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KNOW BEFORE YOU THROW: PHARMACEUTICAL WASTE AND DRUG DISPOSAL

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LEARNING OBJECTIVES

Upon completion of this module, the subscriber will be able to:

1. Identify events which lead to the generation of pharmaceutical waste during the "lifecycle" of a medication.
2. Describe regulatory agency involvement regarding pharmaceutical waste practices.
3. Explain drug disposal methods in community and hospital settings.
4. Review ways to successfully comply with drug disposal requirements in community and hospital settings.
5. List public disposal options for different types of household pharmaceuticals and how to promote these options.

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KNOW BEFORE YOU THROW: PHARMACEUTICAL WASTE AND DRUG DISPOSAL

INTRODUCTION

Patterns of prescription drug use show an increasing number in the United States (US). According to results from a 2015-2016 National Health and Nutrition Examination Survey, 45.8% of the US population used prescription drugs in the past 30 days and drug use increased with age.[1] There are over 5 billion annual prescriptions and incremental increases in prescriptions dispensed each year. From 2013 to 2017, annual dispenses of a 90-day medication supply increased from 570 million to 688 million prescriptions.[2]

Pharmaceutical waste is generated in hospitals, community pharmacies, and patient households when drugs become unused, unwanted, or expired. Appropriate drug disposal practices for different pharmaceutical waste classifications across each of these sites vary.

Inappropriate pharmaceutical waste and drug disposal may lead to harmful consequences that threaten public health and the environment. Pharmaceuticals such as antibiotics, analgesics, and estrogens are frequently measured in US drinking water.[3] For example, a study was initiated in 2019 to identify the presence of pharmaceuticals, hormones, and other contaminants in 1,019 water wells and springs across 46 states. Pharmaceuticals, hormones, and other contaminants were discovered in 60% of the water sources.[4] In 2018, the Washington Department of Fish and Wildlife reported traces of oxycodone in the mussels fished from the Seattle and Bremerton area harbors.[5]

Pharmacy technicians in hospitals and community pharmacy settings are pharmaceutical waste and drug disposal stakeholders who should be included in the design and application of related organizational policies and procedures. Pharmacy technicians in community pharmacies are also stakeholders well positioned to educate patients about recommended drug disposal practices. Respective state and federal regulations regarding patient counseling should be followed. As more prescription drugs enter the drug supply chain and patient households, pharmacy technician efforts to increase public awareness of appropriate pharmaceutical waste and drug disposal are critical.

MEDICATION LIFE CYCLE

An understanding of the medication life cycle will simplify the events leading to generation of pharmaceutical waste and subsequent drug disposal. The medication life cycle includes:

1. Manufacturing
2. Distribution
3. Inventory
4. Dispensing

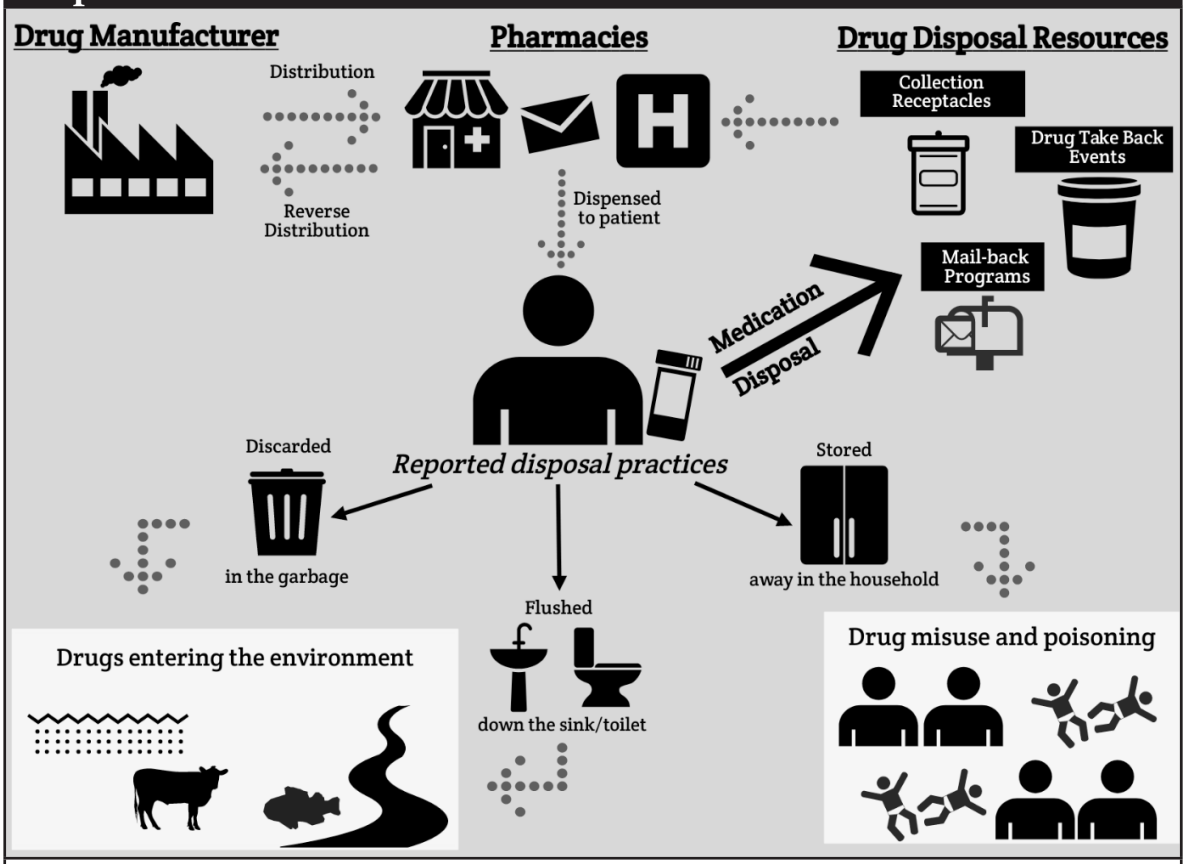
Pharmaceutical companies manufacture drugs in specific package sizes using active and inactive ingredients. Active ingredients have predictable and limited stability and sterility, and therefore medications will have expiration dates that patient administration should not occur after. Manufactured drugs enter the drug supply chain when shipped from pharmaceutical companies to either drug wholesalers or direct to pharmacies. Transportation of medications must be performed with specific handling conditions (ie. temperature, light, humidity, etc.) to maintain drug effectiveness.

Demand created from prescriptions and/or historical patient use will prompt pharmacies to purchase and store drug quantities that are sufficient to meet patient care needs. Maintaining medication inventory levels requires a fine balance between enough supply on hand to meet patient care needs vs. too much supply on hand to avoid excessive carrying costs and medication expiration. There are various stressors on demand and the drug supply chain, including shortages of active ingredients, drug manufacturer business decisions, natural disasters, and pandemics.

Authorized prescribers provide patient access to medication for disease treatment and prevention in the form of a medication order or prescription. A patient who receives a prescribed drug as part of disease treatment or prevention is known as the **ultimate user**. Patients should store medications with specific handling conditions to maintain the drug integrity and effectiveness.

A summary overview of the medication life cycle and implications as it relates to patient drug disposal is found in **Figure 1** on page 4.

Figure 1. Medication Life Cycle and Implications of Common Disposal Practices[3-8]



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Hospital Pharmaceutical Waste Sources

Nurses are the primary healthcare professionals responsible for medication administration to hospitalized patients in hospitals. Generally, these medications are retrieved by nurses from an onsite pharmacy or the patient care unit medication room. Prescribed medications for hospitalized patients are often dispensed by the pharmacy in single unit doses to fulfill a medication order for patient administration.

Hospital technologies such as automated centralized inventory dispensing systems and decentralized dispensing cabinets provide virtual medication expiration date monitoring which decreases pharmaceutical waste generation from expired medication sources. Organization policies typically define pharmacy technician roles and responsibilities to maintain medication inventory within expiration dating.

Despite medication dispensing primarily in single unit doses and the automation that maintains medication inventory within expiration dating, hospitals continue to generate significant amounts of pharmaceutical waste. Some examples of sources of pharmaceutical waste include:

1. Medication is not administered prior to the expiration date.

   Thirty sodium bicarbonate vials are stored in automated dispensing cabinet inventory and only two vials are administered in that respective patient care unit's patients each year. Therefore, much of the sodium bicarbonate vials with future expiration dating expired before use.
2. Medication is prepared with an error discovered by the pharmacist during product verification.

   A pharmacy technician accidentally compounded intravenous phenylephrine with 500 mg instead of the prescribed dose of 250 mg because the medication vial label concentration was difficult to read. The phenylephrine 500 mg dose was not reused for another patient.
3. Medication dose prescribed is not the same as the manufacturer-issued package size.

   A nurse administered fentanyl 50 mcg (1 mL) from a 100 mcg/2 mL vial dispensed from a

patient care unit automated dispensing cabinet. The remaining 1 mL of the fentanyl is not safely stored and/or administered to another patient.

