

A 10-Step Blueprint for Managing Pharmaceutical Waste in US Healthcare Facilities



2022 Edition



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INTRODUCTION

The purpose of this document is to provide a practical guide to help healthcare facilities, including hospitals, surgery centers, and urgent care facilities understand the applicable regulations so they can develop a compliant, holistic, and cost-effective pharmaceutical waste management program. The primary focus is understanding the Environmental Protection Agency's (EPA's) hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) as they apply to hazardous waste pharmaceuticals, but other related regulations are also discussed. RCRA is a preventative regulatory program. As such, RCRA regulations apply to all phases of hazardous waste management – from cradle to grave – with the goal of protecting human health and the environment.

The discovery of a variety of pharmaceuticals in surface, ground, and drinking waters around the country has raised concerns about the potentially adverse environmental consequences of these contaminants. Pharmaceutical compounds in water have been shown to have negative effects, particularly on aquatic ecosystems, and could possibly impact human health.

When the original document, *Managing Pharmaceutical Waste: A Ten-Step Blueprint for Health Care Facilities in the United States*, was originally published in 2006 and then updated in 2008, the concept of applying EPA's hazardous waste regulations to waste pharmaceuticals was still relatively new to many healthcare facilities who were previously unaware that they are subject to the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. At that time, in many hospitals, pharmaceutical waste was generally discarded down the drain or landfilled. These practices were developed at a time when knowledge was not available about the potential adverse effects of introducing waste pharmaceuticals into the environment.

Many professionals in the healthcare sector, including pharmacists, nurses, and environmental services managers, had to begin the process of developing compliance strategies and coming into compliance. Raising awareness of the need for protective pharmaceutical waste management led many healthcare facilities to ensure all types of pharmaceutical waste are incinerated instead of being drain disposed or landfilled. To continue to reduce pharmaceutical waste impacts on our waterways, it is recommended that all healthcare facilities set up a program to incinerate

pharmaceutical waste at the appropriate permitted incinerator as a best practice.

EPA, wanting to ensure a better fit of the protective hazardous waste regulations to improve compliance and keep hazardous waste pharmaceuticals out of our waterways, engaged extensively with stakeholders. Over the years, EPA received many questions and concerns from healthcare facilities regarding the application of regulations that were originally designed with the manufacturing industry in mind. To address these concerns and risk to our environment, EPA published the Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine (referred to as the Pharmaceuticals Rule) on February 22, 2019.¹

The Pharmaceuticals Rule implemented a novel set of regulations tailored specifically to the healthcare sector resulting in numerous changes to the way hazardous waste pharmaceuticals are managed at healthcare facilities. Therefore, the "10-Step Blueprint" has been revised again to assist healthcare facilities in understanding the new regulatory landscape. Many of the regulatory references in the prior editions are now outdated as a result of the Pharmaceuticals Rule. We have incorporated relevant concepts from the 2008 Blueprint into the current document. In addition, the Drug Enforcement Administration (DEA) published additional rules regarding the management of waste controlled substances under the Disposal of Controlled Substances Final Rule (September 9, 2014).² These DEA regulations are referenced in [STEP TWO, Section 7: Managing Outdated Hazardous Waste Controlled Substance Inventory and Waste](#).

The Pharmaceuticals Rule is comprised of two different components:

1. 40 CFR part 266 subpart P (includes the sewerage prohibition), and
2. Exemption for OTC nicotine patches, gums and lozenges.

Together, the two components of the Pharmaceuticals Rule establish cost-saving, streamlined standards for handling hazardous waste pharmaceuticals to better fit the operations of the healthcare sector while maintaining protection of human health and the environment. The prohibition on sewerage hazardous waste pharmaceuticals (sometimes also referred to as the

¹ [Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine. U.S. EPA. Federal Register Vol. 84, No. 36, February 22, 2019.](#)

² [Disposal of Controlled Substances. Drug Enforcement Administration. Federal Register Vol. 79, No. 174, September 9, 2014.](#)

sewering ban) will help address the issue highlighted by a growing body of publicly available studies documenting the presence of pharmaceuticals in drinking and surface waters as well as their negative impacts to aquatic and riparian ecosystems.

The two components of the Pharmaceuticals Rule have different state adoption requirements. See [STEP TWO](#)

for a full discussion about state adoption. This document is written for healthcare facilities in states where the Pharmaceuticals Rule is in effect and it discusses the federal RCRA hazardous waste regulations. Be aware that authorized states may have requirements that are more stringent than the federal regulations.

HOW TO USE THIS DOCUMENT

While many healthcare facilities are in compliance with the waste regulations, some may be at the beginning of their journey to properly managing hazardous and non-hazardous waste pharmaceuticals. This current guide will help these facilities set up a compliant and holistic pharmaceutical waste management program or update their current programs.

The ten steps in this document are presented in two groups.

The first group (STEPS ONE through THREE) is meant to give you an overview of the regulatory landscape that applies to pharmaceutical waste (i.e., what regulations apply to your healthcare facility).

The second group (STEPS FOUR through TEN) walks you through the process of initiating, updating, and maintaining your pharmaceutical waste management program (i.e., how to implement the regulations that apply to your healthcare facility).

That way, you will have a general understanding of the regulatory underpinnings that guide the compliance strategies, recommendations, and best management practices discussed in the second group. In many cases, the second group of steps is not prescriptive. Rather, it offers a variety of compliance strategies and prompts a healthcare facility to determine which one is the best fit.

Because different readers will use the document in different ways, we recognize that not all readers will read the entire document start to finish. We have therefore built in some content redundancy and repetition deliberately to ensure that important concepts are provided regardless of how readers choose to use the document.

A number of acronyms will be used in this document and will be defined upon first use. These are also listed in [Appendix B](#).

STEP ONE: Understanding Which Pharmaceuticals are Regulated as Hazardous Waste Pharmaceuticals When Discarded

The first step towards compliance is understanding the basic definitions of hazardous waste that apply to waste pharmaceuticals. All hazardous waste falls into two broad categories:

1. Listed hazardous wastes (contain specific chemicals) and
2. Characteristic hazardous wastes (exhibit specific hazardous characteristics).

P-Listed and U-Listed Drugs

The listed hazardous wastes are further divided into two categories: P-listed and U-listed hazardous wastes. P-listed wastes are considered acute hazardous waste, whereas U-listed wastes are considered non-acute hazardous waste. There are a few pharmaceuticals commonly found in hospitals that are P-listed hazardous waste when discarded as well as several more that are on the U-list. If the listed chemical is the sole active ingredient in the drug formulation, it will cause the discarded drug to be regulated as a hazardous waste. Table 1 lists some common P- and U-listed chemicals that are also common drugs.

Formerly, the two most commonly generated P-listed pharmaceuticals in healthcare facilities were epineph-

rine and nitroglycerin. However, a combination of interpretations and regulatory revisions by EPA have provided regulatory relief for each of these. Epinephrine salts have been excluded federally as of October 15th, 2007³ and weak medicinal nitroglycerin was excluded federally as of August 14th, 2001.⁴ A few states have not accepted or adopted these federal interpretations or regulatory revisions, so it is important to check with your state agency.

When a drug waste containing a P-listed constituent of concern is discarded or intended to be discarded, it must be managed as hazardous waste if two conditions are satisfied: (1) the discarded drug waste contains a **sole active ingredient** (54 FR 31335) that appears on the P list, and (2) **it has not been used for its intended purpose** (54 FR 31336).

To satisfy the definition of **sole active ingredient**, the listed chemical in the discarded drug must be the only ingredient that performs the intended function of the formulation. Ingredients that serve ancillary functions such as mobilizing or preserving the active ingredient are not considered when determining the sole active ingredient. Saline and dextrose solutions are also not considered to be active ingredients.

Table 1: Examples of the Most Common P- and U-Listed Drugs

| Name of Drug | Medical Use | Hazardous Waste Code |
|---------------------------------|-----------------------|----------------------|
| Arsenic trioxide | Antineoplastic | P012 |
| Dalfampridine (4-aminopyridine) | Multiple sclerosis | P008 |
| Nicotine | Replacement therapy | P075 |
| Physostigmine salicylate | Glaucoma | P188 |
| Warfarin >0.3% | Blood thinner | P001 |
| Chloral hydrate (CIV) | Sedative | U034 |
| Cyclophosphamide | Antineoplastic | U058 |
| Daunomycin | Antineoplastic | U059 |
| Lindane | Lice, scabies | U129 |
| Melphalan | Antineoplastic | U150 |
| Mitomycin C | Antineoplastic | U010 |
| Selenium sulfide | Anti-fungal, dandruff | U205 |
| Streptozotocin | Antineoplastic | U206 |

The drugs noted above are listed hazardous wastes most commonly found in healthcare facilities.

³U.S. EPA, Memorandum: Scope of Hazardous Waste Listing P042 (Epinephrine). October 15, 2007

⁴40 CFR 261.3(g).

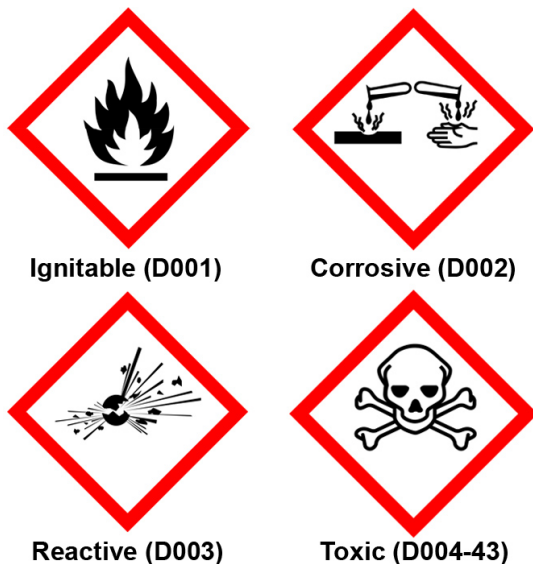
In almost all cases, a discarded pharmaceutical will not have been ***used for its intended purpose***. An example of an exception is mitomycin that has been used either as a bladder or eye irrigant and which is collected and disposed after administration. Because it has been used, the mitomycin would not carry the U010 listing; however, best management practices would be to manage it as trace chemotherapy waste.

While there are only seven antineoplastic chemotherapy drugs on the P- and U-lists that are currently on the market, many more highly toxic drugs have been introduced into the market since 1980 when the lists were published. In addition, the paraphernalia associated with these drugs, such as empty vials, syringes, wipes, gloves, and gowns, are typically accumulated into a separate waste stream commonly called “trace chemotherapy waste” and disposed of as regulated medical waste and incinerated at hazardous waste or medical waste incinerators (regulated under the Clean Air Act as HMIWIs (hospital, medical and infectious waste incinerators)). This practice is discussed more completely in [STEP SIX: Implementing a Pharmaceutical Waste Program in the Pharmacy](#).

Characteristic Hazardous Wastes

Characteristic hazardous waste is defined in four ways (Figure 1): **ignitable, toxic, corrosive, and reactive**.

Figure 1: The Four Types of RCRA Characteristic Hazardous Waste



⁵ [Reactivity characteristic 40 CFR 261.23.](#)

⁶ [Corrosivity characteristic 40 CFR 261.22](#)

⁷ [Ignitability characteristic 40 CFR 261.21.](#)

⁸ [Toxicity characteristic 40 CFR 261.24.](#)

Healthcare facilities generally do not have to worry about generating reactive (D003) hazardous waste pharmaceuticals. As noted above, nitroglycerin is a listed hazardous waste (P081) that was listed because it is reactive and previously the RCRA regulations did require medical forms of nitroglycerin to be managed as hazardous waste. However, because of the low concentration of nitroglycerin used in medical formulations, it is not reactive. As a result, finished dosage forms of nitroglycerin (e.g., sublingual tablets or injectables) are no longer considered P081 or D003⁵ hazardous waste. There are a few states that still regulate nitroglycerin as P081. Always check your state regulations for exceptions.

Likewise, highly corrosive drugs (D002)⁶ with a pH of less than or equal to 2 (acidic), or greater than or equal to 12.5 (basic) are also not common, although a few do exist, such as:

- AimTab RST (which replaced Clinitest Tablets and has a pH of greater than 12.5)
- Cola syrup (acidic)
- Emetrol (acidic)
- Some bulk acids, such as glacial acetic acid and trichloroacetic acid
- Some bulk bases, such as potassium hydroxide.

Much more common are drug formulations that meet the ignitability characteristic.⁷ While the definition of ignitable is a bit complex, it can generally be simplified with respect to drugs by defining it as an aqueous (50% or more water) solution containing 24% or more alcohol, that has a flash point less than 60° C (140° F). Since flash points are not routinely calculated for finished dosage forms, the safest practice is to determine the percentage of alcohol. That is, if the alcohol content is at 24% or more, it will meet the ignitability characteristic definition. Ignitable aerosols and oxidizers, such as silver nitrate, are also regulated as ignitable hazardous waste, as are non-aqueous liquids with low flash points, such as flexible collodion.

The final characteristic to consider is toxicity.⁸ One way to determine whether a drug meets the toxicity characteristic when discarded is to see if it contains any ingredients included in the list of toxic constit-

Table 2: Examples of Drug Formulations That Meet the Ignitability Characteristic, D001

| Name of Drug | Dosage Form | Medical Use | Reason |
|-----------------------------------|-----------------|-----------------------------|---|
| Paclitaxel Injection | Vial | Antineoplastic chemotherapy | Alcohol 49.7% |
| Rubbing alcohol | External Liquid | Antiseptic | Alcohol 70% |
| Aromatic Ammonia Inhalant | Ampule | Restorative | Alcohol 35% |
| Cleocin-T Topical Solution 1% | External Liquid | Antibiotic | Isopropyl Alcohol 50% |
| Compound W Gel 17% Salicylic Acid | Gel | Wart Remover | Alcohol 60%+ |
| Minoxidil Solution | External Liquid | Hair Growth Stimulant | Alcohol >24% |
| Nitroglycerin Injection 5 mg/ml | Vial | Angina | Alcohol 30% |
| Tretinoin Gel 0.025% | Gel | Acne | Denatured Alcohol 83% |
| Testosterone Gel CIII | Gel | Replacement Therapy | Alcohol 74% (also a DEA controlled substance) |
| Swimmer's Ear Drops | External Liquid | Ear Infection | Isopropyl Alcohol 95% |
| Potassium permanganate | Crystals | Antifungal | Oxidizer |
| Silver nitrate | Applicator | Cauterization | Oxidizer |

The drugs noted above are in formulations that meet the characteristic of ignitability due to high alcohol concentration or oxidizing potential.

uents in the table in [§ 261.24 \(b\)](#). See examples in Table 2. EPA has determined that wastes with concentrations of heavy metals and other highly toxic substances at or above these regulatory levels meet the toxicity characteristic. More specifically, EPA developed a test method called the Toxicity Characteristic Leaching Procedure (TCLP),⁹ and any waste that contains at or above the regulatory level for a specific toxic constituent in the leachate is said to “fail” the TCLP test. This test, which must be run in a lab, simulates a landfill scenario in terms of how much these heavy metals or other chemicals will leach into the ground water.

The toxicity characteristic values are all specific to each constituent, and some surprising drug formulations “fail” the TCLP test. Examples include multi-dose insulin vials, due to the preservative m-cresol

(D024), and multi-dose flu vaccines, due to the preservative thimerosal, which is mercury-based (D009). Even multivitamin/mineral products such as Centrum Silver® are considered to be a hazardous waste when discarded due to chromium (D007) and/or selenium (D010). A list of common drugs that fail the TCLP test is shown in Table 3.

You can see from these examples that determining which drugs become a hazardous waste when discarded can be complicated, but making accurate hazardous waste determinations is an integral part of any valid compliance strategy. Most hospitals, however, do not conduct or contract out their own TCLP testing. They rely instead on information provided by their waste vendors, consultants, and drug manufacturers to determine whether the drug waste would fail the TCLP test and manage the waste accordingly. Remember that under RCRA, the hazardous waste generator is ultimately responsible for accurately determining whether they have generated a hazardous waste and managing it appropriately, even if using data provided by a third party.

Performing a TCLP

A conservative approach to determining whether or not a specific drug formulation passes or fails the TCLP is to perform a calculation of the concentration of the specific toxicity constituent in that formulation. Please refer to [Appendix D](#) for a specific example.

⁹ U.S. EPA, SW-846 Test Method 1311: Toxicity Characteristic Leaching Procedure.

Are Hazardous Waste Pharmaceuticals Listed or Characteristic?

Note that a pharmaceutical can be considered characteristic hazardous waste when it:

- Has a single ingredient
- Has multiple ingredients
- Has a toxic constituent that is an active ingredient
- Has a toxic constituent that is not an active ingredient
- Exhibits multiple characteristics (e.g., ignitable and toxic) in addition to a P- or U-listing.

In contrast, a pharmaceutical can only be a P- or U-listed hazardous waste when the P- or U-listed constituent is the sole active ingredient. However, best management practices encourage managing all drugs that contain a P- or U-listed constituent as hazardous waste, regardless of whether or not the listed constituent is the sole active ingredient.

Table 3: Toxicity Characteristic (TC) Constituents Found in Drug Formulations

| Name of Toxicity Characteristic Constituent | Hazardous Waste Code | Max Regulatory Level (mg/L) | Common Drug Formulations |
|---|----------------------|-----------------------------|--|
| Arsenic | D004 | 5.0 | Arsenic trioxide injection |
| Barium | D005 | 100.0 | Entrobar® Suspension |
| Chloroform | D022 | 6.0 | Chloroform |
| Chromium | D007 | 5.0 | M.T.E.-5® Concentrate |
| M-Cresol | D024 | 200.0 | Humalog® Injection 100 units/ml |
| Lindane | D013 | 0.4 | Lindane Lotion |
| Mercury | D009 | 0.2 | Multi-dose Flu Vaccine; Multi-dose Tetanus Diphtheria Toxoids (Thimerosal) |
| Selenium | D010 | 1.0 | Centrum Silver® Tablets |
| Silver | D011 | 5.0 | Silvadene® Cream 1% |

The toxicity characteristic (TC) constituents listed above can be found in certain pharmaceutical dosage forms. The drug formulations noted are examples and not a complete list.

If not conducting the TCLP, the best management practice is to manage the drug as a hazardous waste pharmaceutical when the concentration of the TC constituent is at or above the Maximum Regulatory Level indicated in the table above. However, if the actual TCLP demonstrates concentrations below the Maximum Regulatory Levels, that drug would not be considered a hazardous waste for the toxicity characteristic.

Compounded Items and Reformulations

It is essential to consider all compounded items as well as reformulations and IV admixtures to determine their hazardous waste designation, as the characteristic waste designation for the reformulation or IV admixture may not be the same as for the original formulation. In particular, a pharmaceutical may exhibit the characteristic of ignitability when it is purchased by the pharmacy but no longer exhibit it after being compounded or prepared for administration in the pharmacy. The reverse situation also can occur.

If a raw chemical is formulated into an alcoholic preparation, the resulting product may exhibit the characteristic of ignitability (see examples in Table 4).

Strategies for Identifying Hazardous Waste Pharmaceuticals

Understanding which pharmaceuticals are regulated as hazardous waste is challenging and is a dynamic process. The following three options are examples of strategies that your facility may use to ensure the hazardous waste pharmaceuticals your facility generates are properly identified:

1. Designate someone in your organization to identify your hazardous waste pharmaceuticals and ensure that they have the proper training and resources at their disposal,
2. Hire a company that specializes in identifying hazardous waste pharmaceuticals at the National Drug Code (NDC) level, or

Table 4: Effects of Compounding and Reformulations

| Drug Prepared for Administration | Waste Designation of Prepared Drug | Original Ingredients | Waste Designation of Original Ingredients |
|--|--|--|---|
| Paclitaxel (Taxol®), valrubicin, etoposide, or teniposide diluted in an IV containing less than 24% alcohol | <ul style="list-style-type: none"> Used IV managed as trace chemotherapy waste Unused IV managed as hazardous chemotherapy waste according to BMP (See STEP THREE) | Original vials contain 30% – 50% alcohol | Ignitable Hazardous Waste |
| Compounded wart remover with salicylic acid and other ingredients compounded in a base of flexible collodion | Ignitable Hazardous Waste | Salicylic acid and flexible collodion | <ul style="list-style-type: none"> Salicylic acid is a non-hazardous waste Flexible collodion is an ignitable hazardous waste |

A pharmaceutical may exhibit the characteristic of ignitability when it is purchased by the pharmacy but no longer exhibit it after being compounded or prepared for administration in the pharmacy. The reverse situation also can occur.

3. If your facility is operating under 40 CFR 266 Subpart P, you may choose to manage all pharmaceutical waste as hazardous waste, thereby eliminating the need to make individual hazardous waste determinations for every waste pharmaceutical generated.

Depending on the size of your healthcare facility, there may be a substantial cost increase associated with option 3 as discussed in [STEP FIVE: Choosing Appropriate Vendors](#).

RCRA Hazardous Waste Pharmaceuticals (EPA) vs. Hazardous Materials (DOT)

In addition to knowing which drugs are RCRA hazardous waste pharmaceuticals, you also need to know which drugs are subject to the Department of Transportation (DOT) hazardous materials regulations (HMR) in 49 CFR Parts 171–180.¹⁰ The HMR are implemented by DOT’s Pipeline and Hazardous Materials Safety Administration (PHMSA). An overview of the hazardous materials transportation requirements can be found in the PHMSA publication, **Hazardous Materials Transportation Requirements**.¹¹

DOT hazardous materials are divided into 9 hazard classes. Under the DOT HMR, any hazardous waste that requires a RCRA manifest is considered a class 9 hazardous material. Other hazardous wastes that do not require a RCRA manifest (e.g., potentially creditable hazardous waste pharmaceuticals being shipped to a reverse distributor) may also be considered DOT hazardous material, but only when the hazardous

wastes are otherwise classified as DOT hazardous materials (i.e., DOT hazard class 1–8). While the RCRA hazardous waste regulations apply throughout the management of the hazardous wastes (i.e., from cradle to grave), the DOT HMR applies during transportation. Hospitals typically rely on their hazardous waste vendors to help their staff comply with both the RCRA hazardous waste regulations and the DOT HMR.

