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REGULATORY UPDATE:

EPA Final Rule on Hazardous Waste Pharmaceuticals & What it Means for the Consultant Pharmacist

Veronica Charles, MPA
Government Affairs Manager
American Society of Consultant Pharmacists (ASCP)

This update has been created for informational purposes for ASCP members and does not contain legal advice. This information is intended to help clinicians practicing in the long-term care setting locate necessary information on the disposal of hazardous pharmaceutical waste and should not be relied upon without consulting state and federal regulations and/or legal counsel.

1240 North Pitt Street, 3rd Floor, Alexandria, Virginia 22314
info@ascp.com 703-739-1300 www.ascp.com

On February 22, 2019, the Environmental Protection Agency (EPA) published their long anticipated final rule governing *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine*. The new rule revises management standards for hazardous waste pharmaceuticals (HWPs) for skilled nursing, nursing, and inpatient hospice facilities. The new regulations set forth in the EPA final rule will become effective on August 21, 2019.

The final rule makes substantive changes to Subpart P[1] of *The Resource Conservation Recovery Act* (RCRA) which determines how healthcare facilities and reverse distributors manage their HWPs. The agency believes that these new management standards will benefit pharmacists by creating a streamlined process specifically crafted for healthcare HWPs.

One of the most notable changes under the final rule is the new requirement governing all healthcare facilities (including nursing homes and long term care pharmacies) that prohibits sewering (pouring or flushing down a toilet or drain) of all HWPs. In addition to the sewering ban, this rule also establishes a regulatory framework for the management of HWPs through the use of reverse distributors and creates a single rule that governs the disposal of DEA controlled substances that are also HWPs.

How Long-Term Care Facilities Are Affected

Pharmacists in healthcare facilities, including nursing homes and long-term care pharmacies, must comply with applicable provisions of the new HWP rule in addition to the mandatory sewering ban. According to the EPA, a "long-term care facility," is defined as:

> A licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. *Not included within the scope of this definition are group homes, independent living communities, assisted living facilities and the independent and assisted living portions of continuing care retirement communities.*[2]

After much deliberation with ASCP and other advocacy organizations, the EPA determined that assisted living facilities do not have the authority to collect waste from the residents. Therefore, assisted living facilities are excluded from the above definition of long term care facilities.

[1] Codified in RCRA at 40 C.F.R. Part 266, Subpart P

[2] To be codified at 40 C.F.R. § 266.500.

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Exemptions

In addition to assisted living facilities being exempt from these management standards, the rule also does not require Very Small Quantity Generators (VSQGs) to comply. **However, all healthcare facilities who manage or administer pharmaceuticals are required to comply with the sewering prohibition**.

What is a Very Small Quantity Generator (VSQG)?

In order to be considered a VSQG, a facility must accumulate less than 100 kilograms per month of hazardous waste and one kilogram or less per calendar month of acute hazardous waste. EPA believes that nearly all nursing facilities will be exempt under this provision. Under the final rule, long-term care facilities with 20 or fewer beds are presumed to be VSQGs.

Facilities that qualify as exempt under the rule (VSQGs) may want to be regulated under the provisions of this regulation by notifying EPA as this provides facilities with the advantage of being covered under the provisions of this streamlined approach even if the facilties' generator status changes.

What is Hazardous Pharmaceutical Waste?

According to the EPA, Hazardous Pharmaceutical Waste refers to a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

As thousands of over-the-counter and prescription drugs are currently approved for sale in the United States, it is difficult to provide a precise number of pharmaceuticals that are considered hazardous waste. However, as with any other waste, a solid waste is considered hazardous waste if it meets a listing or exhibits a characteristic described in title 40 of the Code of Federal Regulations Part 261[3].

There are approximately 30 commercial chemical products listed on the P and U hazardous waste lists that have pharmaceutical uses. Since the P and U lists are based on chemical

[3] Resource Conservation and Recovery (RCRA) Regulations
https://www.epa.gov/rcra/resource-conservation-and-recovery-act-rcra-regulations

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designations, this number does not completely represent the total number of brand name pharmaceuticals that may actually be listed hazardous wastes. For example, the following chemotherapy drugs, CTX, Cytotoxan, Neosar and Procytox, are all designated as a U058 hazardous waste for cyclophosamide.

In addition, waste pharmaceuticals may also be hazardous because they exhibit one or more of the four characteristics of hazardous waste: ignitability, corrosivity, reactivity and toxicity. For example, solutions containing more than 24 percent alcohol exhibit the ignitability characteristic. Pharmaceuticals exhibiting the corrosivity characteristic are generally limited to compounding chemicals, including strong acids, such as glacial acetic acid, and strong bases, such as sodium hydroxide.