4. Medication order is discontinued by the prescriber before patient administration.

   A patient was prescribed an intravenous cefepime order in a patient-specific dose that was sterile compounded in the hospital's clean room. The prescriber recognized a patient allergy to the antibiotic and the order was cancelled after it was dispensed, but before it was administered to the patient.

5. Medication is improperly stored.

   Seasonal influenza vaccinations are stored in ambulatory clinic refrigerators for retrieval by nurses for patient administration. Over the weekend, there was a power outage and the refrigerator failed to maintain manufacturer-recommended temperature conditions.

6. Medication is "lost" by nursing prior to administration, and a redispense occurs.

   An albuterol MDI inhaler canister that was used by a patient that contains remaining puffs was stored in the patient care unit automated dispensing cabinet for subsequent use. The patient was transferred from that patient care unit to another, but the albuterol MDI inhaler did not transfer at the same time.

Outside of the hospital pharmacy, pharmaceutical waste is likely to accumulate in patient care unit locations such as medication rooms, soiled utility rooms, and nursing stations.

Community Pharmacy Pharmaceutical Waste Sources

Community pharmacies may store, compound, and often dispense more medications (and in larger quantities) than hospitals. Prescription processing most often requires a pharmacy technician to perform prescription order entry into a processing system from a written, faxed, or verbal order. A pharmacy technician then will retrieve the medication from inventory, count the prescribed quantity, and prepare the prescription for pharmacist verification. Lastly, the pharmacist performs therapeutic review, quality assurance, and ensures the appropriate medication product is dispensed.

Community pharmacies generate pharmaceutical waste in similar ways as hospitals. Some examples of sources of pharmaceutical waste include:

1. Medication is not dispensed prior to the expiration date.

   A bulk bottle of ibuprofen was opened and all tablets were not dispensed prior to the expiration date.

2. Medication is prepared with an error discovered by the pharmacist during product verification.

   Famotidine for oral suspension was reconstituted with 56 mL of water instead of 46 mL of water, and therefore the medication was too dilute for infant administration.

3. Medication is improperly stored.

   A package of epoetin alfa vials were unpacked from the drug wholesaler delivery and stored in the -40°C freezer for an extended period of time, which altered the stability of the product active ingredient.

4. Medication is damaged and/or adulterated by pharmacy staff.

   A pharmacy technician accidentally spilled a bottle of lisinopril on the pharmacy floor.

Household Pharmaceutical Waste Sources

The majority of medication use in the US is by way of patient self-administration at home (or administration by a caregiver). Patient access to medication at home is primarily facilitated via a prescription dispensed from community or mail order pharmacies. Quantity of medication dispensed is based on prescription dosing and duration of treatment. Patients also may access over the counter medications without a prescription.

Various days' supply of medication may be dispensed to patients depending upon patient prescription benefits, community pharmacy offerings, and state-specific board of pharmacy regulations. A 90-day maximum supply is often allowed for ongoing, long-term medication management of chronic disease states (ie. hypertension, diabetes, etc).

Households generate pharmaceutical waste in similar and also more unique ways than hospitals and community pharmacies. Some examples of sources of pharmaceutical waste include:

1. Medication is not self-administered (or by caregiver) prior to the expiration date.

   Oxycodone 5mg tablets were prescribed as needed for pain following a surgical procedure. The patient experienced pain control with acetaminophen and did not require oxycodone. Oxycodone remained in the patient medicine cabinet over 1 year and expired.

2. Medication order is discontinued by the prescriber.
   Patient experienced intolerable weight gain from aripiprazole 15 mg. The prescriber provided a prescription for a therapeutic alternative. The patient only used 25 days of a 90-day supply prescription.
3. Medication is improperly stored.
   Insulin aspart was stored by patient at room temperature on kitchen counter for longer than 28 days.
4. Medication is not tolerated.
   A patient experienced abnormal dreams on varenicline and instead pursued over the counter options for smoking cessation.
5. Medication dispensed is not the ordered medication (pharmacy medication error)
   A patient discovered that refilled warfarin prescription tablet was a different color than usual. The patient called the pharmacy and confirmed that 1 mg tablets were accidentally dispensed instead of 5 mg tablets.

As the number of prescriptions dispensed each year increases,[2] pharmaceutical waste within the household may become more prevalent. Patients possess an estimated 40% of unused medications within their homes.[9] Surpluses of unused medications suggests concern with overprescribing and dispensing practices.

PHARMACEUTICAL WASTE CLASSIFICATION

Environmental Protection Agency Pharmaceutical Waste Classification

According to the **Environmental Protection Agency (EPA)**, there are two primary pharmaceutical waste classifications, non-hazardous and hazardous. Specific pharmaceutical waste classification will determine appropriate drug disposal that is detailed later in this continuing education.

Non-Hazardous Pharmaceuticals are medication waste that DO NOT have any of the following characteristics.[10]

1. Ignitable – medication that has flammable vapor or can cause fire through friction, absorption of moisture, or chemical change
2. Corrosive – medication (generally strong acids or bases) that destroys or damages steel
3. Reactive – medication that has properties leading it to be unstable (potentially explosive) when mixed with water or other specific agents
4. Toxic – medication with poisonous elements

Hazardous Pharmaceuticals are medication waste that DO have one or more of the above stated hazardous characteristics and are further categorized according to the **Resource Conservation and Recovery Act (RCRA)**.

There are four different types of hazardous pharmaceutical waste organized into lists. Each list has specific criteria detailed below.[11]

1. "F-list" – pharmaceutical waste consisting of medication created from hazardous manufacturing processes
2. "K-list" – pharmaceutical waste consisting of medication created from source-specific waste
3. "P-list" – pharmaceutical waste consisting of medication that is a commercial chemical product with immediate toxicity
4. "U-list" – pharmaceutical waste consisting of medication that is a commercial chemical product with non-immediate toxicity

The four hazardous pharmaceutical waste lists are available for reference on the EPA website.[8] Of note, the EPA website also recommends to double check with federal and state regulators for further interpretation of pharmaceutical dosage form classifications.

National Institute for Occupational Safety and Health Hazardous Pharmaceutical Waste Classification

The **National Institute for Occupational Safety and Health (NIOSH)** is a research agency focused on creating safe workplace environments with safe working conditions. According to NIOSH, pharmaceuticals (and pharmaceutical waste) are hazardous if they exhibit one of the following characteristics in humans or animals.[12]

1. Carcinogenic (potential to cause cancer)
2. Teratogenic (potential to cause birth defects)
3. Reproductive toxicity (potential to cause adverse effects on sexual function and fertility)
4. Organotoxic at low doses (potential to damage organs)
5. Genotoxic (potential to damage genetic information within cells)
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

NIOSH publishes a list of hazardous medications that was most recently updated in 2016. NIOSH recommends that health care organizations reference this list and other medication-specific references such as package inserts to identify all hazardous pharmaceutical waste that an

employee may encounter in the workplace.[9] Hazardous medications and pharmaceutical waste may then be better identified for appropriate handling and disposal.

PHARMACEUTICAL WASTE AND DRUG DISPOSAL REGULATIONS

All non-hazardous and hazardous pharmaceutical waste and drug disposal is primarily regulated by the following federal government agencies.[13]

1. Environmental Protection Agency (EPA) – The mission of EPA is to protect human health and the environment.
2. Drug Enforcement Administration (DEA) – The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States.
3. Food and Drug Administration (FDA) – The mission of the FDA is to protect public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.
4. Occupational Safety and Health Administration (OSHA) – The mission of OSHA is to ensure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

State environmental and health departments may also regulate pharmaceutical waste.

