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Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities

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1. INTRODUCTION

1.1 About this Best Management Practices (BMP) Guidance Document

The U.S. Environmental Protection Agency (EPA) conducted outreach and identified that there is near-universal interest from stakeholders to better manage unused pharmaceuticals at health care facilities, as well as general interest in EPA's guidance on managing unused pharmaceuticals. This guidance document describes Best Management Practices (BMPs) that EPA recommends to health care facilities, such as hospitals, long-term care facilities, medical clinics, and doctors' offices, when managing and disposing of unused pharmaceuticals. Environmental managers at health care facilities can use these BMPs to minimize sewer disposal of pharmaceuticals and properly manage unused pharmaceuticals. EPA's goal is to keep pharmaceuticals out of U.S. waters. EPA identified these BMPs after site visits at 12 health care facilities[1]; consulting with over 700 stakeholders including health care professionals, government entities, health care industry associations, and unused pharmaceutical management companies; review of disposal data from 20 hospitals and long-term care facilities; and review of literature data, reports, and state recommendations. These practices are a combination of recommended and implemented practices with the goal of proper unused pharmaceutical management and disposal.

This document presents the steps that environmental managers of health care facilities can take to identify and properly manage unused pharmaceuticals. The steps include:

- Conduct an inventory of pharmaceuticals and unused pharmaceuticals to quantify the amount of medication the facility is disposing of.
- Reduce unused pharmaceuticals by reviewing purchasing practices, using limited dose or unit dose dispensing, replacing pharmaceutical samples with vouchers, and performing ongoing inventory control and stock rotation.
- Properly manage unused pharmaceuticals by identifying types of pharmaceuticals and any federal and state requirements; when possible: reusing or donating unused pharmaceuticals, returning them to the pharmacy; sending them to a reverse distributor for credit and proper disposal; and using EPA recommended practices to dispose of pharmaceutical waste at the facility.
- Segregate waste for disposal to ensure regulations are met and to reduce costs (e.g., nonhazardous pharmaceutical waste disposal in a solid waste landfill may be less expensive than disposal via hazardous waste hauler).
- Train staff in proper disposal methods.

This document also provides a list of other resources, such as EPA and industry association websites, list of current state repository programs[2], sample unused pharmaceutical tracking sheet, and considerations when contracting with a specialty waste hauler.

[1] EPA also visited a long-term care pharmacy, waste management vendor, and reverse distributor.

[2] Current as of 2009.

1.2 Background

To date, scientists have identified numerous pharmaceutical compounds at discernable concentrations in our nation's rivers, lakes, streams and drinking waters. As a result, the U.S. Environmental Protection Agency (EPA) initiated a study on unused pharmaceutical disposal practices at health care facilities. While EPA understands that there are many factors influencing the handling and disposal of pharmaceuticals by the health care industry, the focus of this study was on disposal to sewers. EPA decided to study medical facilities because the Agency believes that these facilities dispose large quantities of unused pharmaceuticals to sewers.

Unused pharmaceuticals are dispensed prescriptions that patients do not use and medications that have expired. The term "unused pharmaceuticals" does not include excreted pharmaceuticals. Another source of unused pharmaceuticals is residue in used and partially-used dispensers, containers, and devices. Health care facilities may dispose of unused pharmaceuticals, especially residues, down the drain (e.g., intravenous (IV) bags emptied into the sink). For many years, a standard disposal practice at many health care facilities was to flush unused pharmaceuticals down the toilet or drain. EPA believes that facilities should not dispose of their pharmaceuticals down the drain. Pharmaceutical chemicals are also biologically excreted following patient use of drugs. Excretion is not addressed in this guidance.

2. CONDUCT AN INVENTORY OF PHARMACEUTICALS AND UNUSED PHARMACEUTICALS

How many waste streams are generated? Before a facility can identify the best means for reducing waste and disposing of the waste, it must understand what the facility is throwing out. This section will help facilities to determine the unused pharmaceuticals being generated and disposed of. EPA recommends that facilities take two steps to understand their unused pharmaceutical generation:

1. Develop a list of pharmaceuticals used at the facility.
2. Identify the unused pharmaceuticals generated and how they are currently managed.

2.1 Develop a List of Pharmaceuticals Used at The Facility

The first step in managing unused pharmaceuticals at health care facilities is to identify the types of pharmaceuticals that the facility uses. EPA recommends starting either at the on-site pharmacy or by contacting the pharmaceutical supplier. Most hospital pharmacies maintain a formulary—a list of pharmaceuticals approved for prescriptions to patients by attending physicians. The hospital pharmacy may also purchase pharmaceuticals not listed in the formulary to meet special circumstances. For this reason, purchasing records will provide a more complete list of what the pharmacy has in stock than the approved formulary alone. EPA suggests reviewing a 12-month summary of purchasing records. This initial review will assist the facility to most accurately categorize the unused pharmaceuticals.

To develop a list of pharmaceuticals used at the facility, find the following information for all of the pharmaceuticals administered at the facility:

- National drug code (NDC);
- Brand name;
- Generic name;
- Manufacturer;
- Dosage(s);
- Form (i.e., liquid, tablet, cream, etc) – different forms of the same medication may expire more quickly or remain in stock longer; and
- Package size.

Using the list of pharmaceuticals prescribed at the facility, next determine how often those pharmaceuticals become waste. Once wasted pharmaceuticals are identified, the facility can use the BMPs recommended in Section 3 to reduce waste.[3] In addition, by knowing what is being disposed of, the facility can reduce its disposal costs by finding ways to reduce waste. Also, the facility could reduce purchasing costs by reducing the pharmacy's inventory of drugs that are identified as often being disposed.

[3] Some health care facilities conduct their own inventory; others hire commercial services that have expertise in cataloging inventories and find that this is cost effective and less burdensome on existing staff.

2.2 Identify the Unused Pharmaceuticals Generated and How They Are Currently Managed

After the facility has a comprehensive list of the pharmaceuticals used, the next step in developing a waste management program is to identify the unused pharmaceuticals generated. Unused pharmaceuticals may be generated at numerous locations throughout the facility, for example at the pharmacy or on the nursing floor. At all possible waste locations, the facility should keep track of the following:

- Pharmaceutical identification (see list in Section 2.1), including any manufacturer samples that need to be disposed. A good initial step is to document the amount and frequency of outdated (expired) samples or stock per out-patient clinic or medical practice area.

- Reason for waste generation. At the pharmacy, reasons include expiration prior to use or spills. On the nursing floor, reasons include patient refusing medication, medication left behind when a patient leaves, or stopping of IV mid-stream.

- Where the waste goes. For example, the facility might currently throw pharmaceuticals away in the trash, collect them for other disposal, drain them in the sink, or flush them down the toilet.

EPA recommends that the facility keep track of the unused pharmaceuticals for two weeks to one month. This time period may differ depending on the variety and frequency of services that the facility provides. Seasonality may also play a role in the types and quantities of pharmaceuticals being used. For example, the length of time depends upon how often doctors' offices dispose of expired pharmaceutical stock and samples, how often hospitals check their crash carts for expired medications, or how often long-term care facilities check their emergency kits for expired medications. Once the facility has the list of discarded pharmaceuticals, it can identify commonly wasted pharmaceuticals and identify reasons for the waste generation. Then, the facility can use the BMPs provided in Section 3 to reduce the amount wasted. See Appendix B of this document for a Sample Unused Pharmaceutical Tracking Sheet.

3. REDUCING OR AVOIDING UNUSED PHARMACEUTICALS

How can a health care facility reduce unused pharmaceuticals? The simplest and least expensive way to minimize pharmaceutical disposal is to reduce and avoid generating unused pharmaceuticals. During outreach activities, EPA heard many facilities give examples of the cost savings from smart pharmaceutical management. Buying medicine in smaller quantities means fewer expire. By using vouchers from pharmaceutical sales representatives instead of using free "sample" pharmaceuticals, facilities can eliminate an entire waste stream. This section walks through how many health care facilities have reduced their waste and cut costs at the same time.

After completing a waste review as described in Section 2, the facility can determine the pharmaceuticals commonly wasted and the reasons. Depending on the reason for the waste generation, it can use the BMPs in this section to reduce waste. Typical reasons why pharmaceuticals become waste include the following:

- Purchased medications expire before they are used;
- Patient refuses the medication;
- Pharmaceutical sales representatives leave samples that expire before they are used;
- Patient dies or is transferred;
- Patient has an adverse reaction, or is successfully treated, and stops medication; and
- Dispensing or other medication error occurs.

3.1 Review Purchasing Practices

Once the unused pharmaceutical profile is completed, the facility should review purchasing practices to determine ways to reduce waste. The review includes:

- Identify any pharmaceuticals that commonly expire before use – buy less to reduce wasted amount.

- Identify pharmaceuticals used by multiple departments – purchasing a standard package size, dose, or form can reduce waste. This allows multiple departments to use the same supply.

  Example: Using the same dosage form for medications used in different departments of a hospital can facilitate stock rotation. For example, Hennepin County Medical Center (HCMC) in Minnesota was using 15-gram glucose (dextrose) gel tubes in its crash boxes. It was also dispensing 45-gram tubes to diabetic patients. The facility's Diabetics Committee recommends 30-gram doses; therefore a portion of the 45-gram tubes went unused. The facility switched all departments to 15-gram glucose gel tubes and was able to rotate short-dated tubes from crash boxes to departments with higher usage, potentially eliminating waste.[4]

[4] Reference: Minnesota Technical Assistance Program (MnTAP). Reducing pharmaceutical waste from patient-care settings. www.mntap.umn.edu/health/94-PharmWaste.htm.

3.2 Order Smaller Container Sizes or Emphasize Unit Dose Dispensing

Dispensed pharmaceuticals may go unused for a variety of reasons: patient refuses the medication, medicine is no longer needed or not effective, treatment or dosage changes, or patient is discharged. To reduce the quantity of unused pharmaceuticals, facilities may want to limit the number of doses dispensed to a patient at one time (unit dose packaging), use trial prescriptions or samples to determine medication effectiveness before writing a full prescription, and use smaller containers of pharmaceuticals at the pharmacy and on nursing floors.

