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Compliance Guide

MARYLAND STANDARDS FOR THE MANAGEMENT OF HAZARDOUS WASTE PHARMACEUTICALS

Code of Maryland Regulations (COMAR) 26.13.10.32 – .49

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COMPLIANCE GUIDE
MARYLAND STANDARDS FOR THE MANAGEMENT OF HAZARDOUS WASTE PHARMACEUTICALS

I. INTRODUCTION

Effective October 1, 2025 Maryland's hazardous waste regulations will include new management standards for hazardous waste pharmaceuticals generated by healthcare facilities. The new requirements are equivalent to federal regulations that are found in the Code of Federal Regulations (CFR) as Subpart P of 40 CFR Part 266. This document highlights the new requirements, and provides guidance on how to comply.

If you have questions after reviewing this document, please contact the Solid Waste Program of the Maryland Department of the Environment at (410) 537-3315.

Disclaimer: This document is intended to serve as an aid to compliance, but it is not a substitute for the regulations themselves. The legally enforceable requirements are the provisions as-specified in the Code of Maryland Regulations (COMAR). Maryland regulations can be found using the "COMAR Online" feature on the Maryland Division of State Documents (DSD) website at https://dsd.maryland.gov. On the DSD website, access COMAR Online using the drop-down menu under "COMAR" on the left of the page.

II. OVERVIEW

The Maryland Department of the Environment (MDE) has adopted new regulations that healthcare facilities will have to follow in managing waste pharmaceuticals that meet the definition of hazardous waste. The new regulations do not expand the class of wastes that are regulated as hazardous wastes. Instead, they establish pharmaceutical-specific management standards that will need to be followed instead of the management standards that apply to general hazardous waste. The new requirements are found in the Code of Maryland Regulations (COMAR), principally at COMAR 26.13.10.32 – 26.13.10.49.

Healthcare facilities must continue to manage non-pharmaceutical hazardous waste in accordance with the standard hazardous waste regulations. The requirements that apply to all generators of non-pharmaceutical hazardous waste are specified in COMAR 26.13.03, "Standards Applicable to Generators of Hazardous Waste".

III. QUICK START GUIDE TO COMPLIANCE

To determine whether the new requirements for management of hazardous waste pharmaceuticals apply to you, do the following (details on how to make these determinations are presented in the next section of this document):

1. Determine whether you meet the specialized definition of "healthcare facility" in the regulations If you are considered to be a healthcare facility, additional questions need to be answered to determine applicability of the regulations (see items 2 and 3 that immediately follow).

Also, determine whether you are operating as a "reverse distributor" as defined in the regulations. Provisions in COMAR 26.13.10.49 apply to reverse distributors.

2. If you are considered to be a healthcare facility, determine whether you generate any pharmaceuticals that meet the definition of hazardous waste.
3. If you are a healthcare facility that generates hazardous waste pharmaceuticals, determine the amount of hazardous waste pharmaceuticals and the amount of non-pharmaceutical hazardous waste that you generate in a calendar month. These quantities will determine whether the regulations apply to you, as discussed in the next section of this document. (Note that COMAR 26.13.10.32C excludes certain pharmaceuticals from being subject to the hazardous waste management standards of COMAR 26.13.01 – 26.13.10. These excluded pharmaceuticals are not counted in determining the quantities of hazardous waste pharmaceuticals that are generated. More details are found in Section VI of this document.)
4. If you determine that the hazardous waste pharmaceutical regulations apply to your situation, see the "Specific Requirements" section of this document (Section VIII) for details on the applicable management standards.

IV. DETERMINING APPLICABILITY – KEY QUESTIONS

Three Key Questions
The following questions are key to determining whether someone is subject to Maryland's standards for the management of hazardous waste pharmaceuticals:

1. **Is the entity potentially subject to the regulations by being either a "healthcare facility" as defined in the regulations, or a "reverse distributor"?**
2. **Does the entity generate pharmaceuticals, as defined in the regulations, that would meet the definition of hazardous waste, if discarded?**
3. **In a given calendar month, what quantity of hazardous waste pharmaceuticals and what quantity of non-pharmaceutical hazardous waste does the entity generate**?

Some relevant considerations for each of these questions will be discussed in turn, Then, an explanation will be given of how to use the answers to the questions to determine the applicability of the regulations.

Re: Q1/key question 1 – (Is an entity potentially subject to the regulations by being either a "healthcare facility" or a "reverse distributor"?)

"Healthcare facility" definition

A "healthcare facility" is one of the types of handlers of pharmaceuticals that is potentially subject to the regulations. The term "healthcare facility" is defined in COMAR 26.13.01.03B(34-2).

The definition of healthcare facility is expansive, and encompasses a number of entities that may not be ordinarily thought of as being a "facility". Here is the definition:

(34-2) Healthcare Facility.

(a) "Healthcare facility" means any person that is legally authorized to:

(i) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care 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;

(ii) Act as a provider of 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

(iii) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

(b) "Healthcare facility" includes, but is not limited to:

(i) Wholesale distributors;

(ii) Third-party logistics providers that serve as forward distributors;

(iii) Military medical logistics facilities;

(iv) Hospitals, psychiatric hospitals, and ambulatory surgical centers;

(v) Health clinics and physicians' offices;

(vi) Optical and dental providers;

(vii) Chiropractors;

(viii) Long-term care facilities;

(ix) Ambulance services;

(x) Pharmacies, long term-care pharmacies, mail-order pharmacies, and retailers of pharmaceuticals;

(xi) Veterinary clinics; and

(xii) Veterinary hospitals.

(c) "Healthcare facility" does not include:

(i) Pharmaceutical manufacturers;

(ii) Reverse distributors with respect to the receipt, accumulation, and processing of prescription pharmaceuticals for the purpose of facilitating or verifying manufacturer credit; or

(iii) Reverse logistics centers.

Some points to note in connection with the definition of "healthcare facility":

- "Person" in this definition means more than just an individual. "Person" is a defined term in the hazardous waste regulations, and means an individual, trust, firm, joint stock company, federal agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body. See COMAR 26.13.01.03B(61).
- "Healthcare facility" refers not only to hospitals and clinics, but to a wide range of other entities that are involved with the handling of pharmaceuticals, such as individual medical service providers, pharmacies, distributors, ambulance services, and entities that dispense or sell pharmaceuticals, including sellers of over-the-counter items that meet the definition of "pharmaceutical" (The definition of pharmaceutical is discussed later in this section under "Re: Q2/key question 2 …" .)
- "Long-term care facility" is defined in COMAR 26.13.01.03B(48-1).
- A "reverse logistics center" (which is excluded from the definition of healthcare facility) refers to a facility that receives a reverse flow of nonprescription pharmaceuticals and

other unsold retail items (such as excess inventory, expired or outdated items, seasonal items, overstock, recalled items, and returned items that cannot be returned to inventory) from retail locations and evaluates the received materials for legitimate use/reuse or reclamation.

"Reverse distributor" definition

In addition to the provisions applicable to healthcare facilities, Maryland's hazardous waste pharmaceutical regulations also include provisions applicable to "reverse distributors". A reverse distributor is defined as a person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit (see COMAR 26.13.01.03B(67-1) or Appendix 1 of this document.)

A "potentially creditable hazardous waste pharmaceutical" is defined in COMAR 26.13.01.03B(64-1) as a prescription hazardous waste pharmaceutical that:

1. Has a reasonable expectation to receive manufacturer credit;
2. Is in original manufacturer packaging;
3. Is not a pharmaceutical that was subject to a recall;
4. Is undispensed; and
5. Is unexpired or is less than 1 year past its expiration date.

Re: Q2/key question 2 – (Are hazardous waste pharmaceuticals generated?)

"Pharmaceutical" definition

A healthcare facility is potentially subject to targeted waste management standards if the healthcare facility generates a pharmaceutical that meets the definition of hazardous waste. For the purposes of these regulations, "pharmaceutical" has the following definition (COMAR 26.13.01.03B(62-2)):

(62-2) Pharmaceutical.
(a) "Pharmaceutical" means:
(i) A drug or dietary supplement for use by humans or other animals;
(ii) An electronic nicotine delivery system, such as an electronic cigarette or vaping pen; or
(iii) A liquid nicotine-containing product packaged for retail sale for use in electronic nicotine delivery systems, and including a pre-filled cartridge, pre-filled vial, or other packaging.
(b) "Pharmaceutical" includes, but is not limited to:
(i) A dietary supplement, as defined by the Federal Food, Drug and Cosmetic Act;
(ii) A prescription drug, as defined by 21 CFR §203.3(y);
(iii) An over-the-counter drug;
(iv) A homeopathic drug;
(v) A compounded drug;
(vi) An investigational new drug;
(vii) A pharmaceutical remaining in a nonempty container;
(viii) Personal protective equipment contaminated with a pharmaceutical; and
(ix) Clean-up material from a spill of a pharmaceutical.
(c) "Pharmaceutical" does not include dental amalgam or sharps.

A container that held a hazardous waste pharmaceutical (including stock or dispensing bottles, unit-dose containers, syringes, IV bags, and other containers such as inhalers and nebulizers) is also subject to the hazardous waste pharmaceutical management standards unless the container is "empty". The regulations include new criteria that define whether a container that held a hazardous waste pharmaceutical is considered to be an empty container. The new criteria are found in COMAR 26.13.10.35, and discussed in Section VIII.D of this document.

"Hazardous waste pharmaceutical" has the following definition (COMAR 26.13.01.03B(34-1)):

> (34-1) Hazardous Waste Pharmaceutical.
>
> (a) "Hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste as defined in COMAR 26.13.02.02 and:
>
> (i) Exhibits one or more characteristics identified in COMAR 26.13.02.10—.14; or
>
> (ii) Is listed in COMAR 26.13.02.15—.19.
>
> (b) "Hazardous waste pharmaceutical" does not include:
>
> (i) A pharmaceutical that will be legitimately used or reused by, for example, being lawfully donated for use for its intended purpose;
>
> (ii) A pharmaceutical that is reclaimed, as described in COMAR 26.13.02.01D(7);
>
> (iii) An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug for which there is a reasonable expectation that the item will be legitimately used or reused by, for example, being lawfully redistributed for use for its intended purpose; or
>
> (iv) An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug for which there is a reasonable expectation that the item will be reclaimed.

"Listed" hazardous wastes are identified in COMAR 26.13.02.15 – 26.13.02.19. For pharmaceuticals, the relevant lists to check are those in COMAR 26.13.02.19 (Discarded Commercial Chemical Products, Off-Specification Species, Containers, and Spill Residues of These). A waste pharmaceutical is considered to be a "listed" hazardous waste if one of the chemicals in the lists in COMAR 26.13.02.19E and G is the sole active ingredient of the pharmaceutical, and the pharmaceutical has not been used for its intended purpose. A constituent of the pharmaceutical that serves a secondary function such as preserving or mobilizing a primary active ingredient is not considered to be an active ingredient. (The other lists of hazardous wastes in COMAR 26.13.02.19 are not relevant for waste pharmaceuticals, but are relevant for making general hazardous waste determinations,)

Wastes on the list in COMAR 26.13.02.19E, which are assigned waste codes that begin with the letter P, are classified as "acute" hazardous wastes. The quantity of acute hazardous waste that a generator produces is given separate consideration in determining the applicable generator category for the generator.