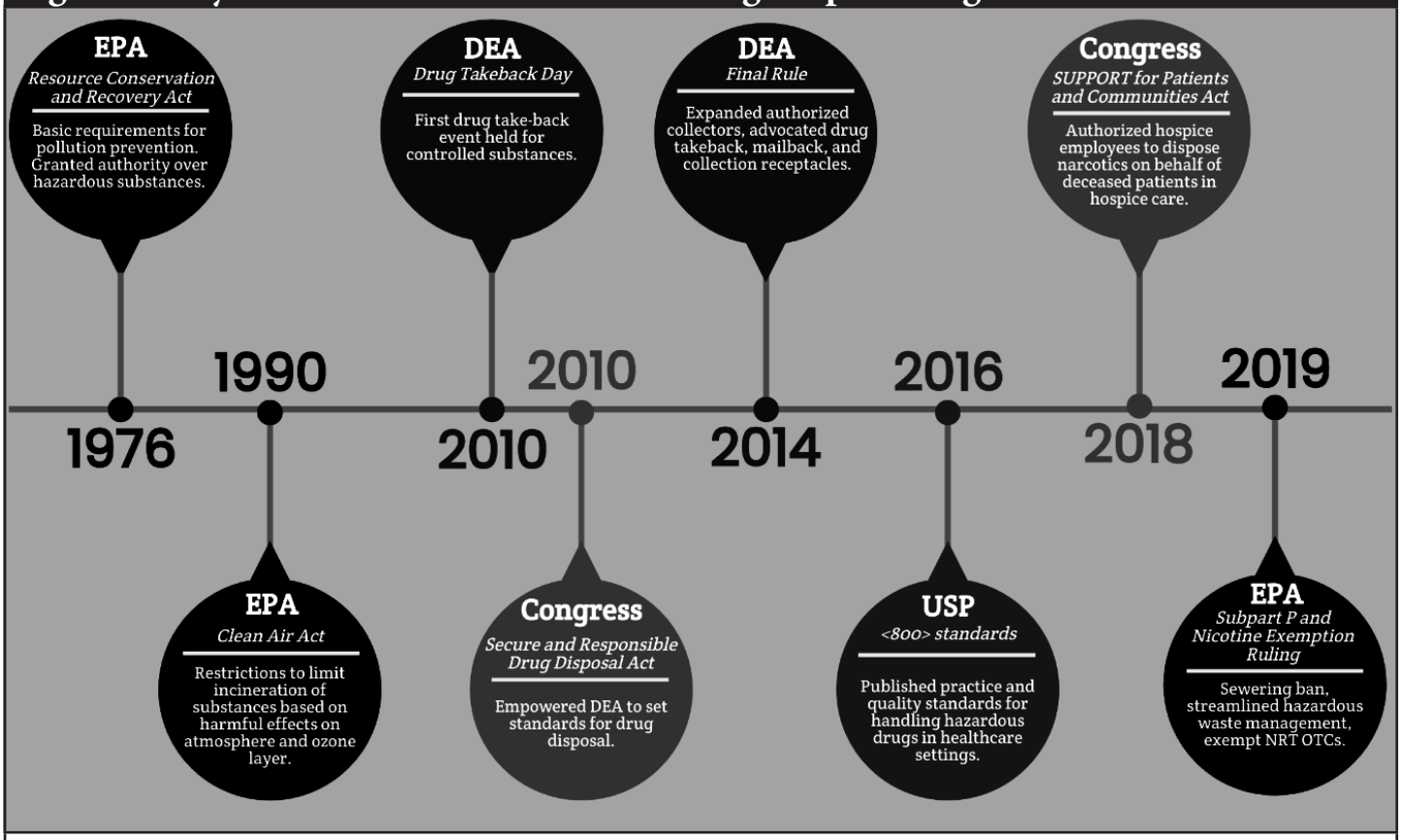
A historical timeline of key regulations that address pharmaceutical waste and drug disposal is found in **Figure 2**.

The EPA and Pharmaceutical Waste

Resource Conservation and Recovery Act

In the 1960s, hazardous wastes received increased national attention. Widespread public concern emerged regarding landfill management and chemical manufacturing practices that were largely unregulated. Between 1950-1960, the amount of trash households created increased by 60%.[14] By 1965, more than four million chemicals were also produced in America, often creating toxic by-products.[14]

Figure 2. Key Pharmaceutical Waste and Drug Disposal Regulation Timeline[13]



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In 1976, these trends shaped waste management policy in the US when Congress passed the RCRA through amendment of the Solid Waste Disposal Act. Basic requirements for pollution prevention were established. New requirements included operating condition standards, hazardous waste regulations, and a system for tracking hazardous waste from its formation to destruction (formerly known as the "cradle-to-grave" concept).[14] This amendment also gave the EPA authority over hazardous substances from their generation, transportation, treatment, storage, to disposal.

Clean Air Act

Signed in 1990, the **Clean Air Act** is a law that gives the EPA authority to protect air quality and the ozone layer in the US.[15] Restrictions limit certain pollutants from entering the air such as volatile chemicals. Some pharmaceutical substances that undergo appropriate disposal methods are ultimately destroyed at incinerator facilities.

Destruction of combustible hazardous pharmaceutical waste is subject to the Clean Air Act regulation. For example, metals often found in pharmaceuticals such as selenium, mercury, chromium, and arsenic should not be incinerated if the compound's total organic content is less than 1%.[13] Pharmacy technicians should review and consider this EPA law when organization policies and procedures use pharmaceutical waste and drug disposal opportunities that involve incineration.

Subpart P and Nicotine Exemption Ruling

In 2019, EPA regulations updated guidelines for hazardous pharmaceutical waste management and over-the-counter (OTC) nicotine replacement therapies known as **Subpart P and Nicotine Exemption**.[18] These guidelines largely apply to all healthcare facilities including hospitals and community pharmacies.[19]

Pharmacy technicians working within hospital and community pharmacy practice settings should be aware of three pharmacy practice implications within this specific EPA regulation.

1. Prohibiting "sewering" (flushing) of hazardous pharmaceutical waste
    a. The EPA prohibits intentional flushing of hazardous pharmaceutical waste down the drain (also referred to as "sewering"). This ban aims to reduce introduction of pharmaceuticals into the water supply and the environment.[18]
    b. Pharmaceutical waste generated in patient households is exempt.
2. Over-the-counter (OTC) nicotine exemption from hazardous waste list
    a. OTC **nicotine replacement therapies** (NRTs) traditionally used for smoking cessation are exempt from EPA's hazardous pharmaceutical waste lists. Specific exempt NRTs include patches, gums, and lozenges. However, this exemption does not apply to electronic cigarettes (e-cigarettes), liquid nicotine, nicotine cartridges, and nicotine used for research.[19]
3. Changes to pharmaceutical waste segregation at disposing healthcare facilities.[13,19]
    a. The EPA changed requirements for disposing healthcare facilities whereby only the pharmaceutical waste that is returned to reverse distributors for financial credit must be disposed of separately. Two categories of pharmaceutical waste to dispose separately were created, potentially creditable and non-creditable waste.
        i. **Potentially creditable waste** is unused or un-administered and less than one year past the expiration date.[19]
        ii. **Non-creditable waste** is hazardous pharmaceutical waste that is not eligible for manufacturer credit. Examples of waste not eligible for credit by the manufacturer include removal from the original package, refused by patient after attempt to administer, returned by patient after payment, and exceeding one year past expiration.[19]

The DEA and Drug Disposal

Controlled Substance Act

The **Controlled Substance Act (CSA)** signed in 1970 created controlled substance schedules (Schedules I-V) based on a medication's abuse and addiction potential and its medical applications. The law also created an unfavorable drug disposal "gray area" where controlled substances identified for drug disposal were not allowed to be transferred from ultimate users back to DEA-registered entities unless law enforcement officers were involved.[20] For example, a patient could not legally dispose unwanted prescription drugs at their community pharmacy. Alternative patient drug disposal options available at the time, such as sewering and trash disposal, were not ideal for the environment and were a drug diversion risk.

Drug Disposal Act

The **Secure and Responsible Drug Disposal Act** (also referred to as the "Disposal Act") signed in 2010 amended the CSA to define and expand DEA-registered entities and processes for ultimate users to legally and appropriately dispose controlled substances.[6,16] The Disposal Act allowed three new safe and responsible drug disposal options for ultimate users in the community:[6]

1. Collection receptacles
2. Take back events
3. Mail back programs

2014 Final Rule for the Disposal of Controlled Substances

The **2014 Final Rule for the Disposal of Controlled Substances** implemented the Disposal Act and controlled substance disposal processes that include transfer, delivery, collection, destruction, return, and recall. This Final Rule applied to processes owned by both DEA registrants and ultimate users.[6]

Ultimate users (i.e. public) became authorized to deliver controlled substances to other individuals for the purpose of disposal. In addition, the Final Rule authorizes lawful possession of controlled substance property of an ultimate user who has passed away.

The Final Rule also stated that all destruction of disposed controlled substances must comply with the **non-retrievable** standard.[6,21,22] Non-retrievable destruction is a process to alter the physical or chemical properties in any way that inactivates the controlled substance therapeutic effects.

The DEA also issued disposal regulations for **unused pharmaceutical inventory** and **pharmaceutical waste**. Although the Final Rule largely applied to unused pharmaceutical inventory (e.g. expired narcotics), such DEA regulations also address healthcare stakeholders seeking appropriate pharmaceutical waste and drug disposal.

Registrants as Authorized Collectors

The Final Rule expanded the types of DEA registrants authorized to accept controlled substances from ultimate users for disposal. Further, all current DEA registrants could modify their DEA registration at no cost[23] to become authorized collectors.[6] These entities include:

1. Hospitals with an onsite pharmacy
2. Community pharmacies
3. Reverse distributors
4. Narcotic treatment programs
5. Drug manufacturers

FDA and Pharmaceutical Waste

SUPPORT Act

Signed into law in 2018, the **Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)** was implemented by the FDA and had several pharmaceutical waste and drug disposal related regulations including: [24]

1. FDA is granted authority to require a drug manufacturer to include controlled substance packaging with special disposal features.
2. Medicare Advantage plan requirements to provide patient information on the safe disposal of prescriptions
3. Licensed hospice personnel permission to dispose of controlled substances on behalf of hospice patients.
4. Review of in-home disposal options for patients and hospice disposal practices for unused controlled substances.