RCRA Hazardous Waste Pharmaceuticals (EPA) vs. Hazardous Drugs (NIOSH)

Before proceeding to a closer examination of the impacts of these regulatory changes on hospital policies and procedures, it’s important to note the common confusion between hazardous waste pharmaceuticals from an EPA perspective and hazardous drugs from a NIOSH perspective. NIOSH is a research institution within the Department of Health and Human Services’ (HHS) Center for Disease Control (CDC). EPA’s primary responsibility is protection of human health and the environment, while the primary responsibility of NIOSH is to develop recommendations to protect employees. While the RCRA hazardous waste regulations only apply to a pharmaceutical once a decision has been made to discard a drug that is considered RCRA hazardous waste, the compliant management of a hazardous drug under NIOSH is required from the point of receipt to the point of administration or through discard at the facility, so it is a much more comprehensive process. Since 2004, NIOSH has periodically updated its lists of hazardous drugs that may be harmful to healthcare personnel if exposed. Healthcare facilities include within their policies and procedures measures that

¹⁰ 49 CFR Parts 171-180.

¹¹ U.S. DOT, [Hazmat Transportation Requirements](#).

mitigate exposure to the hazardous drugs identified by NIOSH, especially where pregnancy or desire to conceive is involved. Healthcare facilities should also apply the NIOSH hazardous drug criteria to all drugs not yet reviewed by NIOSH and add those that meet the criteria to their lists.

- fertility impairment or reproductive toxicity
- serious organ toxicity at low doses or
- a chemical structure or toxicity profile that mimics existing drugs that are determined to be hazardous.

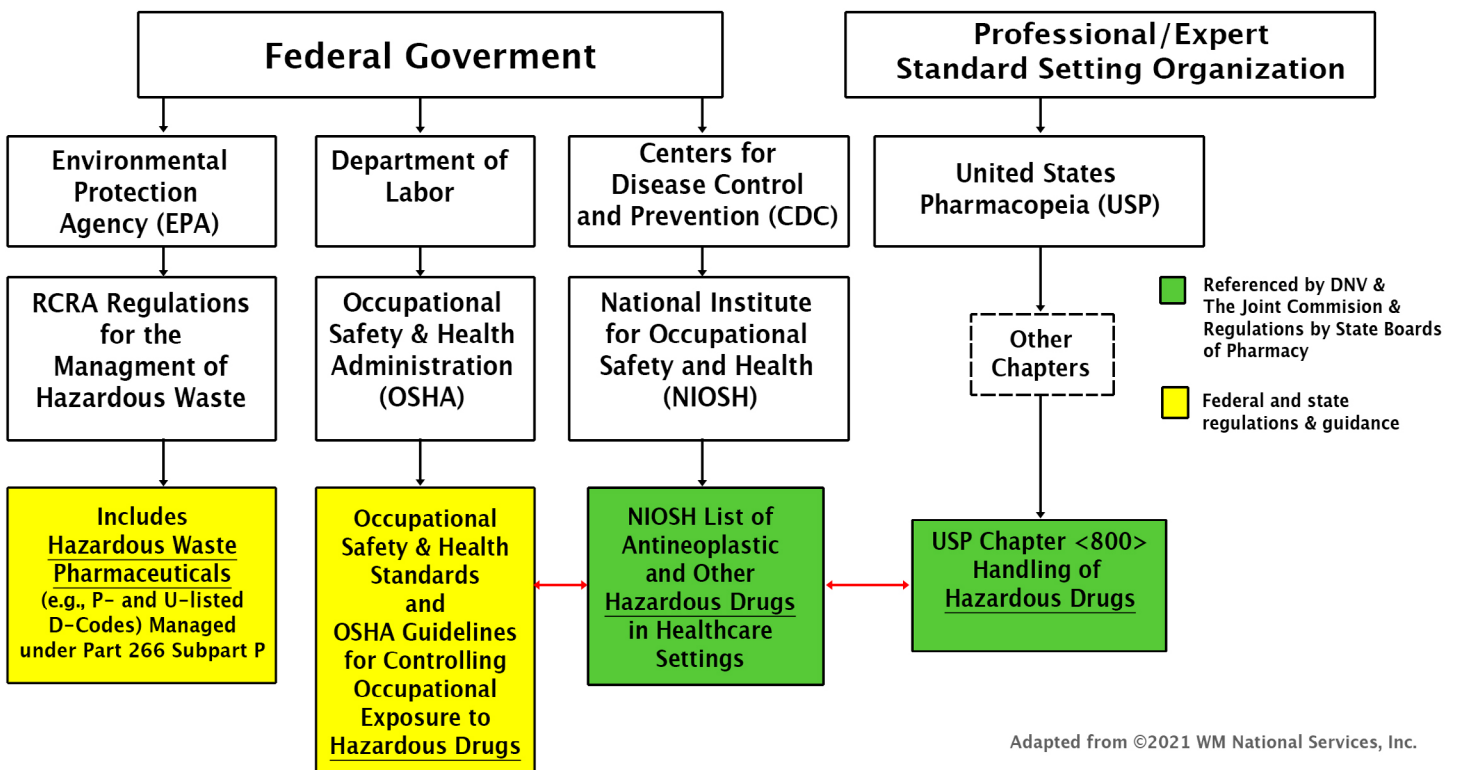
Due to the rising interest in the protection of healthcare personnel, increased attention is being paid to the proper management of hazardous drugs. Hazardous drugs may negatively impact healthcare personnel who are routinely exposed to them during their daily activities. While the names are similar, the definitions are very different. The types of RCRA hazardous waste were discussed in the previous section. In contrast, a hazardous drug is defined by NIOSH¹² as one that exhibits a characteristic of:

- genotoxicity
- carcinogenicity
- teratogenicity

Figure 2 illustrates the relationships between the governmental and non-governmental, as well as the regulatory and non-regulatory, organizations in determining whether and how pharmaceuticals must be managed as hazardous wastes and/or hazardous drugs. EPA is a federal regulatory agency. NIOSH is a federal institution that establishes the list of hazardous drugs, but is not a regulatory body. The Occupational Safety and Health Administration (OSHA) is a federal regulatory agency within the Department of Labor that establishes regulations for worker protection that handle hazardous drugs. OSHA enforces the Hazard Communication Standard in general, including the employee right-to-know requirement if exposed to hazardous chemicals.¹³ Added to that is the non-governmental, non-regulatory standard-setting

Figure 2: Chart of Entities That Regulate Hazardous Waste Pharmaceuticals and Hazardous Drugs

Relationships between: EPA, OSHA, NIOSH, USP



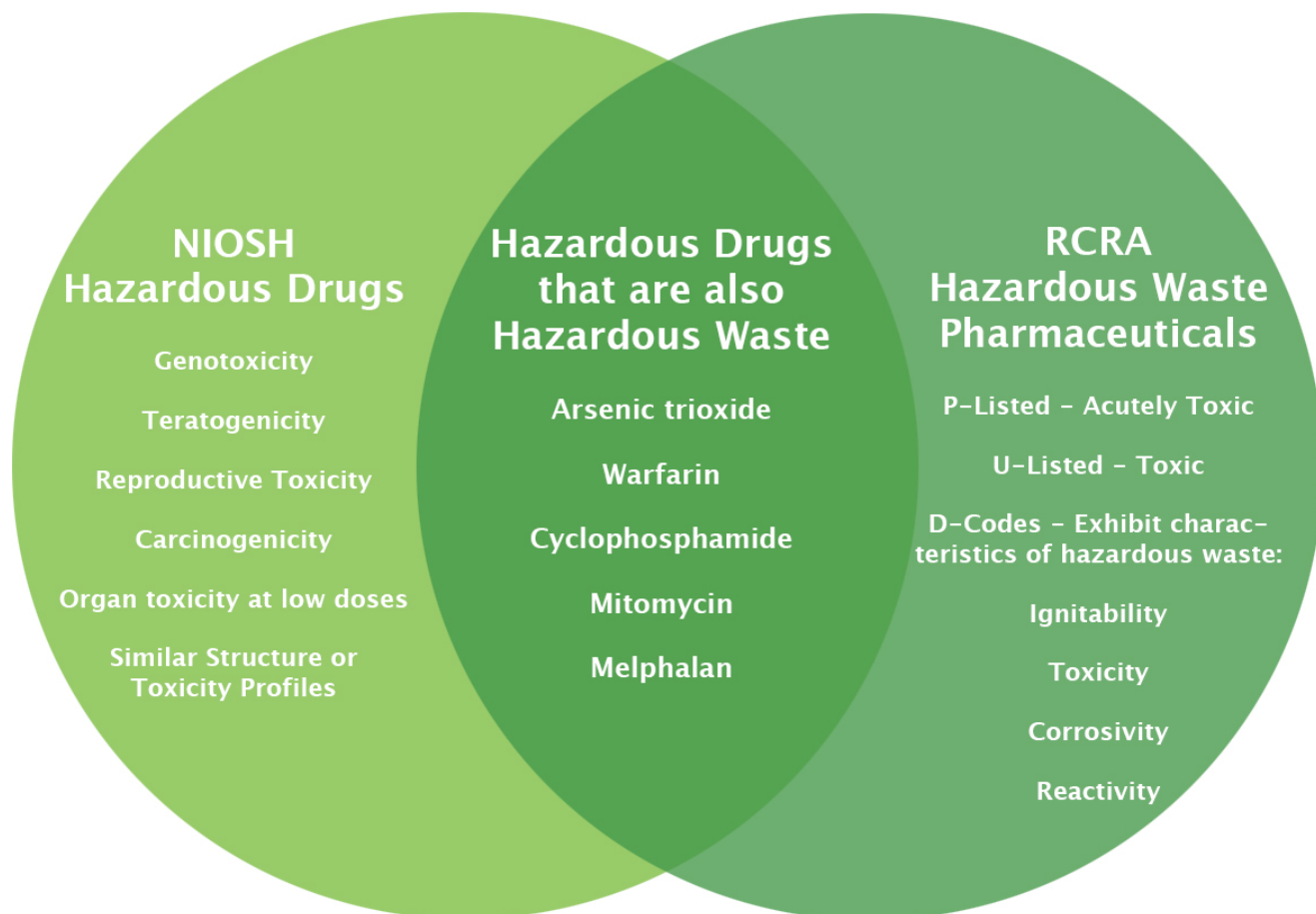
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The chart above illustrates the various entities that are involved with the definitions of RCRA hazardous waste and NIOSH hazardous drugs and their relationships. Healthcare organizations must assimilate and integrate these requirements into their specific hazardous waste and hazardous drug handling operations through policies and procedures and staff training.

¹² [NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016](#)

¹³ [29 CFR 1910.1200 - OSHA, Hazardous Communication Standard.](#)

Figure 3: NIOSH Hazardous Drugs vs. RCRA Hazardous Waste Pharmaceuticals



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This diagram illustrates the different definitions of NIOSH hazardous drugs and EPA hazardous wastes and highlights examples of drugs that meet both definitions.

body, the United States Pharmacopeia, commonly referred to as USP. The USP has developed standards of practice, one of which, USP <800>, refers to hazardous drug handling. While NIOSH establishes the list of hazardous drugs, other governmental and non-governmental organizations may choose to use that list to regulate or accredit healthcare facilities.

Due to the similarity in naming, the terms RCRA hazardous waste pharmaceuticals and NIOSH hazardous drugs are often confused. Figure 3 illustrates the two distinct regulatory regimes while highlighting the overlap. The fact that some drugs meet both EPA

and NIOSH definitions should be kept in mind when operationalizing compliance strategies for these two related but distinctly different categories of drugs. The policies and procedures developed to ensure compliance with both should be kept separate and distinct within the organization.

The focus of this document is RCRA hazardous waste pharmaceuticals. The topic of NIOSH hazardous drugs is mentioned here primarily to accurately distinguish them from hazardous waste to assist facilities in applying the steps that follow. (For more information on NIOSH hazardous drugs please see [Appendix E](#).)

STEP TWO: Reviewing Standards for Healthcare Facilities Operating under the Hazardous Waste Pharmaceuticals Rule

EPA’s Pharmaceuticals Rule implemented a novel set of regulations tailored specifically to the healthcare industry with the intent of facilitating compliance with RCRA regulations at healthcare facilities, while protecting human health and the environment. [STEP TWO](#) provides a detailed discussion of the Pharmaceuticals Rule. Also see [Appendix C](#), “A Quick-Start Guide: Management of Hazardous Waste Pharmaceuticals – OTC Nicotine Exemption and Subpart P” for a short summary of the Pharmaceuticals Rule. Healthcare facilities in states and territories where the Pharmaceuticals Rule is in effect need to update their compliance strategy in accordance with EPA’s Hazardous Waste Pharmaceuticals Rule to both implement the regulations and take advantage of the flexibilities to improve cost savings.

It is also important to note that facilities that are operating as small or large quantity generators of hazardous waste prior to Subpart P are subject to its regulations and must notify their state environmental protection agency. How to notify is discussed in [Appendix F](#) and RCRA generator categories are discussed in [Appendix G](#). Facilities that are currently very small quantity generators of hazardous waste are not required to operate under Subpart P but may find it advantageous to do so. The advantages are listed in [STEP THREE](#).

The Pharmaceuticals Rule has two overarching components:

- The exemption of OTC nicotine patches, gums, and lozenges, from the P075 hazardous waste listing.

Table 5: Pharmaceuticals Rule Effective Dates and Highlights

| Regulation | Citation | Effective Date | Adoption Requirement for Authorized States | Highlights |
|---|---|--|--|---|
| Sewering ban for all hazardous waste pharmaceuticals | 40 CFR 266.505 of subpart P; promulgated under Hazardous & Solid Waste Amendments of 1984 | <ul style="list-style-type: none"> • August 21, 2019 in all states, Indian country, and U.S. Territories – regardless of adoption status | Must be adopted | <ul style="list-style-type: none"> • Applies to all healthcare facilities, nationwide • No hazardous waste pharmaceuticals down any drain. |
| All other provisions of Subpart P | 40 CFR 266 subpart P | <ul style="list-style-type: none"> • August 21, 2019 non-authorized States (Iowa, Alaska), Indian country, US Territories (except Guam) • When authorized state adopts | Must be adopted | <ul style="list-style-type: none"> • HWPs no longer count towards generator status when managed under Subpart P • HWP controlled substances exempt under certain disposal provisions • Changes to empty container regulations for HWP • “PHRM” or “PHARMS” replaces hazardous waste codes on manifest. • Sector-specific, protective on-site management standards for HWPs |
| Exemption for OTC nicotine patches, gums and lozenges, from regulation as hazardous waste | 40 CFR 261.33 (e) | <ul style="list-style-type: none"> • August 21, 2019 in non-authorized states (Iowa and Alaska), Indian country, and US Territories (except Guam) • When authorized state adopts | Adoption is optional, but EPA encourages all states to adopt | <ul style="list-style-type: none"> • OTC nicotine patches, gums, and lozenges are exempt from regulation as hazardous waste • Not limited to healthcare facilities; applies to any generator of OTC nicotine patches, gums and lozenges |

Summary of the highlights of the Pharmaceuticals Rule: the exemption of OTC nicotine patches, gums & lozenges from regulation as a hazardous waste, the sewerage ban, and the other provisions.

- The addition of 40 CFR 266 Subpart P to the RCRA hazardous waste regulations, specifically for the management of Hazardous Waste Pharmaceuticals by healthcare facilities and reverse distributors and includes a sewerage ban on all hazardous waste pharmaceuticals.

Table 5 displays effective dates and some of the highlights of these components. The sewerage ban took effect immediately upon the federal effective date in all states, territories, and Indian country on August 21, 2019. Unlike the other parts of the rule, the sewerage ban is in effect in all states whether or not they have adopted it into their state regulations. All authorized states are required to adopt Subpart P, although states will adopt at different times. At the time of this writing, not all authorized states have yet adopted these regulations. EPA provides periodic updates but it is important to check directly with your state to ensure the most recent information.

As authorized states continue the adoption process, some complications will arise due to differing regulations between states for the generation and management of hazardous waste pharmaceuticals. To better understand and plan for the complications posed by ongoing state adoptions by authorized states please see Table 5 in [STEP TWO](#), as well as the section, “In Transition.” Once the Pharmaceuticals Rule is in effect in all states, this section will no longer be applicable.

Exemption for OTC Nicotine Patches, Gums, and Lozenges (40 CFR 261.33(e))

As noted earlier, the exemption for OTC nicotine patches, gums, and lozenges is expected to provide regulatory relief primarily to the retail industry, but also to hospitals and other healthcare facilities. A few damaged cartons of these products were previously sufficient to cause very small quantity generators (VSQGs) to exceed the monthly 1 kg (2.2 lb) generation limit for P-listed acute hazardous waste. Facilities that are VSQGs but may have become LQGs in the past due to OTC patches, gums and lozenges will benefit the most because these waste OTCs will not cause them to become subject to Subpart P. For hospitals, regardless of generator status, the OTC nicotine patches, gums, lozenges, and packaging will no longer need to be managed as hazardous waste. The best management practice is to keep them out of the trash and discard them as non-hazardous pharmaceutical waste.

This part of the rule is independent from Subpart P and authorized states are not required to adopt it,

however, at the time of publishing, all states that have adopted subpart P have chosen to also adopt the OTC nicotine exemption, and a few have adopted it prior to adopting subpart P.¹⁴

While the wrappers and other packaging for these products can be disposed of in the trash, it is a best practice to manage any used or unused patches as a non-hazardous pharmaceutical waste, not in the trash, for environmental protection. This also reduces the opportunity for accidental poisoning that can occur if placed into the trash due to unintended access or exposure.

It is also important to note that prescription nicotine replacement therapies are still regulated as P075, as are e-cigarettes and e-liquids used in vaping devices. However, if an OTC nicotine lozenge, gum, or patch is prescribed and dispensed as a prescription, its disposal remains exempt from regulation as a hazardous waste.

Prohibition on Sewering Hazardous Waste Pharmaceuticals

The prohibition on sewerage hazardous waste pharmaceuticals, while part of Subpart P, is unique in that EPA promulgated this provision under the authority of the 1984 Hazardous and Solid Waste Amendments (HSWA). HSWA rules go into effect in all states, Indian country, and territories on the federal effective date (August 21, 2019). That means that the sewerage prohibition is currently in effect in all states, regardless of whether a state has adopted Subpart P. In addition to the sewerage prohibition of hazardous waste pharmaceuticals, EPA encourages healthcare facilities to discontinue drain disposal of all pharmaceutical waste, whether or not it meets the definition of a RCRA hazardous waste. Prior to Subpart P, reluctance to commingling hazardous and non-hazardous waste was due to concerns regarding increasing generator status to LQG. EPA hopes that removing hazardous waste pharmaceuticals managed under Subpart P from the calculation of generator status, in addition to easing the waste code requirements on containers and manifests, will incentivize healthcare facilities to no longer dispose of their non-hazardous waste pharmaceuticals down the drain.

The Components of Subpart P

- 1. Hazardous Waste Pharmaceuticals Managed under Subpart P No Longer Count Towards Generator Status (40 CFR 262.13(c)(9))**

¹⁴U.S. EPA, [Map of Where the Amendment to the P075 Listing for Nicotine is in Effect](#).

Hazardous waste pharmaceuticals managed under Subpart P will no longer count towards generator status. Under Subpart P, there is no need to accumulate P-listed hazardous waste pharmaceuticals separately to demonstrate compliance or document how much P-listed or other hazardous waste pharmaceuticals are generated per month. The monthly amount of non-pharmaceutical hazardous waste generated by laboratory, radiology, or maintenance activities, must still be documented, and will count towards generator status.

2. Empty Container Revisions Reduce Items Managed as Hazardous Waste (40 CFR 266.507)

Another major benefit of Subpart P is the revised empty container standards for containers that held hazardous waste pharmaceuticals. Under Subpart P, empty P-listed containers, such as warfarin stock bottles and unit-dose packages, and empty arsenic trioxide vials and IV bags, are not regulated as hazardous waste. The empty warfarin containers can be managed as trash and the empty arsenic trioxide containers, such as vials and IV bags, should be managed as trace chemotherapy waste.

Subpart P redefines what is considered “RCRA empty” for the four types of containers of hazardous waste pharmaceuticals:

- Stock bottles of 1 liter or 10,000 tablets or cap-

sules are considered empty if the entire contents have been removed by normal means.

- Syringes are considered empty if the plunger is fully depressed. If a hazardous waste pharmaceutical remains in a syringe with a needle, it must be managed as “dual” hazardous waste and biohazardous waste, in a sharps container with appropriate labeling for both.
- IV bags are considered empty if they have been completely administered. If an IV bag is not fully administered and contains a P-listed pharmaceutical, the container and its contents must be managed as a hazardous waste. If an IV bag is not fully administered and contains more than 3% by weight of a U-listed or characteristic hazardous waste pharmaceutical, then its contents must be managed as a hazardous waste.
- For other types of pharmaceutical containers found in healthcare settings, if the drug is NOT P-listed and all of the drug has been removed that can be removed through normal means and no more than 3% remains, the container is “RCRA empty.” If the container is not “RCRA empty,” or the container held a P-listed drug, the container and its contents must be managed as hazardous waste.

See Table 6 for criteria classifying containers as RCRA empty.

Table 6: Criteria for Classifying Containers of Hazardous Waste Pharmaceuticals as “RCRA Empty”

| Type of Container | RCRA Empty | |
|--|---|---|
| | Not a P-listed Hazardous Waste Pharmaceutical | P-listed Hazardous Waste Pharmaceutical |
| Stock/dispensing bottles (1 liter or 10,000 tablets/capsules) & Unit-dose containers | Remove all contents | <ul style="list-style-type: none"> • Remove all contents • No triple rinsing required |
| Syringes | Fully depress plunger | <ul style="list-style-type: none"> • Fully depress plunger • No triple rinsing required |
| IV Bags | <ul style="list-style-type: none"> • Fully administer contents or • Remove all contents and no more than 3% by weight remains | <ul style="list-style-type: none"> • Fully administer contents • If not fully administered, must manage as HWP • No triple rinsing allowed |
| Other containers (creams, ointments, aerosols, nebulizers, etc.) | <ul style="list-style-type: none"> • Remove all contents and no more than 3% by weight remains or • Approaches atmospheric pressure if an aerosol | <ul style="list-style-type: none"> • Cannot be RCRA empty; must manage as a HWP • No triple rinsing allowed |

Criteria for determining if a hazardous waste pharmaceutical (HWP) container meets the regulatory definition of “RCRA empty.”