Characterization of a waste pharmaceutical as to whether it meets the definition of hazardous waste also requires a determination of whether the waste exhibits any of four hazardous waste characteristics defined in Maryland and federal regulations. The four characteristics are ignitability (substances that have a flash point less than 140° F, or are oxidizers); corrosivity (pH less than or equal to 2 or greater than or equal to 12.5); reactivity (unstable materials that readily undergo violent change; explosives; materials that can generate dangerous levels of cyanide or sulfide gas); and toxicity (specified metals and organic compounds are present in excess of

specified limits, as determined using a specified standard method). Reactivity is typically not a concern for pharmaceuticals, and corrosivity is only an issue in limited cases. Ignitability can be a concern, especially for pharmaceuticals that have a high alcohol content. The toxicity characteristic can also be a concern – sometimes, because of added preservatives, sometimes because the active ingredient includes toxicity characteristic constituents.

A useful summary of the waste characterization process for pharmaceuticals can be found as Step 1 in the document "10-Step Blueprint for Managing Pharmaceutical Waste in US Healthcare Facilities" prepared by the Healthcare Environmental Resource Center (HERC) in cooperation with the U.S. Environmental Protection Agency (EPA). The document also includes examples of pharmaceuticals that meet the definition of hazardous waste (though not a comprehensive list). The document is available from a link on the HERC website at https://www.hercenter.org/index.php .

Re: Q3/key question 3 – determination of applicability based on quantities of waste generated.

Once it has been determined that an entity meets the definition of a healthcare facility, and that the entity generates hazardous waste pharmaceuticals, then the applicable management standards can be identified. The determining factors are the amount of hazardous waste pharmaceuticals generated during a given calendar month, the amount of non-pharmaceutical hazardous waste generated during the same calendar month, and the federally-defined hazardous waste generator categories that correspond to the amount of these wastes generated during the calendar month.

The federal hazardous waste categories and the waste quantities that define the categories are specified in the following table (Table 1):

Table 1 – Waste Generation Criteria That Define Federal Categories for Hazardous Waste Generators

Federal Category	Amount of Hazardous Waste Generated in a Calendar Month
Large Quantity Generator (LQG)	More than 1 kilogram (kg) of acute hazardous waste, 1000 kg or more of non-acute hazardous waste, or both.
Small Quantity Generator (SQG)	1 kg or less of acute hazardous waste; more than 100 kg and less than 1000 kg of non-acute hazardous waste; or both.
Very Small Quantity Generator (VSQG)	1 kg or less of acute hazardous waste and 100 kg or less of non-acute hazardous waste,

To determine which regulations apply to the management of hazardous waste pharmaceuticals, the healthcare facility should consult the following table (Table 2) after determining the amount of hazardous waste pharmaceuticals generated in a calendar month, the amount of non-pharmaceutical hazardous waste generated in a calendar month, and the total amount of hazardous waste generated in a calendar month. Table 2 also identifies the federal hazardous waste generator category that applies to the generator based on the amounts of waste generated in each of the categories defined by the headings of columns A, B, and C in the table.

To use the table, determine the amount of waste generated in each of the categories defined by the headings of columns A, B, and C in the table. Then, find the line of the table that corresponds to the applicable combination. The two rightmost columns in the table specify whether the hazardous waste pharmaceutical regulations are applicable, and the federal hazardous waste generator classification that applies

For example, a healthcare facility that (A) generates any amount of hazardous waste pharmaceuticals in a calendar month; (B) generates non-pharmaceutical hazardous waste at the SQG level in that calendar month; and (C) generates a combined total of hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste at the LQG levels would correspond to line 3 of the table. The hazardous waste pharmaceutical regulations are applicable to such a generator, and the generator is classified as a small quantity generator for federal reporting purposes (for completing the federal form 8700-12 (site notification), for example).

Note that long-term care facilities with no more than 20 beds are a special case. They are addressed by the last line of the table.

Table 2 – Applicable Requirements, Based on Quantities of Waste Generated

	Defining Characteristics of Generator, Unless Note 1 following this Table Applies (also see Note 2 following this table)			**Subject to Requirements in COMAR 26.13.10.32E(3)?** (see Note 3 following this table)	**Federal Hazardous Waste Generator Category of Healthcare Facility** (see Note 4 following this table)
	Column A Amount of Hazardous Waste Pharmaceuticals Generated, Calendar Month	Column B Amount of Non-Pharmaceutical Hazardous Waste Generated, Calendar Month	Column C Total Hazardous Waste Generated, Calendar Month (Hazardous Waste Pharmaceuticals and Non-Pharmaceutical Haz. Waste)		
1.	Any amount, acute or non-acute	> 1 kg acute, ≥ 1000 kg non-acute, or both [LQG level]	>1 kg acute, ≥ 1000 kg non-acute, or both [LQG level]	Yes – subject to COMAR 26.13.10.32E(3). See COMAR 26.13.10.32E(1)(a)	large quantity generator
2.	Any amount, acute or non-acute	• Acute: ≤ 1 kg; and • Non-acute > 100 kg and < 1000 kg [SQG level]	• Acute: ≤ 1 kg; and • Non-acute > 100 kg and < 1000 kg [SQG level]	Yes – subject to COMAR 26.13.10.32E(3). See COMAR 26.13.10.32E(1)(a)	small quantity generator
3.	Any amount, acute or non-acute	• Acute: ≤ 1 kg; and • Non-acute > 100 kg and < 1000 kg [SQG level]	> 1 kg acute, ≥ 1000 kg non-acute, or both [LQG level]	Yes – subject to COMAR 26.13.10.32E(3). See COMAR 26.13.10.32E(1)(a)	small quantity generator

	Defining Characteristics of Generator, Unless Note 1 following this Table Applies (also see Note 2 following this table)			**Subject to Requirements in COMAR 26.13.10.32E(3)?** (see Note 3 following this table)	**Federal Hazardous Waste Generator Category of Healthcare Facility** (see Note 4 following this table)
	Column A Amount of Hazardous Waste Pharmaceuticals Generated, Calendar Month	Column B Amount of Non-Pharmaceutical Hazardous Waste Generated, Calendar Month	Column C Total Hazardous Waste Generated, Calendar Month (Hazardous Waste Pharmaceuticals and Non-Pharmaceutical Haz. Waste)		
4.	> 1 kg acute, > 100 kg non-acute, or both [exceeds VSQG level]	≤ 1 kg acute and ≤ 100 kg non-acute [VSQG level]	> 1 kg acute, > 100 kg non-acute, or both [exceeds VSQG level]	Yes – subject to COMAR 26.13.10.32E(3). See COMAR 26.13.10.32E(1)(b).	very small quantity generator (see Note 5 following this table)
5.	≤ 1 kg acute, and ≤ 100 kg non-acute [VSQG level]	≤ 1 kg acute and ≤ 100 kg non-acute [VSQG level]	> 1 kg acute, > 100 kg non-acute, or both [exceeds VSQG level]	Yes – subject to COMAR 26.13.10.32E(3). See COMAR 26.13.10.32E(1)(c)	very small quantity generator (see Note 5 following this table)
6.	≤ 1 kg acute, and ≤ 100 kg non-acute [VSQG level]	≤ 1 kg acute and ≤ 100 kg non-acute [VSQG level]	≤ 1 kg acute and ≤ 100 kg non-acute [VSQG level]	Not subject to COMAR 26.13.10.32E(3) unless the generator voluntarily elects to manage hazardous waste pharmaceuticals in accordance with these provisions. The generator is, however, subject to the requirements of COMAR 26.13.10.32D(1).	very small quantity generator (see Notes 5 and 6 following this table)

	Defining Characteristics of Generator, Unless Note 1 following this Table Applies (also see Note 2 following this table)			Subject to Requirements in COMAR 26.13.10.32E(3)? (see Note 3 following this table)	Federal Hazardous Waste Generator Category of Healthcare Facility (see Note 4 following this table)
	Column A Amount of Hazardous Waste Pharmaceuticals Generated, Calendar Month	Column B Amount of Non-Pharmaceutical Hazardous Waste Generated, Calendar Month	Column C Total Hazardous Waste Generated, Calendar Month (Hazardous Waste Pharmaceuticals and Non-Pharmaceutical Haz. Waste)		
	xxxxxx	xxxxxx	xxxxxx		
7.	Long-term Care Facility with ≤ 20 Beds (special category) ("Long-term care facility" is defined in COMAR 26.13.01.03B(48-1))			Not subject to COMAR 26.13.10.32E(3) unless MDE demonstrates that the facility does not qualify to be a Very Small Quantity Generator. See COMAR 26.13.10.32D(2) for details.	Presumed to be a very small quantity generator unless the MDE demonstrates otherwise.

Table 2 Notes

1. If a healthcare facility also generates any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in COMAR 26.13.02.16 or COMAR 26.13.02.19E, the facility shall also consider that waste in determining the federal generator category that corresponds to the amount of nonpharmaceutical hazardous waste that the facility generates.

2. In this table:
   "[VSQG level]" indicates that the category of waste referenced in the table cell is generated in a quantity that is within the limits of the federal Very Small Quantity Generator category;

   "[SQG level]" indicates that the category of waste referenced in the table cell is generated in a quantity that is within the limits of the federal Small Quantity Generator category; and

   "[LQG level]" indicates that the category of waste referenced in the table cell is generated in a quantity that is within the limits of the federal Large Quantity Generator category.

   "<" means less than; "≤" means less than or equal, ">" means greater than, and "≥" means greater than or equal.

3. COMAR 26.13.10.32E(3) identifies the regulations in COMAR 26.13.10.33 – .48 that the generator is subject to in managing hazardous waste pharmaceuticals.

4. The federal hazardous waste generator category is used in Maryland's hazardous waste regulations for the purposes of completing certain federal forms and for determining eligibility for certain exemptions. Details are found in COMAR 26.13.03.01-1C(2).

5. A generator that generates waste in the amounts listed in columns A, B, and C on line 4, line 5, or line 6 of Table 2 needs to consider the amount of non-pharmaceutical hazardous waste that has been accumulated on site at any time and the amount of non-pharmaceutical hazardous waste generated in each calendar month in determining the Maryland hazardous waste generator category that applies. The Maryland hazardous waste generator category determines the applicable requirements for managing the non-pharmaceutical hazardous

waste. If the generator accumulates at any time more than 1 kilogram of acute hazardous waste or more than 100 kilograms of hazardous waste, then the generator is fully regulated under Maryland's hazardous waste regulations. This is the case even if the generator is generating non-pharmaceutical hazardous waste at VSQG levels in every calendar month. Full details on the criteria that define the applicability of Maryland's hazardous waste regulations to generators of hazardous waste are found at COMAR 26.13.03.01A-1 and A-2.

6. COMAR 26.13.10.32D(2)(b) allows a person who is classified as a VSQG based on the criteria in this row of Table 2 to voluntarily elect to manage hazardous waste pharmaceuticals under the provisions of COMAR 26.13.10.32E(3). However, if the person chooses not to manage hazardous waste pharmaceuticals under the voluntary provisions, the person could become fully regulated under Maryland's hazardous waste regulations despite being classified as a VSQG under federal regulations.

   This is because Maryland's hazardous waste generator categories take into account the amount of hazardous waste that has been accumulated on site at any time as one of the criteria in determining whether a generator qualifies as a Maryland-defined small quantity generator (MDSQG – Maryland's version of the federal VSQG category.)