OSHA and Pharmaceutical Waste

OSHA has oversight of pharmaceuticals deemed hazardous by EPA criteria and NIOSH. Drugs on the NIOSH list require special handling (including disposal) based on health risks.[12] Once a drug is on the NIOSH list, OSHA provides recommendations for safe hazardous drug handling to protect healthcare workers, adopting a majority of practices offered by United States Pharmacopeia (USP) guidelines.[13]

PHARMACEUTICAL WASTE AND DRUG DISPOSAL IN HOSPITALS AND COMMUNITY PHARMACIES

Hospital pharmacy technicians have important roles in providing pharmaceutical waste and drug disposal recommendations that comply with laws and quality requirements and to reduce employee occupational exposures.[25]

Evaluation of Current Practices and Education

Not all hospitals handle pharmaceutical waste and drug disposal in a similar fashion, but all are required to comply with current federal and state regulations. As previously described, laws are in place to ensure proper handling and disposal for non-hazardous, hazardous, controlled substance, and non-controlled substance pharmaceutical waste.

A recent survey conducted by the American Society of Health-System Pharmacists (ASHP) suggested that hospitals need to adopt more appropriate pharmaceutical waste and drug disposal practices. Approximately 70% of respondent hospitals developed a hazardous drug list and institutional procedures that address hazardous drug disposal.[26] Further, 20.6% of those respondents that prepare chemotherapy and 50.6% of institutions that do not prepare chemotherapy had not completed formal gap analyses (a method to assess current performance and where you want to be) to evaluate compliance with hazardous pharmaceutical waste handling requirements.[28] Formal gap analyses are often essential to address identified organization knowledge deficits related to pharmaceutical waste handling and disposal.

One hospital developed a gap analysis tool to identify ways to improve pharmaceutical waste and drug disposal practices. Identified opportunities included conducting a medication risk review assessment, hazardous drug list development, facility infrastructure updates to hazardous drug storage and receiving areas, and nursing education.[27] Compliance with pharmaceutical waste and drug disposal laws and quality requirements may take several months of preparation and collaborative efforts across multiple hospital stakeholders.

Pharmacy-led educational programs for nurses and physicians provide value and are recommended by professional organizations.[17,28] A hospital-wide educational program can engage hospital employees regarding medication disposal, automatic reminders of hazardous agents disposal recommendations, and established pharmaceutical waste management procedures for EPA-defined hazardous products.

Reverse Distributors

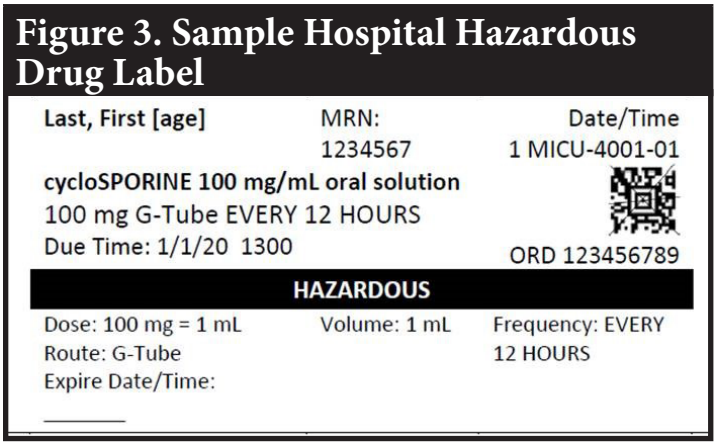
Reverse distribution is the removal of unsold or unsaleable pharmaceuticals from the drug supply chain.[7] Increasingly regulated pharmaceutical handling between drug manufacturers and pharmacies in the 1980-1990s resulted in creation of **reverse logistic providers** that specialize in handling these unsold or unsaleable products.[7] Also considered as "reverse distributors" or "returns processor", reverse logistic providers process pharmaceuticals for manufacturer credit, facilitate transfer of pharmaceutical waste to a licensed destruction company, or engage in drug destruction on behalf of pharmacies.

Hospitals and community pharmacies can send all **potentially creditable waste** to reverse distributors (they cannot send **non-creditable waste**). Therefore, segregation of this pharmaceutical waste is critical. The DEA requires hospitals to send unopened controlled substance pharmaceutical waste to reverse distributors.[29]

Hazardous Pharmaceutical Waste Management

As previously described, the EPA prohibits flushing (sewering) of hazardous pharmaceutical waste down the drain to avoid negative environmental impacts.[4,18,30] Hazardous drugs therefore should be identifiable by all hospital employees including pharmacy technicians and nurses and appropriately segregated from non-hazardous pharmaceutical waste. **Figure 3** is an example of a hospital hazardous drug label with this identification.

Figure 3. Sample Hospital Hazardous Drug Label



If hazardous pharmaceutical waste is also a biological hazard (e.g. infectious substance containing bacteria or virus), it is referred to as "dual waste". Hospitals are required to send dual waste to an appropriately licensed treatment, storage, and disposal facility.[31] Examples of dual waste include a partially administered syringe containing RCRA-designated pharmaceutical or an intravenous bag containing hazardous pharmaceutical residue attached to tubing that was used for administration.

Treatment, Storage, and Disposal Facilities (TSDFs)

TSDFs offer hospitals a hazardous pharmaceutical waste solution that complies with federal and state regulations. Hazardous waste that is combined with non-hazardous pharmaceutical waste may be disposed at these facilities. TSDFs perform treatment to hazardous substances prior to destruction (i.e. incineration) thereby minimizing environmental harm. While TSDFs have emerged due to federal laws, state-specific requirements vary to receive the licensure and permits required to collect pharmaceutical waste from hospitals. TSDFs require permits because these facilities need to establish controls necessary to prevent environmental release of hazardous waste at larger volumes for longer periods of time.[31]

Pharmaceutical waste transferred to TSDFs from hospitals for appropriate disposal undergo a waste analysis. Once pharmaceutical waste is accepted by these TSDFs, a copy of the waste analysis is sent to the hospital within 30 days.

Controlled Substances

Hospital controlled substances disposal policies and procedures should comply with DEA regulations in order to minimize risks for diversion.[6,32] As previously described in the 2**014 Final Rule for the Disposal of Controlled Substances**, controlled substance pharmaceutical waste should be permanently altered as defined by the **non-retrievable standard**.[6] If a controlled substance is also hazardous, a conditional exemption to EPA rulings apply in order to adhere to this non-retrievable standard.[13]

Hospitals should maintain controlled substance "chain of custody" documentation that includes drug disposal detail. Controlled substance waste documentation by a nurse should be timely relative to the patient administration and also observed by a witness to ensure diversion risk is limited.[32] Appropriate controlled substance waste documentation should also include the specific quantity of controlled substances disposed.[32]

Controlled Substance Disposal Systems

Hospitals may use commercially available controlled substance disposal systems to comply with the non-retrievable standard and the EPA sewering ban. Controlled substance disposal systems are often placed in patient care unit locations nearby to patient administration and subsequent pharmaceutical waste generation. Typical designs are bucket- or cartridge-based receptacles. An example of a controlled substance disposal system is seen in **Figure 4**.

Figure 4. Example of Hospital Controlled Substance Disposal System

HOSPITAL AND COMMUNITY PHARMACY DRUG DISPOSAL STRATEGIES FOR SUCCESS

To achieve hospital and community pharmacy compliance with pharmaceutical waste and drug disposal regulations, a comprehensive strategy should aim to put federal and state recommendations into effect. This strategy will require working with organization stakeholders such as senior leadership, nursing, physicians, environmental services, security, and finance. External stakeholders may include law enforcement and regulatory agencies.

A comprehensive drug disposal strategy will include the following practices:

1. Product segregation
2. Education and training
3. Inventory and recordkeeping
4. Leadership support

Product Segregation

The first step in a comprehensive drug disposal strategy is to identify how medications should be segregated across the organization or community pharmacy. The most basic way to segregate pharmaceutical waste is to treat all pharmaceutical waste as hazardous except incompatible medications (those that cannot be incinerated), controlled substances, and potentially creditable medications. However, disposing all pharmaceutical waste as "hazardous" may not be a cost-effective practice and should be weighed against benefits of streamlining operations, space, and environmental protection.[13]

Potentially creditable medications are acceptable for return to a reverse distributor and often for financial incentives. Determining that pharmaceutical waste is creditable is made using reverse distributor reports and may apply to non-hazardous, hazardous, controlled, and non-controlled substance medications. In general, creditable medications include items that are in the original packaging, less than one year from expiration, and not partially administered in a hospital or ambulatory clinic.

After pharmaceutical waste categories are determined, employees should be able to readily identify and segregate the medication products accordingly. Pharmaceutical waste disposal bins labeled with appropriate signage designating the disposal category of acceptable items should be placed in areas close to patient care and medication administration.