3.2.1 Unit Dose Dispensing

The facility can purchase prepackaged unit doses, for example, in blister packs or bingo cards. It can also prepare unit doses at the on-site pharmacy for dispensing to patients (e.g., individually wrapped or dispensed via an automated dispensing system). By limiting the amount of medication dispensed to a patient at one time, unopened pharmaceuticals can more readily be restocked and reused. As long as the packaging is not opened and has been stored properly, the facility may be able to return medications to its pharmacy for reuse (i.e., prescribed to another patient). Reuse of unit doses to another patient is often possible at hospitals, but not always possible for facilities with off-site pharmacies, such as long-term care facilities. However, even if it is not possible for a medication to be dispensed to another patient, an off-site pharmacy will usually accept the return of the unused medications (excluding controlled substances) and dispose of them for the facility.

> Example: At the Walter Reed Army Medical Center in Washington, DC, approximately 99 percent of the pharmaceuticals are dispensed as unit doses to reduce waste. The majority of unit doses are blister packs purchased from the manufacturer as unit doses. Other unit doses are packaged at the on-site pharmacy. For example, liquid medications are dispensed in 5, 15, and 30 milliliter (mL) doses.

3.2.2 Ordering Smaller Container Sizes

If a health care facility finds that portions of bottled liquid pharmaceuticals are going unused and require disposal, it may be able to purchase smaller bottles of liquid pharmaceuticals and reduce the amount wasted. Using smaller container sizes and reducing waste has the additional benefit of reducing the purchasing costs related to the pharmaceutical.

> Example: The Marshfield Clinic in Wisconsin uses lidocaine in small amounts. Rather than purchasing lidocaine in 50 milliliter (mL) bottles that need to be discarded 30 days after opening, the clinic began purchasing 15 mL vials or smaller to minimize wasted medication. This change also reduced the purchasing costs for lidocaine.

3.2.3 Trial Prescriptions

Certain medications have high incidences of side effects, and patients frequently stop taking the medication before the dispensed quantity is used. For these medications, EPA recommends that pharmacies use "trial prescriptions" in which only a small quantity (e.g., 7 to 14 day supply) is dispensed. If the patient stops taking the medication, the unused amount is reduced.

Title III of the Affordable Care Act (2010) includes Section 3310, "Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities under prescription drug plans and MA-PD (Medicare Advantage Prescription Drug) plans." This section limits the number of days (no more than 7) that a long-term care facility can provide prescription supplies to residents. This amendment takes effect January 1, 2012.

> Example: MaineCare, the Medicaid health insurance program managed by the Maine Department of Health and Human Services, instituted a new 15-day limit on initial prescriptions for certain medications they identified as having high rate of waste. These are medications that have high side effect profiles, high discontinuation rates, or require frequent dose adjustments. In addition to reducing wasted medication, MaineCare's policy aims to control health care costs.

3.3 Replace Pharmaceutical Samples with Vouchers

Pharmaceutical sales representatives often provide sample medications to health care facilities. These samples can then be provided to patients at no cost as trial prescriptions. The use of sample medications is more common at doctors' offices and clinics than at hospitals and long-term care facilities. If the samples expire prior to use, the health care facility must properly dispose of the unused pharmaceuticals.

To reduce waste, EPA recommends that health care facilities replace the use of samples with manufacturer vouchers which the patient takes to the pharmacy for a free sample. This minimizes generation of waste from expired sample medications. Another approach is to accept only samples of the pharmaceuticals most frequently prescribed in each clinic.

> Example: The Marshfield Clinic in Wisconsin discourages their individual offices and clinics from accepting samples from pharmaceutical manufacturing company representatives. Instead, clinics and doctors' offices provide their patients with vouchers, which the patients take to a retail pharmacy for a free sample. If the pharmaceutical manufacturing company does not have a voucher system in place, Marshfield Clinic requires that the company representative remove the samples from the clinic before their expiration date.

3.4 On-Going Waste Reduction/Avoidance Practices: Inventory Control and Stock Rotation

3.4.1 On-Going Inventory Control

Once the initial inventory review is complete, a periodic review of the inventory should be established. This periodic inventory review will allow the list of pharmaceuticals to be updated and will aid the facility in identifying pharmaceuticals nearing expiration. Finally, this review will allow the facility to determine whether its waste reduction practices are working.

3.4.2 Stock Rotation

Stock rotation is a practice to reduce expired pharmaceuticals. During the periodic inventory review, any short-dated pharmaceuticals are redistributed to other areas of the facility where they are needed and used immediately.

Example: Fairfax-Northern Virginia Hematology-Oncology is a network of six clinics in the Northern Virginia area. The Fairfax location houses the IV admixture service, which is the central pharmaceutical distribution point for all of the other facilities. Each satellite facility receives a daily delivery of patient-specific doses prepared in most cases the day before treatment. Any pharmaceuticals that are not used are returned to the admixture site. If possible based on stability and dose, the returned pharmaceuticals are used at a later date.

Example: The Walter Reed Army Medical Center in Washington, DC uses an automated dispensing system to distribute 95% of all pharmaceuticals. These machines are primarily used to ensure patient safety and for tracking pharmaceutical distribution, but the facility has found that a secondary use is for inventory control and reduction of overstocking certain pharmaceuticals.

4. IDENTIFYING & MANAGING TYPES OF UNUSED PHARMACEUTICALS AND APPLICABLE DISPOSAL REGULATIONS

Can the facility send the unused pharmaceutical back to the pharmacy for reuse? How many of the facility pharmaceuticals are hazardous waste? How should the facility dispose of controlled substances? This section will help answer these questions.

After waste reduction measures are taken, EPA recommends the following general practices for managing unused pharmaceuticals:

- Reuse unopened pharmaceuticals where possible: either through the pharmacy or through state donation programs.

- Send creditable pharmaceuticals to reverse distributors. Reverse distributors are private companies that provide a service to the health care industry by keeping track of manufacturer unused pharmaceutical reimbursement policies, and thus get facilities credit for the pharmaceuticals prior to sending them off-site for disposal. Reverse distributors are registered with the Drug Enforcement Agency (DEA) and are authorized under the Controlled Substances Act to handle controlled substances that are unused, outdated, or unwanted. Under current law, reverse distributors, however, are only permitted to accept controlled substances from other DEA registrants. EPA recommends that facilities consult with their state regulatory agency to ensure compliance with all state environmental regulations when unused pharmaceuticals are sent to reverse distributors.

- Hospital/clinic's and doctor's controlled substance stock can be transferred to a reverse distributor for disposal.

- Practice proper on-site waste management and waste disposal. Consider using a contracted waste management provider for pharmaceutical waste (specialty waste hauler).

A facility must meet federal and state requirements for managing unused pharmaceuticals. There are federal statutes and programs that regulate the management and disposal of unused pharmaceuticals, including:

- **The Controlled Substances Act (CSA).** Administered by the DEA, CSA provides a closed system for distributing controlled substances. As part of this system, DEA prohibits the return of controlled substances from end-users to nearly all DEA registrants, including pharmacies, hospital staff, and clinic employees. In certain cases, a full duty law-enforcement agent[5] is allowed to accept a controlled substance. Disposal of controlled substances by DEA registrants is carefully regulated to ensure that the substance is destroyed. Voluntary survey submittals, outreach meetings, and site visits indicate that disposing of controlled substances down the drain is a common practice to ensure

[5] An agent is "any officer or employee of any state, or any political subdivision of agency thereof, who is engaged in the enforcement of any state or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties." 21 CFR 1301.24(a)(2)

destruction of controlled substances due to its affordability and ease. However, EPA is recommending BMPs in this guidance to reduce and avoid drain disposal.

- **The Resource Conservation and Recovery Act (RCRA).** RCRA gives EPA the authority to control hazardous waste from "cradle-to-grave." This includes the generation, transportation, treatment, storage, and disposal of hazardous waste. Some pharmaceuticals may be considered RCRA hazardous wastes upon discard. As a result, health care facilities may have to comply with RCRA laws and regulations for the generation, transportation, storage, treatment, and ultimate disposal of some pharmaceuticals. Many states are authorized by EPA to implement their own hazardous waste programs in lieu of the federal RCRA program. States' hazardous waste regulations may be broader or more stringent than the federal RCRA program. Therefore, health care facilities should contact their state environmental regulatory agency to ensure full compliance.

- **The Centers for Medicare & Medicaid Services (CMS)**. CMS is a federal agency within the Department of Health and Human Services (HHS) that administers the Medicare and Medicaid programs. Medicare provides health insurance to elderly and disabled Americans, while Medicaid provides health insurance for low income Americans, including long-term care coverage. While Medicare is a federal program, Medicaid is a state-run program that is partly funded by federal dollars. Therefore, many Medicaid requirements are set at the state level, including regulations for management of unused pharmaceuticals. The primary role of CMS is to pay for medical products and services through the Medicaid and Medicare programs. CMS does not directly regulate pharmaceutical disposal. These policies are determined by each state's board of pharmacy and state health departments as well as any federal regulations.

- **The Health Insurance Portability and Accountability Act (HIPAA).** The Department of HHS administers HIPAA, which provides protection for the privacy of certain individually identifiable health data, such as the names of medications taken by patients. Before a patient's unused pharmaceuticals are disposed of from the health care facility, personal information on the container should be removed or obscured.

This section describes how to identify and properly manage waste under these federal laws. Appendix A provides additional information on state and local requirements and programs. Note that state and local requirements may be broader or more stringent than federal requirements, so it is important to check requirements for the corresponding state and locality. Each subsection provides guidance for managing and disposing of each type of unused pharmaceutical. Table 3 at the end of this section presents EPA's recommended practices for unused pharmaceuticals by type and form.

4.1 Types of Unused Pharmaceuticals

Unused pharmaceuticals include expired medications, unwanted medications (e.g., patient/resident discontinues use), and waste medication (e.g., patient/resident refuses to take or spits out). Unused pharmaceuticals are generated at health care facilities before, during, and after

treatment, as well as during stocking activities needed to ensure sufficient materials are available for regular care. In order to properly manage unused pharmaceuticals, the facility needs to identify the types of materials on site, including:

- Nonwaste (i.e., reusable or returnable medications);
- Hazardous waste, including dual wastes (hazardous and biohazardous);
- Nonhazardous waste;
- Controlled substances; and
- Chemotherapeutic pharmaceuticals.