For examples of compliant disposal practices for empty containers for specific drugs, see Table 7 below.

Table 7: Examples of Compliant Disposal Practices of “RCRA Empty” Containers

| Hazardous Waste Pharmaceutical | Disposal of Drug* | HW Code | RCRA Empty Standard | Disposal of “RCRA Empty” Container |
|--|---|-------------------------------------|--|---|
| OTC Nicotine lozenge, gum, or patch | Non-hazardous pharmaceutical waste (BMP) | N/A | N/A | Trash |
| Rx Nicotine (nasal spray, inhaler) | Hazardous waste | P075 | No regulatory method allowed to empty; manage as hazardous waste | N/A |
| Warfarin tablets Unit dose, stock bottle ≤ 10,000 tablets | Hazardous waste | P001 | Remove all contents | Trash |
| Arsenic trioxide (IV bag) | Hazardous waste (accumulate separately) | P012 | Fully administer | Trace chemotherapy |
| Arsenic trioxide (vial) | Hazardous waste (accumulate separately) | P012 | Remove all contents | Trace chemotherapy |
| Cyclophosphamide tablets/IV | Hazardous waste | U058 | Remove all contents | Trace chemotherapy |
| Multi-dose Flu Vaccine | Hazardous waste | D009 | Remove all contents | Trash |
| Insulin vials | Hazardous waste | D024 | Remove all contents | Trash |
| Physostigmine salicylate pre-filled syringe for emergency use | Hazardous waste/biohazardous waste (dual labeled) | P188 | Plunger fully depressed | Red sharps container |
| Diazepam Injection (CIV) (Dispensed but not administered to patient) | Non-hazardous pharmaceutical waste ⁺ but documented and sequestered to prevent diversion | D001 and a DEA controlled substance | Empty vial or plunger fully depressed | Trash or hospital policy; red sharps if needle attached |
| Diazepam Injection (CIV) (Outdated in pharmacy) | Reverse distribution (DEA regulations) | D001 and a DEA controlled substance | N/A | N/A |
| Silver sulfadiazine cream (partial) | Hazardous waste | D011 | Remove all contents and no more than 3% by weight remains | Trash |

* Disposal of drug can mean that the drug 1) has been removed from a container or 2) remains in a container that is not RCRA empty.

⁺ As a hazardous waste that is also a DEA controlled substance, it is conditionally exempt from RCRA and can be managed with non-hazardous waste pharmaceuticals. See [STEP TWO, Number 7](#). for more details about the conditional exemptions.

Examples of the disposal procedures for containers with drug remaining and for RCRA empty containers under Subpart P. Once a state has adopted the new regulations, pharmacy and nursing personnel need to be trained on the new procedures. Messaging to nurses must be provided in as many venues as possible, including in the automated dispensing cabinets, in the medication administration record, and on the patient labels when appropriate.

3. Container Management and Labeling ([40 CFR 266.502\(d\)](#) and [266.502\(e\)](#))

Subpart P only specifies container management and labeling standards for non-creditable hazardous waste pharmaceuticals. Potentially creditable hazardous waste pharmaceuticals represent sufficient value

that EPA determined healthcare facilities have sufficient incentive to manage them during accumulation in a way that prevents diversion, so that management standards for these containers is unnecessary. Also, they must be in the original manufacturer packaging, so the risk of spills is minimal.¹⁵

¹⁵ Potentially creditable hazardous waste pharmaceuticals that are spilled cannot go to a reverse distributor but must be immediately contained, and any spill clean-up material must be managed as non-creditable hazardous waste pharmaceuticals. See [40 CFR 266.503\(f\)](#).

Containers used to accumulate non-creditable hazardous waste pharmaceuticals must meet the standards required for hazardous waste containment and transport under Subpart P, and must remain closed, not sealed, when not in active use. The industry has generally settled on black containers for this purpose. Open containers continue to be a source of violations within healthcare facilities. The most successful method of reducing these violations is to provide pharmacy, nursing, and other treatment areas with containers mounted on carts that include pedal-operated openings that self-close after the healthcare professional has placed the item into the container. While the industry has generally adopted black containers for this purpose, a color is not designated in the regulations.

Subpart P adds the requirement that the container must also be secured in a way that prevents unauthorized access to its contents. Healthcare facilities have flexibility in how to comply with this performance-based standard. The most common method will be by placing the closed container of hazardous waste pharmaceuticals in a medication room, locked soiled utility room, or locked cart system under constant supervision to prevent diversion. Alternatively, a healthcare facility can use containers that are designed to prevent access to the contents, similar to those used for in-room sharps disposal. If a secure room is not available, then a healthcare facility would need to use secure containers.

Containers must be labeled with the words “Hazardous Waste Pharmaceuticals.” Proper labeling is an extremely common compliance violation. Be aware that only labeling containers as “Hazardous Waste” could result in a violation.

Hazardous waste pharmaceuticals must be shipped off-site within ONE YEAR from the initial placement of drugs in the container. As a practical matter, the recommendation is to place the start date directly on the container at the time it is placed into service. Other methods may be used (e.g., logs) but compliance must be readily demonstrable upon inspection. Therefore, labeling the container with the start date is the recommended method of tracking the one-year accumulation time limit. It is advisable to stage containers of hazardous waste pharmaceuticals for pickup to assure they do not exceed the one-year on-site accumulation time limit.

4. Personnel Training ([40 CFR 266.502\(b\)](#))

All personnel managing hazardous waste pharmaceuticals must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and during emergencies. This is another performance-based standard, which means it is up to the healthcare facility to determine the appropriate training material, methods, etc. While a facility manager, environmental services manager, or other designated manager should be responsible for the hazardous waste program as a whole, including recordkeeping (e.g., manifests, waste determinations), those employees directly involved in the handling and management of hazardous waste pharmaceuticals (e.g., management of accumulation areas and containers, and other routine hazardous waste functions) are required to receive specific training to ensure proper management of these wastes under Subpart P. For example, all pharmacy personnel should be trained on the changes involving empty containers for P-listed drugs, outdated drug management (See [STEP FIVE](#) and [STEP SIX](#)), and the sewerage ban. Nursing personnel and other practitioners, such as those in radiology, respiratory therapy, and surgery, will need training on the revised procedures also involving empty containers, the sewerage ban, and the exemptions for OTC nicotine patches, gums, and lozenges. If the organization also changes its management strategy in terms of sorting or not sorting hazardous waste pharmaceuticals, these changes should also be documented, and training should be provided accordingly. If a healthcare facility chooses to sort all pharmaceutical waste, healthcare personnel need to be trained on how to implement hazardous waste sorting decisions. While not mentioned in the regulations, all healthcare facilities will also need to review and revise their policies and procedures around pharmaceutical waste management to ensure any changes, resulting from the Pharmaceuticals Rule or otherwise, are consistent with their policies and procedures as required by accrediting agencies such as The Joint Commission¹⁶ and Det Norske Veritas (DNV).¹⁷

Proper spill management, containment, and disposal of hazardous waste pharmaceuticals should also be included in any personnel training program. All personnel who may be involved with spill management, including pharmacy and nursing personnel, must have periodic spill training. Spill kits appropriate for the type and quantity of spill must be readily available. Healthcare facilities may want to consider a supplemental spill kit with larger quantities of supplies to augment the kits currently available on the mar-

¹⁶ [The Joint Commission.](#)

¹⁷ [Det Norske Veritas.](#)

ket, which are only appropriate for very small spills. All materials used to contain a spill of a hazardous waste pharmaceutical must be managed as hazardous waste pharmaceuticals. Likewise, any personal protective equipment which is overtly contaminated by a hazardous waste pharmaceutical, either due to spill clean-up or other exposure, must be managed as a hazardous waste pharmaceutical.

Personal Protective Equipment

Trace amounts of a hazardous waste pharmaceutical, such as the administration of a warfarin tablet with a glove or an empty IV bag of mitomycin, are not considered hazardous waste pharmaceuticals. While a glove used to administer warfarin would normally be discarded in the trash, a glove used to administer chemotherapy and an empty IV bag of mitomycin would be considered “trace chemotherapy waste” and managed in a yellow container destined for regulated medical waste incineration as a best management practice. (Refer to waste charts in Figures 7 through 10.)

5. Potentially Creditable vs. Non-creditable Hazardous Waste Pharmaceuticals (40 CFR 266.500)

The Pharmaceuticals Rule defined the terms pharmaceutical and hazardous waste pharmaceutical, as well as the two types of hazardous waste pharmaceuticals generated at healthcare facilities: potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. A hazardous waste pharmaceutical is a pharmaceutical that meets the RCRA criteria of being considered hazardous waste. All hazardous waste pharmaceuticals are either non-creditable or potentially creditable hazardous waste pharmaceuticals, and each has its own separate set of management standards.

To be considered “potentially creditable,” a hazardous waste pharmaceutical must:

- Have a reasonable expectation of receiving manufacturer credit, and
- Be in the original manufacturer package, and
- Be undispensed to a patient, and
- Be unexpired or less than one year past expiration.

Under some circumstances, EPA has concluded that a healthcare facility may send a non-prescription hazardous waste pharmaceutical to a reverse distributor, provided the non-prescription pharmaceutical meets the same criteria and is managed as a potentially creditable hazardous waste pharmaceutical under Part 266 Subpart P.¹⁸

Keep in mind that a healthcare facility does not need to know whether the potentially creditable hazardous waste pharmaceutical will actually receive manufacturer credit, only that there is a reasonable expectation that it will. EPA understands that manufacturers’ credit policies change frequently and does not expect healthcare personnel to always know what those are. Certain items, such as leaky containers or pharmaceuticals already dispensed to patients clearly do not meet the definition of potentially creditable.

In contrast, a non-creditable hazardous waste pharmaceutical:

- Is any hazardous waste pharmaceutical that has no reasonable expectation of receiving manufacturer credit, or
- Is not in its original manufacturer packaging, or
- Has been dispensed to a patient, or
- Is beyond one year past the expiration date.

Hazardous waste pharmaceuticals that have been labeled for patient usage would be considered dispensed and therefore not eligible for manufacturer credit at a reverse distributor. Non-creditable drugs may be either prescription or OTC. Also, contaminated cleanup materials, including PPE from spills of any hazardous waste pharmaceutical, must be managed as non-creditable hazardous waste pharmaceuticals.

Most outdated pharmaceuticals will be potentially creditable hazardous waste pharmaceuticals but some will be non-creditable. Outdated pharmaceuticals that become hazardous waste must be sorted into potentially creditable and non-creditable **at the time they are removed from inventory.**

Potentially creditable hazardous waste pharmaceuticals, while still considered hazardous waste, may be

How Subpart P Changed the Point of Generation for Potentially Creditable Hazardous Waste Pharmaceuticals

Prior to Subpart P, any pharmaceutical that was sent to a reverse distributor was not considered waste at the healthcare facility. The previous policy held that they were not discarded and therefore not subject to RCRA until the reverse distributor made a final determination as to their credit value. EPA learned, however, that virtually all pharmaceuticals sent to reverse distributors are discarded, and changed that policy via the Pharmaceuticals Rule. Now, hazardous waste pharmaceuticals are considered waste at the healthcare facility (usually the pharmacy) when a decision is made to send them to a reverse distributor.

¹⁸U.S. EPA, [Frequent Questions about the Management Standards for Hazardous Waste Pharmaceuticals.](#)

sent to a reverse distributor for evaluation of manufacturer credit via common carrier (see Section 6 below for more information about reverse distribution). Non-creditable hazardous waste pharmaceuticals cannot be sent to a reverse distributor. Instead, they must be manifested to a permitted hazardous waste treatment, storage, and disposal facility. Vendors may assist by creating manifests and labels, but the appropriate hospital personnel must sign the manifest (see e-Manifest Frequent Question #2 under [Manifest Preparation, Brokers](#)).

6. Reverse Distribution ([40 CFR 266.510](#))

The process known as reverse distribution has been widely used for the past 30 years within the pharmaceutical industry to enable pharmacies to obtain manufacturer credit for primarily prescription drugs that outdate prior to being dispensed to a patient. Since these drugs cannot be sold or reused in any other way, they are considered waste at the healthcare facility and drug manufacturers often offer a return credit.

Hospital pharmacies must sort their outdated drugs **at the time they are removed from stock, automated dispensing machines, or returned from the nursing units** to ensure any hazardous waste pharmaceuticals are appropriately identified as either potentially creditable returns or non-creditable, and placed into the appropriate container. The facility should NOT wait for reverse distributor staff to sort and separate them. While EPA does not require labeling of containers that hold potentially creditable hazardous waste pharmaceuticals (typically found in the pharmacy), The Joint Commission and other accrediting bodies will require appropriate labeling to ensure these outdated drugs are not inadvertently dispensed.

The practice of sending all outdated drugs, including those that are non-creditable, to a reverse distributor should be discontinued. In addition, if a hospital pharmacy sends inappropriate materials to the reverse distributor, such as non-creditable hazardous waste pharmaceuticals, hazardous chemical waste, or biohazardous waste, the reverse distributor must submit an unauthorized waste report to both the facility and to their state or Regional EPA office within 45 days of receipt.

To be prepared for an unexpected RCRA inspection, it is a good practice to ensure that several pharmacy staff are able to access the reports generated by the reverse distributor identifying which pharmaceuticals received credit, as a password is generally required.

7. Managing Outdated Hazardous Waste Controlled Substances Inventory and Waste ([40 CFR 266.506](#))

A “hazardous waste controlled substance” is a waste pharmaceutical that is both a RCRA hazardous waste and a DEA controlled substance. One of the challenges around hazardous waste controlled substances is the dual regulation by EPA and DEA. To mitigate this challenge, EPA has exempted hazardous waste pharmaceuticals that are also DEA controlled substances from regulation as hazardous waste – provided a few conditions are met. The first condition is that the hazardous waste controlled substances cannot be sewerred. Second, they must be managed in compliance with DEA regulations. Third, they must be combusted at one of the following types of permitted facilities:

- Large or small municipal waste combustor,
- Hospital, medical, and infectious waste incinerator,
- Commercial and industrial solid waste incinerator,
- Hazardous waste combustor.

In order to allow for future technological innovation, in addition to the above combustion option, EPA allows hazardous waste controlled substances to be destroyed by a method that the DEA has publicly deemed in writing to meet their non-retrievable standard. EPA requires written DEA approval of any method other than combustion to meet the exemption in Subpart P. However, at the time of publication of this document, DEA has not publicly deemed in writing that any other method renders controlled substances non-retrievable. Combustion is currently the only method for the ultimate disposal of hazardous waste controlled substances that meets the conditions for exemption under Subpart P.

Controlled substance inventory versus wastage

Unlike RCRA, DEA has different regulations for the management of outdated inventory of controlled substances as well as pharmaceutical wastage. Controlled substances that outdate in the pharmacy’s inventory must be sent to a DEA-registered reverse distributor. This is a routine process with which all hospital pharmacies should be familiar. Since hazardous waste controlled substances are conditionally exempted by EPA, they do not need to meet the definition of a potentially creditable hazardous waste pharmaceutical.

DEA refers to controlled substances that have been dispensed to a patient, but not entirely administered, as “pharmaceutical wastage.” The DEA regulations for phar-

maceutical wastage are much less prescriptive than for inventory. DEA requires that pharmaceutical wastage:¹⁹

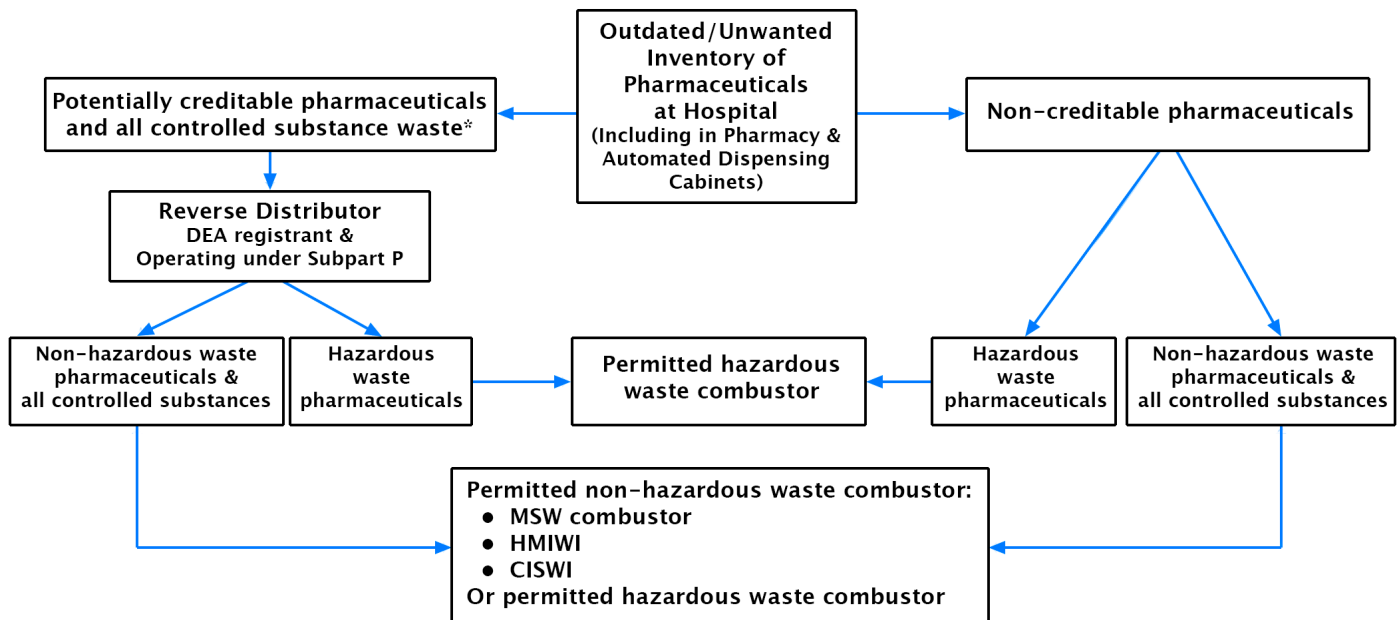
- Be documented with the appropriate information, including the date, the name of the patient, the drug and amount wasted, and the initials of the witnesses,
- Be managed in a way that does not allow the drugs to be diverted, and
- Be managed in compliance with all State, Federal, tribal, and local environmental regulations in such a way as to prevent diversion.

Healthcare facilities often require personnel to place, squirt, etc., their DEA controlled substance **wastage** into a sequestration device. Sequestration devices are containers that are designed to collect liquid and other forms of drug wastage in a way that is highly resistant to diversion. These sequestration devices, or their inner cartridges, can then be incinerated as non-hazardous pharmaceutical waste but **only** when they are used to collect non-hazardous waste pharmaceuticals and/or exempt controlled substances (i.e., the few RCRA hazardous wastes that are also DEA controlled substances). DEA does not allow the use of sequestration devices for disposal of controlled substance from **inventory**. Remember that combustion is required for the Subpart P exemption, so in this case, the sequestration devices **must** be sent for combustion. Because of high cost of the devices, most facilities only use them to collect controlled substances. If healthcare

personnel place any non-controlled hazardous waste pharmaceuticals into these containers, the containers must be managed under subpart P as hazardous waste pharmaceuticals. If a facility wants to manage their sequestration devices as non-hazardous waste, appropriate training is necessary to ensure they are not used to collect hazardous waste. If a hospital cannot be confident that a sequestration device will be used solely for controlled substances, or if the hospital does not want to sort pharmaceutical wastage into multiple bins, then the hospital must take the conservative approach and manage the sequestration device as hazardous waste, ultimately sending it for hazardous waste incineration.

Please see Figure 4 regarding the disposal of inventory of controlled substances, both hazardous and non-hazardous. See Figures 5 and 6 regarding two scenarios for the disposal of pharmaceutical wastage, including controls and non-controls, and hazardous and non-hazardous. Each of these models may be used in the same facility in different departments. Please note that while the DEA regulations do enable two employees to transport controlled substances to the incinerator to witness the incineration and complete the Form 41,²⁰ this practice is highly unlikely due to the logistics involved and incinerators may not be conveniently located near healthcare facilities. The practice is still legal under DEA regulations; however, the regional DEA office should be contacted for permission before utilizing this approach.

Figure 4: Managing Pharmaceutical Waste from the Pharmacy’s Inventory



*See DEA regulations if the hospital prefers to self-transport discarded controlled substance inventory to witness the burn at the combustor

Managing outdated/unwanted inventory of pharmaceuticals, including controlled substances, involves sorting into potentially creditable and non-creditable pharmaceuticals.

¹⁹ 21 CFR 1304.22(c).

²⁰ Drug Enforcement Administration, Registrant Record of Controlled Substances Destroyed - DEA Form 41.

For additional guidance on the management of controlled substance pharmaceutical wastage, please refer to [STEP SEVEN: Implementing A Pharmaceutical Waste Program in the Nursing Unit and Other Patient Care Areas](#).

The following two figures illustrate two scenarios for the appropriate discard of controlled substance waste under Subpart P:

- In Figure 5, only controlled substances (both hazardous and non-hazardous) are placed into the sequestration device. Since hazardous waste controlled substances are exempt under Subpart P (provided certain conditions are met), the sequestration device may be incinerated as non-hazardous pharmaceutical waste.
- In Figure 6, controlled substances (both hazardous and non-hazardous) and other hazardous wastes that are not controlled substances are placed into the sequestration device. This device must then be managed and disposed as a hazardous waste.

8. Shipping Non-creditable and Potentially Creditable Hazardous Waste Pharmaceuticals (40 CFR 266.508 and 266.509)

Subpart P has different shipping requirements for non-creditable and potentially creditable hazardous waste pharmaceuticals.

Non-creditable hazardous waste pharmaceuticals

Non-creditable hazardous waste pharmaceuticals must be shipped on a hazardous waste manifest, via a hazardous waste transporter, to a permitted hazardous waste treatment, storage, and disposal facility (TSDF). Although the standard hazardous waste manifest is required, instead of listing all relevant hazardous pharmaceutical waste codes in item 13, the code “PHRM” or “PHARMS” must be entered.²¹ Arsenic trioxide must be accumulated and shipped separately from other non-creditable hazardous waste pharmaceuticals because it may not be incinerated.