Medication auxiliary labels should properly list the waste category for pharmaceuticals. For example, organization labeling for partially used controlled medications should disclose a message such as "dispose in controlled waste bin" or "dispose in sink" to direct healthcare workers. Albuterol inhalers in the hospital should include labeling like "return to pharmacy" to ensure proper disposal to an incompatible waste container located in the pharmacy. Alerting or information within the medication administration record should also provide assistance with drug disposal recommendations.[28]

Healthcare Professional Education and Training

Education and training sessions should be provided for employees who engage in pharmaceutical waste and drug disposal activities. Sessions should stress the importance of demonstrating safe and effective disposal methods and review organization-specific segregation strategy. Education may also include:

- Unsafe drug disposal practices and risks
- Rationale for pharmaceutical waste segregation
- Medication use process overview as it relates to drug disposal
- Common reasons for non-creditable pharmaceutical waste
- EPA standards related to empty hazardous waste containers

Education and training sessions should also be provided specifically to hospital nurses who transfer creditable pharmaceutical waste to the pharmacy, dispose of medications based on waste category (compatible vs incompatible, creditable vs non-creditable, controlled vs non-controlled), and access informational resources for drug disposal recommendations outlined by organization policy. Nursing managers should receive additional training to ensure nursing practices remain compliant through personal surveillance.

Inventory and Recordkeeping

Pharmacies should fulfill recordkeeping requirements. For hazardous pharmaceutical disposal, the pharmacy should ensure that environmental safety departments have a routine process for checking rejected shipments or missing manifests (e.g. list of goods).[13] Recent EPA recommendations authorize EPA to ask institutions to furnish additional reports for non-creditable hazardous pharmaceutical waste.[18] In these circumstances, pharmacy technicians can provide purchasing and disposal data to document action with these substances.[13]

Unwanted, intact controlled substances destined for reverse distribution should remain in pharmacy inventory prior to return. Professional guidelines recommend that pharmacies conduct routine inventory counts for all controlled substances, including those destined for disposal.[32] These inventory counts should include expired or unused controlled substances awaiting disposal.[32] If feasible, a limited-access safe for expired medications should be installed as space allows.[33] When ready for transfer, a final audit of DEA 222 forms should occur to reconcile the final narcotic quantity to be transported to reverse distributors.[32]

Leadership Support

Senior organization leadership support of appropriate

pharmaceutical waste and drug disposal is essential. Operational and financial challenges require administrative oversight for resource allocation. Critical resources may include devices and equipment essential to handle medications and dispose pharmaceutical waste.[34] Pharmacy departments within hospitals are responsible for at least 30% of drug disposal expenses.[34]

HOUSEHOLD PHARMACEUTICAL WASTE AND DRUG DISPOSAL

Collection Receptacles

Collection receptacles are an appropriate pharmaceutical waste disposal opportunity. Collection receptacles are secure boxes that allow ultimate users (patients, caregivers, healthcare providers, etc.) to safely dispose of unused controlled and non-controlled substance medications during DEA registrant hours of operation. An example of a collection receptacle is seen in **Figure 5**. DEA registrants, including community pharmacies, must modify their existing DEA controlled substance registration to become eligible to place collection receptacles in their facilities.
The U.S. Government Accountability Office reports that approximately half of all ultimate users live less than 5 miles from a medication collection receptacle, as of 2017.[35] Collection receptacle locations within 5 miles from ultimate user households vary between those who live in urban areas (52%) and rural areas (18%).[35] About 44% of the rural population lived 30 miles or more away from the nearest collection receptacle.[35]

Locations of local collection receptacle sites can be found on:

1. DEA website using a zip code
2. Google Maps® or Bing Maps® by searching "drug disposal near me" or "medication disposal near me"[36]

Collection receptacles have inner liners that allow for pharmaceutical waste emptying. DEA registrants determine the frequency of liner changes based on ultimate user usage patterns. A common inner liner replacement frequency is every 2-4 weeks.[37,38] While more frequent liner changes are desirable, DEA registrant expenses should be considered. A 2017 report noted that 12 inner liners cost a federal DEA registrant approximately $2,000 in contracted expense.[37]

Pharmaceutical waste disposed in a collection receptacle cannot be sorted, inventoried, or recorded, especially if ultimate users dispose of controlled substances in the receptacle. Collected pharmaceutical waste destruction must comply with the non-retrievable standard. Collection receptacles must also be fastened to a permanent structure. Collection receptacles must be installed inside the registered location, nearby controlled substance storage, and within employee line of sight for added security (**Figure 6** on page 14).[6]

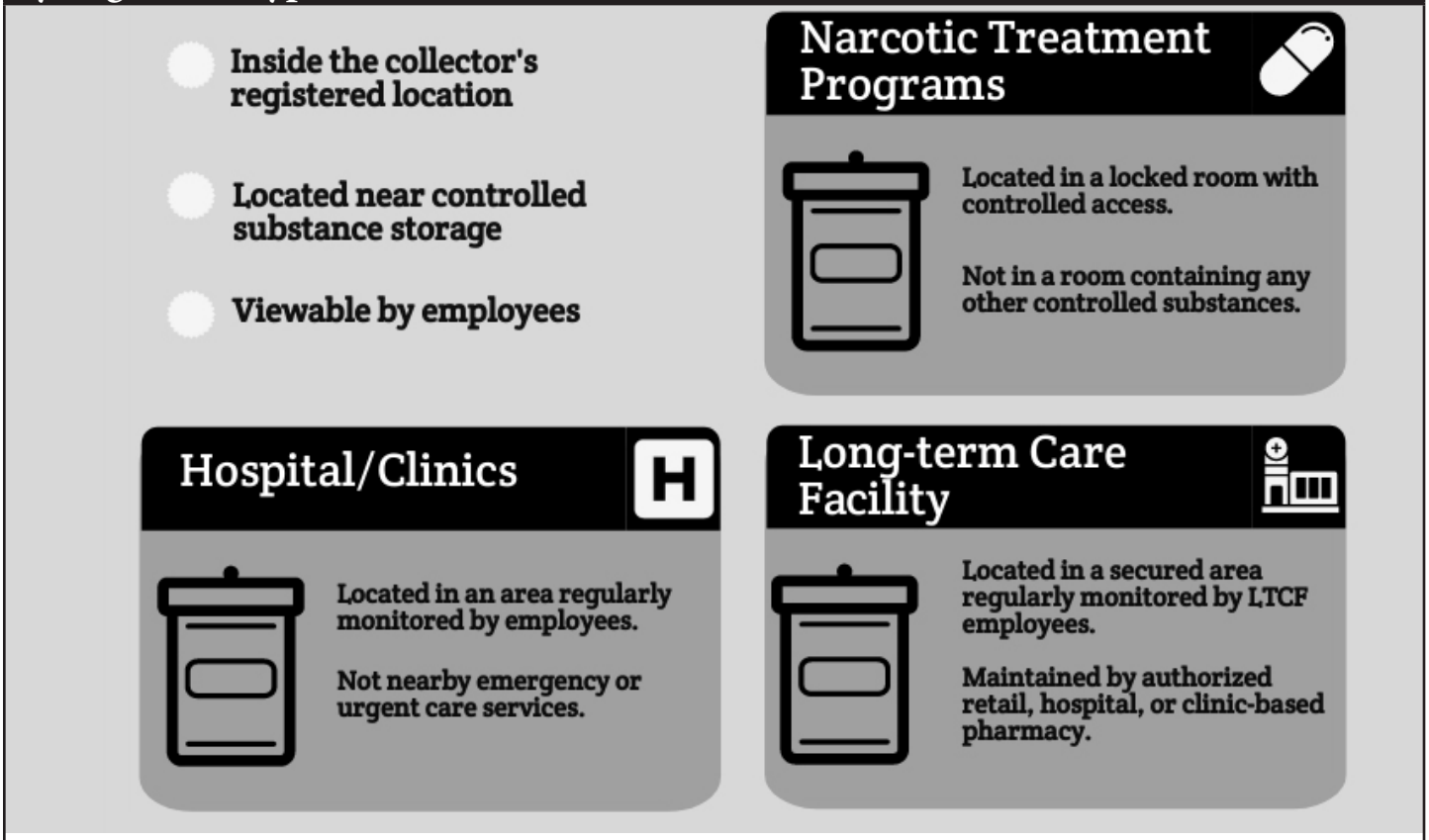
Figure 5. Example of Collection Receptacle

Collection Receptacle Policies and Procedures

DEA registrant collection receptacle policies and procedures require thoughtful consideration of additional DEA requirements.

- Non-retrievable standard compliance also applies to DEA registrants who delegate final responsibility for collected pharmaceutical waste destruction to reverse distributors.
- DEA registrants must ensure that employees do not dispose controlled substances in the collection receptacle on behalf of patients.
- Ultimate users cannot use the collection receptacle to dispose of schedule I controlled substances, syringes, needles, and/or chemotherapy.

Figure 6. Collection Receptacle Requirements, Placement, and Location Exemptions by Registrant Type[6]



Infographic created using Easel.ly and printed with permission from James Rhodes.