Figure 1 presents a summary flowchart to assist facilities in identifying proper management methods. The flowchart provides a summary of the unused pharmaceutical types and how to manage them; a more complete explanation of how to manage unused pharmaceuticals follows the chart.

4.2 Nonwaste Medications – Pharmaceutical Reuse

Many health care facilities return their unused pharmaceuticals, or at least a portion of them, to the dispensing pharmacy. Upon receipt, the pharmacy determines how the unused pharmaceuticals should be managed, including:

- Credit and reuse of medication;
- Donation of medication to state programs;
- Credit and disposal of the unused pharmaceuticals; and
- Disposal of the unused pharmaceuticals.

To determine whether stock unused medication can be reused or donated following return to the facility's pharmacy, ask the following questions:

- Is the medication in the original packaging or still in prepackaged unit doses from the pharmacy?
- Is the expiration date a future date at least six months out?
- Is the label intact? Is all the information for the medication such as type, dose, and expiration date clearly marked?
- Has the medication been properly stored, such as within the proper ranges for temperature, humidity, and light?

Reuse of Medications

When patients pay for part of the medication (and the remaining cost is covered by Medicare Part D and/or private insurance), long-term care facility pharmacies typically cannot give credit to the patient for returned medicines. They are unable to give partial credit to the patient under existing Medicare and private insurance financial tracking systems. Thus, the long-term care facility pharmacies can accept the returned medicines (excluding controlled substances), but can not resell them.

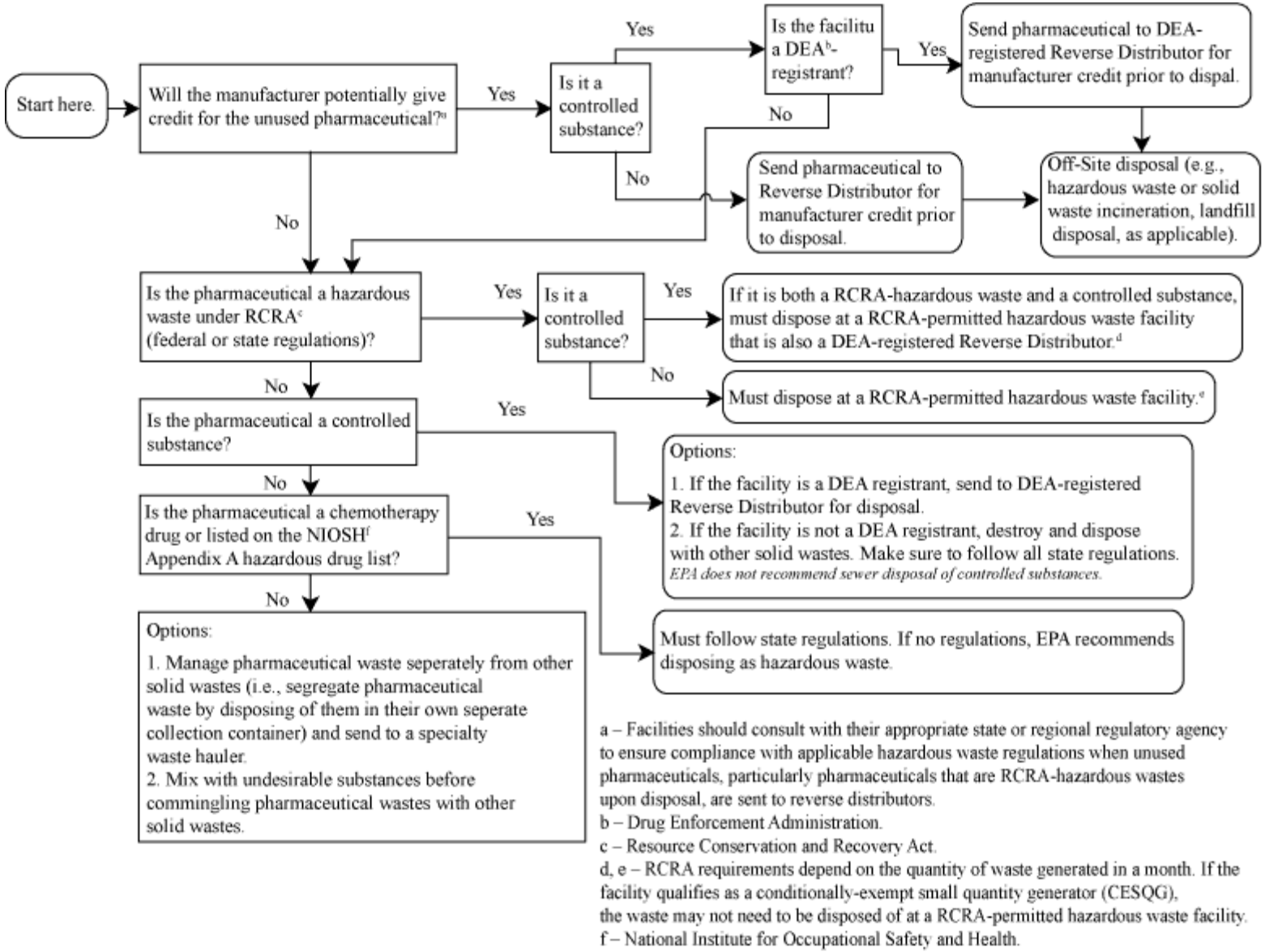

Figure 1. Summary Unused Pharmaceutical Management Flow Chart

If the facility answers "yes" to all the above questions, it might be able to return the unused medication to the pharmacy for reuse, or the pharmacy may be able to donate the unused medication to charitable institutions, such as programs that assist lower-income patients (state repository programs). State boards of pharmacy set policies for the return and reuse of unused pharmaceuticals. Although the policies vary by state, most allow reuse of uncontaminated medications that have been in a controlled environment, **excluding controlled substances**. Medications that can be reused are typically solid doses such as pills, tablets, and capsules that do not require special handling for temperature such as refrigeration. The pharmacy must remove any patient-specific information from the medication before donating.

If the facility answers "no" to any of the above questions, the pharmacy cannot reuse the unused medication. However, the pharmacy may accept returns of pharmaceuticals for credit or for proper disposal. To receive credit from the pharmaceutical manufacturer, pharmacies send the unused medication to a reverse distributor for potential credit and eventual disposal. The reverse distributor determines which medications can receive credit from the manufacturer and then arranges for disposal of the unused and/or expired medications. Health care facilities and pharmacies should confer with state and/or local environmental agencies to ensure regulatory compliance when using reverse distributors.

If the health care facility cannot return the unused medication to the pharmacy and it must be discarded, the unused medication becomes waste and the facility must follow applicable federal, state, and local laws and ordinances for waste disposal. The following subsections describe management options for unused pharmaceuticals depending on their classification.

4.3 Identifying Hazardous Vs. Nonhazardous Waste

Federal hazardous waste law (the Resource Conservation and Recovery Act, or RCRA), its implementing regulations, and state regulations define hazardous wastes. Some state hazardous waste requirements may be broader or more stringent than federal requirements. The discussion in this subsection is only for reference and is not intended to be used as a substitute for RCRA itself or its implementing regulations, contained in the Code of Federal Regulations (CFR). Finally, failing to comply with RCRA can result in the initiation of enforcement actions against the facility.

To be classified as a hazardous waste under RCRA, the waste must be listed in EPA regulations at 40 CFR 261 or exhibit certain characteristics. Thus, a pharmaceutical waste may be considered hazardous under RCRA if:

1. The pharmaceutical or its sole[6] active ingredient is specifically listed on
   - The P List: Acutely Hazardous Waste (40 CFR 261.33(e)) or
   - The U List: Discarded Commercial Chemical Products (40 CFR 261.33(f)); and/or

[6] Many pharmaceuticals have more than one active ingredient. If the pharmaceutical contains an active ingredient that is on the P List or U List AND the pharmaceutical has more than one active ingredient (i.e., not "sole" ingredient), then that pharmaceutical waste does not meet RCRA's definition of a listed hazardous waste. However, the pharmaceutical waste may still be hazardous waste if it exhibits characteristics of hazardous waste. Although pharmaceutical waste with more than one active ingredient does not meet RCRA's definition of a listed hazardous waste, EPA recommends that health care facilities still manage the waste as RCRA hazardous waste.

2. The waste exhibits one or more hazardous waste characteristic as defined in 40 CFR 261.21-24, (ignitability, corrosivity, reactivity, or toxicity).

Many health care facilities also use the National Institute for Occupational Safety and Health (NIOSH) list of hazardous materials to identify additional unused pharmaceuticals that should be handled similarly to waste defined as hazardous under RCRA. Although RCRA does not require facilities to manage NIOSH listed hazardous materials the same as RCRA hazardous waste, EPA recommends that the NIOSH-listed hazardous materials be managed using RCRA guidelines as a BMP.

The P and U- Listings (40 CFR 261.33 (e) and (f))

A waste pharmaceutical can meet RCRA's definition of hazardous waste if the pharmaceutical (including its generic name) or the sole active ingredient of the pharmaceutical is listed on RCRA's P List or U List. P-listed and U-listed wastes fall under the hazardous waste definition included at 40 CFR 261.33, *Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof*. Once the decision is made to discard of the unused pharmaceutical, the health care facility must identify whether or not the pharmaceutical (including its generic name) or the pharmaceutical's sole-active ingredient appears on the P-List or U-List.

If the pharmaceutical (including its generic name) or its sole active ingredient is a P- or U-listed waste, then the health care facility must manage that waste pharmaceutical as a hazardous waste in accordance with all applicable federal, state and local environmental regulations[7].

Table 1 lists examples of P- and U-listed commercial chemical products that have pharmaceutical uses.