Potentially creditable hazardous waste pharmaceuticals

Hazardous waste manifests and transporters are not required for potentially creditable hazardous waste pharmaceuticals, but there are a few other

requirements. Under Subpart P, healthcare facilities may ship the potentially creditable hazardous waste pharmaceuticals via common carrier (e.g., UPS, USPS, FedEx), and must receive delivery confirmation from the reverse distributor to ensure that the shipment has reached its destination. The regulations do not require a signature for delivery, but they do specify that shipments must be under the control and custody of the reverse distributor to ensure packages do not get left outside unattended at their destination. Therefore, it is highly advisable to require a delivery signature for any outgoing shipments. The electronic tracking system used by common carriers will suffice for delivery confirmation, which means that you will be in compliance as long as you can look up the tracking history. Just be sure that electronic tracking is enabled for whatever shipping method you use. These delivery confirmation records must be stored for three (3) years. If a delivery confirmation is not received within 35 calendar days from the date the shipment was initiated, the healthcare facility must attempt to locate it by contacting both the carrier and the reverse distributor.

Shipping incompatible non-creditable hazardous waste pharmaceuticals

In most cases, hazardous waste pharmaceuticals may be commingled; and the DOT shipping description would be:

- UN3248, Waste medicine, liquid, flammable, toxic, n.o.s., 3 (6.1), PG II.

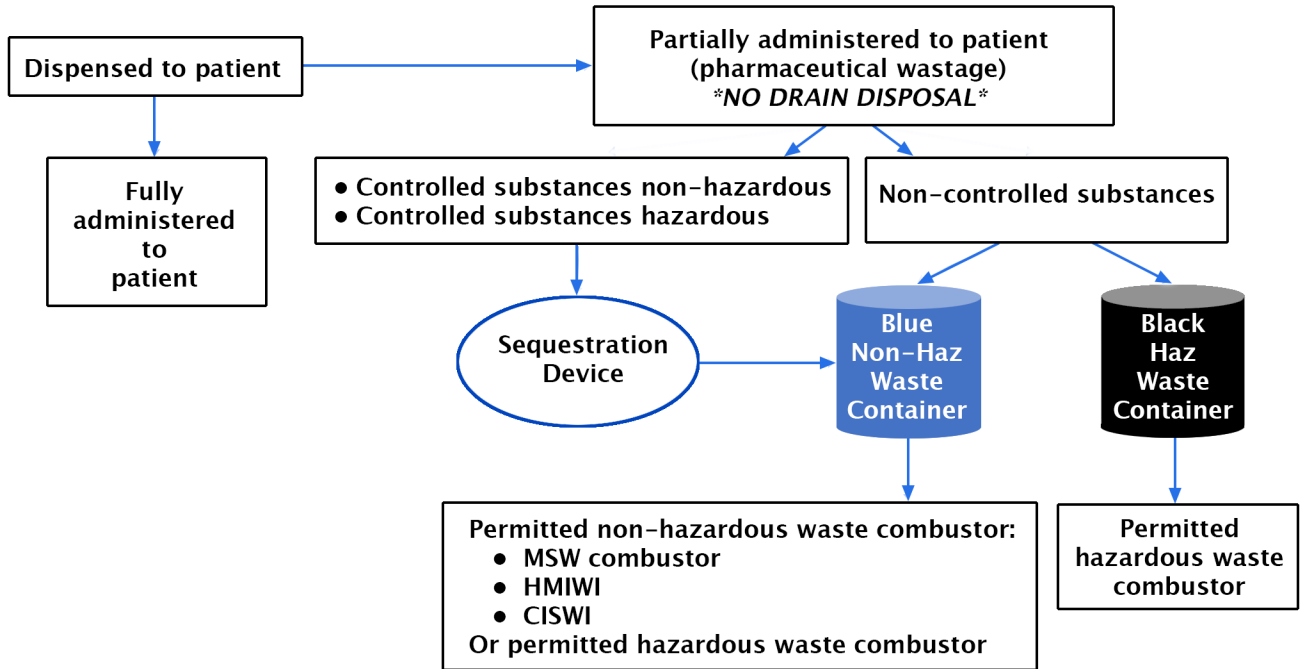
However, there are exceptions you should consider. The DOT HMR does not include a list of hazardous materials that must be shipped in separate containers due to their incompatibility; rather, the DOT HMR includes a performance-based standard that must be met to ensure safety during transportation.²² For example, some drug formulations, such as pressurized aerosols, acids, bases, and oxidizers must be put into separate containers, in order to comply with the DOT HMR to prevent dangerous reactions during transportation. In addition, arsenic trioxide must also be accumulated separately to comply with the Land Disposal Restrictions (LDRs) which prohibit the combustion of heavy metals.²³ Your hazardous waste vendor can assist with proper labeling, manifesting and disposal of these unique waste streams, including bulk pharmaceuticals. Non-hazardous pharmaceutical waste may be accumulated and managed separately or may be commingled and managed as hazardous waste.

²¹ EPA originally finalized a requirement to use the six-character code, “PHARMS” in Item 13. However, because of implementation challenges, EPA subsequently approved and recommends using the four-character “PHRM” code. See EPA Memo [“Manifesting Non-Creditable Hazardous Waste Pharmaceuticals – New Four Character Code”](#)

²² [49 CFR 173.24\(e\)](#).

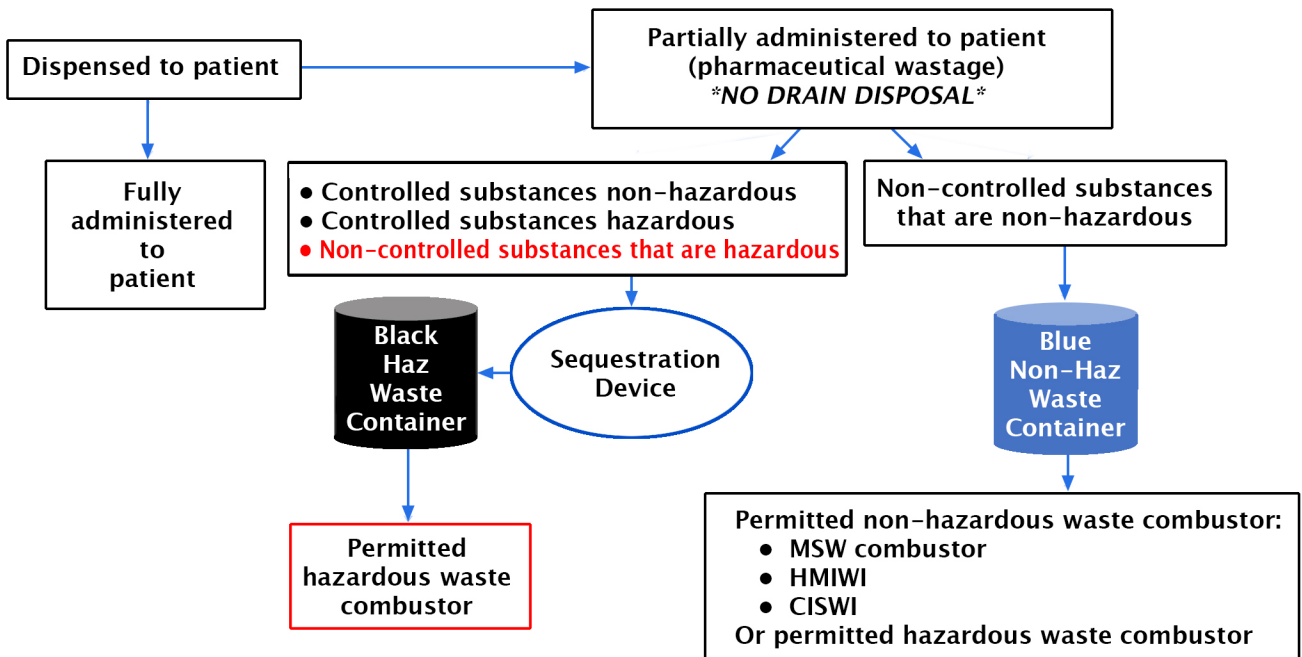
²³ [U.S., Land Disposal Restriction Requirements](#).

**Figure 5: Managing “Pharmaceutical Waste”
Scenario 1**



Only controlled substances are placed into the sequestration device, which can then be disposed as non-hazardous pharmaceutical waste in the appropriate container.

**Figure 6: Managing “Pharmaceutical Waste”
Scenario 2**



Red denotes differences from Scenario 1

Hazardous waste pharmaceuticals other than controlled substances are placed into the sequestration device which must then be managed and disposed as hazardous waste in the hazardous waste container.

Table 8: Examples of Incompatible Hazardous Waste Pharmaceuticals

| Pharmaceutical | RCRA HW Code(s) | DOT Shipping Description |
|---|-----------------|---|
| Albuterol Inhaler Tolnaftate Aerosol Cetacaine Aerosol | D001 | UN1950, Waste aerosols, flammable, 2.1, PG II |
| Cola Syrup Emetrol Solution Bichloroacetic Acid KAHLENBERG Replenishment Unit w/Applicator | D002 | UN3265, Waste corrosive liquid, acidic, organic, n.o.s., 8, PG II |
| Clinitest Tablets | D002 | UN3267, Waste corrosive liquid, basic, organic, n.o.s., 8, PG II |
| Silver Nitrate Solution | D001, D011 | UN3139, Waste oxidizing liquid, n.o.s., 5.1, PG II (D001, D011) |

Some Hazardous Waste Pharmaceuticals may NOT be commingled due to incompatibility. The hazardous waste pharmaceuticals listed above include examples of appropriate DOT shipping descriptions for common classes of DOT hazardous materials that must be shipped on a hazardous waste manifest to an appropriate RCRA waste management facility. Most acids and bases in pharmacies are bulk chemicals that require lab packing when disposed.

9. Considerations for Very Small Quantity Generators (40 CFR 266.504)

If your facility is currently a very small quantity generator (VSQG) when counting all your hazardous waste, including potentially creditable and non-creditable hazardous waste pharmaceuticals, you have the option, but not the requirement, to operate under Subpart P. The primary benefit of operating under Subpart P is to avoid the need to document your monthly generation of hazardous waste pharmaceuticals, including P-listed drugs such as warfarin. This may be particularly helpful for facilities that are close to exceeding the monthly VSQG generation threshold. It also reduces the compliance risk if a facility unknowingly exceeds the VSQG threshold.

It is important to remember that:

- All VSQG healthcare facilities are subject to the sewerage prohibition and the empty container standards, regardless of whether they have opted into subpart P.
- Any VSQG that opts into Subpart P is subject to all the requirements of Subpart P.

VSQGs have the option to opt into Subpart P and comply with all its provisions, OR they can take advantage of these optional provisions:

1. A VSQG healthcare facility can continue to send potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

2. A VSQG healthcare facility can send its hazardous waste pharmaceuticals off-site to another healthcare facility for subsequent reverse distribution or disposal as hazardous waste, provided the receiving healthcare facility meets all the conditions for off-site consolidation and is either:

- a. Operating under Subpart P and meets certain conditions, including managing the hazardous waste pharmaceuticals it receives under Subpart P, or
- b. An LQG for non-pharmaceutical hazardous waste, is operating under Subpart P, and meets certain conditions, including managing the hazardous waste pharmaceuticals it receives under Subpart P.²⁴

It's important to note that if a VSQG healthcare facility does NOT opt into Subpart P, it must continue to manage its hazardous waste pharmaceuticals in compliance with 40 CFR section 262.14, which means that it will need to continue documenting that it does not exceed any of the relevant quantity limits, including the 1 kg (2.2 lbs) of P-listed hazardous waste in a calendar month, including both pharmaceuticals and non-pharmaceuticals. VSQG healthcare facilities should check with their state to determine options for disposal of hazardous waste. Any healthcare facility that exceeds VSQG limits must operate under Subpart P.

To opt into Subpart P, VSQGs must complete the Site Identification Form (Form 8700-12) or their equivalent state form. More information on notifying under Subpart P is provided in [Appendix F: Step-by-Step Guide to Notifying under Subpart P](#).

²⁴ 40 CFR 266.504(b).

STEP THREE: Determining which Facilities Must Operate Under Subpart P

If your facility is currently a small quantity generator (SQG) or a large quantity generator (LQG) when counting all your hazardous waste, including potentially creditable and non-creditable hazardous waste pharmaceuticals, your facility must operate under Subpart P and notify using the Site ID form (Form 8700-12 or your state's equivalent form). SQGs must notify under Subpart P within 60 days of your state's adoption of the Pharmaceuticals Rule, unless your state requires you to submit an annual or biennial report, which would satisfy the notification requirement. LQGs may notify under Subpart P on their annual or biennial report, but you may also choose to notify

sooner. Please see [Appendix F](#) "Step-by-Step Guide to Notifying Under Subpart P" for more information.

It's important to note that, with few exceptions, all non-pharmaceutical hazardous waste must be managed under the standard 40 CFR Part 262 hazardous waste generator regulations,³⁰ and counted toward determining your generator category. This includes lab wastes, such as xylene, methanol, gram stain and acetone, unrecycled lead aprons from radiology, and hazardous waste chemicals from building and grounds maintenance. One exception is that universal waste managed under Part 273 does not need to be counted toward determining your generator category.

STEP FOUR: Leadership and Current Program Review

One of the most challenging aspects of either refining a pharmaceutical waste program or starting one from scratch is determining who will have the responsibility to lead the effort and who will be part of the implementation team. Teams are often led either by:

- The Pharmacy Director or one of their pharmacy managers, or
- The Environmental Services Manager or Environmental Health and Safety Manager.

Ideally, the Chief Operating Officer is involved with providing support and resources and ensuring the program stays on track. Regardless of who takes the lead, the following departments must be represented initially and throughout the program to ensure successful implementation:

- Pharmacy,
- Nursing, and
- Environmental Services and Safety (if a separate department),

with representatives from the following specialties:

- Respiratory Therapy,
- Radiology,
- Surgery,
- Outpatient Oncology, and
- Other specialty departments if offered at the facility.

A project management plan should be established with clearly assigned tasks and deadlines, and meetings should ideally be held monthly to ensure consistency and progress. Often a program is already in place, so the following steps are intended to assist the team in evaluating the current situation and determining what changes are needed to either comply with the new regulations or provide relief from the former regulations.

Review and Update Your Current Program to Operationalize Subpart P

Over the past 15 years, healthcare facilities have become increasingly aware of the RCRA regulations and have been making concerted efforts to improve compliance. To ensure compliance and fully benefit from the Pharmaceuticals Rule, it's important to review your current program, determine what is working, what has been problematic, and which approach makes the most sense going forward. The following questions should be helpful in guiding your decisions.

Table 9: Pros and cons of sorting hazardous waste pharmaceuticals from non-hazardous waste pharmaceuticals

The threshold question is: Will your healthcare facility sort its hazardous waste pharmaceuticals from its non-hazardous waste pharmaceuticals?

NOT SORTING

- 1. Are pharmacy and nursing staff currently sorting hazardous and non-hazardous pharmaceutical waste?** Sorting is often the most economical approach from a waste management perspective, since the disposal costs may be higher for hazardous waste disposal. However, EPA encourages the management of all pharmaceutical waste as hazardous waste as a best management practice, and there may be some other cost savings, especially related to training staff, to offset the increased waste management costs. Each organization should perform a cost analysis to determine which scenario is most appropriate for their organization. And you may choose to have different procedures for different areas. For example, you may choose to have pharmacy staff sort hazardous and non-hazardous pharmaceutical waste, while choosing to have nursing staff commingle all pharmaceutical waste in the same container. See [STEP TEN](#) for a detailed discussion of various sorting models.

SORTING

- 1. Does your facility have an up-to-date waste determination strategy at the National Drug Code (NDC) level for all pharmaceuticals stocked by your pharmacy or in other departments, such as Radiology?** The NDC identifies each drug by manufacturer, product name, and package size. Your pharmacy routinely works with NDCs in their purchasing processes, along with the generic name of the drug. Certain regulatory changes finalized by the Pharmaceuticals Rule, such as OTC nicotine patches, gums, and lozenges no longer being regulated as hazardous waste, and the new empty container standards for pharmaceutical containers, will necessitate revisions to your waste determination strategy. Therefore, you should start with an updated list of those drugs in your inventory that are categorized as RCRA hazardous waste. Much of the information available on the Internet regarding whether specific drugs are hazardous waste pharmaceuticals when discarded may be out of date, so it is important to obtain updated information from a reliable vendor. More information on which drugs become hazardous waste when discarded is available in [STEP ONE](#). Please note your pharmacy will also need a “hazardous drug” list based on NIOSH and USP regulations. The hazardous waste list and the hazardous drug list should not be confused.
- 2. If sorting in pharmacy, have pharmacy staff been informed as to which drugs to discard in black hazardous waste containers?** Once you have updated your list of which pharmaceuticals and containers must be managed as hazardous waste under Subpart P, it will be important to apply this information to all current methods of training (see [STEP TWO, Number Four](#)) and informing pharmacy staff. Disposal information conveyed on shelf stickers and waste charts will need to be updated. Revised training programs should emphasize changes to the empty container rules. A good example would be empty warfarin stock bottles in the outpatient pharmacy which no longer need to be managed as hazardous waste.
- 3. If sorting in the nursing units, how have nursing staff been informed as to which drugs and containers to discard into the black hazardous waste containers?** Often this is done through messaging by pharmacy staff through the medication administration record (MAR), automated dispensing cabinets (ADCs), or direct messages on IV labels (see [STEP SEVEN](#), Figures 12 and 13, for examples of markings for nursing). Consider all the situations for P-listed wastes where the empty wrappers no longer need to be disposed as hazardous waste. Warfarin is again an obvious example, along with OTC nicotine patches, gums, and lozenges. Fully administered IV bags are considered “RCRA empty” regardless of what was in them. Therefore, empty arsenic trioxide IV bags can be disposed into the trace chemotherapy container, potentially eliminating the need for a black hazardous waste container in the oncology infusion center. Syringes with fully depressed plungers are also “RCRA empty” and can be disposed in red sharps or yellow chemo containers, depending on the drug. Be particularly sensitive to the issue of hazardous waste pharmaceuticals versus hazardous drugs (NIOSH). It is not uncommon that messaging gets confused between these two. Both can be designated on labels and in the MAR if planning is done with these precise designations in mind.

What Factors Should be Considered When Deciding Whether to Sort or Not to Sort into Hazardous and Non-Hazardous Waste?

Subpart P was designed to encourage healthcare facilities to manage all pharmaceutical waste as hazardous waste by not counting them toward generator category, as noted earlier. There are many logistical and financial factors to consider when determining your preferred management method, and you may even choose to employ multiple pharmaceutical waste management methods at different areas within your facility. The three models of hazardous waste pharmaceutical management are:

Model 1: Manage all pharmaceutical waste from the pharmacy and nursing unit as hazardous waste (See Figure 7)

- a. Advantages: Lowers the burden for providing staff training, higher compliance levels
- b. Disadvantages: Transportation and incineration costs may be higher, depending on the size and location of your healthcare facility.

Model 2 (hybrid): Pharmaceutical waste generated in the pharmacy department is sorted into hazardous and non-hazardous waste, whereas the nursing unit manages all pharmaceutical waste as hazardous. (See Figures 8.1 (Pharmacy) and 8.2 (Nursing))

- c. Advantages: Easier to train a smaller pharmacy staff on sorting than a large nursing staff; lower disposal costs for pharmaceutical waste generated in the pharmacy, compliance risk for pharmacy unit is relatively low with proper training, low compliance risk and less training required for

nursing unit

- d. Disadvantages: Higher pharmacy training costs; higher disposal costs for pharmaceutical waste generated in the nursing unit depending on the size of your healthcare facility

Model 3: Sort all pharmaceutical waste into hazardous and non-hazardous throughout the facility (See Figure 9)

- f. Advantages: Least expensive disposal costs (least amount of hazardous waste)
- g. Disadvantages: More training costs for both pharmacy and nursing, more compliance cost (e.g., more accumulation containers required), higher compliance risk, more frequent internal audits needed

To generate an accurate cost analysis, obtain actual or estimated costs from current and prospective waste vendors for all pharmaceutical waste services, including hazardous waste, combined hazardous waste and sharps, also known as “dual waste,” and non-hazardous pharmaceutical waste. If on-site services are included with the quotes, you will need to itemize the actual disposal costs to make accurate comparisons.

Hazardous waste pharmaceuticals from the pharmacy typically consist of both potentially creditable and non-creditable hazardous waste pharmaceuticals. The potentially creditable hazardous waste pharmaceuticals have limited management requirements (see [STEP TWO, Number Five](#)) and do not have to be placed in the black bins. Nursing units, however, almost exclusively generate non-creditable hazardous waste pharmaceuticals, which must be placed in the black hazardous waste bins.

Table 10: Additional considerations with regard to compliance

Other questions will apply to all healthcare facilities, regardless of the decision that is made about sorting hazardous waste pharmaceuticals from non-hazardous waste pharmaceuticals

- 1. Are any IV medications being drain-disposed (sewered) either in the nursing units or when returned to the pharmacy?** Under Subpart P, drain disposal (sewering) of any hazardous waste pharmaceutical has been prohibited at all healthcare facilities nation-wide since the Pharmaceuticals Rule went into effect on August 21, 2019. Technically, the sewerage ban only applies to hazardous waste pharmaceuticals, but since it is difficult to train personnel to manage and dispose of IV waste in two different ways, and since drain disposal of non-hazardous drugs is highly discouraged by EPA, it is best not to drain dispose any unused IVs. IV bags should be placed into sealed plastic bags prior to disposal to prevent free liquids from leaking into the pharmaceutical waste containers.

Although EPA discourages the sewerage of all pharmaceuticals there are a few exceptions for drugs like sterile water, 0.9 percent sodium chloride (saline), and Ringer's lactate solution.²⁵

- 2. How is unadministered medication in syringes being disposed?** Syringes may contain a larger dose than that prescribed. The excess medication must be managed in compliance with all applicable regulations. The common practice for nurses has been to squirt excess medication into the red sharps container. Red sharps containers will most likely be autoclaved, however, which can cause the medication to enter the atmosphere and/or sewer system. Excess medication should not be squirted into the red sharps container or down the sink to avoid any compliance risk. Syringes are considered "RCRA empty" when the plunger is fully depressed. Ideally, syringes will be emptied when administering the drug to a patient. However, if a syringe is not emptied by administering its contents, then the unadministered medication may also be emptied onto a carbon sequestration pad before being placed in the appropriate pharmaceutical waste container. Empty syringes with a needle attached should be disposed into a sharps container.