Depending on the concentration in different pharmaceutical preparations, pharmaceuticals may also exhibit the toxicity characteristic because of the use of arsenic (D004), barium (D005), cadmium (D006), chloroform (D022), chromium (D007), lindane (D013), m-cresol (D024), mercury (D009), selenium (D010), and silver (D011)[4]. [See EPA Explanation], See Also EPA List of P and U Listed Waste.

Nicotine: Under the provisions of this rule, EPA has determined that patches, gums and lozenges do not meet the regulatory criteria for acute hazardous waste and may disposed of as non-HPW.

Managing Hazardous Pharmaceutical Waste

Once a long-term care facility is determined to meet the criteria of the management standards of Subpart P, the management requirements differ based on whether or not a pharmaceutical is an over-the-counter or prescription pharmaceutical. For prescription pharmaceuticals, the facility must determine if they are disposing of a *potentially creditable* HWP or a *non-creditable* HWP.

The EPA uses the term "potentially creditable hazardous waste" because certain prescription pharmaceuticals would have to meet the following criteria in order to be creditable by a manufacturer through reverse distribution:

- Prescription pharmaceutical(s) must be in original manufacturer packaging, (except pharmaceuticals that were subject to a recall even if opened);
- Prescription pharmaceuticals must be undispensed; and
- Prescription pharmaceuticals must be unexpired or less than one year past expiration date."[5]

[4] EPA Explanation of Hazardous Waste
https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes#PandU
[5] To be codified at 40 C.F.R. § 266.500.

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A non-creditable HWP is a prescription pharmaceutical that does not meet the above criteria and is not likely to receive credit from the manufacturer.

While some non-prescription over the counter pharmaceuticals could go through reverse logistics and have a reasonable expectation of being recycled, non-prescription HWPs are not classified as "solid waste" under RCRA regulations, which means they are not subject to any of these Subpart P requirements.

Additionally, since a pharmaceutical is required to be undispensed in order to be creditable, it is highly likely that only long-term care facilities with in house long-term care pharmacies will be managing potentially creditable HWPs. The vast majority of long-term care facilities that utilize external pharmacies will be managing non-creditable HWPs because pharmaceuticals will have already been dispensed.

Potentially Creditable

For drugs that are potentially creditable, drugs may be sent to a reverse distributor, who will either evaluate them for credit or send them to another reverse distributor. Once the determination is made, the reverse distributor will arrange for destruction by a treatment, storage, and disposal facility (TSDF). EPA Gives participating Healthcare Facilities Two Options when dealing with potentially creditable waste:

- Determine which waste is hazardous under the EPA definition and manage that as potentially-creditable hazardous waste;
- Comingle all pharmaceutical waste and treat it all as potentially creditable under the provisions of subpart P.

Non-Creditable

Drugs that are determined to be non-creditable will be managed through a TSDF, not by a reverse distributor. While accumulating in the facility the receptacle needs to be labeled "Hazardous Waste Pharmaceuticals". Hazardous waste numbers need not be included. These drugs may be accumulated on site for up to one year. Non-creditable waste is not required to be reported to EPA on its biennial report. However, facilities must notify EPA if they do not receive a signed copy of the delivery manifest on a shipment of non-creditable waste to a TSDF.

Evaluated Waste

Once a potentially creditable drug has been evaluated through a reverse distributor and determined not to be creditable, it becomes an evaluated waste and must be disposed of through a TSDF.

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LTC Facility Non-Creditable Waste Management by LTC Pharmacies

EPA allows pharmacies to manage the non-creditable waste of LTC facilities without a manifest provided certain conditions are met:

- The pharmacy Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;
- The pharmacy is managing its non-creditable waste under Subpart P (this section of environmental regulations);
- The waste is being managed under the provisions of Subpart P;
- The pharmacy keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

Recordkeeping Requirements

EPA requires records to be maintained on site for three years:

- Exceptions reports to EPA on failure to receive signed copies of manifests;
- Records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals regarding which pharmaceuticals are hazardous waste;
    - This is not required if the facility manages all its waste as hazardous waste.
- Retention periods be automatically extended during the course of ongoing enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Regional Administrator.

***Notification Requirement**: All healthcare facilities must submit a one-time notification that they are operating under Subpart P (using Site ID Form: 8700-12).*

LTC Facility Potentially Creditable Waste Management by LTC Pharmacies

EPA allows LTCFs to send their potentially creditable waste to its pharmacy with the same provisions as are included for non-creditable waste.

No Time Limit on Accumulation of Potentially Creditable Waste

EPA has not established a time limit on accumulation of potentially creditable waste.