   If a hazardous waste pharmaceutical is being managed under COMAR 26.13.10.32E(3), then it is excluded from being counted for the purposes of determining the Maryland hazardous waste generator category (see COMAR 26.13.02.05A(2)(h)), and only the inventory of non-pharmaceutical hazardous waste has to be counted in determining whether the MDSQG accumulation limit has been exceeded. However, if the generator is not managing hazardous waste pharmaceuticals under COMAR 26.13.10.32E(3), then the total inventory of hazardous waste that is on site at any time (pharmaceutical and non-pharmaceutical) must be counted to determine if the limit for the Maryland-defined small quantity generator has been exceeded. The quantity of accumulated hazardous waste pharmaceuticals, when added to the quantity of accumulated non-pharmaceutical hazardous waste, could be enough to exceed the MDSQG limit even though the generator would be classified as MDSQG when only the non-pharmaceutical hazardous waste is taken into account

   To avoid this potential pitfall, a generator who qualifies for the federal VSQG category should consider whether the total amount of hazardous waste accumulated on site (non-pharmaceutical hazardous waste plus hazardous waste pharmaceuticals) might, at some point, exceed the accumulation limits for the MDSQG category. If that is a possibility, then the generator should consider voluntarily managing their hazardous waste pharmaceuticals under the provisions of COMAR 26.13.10.32e(3).

V. EXCLUDED ENTITIES

As noted on lines 6 and 7 of Table 2, an entity that meets the definition of "healthcare facility" that generates hazardous waste pharmaceuticals, non-pharmaceutical hazardous waste, and hazardous waste (pharmaceutical plus non-pharmaceutical) at levels that define the federal Very Small Quantity Generator (VSQG) category is not required to comply with most of the provisions of COMAR 26.13.10.33 – 26.13.10.48. A similar exclusion applies to a long-term care facility, as defined in COMAR 26.13.01.03B, unless MDE can demonstrate that the facility does not meet the criteria to be considered a Very Small Quantity Generator.

COMAR 26.13.10.32D identifies the applicable requirements for these entities. They are subject to the prohibition on sewer disposal of hazardous waste pharmaceuticals (COMAR 26.13.10.34), and the requirements of COMAR 26.13.10.35 that determine whether a pharmaceutical-related item that is considered a container (such as a stock, dispensing, or unit-dose container; a syringe, an intravenous (IV) bag, or other item used to dispense or apply a hazardous waste pharmaceutical) is considered "empty". These provisions are discussed in Section VIII.D of this document.

These excluded entities are required to manage their hazardous waste pharmaceuticals in accordance with COMAR 26.13.02.05, which establishes standards for management of

hazardous waste generated by Maryland-defined small quantity generators. However, as an alternative, they are allowed to manage their hazardous waste pharmaceuticals in accordance with the provisions of COMAR 26.13.10.33 – 26.13.10.48. Also, they are allowed to take advantage of the optional provisions in COMAR 26.13.10.36, which provides some additional options for off-site disposition of pharmaceuticals. These optional provisions are discussed in Section VIII.E of this document.

Note that the scope of the regulations discussed in this document is limited to "healthcare facilities" as defined in the regulations. Other entities that generate hazardous waste pharmaceuticals but are not healthcare facilities are required to manage those wastes in accordance with COMAR 26.13.03, Standards Applicable to Generators of Hazardous Waste, rather than the regulations discussed in this document. Examples of such entities include pharmaceutical manufacturers, and farmers, ranchers, and fisheries that administer pharmaceuticals to their animals in the regular course of business.

VI. EXCLUDED PHARMACEUTICALS

COMAR 26.13.10.32C excludes certain pharmaceuticals from being subject to the hazardous waste management standards of COMAR 26.13.01 – 26.13.10. Excluded materials include:

- A pharmaceutical that is not a solid waste, as defined in COMAR 26.13.02.02, because the pharmaceutical is to be reclaimed (i.e., processed to recover a useful product or regenerated), or is legitimately used or legitimately reused, such as by being lawfully donated for use for the pharmaceutical's intended purpose;
- An over-the-counter pharmaceutical, a dietary supplement, or a homeopathic drug that is not a solid waste, as defined in COMAR 26.13.02.02, because the material is going to be reclaimed, or there is a reasonable expectation that the material will be legitimately used or legitimately reused, such as by being lawfully redistributed for use for its intended purpose;
- As qualified by COMAR 26.13.10.32C(1)(c) and (d), a pharmaceutical that is being managed under (a) a recall strategy approved by the U.S. Food and Drug Administration (FDA), or (b) a recall corrective action plan that has been approved by the U.S. Consumer Product Safety Commission;
- Until a decision has been made to discard it, a pharmaceutical that is being stored during an investigation, during a judicial proceeding, or according to a preservation order;
- An investigational new drug for which an investigational new drug application is in effect in accordance with the FDA's regulations in 21 CFR Part 312, until a decision has been made to discard the investigational new drug;
- Household waste pharmaceuticals; and
- Residues of hazardous waste pharmaceuticals that remain in certain items if the item meets criteria to be considered "empty" under COMAR 26.13.10.35.

VII. REVERSE DISTRIBUTION AND REVERSE LOGISTICS SYSTEMS

One of the goals of the EPA in developing the federal regulations on which Maryland's regulations on hazardous waste pharmaceuticals are based was to provide clarity on the status of pharmaceuticals that are managed through "reverse distribution" and "reverse logistics" systems.

EPA drafted the regulations in a manner that took into account existing business practices for the management of unused products.

"Reverse distribution system" refers to a system through which pharmaceutical manufacturers offer a manufacturer's credit for returned prescription pharmaceuticals. The regulations include special provisions to facilitate the transfer of prescription pharmaceuticals that are potentially eligible for manufacturer credit to "reverse distributors". The reverse distributors determine whether items qualify for manufacturer credit.

Items that are eligible for handling via the reverse distribution system include undispensed pharmaceuticals in original manufacturer's packaging that have not been subject to a recall and that are unexpired or less than one year past their expiration date. As discussed in Section VIII.P of this document, the regulations include requirements for the generators of pharmaceuticals that are being processed through the reverse distribution system, and for the reverse distributors who are evaluating the pharmaceuticals for potential manufacturer credit.

"Reverse logistics system" refers to the system of business practices that is in place to collect and evaluate unsold retail items to determine whether there are secondary markets for those items, and evaluate whether particular items have a potential for use, reuse, or reclamation. Unsold items at a retailer may have value as something that can be donated for use for its intended purpose, sold to another retailer (such as an overstock outlet or discount vendor) for sale to the public, or sent for legitimate recycling or reclamation.

In the context of the hazardous waste pharmaceutical regulations, considerations concerning reverse logistics come into play for nonprescription pharmaceuticals, such as over-the-counter medications, dietary supplements, and homeopathic drugs. If there is a reasonable expectation that a nonprescription pharmaceutical will (a) be used or reused by, for example, being lawfully redistributed for use for its intended purpose, or (b) be reclaimed, the pharmaceutical is not considered to be regulated as a solid waste, and is therefore excluded from regulation as hazardous waste.

VIII. SPECIFIC REQUIREMENTS

The remainder of this document discusses specific requirements applicable to the management of hazardous waste pharmaceuticals generated by healthcare facilities, and requirements related to reverse distribution and reverse logistics systems for prescription and non-prescription hazardous waste pharmaceuticals. Requirements are discussed in the order that they appear in COMAR. These discussions are only intended to be an overview of the requirements, rather than a comprehensive presentation of all the nuances. The regulations themselves should be reviewed to gain a complete understanding of what is required to be in compliance.

A. Defined Terms

COMAR 26.13.10.32B identifies several specialized terms that have particular meanings for the purposes of the hazardous waste pharmaceuticals regulations. The definitions for these terms are found in COMAR 26.13.01.03B. These terms are:

(1) "Evaluated hazardous waste pharmaceutical";

(2) “Hazardous waste pharmaceutical”;
(3) “Healthcare facility”;
(4) “Household waste pharmaceutical”;
(5) “Long-term care facility”;
(6) “Non-creditable hazardous waste pharmaceutical”;
(7) “Non-hazardous waste pharmaceutical”;
(8) “Non-pharmaceutical hazardous waste”;
(9) “Pharmaceutical”;
(10) “Potentially creditable hazardous waste pharmaceutical”; and
(11) “Reverse distributor”.

Refer to the definitions of these terms in COMAR 26.13.01.03B to ensure that you understand what the regulations are referring to, and what actions need to be taken to be in compliance.

For the convenience of the reader, the definition for these terms are provided in **APPENDIX 1** of this document.

The defined terms include definitions for three types of hazardous waste pharmaceuticals: “evaluated hazardous waste pharmaceuticals”, “non-creditable hazardous waste pharmaceuticals”, and “potentially creditable hazardous waste pharmaceuticals”. The category that applies to a given hazardous waste pharmaceutical will determine the applicable management standards and the available disposition pathways for that pharmaceutical.

A “**non-creditable hazardous waste pharmaceutical**” is either:

1. A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit; or
2. A nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be reclaimed, legitimately used, or legitimately reused.

A healthcare facility managing non-creditable hazardous waste pharmaceuticals that is subject to the hazardous waste pharmaceutical regulations is subject to the general management standards in COMAR 26.13.10.37 – 26.13.10.38, the standards specific for the management of non-creditable hazardous waste pharmaceuticals in COMAR 26.13.10.39 – 26.13.10.45, and the shipping requirements of COMAR 26.13.10.47.

A “**potentially creditable hazardous waste pharmaceutical**” is a prescription hazardous waste pharmaceutical that:

1. Has a reasonable expectation to receive manufacturer credit;
2. Is in original manufacturer packaging;
3. Is not a pharmaceutical that was subject to a recall;
4. Is undispensed; and
5. Is unexpired or is less than 1 year past its expiration date.

A healthcare facility managing potentially creditable hazardous waste pharmaceuticals that is subject to the hazardous waste pharmaceutical regulations is subject to the general management standards in COMAR 26.13.10.37 – 26.13.10.38, the standards specific for the management of potentially creditable hazardous waste pharmaceuticals in COMAR 26.13.10.46, and the shipping requirements of COMAR 26.13.10.48.

An "**evaluated hazardous waste pharmaceutical**" is a prescription hazardous waste pharmaceutical that:

1. Has been evaluated by a reverse distributor to determine whether the pharmaceutical is eligible for a manufacturer credit in accordance with COMAR 26.13.10.49 and 40 CFR §266.510(a)(3); and
2. Will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

This category of waste is governed by rules that apply to reverse distributors. Shipping requirements for an evaluated hazardous waste pharmaceutical are specified in COMAR 26.13.10.47. Management standards for evaluated hazardous waste pharmaceuticals (which apply to reverse distributors) are specified in COMAR 26.13.10.49.

B. <u>Prohibition on sewer disposal of hazardous waste pharmaceuticals</u> (COMAR 26.13.10.33)

This provision prohibits certain entities from discharging hazardous waste pharmaceuticals to a sewer system. The prohibition applies to:

(1) Healthcare facilities that:
- Are managing hazardous waste pharmaceuticals under the requirements for MDSGQs in COMAR 26.13.02.05;
- Are voluntarily managing hazardous waste pharmaceuticals under COMAR 26.13.10.37 – 26.13.10.48, rather than 26.13.02.05; or
- Are required to manage hazardous waste pharmaceuticals under COMAR 26.13.10.37 – 26.13.10.48; and

(2) Reverse distributors

(Note: see Table 2 in Section IV of this document and the associated discussion in Section IV to determine what regulations apply to a healthcare facility that generates hazardous waste pharmaceuticals.)

Although the prohibition on sewer disposal only applies to specified entities, even if the sewer disposal is not applicable to you, sewering of pharmaceuticals by any entity is strongly discouraged.

C. <u>Conditional exemptions – DEA Controlled Substances and household waste pharmaceuticals</u> (COMAR 26.13.10.34)

These provisions are intended to facilitate the collection and proper disposition of the few hazardous waste pharmaceuticals that are also controlled substances under regulations of the federal Drug Enforcement Administration (DEA). The provisions establish conditional exemptions for healthcare facilities and reverse distributors for:

- Hazardous waste pharmaceuticals that are DEA controlled substances; and
- Household waste pharmaceuticals that are collected in a take-back event or program.

