

Pharmaceutical Waste Management

A Guide for South Dakota Healthcare Facilities

Pharmacies, hospitals, health care and veterinary clinics generate not only infectious medical waste, but pharmaceutical wastes. While infectious medical wastes must be rendered noninfectious prior to disposal as a solid waste, pharmaceutical wastes are different in that some may need to be managed and disposed as a hazardous waste. Healthcare personnel can use this guidance to help determine whether a pharmaceutical waste is hazardous waste. It also provides an overview of requirements to ensure hazardous waste pharmaceuticals are properly managed, and offers additional resources to obtain information applicable to your facility. The focus of this guidance is on non-creditable hazardous waste pharmaceuticals addressed in the federal Pharmaceutical Waste Rule (also known as the Subpart P Rule) finalized by the Environmental Protection Agency (EPA) on February 22, 2019, and recently adopted by the state. While requirements for potentially creditable, and evaluated hazardous waste pharmaceuticals, as well as Reverse Distributor operations are also covered in the Subpart P Rule, those requirements are not spelled out in this guidance.

Background

South Dakota's hazardous waste rules are found in the Administrative Rules of South Dakota (ARSD) Chapter 74:28. Rules specific to managing hazardous waste pharmaceuticals are found in ARSD 74:28:27:01, which adopts the federal Subpart P regulations by reference. These rules are enforced by the South Dakota Department of Environment and Natural Resources' (DENR) Hazardous Waste Program. Although the program is not implemented directly by the federal Environmental Protection Agency (EPA), the EPA does ensure the state maintains an adequate program by performing annual oversight evaluations. Refer to the Additional Resource Section for links to both the state and federal hazardous waste regulations.

How does this apply to me?

To begin, two criteria must be met to know whether your site is regulated under the state's pharmaceutical waste rules. The first: your operation must meet the definition of "*healthcare facility*"; and second: the unwanted *pharmaceuticals must be considered a hazardous waste*. Details regarding those facets follow:

Definition of Healthcare Facility

(see ARSD 74:28:27:01 adopting 84FR No. 36, Section 266.500)

Healthcare facility means any person that is lawfully authorized to –

1. Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and 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 over-the-counter 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, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Identifying a Hazardous Waste Pharmaceutical
(see ARSD 74:28:22:01, adopting 40 CFR Part 261)

As with any type of waste destined for disposal, it is the generator's responsibility to determine whether that waste is a hazardous waste. Waste pharmaceuticals (non-creditable and potentially creditable) may be specifically listed in the P- or U-series lists under 40 CFR 261.33. When not specifically listed, if the pharmaceutical exhibits one or more hazardous waste characteristics assigned under 40 CFR 261.21 to 261.24 (ignitable; corrosive; reactive; or toxic using the Toxicity Characteristic Leaching Procedure test), it will also be a hazardous waste.

Product Safety Data Sheets and/or drug information pamphlets can help with many waste determinations. Additional help can be obtained through the DENR's website at: <http://denr.sd.gov/des/wm/hw/hwpharma.aspx> or by contacting the Waste Management Program's hazardous waste staff at 605-773-3153. Although not an exhaustive list, the link: https://www.epa.gov/sites/production/files/2019-08/documents/wikispace_pharms_list_for_web_draft_date_disclaimer.pdf provides a user-generated list of hazardous waste pharmaceuticals as well.

Wastes generated from an on-site laboratory or through a healthcare facility's maintenance department can also be considered hazardous wastes; however, those wastes need to be counted separately from hazardous waste pharmaceuticals. As provided in more detail below, facilities need to calculate the amount of hazardous waste pharmaceuticals generated within a calendar month separately from the amount of non-pharmaceutical hazardous waste.

Monthly Generation Rate

Once you've determined the hazardous waste pharmaceuticals generated at your facility, make separate calculations of the weight of the pharmaceutical and non-pharmaceutical hazardous wastes generated within a calendar month. This monthly generation rate establishes your facility's *generator category*, and the respective requirements you'll need to follow.

Hazardous Waste Generator Categories
(see ARSD 74:28:23:01 adopting 40 CFR 262)

1. Large Quantity Generator (LQG): generates more than 2,200 pounds of hazardous waste; *and/or* more than 2.2 pounds of acute (P-series) hazardous waste per calendar month.

2. Small Quantity Generator (SQG): generates more than 220 pounds but less than 2,200 pounds of toxic hazardous waste within one calendar month, *and* less than 2.2 pounds of acute hazardous waste within one calendar month.
3. Very Small Quantity Generator (VSQG): generates less than 220 pounds of toxic hazardous waste, *and* less than 2.2 pounds of acute hazardous waste within one calendar month.