Table 1. Examples of Active Pharmaceutical Ingredients that are Considered Hazardous Under RCRA (P-Listed and U-Listed)

Pharmaceutical Name	No.	Pharmaceutical Name	No.
P-Listed			
Arsenic trioxide (chemotherapy drug)	P012	Phentermine (controlled substance)	P046
Epinephrine (a)	P042	Physostigmine	P204
Nicotine	P075	Physostigmine salicylate	P188
Nitroglycerin (b)	P081	Warfarin >0.3%	P001
U-Listed			
Azaserine (chemotherapy drug)	U015	Mitomycin C (chemotherapy drug)	U010
Chloral hydrate (controlled substance)	U034	Paraldehyde (controlled substance)	U182
Chlorambucil (chemotherapy drug)	U035	Phenacetin	U187
Chloroform	U044	Phenol	U188
Cyclophosphamide (chemotherapy drug)	U058	Reserpine	U200
Daunomycin (chemotherapy drug)	U059	Resorcinol	U201

[7] Note that the applicable regulations will depend on the quantity of waste generated each month, as described in Section 4.3.1.

Table 1. Examples of Active Pharmaceutical Ingredients that are Considered Hazardous Under RCRA (P-Listed and U-Listed)

Pharmaceutical Name	No.	Pharmaceutical Name	No.
Dichlorodifluromethane	U075	Saccharin	U202
Diethylstilbestrol	U089	Selenium sulfide	U205
Hexachlorophene	U132	Streptozotocin (chemotherapy drug)	U206
Lindane	U129	Trichloromonofluromethane	U121
Melphalan (chemotherapy drug)	U150	Uracil mustard (chemotherapy drug)	U237
Mercury	U151	Warfarin <0.3%	U248

Source: Practice Greenhealth. 2008. Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States. Revised August 2008. Accessed online at: http://www.practicegreenhealth.org/page_attachments/0000/0102/PharmWasteBlueprint.pdf; Washington Department of Ecology Example RCRA Waste Codes for Pharmaceuticals. Accessed online at: http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/pages/pu_metals.html. For a complete listing of discarded commercial chemical products found on RCRA's P- and U-lists, please see 40 CFR 261.33(e) and (f), respectively, at http://www.epa.gov/wastes/hazard/wastetypes/listed.htm.

a – The Agency clarified its regulation at 40 CFR 261.33, explaining that epinephrine salts are not included in the epinephrine P042 listing; therefore, the waste epinephrine salt would be hazardous only if it exhibited one or more of the hazardous waste characteristics. Please confer with state and/or local environmental regulatory authorities to determine if this clarification is accepted in that state. (See "Scope of Hazardous Waste Listing P042(Epinephrine)," October 15, 2007, RCRA Online# 14778: http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2f701627eb73b2ab852573d2005e0b4f!OpenDocument).

b – Medicinal nitroglycerin may be excluded from the listing as it typically does not exhibit the characteristic of reactivity (for which nitroglycerin was listed). Please confer with state and/or local environmental regulatory authorities to determine if this exclusion is accepted in that state. (See "Regulation of Nitroglycerin Under Revised Mixture and Derived-From Rules," March 18, 2003, RCRA Online# 14654: http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7acfec572de8897f85256d1600748bcb!OpenDocument).

RCRA Hazardous Waste Characteristics (40 CFR 261. 21-24)

If it is determined that the waste pharmaceutical is not a listed hazardous waste, then the health care facility must determine if that waste pharmaceutical meets one of RCRA's hazardous waste characteristics. The generator of the waste can either use a standardized test method or apply general knowledge of the waste's properties in making this determination. Examples of RCRA hazardous waste characteristics exhibited by pharmaceutical wastes include the following[8]:

- Ignitability (D001): the presence of a flammable solvent is the most common reason pharmaceuticals meet this characteristic. For alcohol, RCRA sets a threshold limit of 24% (i.e., if the formulation contains more than 24% alcohol, then the waste is considered hazardous waste). Strong oxidizers, such as silver nitrate and potassium permanganate, in pharmaceutical formulations may also meet the definition of ignitability.

[8] Source: Healthcare Environmental Resources Center, Pharmaceutical Wastes in Health Care Facilities. Accessed online at: http://www.hercenter.org/hazmat/pharma.cfm

- Corrosivity (D002): applies to strong acids (pH≤2) or strong bases (pH≥12.5). In pharmaceutical compounding, glacial acetic acid and concentrated sodium hydroxide might be used. Their wastes are corrosive and thus considered hazardous.

- Reactivity (D003): nitroglycerin, a P-listed hazardous waste, would fall into this category if used in bulk. However, dosage forms typically do not exhibit characteristics of reactivity[9]:

- Toxicity (D004 to D043): The toxicity characteristic (TC) identifies wastes that are likely to leach concentrations of any one of 40 different toxic chemicals in amounts above the specified regulatory levels. Examples of TC chemicals/heavy metals that have pharmaceutical uses and their toxicity threshold levels are:
  - Arsenic (D004): 5.0 mg/L;
  - Barium (D005): 100.0 mg/L;
  - Cadmium (D006): 1.0 mg/L;
  - Chloroform (D022): 6.0 mg/L;
  - Chromium (D007): 5.0 mg/L;
  - m-Cresol (D024): 200 mg/L;
  - Lindane (D013): 0.4 mg/L;
  - Mercury (D009): 0.2 mg/L;
  - Selenium (D010): 1.0 mg/L; and
  - Silver (D011): 5.0 mg/L.

4.3.1 Requirements for Managing Hazardous Waste

Any facility that generates a hazardous pharmaceutical waste is subject to the RCRA generator regulations at 40 CFR 262.[10] Under the federal program there are three RCRA hazardous waste generator categories, and the extent of the requirements for each generator category is defined by the amount of hazardous waste generated in a calendar month. A facility that generates 1000 kilograms (kg) or more of hazardous waste in a month, or greater than 1 kg of acute (P list) hazardous waste in a month is a large quantity generator (LQG). LQGs are subject to the full extent of the RCRA generator regulations (see 40 CFR 262). For example, LQGs must:

- Obtain an EPA identification number;
- Can store waste for only 90 days (accumulation requirement) or otherwise obtain a RCRA permit;
- Meet manifest and reporting requirements; and
- Comply with certain training requirements.

[9] If a listed hazardous waste is listed solely because it exhibits the characteristics of ignitability, corrosivity and/or reactivity, and the waste at its point of generation no longer exhibits the characteristic for which it was listed, then it is not a hazardous waste (66 FR 27286, May 16, 2001). Since local and state regulations may be broader or more stringent than the federal regulations, EPA recommends the regulated community contact their local regulatory authorities to determine if this exemption applies in their states.

[10] For more information regarding the various federal RCRA generator requirements, please see the following links: http://www.epa.gov/epawaste/hazard/generation/summary.htm and http://www.epa.gov/epawaste/hazard/downloads/tool.pdf

If a facility generates more than 100 kg but less than 1000 kg of hazardous waste in a month, then it is a small quantity generator (SQG). SQGs are subject to fewer requirements than LQGs. For example, SQGs do not need to complete a biennial report, and SQGs have fewer personnel training and contingency planning requirements than LQGs (see 40 CFR 262.34(d)(5)). Moreover, SQGs must meet the 180 day (rather than the 90 days for LQGs) accumulation requirements or otherwise obtain a RCRA permit.

A facility generating no more than 100 kg of hazardous waste in a month, or no more than 1 kg of acutely hazardous waste (P list) in a month, is a conditionally-exempt small quantity generator (CESQG) under the federal program. CESQGs have the least stringent requirements of all generators (see 40 CFR 261.5). For example, CESQGs are not required to obtain an EPA identification number, manifest waste sent off-site for disposal, or meet any storage time limits. In addition, under the federal regulations, CESQGs can send hazardous wastes to either a state-approved solid waste facility or to a hazardous waste disposal facility. States authorized to implement the RCRA hazardous waste program may have broader or more stringent generator requirements than the federal RCRA program, so facilities should contact their state environmental regulatory agency to ensure full compliance.

The discussion on handling hazardous waste in this document assumes the health care facility is a SQG or LQG. Some health care facilities will fall into the CESQG category and certain federal RCRA hazardous waste requirements will not apply. For example, under federal regulations, a CESQG can send hazardous waste to certain nonhazardous waste facilities[11]. This document provides suggestions on how to best handle unused pharmaceuticals that are hazardous wastes, regardless of the generator size.

Federal regulations also require that hazardous wastes from SQGs and LQGs be transported in approved containers by an authorized hazardous waste transporter and transported to permitted hazardous waste treatment, storage, and disposal facilities. RCRA also prohibits health care facilities that qualify as small quantity or large quantity generators of hazardous waste from disposing of hazardous pharmaceutical waste in solid waste landfills, solid waste incinerators, or hospital/medical/infectious waste incinerators (40 CFR 268). **Hazardous waste from SQGs and LQGs cannot be collected with biohazardous (red bag) waste for sterilization as the sterilized waste is disposed in solid waste landfills. As a BMP, EPA recommends that all health care facilities, regardless of generator size, should not dispose of hazardous waste with red bag waste.** Also, some states require hazardous waste that is also biohazardous (infectious) to be disposed of as "dual" wastes. Health care facilities should check state hazardous waste requirements as they may be broader or more stringent than the federal requirements.

4.3.2 Recommended Management of Hazardous Pharmaceutical Waste

Health care facilities must comply with RCRA requirements for the management and disposal of hazardous pharmaceutical waste. Waste may be disposed of via incineration at a hazardous waste incinerator or in a hazardous waste landfill after the waste is treated under the Land Disposal Restrictions program (see http://www.epa.gov/epawaste/hazard/tsd/ldr/resource.htm). Hazardous

[11] The EPA CESQG Landfill/Municipal Solid Waste Landfill regulations do not require state approval of a facility. The regulations apply to all facilities without state action, although in practice most states have permitting programs in place.

pharmaceutical waste is most commonly treated by hazardous waste incineration, with the resulting incinerator ash disposed in a permitted hazardous waste landfill. EPA recommends segregation of hazardous waste (rather than handling all waste as hazardous). Because only approximately 5% of all pharmaceutical waste is hazardous, it may be more expensive to dispose of all pharmaceutical waste (hazardous and nonhazardous) as hazardous waste. Facilities should then follow the applicable federal and state regulations for proper disposal. EPA also recommends that health care facilities collect, store, and package hazardous waste oxidizers separately from other hazardous waste. Links to state waste programs are available at: http://www.epa.gov/epawaste/wyl/stateprograms.htm.