For either of these activities, if the healthcare facility or reverse distributor meets the following conditions, then the eligible wastes are not subject to management as hazardous waste under COMAR 26.13.03 – 26.13.10.

The conditions of exemption (COMAR 26.13.10.34B) are that the wastes must be:

- Managed in accordance with the prohibition on sewer disposal of hazardous waste pharmaceuticals (COMAR 26.13.10.34);
- Managed in accordance with all applicable DEA regulations for controlled substances; and
- Destroyed using a method that the DEA has deemed to meet the DEA's non-retrievable standard of destruction, or destroyed by combustion using one of the types of facilities specified in the regulation (municipal waste combustors, hospital medical and infectious waste incinerators, commercial and industrial solid waste incinerators, and hazardous waste combustors).

An example of a take-back program that could potentially qualify for the exemption would be a hospital or retail pharmacy that is registered with the DEA and that has their registration amended so that they become an "authorized collector" under the DEA rules. The hospital or retail pharmacy could then install, consistent with DEA requirements, a kiosk for permanent take-back of household pharmaceuticals. The collected material could include DEA controlled substances as well as other household pharmaceuticals. As long as the conditions of exemption in the preceding paragraph are met, the wastes are not subject to management as hazardous waste under COMAR 26.13.03 – 26.13.10.

D. <u>"Empty container" Criteria</u> (COMAR 26.13.10.35)

Criteria in COMAR 26.13.02.07 define when a container that previously held hazardous waste is considered to be "empty". A container that meets these criteria does not have to be managed as hazardous waste even though it may still contain some residues of hazardous waste.

The "empty container" criteria in COMAR 26.13.02.07 were developed for general commercial and industrial hazardous wastes. Such wastes would typically be held in drums, totes, bottles, boxes. and similar containers that are amenable to effective emptying by pouring, pumping, aspirating, rinsing, and similar actions.

In the healthcare setting, the "empty container" criteria for general hazardous wastes are, in many cases, not suitable for the types of items that may hold a hazardous waste pharmaceutical. For example, "triple rinsing", which the criteria in COMAR 26.13.02.07 require in order to render empty a container that held an acute hazardous waste is not practical for a unit-dose container such as a blister pack or a unit-dose packet that held a hazardous waste pharmaceutical. There has also been confusion on how to apply the "empty container" criteria to healthcare-related materials such as intravenous (IV) bags and tubing, syringes, inhalers, and nebulizers.

COMAR 26.13.10.36 establishes "empty container" criteria for the following types of containers used for hazardous waste pharmaceuticals at healthcare facilities:

- Stock, dispensing, and unit-dose containers;
- Syringes;
- Intravenous (IV) bags; and
- Other containers, including delivery devices, that are not covered by the first 3 categories.

The following table summarizes the criteria that define an empty container for these types of containers and the actions that need to be taken for an item to be considered empty.

Table 3 – "Empty Container" Criteria – Hazardous Waste (HW) Pharmaceuticals at Healthcare Facilities

Container Category	Actions Needed to Render Container "Empty":	
	Container Contents	
	Non-Acute HW Pharmaceutical	Acute HW Pharmaceutical
Stock dispensing bottles (capacity not more than 1 liter and not more than 10,000 pills)	Remove contents	Remove contents
Unit-dose containers	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents, or meet "empty container" criteria of COMAR 26.13.02.07B(1)	Fully administer contents
Other containers (a container that does not fall into any of the above categories – examples: inhalers, aerosol cans, nebulizers, and tubes of ointments, gels or creams)	Meet "empty container" criteria of COMAR 26.13.02.07B(1) or B(2)	Not applicable – cannot be considered an empty container. Manage as a non-creditable hazardous waste pharmaceutical under COMAR 26.13.10.33 – .47.

E. Optional Provisions – Healthcare Facilities that Qualify as Very Small Quantity Generators (COMAR 26.13.10.36)

As indicated on lines 6 and 7 of Table 2 in Section IV of this document ("Applicable Requirements, Based on Quantities of Waste Generated"), certain healthcare facilities are exempted from most of the provisions of COMAR 26.13.10.33 – 26.13.10.48 in managing hazardous waste pharmaceuticals. Specifically, an entity that generates hazardous waste pharmaceuticals, non-pharmaceutical hazardous waste, and hazardous waste (pharmaceutical plus non-pharmaceutical) at levels that define the federal Very Small Quantity Generator (VSQG) category is not required to comply with most provisions of COMAR 26.13.10.33 – 26.13.10.48. A similar exclusion applies to a long-term care facility, as defined in COMAR 26.13.01.03B, unless MDE can demonstrate that the facility does not meet the criteria to be considered a Very Small Quantity Generator.

These entities that are excluded from most provisions of COMAR 26.13.10.33 – 26.13.10.48 are required to manage their hazardous waste pharmaceuticals in accordance with the provisions of COMAR 26.13.02.05, which are requirements that apply to Maryland-defined small quantity generators. Alternatively, they can voluntarily elect to manage their hazardous waste pharmaceuticals under the provisions of COMAR 26.13.10.33 – 26.13.10.48.

COMAR 26.13.10.36C allows an entity that is managing its hazardous waste pharmaceuticals under COMAR 26.13.02.05 (provisions for hazardous waste generated by Maryland-defined small quantity generators), and is not voluntarily following the provisions of COMAR 26.13.10.33 – 26.13.10.48, some additional disposition options for their hazardous waste pharmaceuticals beyond those allowed by COMAR 26.13.02.05 for non-pharmaceutical hazardous waste. Potentially creditable pharmaceuticals may be sent to a reverse distributor. The entity may also send its hazardous waste pharmaceuticals to an off-site healthcare facility for consolidation with the off-site facility's hazardous waste pharmaceuticals, subject to certain conditions.

The conditions under which waste may be sent for consolidation at an off-site healthcare facility include:

- The entity that generated the waste and the healthcare facility to which the waste is being sent must be under the controls of the same "person", as defined in COMAR 26..13.01.03B; and
- The receiving facility must manage the waste in accordance with COMAR 26.13.10.45 if a non-creditable hazardous waste pharmaceutical is being sent for consolidation, or COMAR 26.13.10.46B if a potentially creditable hazardous waste pharmaceutical is being sent for consolidation.

Alternatively, the waste intended for consolidation could be shipped to an off-site hazardous waste generator if the generator and the consolidating facility are under the control of the same person, and the conditions of COMAR 26.13.02.05D(2)(h) and 26.13.03.03-11 (which relate to consolidation of general hazardous waste generated by Maryland-defined small quantity generators) are met.

COMAR 26.13.10.36D allows a long term care facility that qualifies as a very small quantity generator under federal regulations, taking into account the amount of both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste generated, to dispose of hazardous waste pharmaceuticals through channels used for DEA controlled substances, subject to certain conditions.

F. <u>Standards for Healthcare Facilities Managing Hazardous Waste Pharmaceuticals — Applicability</u> (COMAR 26.13.10.37)

COMAR 26.13.10.37 identifies the healthcare facilities that are subject to the hazardous waste pharmaceutical regulations in COMAR 26.13.10, and identifies the particular regulations within COMAR 26.13.10 that are applicable to non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals.

G. Notification – Healthcare Facilities Managing Hazardous Waste Pharmaceuticals (COMAR 26.13.10.38)

COMAR 26.13.10.38 establishes a notification requirement for persons who are managing hazardous waste pharmaceuticals under COMAR 26.13.10.32 – 26.13.10.49. Notification is made by submitting information using EPA Form 8700-12 (RCRA Subtitle C Site Identification Form), either as an initial notification if there is not an EPA Site Identification Number (EPA Site ID number) associated with the site, or as a subsequent notification if the site was previously assigned an EPA ID number.

Persons who qualify as large quantity generators (LQGs) under federal regulations are allowed to satisfy the notification requirement for hazardous waste pharmaceuticals by submitting EPA Form 8700-12 as part of their next biennial report submission. Others are required to submit a completed stand-alone copy of the 8700-12 form.

The notification requirement applies to:

- Healthcare facilities that are required to manage hazardous waste pharmaceuticals under COMAR 26.13.10.32 – 26.13.10.49 (see Section IV of this document for details);
- Persons who voluntarily elect to manage hazardous waste pharmaceuticals under COMAR 26.13.10.32 – 26.13.10.49 (see Section VIII.E of this document for qualifying entities); and
- Reverse distributors.

Persons subject to the notification requirement are required to notify that they are operating under the provisions of 40 CFR Part 266, Subpart P, the federal version of the pharmaceutical provisions in COMAR 26.13.10.32 – 26.13.10.49. They are required to notify again once a determination is made that they will no longer be operating under the pharmaceutical provisions.

Persons who are subject to the notification requirement will have to file an initial or revised EPA Form 8700-12, being sure to complete item 11D ("Pharmaceutical Activities). Details on how to submit the notification form are provided in Appendix 2 of this document.

If an entity operates multiple healthcare facilities as dispersed locations, a separate notification is required for each location that is subject to the hazardous waste pharmaceutical regulations. So, for example, a hospital system that operates multiple off-site clinics would have to submit a separate notification for each of those locations. However, only a single notification is required for a location with multiple sites under control of the same operator that are considered to be on the site of a single facility (such as a military base, for instance.)

Initial notification deadline: The deadline to submit the initial notification that a facility is operating under the hazardous waste pharmaceutical regulations depends on the federal generator status of the facility, and whether the facility already has an EPA ID number, as follows:

1. Sites that already have an EPA ID number:
   - Federal generator category: LQG
     - Notification requirement is met by submitting the next biennial report of hazardous waste activity before the report filing deadline

- Federal generator category: SQG
  - Submit notification by filing an updated EPA 8700-12 form within 60 days after October 1, 2025, or within 60 days after first becoming subject to the hazardous waste pharmaceuticals regulations.
  - EXCEPTION: a facility that is not classified as LQG but is required under federal regulations to submit a biennial report of hazardous waste activity will be considered to have met the notification requirement by submitting the next biennial report of hazardous waste activity before the report filing deadline. Examples of such facilities are facilities subject to an operating permit for treatment, storage or disposal of hazardous waste; facilities that receive waste from off-site for management in a unit subject to an operating permit for hazardous waste management; and facilities that recycle hazardous waste received from off site.
- Federal generator category: VSQG (if facility is voluntarily electing to manage its hazardous waste pharmaceuticals under the hazardous waste pharmaceutical regulations)
  - Submit notification by filing an updated EPA 8700-12 form within 60 days after October 1, 2025, or within 60 days after first becoming subject to the hazardous waste pharmaceuticals regulations.

2. Sites that do not have an EPA ID number (all generator categories):
  - Submit notification by filing an updated EPA 8700-12 form within 60 days after October 1, 2025, or within 60 days after first becoming subject to the hazardous waste pharmaceuticals regulations.

(Note: For guidance on determining your federal hazardous waste generator status, see Table 2 in Section IV of this document and the associated discussion in Section IV.)

Notification of withdrawal

A facility is required to notify MDE that it will no longer be operating under the hazardous waste pharmaceutical regulations. This applies to a facility that was classified as LQG or SQG under federal regulations, but has become a VSQG and does not elect to voluntarily continue to manage hazardous waste pharmaceuticals under the requirements that apply to LQGs and SQGs. It also applies to a VSQG that had been voluntarily managing hazardous waste pharmaceuticals under the requirements that apply to LQGs and SQGs, but no longer wishes to do so. This notification requirement is met by submitting an updated EPA Form 8700-12 (RCRA Subtitle C Site Identification Form).