Healthcare facilities generating hazardous waste pharmaceuticals at SQG and LQG levels are subject to the Subpart P requirements. Note: some facilities may wish to manage non-hazardous waste pharmaceuticals with their hazardous waste pharmaceuticals. For example, many potent chemotherapy drugs are not found on the P- or U-series waste lists and may not exhibit any of the four hazardous waste characteristics. Although such wastes would not be regulated hazardous wastes, managing them along with regulated hazardous wastes would be protective of human health and the environment and considered a Best Management Practice (BMP). Healthcare facilities generating hazardous waste pharmaceuticals at VSQG levels have the option of following specific (reduced) Subpart P requirements (see ARSD 74:28:27:01, adopting 84FR No. 36 Section 266.504), or following standard hazardous waste generator requirements for VSQGs (see ARSD 74:28:23:01, adopting 40 CFR Part 262). Non-pharmaceutical hazardous wastes (e.g. laboratory and maintenance wastes) need to be managed in accordance with the standard hazardous waste requirements in ARSD 74:28:23:01, adopting 40 CFR Part 262.

Notification/Hazardous Waste Identification Number (HW ID)

Healthcare facilities subject to Subpart P requirements need to notify the state, using EPA Form 8700-12

(https://rcrapublic.epa.gov/rcrainfoweb/documents/rcra_subtitleC_forms_and_instructions.pdf) (see ARSD 74:28:27:01, adopting Section 266.502). If a healthcare facility obtained a hazardous waste ID number in the past, that number will be retained and can be used on the notification form. However, the facility will still need to complete the notification form. No fees are associated with applying and obtaining a hazardous identification number in South Dakota.

Completed, signed forms should be sent to:
SDDENR-Waste Management Program
523 E. Capitol Avenue
Pierre, SD 57501

Personnel Training

Healthcare facilities must ensure all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

Pharmaceutical Waste Storage under Subpart P

Container storage: Non-creditable hazardous waste pharmaceuticals must be placed:

- In containers that are compatible with the wastes they contain, structurally sound, and lack evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions;
- In containers that are securely closed and secured in a manner that prevents unauthorized access to its contents;
- In containers that are properly labeled with the words “Hazardous Waste Pharmaceuticals”; and
- In containers where both non-hazardous, non-creditable hazardous waste pharmaceuticals and hazardous waste pharmaceuticals are accumulated.

Time Limits: A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on-site for a maximum of one year. Documentation of this accumulation time period may be shown by one of the following methods:

- Marking or labeling the container with the date hazardous waste pharmaceuticals first became a waste;
- Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;
- Placing the non-creditable HW pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals became a waste.

Manifesting, Shipment and Disposal

Sewering Prohibition: All healthcare facilities, including VSQGs operating under ARSD 74:28:23:01 adopting 40 CFR Part 262.14 in lieu of Subpart P, are prohibited from discharging hazardous waste pharmaceuticals to a sewer system connected to a publicly-owned treatment works (POTW).

Potentially Creditable Hazardous Waste Pharmaceuticals: Healthcare facilities may ship potentially creditable hazardous waste pharmaceuticals to a reverse distributor in order to establish credit for those pharmaceuticals. Once evaluated, those hazardous waste pharmaceuticals must be shipped off-site by the reverse distributor for disposal to a permitted hazardous waste treatment storage or disposal facility.

Non-creditable Hazardous Waste Pharmaceuticals: Healthcare facilities must ensure non-creditable hazardous waste pharmaceuticals are shipped to a permitted hazardous waste treatment, storage or disposal facility (TSDF) for disposal.

Recordkeeping

A copy of the final signed shipping manifest that accompanies each off-site waste shipment needs to be retained for at least three years. Any exception report associated with a waste shipment must also be maintained on file for three years.

Healthcare facilities must keep records of any test results, waste analyses or other determinations made to support its hazardous waste determination(s) for at least three years from the date the

waste was last sent to a disposal facility. Note: a healthcare facility that manages all of its non-creditable non-hazardous pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of those hazardous waste determinations.

Additional Resources

Additional resources and assistance available to medical facilities specific to identifying and managing pharmaceutical wastes can be obtained through the following links. Please note that inclusion of service companies does not represent an endorsement by DENR.

- South Dakota's Hazardous Waste Regulations (ARSD 74:28): <http://denr.sd.gov/des/wm/hw/hwmainpage.aspx>
- Federal (EPA) Hazardous Waste Regulations (40 CFR Parts 260 – 279):
 - Parts 260-265: https://www.ecfr.gov/cgi-bin/text-idx?SID=941ed272f177590131de87ab4b36ae02&pitd=20180701&tpl=/ecfrbrowse/Title40/40cfrv28_02.tpl#0
 - Parts 266-279: https://www.ecfr.gov/cgi-bin/text-idx?SID=941ed272f177590131de87ab4b36ae02&pitd=20180701&tpl=/ecfrbrowse/Title40/40cfrv29_02.tpl#0
- Federal Environmental Protection Agency (EPA) Pharmaceutical Waste Rule website and rule (84 FR No. 36): <https://www.epa.gov/hwgenerators/management-hazardous-waste-pharmaceuticals>
- EPA Compliance Assistance website: <http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/health.pdf>
- Healthcare Environmental Resource Center (HER) Website: <https://www.hercenter.org/>
- PharmEcology Website: <http://www.pharmecology.com/pedd/jsp/index.jsp>
- Practice Greenhealth Website: <https://www.practicegreenhealth.org/>