4.3.3 Definition of RCRA-Empty Containers

Under 40 CFR 261.7, empty containers of hazardous waste are not subject to hazardous waste regulations under RCRA (40 CFR 261 through 265, 267, 268, 270, or to the notification requirements of section 3010). However, if the container does not meet the definition of "RCRA-empty," the container must be disposed of as a hazardous waste and meet all the RCRA requirements. Table 2 presents the definition of "empty containers" under RCRA.

Table 2. RCRA Definition of "Empty Containers"

Type of RCRA Waste	RCRA Definition of Empty Container
Acute Hazardous Waste (e.g., P-Listed)	(i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate [a] ; (ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or (iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container has been removed.
Toxic Waste (U-Listed and Characteristic Hazardous Wastes)	(i) All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, e.g., pouring, pumping, and aspirating, and (ii) No more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, or (iii)(A) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or (B) No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.
Compressed Gas Containers	A container that has held a hazardous waste that is a compressed gas is empty when the pressure in the container approaches atmospheric.

Source: 40 CFR 261.7
a – The rinsates from the triple-rinsing of containers which have held commercial chemical products listed in 40 CFR 261.33(e) are also RCRA hazardous wastes (see 40 CFR 261.3(a)(2)(iv)).

Triple rinsing at health care facilities is not always practical. Therefore, facilities often dispose of all vials, IVs, and other containers that have held P-listed pharmaceuticals as hazardous wastes

even if "empty." Some states exclude certain containers from inclusion as hazardous waste. These containers may include those that held solid pharmaceutical doses (i.e., tablets, capsules, and patches) and empty warfarin stock bottles and unit-dose packaging.

For syringes containing P-listed or U-listed pharmaceuticals, used syringes do not need to be handled as hazardous waste as long as no characteristic hazard remains (i.e., ignitability, corrosivity, reactivity, or toxicity). EPA issued this interpretation in 1994 for the P-listed pharmaceutical epinephrine. In an April 2008 letter[12], EPA extended this interpretation to all P-listed or U-listed pharmaceuticals.

4.3.4 Proposed Universal Waste Rule

In December 2008, EPA **proposed** adding hazardous pharmaceutical wastes to the Universal Waste Rule in order to provide an alternate system for management of hazardous pharmaceutical wastes that is protective of public health and the environment. The proposed addition is intended to make it easier for generators to collect and properly dispose of these items as hazardous wastes, resulting in a simpler and more streamlined waste management system. This proposed rule would apply to pharmacies, hospitals, doctors' offices, dentists' offices, outpatient care centers, ambulatory health care services, residential care facilities, veterinary clinics, and other facilities that generate hazardous pharmaceutical wastes.

Under the **proposed** universal waste program, generators of hazardous pharmaceutical wastes will have the option of managing these wastes as "universal wastes." If the facility chooses to manage its hazardous pharmaceutical waste under the **proposed** universal waste option once the rule is finalized and adopted by its state, then the facility will become a "handler" of pharmaceutical universal waste, rather than a "generator" of hazardous pharmaceutical waste. Compared to a generator of hazardous pharmaceutical waste, as a handler of pharmaceutical universal waste, the facility will have the following benefits: 1) an increased accumulation volume threshold for small quantity handlers; 2) an increased on-site accumulation time limit; 3) no manifest requirement; and 4) simplified training requirements.

Currently, EPA is reviewing public comments received on the proposed rule. EPA expects that this rule will be finalized in 2011. This draft guidance document will be updated to reflect the final rule.

[12] Available online at: http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/$file/14788.pdf

4.4 Recommended Management of Nonhazardous Unused Pharmaceuticals

Nonhazardous[13] pharmaceuticals include both controlled and non-controlled substances. Section 4.5 outlines how EPA recommends that health care facilities manage controlled substances that are not hazardous waste under RCRA. For unused non-controlled pharmaceuticals, EPA recommends that health care facilities send the pharmaceuticals to a reverse distributor for potential credit and proper disposal[14]. For unused non-controlled pharmaceuticals that cannot be sent to a reverse distributor, EPA recommends that the facility segregate the nonhazardous pharmaceutical wastes from other solid wastes. Nonhazardous pharmaceutical waste should not be sewered, but rather should be disposed in a solid waste landfill or incinerated in a solid waste incinerator[15]. When commingling nonhazardous pharmaceutical waste with other solid waste, EPA recommends that the facility:

Red Bags/Sharps Containers Should Not Be Used

As a best management practice, unused pharmaceuticals should not be disposed of with biohazardous waste or red bag waste. Biohazardous waste is typically sterilized (e.g., in an autoclave) prior to disposal in landfills. The temperature achieved during autoclaving is insufficient to destroy most pharmaceutical ingredients. During sterilization, wastewater potentially containing pharmaceuticals may be generated and discharged to the sewer, through which it reaches waterways. EPA's goal is to keep pharmaceuticals out of U.S. waters.

1. Take the medication out of the original containers.
2. Mix medication, either liquid or solid, with an undesirable substance. Undesirable substances include sand, coffee grounds, kitty litter, or other absorbent materials.
3. Place the waste mixture in a sealable bag, empty can, or other container to prevent leakage.
4. Dispose with the solid waste (i.e., regular trash).

Use of Specialty Waste Haulers by Hospitals

The hospital pharmacies that EPA visited used specialty waste haulers for their segregated nonhazardous pharmaceutical waste.

EPA also recognizes that there are drug disposal kits and drug removal technologies available for use by health care facilities. EPA does not recommend or endorse a particular product for health care facilities. EPA does acknowledge that these technologies may be effective.

If the facility segregates and manages its unused pharmaceuticals separately from other solid wastes and uses a specialty waste hauler for the pharmaceutical waste, the facility may not need to mix medication with an undesirable substance. Any waste identified as hazardous should be disposed as discussed in Section 4.3.

[13] Nonhazardous: not a federally-listed or state-listed hazardous waste and does not meet a federal or state hazardous waste characteristic.

[14] EPA strongly recommends that the state regulatory agency is consulted to ensure compliance with all state environmental regulations when unused pharmaceuticals are sent to reverse distributors.

[15] Nonhazardous wastes (or solid wastes) are regulated at the state or local level. Please contact the state regulatory agency for restrictions on the disposal of nonhazardous pharmaceutical wastes in solid waste landfills.

4.4.1 Chemotherapy Pharmaceuticals

Health care facilities generate trace chemotherapy waste (yellow bag waste), hazardous chemotherapy waste (sometimes referred to as bulk chemotherapy waste), and nonhazardous chemotherapy waste. Trace chemotherapy waste includes empty IV bags, tubings, gowns, etc. that may be contaminated with nonhazardous chemotherapy pharmaceuticals. Yellow bags with trace chemotherapy waste are typically picked up by a specialty waste hauler and disposed of via medical waste incineration. Hazardous waste from chemotherapy treatment and non-RCRA-empty[16] containers that once contained hazardous chemotherapy pharmaceuticals must be managed in accordance with applicable hazardous waste regulations, as described in Section 4.3.

While not all chemotherapy pharmaceutical waste may be regulated as hazardous under the federal RCRA regulations, EPA recommends that facilities manage all unused chemotherapy pharmaceuticals as hazardous waste as a best management practice.

4.4.2 Radioactive Pharmaceuticals

Collect and store radioactive pharmaceutical waste in accordance with NRC regulations (10 CFR Part 20). Radioactive pharmaceuticals that are also RCRA hazardous wastes when disposed (i.e., mixed wastes) are regulated by multiple agencies. The hazardous portion is regulated by EPA or the authorized state, while the radioactive component of the waste is regulated under the Atomic Energy Act (AEA) by either the NRC or the Department of Energy (DOE).[17] Section 1006 of RCRA states that if RCRA regulations are inconsistent with the AEA requirements, then the RCRA regulations do not apply. Therefore, if a facility managing a mixed hazardous pharmaceutical waste under RCRA subtitle C encounters RCRA requirements that are inconsistent with the AEA requirements, the AEA requirements apply. However, as discussed in the Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste (62 FR 62079, 62085; November 20, 1997), an inconsistency occurs when compliance with one statute or set of regulations would necessarily cause non-compliance with the other and relief from an inconsistency would be limited to that specific RCRA requirement, and that the determination of inconsistency would not relieve the generator from all other RCRA requirements.

4.5 Identifying Controlled Substances

The Drug Enforcement Administration (DEA) regulates the distribution, shipping, and transfer of controlled substances. The Controlled Substances Act (CSA) includes requirements for transferring (recordkeeping) controlled substances (e.g., narcotics, opiates, and stimulants). For a list of controlled substances, go to the following DEA Office of Diversion Control website: http://www.deadiversion.usdoj.gov/schedules/index.html. Some example pharmaceuticals on the controlled substance list include the following:

- Codeine;
- Diazepam;
- Dextropropoxyphene dosage forms (e.g., propoxyphene);

[16] See Section 4.3.2 for the definition of RCRA-empty.

[17] The NRC regulates radioactive wastes generated by commercial entities or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

- Fentanyl;
- Hydrocodone;
- Hydromorphone and Hydrocodone combination product;
- Lorazepam;
- Morphine; and
- Oxycodone.

4.5.1 Requirements for Managing Controlled Substances

The CSA has specific requirements on how to handle controlled pharmaceuticals. These requirements prohibit the transfer or shipping of controlled substances from health care facilities to any other entity, unless the transfer occurs between DEA registrants. As a result, a health care facility can send unused stock of controlled substance pharmaceuticals to another facility for reuse or disposal if both facilities are DEA registrants.

If the facility is a DEA registrant, such as a pharmacy, hospital, or a practitioner, the facility has options for disposing of an unused controlled substance. It may destroy the unused pharmaceutical in accordance with state guidance and with appropriate documentation; or send the waste to a DEA-registered reverse distributor[18].

If the facility is a non-DEA registrant, such as a long-term care facility, it must directly dispose of controlled substances, except that DEA allows returns when the storage, dispensing, and returning occurs using an automated dispensing system (ADS) operated by a DEA-registered pharmacy.

A health care facility cannot return patient dispensed (even unit dosing) controlled substances. If pharmaceuticals have been dispensed under a prescription, the controlled substance cannot be sent to a registrant. Non-DEA registrants may dispose of controlled substances upon instruction by DEA Special Agents in Charge. This procedure involves the non-DEA registrant submitting a letter to the local DEA Special Agent in Charge. The letter must include:

- Name and address of the person;
- Name and quantity of each controlled substance to be disposed of;
- How the applicant obtained the controlled substance, if known; and
- Name, address, and registration number of the person who possessed the controlled substance prior to the applicant, if known.