Several organizations provide useful frameworks for DEA registered entities that are interested in installing a collection receptacle. The Product Stewardship Institute (PSI) is a national non-profit organization that has outlined related recommendations. Between 2015-2016, PSI collaborated with the New York Product Stewardship (NYPS) to support pharmaceutical waste collection in five community pharmacies in New York State rural areas.[39]

Pharmacy technicians can assist with collection receptacle installation planning using the checklist provided by PSI/NYPS (**Table 1**).

Take Back Events

Medication take back events are described by the FDA to the public as "the best way to safely dispose of most types of unneeded or expired prescription and over the counter medicines".[36] These events are hosted by DEA registered entities, including community pharmacies, where the public is welcome to return all household pharmaceutical waste for appropriate drug disposal on a specific date and time.

National Prescription Drug Take Back Days are periodic events hosted by the DEA where temporary collection sites are established nationwide to promote safe disposal of medications.

DEA registered entities can partner with federal, state, and local law enforcement to conduct take back events. Law enforcement are required to oversee the collection and chain of custody for the secured transfer, storage, or destruction of controlled substances.

In a recent analysis of DEA registrants eligible to engage in take back events, only 2-4% of pharmacies volunteered to participate.[35] Barriers that impact DEA registrant ability to host take back events include costs to maintain a collection receptacle and costs required to transport collected medications for appropriate destruction.

Table 1. Guide to Managing a Collection Receptacle[39]

Step	Description	Resource
Step 1	Comply with federal regulations	• Modify DEA registration online to collect controlled substances • Apply for Department of Transportation Special Permit
Step 2	Choose the right collection system	• Choose the right collection system ○ Collection receptacle ○ Reverse distributor (+/- a collection receptacle)
Step 3	Determine a funding source	• Voluntary Programs: ○ Government ○ Retailers ○ Community sponsorship • Legislated Programs: ○ Extended producer responsibility laws
Step 4	Set up the program	• Collection receptacle installation • Log, Liner, Signs, and Mail-back
Step 5	Operate the program	• Educate and train employees • Monitor receptacle (drugs are appropriately placed inside) • Replace full liners • Order new liners
Step 6	Spread the word	• In-pharmacy advertising • Outreach in the community ○ Newsletter or email ○ Social media ○ Press release ○ Media outreach ○ Radio advertisement ○ Television advertisement ○ Billboards

Take Back Events and Public Education and Awareness

As drug take back events become more common across the country since the Disposal Act, public education and awareness are critical to household pharmaceutical waste collection success. Pharmacy technicians in community pharmacy practice settings who host take back events should engage patients to advocate for the appropriate pharmaceutical waste and drug disposal opportunity. Pharmacy technicians can also help with setting up take back events and direct patients to other events in the area.

A 2013 study revealed that a majority of people go to a pharmacy or pharmacist for advice when asked who to consult for drug disposal information.[40] Respondents from the same study also believed that pharmaceutical waste and drug disposal in a "secured lockbox" was the safest means to do so (65%).[40] Patient education about appropriate pharmaceutical waste and drug disposal methods including take back events promote their use.[40–42] Public awareness of the take back event location relative to patient households should be considered for success. A survey that explored patient perceptions of take back events reported that 53% of patients would travel 5 miles or more to a take-back program, while just 8% of patients would travel 15 miles or more.[43]

There are patient populations that are more likely to benefit from take back events. Parents of younger children reported fewer barriers for safe storage of opioids compared to parents of older children/teens.[44] Additional interventions for high school students and their parents have been reported which reviewed the dangers of substance abuse, importance of safe disposal practices, and marketing of local take back events.[45]

Test Your Knowledge #1

Disposal Scavenger Hunt

Adapted online learning using drug disposal resources

DIRECTIONS: Use the information you find at the web site below to answer questions about drug disposal.

Web site: DEA (Drug Enforcement Administration)

URL: www.DEA.gov

1. Hover over the "What We Do" tab at the top of the webpage. Q: Which section would direct you to information about DEA's Takeback Events?

2. Click on the section from Question #1 to be taken to a new webpage. Q: When was the most recent DEA National Take Back Day?

3. Locate a Collection Site Near You using the same webpage from Question #2. (You will be taken to a new webpage). Q: What is the section title of the new website?

4. Search for an authorized collector by zip code using the same webpage from Question #3. List three business names below.

Disposal Location #1 — Name: _____ Address: _____

Disposal Location #2 — Name: _____ Address: _____

Disposal Location #3 — Name: _____ Address: _____

Mail Back Programs

Mail back programs are also an appropriate pharmaceutical waste and drug disposal alternative for ultimate users, especially those with households far from collection receptacles or take back events.

Mail back programs encourage ultimate users to fill and seal provided envelopes with household pharmaceutical waste in original drug containers.[46] An example of a mail back program envelope is seen in **Figure 7**. Liquid pharmaceutical waste is recommended to be placed in a sealed plastic bag to prevent leaking. Sealed envelopes are then mailed by ultimate users back to DEA registered entity for proper pharmaceutical waste destruction.[46]

Figure 7. Example of Mail Back Envelope

Provided mail back program envelopes will not have any markings to indicate that they contain pharmaceutical waste. This is to ensure that risk of diversion during mail transit is limited. Additional envelope specification requirements are detailed in **Table 2**. Further, ultimate users are not required to provide personal information when mailing controlled substances to a collector.

Table 2. Envelope Specification Requirements for Mail-back Programs

1. Packaging shall NOT include information indicating the package contains controlled substances
2. Water- and spill-proof; tamper-evident, and sealable
3. Preaddressed and delivered to collector's registered address
4. Cost of shipping and postage is paid
5. Unique identified number that allows tracking
6. Package shall include instructions that package will be accepted for destruction

A survey of large metropolitan area residents found that mail back programs are viewed less favorably by ultimate users than collection receptacles and take back events at community pharmacies.[40] Evidence also suggests mail back programs bring in 15 times less than alternative appropriate pharmaceutical waste and drug disposal methods.[37] Potential reasons for low ultimate user participation include envelope size restrictions, poor public perception about drug security, inadequate public awareness, and mail back program coordination burden over time.

Ultimate user willingness to participate in mail back programs has been evaluated. A recent survey of patients who were prescribed controlled substances found that the majority of respondents (83%) were more likely to use these programs if they were incentivized. The most preferred incentives were $1-$5 in cash (70%), pharmacy coupon (40%), charity donation (40%), and pharmacy reward points (39%). Decisions for DEA registrants

to incentivize mail back programs to increase success depends on cost effectiveness. However, tracking cost-effectiveness of incentivizing ultimate users is challenging because DEA-registrants are not required to track whether packages were returned.[6]

Additional Mail Back Program Barriers

Mail back program requirements create logistical challenges for DEA registrants seeking to host a program:

- DEA registrants that host mail back programs must fulfill onsite destruction requirements that are outlined by the **2014 Final Rule for the Disposal of Controlled Substances**. Since onsite destruction must occur after receipt of mail back packages,[6] this requirement can be a barrier for community pharmacies lacking the related resources. The DEA has encouraged empty envelopes to be given out at community pharmacies and mailed back instead of using a reverse distributor to comply with this standard.[6]
    - Reverse distributors that support DEA registrants with mail back programs include Stericycle and Sharps Compliance.[46,47] These reverse distributors provide preaddressed mail back program envelopes with a prepaid United States Postal Service (USPS) label.
- DEA registrants should describe prohibited pharmaceutical waste for return to reverse distributors in mail back program policies. Prohibited items must be shared via verbal and written communication to ultimate users when providing mail back envelopes. Examples of mail back program prohibited items may include syringes and inhalers.
- DEA registrants or reverse distributors that receive envelopes containing pharmaceutical waste for destruction must notify their local DEA Field Division Office of Administration.[6]

Commercial Disposal Systems

Commercial disposal systems offer ultimate users with unused, unwanted, or expired medications an at home alternative drug disposal method. These commercial disposal systems offer a proprietary blend of substances for patients to mix with unused drugs to inactive them, before throwing them into household trash. Commercial disposal system products are marketed as a convenient and safer option for household disposal of medications, especially controlled substances. Research demonstrates that these products show an increased likelihood that patients engage in proper opioid disposal practices at home.[8,48]

Patients are instructed to mix medications with the commercial disposal systems containing proprietary blends to inactivate medication therapeutic effects and then seal the mixture and dispose of it in the trash. Examples of active ingredients within these systems include activated carbon, bentonite clay, as well as other adsorbent and absorbent ingredients.[49]

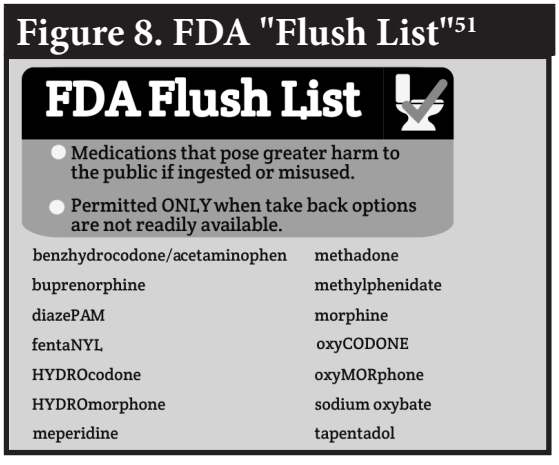
While the FDA, DEA, and EPA acknowledge commercial disposal systems for household pharmaceutical waste disposal, they have not made any recommendations related to these methods.[21,50] A review of ten commercial disposal systems concluded that additional independent tests are needed to validate the performance on deactivating pharmaceutical products.[49] Affordability is also a concern as list prices range from $1.60 to $16 for disposal unit capacities of 15-300 pills.[49] However, these products may also be acquired at discounted prices or free of charge.

