and a term for the PPE used to protect the handler.

"For example, there is confusion with some of the devices in which IVs are mixed because manufacturers of those devices have provided information that you don't have to wear certain articles of garb," she says. "That may be true for the protection of the *preparation* that you're making. But what USP <800> brings in is that it's protecting us as healthcare workers, so PPE has to be worn."

Kienle repeats that this is still no different than what's been in USP <797> since 2008. That said, people still sometimes miss that they need to protect themselves as well. Though the importance of PPE in environment and patient safety can't be ignored either.

Resources

USP: FAQs on USP <800> (www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings#personal)

USP <800> training: USP has several courses on its <800> chapter. This includes 6.5-hour didactic course offered both live and on demand. The organization also plans to release a modular version of the course around February. All have continuing education credits available which pharmacists and techs need to maintain their licenses (www.education.usp.org).

NIOSH: List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016 (www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf)

Critical Point: Runs a boot camp for sterile compounding which includes hands-on learning. The hands-on piece includes properly donning and doffing PPE, physical tests like media fills and glove fingertip tests, how to place things in the hood, understanding air handling. (www.criticalpoint.info/boot-camp/)

American Society of Health-System Pharmacists: Sterile Compounding Resource Center (www.ashp.org/sterilecompounding)

"And the data is certainly there to prove potential for contamination when they are making IVs, for example, and it's primarily on their gloves, gowns, and shoe covers," she says. "Those are really critical pieces of PPE that need to be worn appropriately; not only donned, but also doffed. [They need to be] taken off before they leave the negative pressure area so they're not tracking potential contamination into other areas."

"The key point is ensuring that people know PPE is to protect themselves as well as patients," Kienle continues. "Because we don't want to transmit that potential contamination to patients. And it's not only using the PPE, but understanding the process and the potential sources of contamination, so they know what to avoid. It's a lot of training issues that people need to be brought up to speed on to ensure best practice as well as healthcare provider and patient safety."