Provided such disposal is permissible under the CSA, the Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance through any of the following methods: 1) transfer of the substance to a person registered under the CSA and authorized to possess the substance; 2) delivery to an agent of the Administration or to the nearest office of the Administration; 3) by destruction in the presence of an agent of the Administration or other authorized person; or 4) by such other means as the Special Agent in Charge may determine to ensure that the substance does not become available to unauthorized persons. Though this is an option currently available to end users, it is used in extremely limited circumstances.

[18] Please confer with state and/or local environmental agencies to ensure regulatory compliance when using reverse distributors.

Typically, the facility needs to destroy the unused controlled substances on site, witnessed by two health care professionals, generally a pharmacist and a nurse or two nurses. Two-witness destruction practices that EPA identified in use at health care facilities include disposal down the drain and crushing and mixing the controlled substances with an undesirable material (e.g., absorbent material such as kitty litter, sand, or coffee grounds). For personnel safety reasons, EPA does not recommend that pharmaceuticals be crushed and recommends that medications be disposed of unaltered.

Facilities may use disposal down the drain sewer (or flushing) as an acceptable destruction option for controlled substances. **However, EPA recommends that health care facilities use other destruction options (see below).**

Red Bags/Sharps Containers Should Not Be Used

As a best management practice, unused pharmaceuticals should not be disposed of with biohazardous waste or red bag waste. Biohazardous waste is typically sterilized (e.g., in an autoclave) prior disposal in landfills. The temperature achieved during autoclaving is insufficient to destroy most pharmaceutical ingredients. During sterilization, wastewater potentially containing pharmaceuticals may be generated and discharged to the sewer, through which it reaches waterways. EPA's goal is to keep pharmaceuticals out of U.S. waters.

4.5.2 Recommended Management of Controlled Substances

For unused controlled pharmaceuticals, EPA recommends that health care facilities send the pharmaceuticals to a reverse distributor for potential credit and proper disposal[19]. Facilities may also send the unused stock of controlled pharmaceuticals back to their pharmacy for proper disposal. If the facility is not a DEA registrant, it can check with the regional DEA and state board of pharmacy to request approval to send controlled substances back to the pharmacy for disposal. How non-DEA registrants handle controlled substances may change based on an on-going review by DEA (see 74 FR 3480, January 21, 2009).

If the facility cannot send unused controlled substances back to the pharmacy or to a reverse distributor, follow the steps outlined below.

Controlled Substances that are RCRA Hazardous

EPA strongly discourages the practice of sewer disposal for pharmaceuticals wastes that are both hazardous wastes under RCRA and controlled substances. Any controlled substance identified as hazardous should be managed in accordance with federal, state, and local hazardous waste regulations as well as the Controlled Substances Act and DEA regulations.

Controlled Substances that are Nonhazardous

For unused, nonhazardous controlled pharmaceuticals that cannot be sent to a reverse distributor or pharmacy for disposal (because the reverse distributor or pharmacy will not accept it), EPA recommends that the facility dispose of with solid waste (i.e., regular trash). For disposal with regular trash, EPA recommends that the facility:

[19] EPA strongly recommends that facilities consult with their state regulatory agency to ensure compliance with all state environmental regulations when unused pharmaceuticals are sent to reverse distributors.

1. Take the medication out of the original containers.
2. Mix medication, either liquid or solid, with an undesirable substance. Undesirable substances include sand, coffee grounds, kitty litter, or other absorbent materials.
3. Place the waste mixture in a sealable bag, empty can, or other container to prevent leakage.
4. Dispose with the solid waste (i.e., regular trash).

If the facility segregates controlled substances that are nonhazardous pharmaceuticals from other solid wastes, the mixing with an undesirable substance may not be necessary, but the waste must be managed in accordance with the Controlled Substances Act and DEA regulations.

4.6 Additional Resources for Identifying Waste Types

The U.S. EPA's hazardous waste website, http://www.epa.gov/osw/hazard/index.htm can help health care facilities correctly identify unused pharmaceutical types and proper disposal requirements. Other publications and websites may also provide assistance, such as Practice Greenhealth's *Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States* and the Healthcare Environmental Resource Center (HERC). See Section 6 for websites and other resources. Facilities can also purchase proprietary databases from commercial services (for example, PharmEcology's PharmE® Inventory Analysis or PharmWaste Technology, Inc.'s Pharmaceutical Waste-ID Systems™)[20].

[20] EPA does not endorse any of these services but has provided them as an additional resource.

Table 3. Recommended Management of Unused Pharmaceuticals

Unused Pharmaceutical Stream	Pharmaceutical Type	Medication Form	Best Management Practices, Listed in Order of Preference (X – Recommended by EPA for type and form of pharmaceutical)				
			Donation [a]	Reverse Distribution [b]	Management as Hazardous Waste [c]	Solid Waste Incineration [d]	Disposal in Solid Waste Landfill After Mixing with Undesirable Substance
Unopened/not yet expired	Non-Controlled Substance	Solid (tablet, capsule)	X	X	X (if pharmaceutical is a RCRA hazardous waste)	X	X
		Liquid (IV, vials, drops)	X	X		X	X
		Gels, creams, and lotions)	X	X		X	X
		Patches	X	X		EPA requests input on BMPs	EPA requests input on BMPs
		Orally inhaled and nasal drug products	X	X		EPA requests input on BMPs	EPA requests input on BMPs
	Controlled Substance [e]	Solid	X	X	X (if pharmaceutical is a RCRA hazardous waste)	X	X
		Liquid	X	X		X	X
		Gels, creams, and lotions)	X	X		X	X
		Patches	X	X		EPA requests input on BMPs	EPA requests input on BMPs
		Orally inhaled and nasal drug products	X	X		EPA requests input on BMPs	EPA requests input on BMPs
	Chemotherapy Pharmaceutical	All	X	X	X		
	Biohazardous	Syringe contents [f]				X	X
		EPA requests input on any other form				X	X
	Hazardous and biohazardous "dual" waste	Syringe contents [f]			X		
		EPA requests input on any other form			X		

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Unused Pharmaceutical Stream	Pharmaceutical Type	Medication Form	Best Management Practices, Listed in Order of Preference (X – Recommended by EPA for type and form of pharmaceutical)				
			Donation [a]	Reverse Distribution [b]	Management as Hazardous Waste [c]	Solid Waste Incineration [d]	Disposal in Solid Waste Landfill After Mixing with Undesirable Substance
Unopened/ expired	Non-Controlled Substance	Solid		X	X (if pharmaceutical is a RCRA hazardous waste)	X	X
		Liquid		X		X	X
		Gels, creams, and lotions)		X		X	X
		Patches		X		EPA requests input on BMPs	EPA requests input on BMPs
		Orally inhaled and nasal drug products		X		EPA requests input on BMPs	EPA requests input on BMPs
	Controlled Substance [e]	Solid		X	X (if pharmaceutical is a RCRA hazardous waste)	X	X
		Liquid		X		X	X
		Gels, creams, and lotions)		X		X	X
		Patches		X		EPA requests input on BMPs	EPA requests input on BMPs
		Orally inhaled and nasal drug products		X		EPA requests input on BMPs	EPA requests input on BMPs
	Chemotherapy Pharmaceutical	All		X	X		
	Biohazardous	Syringe contents [f]				X	X
		EPA requests input on any other form				X	X
	Hazardous and biohazardous "dual" waste	Syringe contents [f]			X		
		EPA requests input on any other form			X		

Table 3. Recommended Management of Unused Pharmaceuticals

Unused Pharmaceutical Stream	Pharmaceutical Type	Medication Form	Best Management Practices, Listed in Order of Preference (X – Recommended by EPA for type and form of pharmaceutical)				
			Donation [a]	Reverse Distribution [b]	Management as Hazardous Waste [c]	Solid Waste Incineration [d]	Disposal in Solid Waste Landfill After Mixing with Undesirable Substance
Opened	Non-Controlled Substance	Solid			X (if pharmaceutical is a RCRA hazardous waste)	X	X
		Liquid				X	X
		Gels, creams, and lotions)				X	X
		Patches				EPA requests input on BMPs	EPA requests input on BMPs
		Orally inhaled and nasal drug products				EPA requests input on BMPs	EPA requests input on BMPs
	Controlled Substance [e]	Solid			X (if pharmaceutical is a RCRA hazardous waste)	X	X
		Liquid				X	X
		Gels, creams, and lotions)				X	X
		Patches				EPA requests input on BMPs	EPA requests input on BMPs
		Orally inhaled and nasal drug products				EPA requests input on BMPs	EPA requests input on BMPs
	Chemotherapy Pharmaceutical	All			X		
	Biohazardous	Syringe contents [f]				X	X
		EPA requests input on any other form				X	X
	Hazardous and biohazardous "dual" waste	Syringe contents [f]			X		
		EPA requests input on any other form			X		

a – If allowed by the state.
b – Reverse distribution of controlled substances is only permissible by 1) DEA registrants; or 2) with special permission from the state. EPA strongly recommends that facilities contact their state regulatory agency to ensure compliance with all state environmental regulations when unused pharmaceuticals are sent to reverse distributors.
c – RCRA hazardous waste requirements depend on the quantity of waste generated in a month. If the facility qualifies as a conditionally-exempt small quantity generator (CESQG), the waste may not need to be disposed of at a RCRA-permitted hazardous waste facility.
d – Solid waste incineration includes incineration in units that are subject to 40 CFR 60 subpart Cb, Eb, AAAA, BBBB, CCCC, DDDD, EEEE, and FFFF.
e – Dispose in accordance with the Controlled Substances Act and DEA requirements.
f – Empty syringe contents; dispose of empty syringe in red sharps container.

5. STARTING A WASTE MANAGEMENT PROGRAM

EPA recommends that health care facilities implement a waste management program that includes waste segregation to ensure that facilities meet all applicable regulations and potentially minimize costs. For example, by separating the nonhazardous pharmaceutical waste from hazardous pharmaceutical waste, facilities may minimize cost and still comply with applicable federal regulations. Another important part of the waste management program is to communicate with staff so all pharmaceuticals are disposed properly.

