It’s been estimated by University of Chicago researchers and others that more than $2 billion a year in drugs are being wasted in nursing homes. That equates to roughly 2,300 tons of dangerous drugs, most of which have been literally tossed down the drain, according to Wade Scheel, director of governmental affairs for Stericycle Environmental Solutions.

Another 4,100 tons of drug waste ends up in landfills.

In late 2015, came the first hint from the EPA about strict new hazardous waste management rules affecting nursing homes. Among the predictions was a possible ban on disposing drugs in toilets – a longstanding practice that left so many otherwise environmentally conscious healthcare workers wincing as they pressed down on the flush handles.

The American Society of Consultant Pharmacists’ (ASCP) former CEO and executive director Frank Grosso was perplexed about how the government would be able to pull that off, telling McKnight’s Long-Term Care News the industry sorely needed “more government agency collaboration in the development of clear rules for drug disposal.”

Nursing home industry officials complained about the onerous costs accompanying more expensive alternatives that would indubitably include boxes and shipping manifests and reams of paperwork, all while acknowledging drug storage and handling practices could be contributing to a certain amount of pre-mature expiration and diversion. The assisted living industry was even more vociferous in its objections, given the comparatively low level of meds among their resident populations and the lack of infrastructure or means to dispose of them. Moreover, a maze of laws over drug ownership in assisted living facilities seemed destined to thwart such efforts.

Four years later, earlier this fall, assisted living facilities learned they would be exempt. For skilled nursing facilities, the strict new rules went into effect.

For decades, the long-term care industry has been mired in a maze of onerous, voluminous and often overlapping and contradictory rules and regulations around hazardous waste disposal involving myriad government agencies from the FDA and DEA to the EPA. The new hazardous waste rules are the government’s response.
What’s in the Regulation?

The 500-page rule, *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine* was published in the February 22, 2019 Federal Register.

The three major components of the rule are:

- “Sub Part P” EPA amendments: These concern rules around disposing hazardous drug waste in nursing homes (including a national ban on discarding drugs in toilets as of August 21). The ban reportedly only applies to hazardous waste pharmaceuticals, but the EPA recommends not “sewering” any pharmaceutical.

- “USP 800” recommendations: These address the handling of hazardous drugs by healthcare personnel in all settings.

- The DEA’s “21 CFR Final Rule”: This enables long-term care facility staff, managed under DEA-registrant consultant pharmacists, to dispose of residents’ pharmaceutical waste, including controlled substances, on their behalf.

“I think two under-the-radar regulations that will affect facilities are the “Sub Part P” amendments to EPA regulations and USP 800 recommendations,” says Stephen Creasy, PharmD., director of clinical services for PharMerica. “The EPA’s amendments regarding Sub Part P pertain to the disposal of hazardous waste pharmaceuticals in skilled nursing settings whereas USP 800 affects the handling of hazardous drugs by all healthcare personnel regardless of setting.”

Creasy adds that the rules now categorize certain healthcare facilities as generators of hazardous waste, which potentially subjects them to stricter regulations for the disposal of hazardous waste pharmaceuticals. Under the Resource Conservation and Recovery Act (RCRA) regulations, nursing homes were generally treated as less restrictive “household” generators. Assisted living, independent living communities, group homes, and continuing care retirement communities are exempt.

Other notable parts of the regulation:

- A so-called “nicotine exception” that exempts over-the-counter nicotine replacement therapies such as gums, lozenges and patches, from being defined as acute hazardous waste (otherwise referred to as “P” waste) prescription nicotine products, e-cigs, and other liquid nicotine devices will still be considered hazardous waste. This part of the rule does not have an adoption timeline because it’s more lenient than the law currently in place and states can choose to not adopt it.

- Limits to storing hazardous waste to one year.

- Employee training around management and storage of pharmaceutical waste.

- Categorizing healthcare facilities by the amount of hazardous drug waste they generate each month - between 100 and 1,000 kilograms. Facilities with 20 or fewer beds are assumed to be very small quantity generators (VSQG), or generating less than or equal to 100 kg (220 pounds) per calendar month of hazardous waste.
• Special rules around when empty “pharmaceutical containers” (bottles, vials, bags, etc.) and when they can be disposed of as regular household waste.