Record keeping requirements related to notifications

A healthcare facility shall keep a copy of its initial notification on file for as long as the healthcare facility is operating under the standards of this chapter relating to the management of hazardous waste pharmaceuticals.

A healthcare facility shall keep a copy of its withdrawal notification on file for at least 3 years from the date of signature on the notification of withdrawal.

H. General Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (COMAR 26.13.10.39)

Training: The healthcare facility is required to ensure that 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. Though not required by the regulations, it is recommended as a best management practice that the healthcare facility have a written training plan that identifies staff positions that have responsibilities with respect to management of hazardous waste pharmaceuticals, and staff positions with emergency response responsibilities, and the training that is provided to allow staff to meet these responsibilities.

Hazardous waste determination: A healthcare facility that generates non-creditable waste pharmaceuticals is required to characterize those wastes as to whether they meet the definition of hazardous waste. How to determine whether a waste pharmaceutical meets the definition of hazardous waste is addressed in Section IV of this document as part of the discussion of "key question 2" ("whether hazardous waste pharmaceuticals are generated"). Additional details are found in COMAR 26.13.03.02-1 ("Hazardous Waste Determination – Procedures").

Rather than evaluating each non-creditable pharmaceutical as to whether it meets the definition of hazardous waste, a healthcare facility could elect to manage all its non-creditable pharmaceuticals as if they were hazardous waste.

Land disposal restrictions: Any hazardous waste pharmaceuticals that are destined for land disposal are subject to the land disposal restriction (LDR) regulations that are found in the Code of Federal Regulations (CFR) at 40 CFR Part 268. They are also subject to certain restrictions under the LDR rules on what wastes may be incinerated. (Maryland has adopted these regulations through incorporation by reference.)

One of the restrictions involves a prohibition on the incineration of certain metal-bearing wastes. These wastes are required to be accumulated in separate containers from wastes that will be combusted. Examples of such wastes that are hazardous waste pharmaceuticals include:

Hazardous Waste Code	**Hazardous Waste Chemical Name**
D009	Mercury (toxicity characteristic)
P012	Arsenic Trioxide
P076	Nitric Oxide
U151	Mercury

A detailed explanation of LDR provisions relevant to hazardous waste pharmaceuticals is available from a link to a "frequent questions" collection that can be accessed from EPA's web page on the hazardous waste pharmaceuticals rule at https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075 .

Response to spills: A healthcare facility is required to immediately contain a spill of a non-creditable hazardous waste pharmaceutical, and manage spill cleanup materials as non-creditable hazardous waste pharmaceuticals.

I. <u>Container Standards - Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals</u> (COMAR 26.13.10.40)

A non-creditable hazardous waste pharmaceutical may only be placed in a container that:

- Is structurally sound;
- Is compatible with the contents of the container; and
- Lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions

Ignitable or reactive non-creditable hazardous waste pharmaceuticals that are placed in containers have to be managed in a way that precludes the generation of extreme heat or pressure; initiation of a fire, explosion, or a violent reaction; the generation of toxic fumes or mists capable of threatening human health; the damaging of the structural integrity of the container; or otherwise threatening human health or the environment.

Containers are to be kept closed, and secured in a manner that prevents unauthorized access to the contents of the containers.

<u>Commingling</u>: With certain exceptions, non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable hazardous waste pharmaceuticals may be commingled in the same container. The exceptions are that non-creditable hazardous waste pharmaceuticals that the land disposal restriction regulations of 40 CFR Part 268 either prohibit from being combusted, or prohibit from being lab packed may not be commingled with non-hazardous non-creditable pharmaceuticals. The specifics are in COMAR 26.13.10.40D(2)

<u>Labeling</u>:

- Each container of non-creditable hazardous waste pharmaceuticals is to be labeled or clearly marked with the phrase “Hazardous Waste Pharmaceuticals”.
- Containers that contain non-creditable pharmaceuticals that the land disposal restriction regulations of 40 CFR Part 268 either prohibit from being combusted, or prohibit from being lab packed must be labeled with all applicable EPA hazardous waste numbers (hazardous waste codes). See COMAR 26.13.10.40 D(3).

J. <u>Accumulation Time Limit – Non-Creditable Hazardous Waste Pharmaceuticals</u> (COMAR 26.13.10.41)

A healthcare facility may accumulate a non-creditable hazardous waste pharmaceutical for up to 1 year without having to obtain a hazardous waste storage facility permit. To demonstrate that the 1-year time limit has not been exceeded, the facility may:

- Mark or label the container with the earliest date that a non-creditable hazardous waste pharmaceutical in the container became a hazardous waste;
- Maintain an inventory system that identifies the date when each non-creditable hazardous waste pharmaceutical became a waste; or
- Place the non-creditable hazardous waste pharmaceutical in a specific area in which non-creditable hazardous waste pharmaceuticals are accumulated, identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became

a waste, and have that information readily available during a compliance inspection, by, for example, marking or labeling the accumulation area with the accumulation start-date, or by entering the current earliest accumulation start-date in a log book or facility operating record.

K. Management of Rejected Shipments of Non-Creditable Hazardous Waste Pharmaceuticals by Healthcare Facilities. (COMAR 26.13.10.42)

This regulation establishes requirements for situations when a healthcare facility sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions in the general hazardous waste regulations.

The healthcare facility is allowed to accumulate the returned, rejected shipment for up to 90 days if the waste is managed in accordance with the container management standards in COMAR 26.13.10.40. The healthcare facility should also use one of the methods in COMAR 26.13.10.41 to demonstrate that the 90-day accumulation time limit has not been exceeded.

COMAR 26.13.10.42 also describes the procedures that need to be followed in handling the hazardous waste manifest that accompanied the rejected shipment.

L. Reporting by Healthcare Facilities for Non-Creditable Hazardous Waste Pharmaceuticals (COMAR 26.13.10.43)

Biennial reporting: Healthcare facilities that manage non-creditable hazardous waste pharmaceuticals are not subject to the biennial reporting requirements of COMAR 26.13.03.06B with respect to non-creditable hazardous waste pharmaceuticals being managed under COMAR 26.13.10.32 – .49. They are subject to applicable biennial reporting requirements with respect to non-pharmaceutical hazardous waste that they generate.

Exception reporting (missing copy of a manifest):

A report that contains the information specified in COMAR 26.13.10.43B(1) is required if a healthcare facility has not received, within 60 days of the date that the initial transporter accepted a shipment of non-creditable hazardous waste pharmaceutical for transport to a designated facility, a copy of the manifest with the signature of the owner or operator of the designated facility.

A similar report is required by COMAR 26.13.10.43B(2) when a final manifest copy for a rejected load that was sent from a rejecting facility to an alternate facility has not been received by the healthcare facility within 60 days of the date that the initial transporter for the load following rejection accepted the load for transport to an alternate facility.

The exception reports should be submitted to the Hazardous Certifications and Reporting Section of MDE's Solid Waste Program.

M. <u>Record Keeping by Healthcare Facilities for Non-Creditable Hazardous Waste Pharmaceuticals</u> (COMAR 26.13.10.44)

A healthcare facility is required to keep copies of hazardous waste manifests and manifest exception reports as follows:

- The generator's copy of a manifest for a non-creditable hazardous waste pharmaceutical is required to be kept for three (3) years from the date the initial transporter accepted the waste, or until the healthcare facility has received a signed copy from the designated facility to which the shipment was being sent.
- The manifest copy signed by the designated facility to which the shipment was being sent is required to be kept for three (3) years from the date the initial transporter accepted the waste, with the period of retention extended in the case of an enforcement action.
- Each exception report required by COMAR 26.13.10.43 is required to be kept for at least three (3) years, with the period of retention extended in the case of an enforcement action.

A healthcare facility is also required to keep records that support required hazardous waste determinations made for pharmaceuticals generated by the facility, except that such records are not required to be kept if the facility manages all of its non-hazardous non-creditable waste pharmaceuticals as if they were non-creditable hazardous waste pharmaceuticals.

Records required by COMAR 26.13.10.44 must be readily made available upon request of an inspector representing MDE or the U.S. Environmental Protection Agency.

N. <u>Acceptance of Non-Creditable Hazardous Waste Pharmaceuticals from Off Site</u> (COMAR 26.13.10.45)

This regulation establishes conditions under which a healthcare facility may accept non-creditable hazardous waste pharmaceuticals from off site for consolidation and subsequent management without having to obtain a hazardous waste facility permit. Circumstances under which such consolidation may occur include:

- A central facility accepting non-creditable hazardous waste pharmaceuticals from healthcare facilities that qualify as Very Small Quantity Generators (VSQGs), with the central facility and the off-site facilities under the control of the same "person" (as defined in COMAR 26.13.01.03B); and
- A receiving facility that has a contractual or other documented business relationship by which the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility.

An example of the former is a hospital system that operates off-site clinics. An example of the latter is a long term care facility that is a VSQG that returns the hazardous waste pharmaceuticals to long-term care pharmacies that they have contracted with to be a supplier of pharmaceuticals.

The receiving facility is required to be managing its own hazardous waste pharmaceuticals in accordance with COMAR 26.13.10.32 – .48, and must manage any non-creditable hazardous waste pharmaceuticals received from off site in accordance with those regulations. The off-site

VSQG that is sending non-creditable hazardous waste pharmaceuticals to the central facility is not required to use a hazardous waste manifest for those shipments. An off-site facility operating under these provisions is not considered to be operating under the full range of requirements in COMAR 26.13.10.32 – .48, and therefore is not required to follow the notification requirements of COMAR 26.13.10.38.

The receiving facility is required to keep records of the non-creditable hazardous waste pharmaceuticals that the facility receives from off site for 3 years from the date that the shipment is received.

O. <u>Shipping Requirements – Non-creditable Hazardous Waste Pharmaceuticals</u> (COMAR 26.13.10.47)

A healthcare facility that ships non-creditable hazardous waste pharmaceuticals off site is required to do so in accordance with the requirements of COMAR 26.13.10.47. (Note: Some requirements of COMAR 26.13.10.47 also apply to reverse distributors shipping evaluated hazardous waste pharmaceuticals off site. These provisions are discussed in Section VIII.Q of this document.)

A healthcare facility is only allowed to ship a non-creditable hazardous waste pharmaceutical to a designated facility that is authorized to accept that specific waste by a hazardous waste facility permit, interim status authority under state or federal regulations, or some other legal mechanism consistent with state and federal hazardous waste regulations. The non-creditable hazardous waste pharmaceutical must be transported by a transporter that has been issued a Controlled Hazardous Substance Hauler certificate in accordance with COMAR 26.13.04.01C.

Before shipment, the non-creditable hazardous waste pharmaceutical must be packaged, labeled, and marked in accordance with U.S. Department of Transportation (DOT) hazardous materials transportation regulations. Specifics are provided in the text of COMAR 26.13.10.47.

Lab pack containers that will be incinerated in accordance with 40 CFR 268.42(c) have some additional requirements regarding marking the container with specified waste codes, if applicable. Other than this, marking a container of non-creditable hazardous waste pharmaceuticals with other waste codes is not required.

The shipment must be placarded in accordance with DOT hazardous materials transportation regulations.

The healthcare facility is required to comply with the hazardous waste manifest requirements of COMAR 26.13.03.04, except that, instead of entering on the manifest the hazardous waste number (waste code) that applies to each non-creditable hazardous waste pharmaceutical being shipped, the code "PHRM" (or, alternatively, the code "PHARMS") is required to be entered in the "Waste Codes" section of the manifest form. (Note: as mentioned in Section VIII.N of this document, a VSQG that is sending non-creditable hazardous waste pharmaceuticals off site for consolidation at a healthcare facility operated by the same person is not required to use a hazardous waste manifest for that shipment.)