- 3. Are outdated drugs being sorted by the pharmacy staff into potentially creditable or non-creditable hazardous waste pharmaceuticals at the time they outdate?** Previously, outdated drugs were considered to be products until a reverse distributor made the final decision as to their creditability. Under Subpart P, outdated drugs are considered to be a waste at the time they outdate. The pharmacy must therefore make a determination at that time whether or not the drug meets the four criteria of the definition of potentially creditable hazardous waste pharmaceutical (see [STEP TWO, Number Five](#)).

If all four criteria are met, the outdated drug can be placed into the "Returns" box for later shipment to a reverse distributor by pharmacy staff or by the reverse distributor. If the item is a hazardous waste pharmaceutical under Subpart P and does not meet these criteria, it is considered a non-creditable hazardous waste pharmaceutical and must be sorted immediately into a hazardous waste pharmaceutical container. This is a significant change in procedure for most pharmacies.

- 4. How are outdated controlled substances being managed by the pharmacy staff?** There are very few controlled substance drugs that are also RCRA hazardous waste when discarded. Because the management of unwanted controlled substance inventory under both EPA and DEA regulations is complicated, EPA added a conditional exemption from RCRA hazardous waste regulations in subpart P. If managed in accordance with DEA regulations and incinerated, outdated hazardous waste controlled substances are not subject to the RCRA hazardous waste regulations.

Under DEA regulations, any unwanted controlled substance in the pharmacy's inventory must be sent to a reverse distributor using either a Form 222 order form for Schedule II controlled substances, or with an accompanying inventory for Schedule III through V controlled substances. Every pharmacy manager should be familiar with these processes as they are used daily to order controlled substances from drug wholesalers and manufacturers. Managing the controlled substances that are outdated is essentially the reverse of this process where the drug is "ordered" by the reverse distributor. DEA has stated that all unwanted controlled substances in the pharmacy's inventory must be sent to a reverse distributor, who may or may not issue manufacturer credit, based on the circumstances. The exception is when the pharmacy has access to an incinerator or other disposal method approved by DEA, and two employees can witness the destruction and complete a Form 41 Registrant Record of Controlled Substances Destroyed. The reverse distributor will either forward the controlled substance to a second reverse distributor or will transport the controlled substance to an appropriate incinerator, witness the destruction, and complete the Form 41.

²⁵ U.S. EPA, [Frequent Questions about the Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine Final Rule](#). (See FQ Number 1 in the Sewering Ban section of the webpage.)

5. How are controlled substances which are dispensed to a patient (commonly referred to as being “charged out” to the patient) but not fully administered, being managed? DEA refers to drugs that have been dispensed but not fully administered as “pharmaceutical wastage,” and has essentially stated these drugs are out of the DEA closed loop. Their disposal should, however, be documented by two witnesses, and must include the information required by the DEA regulations, must follow all Federal, State, tribal, and local laws and regulations, and must be done in a manner that prevents diversion. A commonly accepted best management practice to prevent diversion is the use of a sequestration device which must then be placed into the appropriate pharmaceutical waste container. See Figures 5 and 6.

As noted above, EPA has conditionally exempted the few controlled substances that are also hazardous waste from hazardous waste regulations. The conditions are that they:

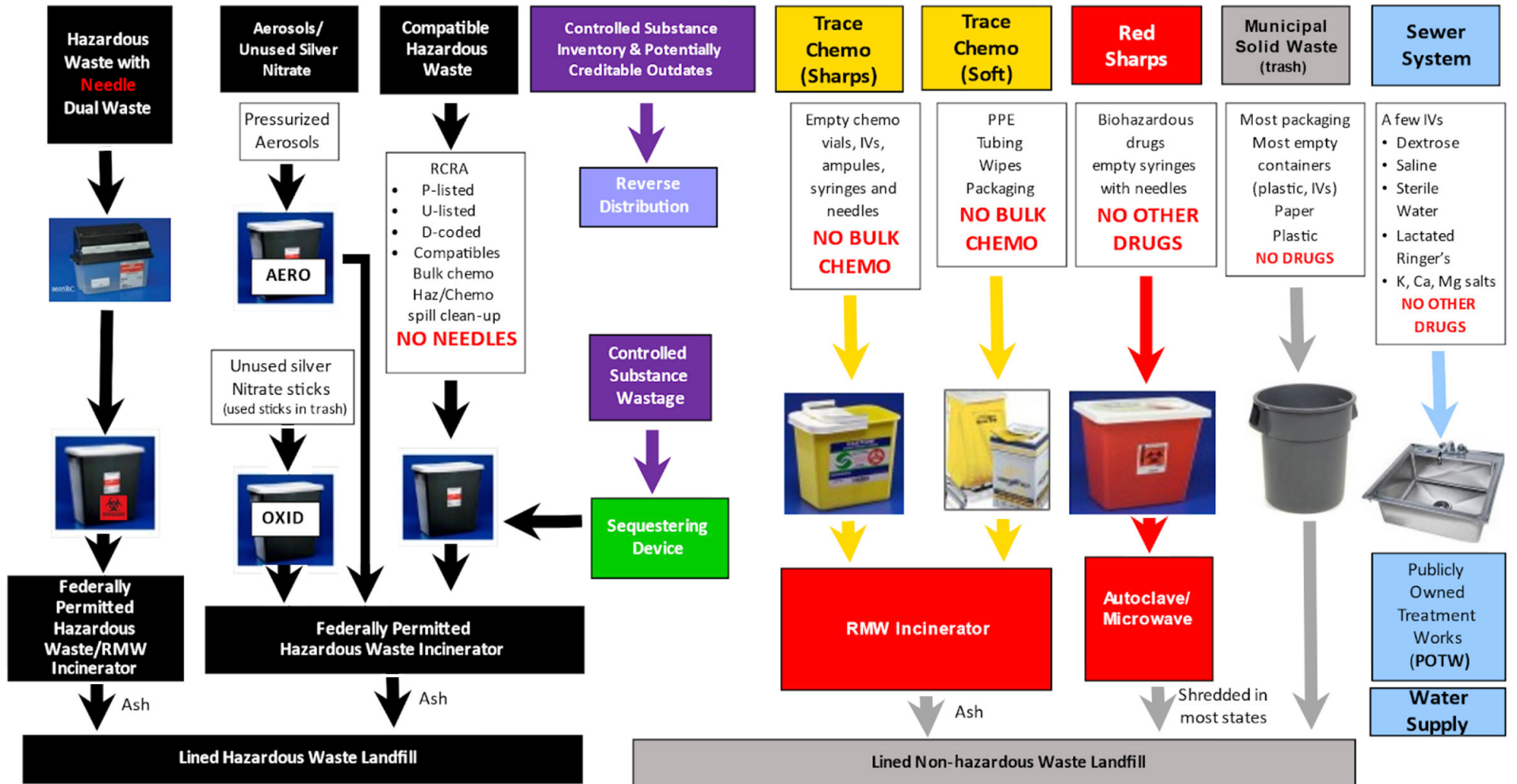
1. Must not be drain disposed
2. Must be managed in compliance with all applicable DEA regulations, and
3. Must be destroyed in a way that DEA has deemed in writing meets their non-retrievable standard, or incinerated at one of the following types of permitted incinerators:
 - large or small municipal waste combustor,
 - hospital, medical and infectious waste incinerator,
 - commercial and industrial solid waste incinerator, or
 - hazardous waste combustor.

At the time of this writing, DEA has not deemed in writing that any disposal method renders controlled substances non-retrievable other than incineration. See Figures 5 and 6 flow charts depicting these scenarios.

For more information on management of controlled substances, see [STEP TWO, Number Seven. Managing Outdated Hazardous Waste Controlled Substances Inventory and Waste.](#)

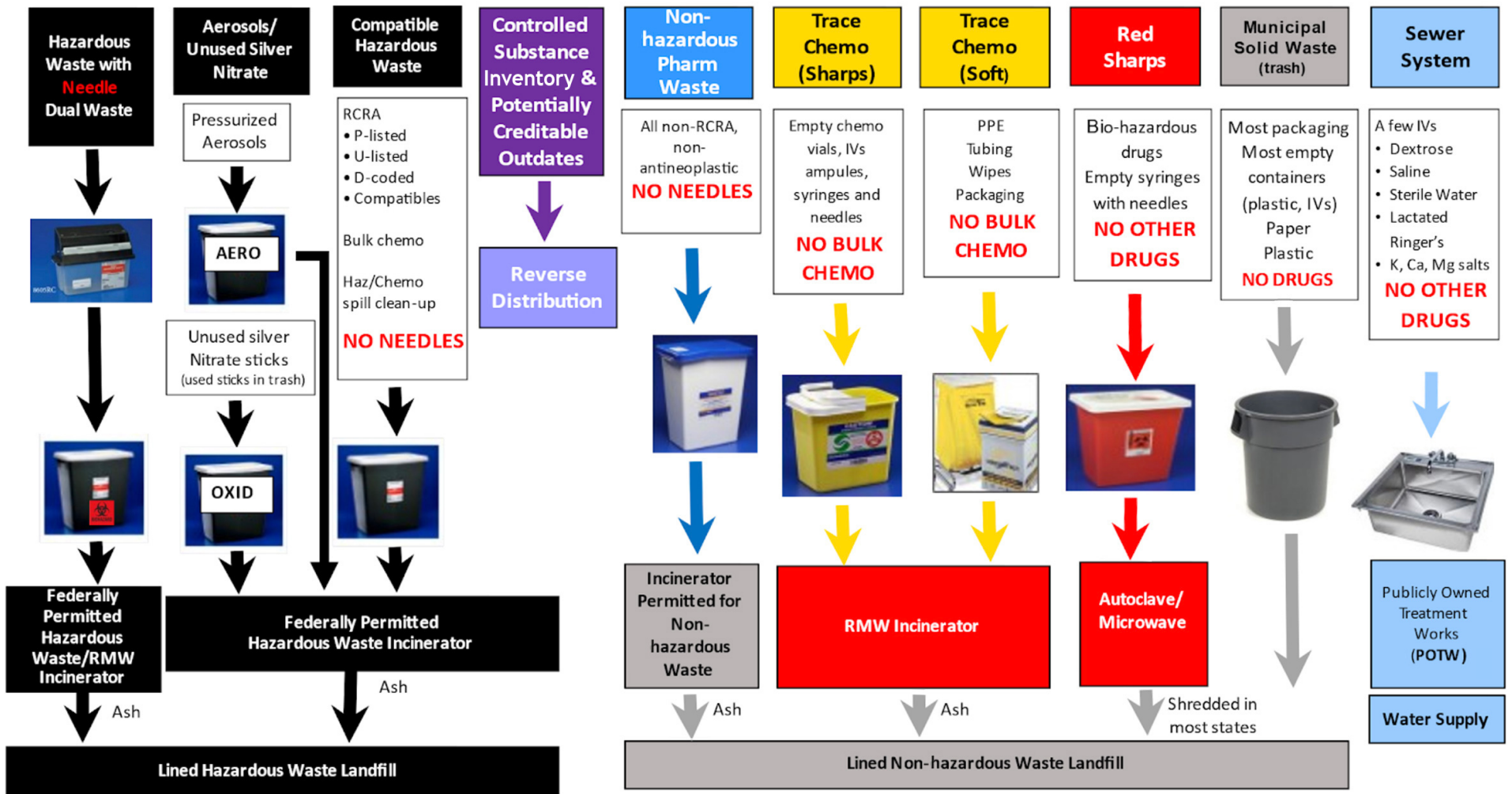
Figures 7–9 illustrate the various sorting models. Note that the waste streams on the left side of the chart are variable based on the chosen sorting model. Following the figures, Table 11 lists and compares additional considerations that should be taken into account when deciding which sorting model is best for your healthcare facility.

Figure 7: Model 1 – All Pharmaceutical Waste in Pharmacy and Nursing Managed as Hazardous Waste



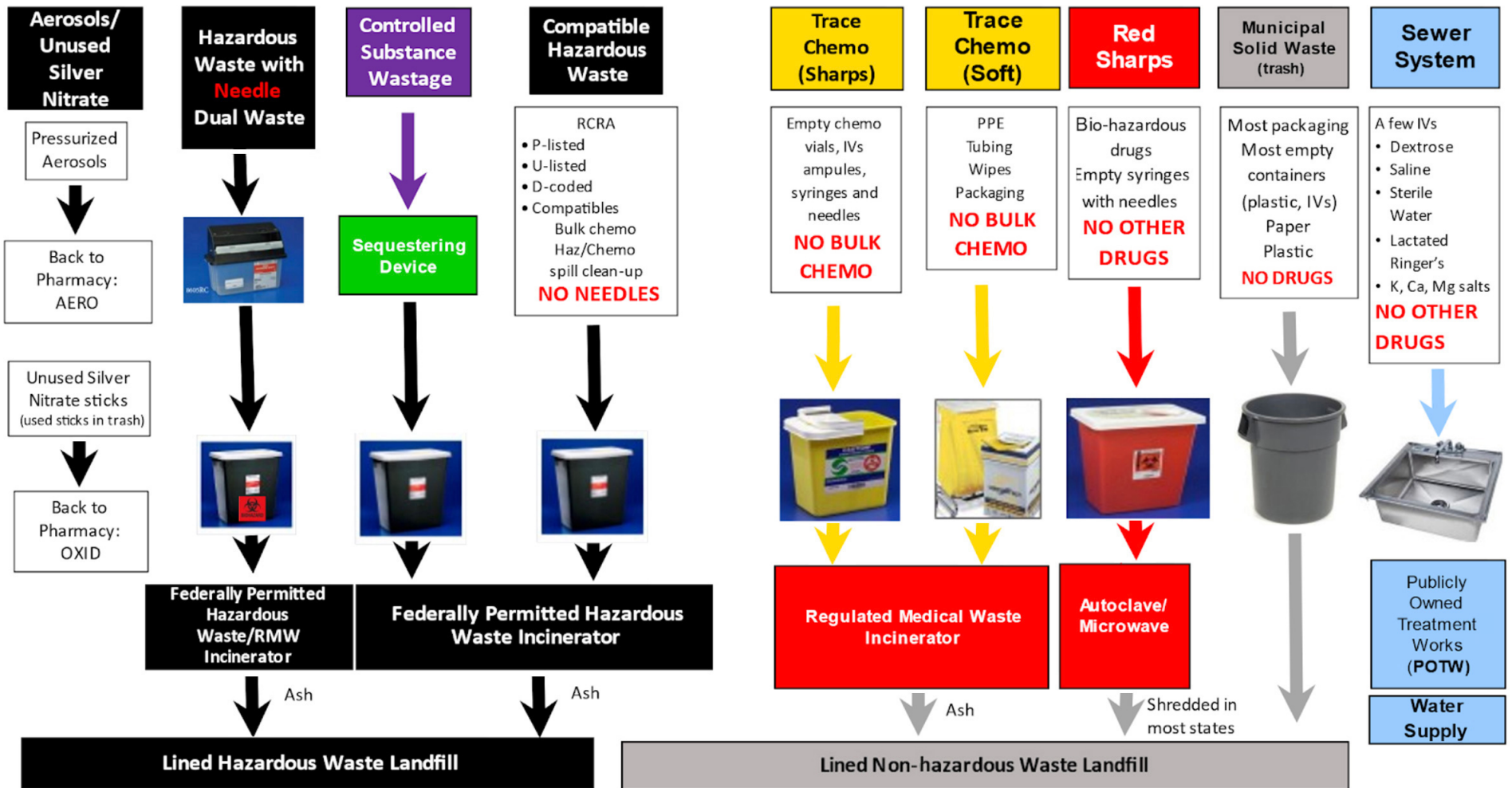
Adapted from ©2022 WM National Services, Inc.

Figure 8.1: Model #2 (in the Pharmacy) – Pharmaceutical Waste Sorted into Hazardous and Non-hazardous



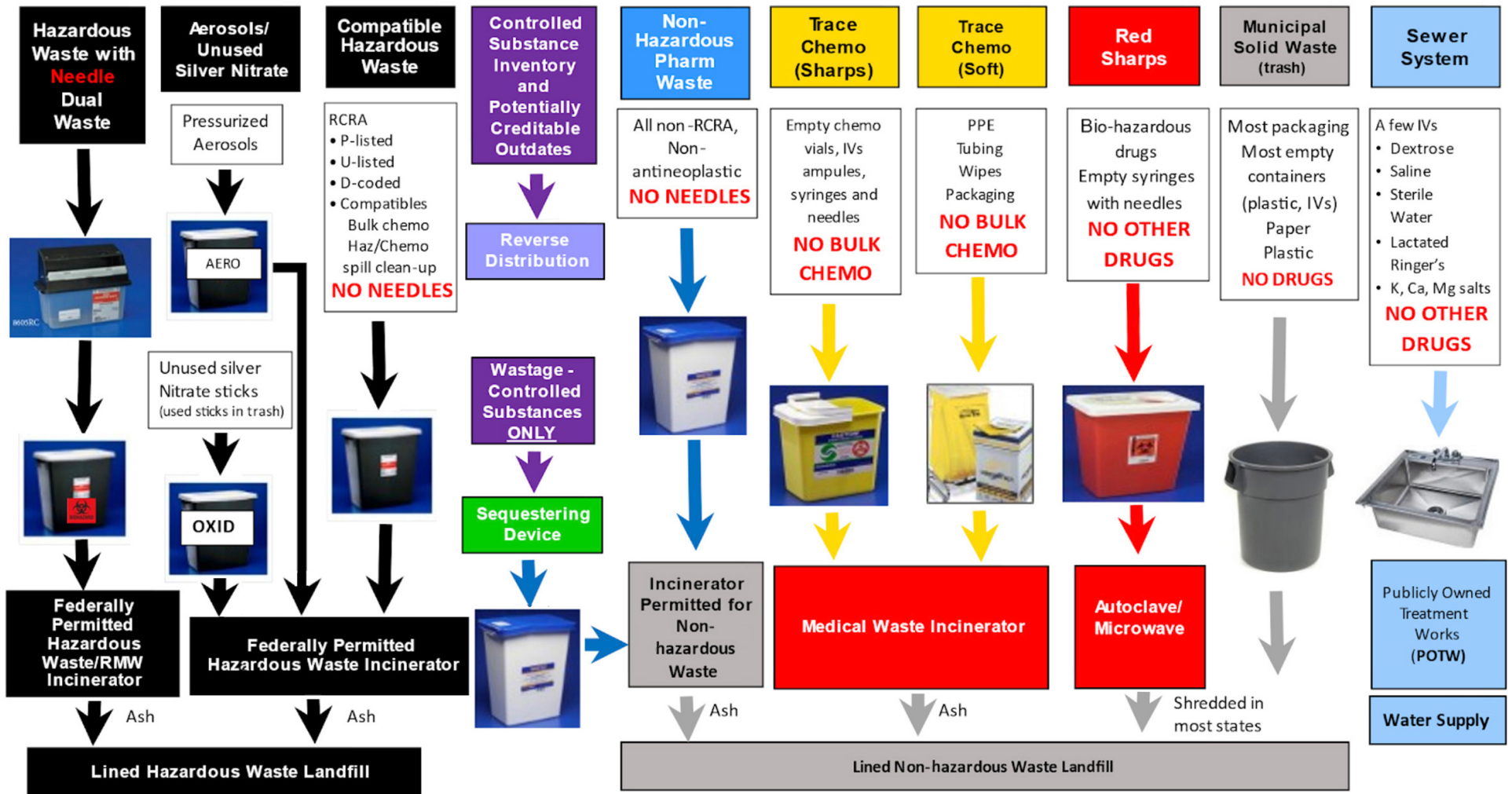
Adapted from ©2022 WM National Services, Inc.

Figure 8.2: Model #2 (in the Nursing Unit) – All Pharmaceutical Waste Managed as Hazardous Waste



Adapted from ©2022 WM National Services, Inc.

Figure 9: Model #3: Full Sorting of Hazardous and Non-hazardous in Pharmacy & Nursing



Adapted from ©2022 WM National Services, Inc.

Table 11: Additional Information to Consider when Choosing a Sorting Model

| Model #1 Pharmacy & Nursing | Model #2 (Hybrid) Pharmacy | Model #2 (Hybrid) Nursing | Model #3 Pharmacy & Nursing |
|--|---|---|---|
| An analysis of the pharmacy's purchasing history, as well as that of other departments that may purchase pharmaceuticals, such as radiology, should identify any other drugs, such as ethyl chloride, that may be incompatible and require segregation | Same | Same | Same |
| Pharmaceutical waste generated in the pharmacy and nursing not sorted; manage as hazardous waste pharmaceuticals | Pharmaceutical waste generated in the pharmacy sorted into hazardous and non-hazardous pharmaceutical waste containers | Pharmaceutical waste generated in the nursing not sorted; manage as hazardous waste pharmaceuticals | Pharmaceutical waste generated in the pharmacy and nursing sorted into hazardous and non-hazardous pharmaceutical waste containers |
| Outdated or unwanted pharmaceuticals in the pharmacy's inventory are sent to a reverse distributor | Same | Not applicable | Outdated or unwanted pharmaceuticals in the pharmacy's inventory are sent to a reverse distributor |
| All other compatible waste pharmaceuticals should be placed into the black containers commonly used for hazardous waste | All other compatible hazardous waste pharmaceuticals should be placed into the black containers commonly used for hazardous waste All compatible non-hazardous pharmaceuticals should be placed into the blue containers commonly used for non-hazardous waste | All other compatible waste pharmaceuticals should be placed into the black containers commonly used for hazardous waste | All other compatible hazardous waste pharmaceuticals should be placed into the black containers commonly used for hazardous waste All compatible non-hazardous pharmaceuticals should be placed into the blue containers commonly used for non-hazardous waste |
| Sequestration devices used by nurses for wasting of DEA controlled substances are managed as hazardous waste | There should be no need for sequestration devices in the pharmacy since DEA defines wastage as occurring after a controlled substance has been dispensed but not fully administered to a patient | Sequestration devices used by nurses for wasting of DEA controlled substances are managed as a hazardous waste | Sequestration devices used by nurses for wasting of DEA controlled substances are managed as non-hazardous pharmaceutical waste, as long as it contains only controlled substance pharmaceutical wastage |
| Arsenic trioxide, which may not be incinerated, must be accumulated and managed separately | Same | Same | Same |
| Due to the DOT HMR, incompatibles (e.g., certain pressurized aerosols, silver nitrate sticks) must be placed in separate containers | Same | Same | Same |
| The right side of the chart indicates the best management practices for trace chemotherapy waste and required medical waste management for sharps and other appropriate waste | Same | Same | Same |
| No drugs (other than IV hydration fluids) should be disposed down the drain | Same | Same | Same |

Various aspects of sorting models #1-3 are compared.