Specific commercial disposal systems may also exclude certain types of medicines or dosage forms (e.g. hazardous, chemotherapy, antacids, transdermal patch, creams).[49] Therefore, it is important consumers follow directions provided on the packaging and contact the drug manufacturer or pharmacy for assistance.

FDA Flush List

Despite the harmful consequences that threaten public health and the environment by sewering medications, the FDA has a list of medicines that should be flushed down the sink or toilet if appropriate drug disposal options are not readily available.[51] The *FDA Flush List* (**Figure 8**) includes 14 generic medications that will result in harm or death if even one dose is ingested by someone other than the person for whom it was prescribed.[51] The FDA continues to perform human exposure and environmental risk assessments for these medications.

Figure 8. FDA "Flush List"[51]



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Household Trash

If all other appropriate pharmaceutical waste and drug disposal opportunities are not available, the FDA advises that some prescription medications can be thrown into household trash. It is recommended to first remove all personal health information from the medications to protect identity and privacy. Medications can be thrown in household trash using the following steps.

1. Remove medication from original container.
2. Mix the medications with something undesirable for ingestion by children or animals such as dirt, cat litter, or coffee grounds.
3. Place the mixture in a sealed container such as a plastic bag or can.
4. Throw the container in the household trash.

Disposal of Unique Medication Dosage Forms

Needles and Syringes

Medications administered using needles and syringes are often used to manage disease states such as allergies, arthritis, cancer, diabetes, hepatitis, HIV/AIDS, infertility, migraines, multiple sclerosis, osteoporosis, blood clotting disorders, and psoriasis.[52] To prevent harm to others, needles and syringes should be placed in a sharps disposal container immediately after use. Sharps disposal containers can be disposed of at supervised collection sites (at doctors' offices, hospitals, pharmacies, and police or fire stations), household hazardous waste collection sites, mail-back programs, and residential special waste pickup services.

Safe Needle Disposal (SafeNeedleDisposal.org) provides state-specific assistance regarding types of sharp containers that can be used, area disposal programs, labeling, container security, and whether full sharps containers can be thrown away in municipal trash.[53] They can be reached by phone (1-800-643-1643) or e-mail (info@safeneedledisposal.org).

Additional related recommendations for needle and syringe disposal are as follows:

- Sharps disposal containers are safe options for needles, syringes, lancets, auto injectors, infusion sets, and connection needles/sets.[52]
- While sharps disposal containers are commercially available for purchase, any hard metal or plastic container with a covered narrow opening is also acceptable (such as a laundry detergent bottle).
- Sharps disposal containers should not be overfilled. Used sharps containers should be disposed when the container is three-quarters full.[53]
- A travel-size sharps disposal container should be packed when traveling.[53] The Transportation Security Administration (TSA) website has up-to-date information on what to do with sharps when traveling.

Adhesive Skin Patches

Medications administered to patients through adhesive skin patches are often prescribed to manage smoking cessation and disease states such as hypertension, musculoskeletal (muscle/bone) and neuropathic (nerve) pain. Adhesive skin patches can be worn for as few as 6-12 hours and up to 7 days, although active medication can remain when the patch is removed from the body. In general, patches removed from the body should be folded against itself using the adhesive side prior to disposal.

Previous research has recommended that adhesive skin patches should be flushed whole or in fragments to allow the drug to diffuse in water.[54] Ultimate users that cut adhesive skin patches should wear gloves to prevent inadvertent medication exposure.[54] Cut patches may release all medication at once and should not be thrown into the trash to avoid increased risks to children and animals.[53]

Inhaler Products or Aerosols

Medications administered to patients via inhalation are prescribed to manage disease states such as asthma or chronic obstructive pulmonary disease (COPD). Inhaler products and aerosols have unique risks to the environment when improperly discarded. Since the most common form of appropriate medication disposal is incineration, the combustion of inhaled or aerosolized products can occur and be dangerous. Inhaler products and aerosols should not be punctured or thrown into a fire for drug disposal.[55] Prior to 2013, inhalers often used chlorofluorocarbons as propellants, which posed harmful risks to the environment.[56]

Not all drug takeback programs accept inhaler products or aerosols. Therefore, patients should ask the drug take back program host if inhalers or aerosols are accepted. The FDA advises patients with inhaler products or aerosol pharmaceutical waste to follow local regulations and contact affiliated trash or recycling facilities.[55] If drug takeback programs are not readily available, most inhalers can be safely thrown into municipal trash or recycled.

Test Your Knowledge #2

Match the Term to the Description.

Description

_____ 1. Acquisition of controlled substances for purpose of return to manufacturer or for destruction.
_____ 2. CANNOT use this method to dispose of unused inventory or stock.
_____ 3. Emergency or urgent care
_____ 4. Located on or at physical premises.
_____ 5. Person who lawfully obtained or possessed controlled substance for own use or use by a member of household.
_____ 6. Process that permanently changes the substance's physical or chemical condition. Makes the drug unusable for diversion or abuse.
_____ 7. Scheduled I controlled substances
_____ 8. Takeback events, collection receptacles, mail-back programs.

Term

A. Authorized collectors with collection receptacle
B. Three appropriate drug disposal types
C. Ultimate user
D. Non-retrievable
E. On-site
F. Prohibited areas for collection receptacles
G. Prohibited from disposal in collection receptacles
H. Reverse distribution

Answers can be found on page 22.

PHARMACEUTICAL WASTE AND DRUG DISPOSAL AWARENESS

Pharmacy Professional Awareness

Evaluations of the pharmaceutical waste and drug disposal knowledge base of pharmacy professionals suggest that additional education is needed. Drug disposal information is rarely provided to patients according to a 2016 survey that revealed only 9% of pharmacists gave related education on a daily basis.[57] When drug disposal advice is requested by patients, the information provided by community pharmacy professionals is mostly inaccurate. A 2018 survey revealed that only 47% of pharmacies gave correct instructions on appropriate antibiotic disposal, and just 34% gave correct instructions for opioids.[58]

Barriers to providing accurate advice may be due to pharmacy professional education gaps. Specifically in college of pharmacy curriculums, just 19% of faculty believed pharmacy students were adequately trained to manage compounded sterile preparation competencies including drug disposal and waste management.[59] Another survey revealed that only 20% of pharmacy students and 11% of pharmacists received education related to drug disposal.[60]

Public Awareness

Drug disposal education promotes safer drug disposal practices.[41] However in one study, the majority of respondents in a state-based survey (80%) reported never receiving information about drug disposal at all from healthcare providers.[40] In a survey of cancer patients receiving controlled substance opioids, almost 75% of respondents were unaware of correct drug disposal methods.[61]

CONCLUSION

Hospitals, community pharmacies, and the public must engage in safer pharmaceutical waste and drug disposal practices in the interest of public health and the environment. Pharmacy technicians in hospitals and community pharmacy settings are key stakeholders who are well positioned to promote this change and should follow organization policies and state and federal regulations.

To be successful in this endeavor, pharmacy technicians should consider:

- Risks of inappropriate pharmaceutical waste and drug disposal
- Common ways that pharmaceutical waste is generated

in the medication life cycle
- Pharmaceutical waste and drug disposal regulations
- Appropriate drug disposal opportunities for household pharmaceutical waste
    - Collection receptacles
    - Drug take back events
    - Mail back programs
- Hospital and community pharmacy strategies to comply with regulations

Test Your Knowledge #3

Answers on page 22

Fill-in-the-blank and word Search

Directions: Read the question and fill-in-the-blanks for the correct answer. Spaces are removed for answers with two or more words. Once the answer is correct, search for the answer in the word search.

Question	Letters	Answer
1. Ultimate users fill and seal provided envelopes with household pharmaceutical waste in original drug containers	8	_____
2. Legislation in 1976 which granted authority over hazardous substances. (hint: abbreviated)	4	____
3. Terminal facilities who are licensed to destroy hazardous substances (hint: abbreviation)	4	____
4. Legislation signed by Congress which amended the Controlled Substance Act and authorized DEA to promulgate the Final Rule in 2014.	11	_____
5. Agency who is authorized to regulate substances that have environmental harm.	3	___
6. Process of permanently altering the chemical, physical, and therapeutic properties of a drug.	14	_____
7. Prohibiting disposal method for healthcare facilities, according to EPA's 2019 ruling on hazardous substances.	8	_____
8. Person lawfully obtained CS for personal use	12	_____
9. Agency that uses the NIOSH list to set standards for healthcare worker conditions. (hint: abbreviation)	4	____

Options:

mailback | CSA | FDA | Congress | disposalact | DOT | cleanairact | receptacle | syringes | incineration | flushlist | RCRA | sewering | segregation | labeling | TSDF | finalrule | hazardous | EPA | noncreditable | NIOSH | subpartP | DEA | takeback | manifest | nonretrievable | disposal | OSHA | ultimateuser

Test Your Knowledge #4

Fill-in-the-blank and word Search

Find your answers from the fill-in-the-blank activity in the word search.