P. Provisions for Potentially Creditable Hazardous Waste Pharmaceuticals

1. Overview

As discussed in Section VII of this document, there is a well-established "reverse distribution system" for prescription pharmaceuticals through which unused prescription pharmaceuticals are sent to a "reverse distributor" for evaluation of eligibility for a manufacturer's credit. Prescription pharmaceuticals that are potentially eligible for a manufacturer's credit and that are going to be sent to a reverse distributor for evaluation for awarding of a manufacturer's credit are referred to in the hazardous waste pharmaceutical regulations as "potentially creditable hazardous waste pharmaceuticals.

COMAR 26.13.10.46 – .48 establish management standards for healthcare facilities with respect to potentially creditable hazardous waste pharmaceuticals. Standards for the reverse distributors are established by COMAR 26.13.10.47 (shipping requirements) and COMAR 26.13.10.49 (management standards).

The definition of "potentially creditable hazardous waste pharmaceutical" in COMAR 26.13.01.03B establishes what items may be sent from a healthcare facility to a reverse distributor. A hazardous waste pharmaceutical may be transferred to a reverse distributor only if it is a prescription drug that:

- Has a reasonable expectation to receive a manufacturer credit;
- Is in original manufacturer packaging;
- Is not a pharmaceutical that was subject to a recall;
- Is undispensed; and
- Is unexpired or is less than 1 year past its expiration date.

Non-prescription drugs do not qualify to be a potentially creditable hazardous waste pharmaceutical.

2. Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (COMAR 26.13.10.46)

Waste Characterization

A healthcare facility that has a potentially creditable pharmaceutical is required to characterize it as to whether it meets the definition of hazardous waste. To perform the waste characterization, the procedures of COMAR 26.13.03.02-1. If the potentially creditable pharmaceutical meets the definition of hazardous waste, then it must be managed in accordance with COMAR 26.13.10.46 – .48 if it is going to be sent to a reverse distributor for evaluation for eligibility for manufacturer credit

If the potentially creditable pharmaceutical does not meet the definition of hazardous waste, the healthcare facility may voluntarily elect to manage it as a potentially creditable hazardous waste pharmaceutical.

Acceptance of Potentially Creditable Hazardous Waste Pharmaceuticals from Off Site

Similar to the provisions of COMAR 26.13.10.45 that allow for consolidation of non-creditable hazardous waste pharmaceuticals at a healthcare facility from off-site locations under limited conditions, COMAR 26.13.10.46B allows such consolidation to occur for potentially creditable hazardous waste pharmaceuticals under the following circumstances:

- A central facility accepting potentially creditable hazardous waste pharmaceuticals from healthcare facilities that qualify as Very Small Quantity Generators (VSQGs), with the central facility and the off-site facilities under the control of the same "person" (as defined in COMAR 26.13.01.03B); and
- A receiving facility that has a contractual or other documented business relationship by which the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility.

The receiving facility is required to be managing its own hazardous waste pharmaceuticals in accordance with COMAR 26.13.10.32 – .49, and must manage any potentially creditable hazardous waste pharmaceuticals received from off site in accordance with those regulations. . An off-site facility operating under these provisions is not considered to be operating under the full range of requirements in COMAR 26.13.10.32 – .48, and therefore is not required to follow the notification requirements of COMAR 26.13.10.38.

The receiving facility is required to keep records of the potentially creditable hazardous waste pharmaceuticals that the facility receives from off site for 3 years from the date that the shipment is received.

Prohibition of Shipment

Except for potentially creditable hazardous waste pharmaceuticals, a healthcare facility may not send hazardous waste to a reverse distributor

Biennial Reporting Not Required

A healthcare facility is not subject to biennial reporting requirements under COMAR 26.13.03.06B with respect to potentially creditable hazardous waste pharmaceuticals managed under COMAR 26.13.10.32—.49.

Record Keeping

A healthcare facility that initiates a shipment of a potentially creditable hazardous waste pharmaceutical to a reverse distributor is required to keep the following records, in either a paper or electronic format, for each shipment of a potentially creditable hazardous waste pharmaceutical:

- The confirmation of delivery; and
- The shipping paper or papers prepared in accordance with 49 CFR Part 172 Subpart C, if applicable.

Records required by COMAR 26.13.10.46 must be readily made available upon request of an inspector representing MDE or the U.S. Environmental Protection Agency.

Response to Spills

In the event of a spill of a potentially creditable hazardous waste pharmaceutical, the healthcare facility shall immediately contain the spill, and shall manage the clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with COMAR .32—.48.

3. Shipments of Potentially Creditable Hazardous Waste Pharmaceuticals to a Reverse Distributor (COMAR 26.13.10.48)

Transport requirements

A healthcare facility that sends a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor is required to comply with applicable U.S. Department of Transportation hazardous material transport regulations in 49 CFR Parts 171 – 180. The shipment does not have to be accompanied by a hazardous waste manifest, and the shipment does not have to be transported by a certified hazardous waste hauler.

Delivery confirmation

The reverse distributor is required to provide the healthcare facility with confirmation of receipt of a shipment of potentially creditable hazardous waste pharmaceuticals upon receipt of the shipment. The confirmation of receipt may be in a paper format or an electronic format.

If the healthcare facility has not received the delivery confirmation after 35 days have elapsed since the shipment was initiated, the healthcare facility is required to contact the carrier that was transporting the shipment and the reverse distributor that was the intended recipient of the shipment to report that the delivery confirmation has not been received, and to inquire about the status of the shipment.

As noted in Section VIII.P.2 on management standards for potentially creditable hazardous waste pharmaceuticals, the healthcare facility has record keeping requirements with respect to the confirmations of receipt from the reverse distributor.

Q. Provisions for Reverse Distributors

1. Overview

A reverse distributor is the entity that evaluates potentially creditable hazardous waste pharmaceuticals to determine whether the healthcare facility that sent a pharmaceutical for evaluation is eligible for a manufacturer credit. The reverse distributor will either evaluate the pharmaceutical to determine credit, or send the pharmaceutical to another reverse distributor for evaluation.

MDE is not aware of any reverse distributors currently operating in Maryland. Because of the limited or nonexistent universe of reverse distributors in the state, MDE chose to adopt required regulations for reverse distributors mainly through incorporation by reference of federal regulations. This section highlights some of the requirements applicable to reverse distributors, and identifies the main areas covered by the applicable federal regulations.

2. Management Standards

COMAR 26.13.10.49 establishes standards for reverse distributors. The regulation includes requirements for the management of:

- Potentially creditable hazardous waste pharmaceuticals that are sent to a reverse distributor for determination of manufacturer credit; and
- Evaluated hazardous waste pharmaceuticals (i.e., pharmaceuticals that have been evaluated for manufacturer credit by a reverse distributor).

The requirements of 40 CFR 266.510(a), (b), and (c) have generally been incorporated by reference, with references to "EPA Regional Administrator" replaced by "Department" (meaning MDE). Requirements concerning shipping potentially creditable hazardous waste pharmaceuticals from one reverse distributor to another reverse distributor are found in COMAR 26.13.10.48. Requirements concerning shipping evaluated hazardous waste pharmaceuticals are found in COMAR 26.13.10.47.

The management standards for reverse distributors that have been incorporated by reference address such things as

- Notification requirements (providing notification of operation as a reverse distributor);
- Maintenance of a current inventory list;
- Deadlines for conducting the evaluation for manufacturer credit;
- Maximum accumulation time for hazardous waste pharmaceuticals;
- Security;
- Contingency plan and emergency procedures;
- Closure;
- Reporting requirements – (unauthorized waste report);
- Record keeping; and
- Management requirements regarding accumulation of evaluated pharmaceuticals

IX. AREA OF SPECIAL FOCUS: VAPE SHOPS AND E-CIGARETTES

1. Overview

Consistent with the federal regulations on management of hazardous waste pharmaceuticals, Maryland regulations specifically include as part of the definition of "pharmaceutical":

- An electronic nicotine delivery system, such as an electronic cigarette or vaping pen; and
- A liquid nicotine-containing product packaged for retail sale for use in electronic nicotine delivery systems

Because of this, vape shops that sell these products fall within the scope of the definition of "healthcare facility" in the hazardous waste pharmaceutical regulations because they are "retailers of pharmaceuticals" (see COMAR 26.13.01.03B(34-2)(b)(x), part of the definition of "healthcare facility".)

To assist vape shops with understanding their obligations under the hazardous waste pharmaceuticals regulations, this section presents a series of frequent questions on e-cigarettes and the hazardous waste pharmaceutical regulations. The questions and answers are edited versions of frequent questions prepared and posted by the U.S. Environmental Protection Agency. The main edits were to substitute COMAR citations for the corresponding citations to the Code of Federal Regulations.

2, Frequent Questions on E-cigarettes

Note: in these questions, "Part 266 Subpart P" should be interpreted as the regulations in COMAR 26.13.10.32 – 26.13.10.49

Q1. Are e-cigarettes hazardous waste when discarded?
Q2. Are e-cigarettes considered pharmaceuticals under part 266 subpart P of RCRA?
Q3. Are e-cigarettes considered hazardous waste pharmaceuticals under part 266 subpart P?
Q4. Are vape shops considered healthcare facilities under part 266 subpart P of RCRA?
Q5. When is a vape shop regulated under part 266 subpart P?
Q6. How is a vape shop that is a VSQG regulated under RCRA?
Q7. How is a vape shop that is not a VSQG regulated under RCRA?

Q1. Are e-cigarettes hazardous waste when discarded?

Yes. Nicotine is an acute hazardous waste with the hazardous waste code P075. Therefore, when discarded, nicotine-containing e-cigarettes, e-liquids, electronic nicotine delivery systems, etc., are considered acute hazardous waste with the hazardous waste code P075. Refer to RCRA Online #14850 for a detailed explanation. Most e-cigarettes also have lithium-ion batteries which are likely at least ignitable hazardous waste with the RCRA hazardous waste code D001. E-cigarettes that are discarded at a household are not subject to the Maryland or federal RCRA hazardous waste regulations; however, households should consider any state or local requirements or restrictions that may apply to the disposal of e-cigarettes within household trash. Further, MDE strongly encourages people to seek alternatives to household trash disposal, such as household hazardous waste collection sites. (*Note: "RCRA Online is an online compendium of EPA correspondence, memoranda, and guidance on topics related to the federal hazardous waste regulations. The site can be found by performing an internet search for "RCRA Online". An "advanced search" feature on the site can be used to search for a document by RCRA Online document number.)*

Q2. Are e-cigarettes considered pharmaceuticals under part 266 subpart P of RCRA?

Yes. For the limited purposes of part 266 subpart P of the RCRA regulations, which govern the disposal of hazardous waste pharmaceuticals, e-cigarettes are considered pharmaceuticals. Under part 40 CFR part 266 subpart P of the RCRA regulations, the definition of 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)* [emphasis added].

When defining "pharmaceutical", EPA refers to the FDA's definition of drug; however, EPA's definition of pharmaceutical is much broader than FDA's definition of drug. EPA chose to use a single, umbrella term – pharmaceutical – to encompass the various types of items being regulated under part 266 subpart P, even though some of the items are not considered drugs by FDA. For example, e-cigarettes are not considered drugs by FDA, but they are considered pharmaceuticals for the purposes of the RCRA hazardous waste regulations under part 266 subpart P (refer to FDA's Final Rule "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ''Intended Uses" (82 FR 2193, 1/9/2017) for when e-cigarettes would be considered drugs.)

It is important to note that the EPA definition of "pharmaceutical", which determines how e-cigarettes are regulated when they become waste, does not alter and has no bearing on how FDA or others regulate e-cigarettes as products.