5.1 Waste Segregation

The waste management plan should include a process to segregate pharmaceutical waste by how the facility plans to dispose of them. The process can identify the type of pharmaceutical (controlled or non-controlled, hazardous or nonhazardous, chemotherapy) either at time of delivery or when waste is collected. For example, some facilities find it useful after delivery and during stocking, to apply color-coded stickers on supplies that match the disposal bin color placed at their facility to collect and segregate various types of waste (e.g., black color indicates hazardous waste).

5.2 Training Staff in Proper Disposal Methods

After developing a waste management plan, the facility should train staff (pharmacy personnel, nurses on the patient floors, and others who will manage unused pharmaceuticals) to recognize the type of unused pharmaceutical and its proper disposal. The staff should recognize when unused pharmaceuticals should be returned to the pharmacy and when they should be disposed of and how. Training should be revisited to update and refresh staff on proper unused pharmaceutical management and waste handling. Staff can also provide feedback on how the program is working and ways to improve the process.

Posters and signs should also be placed near disposal areas to remind staff of disposal policies. During periodic pharmaceutical stock inventory, consider auditing waste disposal practices to determine how well facility staff is following the waste management plan. With the audit findings, the facility can identify where additional training is needed.

6. OTHER RESOURCES

U.S. Drug Enforcement Administration (DEA) website: http://www.deadiversion.usdoj.gov

U.S. EPA RCRA hazardous waste website: http://www.epa.gov/osw/hazard/

The following is a list of various RCRA documents that pertain to pharmaceutical wastes. These documents are publicly available in the RCRA Online database:
http://www.epa.gov/epawaste/inforesources/online/index.htm

- Scope of P042 (epinephrine) listing memo (RCRA Online #14778):
  http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2F701627EB73B2AB852573D2005E0B4F/$file/14778.pdf

- Epinephrine residue in a syringe is not P042 (RCRA Online #13718):
  http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/$file/13718.pdf

- Syringes containing P- or U-listed residues are not hazardous waste (RCRA Online #14788):
  http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/$file/14788.pdf

- Regulation of medicinal nitroglycerine (RCRA Online #14654):
  http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7ACFEC572DE8897F85256D1600748BCB/$file/14654.pdf

- Hazardous Waste Generator Regulations: A User-Friendly Reference Document (RCRA Online #51186):
  http://www.epa.gov/epawaste/hazard/downloads/tool.pdf

- Hazardous Waste Listings: A User-Friendly Reference Document:
  http://www.epa.gov/epawaste/hazard/wastetypes/pdfs/listing-ref.pdf

NIOSH Pocket Guide to Chemical Hazards: http://www.cdc.gov/niosh/npg/default.html

U.S. Department of Health and Human Services – HIPAA Privacy Rule:
http://www.hhs.gov/ocr/privacy/

National Association of Boards of Pharmacy: http://www.nabp.net/

American Society of Consultant Pharmacists: http://www.ascp.com/

American Society of Health-System Pharmacists: http://www.ashp.org/

State Waste Programs, including hazardous waste (links):
http://www.epa.gov/epawaste/wyl/stateprograms.htm

State Medical Waste Programs and Regulations (links):
http://www.epa.gov/osw/nonhaz/industrial/medical/programs.htm

Example of State Guidance:

- Minnesota Technical Assistance Program (MNTAP): http://www.mntap.umn.edu/
- Kansas' *Disposal Options for Expired or Surplus Medications/Pharmaceuticals*: http://www.kdheks.gov/waste/techguide/sw07-01.pdf

Healthcare Environmental Resource Center: http://www.hercenter.org/index.cfm

- State program locator for hazardous waste (http://www.hercenter.org/hz.cfm)
- State medical waste locator (http://www.hercenter.org/rmw/rmwlocator.cfm)
- State universal waste programs (http://www.hercenter.org/uw.cfm)

Practice Greenhealth (formerly Hospitals for a Healthy Environment):
http://www.practicegreenhealth.org/

Practice Greenhealth's 10-Step Blueprint (updated August 2008):
http://www.practicegreenhealth.org/tools/toolkit/guides/

APPENDIX A: STATE LAWS AND LOCAL ORDINANCES

State regulations on the management of unused pharmaceuticals vary from no regulation, to encouragement to "follow all applicable laws," to specific destruction and recordkeeping requirements. Practices are regulated by a variety of state entities including departments of health and environment, boards of pharmacy, and licensing agencies. In addition, state rules can vary by type of facility.

State Donation Programs

Some states have programs in place to allow the reuse of unused pharmaceuticals through state repository programs. Typically, these programs allow the reuse of unopened medications (e.g., still in tamper-proof packaging or packaged as unit doses) that are non-controlled substances. Other common requirements include that the medication is properly maintained (e.g., under control by the facility or pharmacy) and expiration date is beyond six months at time of donation.

Before use, the state requires that the unopened medication be inspected or reviewed, often by a pharmacist, to determine if the product is reusable. The type of pharmaceuticals, who can donate, and who can accept the donation varies by state as described in Table A-1. The federal government does not oversee the state programs; all programs listed in the table are managed at the state level.

Table A-1. Summary of State Donation Programs

State	Program Type	Types of Pharmaceuticals	Who Can Donate? [a]	Who Can Accept?	Notes
Arizona	Legislative (HB 2382)	Rx Board will issue list of unacceptable products	Individuals, manufacturers, or health care institutions	Volunteer participants: pharmacies, hospitals, or nonprofit clinics	Effective 6/6/2008; not operational as of 8/2009
Arkansas	Legislative (HB 1031)	Non-controlled substances	Nursing facilities by clinic pharmacies	Charitable clinic pharmacies	Signed 2/15/2005; program is currently in operation
California	Legislative (SB 798)	Prescription drugs	Licensed health care facilities, licensed pharmacies, and drug manufacturers	Established by counties	Signed 9/30/2005; not operational as of 8/2009
Colorado	Legislative (SB 07-231)	Chemotherapeutic drugs and medical devices	Cancer patients or their families	Volunteer participants: pharmacies or health care facilities	Effective 8/8/2007; program is currently in operation
Connecticut	Legislative (HB 6002)	Non-controlled substances	Long-term care facilities	Vendor pharmacies or Department of Social Services	Signed 6/21/2000; program is currently in operation

State	Program Type	Types of Pharmaceuticals	Who Can Donate? [a]	Who Can Accept?	Notes
Florida	Legislative (SB 22A and HB 371)	Chemotherapeutic drugs and supplies	Any entity including individuals, health care facilities, pharmacies, manufacturers, or wholesalers	Volunteer participants: pharmacies or health care facilities	Effective 7/1/2006; program is currently in operation
Georgia	Legislative (HB 430)	Non-controlled, prescription drugs	Any individual or entity including a drug manufacturers or health care facilities	Volunteer participants: pharmacies, hospitals, or nonprofit clinics	Required to be implemented no later than 1/1/2007
Guam	Legislative (Chapter 5, Sections 5103 and 5104)	Not limited except to meet standards established by Guam or the U.S.	Health care facilities, pharmacies, manufacturers, wholesalers, or charitable institutions	Medicine Bank, created at Community Health Centers and various institutional facilities that are government owned and operated	Signed in 2004
Hawaii	Legislative (HB 2005 final)	Prescription drugs previously dispensed or distributed at an institutional facility	Health care facilities (initiated by patients or facility personnel)	Institutional facilities or repositories in the state	Effective 7/1/2004; not operational as of 8/2009
Indiana	Legislative (HB 1251)	Unused medication	Health care facilities	Pharmacy/ pharmacist that dispensed prescription	Effective 7/1/2004; not in operation as of 8/2009; requires the office of Medicaid policy and planning to review the process
Iowa	Legislative (HF 724)	Prescription drugs	Patients	Volunteer participants: pharmacies or medical facilities	Signed 5/3/2005; program is currently in operation

State	Program Type	Types of Pharmaceuticals	Who Can Donate? [a]	Who Can Accept?	Notes
Kansas	Legislative (HB 2578)	Non-controlled substances; donated from a controlled storage unit of the donating entity; excludes drugs purchased under Medicaid or State Children's Health Insurance Program (SCHIP)	Long-term care residents, donating entities (e.g., health care facilities)	Qualifying medical centers or clinics in consultation with pharmacists	Signed 3/20/2008; program is currently in operation
Kentucky	Legislative (SB 23)	Chemotherapeutic (prescription) drugs and supplies; non-controlled substances	Health care facilities, pharmacies	Volunteer participants: pharmacies or health care facilities	Effective 3/18/2005; not in operation as of 8/2009
Louisiana	Legislative (HB 1402)	Prescription drugs	Any individual or entity, including drug manufacturers, health care facilities, or government entities	Charitable pharmacies	Effective 8/15/2004
	Legislative (SB 19)	Prescription drugs	Health care facilities or government entities enrolled in Medicaid program	Charitable pharmacies	Effective 6/29/2006; program is currently in operation
Maine	Legislative (HP 105 and HP 327/LD 411)	Prescription drugs	Health care facilities, manufacturers, or wholesalers	Pharmacies and certain health care facilities	HP 105 effective 5/31/2005; HP 327/ LD 411 provided $300,000 for pilot mail-back program (signed 6/27/2007)
Maryland	Legislative (SB 1059)	Non-controlled, prescription drugs	Individuals	Board-approved drop-off sites and repositories	Effective 7/1/2006; program is currently in operation
Massachusetts	Legislative (Chapter 111, Section 25l)	Unused medication	Residents or consultant pharmacists in health care facilities	Health care facilities	Signed in 2004; program is currently in operation
Michigan	Legislative (Public Act 329 of 2004)	Unused medication from the Department of Corrections	Michigan Department of Corrections		Effective 2004