STEP FIVE: Choosing Appropriate Vendors

When choosing appropriate vendors, it's helpful to first delineate all the functions a vendor can provide and then determine which of these are important to your organization, and which vendors are most appropriate for each function. You may choose to use one vendor or multiple vendors to provide all these functions. Potential vendor functions can include:

- Providing information for EPA hazardous waste determination with or without NIOSH hazardous drug categorization,
- Audits and training, including DOT and other non-RCRA training,
- On-site hazardous and non-hazardous waste management,
- Provision of containers, including sharps containers,
- Provision and management of sequestration devices for controlled substances,

- Labeling containers in preparation for transport,
- Preparation of manifests (facility representative still must sign), and
- Transport and disposal of the pharmaceutical waste at an appropriate hazardous or non-hazardous incineration facility.

While some vendors offer more comprehensive services than others, they will often be utilizing the services of subcontractors. Each organization should perform a cost-benefit analysis regarding the advantages and disadvantages of single-source vendors versus managing their own contracts with respect to ancillary products and services. It's important to remember that regardless of which vendor you choose, your facility is still liable for hazardous determinations and for cradle-to-grave management of hazardous waste, therefore it's important to perform due diligence when choosing a vendor.

STEP SIX: Implementing a Pharmaceutical Waste Program in the Pharmacy

Regardless of which sorting model you decide to implement, all hospital pharmacies must start with [STEP ONE: Understanding Which Pharmaceuticals are Regulated as Hazardous Waste Pharmaceuticals When Discarded](#). This will ensure the identification of hazardous waste pharmaceuticals in a manner that is clear and concise for both pharmacists and pharmacy technicians and is readily apparent regardless of what stage of operations is involved. For example, a drug may become a hazardous waste when it outdates. If it is potentially creditable, it can be returned to a reverse distributor, otherwise it must be managed as a non-creditable hazardous waste. Empty containers that held P-listed drugs, such as warfarin, will no longer need to be managed as hazardous waste under Subpart P (see [STEP TWO: Reviewing Standards for Healthcare Facilities Operating Under the Hazardous Waste Pharmaceuticals Rule](#)). Also refer to [STEP TWO, Number Five: Components of Subpart P. Potentially Creditable VS Non-Creditable Hazardous Waste Pharmaceuticals](#) to review the change in the regulations regarding the management of outdated pharmaceuticals.

Just as pharmacy staff need to be aware of how to manage RCRA hazardous waste in the pharmacy, they also need to recognize NIOSH hazardous drugs in the pharmacy and manage them appropriately in all

phases of drug handling, of which waste management is only one part. All hazardous drugs should be labeled as such and assigned appropriate personal protective equipment to be worn by the staff. As noted earlier, some hazardous drugs are also hazardous waste and in these instances the staff need to properly protect themselves during handling but also manage the waste in a manner that is protective of human health and the environment when disposed. Shelf labels and drug package labeling assist in this communication.

When operating under Subpart P, hazardous waste pharmaceuticals no longer need to be counted toward determining generator category, so P-listed acute hazardous waste pharmaceuticals no longer need to be accumulated separately. However, some drug formulations, such as pressurized aerosols, acids, bases, and oxidizers, must be put in separate containers in order to comply with the DOT HMR to prevent dangerous reactions during transportation, and therefore should be specifically labeled to ensure they are placed in separate containers. Some commercially available examples of shelf labels are illustrated in Figure 10. Labels to aid in separating incompatibles may not be commercially available as shelf stickers and may need to be created by the pharmacy staff.

Figure 10: Examples of Shelf Label Prompts for Pharmaceutical Products BEFORE they are Wastes

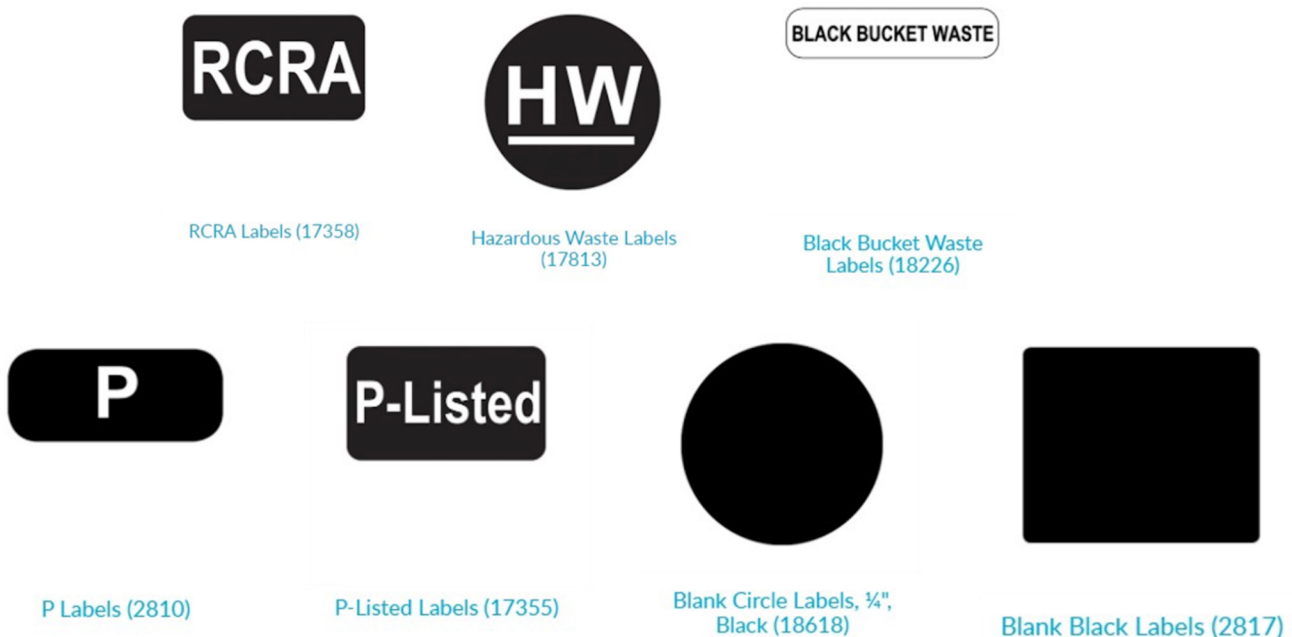


Figure 10: The labels above are examples from Health Care Logistics, Inc.[®] The mention of a vendor's name in this document should not be construed as a recommendation or endorsement.

Hazardous waste flags should also be placed into the dispensing software so that nursing can readily access disposal information in the medication administration record and properly dispose of any unadministered drug. In addition, labeling should direct nursing to return unused or partially used incompatible drugs, such as pressurized aerosols, to the pharmacy for proper segregation and disposal. While not a requirement, this type of messaging is a best management practice to ensure compliance. See examples of software labeling in [STEP SEVEN: Implementing in the Nursing Unit and other Patient Care Areas](#).

STEP SEVEN: Implementing a Pharmaceutical Waste Program in the Nursing Unit and other Patient Care Areas

In addition to the primary focus of nursing staff on patient care, implementing a pharmaceutical waste management program in the nursing unit is challenging for a variety of reasons, including but not limited to:

- Physical layout,
- Staff shortages and turnover,
- The sophistication of the medication administration record or lack thereof,
- Managing disposal in multiple locations,
- DEA drug disposal requirements involving wastage of unused controlled substances,
- Relief from the management of empty containers of P-listed drugs as hazardous waste,
- Direction as to the disposal of empty syringes with needles and other empty containers.

With respect to physical layout, to promote a successful program, it's important to provide appropriate hazardous and, if sorting, non-hazardous pharmaceutical waste containers in locations that are convenient for nurses as they manage their daily routines. Common locations are the medication storage areas, or "med rooms," and restricted entry soiled utility rooms (remember that containers have to be secured in a manner that prevents unauthorized access to their contents). Alternative options are locked carts specifically designed for pharmaceutical waste containers that can be placed in hallways, (see example in Figure 11) and smaller restricted entry containers placed in patient rooms. Placing accumulation containers in carts can be problematic due to the potential confusion between regulated medical waste, including sharps, and pharmaceutical waste, but the carts do provide convenient options where space is limited. Both the carts and containers should be clearly labeled and used for disposal of either hazardous and non-hazardous pharmaceutical waste (if a sorting model is implemented) or only hazardous waste (if not sorting). The carts should NOT be used for medical waste (including sharps) or controlled substance disposal.

²⁶ Refer to [STEP TWO, Number Seven](#): The Components of Subpart P, for a more complete discussion of the exclusion of hazardous waste controlled substances.

²⁷ [21 CFR 1304.22\(c\)](#). Records for dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.

Figure 11: HCL Pharmaceutical Waste Cart Example



Figure 11: Custom cart designed specifically to hold two pharmaceutical waste containers ([Courtesy of Healthcare Logistics, Inc.](#)).

Sequestration Devices

To ensure that DEA controlled substance pharmaceutical wastage is not diverted, many facilities are using "sequestration devices." These sequestration devices are designed to render the drugs "non-divertable," in the sense that they are either adsorbed onto activated carbon or denatured by a chemical digestant. **"Non-divertable" should not be confused with DEA's very strict "non-retrievable" standard of destruction for inventory of controlled substances.** While DEA requires drugs from the pharmacy's inventory to ultimately be destroyed to meet the "non-retrievable" standard, DEA does not require pharmaceutical wastage to meet the non-retrievable destruction standard. EPA's conditional exemption for hazardous waste controlled substances from the hazardous waste regulations requires either incineration or another method that DEA has deemed in writing to meet its "non-retrievable" standard.²⁶ DEA strongly encourages, but does not require, that the disposal of the DEA wastage be observed by two witnesses. Nevertheless, DEA does require documentation that must include the required information,²⁷ including the date,

the name of the patient, the drug and amount wasted. The wastage must be managed in a way that does not allow the drugs to be diverted, and must follow all State, Federal, tribal, and local environmental regulations. Documenting the wastage procedure in the ADC or medication administration record meets the DEA requirement. This is an important concept when discussing DEA controlled substances. For example, if only a partial vial or partial syringe contents are needed for the patient, DEA refers to the remainder of the controlled substance as pharmaceutical wastage. DEA has different requirements for the disposal of inventory vs. disposal of pharmaceutical wastage. The responsibility for disposal of pharmaceutical wastage falls to the nursing staff.

As noted earlier, the contents of these sequestration devices should be managed as either hazardous or non-hazardous pharmaceutical waste, depending on what is put into them. If they are used solely for DEA controlled substances (hazardous and non-hazardous), they may go to a permitted non-hazardous incinerator.²⁸ The devices may not be put in the trash. If a hospital cannot be confident that a sequestration unit will be used solely for controlled substances, then the hospital should take the conservative ap-

proach and manage the sequestration device as a hazardous waste accumulation container and send it to a hazardous waste incinerator.

Messaging to Nursing

One of the most difficult aspects of any pharmaceutical waste program is providing accurate, timely, and convenient messages to nursing at the time and place they are disposing of the medication. While charts and lists can be used to summarize requirements, the most effective method for reinforcing proper disposal is dual documentation in both the patient's medication administration record (MAR) and on the drug label, when possible. A number of creative solutions have been used, including:

- Coding, such as B or black and W or white for black and white container,
- Another example below illustrates F for full container or P for partial container. E refers to empty containers and yellow indicates trace chemotherapy containers,
- Red is indicated for biohazardous waste pharmaceuticals such as albumin.

Figure 12: Example 1 of Coding on the Label or in the eMAR – Antineoplastic Chemotherapy Drug

| | |
|---------------------------------------|----------------------------|
| vinCRISTine | 2 mg |
| sodium chloride 0.9% | 28 mL |
| | Total Volume: 30 mL |
| d11 of Chemo | |
| F/P: Black E: Yellow | |
| Max Dose = 2 mg | |
| High Alert Anti-Neoplastic | |
| Requires chem order form and consent. | |
| For IV use only. | |
| DATE/TIME MADE: _____ | |
| MIXED BY: _____ CHECKED BY: _____ | |

Figure 13: Example 2 of Coding on the Label or in the eMAR – Biohazardous Drug

| | |
|-----------------------------------|-----------------------------|
| NDC 68516-5214-2 | |
| ALBUMIN (HUMAN) U.S.P. | |
| ALBUTEIN® 5% | |
| Solution 25 g 500 mL | |
| 5% | |
| albumin human 5% | 25 g |
| premixed diluent | 500 cc |
| | Total Volume: 500 mL |
| F/P: Red E: Red | |
| Cons = 0.05 g/mL | |
| Do NOT use 0.2 micron filter. | |
| Contains Na+ 145 mEq/L | |
| Route: Intravenous | |
| INFUSE AT: 500 mL / hour | |
| DUE: 07/18/2011 0901 | |
| EXPIRES: 07/19/2011 | |
| DATE/TIME MADE: _____ | |
| MIXED BY: _____ CHECKED BY: _____ | |
| ORD# M001GQHCFX | |
| P1 OF 1 | |

Figures 12 and 13: F/P = Full or Partial E = Empty

²⁸ 40 CFR Subpart P 266.506. Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

STEP EIGHT: Management Responsibilities: Team Management, Policy and Procedure Development, and Process Improvement

One of the least favorite and yet most important activities required of healthcare management personnel is policy and procedure development. Not only does this process document the consensus compliance strategy developed within an organization and provide guidance to personnel to ensure compliance with the myriad of rules and regulations existing within the healthcare environment, it also maintains this common knowledge over time as personnel change positions or are replaced by others. The importance of this process is emphasized by the fact that The Joint Commission, Det Norske Veritas, and other accrediting organizations consider the comparison of actual practice to written policies and procedures to be of utmost importance. The organization should designate one person and an alternate who have access to all relevant policies and procedures, reverse distribution records, and hazardous waste shipments. Ideally, mock environmental audits should be held every six or twelve months and included in the pre-Joint Commission preparation.

Hopefully, every healthcare facility already has basic pharmaceutical waste management policies and procedures in place, as this topic has become more widely addressed in the past twenty years. Regardless, due to the change in the EPA regulations dis-

cussed earlier, it will be necessary for every organization to review their current practices in light of the new rules when they go into effect in their state. Fortunately, Subpart P and the nicotine exemption will provide regulatory relief in a number of areas that have caused consternation in the past, especially around the management of empty P-listed containers and the necessity of documenting monthly amounts of hazardous waste pharmaceutical generation.

To summarize, management responsibilities should include the following:

- Re-address current pharmaceutical waste management practices,
- Conduct walk-throughs to determine the current state of compliance,
- Create a working group involving pharmacy, nursing, environmental services, respiratory therapy, and other related practices to review the existing policies and procedures and modify them accordingly,
- Conduct monthly pharmaceutical waste audits of selected areas, and
- Ensure annual updates to training materials in compliance with the most current policies and procedures.

STEP NINE: Training Programs – Program Re-launch and Online Training

To say that constant training and continuing education are required in the healthcare environment is an understatement. Between changes in technology, new drug development, new procedural methods, and changing regulations, healthcare professionals are constantly being challenged to learn on the job. Fortunately, Subpart P and the OTC nicotine exemption provide learning incentives since they simplify pharmaceutical waste disposal practices. And an adequate training program is the first line of defense in ensuring compliance and protecting human health and the environment.

Once policies and procedures have been reviewed and a model of waste sorting has been determined for your healthcare facility, it will be important to develop separate training programs for pharmacy, nursing, and environmental services. Other departments, such as radiology, surgery, etc., can usually use the nursing training material and apply it to their specific situation. If a total re-launch of the pharmaceutical waste management program is planned, having on-site training dedicated to waste management during shift hours is ideal. Pharmacy managers and nurse educators usually lead these discussions. Given the 24-hour nature of healthcare, there will be employees who are not present during on-site training events, and on-line training will also be needed. In addition, while shift change “huddles” focus primarily on patient care, they can also be used to address any pharmaceutical waste compliance issues that have been observed. Environmental services (EVS) staff are the most likely to notice inappropriate pharmaceutical waste management and should be encouraged to bring these to the attention of the nurse manager and/or their EVS supervisor. The most common violation is often not closing a hazardous waste pharmaceutical container when not in active use. The purchase of foot pedal carts with self-closing lid devices can quickly alleviate this violation.

Training can either be developed in-house, or is also offered by a number of waste vendors and consultants. The Subpart P regulations do not specify the content of hazardous waste pharmaceutical training programs. Instead, the regulations require that all personnel that manage such wastes be thoroughly familiar with the proper waste handling and emergency procedures relevant to their responsibilities during both normal and emergency operations. Therefore, all training should be customized to the organization and the department, typically environmental services, pharmacy, nursing, and other related disciplines such as respiratory therapy, radiology, and surgery. The training should be documented, including the content, date of offering, and names of participants. The training itself should be reviewed and updated periodically to maintain relevance and accuracy in response to changing regulations, business practices, etc. Subpart P does not specify a training interval, but as a best practice, personnel should receive training annually, whenever job responsibilities change, and during new employee orientation.

In addition to training healthcare personnel how to sort and manage pharmaceutical waste, certain other training requirements must be met depending on the generator status of the organization.²⁹ For example, there are no specific training requirements for VSQGs, but SQGs must provide required training for relevant staff as defined in 40 §262.16(b)(9)(iii) and LQGs must provide more complete training as defined in 40 §262.17(a)(7).

Both OSHA³⁰ and DOT³¹ also require training based on the duties assigned to and performed by the employee. Environmental services training may include all three regulations: EPA, OSHA, and DOT. Other departments not involved with the shipping process may only require EPA and OSHA training.

²⁹ U.S. EPA, [Hazardous Waste Regulatory Summary](#).

³⁰ [40 CFR 1910.1200](#).

³¹ [U.S. DOT, Training Modules](#).

STEP TEN: RCRA Generator Category for Facilities Operating under Subpart P

Hospitals operating under Subpart P for the management of hazardous waste pharmaceuticals will also have to comply with other parts of RCRA for the management of the non-pharmaceutical hazardous wastes they generate (e.g., lab chemicals, cleaning supplies, some paints). A hospital will need to determine its RCRA generator category in order to determine which RCRA regulations will apply to those non-pharmaceutical hazardous wastes. Hospitals operating under Subpart P do not need to count their hazardous waste pharmaceuticals when determining their generator category. A hospital operating under Subpart P can be a VSQG, SQG, or LQG for its non-pharmaceutical hazardous waste. A hospital operating under Subpart P that was formerly an LQG or SQG may drop down to a lower generator category with respect to its non-pharmaceutical hazardous waste since it no longer needs to count its hazardous waste pharmaceuticals towards generator status.

The RCRA generator status of the facility will affect what standards will apply to non-pharmaceutical hazardous waste, including certain reporting requirements which must also be completed. For example, if the facility is large enough to generate amounts of non-pharmaceutical hazardous waste to be considered an LQG, Biennial or Annual Reports must continue to be submitted, depending on the state. Hazardous waste pharmaceuticals do not need to be included on the Biennial Report. SQGs of non-pharmaceutical hazardous waste must notify their respective state at least every four years under the Generator Improvements Rule (GIR),³² which is also going into effect around the country. The first re-notification deadline was September 1, 2021, and then subsequent re-notification deadlines are every four

years thereafter i.e., September 1, 2025, September 1, 2029, etc. SQG healthcare facilities should check with their state to determine whether SQG re-notification is in effect in their state.

If a hospital is a VSQG for its non-pharmaceutical hazardous waste, it should continue to document its monthly hazardous waste generation amounts of non-pharmaceuticals to ensure it does not move above VSQG status at any time. This is most likely to occur with respect to laboratory wastes. Often smaller facilities only schedule laboratory waste pickups once a quarter or every six months. If the laboratory personnel do not document the actual monthly hazardous waste generation rate, they can easily exceed the 220 lb. monthly generation limit by the time of the waste pickup. Since this is the only documented value, a regulator may assume all of the laboratory waste was generated in the same calendar month and require the hospital to notify as an SQG, and potentially view the facility as out of compliance.

Often there is not regular communication between the laboratory manager and environmental services manager, and two vendors may be involved, further hampering communications. Typical non-pharmaceutical hazardous waste chemicals that may be generated in the lab include ignitable hazardous wastes such as xylene, methanol, ethyl alcohol, and gram stain. Occasional items such as lead aprons from Radiology that are not recycled also count toward generator status. Non-pharmaceutical items managed under the universal waste regulations³³ do not count towards generator status, including batteries, mercury-containing equipment, lamps, and non-pharmaceutical aerosol cans.

³² [U.S. EPA, Final Rule: Hazardous Waste Generator Improvements.](#)

³³ [U.S. EPA, Overview of the Universal Waste Program.](#)

Summary and In Transition

Summary

While developing and maintaining a compliant hazardous waste pharmaceuticals program can seem daunting, EPA has made a great effort to understand the healthcare industry and to tailor the new regulations as much as possible to reduce the regulatory burden while maintaining appropriate levels of protection. While there are many components to managing pharmaceutical waste in compliance with multiple regulations, the primary goals of every healthcare facility's waste management strategy should be four-fold:

1. No drugs are sewered, to assure compliance and as a best practice,
2. No drugs are disposed in the trash, as a best practice to ensure compliance with waste land-fill restrictions, and to ensure the protection of human health and the environment,
3. No controlled substances are diverted during "wasting,"
4. Only potentially creditable hazardous waste pharmaceuticals are sent through reverse distribution.

By following these four principles, each healthcare facility can do its part to reduce the amount of drug waste contaminating the environment, can enhance employee safety, can help assure its compliance with state and federal regulations, and can satisfy the accreditation organizations' requirements.

Transition

A hospital cannot use the OTC nicotine exemption or Subpart P provisions until they have gone into effect in their state. Therefore, it is important to account for the following considerations during this interim period:

1. The sewerage prohibition is now in effect in all states, Indian country and US territories, and applies to all healthcare facilities regardless of generator category.
2. A healthcare facility should not notify or operate under Subpart P until it is in effect in their state.

