HAZARDOUS MATERIALS PROGRAM ENVIRONMENTAL FACT SHEET

Hazardous Waste Pharmaceuticals

The Environmental Protection Agency (EPA) published "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine" in 2019. The rule established streamlined standards for handling hazardous waste pharmaceuticals while protecting human health and the environment. In February of 2022, the Vermont Hazardous Waste Management Regulations (VHWMR) adopted many of these standards into Subchapter 10. This fact sheet is intended to give guidance to healthcare facilities in Vermont that have questions regarding the management of hazardous waste pharmaceuticals.

Please note that hazardous waste pharmaceuticals in the healthcare sector have been managed under the hazardous waste regulations prior to the implementation of this pharmaceutical rule. The rule changes how they are regulated and managed moving forward. To view the entire rule please see Subchapter 10: Hazardous Waste Pharmaceuticals of the VHWMR.

Definitions

- For the purposes of this fact sheet a **"pharmaceutical"** includes drugs for human or animal use, including prescription and over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, compounded drugs, investigational new drugs, as well as nicotine e-liquids packaged for retail sale and electronic nicotine delivery systems (e.g., e-cigarette or vaping pen).
- A **"hazardous waste pharmaceutical"** is a pharmaceutical that is a waste, and exhibits one or more of the characteristics identified as hazardous in the VHWMR in §§ 7-205 through 7-208, or is listed in §§ 7-210 through 7-215. Please note that a pharmaceutical is not a waste if it is legitimately used/reused or reclaimed.
- A **"non-hazardous waste pharmaceutical"** is a pharmaceutical that is a waste, and does not exhibit one or more of the characteristics identified as hazardous in the VHWMR in §§ 7-205 through 7-208, and is not listed in §§ 7-210 through 7-215.
- A **"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. Examples of healthcare facilities include hospitals, veterinary clinics, and pharmacies.
- 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 the original manufacturer packaging (except pharmaceuticals that were subject to recall), (2) undispensed, and (3) unexpired or less than one year past expiration date. This term does not

include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

What parts of the management standards apply to all healthcare facilities?

- All healthcare facilities are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through a publicly owned treatment works.
- Residues of hazardous waste pharmaceuticals in empty containers are no longer regulated as hazardous waste. Refer to VHWMR § 7-1008 for details.
- All healthcare facilities may send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Refer to VHWMR § 7-1010 for details.
- Over-the-counter nicotine replacement therapies (such as patches, gums, and lozenges) are no longer regulated as hazardous waste and do not need to be managed as such. Prior to the rule change, these wastes were regulated as acutely hazardous waste (waste code P075).

Note: The above standards apply to *all* healthcare facilities, regardless of whether they are operating under the standards set forth in Subchapter 10.

What are the notification requirements for operating under Subchapter 10?

- Healthcare facilities notified as very small quantity generators (VSQGs) have the option of notifying the Secretary and operating under Subchapter 10 or complying with the hazardous waste management standards for VSQGs. facilities must file a Hazardous Waste Handler Site Identification Form (EPA Form 8700-12) to notify the Secretary that they are operating under this subchapter.
- Healthcare facilities notified as small quantity generators (SQGs) or large quantity generators (LQGs) were required to notify the Secretary and begin operating under Subchapter 10 by April 1, 2022.

If operating under Subchapter 10, what does my healthcare facility need to do to comply?

- Healthcare facilities must ensure that all personnel that manage hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures.
- Containers of hazardous waste pharmaceuticals must be labeled with the words “Hazardous Waste Pharmaceuticals.” Generators must be able to document that they have accumulated the hazardous waste pharmaceuticals for less than one year from the date it was generated. Dating the container is recommended to satisfy this requirement.
- Containers of non-creditable hazardous waste pharmaceuticals must be closed and secured, structurally sound, and compatible with their contents.
- Healthcare facilities must ship non-creditable hazardous waste pharmaceuticals on a hazardous waste manifest and retain records for at least three years.

- Healthcare facilities shipping non-creditable hazardous waste pharmaceuticals on a manifest must write the word "PHRM" in Item 13. If the healthcare facility is shipping to a state that has not adopted the pharmaceutical rule, all other waste codes must be included in addition to "PHRM" for Item 13.
- Potentially creditable hazardous waste pharmaceuticals may be shipped to a reverse distributor. Refer to VHWMR § 7-1004(e) and § 7-1010 for details.

Are there any special considerations for managing hazardous waste at healthcare facilities?
Generators should note that it is typical for healthcare facilities to generate hazardous waste pharmaceuticals regulated by Subchapter 10 *and* hazardous waste regulated by Subchapters 1 through 7 of the VHWMR. Healthcare facilities may choose to manage non-hazardous waste pharmaceuticals according to Subchapter 10. It is the responsibility of the generator to make an accurate waste determination and manage their waste streams according to the applicable regulations.

Hazardous waste generated at a healthcare facility that does *not* meet the definition of "hazardous waste pharmaceutical" may *not* be managed per the standards in Subchapter 10. These wastes must be managed according the requirements set forth in Subchapters 1 through 7. Examples might include hazardous waste generated in healthcare facility labs (e.g., xylene) and exam rooms (e.g., barium), as well as those generated through healthcare facility maintenance (e.g., oily waste, waste sanitizers).

Although it is not required, generators may choose to manage non-hazardous waste pharmaceuticals per Subchapter 10 if they are generated through similar processes and/or at similar locations as hazardous waste pharmaceuticals. Ultimately it is up to the healthcare facility to manage their waste streams in a way that makes sense for their facility and is compliant with the regulations.

What is the NIOSH Hazardous Drug List?
In 2004, the National Institute for Occupational Safety and Health (NIOSH) developed and has since periodically updated a "hazardous drug list." This list indicates those drugs that NIOSH considers hazardous to employees due to prolonged occupational exposure. Please be aware that the NIOSH hazardous drug list should *not* be used by healthcare facilities as the *sole basis* for making waste determinations.

The NIOSH list includes many examples of materials that would be regulated as hazardous waste pharmaceuticals. However, the list is based on *occupational safety* criteria—not the criteria established in the federal or state hazardous waste regulations for what constitutes *hazardous waste*. As a case in point, the NIOSH list includes examples of waste that would *not* be regulated as hazardous waste. Additionally, since pharmaceuticals are under constant research and development, it would be virtually impossible for NIOSH or anyone else to develop a current, comprehensive list.

The NIOSH hazardous drug list may well be a useful resource for healthcare facilities working to maintain compliance with the VHWMR, but for the aforementioned reasons, we advise against using it as the sole basis for making waste determinations. Additional background information on the NIOSH list can be found in Appendix E (p. 50) of EPA's, "A 10-Step Blueprint for Managing Pharmaceutical Waste in US Healthcare Facilities."

What About Regulated Medical Waste?

Hazardous waste generated by Vermont healthcare facilities is regulated by the VHWMR, either under Subchapters 1 through 7, or under Subchapter 10. "Regulated medical waste" (RMW), on the other hand, requires special handling and treatment prior to disposal, but is regulated by Vermont's Solid Waste Management Rules. Examples of RMW include sharps, blood, animal infectious waste, and other potentially infectious materials. For more information on managing RMW, please refer to the Solid Waste Program's Procedure Addressing Regulated Medical Waste Definitions and the Handling and Treatment of Regulated Medical Waste. Questions about RMW should be directed to the Solid Waste Program at 802-828-1138. For additional resources related to handling sharps, please refer to the Vermont Department of Health's Safe Needle Disposal in Vermont webpage.

For more information regarding pharmaceutical hazardous waste, or if you have other hazardous waste management questions, please contact:

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