C	K	P	G	Q	L	Q	V	Z	E	F	P	M	N	A
Y	B	C	Z	V	M	W	A	L	D	X	A	O	T	H
X	Y	T	X	S	P	A	B	S	I	I	N	F	C	S
D	C	J	Z	Z	P	A	T	T	L	R	Y	I	A	O
O	V	Y	W	X	T	R	H	B	E	W	G	N	L	J
T	F	L	U	I	J	U	A	T	D	U	H	A	A	F
H	B	O	D	S	N	C	R	H	Q	L	M	L	S	E
E	N	E	E	G	K	I	M	A	S	Q	M	R	O	H
K	R	E	S	U	E	T	A	M	I	T	L	U	P	P
C	Q	D	I	V	E	R	S	I	O	N	C	L	S	M
E	Y	A	A	T	N	R	C	R	A	E	K	E	I	P
V	P	B	U	E	P	G	M	L	C	H	B	T	D	D
H	L	A	Y	Z	D	S	G	N	I	R	E	W	E	S
E	U	G	J	E	H	K	F	B	M	L	J	Y	A	N
H	Y	W	V	B	L	B	E	I	C	C	H	O	Y	C

Answers on page 22

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Test Your Knowledge Answer Key

Test Your Knowledge #1

1. Education and Prevention
2. Answers will vary
3. US Dept of Justice
   DEA Diversion Control Division
4. Answers will vary

Test Your Knowledge #2

1. H
2. A
3. F
4. E
5. C
6. D
7. G
8. B

Test Your Knowledge #3

	Letters	Answer
1.	8	mailback
2.	4	RCRA
3.	4	TSDF
4.	11	disposalact
5.	3	EPA
6.	14	nonretrievable
7.	8	sewering
8.	12	ultimateuser
9.	4	OSHA

Test Your Knowledge #4

USPS Statement of Ownership, Management, and Circulation

Manditory Annual Statement

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Scott A. Meyers Executive Vice President	September 30, 2019

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SELF ASSESSMENT QUESTIONS

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1. **Which of the following is an INCORRECT pairing with their role in the pharmaceutical supply chain? Pair the stakeholder with the respective role in the pharmaceutical supply chain.**
    a. Pharmaceutical companies ship manufactured drugs to wholesalers or pharmacies
    b. Pharmacies purchase and store drug quantities sufficient to meet patient care needs
    c. Grocery stores provide patient access to medications for disease treatment and prevention in the form of a prescription
    d. Ultimate users who should store medications with specific handling conditions

2. **Which of the following is NOT an example of pharmaceutical waste generation in hospitals?**
    a. Medications administered prior to the expiration date
    b. Medications with an error discovered by pharmacist during product verification
    c. Medication doses prescribed is not the same as the manufacturer-issued package size and cannot be administered to another patient
    d. Medications "lost" by nursing prior to administration, creating a redispense

3. **Which of the following is NOT an example of pharmaceutical waste generation in community pharmacies?**
    a. Medications not dispensed prior to the expiration date
    b. Medications prepared with an error discovered by pharmacist during product verification
    c. Medication damaged and/or adulterated by pharmacy staff.
    d. Medications "lost" by nursing prior to administration, creating a redispense

4. **Which of the following is NOT an example of pharmaceutical wasted generation in household?**
    a. Medication is not self-administered prior to the expiration date
    b. Medication is properly stored
    c. Medication is not tolerated
    d. Medication dispensed is not the ordered medication.

5. **Which of the following is a research agency focused on creating safe workplace environments with safe working conditions and classifies hazardous pharmaceutical substances that an employee may encounter in the workplace?**
    a. EPA
    b. NIOSH
    c. DEA
    d. FDA

6. **Which of the following practices is now prohibited in healthcare facilities following EPA's Subpart P and Nicotine Exemption Ruling?**
    a. Reverse distribution
    b. Onsite destruction
    c. Sewering (otherwise called, "flushing down the drain")
    d. Drug take back events

7. **Which of the following legislations became enacted which expanded authorized registrants to collect controlled substances and permitted three safe drug disposal options for ultimate users in the community?**
    a. EPA Final Rule
    b. DEA Subpart P and Nicotine Exemption Ruling
    c. EPA Clean Air Act
    d. Secure and Responsible Drug Disposal Act 2010 (or the "Disposal Act")

8. **Which of the following legislations authorized hospice employees to dispose controlled substances on behalf of deceased patients in hospice care?**
    a. Final Rule 2014
    b. Subpart P and Nicotine Exemption
    c. Drug Takeback Events
    d. SUPPORT for Patients and Communities Act

9. **Which of the following is a process of removing unsold or unsalable pharmaceuticals from the supply chain, processing pharmaceuticals for manufacturer credit, facilitate transfer of pharmaceutical waste to a licensed destruction company, or engage in drug destruction on behalf of pharmacies?**
    a. Reverse distribution
    b. Hazardous drug manufacturing
    c. Medication risk review assessment
    d. Pharmacy-led reminders

10. **Treatment, storage, and disposal facilities (TSDFs) serve what role in terms of drug disposal?**
    a. Perform treatment to hazardous substances prior to destruction (i.e. incineration), thereby minimizing environmental harm
    b. Comply with EPA Final Rule 2014 standards
    c. Engage in reverse logistics with the manufacturer for manufacturer credit
    d. Store pharmaceutical waste that is otherwise non-hazardous according the EPA standards

11. **Which of the following product alteration requirements should hospitals achieve when disposing controlled substances comply with the DEA Final Rule?**
    a. Reverse distribution
    b. Non-retrievable
    c. Ignitable
    d. Toxic

12. **Which of the following is <u>NOT</u> a successful strategy for facilitating drug disposal compliance in the community and hospital pharmacy settings?**
    a. Product segregation
    b. Education and training
    c. Leadership support
    d. Sewering (otherwise called, "flushing down the drain")

13. **Which of the following is the most basic approach in segregating pharmaceutical waste?**
    a. Consider all pharmaceutical waste as hazardous with exceptions to incompatible, controlled substances, and creditable.
    b. Consider all pharmaceutical waste as non-hazardous.
    c. Consider all pharmaceutical waste as non-creditable.
    d. Consider all pharmaceutical waste as controlled substances, with the exception of inhalers

14. **What sources of information can pharmacy technicians provide when the EPA asks pharmacies to provide reports for non-creditable, hazardous pharmaceutical waste?**
    a. Purchasing and disposal data
    b. Education provided to nursing staff
    c. Only DEA 222 forms
    d. All of the above

15. **Which of the following is an appropriate pharmaceutical disposal option for ultimate users?**
    a. Hospital commercial disposal system
    b. Collection receptacle
    c. Medicine cabinet
    d. Community pharmacy without a collection receptacle

16. Which of the following are true about medication collection receptacles?

a. Less than 30% of ultimate users live less than 5 miles from a collection receptacle
b. Collection receptacles within 5 miles are more prevalent in urban areas compared to rural areas
c. Collection receptacles require outer liner changes at least once a month
d. Ultimate user's controlled substances must be inventoried at the DEA registrant site first prior to disposal in collection receptacle

17. Which of the following is true about mail-back envelopes?

a. Packaging should indicate on the outside that contents inside contains controlled substances
b. Postage and shipping costs are paid separately by the ultimate user
c. Studies suggest mail-back envelopes bring in more pharmaceutical waste than other approved agents
d. Package should include instructions that package will be accepted for destruction

18. Which of the following best describes commercial in-home disposal systems?

a. FDA, DEA, EPA recommend this method because they undergo rigorous testing phases for drug inactivation
b. It provides an at-home alternative method, using a proprietary blend of substances that inactivate disposed drugs
c. They are cheap and affordable at full retail price
d. All commercial disposal systems accept all types of medications or dosage forms

19. What is the FDA Flush List?

a. A list of 14 generic medications which should not be flushed because of their harmful impact to the environment.
b. A list of generic medications which will result in harm or death if even one dose is ingested by someone other than the person for whom it was prescribed.
c. A list of hazardous medications as outlined by EPA's definition
d. List of medications that are permitted to be flushed when drug take back options are readily available

20. Which of the following is true about disposal of medications administered by needles and syringes?

a. They can be disposed in the household, municipal trash without additional packaging
b. Should be mixed with a substance undesirable for ingestion such as coffee grounds
c. Needles and syringes should be placed in a hard metal or plastic container with a narrow opening (e.g. empty laundry detergent bottle)
d. Used sharps containers should be disposed in municipal trash when the whole container is full)