3. Once a state adopts the OTC nicotine exemption, these items can be disposed as non-hazardous pharmaceutical waste as a best management practice. In contrast, empty OTC nicotine packaging can be discarded in the trash. OTC nicotine patches, gums, and lozenges should not be included in shipments to non-hazardous waste incineration facilities if the incineration facility is in a state that has not yet adopted the OTC nicotine exemption. Facilities should check with their non-hazardous waste vendors prior to making changes in sorting procedures by nurses to assure acceptance of all exempted items.
4. Empty containers that held P-listed acute hazardous waste are not hazardous waste under Subpart P. Ensure that the state to which the waste is being sent has also adopted Subpart P. If not, the same containers would likely be considered hazardous waste in the destination state.
 - a. Under Subpart P, empty arsenic trioxide containers are not hazardous waste and can be managed as trace chemotherapy.
 - b. Under Subpart P, empty warfarin containers are not hazardous waste and can be placed in the trash.
5. Hazardous waste controlled substances are not exempted from RCRA until the state adopts Subpart P. At that time, to maintain the RCRA exemption, any discarded hazardous waste controlled substances, including within sequestering devices, must be incinerated at either a hazardous or non-hazardous waste facility (this includes large and small municipal waste combustors (MWCs); hospital, medical, and infectious waste incinerators (HMIWIs); and commercial industrial solid waste incinerators (CISWIs)). The non-hazardous waste incinerator must also be in a state that has adopted Subpart P. Check with all treatment and disposal vendors prior to shipment to ensure compliance.
6. Hazardous waste manifests must include all hazardous waste codes if the generating or receiving state has not yet adopted Subpart P. If the healthcare facility is in a state where Subpart P is in effect, the code "PHRM" or "PHARMS" must be entered in item 13 on the manifest.³⁴ Therefore, the manifest for shipments of non-creditable hazardous waste pharmaceuticals will require

³⁴ U.S. EPA, [Memo RCRA Online #14919](#).

both the PHARMS or PHRM code AND all other applicable hazardous waste codes when either the destination or origin state has not yet adopted Subpart P.

7. Reverse distributors in states where Subpart P is not in effect do not need to notify EPA and the hospital if inappropriate items are sent. As a best practice, the reverse distributor should discourage the shipment of non-potentially creditable items.
8. If the healthcare facility is in a state where Subpart P is in effect, it is prohibited from sending non-creditable hazardous waste pharmaceuticals to a reverse distributor regardless of whether the reverse distributor's state has adopted Subpart P.
9. When your state does adopt these rules, take advantage of any training or outreach they might conduct. Request the state regulators add you to any mailing/outreach list. Express your interest in getting compliance assistance support from them.

Appendix A. Links to Code of Federal Regulations (40 CFR) for Subpart P

[266.500 – Definitions](#)

[266.501 – Applicability](#)

[266.502 – Standards – Non-creditable](#)

[266.503 – Standards – Potentially creditable](#)

[266.504 – VSQG's](#)

[266.505 – Sewering ban](#)

[266.506 – DEA/HWP exemption](#)

[266.507 – Empty container exemption](#)

[266.508 – Shipping – Non-creditable](#)

[266.509 – Shipping – Potentially creditable](#)

[266.510 – Standards – Reverse distributors](#)

Appendix B. Common Acronyms

The following terms and acronyms are used throughout this document:

ADC: Automated Dispensing Cabinet

CSTD: Closed System Transfer Device

CISWI: Commercial and Industrial Solid Waste Incinerator

DEA: Drug Enforcement Administration

DNV: Det Norske Veritas

DOT: Department of Transportation

EPA: Environmental Protection Agency

EVS: Environmental Services

FDA: Food and Drug Administration

GIR: Generator Improvements Rule

HMIWI: Hospital, Medical, and Infectious Waste Incinerator

HMR: Hazardous Materials Regulations

HSWA: Hazardous and Solid Waste Amendments

HWP: Hazardous Waste Pharmaceutical

IARC: International Agency for Research on Cancer

LDR: Land Disposal Restrictions

LQG: Large Quantity Generator

MAR: Medication Administration Record

MSHG: Manufacturer's Safe-Handling Guidance

MSHI: Manufacturer's Safe-Handling Instructions

MWC: Municipal Waste Combustor

NDC: National Drug Code

NIOSH: National Institute for Occupational Safety and Health

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration

OTC: Over-the-Counter

RCRA: Resource Conservation and Recovery Act

SQG: Small Quantity Generator

TC: Toxicity Characteristic

TCLP: Toxicity Characteristic Leaching Procedure

TJC: The Joint Commission

TSDF: Treatment, Storage, and Disposal Facility

USP: United States Pharmacopeia

VSQG: Very Small Quantity Generator

Appendix C: Quick Start Guide

Management of Hazardous Waste Pharmaceuticals OTC Nicotine Exemption & Subpart P

This Quick Start Guide contains a short overview of the EPA regulations governing the management of hazardous waste pharmaceuticals at healthcare facilities. In 2019, EPA finalized the rule, Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine. It is a tailored set of regulations that apply specifically to the healthcare industry, and it addresses the unique challenges faced by healthcare facilities in complying with RCRA hazardous waste regulations. It is important to note that your state must adopt Subpart P and the OTC nicotine replacement therapy exemption before either can be used by your healthcare facility. For state adoption status of these rules, check with your state environmental agency or use this [EPA State Adoption Map](#). Also, be aware that states may have regulations that are more stringent than the federal regulations discussed in this document.

Exemption for OTC Nicotine Patches, Gums, and Lozenges

- OTC nicotine replacement therapies (i.e., lozenges, gums, and patches) and their wrappers are no longer hazardous waste and can be disposed as non-hazardous pharmaceutical waste or in the trash. This is a separate rule and applies whether or not you are subject to Subpart P. Unlike Subpart P, there is no need to notify your state if you are using the OTC NRT exemption but it can only be used once your authorized state has adopted this rule.

Subpart P

Sewer Ban:

- The sewer ban is in effect in all states, territories, and in Indian country. Regardless of your state's adoption status of Subpart P, as of August 21, 2019, NO hazardous waste pharmaceuticals can be disposed of down the drain at any healthcare facility in any state or territory or in Indian country.

Applicability

- All healthcare facilities must operate under Subpart P, except very small quantity generators (VSGQs).
- If you are a VSQG when counting all your hazardous waste, including hazardous waste pharma-

ceuticals, your healthcare facility is not required to operate under Subpart P. However, EPA encourages VSQG healthcare facilities to opt into Subpart P. That way, you can take advantage of all of the benefits of the rule while managing your pharmaceutical waste in a more environmentally protective manner. For example, if your healthcare facility is operating under Subpart P, then you no longer need to count the amount of hazardous waste pharmaceuticals generated or make individual hazardous waste determinations for each pharmaceutical waste. If you, as a VSQG, opt into subpart P, you must comply with all parts, including notifying your state. For Alaska, Iowa, and most territories, notify your EPA region.

- If a healthcare facility is managing hazardous waste pharmaceuticals under Subpart P, the hazardous waste pharmaceuticals will no longer count towards generator category going forward, but must be accounted for initially when determining whether you must operate under Subpart P. Based on the amounts of non-pharmaceutical hazardous waste generated, a healthcare facility may be able to reduce its generator category. Therefore, you must first determine whether you must operate under Subpart P based on total hazardous waste generated, including hazardous waste pharmaceuticals. Then, once you are operating under Subpart P, subtract the volume of hazardous waste pharmaceuticals to determine your new hazardous waste generator status for managing non-pharmaceutical hazardous waste.
- After Subpart P has been adopted by a state, the regulations are in effect regardless of notification by the healthcare facility. Your state environmental regulatory authority will indicate the exact date of when it goes into effect.

Notifying Under Subpart P

- If your healthcare facility is a small quantity generator (SQG) or a large quantity generator (LQG) of hazardous waste, including hazardous waste pharmaceuticals, you must notify the state by submitting Form 8700-12, the Site Identification Form, or corresponding state form. Some states also allow electronic notification via [myRCRAid](#). SQGs must notify within 60 days of adoption by their state but LQGs may notify with their Annual or Biennial Report, instead. For Alaska, Iowa, and most territories, notify your EPA region.
- The notification requirement applies even if the healthcare facility has already notified previously

and has an EPA ID number. If the healthcare facility does not have an ID number, it will be assigned one by EPA upon notification.

Hazardous Waste Determination

- If a healthcare facility is managing hazardous waste pharmaceuticals under Subpart P, the organization does not need to perform a hazardous waste determination on each drug if all pharmaceutical waste, including non-hazardous pharmaceutical waste, is being managed as hazardous waste pharmaceuticals. However, incompatible hazardous waste pharmaceuticals, such as aerosols and oxidizers, must still be accumulated and managed separately, as must a drug that is prohibited from being incinerated, such as discarded arsenic trioxide.

Controlled Substances

- Hazardous waste controlled substances are exempted from hazardous waste regulation IF they are incinerated at one of five types of permitted incinerators listed in 40 CFR §266.506(b)(3). In addition, if in the future, DEA deems in writing that another method of destruction meets the non-retrievable standard, then that method may be used to destroy the hazardous waste controlled substances under this exemption. As of the date of this publication, DEA has not identified any additional methods of destruction that meet their non-retrievable standard.

Empty Container Standards

- Containers that once held pharmaceutical waste are considered RCRA empty, and are therefore, not regulated as hazardous waste if emptied by commonly employed practices. This applies to containers of up to 10,000 pills, and bottles/vials up to 1 liter.
- Empty warfarin containers, including stock bottles up to 10,000 pills and unit dose containers, are no longer P-listed hazardous waste and can be disposed in the trash.
- Empty arsenic trioxide vials and empty IV bags can be discarded as trace chemotherapy waste instead of hazardous waste.
- Arsenic trioxide waste itself must be accumulated and packaged separately and labeled as such by your hazardous waste vendor.
- Triple rinsing of containers that held P-listed hazardous waste pharmaceuticals is no longer allowed.

Outdated/Expired Hazardous Waste Pharmaceuticals

- Expired hazardous waste pharmaceuticals become a waste the day of expiration, or sooner, if a decision has been made to discard them. If they are in the original manufacturer's packaging, have not been dispensed to a patient, are within one year of expiration, and have a reasonable expectation of receiving manufacturer credit, they are considered to be "potentially creditable" and can be accumulated in your returns area and sent to a reverse distributor. If they do not meet these criteria, they must be placed into a hazardous waste pharmaceutical container immediately and managed as non-creditable hazardous waste pharmaceuticals.

Appendix D

How to Evaluate the Toxicity Characteristic Using Total Constituent Analysis in lieu of the TCLP Case Study: Thimerosal

If it is not practical to perform an actual TCLP on the waste pharmaceutical to determine if it designates as a hazardous waste under the toxicity characteristic, a total constituent analysis can be performed, as described below.

Thimerosal Molecular Weight: 404.81
 Thimerosal Molecular Formula: $C_9H_9HgNaO_2S$
<https://www.rsc.org/Merck-Index/searchresults?searchterm=thimerosal>

| Element | Abbreviation | % by Weight |
|----------|--------------|-------------|
| Carbon | C | 26.70% |
| Hydrogen | H | 2.24% |
| Mercury | Hg | 49.55% |
| Sodium | Na | 5.68% |
| Oxygen | O | 7.90% |
| Sulfur | S | 7.92% |

The RCRA toxicity characteristic regulatory limit for mercury is³⁵

$$\frac{0.2 \text{ mg}}{1 \text{ liter}}$$

Below are two examples of concentrations of the preservative thimerosal that are commonly used in drug formulations:

Example 1: Thimerosal may be used as a preservative in a concentration of **1:1000**, which means, by definition, 1 gram of thimerosal in 1000ml of solution.

Since thimerosal is 49.55% mercury (see above):
 1g thimerosal x 49.55% = 0.4955g mercury.

So:

$$\frac{1 \text{ g thimerosal}}{1000 \text{ ml}} = \frac{0.4955 \text{ g Hg}}{1000 \text{ ml}} = \frac{495.4 \text{ mg Hg}}{1000 \text{ ml}} = \frac{495.5 \text{ mg Hg}}{1 \text{ liter}}$$

Example 2: Thimerosal may also be used as a preservative in a concentration of 1:10,000, which means, by definition, 1 gram of thimerosal in 10,000ml of solution.

$$\frac{1.0 \text{ g}}{10,000 \text{ ml}} = \frac{0.1 \text{ g}}{1000 \text{ ml}}$$

Since thimerosal is 49.55% mercury (see above):
 0.1g thimerosal x 49.55% = 0.04955g mercury.

So:

$$\frac{0.1 \text{ g thimerosal}}{1000 \text{ ml}} = \frac{0.04955 \text{ g Hg}}{1000 \text{ ml}} = \frac{49.55 \text{ mg Hg}}{1000 \text{ ml}} = \frac{49.55 \text{ mg Hg}}{1 \text{ liter}}$$

Therefore, in both examples, products containing thimerosal as a preservative exceed the regulatory limit for mercury and exhibit the toxicity characteristic of a RCRA hazardous waste (D009).

³⁵ 40 CFR 261.24.

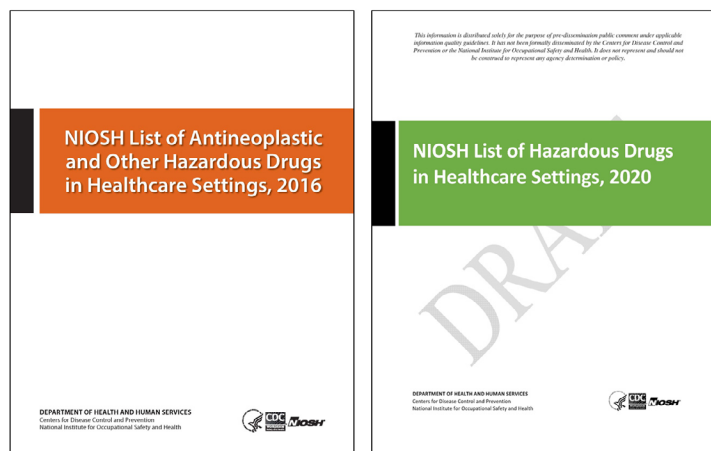
Appendix E: NIOSH Hazardous Drug List

The National Institute for Occupational Safety and Health (NIOSH) resides within the Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) and is responsible for research and recommendations to prevent occupational injury and illness. In 2004, a NIOSH Hazardous Drug Working Group began the process of identifying those drugs that are considered hazardous to employees due to prolonged occupational exposure when it published the first list of "Drugs Considered Hazardous."³⁶ Periodically, NIOSH publishes updates to the list of hazardous drugs as new drugs enter the marketplace. NIOSH last updated its list of hazardous drugs in 2016.³⁷ In 2020, NIOSH released a draft update to the list of hazardous drugs; however, this has not been finalized as of the date of this publication.³⁸

The purpose of this Appendix is to:

- Discuss the major differences between the 2016 and draft 2020 NIOSH hazardous drug lists,
- Differentiate between RCRA hazardous waste and NIOSH hazardous drugs, and
- Identify those NIOSH hazardous drugs that should be managed as RCRA hazardous waste as a best practice.

After NIOSH finalizes its 2020 draft update, we will update this Appendix, if necessary. In the meantime, the content of Appendix E is based on NIOSH's 2020 draft update.



The NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

This 2016 NIOSH document divided drugs that may be considered hazardous to employee health into three tables. It should be stated that it is NIOSH's position that placement on a particular table does not indicate a greater or lesser danger with respect to employee safety. However, in practice, the antineoplastics have always ranked at the top of the list in terms of reduction of employee exposure. The same might be said for environmental concerns, although the reproductive toxins have certainly garnered greater attention in recent years based on a better understanding of the risks of hormone altering substances in aquatic systems. And while NIOSH does not indicate different risk levels among the tables, pharmacists and nurses have always considered Table 1 drugs to be the most hazardous to employee health. In the 2016 list, NIOSH defines hazardous drugs in Table 1 as follows:

"The drugs in Table 1 meet one or more of the NIOSH criteria for a hazardous drug. In addition to many of these drugs being cytotoxic, the majority are hazardous to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breastfeeding, because they may be present in breast milk."³⁹

Table 1 contains only **antineoplastic drugs**, including those with manufacturer's special handling guidance (MSHG). As a result, most healthcare facilities routinely manage any wastage of NIOSH hazardous drugs in Table 1 as RCRA hazardous waste pharmaceuticals, out of an abundance of caution and as a best management practice. Many of the older RCRA P- and U-listed drugs are on Table 1, including arsenic trioxide, chlorambucil, cyclophosphamide, daunorubicin, melphalan, mitomycin, and streptozocin (a.k.a. streptozotocin). In addition, one hazardous drug in Table 1 has a formulation that contains mercury (D009) and nine have formulations that meet the RCRA ignitability characteristic (D001).

Table 2 contains **non-antineoplastic drugs** that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's special handling guidance (MSHG). There are no RCRA

³⁶ NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings (see Appendix A).

³⁷ NIOSH, List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016.

³⁸ NIOSH List of Hazardous Drugs in Healthcare Settings (Draft), 2020.

³⁹ NIOSH, List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016 (page 9).

P- or U-listed hazardous wastes in Table 2. There are, however, three drugs that have formulations that meet the RCRA ignitability characteristic (D001).

Table 3 contains drugs that meet the NIOSH criteria for **reproductive hazards**, including to men and women who are actively trying to conceive, women who are pregnant, or women who are breastfeeding. The only RCRA listed hazardous waste in Table 3 is warfarin (P001). There are also five drug entities that have formulations that meet the RCRA ignitability characteristic (D001).

From the perspective of best management practices, it has been relatively easy for healthcare facilities to simply manage all the antineoplastic hazardous drugs listed in Table 1 as RCRA hazardous waste and to manage any empty vials, syringes, and personal protective equipment as trace chemotherapy waste.

Draft NIOSH List of Hazardous Drugs in Healthcare Settings, 2020

The draft 2020 NIOSH list of hazardous drugs proposes to add 16 drugs to the list and remove five. Having said that, it is important to note that the draft 2020 list only reviews drugs that had been introduced to the market up through December of 2015. In fact, there are ten additional drugs noted on the NIOSH website that have been approved since 2015 and recommended for addition.⁴⁰ Even more challenging is the change from three tables in the 2016 list to two tables in the draft 2020 list.

“Table 1 now includes drugs that meet the NIOSH definition of a hazardous drug and contain MSHI in the package insert and/or are classified by the NTP as “known to be a human carcinogen” or classified by IARC as “carcinogenic” or “probably carcinogenic.” In the 2016 List this table identified antineoplastic drugs, however, in this update not all of the drugs on Table 1 are antineoplastic drugs.”⁴¹

To clarify,

- MSHI refers to manufacturer’s special handling information and implies an increased risk to the healthcare worker,
- NTP refers to the National Toxicology Program⁴²

and their 15th Report on Carcinogens⁴³ which lists chemicals known to be human carcinogens,

- IARC is the International Association for Research on Cancer,⁴⁴ part of the World Health Organization, and their list divides substances into four groupings:⁴⁵

- Group 1, Carcinogenic to humans
- Group 2A, Probably carcinogenic to humans
- Group 2B, Possibly carcinogenic to humans, and
- Group 3, Not classifiable as to its carcinogenicity to humans, and not relevant to the NIOSH list.

Not all chemotherapy drugs prescribed to treat oncological conditions are antineoplastic agents or RCRA hazardous waste. In fact, only seven drugs in Table 1 of the 2020 draft update are listed as RCRA hazardous wastes.⁴⁶

1. Arsenic trioxide (P012),
2. Chlorambucil (U035),
3. Cyclophosphamide (U058),
4. Daunorubicin (aka daunomycin) (U059),
5. Melphalan (U150),
6. Mitomycin C (U010), and
7. Streptozotocin (U206).

Table 1 of the 2020 draft update also includes ten formulations of antineoplastic drugs that meet the ignitability characteristic, and one hazardous drug (trifluridine ophthalmic) that has a formulation that contains mercury (D009). Melphalan flufenamide has also been added to the 2020 draft update but as a salt of melphalan, it is not considered a RCRA listed waste.

“Table 2 contains drugs that meet one or more of the NIOSH definitions of a hazardous drug but are not drugs which have MSHI or are classified by the NTP as “known to be a human carcinogen,” or classified by the IARC as “carcinogenic” or “probably carcinogenic,” some of which also have adverse reproductive effects for populations at risk. This table now also includes drugs that only meet the NIOSH criteria as a developmental (including teratogenicity) and/or reproductive hazard. In the 2016 update of the List this table did not include drugs that only posed a developmental and/or reproductive hazard.”⁴⁷

⁴⁰ [NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016](#)

⁴¹ [NIOSH, List of Hazardous Drugs in Healthcare Settings \(Draft\), 2020](#) (p 10).

⁴² [U.S. Department of Health and Human Services, National Toxicology Program.](#)

⁴³ [U.S. Department of Health and Human Services, 15th Report on Carcinogens, December 21, 2021.](#)

⁴⁴ [World Health Organization, International Agency for Research on Cancer.](#)

⁴⁵ [World Health Organization, International Agency for Research on Cancer. Agents Classified by the IARC Monographs.](#)

⁴⁶ Uracil mustard (U237) is listed but is not in clinical use.

⁴⁷ [NIOSH, List of Hazardous Drugs in Healthcare Settings \(Draft\), 2020](#) (p 10).

There is one new NIOSH hazardous drug in Table 2 that is also a RCRA hazardous waste: exenatide in a formulation containing m-cresol (D024).