• The maximum fine for offenders could reportedly be more than $70,000 per day per violation.

• A pharmaceutical waste may also be considered hazardous if it exhibits one of the following four characteristics: ignitability, corrosivity, reactivity, or toxicity.

• Rules that deem certain hazardous waste as “non-creditable” after being technically dispensed.

• Special rules on DEA controlled substances, including provisions exempting them from the regulation as long as they are not “sewered” and managed and destroyed in accordance with DEA rules.

What’s the Impact on Nursing Homes?

“These rules are significant because they fundamentally alter how certain hazardous medications have to be handled from delivery to disposal,” says Creasy.

The EPA estimates the rule will only effect about 5 percent of a facility’s drug formulary, but many states can have additional definitions surrounding what qualifies as a hazardous waste.

PharMerica urges facilities to work with a vendor specifically qualified to manage hazardous waste to help characterize their generator status, and advises nursing facilities to refer to the EPA Hazardous Waste Regulatory Summary for additional information.

Nursing homes also will quickly discover that each regulation is from a different organization, has separate timelines for implementation depending upon state, and has differing definitions of what constitutes hazardous, Creasy adds.

He also reminds facilities that policies and procedures will have to be in place for appropriate handling and disposal of hazardous medications. This includes identification of the medications as hazardous and appropriate training. “For USP 800, this also would include an additional role of a ‘designated person’,” he says. “Additional financial impacts and liability concerns concern purchasing appropriate personal protective equipment and contracting with the appropriate hazardous waste vendors.”

The rules also carry onerous financial burdens, as well as “increased higher liability concerns if appropriate precautions aren’t taken to ensure proper education and training of personnel as well as awareness of state-specific regulations, which may be stricter than federal,” Creasy adds.

The”21 CFR Final Rule” enables long-term care facility staff, managed under DEA-registrant consultant pharmacists, to dispose of residents’ pharmaceutical waste, including controlled substances, on their behalf. Proper oversight by appropriate clinical staff will go far in avoiding issues like diversion.
Challenges Ahead

“Both Sub Part P and USP 800 provisions will fundamentally change how facilities currently operate and will require much education,” while regulators will need to exercise patience and provide ample opportunity for correction of initial deficiencies, Creasy says.

He also believes consultant pharmacists and pharmacy services providers in long-term care may be challenged “finding clarity from the EPA about how to best educate these facilities. Moving facilities from a residential household mindset to a healthcare facility mindset in terms of hazardous medication disposal is a very complex matter,” he adds. “Currently only two states - Iowa and Alaska - follow the federal rules. The other states are currently deciding the best course to follow. We’re getting a lot of questions. It’s easy to say, ‘this is what you need to do’.”

Meanwhile, some industry officials say they are concerned with the unusually short deadlines for compliance.

Creasy said USP officials told him “they were leaving some of the guidance vague so facilities could decide what to do” with USP 800, which goes into effect December 1.

“We are concerned with the short timeframe of six months when the final rule becomes effective due to the operational changes that nursing centers face to comply with these new regulations,” Holly Harmon, AHCA associate vice president of quality and clinical affairs, told McKnight’s Long-Term Care News.

Attorneys at Arnall Golden Gregory also advised nursing facilities against procrastination. “They’re going, in essence, from zero to 60 in about six months, and it’s a very short time period in which they need to become familiar with how this regulation works,” added the firm’s Of Counsel, Jennifer Hilliard.

Sweeping changes such as these can often lead to confusion or hesitation for any large organization, but there are many resources available to you. Taking action will only be the first part in keeping up with these new regulations. PharMerica customers seeking additional information and guidance about the new rules around disposal of hazardous pharmaceutical waste should call (877) 874-2768.

Topics: Medication Management, Consultant Pharmacists, Long-Term Care, Skilled Nursing, Hazardous Waste Regulations, Clinical Services