Q3. Are e-cigarettes considered hazardous waste pharmaceuticals under part 266 subpart P?

Yes. For the limited purposes of part 266 subpart P of the RCRA regulations, e-cigarettes are considered hazardous waste pharmaceuticals. E-cigarettes meet the definition of hazardous waste and pharmaceutical; therefore, they meet the definition of hazardous waste pharmaceutical and are subject to the regulations in 40 CFR part 266 subpart P when discarded by healthcare facilities or reverse distributors.

Q4. Are vape shops considered healthcare facilities under part 266 subpart P of RCRA?

Yes. For the limited purposes of part 266 subpart P of the RCRA regulations, which govern the disposal of hazardous waste pharmaceuticals, vape shops are considered healthcare facilities. Vape shops are regulated as healthcare facilities under 40 CFR part 266 subpart P of the RCRA hazardous waste regulations because they sell e-cigarettes and pre-packaged nicotine e-juices, which are considered pharmaceuticals when they are discarded.

Under 40 CFR part 266 subpart P, any facility that sells a pharmaceutical is considered a healthcare facility, and nicotine e-juices that are pre-packaged for retail sale and e-cigarettes are considered pharmaceuticals (refer to question #2 of this section). Therefore, as with other retailers of pharmaceuticals, vape shops meet the definition of healthcare facility under 40 CFR part 266 subpart P. EPA chose to use a single, umbrella term – healthcare facility – to encompass the various types hazardous waste generators being regulated under part 266 subpart P, even though it may seem counterintuitive to call vape shops healthcare facilities.

It is important to note that the EPA definition of healthcare facility does not alter and has no bearing on how FDA or others regulate vape shops.

Q5. When is a vape shop regulated under part 266 subpart P?

Vape shops sell nicotine-containing products that are regulated as hazardous waste pharmaceuticals when discarded. Nicotine is an acute hazardous waste that is listed as hazardous waste code P075 due to its acute toxicity. If a vape shop generates in a calendar month more than 1 kg (2.2 pounds) of acute hazardous waste, or more than 100 kg (220 pounds) of non-acute hazardous waste, it must comply with 40 CFR part 266 subpart P of RCRA for the management

and disposal of its discarded e-cigarette and e-juices, which are considered hazardous waste pharmaceuticals (refer to question #3 in the Applicability section).

Part 266 subpart P did not newly apply RCRA regulations to discarded e-cigarettes. E-cigarettes have always been considered hazardous waste; therefore, generators of these hazardous wastes have always been subject to regulation under RCRA. When EPA promulgated 40 CFR part 266 subpart P, it changed the way healthcare facilities, and thus vape shops, that generate hazardous waste pharmaceuticals are regulated. Prior to the promulgation of 40 CFR part 266 subpart P, a vape shop that generated more than 1 kg of acute hazardous waste in a calendar month was regulated as a large quantity generator (LQG) under 40 CFR part 262.

A vape shop that generates less than or equal to 1 kg of acute hazardous waste and less than or equal to 100 kg of non-acute hazardous waste, continues to be subject to the Maryland-defined small quantity generator (MDSQG) regulations in COMAR 26.13.02.05 and COMAR 26.13.03.01A-3 as long as they do not accumulate at any time more than 1 kg of acute hazardous waste or more than 100 kg of nonacute hazardous waste. However, a VSQG vape shop is also subject to several provisions of part 266 subpart P: the sewer prohibition of COMAR 26.13.10.33, the empty container standards of COMAR 26.13.10.35, and the optional provisions of COMAR 26.13.10.36.

Q6. How is a vape shop that is a VSQG regulated under RCRA?

Healthcare facilities, such as vape shops, that generate above VSQGs amounts of hazardous waste (i.e., SQG or LQG under federal regulations) must manage their hazardous waste pharmaceuticals under 40 CFR part 266 subpart P (refer to question #7 of this section).

Healthcare facilities that generate VSQG amounts of hazardous waste are subject to the Maryland-defined small quantity generator (MDSQG) regulations in COMAR 26.13.02.05 and COMAR 26.13.03.01A-3, as well as three sections of part 266 subpart P:

1. the prohibition of sewering hazardous waste pharmaceuticals in COMAR 26.13.10.33
2. the empty containers standards in COMAR 26.13.10.35, and
3. the optional provisions for VSQGs in COMAR 26.13.10.36.

Alternatively, any healthcare facility (e.g., vape shop) that is a VSQG of hazardous waste has the choice of opting into 40 CFR part 266 subpart P, in which case, that facility is subject to all of the required provisions applicable to healthcare facilities in 40 CFR part 266 subpart P.

Q7. How is a vape shop that is not a VSQG regulated under RCRA?

A vape shops that generates above VSQG amounts of hazardous waste (refer to question #5 of this section) is regulated under 40 CFR part 266 subpart P for the management and disposal of its hazardous waste pharmaceuticals.

Under subpart P, the nicotine e-cigarettes and e-liquid wastes that a vape shop generates are considered non-creditable hazardous waste pharmaceuticals. The requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals on site are in COMAR 26.13.10.38 – 26.13.10.45.

In brief, a vape shop must comply with standards related to the on-site accumulation, as well as the off-site transportation, treatment, and disposal of the hazardous waste pharmaceuticals. More specifically, a vape shop that is regulated under subpart P may accumulate the hazardous waste

pharmaceuticals on site for up to one year. During that accumulation, the vape shop must comply with container management and labeling standards in COMAR 26.14.10.40. The vape shop must use a hazardous waste transporter and hazardous waste manifest and send the non-creditable hazardous waste pharmaceuticals to a hazardous waste treatment, storage, and disposal facility COMAR 26.13.10.47).

In addition, the vape shop must not dispose of any of its hazardous waste pharmaceuticals down the drain (COMAR 26.13.10.33) and must use the new provisions for determining when containers of hazardous waste pharmaceuticals are considered "RCRA empty" (COMAR 26.13.10.35).

If a vape shop generates other hazardous waste, then other applicable RCRA regulations apply to the management and disposal of that hazardous waste (e.g. COMAR 26.1310.06 – .25 for universal waste or COMAR 26.13.03 for most other hazardous waste).

X. ADDITIONAL RESOURCES

The U.S. Environmental Protection Agency (EPA) maintains a webpage on the hazardous waste pharmaceuticals rule that has links to many useful resources ("frequent questions", archived training presentations, etc.) The web page is found at:

https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075 .

This page can be easily found through an internet search on "EPA hazardous waste pharmaceuticals

A number of organizations have provided their own summaries of the requirements under EPA's hazardous waste pharmaceuticals rule. Examples include the following (note – links provided for informational purposes only, and the linkage to these references is not to be taken as an endorsement by the Maryland Department of the Environment):

- Healthcare Environmental Resource Center (HERC)
  Hazardous Waste Pharmaceuticals webpage at
  https://www.hercenter.org/hazmat/pharma.php .

  Information about HERC from their webpage:
  "HERC provides pollution prevention and environmental compliance assistance information for the healthcare sector. It is intended to be a comprehensive resource, covering all the varieties of hospital wastes, and all the rules that apply to them, including both federal regulations and the specific rules that apply in your state. HERC also includes environmental compliance information for dental offices and assisted living/nursing care communities."

  "This website was developed and is maintained by the National Center for Manufacturing Sciences. Funding for this project has been provided by EPA under the National Compliance Assistance Centers program."

- U.S. Army Public Health Center
  New Management Standards for Hazardous Waste Pharmaceuticals
  Technical Information Paper TIP NO. 37-090-022
  https://ph.health.mil/PHC%20Resource%20Library/ehse-wm-new-management-standards-for-hw-pharmaceuticals.pdf ,

Appendix 1 – Definitions

For the convenience of the reader, this appendix presents key definitions from COMAR 26.13.01.03B that are related to the hazardous waste pharmaceuticals regulations. Definitions for the following terms are provided in this appendix:

(1) "Evaluated hazardous waste pharmaceutical";
(2) "Hazardous waste pharmaceutical";
(3) "Healthcare facility";
(4) "Household waste pharmaceutical";
(5) "Long-term care facility";
(6) "Non-creditable hazardous waste pharmaceutical";
(7) "Non-hazardous waste pharmaceutical";
(8) "Non-pharmaceutical hazardous waste";
(9) "Person"
(10) "Pharmaceutical";
(11) "Potentially creditable hazardous waste pharmaceutical"; and
(12) "Reverse distributor".

Note that all of the defined terms included in this appendix, except for "person", are newly added to COMAR in connection with the pharmaceuticals provisions):

COMAR 26.13.01.03 Definitions

…

(20-1) "Evaluated hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that:

(a) Has been evaluated by a reverse distributor in accordance with COMAR 26.13.10.49 and 40 CFR §266.510(a)(3); and

(b) Will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

…

(34-1) Hazardous Waste Pharmaceutical.

(a) "Hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste as defined in COMAR 26.13.02.02 and:

(i) Exhibits one or more characteristics identified in COMAR 26.13.02.10—.14; or

(ii) Is listed in COMAR 26.13.02.15—.19.

(b) "Hazardous waste pharmaceutical" does not include:

(i) A pharmaceutical that will be legitimately used or reused by, for example, being lawfully donated for use for its intended purpose;

(ii) A pharmaceutical that is reclaimed, as described in COMAR 26.13.02.01D(7);

(iii) An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug for which there is a reasonable expectation that the item will be legitimately used or reused by, for example, being lawfully redistributed for use for its intended purpose; or

(iv) An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug for which there is a reasonable expectation that the item will be reclaimed.

(34-2) Healthcare Facility.

(a) "Healthcare facility" means any person that is legally authorized to:

(i) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care 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;

(ii) Act as a provider of 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

(iii) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

(b) "Healthcare facility" includes, but is not limited to:

(i) Wholesale distributors;

(ii) Third-party logistics providers that serve as forward distributors;

(iii) Military medical logistics facilities;

(iv) Hospitals, psychiatric hospitals, and ambulatory surgical centers;

(v) Health clinics and physicians' offices;

(vi) Optical and dental providers;

(vii) Chiropractors;

(viii) Long-term care facilities;

(ix) Ambulance services;

(x) Pharmacies, long term-care pharmacies, mail-order pharmacies, and retailers of pharmaceuticals;

(xi) Veterinary clinics; and

(xii) Veterinary hospitals.

(c) "Healthcare facility" does not include:

(i) Pharmaceutical manufacturers;

(ii) Reverse distributors with respect to the receipt, accumulation, and processing of prescription pharmaceuticals for the purpose of facilitating or verifying manufacturer credit; or

(iii) Reverse logistics centers.

(34-3) "Household waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in COMAR 26.13.02.02, but is excluded from being a hazardous waste under COMAR 26.13.02.04-1A(1).

(1) "Evaluated hazardous waste pharmaceutical";

(2) "Hazardous waste pharmaceutical";

(3) "Healthcare facility";

(4) "Household waste pharmaceutical";

(5) "Long-term care facility";

(6) "Non-creditable hazardous waste pharmaceutical";

(7) "Non-hazardous waste pharmaceutical";

(8) "Non-pharmaceutical hazardous waste";

(9) "Person"

(10) "Pharmaceutical";

(11) "Potentially creditable hazardous waste pharmaceutical"; and

(12) "Reverse distributor".

…

(48-1) Long-term Care Facility.

(a) "Long-term care facility" means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility.

(b) "Long-term care facility" 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.

(c) "Long-term care facility" does not include:

(i) A group home;

(ii) An independent living community;

(iii) An assisted living facility; or

(iv) The independent and assisted living portions of a continuing care retirement community.

…

(55-2) Non-creditable Hazardous Waste Pharmaceutical.