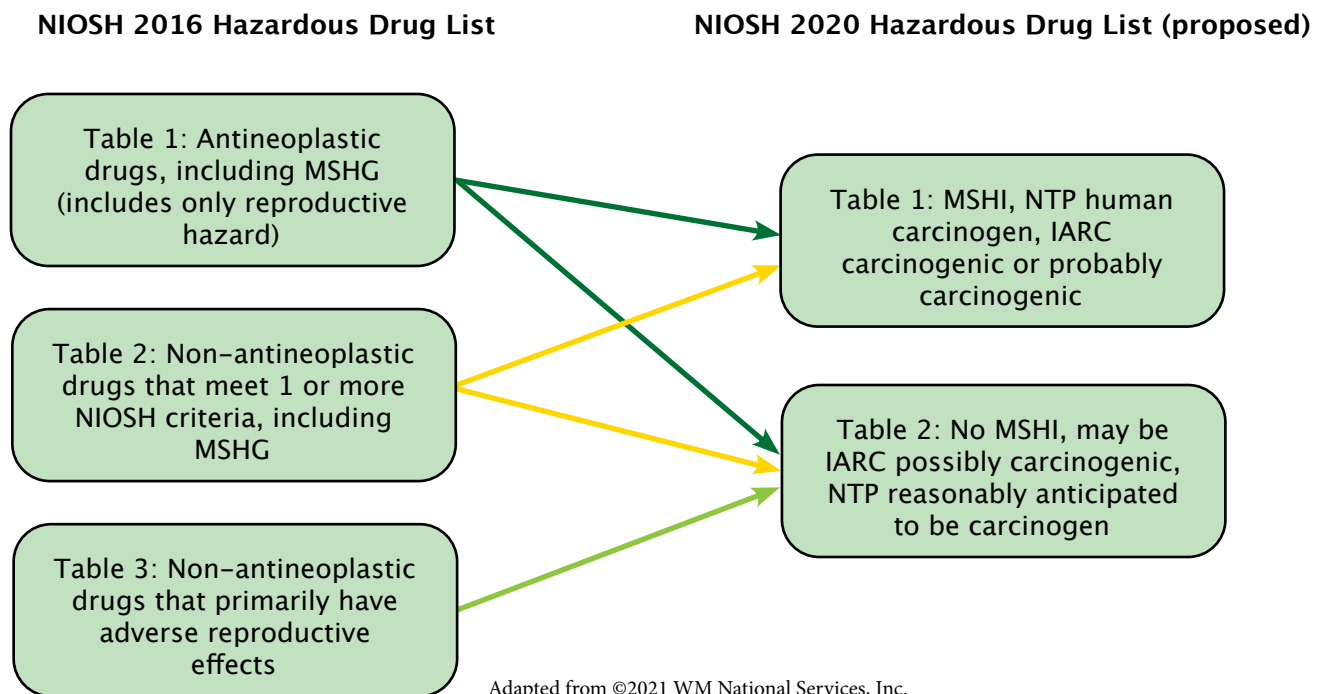
RCRA Best Management Practices for NIOSH Hazardous Drugs, 2016 vs 2020

The healthcare sector has generally stepped up and managed all antineoplastic drugs on Table 1 of the 2016 NIOSH hazardous drug list as RCRA hazardous waste. Items trace contaminated with these drugs, including gloves, gowns, wipes, empty vials, empty IV bags, and empty closed system transfer devices (CSTDs), are managed as trace chemotherapy waste, and incinerated at medical waste incineration facilities or hazardous waste facilities permitted to accept regulated medical waste. While only a few states require this level of management (including California and Wisconsin), healthcare providers recognize the danger posed by these drugs when people other than patients are exposed to them, and this extra care in disposal is recommended and has been widely implemented.

You can see from the diagram below, however, with the draft 2020 update, there is no longer a clear delineation in terms of using one or more tables to determine which discarded NIOSH hazardous drugs should be managed as a RCRA hazardous waste. It was never the intent of the NIOSH tables to provide this delineation, but the 2016 tables did provide a rather convenient demarcation, which is no longer the case in the draft 2020 version.

The simple answer to this conundrum is to manage all NIOSH hazardous drug waste as RCRA hazardous waste pharmaceuticals. Financial considerations must be examined when making that decision. At a minimum, a best practice would be to manage all the antineoplastics from Table 1 of the draft 2020 list as RCRA hazardous waste. Similarly, the best practice would be to manage any empty vials, syringes, and personal protective equipment that have become contaminated with antineoplastics as trace chemotherapy waste.

NIOSH Hazardous Drug List Summary of Changes



MSHG = Manufacturer’s Safe-Handling Guidance
 MSHI = Manufacturer’s Safe-Handling Instructions
 NTP = National Toxicology Program
 IARC = International Agency for Research on Cancer

Appendix F: Step-by-Step Guide to Notifying under Subpart P

The Q&As and recommendations included below are intended for use by healthcare facilities whose primary function is patient care, including hospitals and urgent care facilities. Other types of RCRA hazardous waste generators (e.g., pharmaceutical manufacturers, oil refineries) that have on-site facilities that meet the definition of healthcare facility are also subject to Subpart P for the management of their hazardous waste pharmaceuticals, but there may be some notable differences in how the 8700-12 Site Identification Form should be completed.

Be aware that some states require the use of their own notification form which should be used in lieu of the 8700-12 Site Identification Form. Although state-specific forms are equivalent to the federal form, the instructions below may not be applicable. The instructions below are for notification using the federal 8700-12 Site Identification Form.

1. Why do some healthcare facilities need to notify to report their hazardous waste pharmaceutical activities?

The notification requirement for healthcare facilities was finalized by the [2019 final rule](#), “Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine.”

2. Who must notify under Subpart P?

Any healthcare facility operating under Subpart P must notify, even if it previously received a RCRA ID number.

Healthcare facilities that are very small quantity generators (VSQGs) of hazardous waste are not federally required to operate under Subpart P but may opt in, in which case, they must notify. All other healthcare facilities that generate hazardous waste pharmaceuticals (i.e., SQGs and LQGs) must operate under Subpart P and notify their state or EPA Region.

3. Whom do I notify?

If the healthcare facility is in Iowa, Alaska, Indian country, or U.S. territories (other than Guam), then it must notify the EPA Regional Office. In all other cases, the healthcare facility must notify the [state environmental agency](#).

4. When do I have to notify under subpart P?

If the healthcare facility is required to submit a Biennial Report (or state annual report), it can notify as part of that report. Otherwise, the healthcare facility must notify within 60 days of Subpart P becoming effective in that state, or within 60 days of becoming subject to subpart P (e.g., moving up in generator category from VSQG to SQG).

5. How do I notify under subpart P?

A healthcare facility can notify by submitting the EPA Site Identification Form ([Form 8700-12](#)) or equivalent state notification form to your authorized state or EPA Region.

Some states also allow users to notify electronically via the myRCRAid online tool of U.S. EPA’s RCRAInfo hazardous waste data system. To notify using myRCRAid, you must first [register as an industry user](#) with RCRAInfo. After you have access, you must complete and submit the required information and indicate that you are operating under Subpart P. EPA encourages healthcare facilities to notify electronically wherever possible. Please check with your state environmental agency to see if the electronic myRCRAid tool is available to you. If you are located in Iowa, Alaska, Indian country, or a U.S. Territory, EPA encourages you to use myRCRAid. The instructions for this form are available at: <https://www.epa.gov/hwgenerators/instructions-and-form-hazardous-waste-generators-transporters-and-treatment-storage-and>.

6. How do I determine if my healthcare facility has an EPA Identification Number?

If your healthcare facility has an existing EPA Identification Number you will be able to look it up on RCRAInfo Web’s Search by Site page: <https://rcrapublic.epa.gov/rcrainfoweb/action/modules/hd/handlerindex>. One simple way to find your facility is to enter your zip code and browse the results. If your facility has an EPA Identification Number, it will be listed. If you do not see your healthcare facility, it is likely you do not have an EPA Identification Number and you will be assigned one as part of the notification process. This will inform how you complete Items No. 1 and 2 of Form 8700-12.

Note that none of the fields on the Search by Site page are required, so you can enter as much or as little information as you like. Keep in mind, however, that the more information you enter, the more you risk not retrieving the correct results (e.g., typos or information that does not match what is in RCRAInfo will not return results).

7. How do I complete Form 8700-12?

If you are not familiar with the Form 8700-12, it may be helpful to complete the Form 8700-12 offline first, even if you plan to enter your information into myRCRAid.

Item No. 1. Reason for Submittal: If notifying independent of a biennial report, check “Obtaining or updating an EPA ID Number of an on-going regulated activity that will continue for a period of time.” If notifying as part of your biennial report, check, “Submitting as a component of the Hazardous Waste Report for _____ (Reporting Year).” Select only one.

Item No. 2. Site EPA ID Number: Enter the number if you already have one (see Question 6 above for information on how to find it) or leave blank if you do not yet have an EPA ID Number.

Item No. 3. Site Name: The common name used to identify the site, e.g., Anytown Medical Center. If your facility is part of a chain, group, etc. with the same or similar names, try to use the convention already in the system (e.g., Anytown Medical vs. Any Town Medical).

Item No. 4. Site Location Address: Enter a physical address, not a Post Office box number. EPA ID Numbers are issued to a specific piece of land and stay with the land regardless of ownership changes. You can ignore the latitude and longitude coordinates.

Item No. 5. Site Mailing Address: If this is the same as the physical address, check the “Same as Location Address” box. If different than the physical address, enter the mailing address. This entry may include a Post Office box number, if appropriate.

Item No. 6. Site Land Type: This will usually be “private” for a healthcare facility, but could be County, Federal, Tribal, etc. Select only one type: Private, County, District, Federal, Tribal, Municipal, State, or Other. If your site’s Land Type could be described as Municipal and another Land Type, such as County, District, or Tribal, do not place an “X” in Municipal. Instead, choose the other appropriate Land Type. (For example, if your site’s Land Type is both Municipal and County, you would place an “X” in the box for County.)

Item No. 7. North American Industry Classification System (NAICS) Codes: Provide the code that best fits your primary function in Box A. A six-digit code is preferable, although a five-digit code is allowed. A four-digit code is not acceptable. This code should be available from your accounting department, or you may search on <https://www.census.gov/naics/>. NAICS Codes are very specific, so be sure to review all relevant options. For example, general hospitals are listed as: 622110 (General Medical and Surgical Hospitals), whereas emergency centers are listed as 621493 (Free-standing Ambulatory Surgical and Emergency Centers). Including more than one NAICS code is optional.

Item No. 8. Site Contact Information: Enter the information for the primary RCRA hazardous waste contact responsible for your submission. This will allow the state agency to follow up if they need any clarification or additional information. If there are additional people who may be contacted about your submission, enter their information in Item 18: Comments.

Item No. 9. Legal Owner of the Site and Operator of the Site: Since many hospitals operate under names different from the name of the legal owner, check with your business office to determine the legal owner of the site for this entry. List all owners of the site. The Date Became an Owner entry is optional and usually difficult to determine, so it may be left blank. Also indicate the owner type, which may be different than the Site Land Type indicated in No. 6. Pick only one owner type, choosing the most descriptive, e.g., County rather than Municipal.

Also provide the name of the Operator. Be aware that the Operator is responsible for the overall operation of a RCRA site. This is the legal entity which controls the RCRA site operation rather than the plant or site manager. This is usually a company or business name, most likely to be the name under which the healthcare facility is commonly known in the community. The date they became an Operator is also optional.

Item No. 10. Type of Regulated Waste Activity: This section has multiple parts, with suggested responses noted below.

- A. *Hazardous Waste Activities: 1. Generator of Hazardous Waste.* Indicate if your facility is an LQG, SQG, or VSQG. If you are operating under Subpart P, when you determine your generator category (See [Appendix G](#)) you do not need to count your hazardous waste pharmaceuticals. Most healthcare facilities will respond “No” to the remainder of the questions in section A.

- B. *Waste Codes for Federally Regulated Hazardous Wastes.* List all NON-PHARMACEUTICAL hazardous waste codes. When notifying under Subpart P, you are not required to list the waste codes for hazardous waste pharmaceuticals. You are, however, required to list the other non-pharmaceutical hazardous waste codes you generate. Your hazardous waste vendor can provide you a list of waste codes from either the profile they have created or a year-to-date list of hazardous wastes transported, which will include the waste codes. Typical waste codes will include D001, for ignitable lab waste, and F003, for spent non-halogenated solvents, again from the lab. All other relevant waste codes (excluding hazardous waste pharmaceuticals) should be included and added to this section.
- C. *Waste Codes for State-Regulated (non-Federal) Hazardous Wastes.* A number of states list additional wastes as state-only hazardous wastes, including for pharmaceuticals. Check with your state to determine if this is the case and if these must be included on this form.

Item No. 11. Additional Regulated Waste Activities:

- A. Other Waste Activities. Suggested answer: “No.” Most healthcare facilities will not be involved in the activities in this section.
- B. Universal Waste Activities. Suggested answer: “No.” While it is likely healthcare facilities will generate batteries, lamps, etc. as universal waste, it is unlikely they will qualify as a Large Quantity Handler of Universal Waste (accumulation of 5,000 kg or more).
- C. Used Oil Activities. Suggested answer: “No.” It is also unlikely for most healthcare facilities to be involved in used oil activities.
- D. Pharmaceutical Activities. Required answer: “Yes.” 1. Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals. Mark only a. Healthcare Facility. Do not mark b. Reverse Distributor. 2. Withdrawing from operating under 40 CFR Part 266 Subpart P for the management of hazardous waste pharmaceuticals. Required answer for initial notification: “No.”

Item No. 12. Eligible Academic Entities with Laboratories: Suggested answer: “No.” Most healthcare facilities will not be operating under the Academic Labs Rule (also known as Subpart K). If the hospital is a teaching hospital that has opted into using Subpart K for its laboratory hazardous waste, answer “Yes.”

Item No. 13. Episodic Generation: Suggested answer: “No.” It is unlikely that a healthcare facility would need to submit an episodic notification in conjunction with their initial Subpart P notification. However, VSQG or SQG healthcare facilities operating under Subpart P may use the episodic generation provisions in 40 CFR part 262 Subpart L as necessary with respect to their non-pharmaceutical hazardous waste. They would also have to fill out the Addendum to the Site Identification Form: Episodic Generator.

Item No. 14. LQG Consolidation of VSQG Hazardous Waste: Suggested answer: “No.” This item on the notification is not required for off-site consolidation that is done under Subpart P. Under Subpart P, a VSQG healthcare facility is allowed to send its hazardous waste pharmaceuticals to another healthcare facility that is operating under Subpart P, provided the receiving healthcare facility meets certain conditions, but notification of the consolidation activity is not required by either healthcare facility.

A healthcare facility that is an LQG with respect to its non-pharmaceutical hazardous waste may receive hazardous waste (both pharmaceutical and non-pharmaceutical) from an off-site VSQG under the consolidation provisions in 40 CFR 262.17(f), and accordingly, would answer “yes” to this question and fill out the required Addendum to the Site Identification Form: LQG Consolidation of VSQG Hazardous Waste.

Item No. 15. Notification of LQG Site Closure for a Central Accumulation Area (CAA) OR Entire Facility: Suggested answer: “No.” This is not a Subpart P provision and likely not applicable to healthcare facilities upon initial notification, unless the facility is closing the CAA or the entire facility in conjunction with initial notification.

Item No. 16. Notification of Hazardous Secondary Material Activity: Suggested answer: “No.” not relevant to a healthcare facility.

Item No. 17. Electronic Manifest Broker: Required answer: “No.” Not applicable for healthcare facilities.

Item No. 18. Comments: This section is available for any additional information generated above that

requires more space. Include the item number and box letter, if applicable. Add your EPA Identification number to any additional sheets.

Item No. 19. Certification: Upon submission of the form either via mailed hard copy or scanned and emailed copy, this certification must be signed and dated by the generator’s owner, operator, or authorized representative of the site. Only one signature is required, but multiple people may sign. An authorized representative is a person responsible for the overall operation of the site or a hazardous waste accumulation area (i.e., a plant manager or superintendent, or a person of equivalent responsibility). Authorized representatives must be authorized by one of the officers of the organization by submitting their name in writing to the state Director in an authorized state or the EPA Regional Director in non-authorized states (e.g., IA, AK), Indian country, and U.S. territories. This certification is a serious responsibility and should not be taken lightly. Misinformation could lead to enforcement actions and significant civil and even criminal penalties.

Submitting Form 8700-12. If submitting the hard copy of the form to the state, some states require what is still referred to as a “wet ink” copy to be sent to the person indicated on the [State Contacts web-page](#). In other words, print out the completed form, have the appropriate site representative physically sign the document, and deliver it to the appropriate state contact. Other states accept a scanned copy sent via email. Check with your state to determine their preferred method. If submitting the information via myRCRAid, see the suggested websites below for additional guidance or contact your EPA Regional Office or your state environmental agency directly.

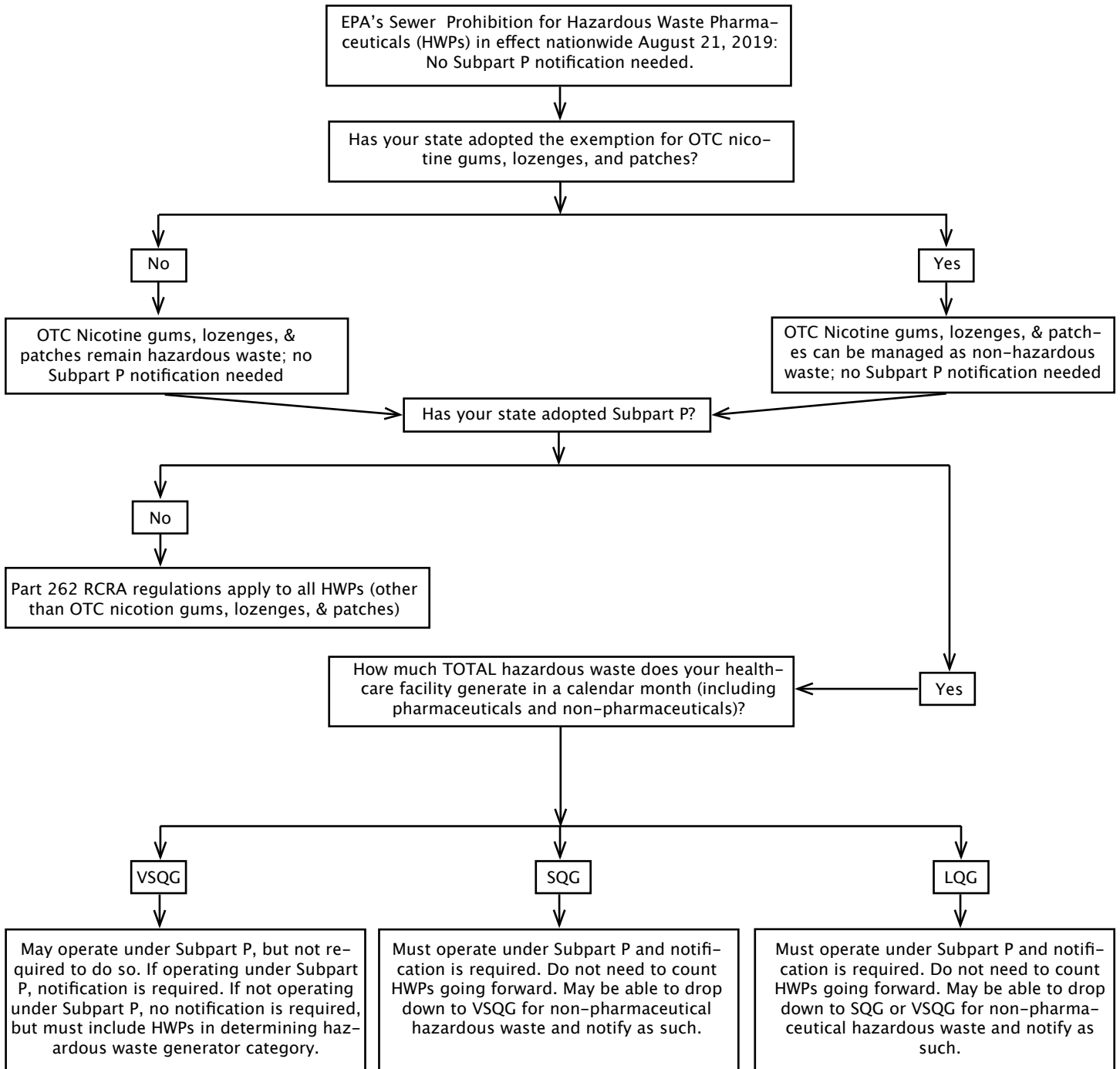
Federal Resources for myRCRAid:

- [RCRAInfo State Contacts](#)
- [RCRAInfo Registration or Sign In](#)
- [RCRAInfo FAQs](#)

Examples of Helpful State Resources for myRCRAid

- [California](#)
- [Delaware](#)
- [Ohio](#)

Pharmaceuticals Rule Notification Flowchart



Appendix G: RCRA Hazardous Waste Generator Categories

What are the RCRA hazardous waste generator categories?

Each healthcare facility should be knowledgeable regarding its RCRA hazardous waste generator status, regardless of whether or not their state has adopted the Pharmaceuticals Rule which includes Part 266 Subpart P. The RCRA hazardous waste regulations define the three levels of hazardous waste generator status:

1. Large quantity generator (LQG),
2. Small quantity generator (SQG), and
3. Very small quantity generator (VSQG).⁴⁸

Review the quantity limits for each of the RCRA hazardous waste generator categories on the chart below to make your determination.⁴⁹

What regulations apply to each RCRA hazardous waste generator category?

Each category of hazardous waste generator has its own set of regulations that apply to it. Broadly speaking, the regulations are designed so that, as a facility generates more hazardous waste, the regulations that apply to the facility become more stringent.

This Appendix will not attempt to replicate or summarize the RCRA hazardous waste generator regulations. Instead, please see the Summary Table on [EPA's Hazardous Waste Generator website](#) for a detailed comparison of the regulations that apply to each hazardous waste generator category.⁵⁰

| Quantity of acute hazardous waste generated in a calendar month | Quantity of non-acute hazardous waste generated in a calendar month | Generator category |
|---|---|--------------------------------------|
| > 1 kg | Any amount | Large quantity generator (LQG) |
| Any amount | ≥ 1000 kg | Large quantity generator (LQG) |
| ≤ 1 kg | > 100 kg and < 1000 kg | Small quantity generator (SQG) |
| ≤ 1 kg | ≤ 100 kg | Very small quantity generator (VSQG) |

⁴⁸ U.S. EPA, [Categories of Hazardous Waste Generators](#).

⁴⁹ Adapted from Table 1 in [40 CFR 262.13](#). The quantity of residues from a cleanup of acute hazardous waste generated in a calendar month also affects a facility's generator category but has been omitted here based on the assumption that it will not apply in most cases.

⁵⁰ U.S. EPA, [Hazardous Waste Generator Regulatory Summary](#).