Labeling of Potentially Creditable Waste

EPA has decided not to create standards for labeling of containers, primarily because of the possibility that wastes will be co-mingled with non-hazardous waste. The agency believes that waste in original containers will be in original packaging, which lessens the overall risk.

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Reporting Requirements

EPA will not require reporting by healthcare facilities for potentially creditable waste, as the reporting will become the responsibility of reverse distributors.

Record Keeping Requirements

Healthcare facilities initiating shipments of potentially creditable hazardous waste pharmaceuticals must keep:

- Delivery confirmation for each shipment and
- Shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

EPA is finalizing that these records must be retained for three years unless there is an unresolved enforcement activity or a request by the EPA Regional Administrator to keep them longer.

Disposal of Hazardous Waste that are also DEA Controlled Substances

EPA has determined that in order to avoid requirements to comply with multiple regulations, it will defer to DEA requirements for the safe management of controlled drug waste. This represents no change from current requirements.

Subpart P Impact on Long-Term Care

This brief summary attempts to prepare long term care facilities, namely long term care pharmacies and skilled nursing facilities, for the changes in the management of pharmaceutical waste that will begin on August 21, 2019. However, while Subpart P goes into effect on the above date, each provision of Subpart P, **except for the sewering ban,** will not go into effect in states with authorized hazardous waste programs until those states adopt their own generator requirements per EPA regulations. The sewering ban will be effective in every state under Federal law on August 21, 2019.

Since states may control other provisions of Subpart P, it is possible that certain states may include stricter hazardous waste requirements than the regulations outlined in EPA's final rule. Given the considerable state latitude, long term care facilities need to closely monitor new and evolving policies in their respective state(s).

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Notable Definitions in Final Rule

Definition of Pharmaceutical

In this final rule, "pharmaceutical" means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen), or any liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); OTC drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

The final definition of pharmaceutical includes both prescription drugs, as defined by 21 CFR 203.3(y) and OTC drugs. As previously mentioned, commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use.141 If an OTC product is required by the FDA to include "Drug Facts" on the label, it would be considered a pharmaceutical for the purposes of this rule.

Definition of Reverse Distributor

Under the final rule, reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

EPA's definition of "reverse distributor" only includes prescription hazardous waste pharmaceuticals that are evaluated for credit and then disposed.

Definition of a Potentially Creditable Hazardous Waste Pharmaceutical

For the final rule, a potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is (1) in original manufacturer's packaging (except pharmaceuticals that were subject to recall); (2) undispensed; and (3) unexpired or less than one year past expiration date. **The term does not include** evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, OTC drugs, homeopathic drugs, and dietary supplements.

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Definition of Non-Creditable Hazardous Waste Pharmaceutical

Under the final rule, non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

Definition of Evaluated Hazardous Waste Pharmaceutical

EPA is finalizing that "evaluated hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with §266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit. *Under the definition of evaluated hazardous waste pharmaceutical, if credit has been determined and no other verification is needed, then the waste would be considered evaluated. If the prescription hazardous waste pharmaceutical needs further evaluation for credit, it can be sent on to another reverse distributor for that determination. It will not be considered evaluated until the credit is verified.*

Definition of Household Waste Pharmaceutical

In the final rule, "household waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

Definition of Non-Hazardous Waste Pharmaceutical

In this rule, a "non-hazardous waste pharmaceutical" is a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

Definition of Non-Pharmaceutical Hazardous Waste

The proposed definition was needed because the management of non-pharmaceutical hazardous wastes is not regulated under subpart P; rather, generators of non-pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to part 262 and other applicable Subtitle C hazardous waste regulations for the management of those hazardous wastes.]

In this final rule, "non-pharmaceutical hazardous waste" is a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in §266.500.

Definition of Healthcare Facility

EPA is finalizing that "healthcare facility" means any person that is lawfully authorized to (1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and

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counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals and veterinary clinics and hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Definition of Long-Term Care Facility

This final rule defines "LTCF" as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

Long-Term Care Facilities and The Household Hazardous Waste Exclusion

EPA is finalizing that LTCFs are included within the final definition of healthcare facility. Accordingly, EPA is also finalizing that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be excluded as household hazardous waste: it will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the final subpart P management standards for hazardous waste pharmaceuticals. EPA is revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate.

It is also important to note that, because of the change to the definition of LTCF, this change in policy regarding the household hazardous waste exclusion and LTCFs will not impact residents in assisted living facilities. Under the final rule, group homes and independent living communities are also not defined as LTCFs but rather are considered residences that are eligible to use the household hazardous waste exclusion.

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