(a) "Non-creditable hazardous waste pharmaceutical" means:

(i) A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit; or

(ii) A nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be reclaimed, legitimately used, or legitimately reused.

(b) "Non-creditable hazardous waste pharmaceutical" includes, but is not limited to:

(i) Investigational drugs;

(ii) Free samples of pharmaceuticals received by healthcare facilities;

(iii) Residues of pharmaceuticals remaining in empty containers;

(iv) Contaminated personal protective equipment;

(v) Floor sweepings; and

(vi) Cleanup material from the spills of pharmaceuticals.

(55-3) "Non-hazardous waste pharmaceutical" means a pharmaceutical that:

(a) Is a solid waste as defined in COMAR 26.13.02.02;

(b) Is not listed in COMAR 26.13.02.15—.19; and

(c) Does not exhibit any of the characteristics of hazardous waste identified in COMAR 26.13.02.10—.14.

(55-4) "Non-pharmaceutical hazardous waste" means a solid waste, as defined in COMAR 26.13.02.02, that is not a pharmaceutical, as defined in this section, and:

(a) Is listed in COMAR 26.13.02.15—.19; or

(b) Exhibits one or more of the characteristics of hazardous waste identified in COMAR 26.13.02.10—.14.

…

(61) "Person" means an individual, trust, firm, joint stock company, federal agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.

…

(62-2) Pharmaceutical.

(a) "Pharmaceutical" means:

(i) A drug or dietary supplement for use by humans or other animals;

(ii) An electronic nicotine delivery system, such as an electronic cigarette or vaping pen; or

(iii) A liquid nicotine-containing product packaged for retail sale for use in electronic nicotine delivery systems, and including a pre-filled cartridge, pre-filled vial, or other packaging.

(b) "Pharmaceutical" includes, but is not limited to:

(i) A dietary supplement, as defined by the Federal Food, Drug and Cosmetic Act;

(ii) A prescription drug, as defined by 21 CFR §203.3(y);

(iii) An over-the-counter drug;

(iv) A homeopathic drug;

(v) A compounded drug;

(vi) An investigational new drug;

(vii) A pharmaceutical remaining in a nonempty container;

(viii) Personal protective equipment contaminated with a pharmaceutical; and

(ix) Clean-up material from a spill of a pharmaceutical.

(c) "Pharmaceutical" does not include dental amalgam or sharps.

…

(64-1) Potentially Creditable Hazardous Waste Pharmaceutical.

(a) "Potentially creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that:

(i) Has a reasonable expectation to receive manufacturer credit;

(ii) Is in original manufacturer packaging;

(iii) Is not a pharmaceutical that was subject to a recall;

(iv) Is undispensed; and

(v) Is unexpired or is less than 1 year past its expiration date.

(b) "Potentially creditable hazardous waste pharmaceutical" does not include:

(i) An evaluated hazardous waste pharmaceutical; or

(ii) Nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

…

(67-1) Reverse Distributor.

(a) "Reverse distributor" means a person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit.

(b) "Reverse distributor" includes a forward distributor, a third-party logistics provider, a pharmaceutical manufacturer, or another person who processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit.

Appendix 2 – Details on Filing Form EPA 8700-12

(required to satisfy the notification requirements of COMAR 26.13.10.38)

COMAR 26.13.10.38 establishes notification requirements for healthcare facilities managing hazardous waste pharmaceuticals. Details are found in Section VIII.G of this compliance guide.

The notification requirement is met by filing a completed copy of EPA Form 8700-12 (RCRA Subtitle C Site Identification Form) with the Maryland Department of the Environment's Solid Waste Program. The form and instructions are available from links on the following EPA web page: https://www.epa.gov/hwgenerators/instructions-and-form-hazardous-waste-generators-transporters-and-treatment-storage . This page can be easily found by performing an internet search for "EPA 8700-12".

Electronic Submission (preferred)

The preferred method for submitting the form is to submit the form electronically via the internet. This is accomplished using EPA's "RCRAInfo Industry Applications".

The RCRAInfo Industry Applications are:

- myRCRAid (which is used for submitting information related to the Site Identification Number (EPA ID number);
- Biennial Report (which is used for submitting required biennial reports of hazardous waste activities); and
- eManifest (which is used for generating and tracking electronic hazardous waste manifests for shipments of hazardous waste that require use of a hazardous waste manifest)

To utilize the RCRAInfo Industry applications, sites must register and assign a Site Manager. It is recommended that each site have at least two Site Managers. Site Managers must be someone who is in management.

Once a facility has a site manager(s), they will be able to utilize all EPA's industry applications.

As a Site Manager, you will have permission to read, write and certify (sign electronic documents). In addition, as a Site Manager, you will be able to assign roles to your employees. Your employees will register just like the site manager did, but the request will go to the site manager(s) for the facility. Maryland will not approve employees or consultants' requests for site manager, preparer, or viewer.

All registration regardless of approved access level will first have to be processed through EPA's Central Data Exchange (CDX).

How does a user register?

To register as a site manager, a person from the site who has management responsibilities can go to https://rcrainfo.epa.gov/rcrainfoprod , select "Register" below the sign-in button, and then select "Industry User". The user should provide their full legal name and work email address. Accounts cannot be shared. Each individual must have their own account.

During the registration, the approval process through the CDX will occur. The user must select RCRAInfo: Resource Conservation and Recovery Act Information. If you already have a CDX account, you can log in with those credentials. If not, please answer the questions until the end.

After registering, if the site(s) already have an EPA ID Number, then the user must request permission to each site. If the site(s) does not have an EPA ID Number, then the user can submit a new request through myRCRAid.

For more information or help please go to:

https://rcrainfo.epa.gov/rcrainfo-help/application/industryHelp/index.htm#t=UserManagement%2FUG-UserMgmtCreateNewUser.htm

There is a table of contents on the left side. To get to the instructions on how to register, click on "User's Guide", "User Management", then "Create New User". It also has other helpful information, such as Roles and Responsibilities of a Site Manager, and How to Request Permission to Site(s), etc.

In addition, once you have registered to be a user in RCRAInfo, there is online training available for different applications, such as, "How to complete a biennial report". The training is available on a separate site called "Learning Zen". You will have to register to access the training. Your RCRAInfo log in will not work. To gain access to the training, log into RCRAInfo, and under the tab "Documentation" there is a link to Online Training. The access code is "RCRAInfo".

What are the Industry Applications?

eManifest is the National Database for all manifests as of June 30, 2018. For more information about eManifest, please go to: https://www.epa.gov/e-manifest .

Biennial Report is the software to complete and submit the Biennial Report electronically.

myRCRAid is the application to obtain, update or deactivate an EPA ID Number electronically. This is the electronic version of the 8700-12 form.

Questions

If you have any questions about the RCRAInfo Industry Applications, please contact one of the following staff:

- Jennifer Hopper, Section Head, 410-537-3350 or Jennifer.hopper@maryland.gov
- Paul "Brian" Sodeman, 410-537-3397 or paul.sodeman@maryland.gov
- Lynn Jagdeo, 410-537-3475 or lynn.jagdeo@maryland.go

Paper Submission

A person can also submit a paper copy of the EPA 8700-12 notification form by mailing it to:

Maryland Department of the Environment
Land and Materials Administration
Solid Waste Program
1800 Washington Boulevard
Baltimore MD 21230-1719

Appendix 3

Crosswalk – Provisions in the Code of Maryland Regulations (COMAR) Corresponding to Provisions in 40 CFR Part 266 Subpart P

Effective October 1, 2025, the Maryland Department of the Environment (MDE) has adopted regulations that are equivalent to the U.S. Environmental Protection Agency's regulations on management of hazardous waste pharmaceuticals at healthcare facilities (40 CFR Part 266 Subpart P). This document identifies the Code of Maryland Regulations (COMAR) provisions that correspond to the various provisions in 40 CFR Part 266 Subpart P. The text of the final regulations will be identical to the proposed text, which may be found in the Notice of Proposed Action published on May 16, 2025 in the Maryland Register (52:10 Md. R. 478), available on the website of the Maryland Division of State Documents (https://dsd.maryland.gov/).

Federal Provision in Subpart P of 40 CFR Part 266 (40 CFR 266.*xxx*)	Corresponding MD Provision (COMAR 26.13.*xx.yy*)	Notes
266.500 Definitions for this subpart.	26.13.01.03B; 26.13.10.32B	26.13.10.32B lists specialized defined terms used in the hazardous waste pharmaceuticals regulations. The specific definitions for these terms are found in COMAR 26.13.01.03B. The following defined terms have been introduced in connection with the hazardous waste pharmaceuticals regulations: *(1) "Evaluated hazardous waste pharmaceutical";* *(2) "Hazardous waste pharmaceutical";* *(3) "Healthcare facility";* *(4) "Household waste pharmaceutical";* *(5) "Long-term care facility";* *(6) "Non-creditable hazardous waste pharmaceutical";* *(7) "Non-hazardous waste pharmaceutical";* *(8) "Non-pharmaceutical hazardous waste";* *(9) "Pharmaceutical";* *(10) "Potentially creditable hazardous waste pharmaceutical"; and* *(11) "Reverse distributor".*
266.501 Applicability.	26.13.10.32C – G	
266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.		

Federal Provision in Subpart P of 40 CFR Part 266 (40 CFR 266.*xxx*)	Corresponding MD Provision (COMAR 26.13.*xx.yy*)	Notes
266.502(a) – notification and withdrawal	26.13.10.38	
266.502(b) – training	26.13.10.39A	
266.502(c) – hazardous waste determination	26.13.10.39B	
266.502(d) – standards for containers	26.13.10.40A - D	
266.502(e) – container labeling	26.13.10.40E	
266.502(f) – accumulation time limit	26.13.10.41	
266.502(g) – land disposal restrictions	26.13.10.39C	
266.502(h) – management of rejected shipments	26.13.10.42	
266.502(i) – reporting requirements	26.13.10.43	
266.502(j) – record keeping	26.13.10.44	
266.502(k) – response to spills	26.13.10.39D	
266.502(l) – acceptance from off-site facilities	26.13.10.45	
266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.	26.13.10.46	
266.503(a) – hazardous waste determination	26.13.10.46A	
266.503(b) – acceptance from off-site facilities	26.13.10.46B	
266.503(c) – prohibition of shipment	26.13.10.46C	
266.503(d) – biennial reporting exemption	26.13.10.46D	
266.503(e) – record keeping	26.13.10.46E	

Federal Provision in Subpart P of 40 CFR Part 266 (40 CFR 266.*xxx*)	Corresponding MD Provision (COMAR 26.13.*xx.yy*)	Notes
266.503(f) – response to spills	26.13.10.46F	
266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and nonpharmaceutical hazardous waste that are not operating under this subpart. (266.504(a) – (c))	26.13.10.36	Optional provisions – qualifying facilities may elect to use these provisions.
266.504(d) – long-term care facilities with 20 beds or fewer	26.13.10.32D(2)	
266.505 Prohibition on sewering hazardous waste pharmaceuticals.	26.13.10.33	Applies to all healthcare facilities with respect to hazardous waste pharmaceuticals.
266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected by an authorized collector.	26.13.10.34	
266.507 Residues of hazardous waste pharmaceuticals in empty containers.	26.13.10.35	Addresses stock, dispensing, and unit-dose containers; syringes; intravenous (IV) bags; and other containers, including delivery devices.
266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.	26.13.10.47	
266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.	26.13.10.48	

Federal Provision in Subpart P of 40 CFR Part 266 (40 CFR 266.*xxx*)	Corresponding MD Provision (COMAR 26.13.*xx.yy*)	Notes
266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors	26.13.10.49 26.13.47D (pre-transport requirements)	