State	Program Type	Types of Pharmaceuticals	Who Can Donate? [a]	Who Can Accept?	Notes
Minnesota	Legislative (Statute 151.55)	Chemotherapeutic drugs and supplies	Pharmacies, medical facilities, manufacturers, or wholesalers; individuals over 18	Volunteer participants: pharmacies or medical facilities on the premises	Effective 2007; program is currently in operation
Mississippi	Legislative (State Code Section 43-13-503)	Prescription drugs	Any individual or entity, including drug manufacturers, health care facilities, or government entities; the State Board of Pharmacy; the State Department of Health; and the Division of Medicaid	Pharmacies, hospitals, nonprofit clinics, or health care professionals	Was to be implemented by 7/1/2005; not in operation as of 8/2009
Missouri	Legislative (HB 898, SB 1160)	Prescription drugs	Any individual or entity	Volunteer participants: hospitals, pharmacies, nonprofit clinics	Effective 8/28/2004; program is currently in operation
	Legislative (HB 1687)	Prescription drugs	Any individual or entity, including but not limited to manufacturers or health care facilities		Approved 7/12/2006; not in operation as of 4/2009
Montana	Legislative (SB 288)	Non-controlled, prescription drugs	Long-term care facilities	Provisional community pharmacies	Effective 10/1/2001; program is currently in operation
Nebraska	Legislative (LB 756 and LB 1116)	Chemotherapeutic drugs	Any individual or entity, including but not limited to manufacturers or health care facilities	Volunteer participants: physician's offices, pharmacies, hospitals, or health clinics	Effective 9/15/2003 and clarified in 2006; program is currently in operation
Nevada	Legislative (SB 327)	Non-controlled, prescription drugs (unit dose, sealed individual dose, or sealed bottle)	Public or private mental health facilities	Dispensing pharmacies	Effective 7/1/2003; program is currently in operation
New Hampshire	Legislative (State law, NH RSA Section 318.58)	*No details*	*No details*	*No details*	Authorizes reuse program; not in operation as of 12/2009.
New Jersey	Legislative (Title 24)	Prescription drugs	Licensed health care facilities	Same licensed health care facilities	Not operational as of 8/2009

State	Program Type	Types of Pharmaceuticals	Who Can Donate? [a]	Who Can Accept?	Notes
New Mexico	Legislative (SN 82)	Prescription drugs	Corrections facilities with a registered or licensed nurse	Pharmacies operated by or under contract with the Corrections Department	Signed 4/7/2009; program is currently in operation
New York	Legislative (S 2803-e)	Unused medication	Residential health care facilities (by a resident, consultant pharmacist, or designee)	Dispensing pharmacies	Referred to New York Health Department on 1/9/2008
North Carolina	Specific guidelines are being developed for a drug repository/return program [b]				
North Dakota	Legislative (HB 1256)	Prescription drugs	Any individual or entity	Volunteer participants: practitioners or pharmacies	Signed 4/2007; program is currently in operation
Ohio	Legislative (HB 221)	Prescription drugs	Any individual, including manufacturers or health care facilities	Volunteer participants: pharmacies, hospitals, or nonprofit clinics	Signed 1/6/2003. Program is currently in operation.
Oklahoma	Legislative (HB1297 and SB 1640)	Non-controlled, prescription drugs	Long-term care facilities, public intermediate care facilities for people with mental retardation (ICF/MR), or manufacturers	Certain pharmacies or charitable clinics	Effective 11/1/2006; program is currently in operation
Oregon	Repository/donations not permitted; return and reuse of medications allowed only in long-term care pharmacies where drugs have not been dispensed (remain in control of facility staff) [b]				
Pennsylvania	Legislative (SB 638)	Chemotherapeutic drugs	Health care facilities or pharmacies	Authorized, participant pharmacies	Signed 5/13/2008; not in operation as of 8/2009
Rhode Island	Legislative (HB 5107 and HB 5850)	Prescription drugs, including chemotherapeutic drugs	Nursing home, assisted living center, and drug manufacturer	Authorized, participant pharmacy	Not operational as of 8/2009
South Carolina	Repository/donations not permitted; return and reuse of medications allowed based on pharmacist's professional judgment [b]				
South Dakota	Legislative (HB 1165)	Unit-dose medications	Patients in hospice programs, nursing facilities, or assisted living facilities	Hospice programs, nursing or assisted living facilities	Signed 2/19/2004; not in operation as of 8/2009
Tennessee	Legislative (HB 3560 and SB 3660)	Non-controlled, prescription drugs	Nursing home or hospice services	Charitable clinic pharmacies	Effective 7/1/2006; program is currently in operation

State	Program Type	Types of Pharmaceuticals	Who Can Donate? [a]	Who Can Accept?	Notes
Texas	Legislative (SB 1896)	Non-controlled substances	Pharmacists who practice in or consult with a health care facility; licensed health care professionals responsible for administration of drugs in a penal institution	Pharmacies	Signed 6/15/2007; program is currently in operation
Utah	Legislative (58-17b-503)	Non-controlled, prescription drugs	Pharmacists receiving return; drug must have been prescribed to a patient in a nursing care facility, ICFMR, state prison, county jail, or state hospital	Dispensing pharmacy	Effective 7/1/2005; not in operation as of 8/2009
Vermont	Legislative (H. 711)	Prescription drugs (unsold or unused)	Health care facilities or wholesale distributors	Volunteer participants: pharmacies, hospitals, or nonprofit clinics	*No details*
Virginia	Legislative (HB 154, HB 1854, and HB 2682)	Prescription drugs	Hospitals (medications dispensed to patients but not used)	Pharmacies, clinics (2005), or hospitals (2009)	Signed 4/6/2002 and 3/24/2005; program is currently in operation
West Virginia	Return of unit-dosed, non-controlled substances allowed [b]				
Wisconsin	Legislative (SB 56)	Prescription drugs	State prison pharmacies	State prison pharmacies	Approved 8/20/2003
	Legislative (AB 845 and AB 197)	Chemotherapeutic drugs and supplies; prescription drugs for all other chronic diseases (e.g., diabetes)	Any individual or entity	Volunteer participants: medical facilities or pharmacies	Enacted 4/6/2004; expanded in 2005
Wyoming	Legislative (HB 194)	Prescription drugs	Any individual or entity, including but not limited to manufacturers, physicians, or health care facilities	Volunteer participants: pharmacies, physicians, or health care facilities	Signed 3/2/2005; program is currently in operation

Source: National Conference of State Legislatures (NCSL), State Prescription Drug Return, Reuse and Recycling Laws (website), http://www.ncsl.org/programs/health/rx-reuse.htm. Accessed July 1, 2010.
[a] – Health care facility may include hospitals, long-term care facilities, medical clinics, physician offices, et al. Check the state program's definition of health care facility.
[b] – National Association of Boards of Pharmacy, *2009 Survey of Pharmacy Law*

State Regulations for the Disposal of Unused Pharmaceuticals

States generally do not specifically regulate the disposal of unused pharmaceuticals, but some regulate pharmaceutical management and disposal options, or they provide guidance. Some states require unused pharmaceuticals to be destroyed but do not specify the process of

destruction; however, many states have requirements for the types of personnel required to conduct and oversee the destruction, especially for controlled substances. States may also have more stringent requirements than EPA for the disposal of hazardous waste. Check with the state environmental management agency for more details. To identify state requirements, facilities can check the state links provided at the following website: http://www.epa.gov/osw/nonhaz/industrial/medical/programs.htm or the state program locators at http://www.hercenter.org/regsandstandards/stateandlocal.cfm.

APPENDIX B: SAMPLE UNUSED PHARMACEUTICAL TRACKING SHEET

Location	Date	Pharmaceutical Name	Form	Strength	Amount Wasted	Disposal Method	Reason Wasted	Notes
Example: Pharmacy	*01/01/2010*	*Hydrocodone*	*Tablet*	*5 mg*	*25 tablets*	*Reverse distribution*	*Expired*	
Example: Room 512	*01/01/2010*	*Hydrocodone*	*Tablet*	*5 mg*	*1 tablet*	*Drain*	*Patient refused*	
Example: Med sta 3	*01/01/2010*	*Amoxicillin*	*Liquid*	*125 mg/5mL*	*15 mL*	*Trash can*	*Patient discharged*	*Opened bottle*

Location: Nurses station number or pharmacy
Form: tablet, capsule, vial, IV, cream, gel, emulsion, inhalant, etc.
Amount wasted: number of items or liquid volume

APPENDIX C: CONSIDERATIONS WHEN CONTRACTING WITH A SPECIALTY WASTE HAULER

Your facility might want to consider the following factors when choosing a specialty waste hauler. Remember: you are hiring a company to transport your waste, but the waste is still yours and is still your responsibility.

Confirm that the specialty waste hauler is familiar with all regulations that apply to your facility.
Your specialty waste hauler should be aware of all federal, state, and local pharmaceutical disposal, storage, and transport laws. If you are not familiar with the regulations, ask the specialty waste hauler for a list of regulations and have them explain to you what laws apply. Federal agencies that may regulate waste disposal include the following:

- U.S. Environmental Protection Agency (EPA): http://www.epa.gov/;
- Occupational Safety and Health Administration (OSHA): http://www.osha.gov/;
- U.S. Department of Transportation (DOT): http://www.dot.gov/;
- Nuclear Regulatory Commission (NRC): http://www.nrc.gov/;
- Centers for Medicare and Medicaid Services (CMS): http://www.cms.hhs.gov/; and
- Centers for Disease Control and Prevention (CDC): http://www.cdc.gov/.

Other regulations may be required by state health departments, environmental boards, and Medicaid programs and local health departments.

Confirm that the hauler dedicates resources to keep current with regulations, such as an environmental regulations department. Regulations are updated often, and you will want your hauler to be familiar with the latest requirements.

Get to know the hauler staff.

- Have they been properly trained? Are they familiar with the laws governing waste handling, transport, and storage of the types of waste your facility generates?
- Can they handle emergencies, such as natural disasters and spills?

Get to know the company.
Where do they take your waste? How does it get there?
Does your hauler deliver it directly to a landfill or incinerator?
Does your hauler operate the landfill or incinerator? Are they licensed to do so?
Does your hauler transport your waste to another hauler?
Do they provide you adequate records, such as waste manifests?
Can they provide proof of training for hauler employees and hauler insurance?

Request full service.
Request training for you and your staff on waste management. Make sure proper transport and disposal records are provided to you. At a minimum, you should receive a waste manifest identifying the types and quantities of waste and their destination[21]. Will they provide assistance with drug inventories?

[21] RCRA includes manifest requirements for large quantity and small quantity generators (LQGs and SQGs).