

# Best practices for disposal of controlled substances



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There is increased concern over pharmaceuticals in waterways. There are “no drugs down the drain” rules in certain states. And harm can come from unauthorized access to controlled substances and the resulting wastage. Health care facilities must address these issues and ensure alignment with Drug Enforcement Administration (DEA) and Environmental Protection Agency (EPA) regulations as well as local rules. So Practice Greenhealth and a team of stakeholders developed this guidance to support hospitals and clinicians in managing controlled substances and the resulting wastage.

This document summarizes and builds upon the September 2014 promulgation of the [DEA rule](#) on the disposal of controlled substances, which addresses specific management practices under a new Part 1317 Title 21 USC The Controlled Substances Act. A month later, the DEA published a [practitioner letter](#), which clarified that Part 1317 does not apply to pharmaceutical wastage. The DEA made a distinction between inventory and wastage. Health care facilities continue to seek ways to explain whether the DEA rule is applicable to staff who administer controlled substances to patients or those who have the responsibility to dispose of unused or expired medications.

## Definitions

Certain definitions are important to understand so the management and disposal of controlled substances are put in their proper context. The following terms from the DEA rule and other sources will be helpful:

**Controlled substance:** At a minimum, any medication or other substance identified in [Title 21 USC Controlled Substances Act](#). Examples: hydromorphone, oxycodone, morphine, opium, codeine, and hydrocodone.

**Registrant:** A person who has applied to DEA and, based on DEA criteria, has been assigned a DEA number and been given specific authorization to order, stock, sell, dispense, prescribe, administer, or engage in authorized functions involving the legal possession of controlled substances.

**Inventory:** Controlled substances that are part of stock and have not been dispensed or administered.

**Wastage:** Occurs when a controlled substance that has been removed from inventory in accordance with a physician’s order for administration to a patient and which has not been entirely administered to the patient.

**Diversion:** The transfer of a controlled substance from a lawful to an unlawful channel of distribution or use. (See the 2011 [Drug Abuse Prevention and Control Act 21 USC Chapter 13](#).)

Note: While this document says controlled substance wastage (not from inventory) is not under the DEA, “diversion” is used in several places in this guidance document where wastage is mentioned because diversion is an easily understood term, outside of this technical definition, for the general meaning of unauthorized access or use.

**Disposal:** Disposal includes the transfer, delivery, collection, destruction, return, and recall of pharmaceutical controlled substances by both registrants and non-registrants. Pharmaceutical wastage must be destroyed in accordance with applicable federal, state, tribal, and local laws and regulations (e.g. environmental, hazardous/biohazard, and other safety-related laws and regulations).

**Destruction:** The standard of destruction established in the DEA rule is to render controlled substances to a non-retrievable state.

“Destruction” outside of Part 1317: Used here for general understanding that the controlled substance wastage is to be managed appropriately for the situation, and the non-retrievable standard is not required under destruction as defined by the DEA.

**Non-retrievable:** The condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance’s physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. (See [Title 21 CFR Part 1300.05\(b\)](#).)

There is no specific disposal methodology mentioned in the DEA rule as either a requirement or a recommendation, and the definition of non-retrievable does not specify a particular destruction method. DEA has indicated in Part 1317 that to meet the standard of non-retrievability, both the chemical compounds and the analogs must be destroyed. When Part 1317 went into effect, the DEA offered no recommendation in the regulation, but in discussions has indicated incineration as the only destruction method they have reviewed which accomplishes both objectives of destroying chemical compounds and analogs. While the DEA does not endorse any technology or method, some products advertise meeting the DEA standard of non-retrievability. According to the DEA, some of those claims can be inaccurate. (Meeting with Loren Miller, DEA Office of Diversion Control, at Waste Expo in New Orleans, May 2017). Organizations wishing to use an alternative to incineration should seek authorization from their regional DEA office.

**Reverse distribute:** To acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction. (See [DEA Office of Diversion Control letter, Sept. 9, 2014, page 3](#).)

**Reverse distributor:** Any person registered by the DEA and the appropriate state boards of pharmacy as a reverse distributor and allowed to acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction. (See [Title 21 CFR Parts 1301 and 1304](#).)

## The cycle of controlled substances

### Inventory

From the time DEA-regulated controlled substances are received at the health care facility, they become the registrant’s responsibility from acceptance through administration, transfer to another registrant, or appropriate disposal.

Security, documentation, and recordkeeping are all critical. The pharmacy logs all controlled substances into their inventory. Those drugs remain a part of the pharmacy’s inventory until one of two things happens: 1) The drugs are expired or unwanted and removed from inventory either through reverse distribution by a transfer between DEA registrants or DEA authorized witnessed destruction, or 2) they are dispensed to a patient (specifically, removed from inventory as noted in the [DEA letter](#)).

Under Part 1317, expired or unwanted controlled substances in the pharmacy’s inventory must be sent to a reverse distributor or undergo incineration witnessed by two of the registrant’s employees or other DEA-authorized destruction method. Not only can the process of reverse distribution be a cost benefit to the hospital as these entities will handle any items that can be credited, but under the DEA rule, this is a process available to ensure the drugs that are in inventory are rendered “non-retrievable” from the DEA’s perspective.

If the pharmacy has access to a permitted incinerator where two authorized employees can witness the destruction and complete the [Form 41 Registrant Record of Controlled Substances Destroyed](#), this process also meets the standard. Organizations wishing to use an alternative to reverse distribution or incineration should seek specific authorization in writing from DEA. Dispensed medications should be documented as having been removed from inventory.

### Wastage

As clarified in the DEA’s practitioner letter, once dispensed for administration, any remaining residue is considered wastage. Security, recordkeeping, and reporting protocols must remain in place, as articulated in [CFR Title 21 Section 1304.22\(c\)](#).

The DEA directs that destruction and/or disposal of wastage must not violate any other federal, state, tribal, or local environmental rule, regulation, or statute. However, the DEA does not regulate the destruction or disposal of pharmaceutical wastage as they do for inventory. Additionally, one must be aware of circumstances where there are controlled substances that – even when wastage – become an EPA hazardous waste. Chloral hydrate (U034), testosterone gels (D001), and valium injectable (D001) are examples which have been [provided by the EPA](#). A best practice for facilities is to include relevant health care stakeholders in discussions regarding management of this wastage.

### The role of reverse distributors

A DEA-registered reverse distributor may accept controlled substances from another registrant for the purpose of either processing the return based on the manufacturer’s credit return policy or processing the controlled substances for disposal by witnessed incineration.

### Recordkeeping and reporting

Under the 2014 rule, all recordkeeping and reporting requirements, including security controls and chain of custody documentation, from prior DEA rules remain unchanged. However, Part 1317 of the 2014 rule specifies the disposal requirements for controlled substances within the organization’s inventory. While the disposal requirements in Part 1317 do not apply to wastage, the DEA mandates all other security and recordkeeping policies and procedures remain in place.

## Application for pharmacy

### Inventory

Under Part 1317, the biggest change in the cycle of controlled substances is the management of outdated compounded IVs containing controlled substances. Outdated compounded IVs are included in pharmacy inventories. Therefore, they must be managed as inventory and either sent through reverse distribution or undergo witnessed destruction through a DEA-authorized destruction method that meets the non-retrievable standard.

### Wastage

The pharmacy should also take responsibility for working with nursing management to develop a sequestration program in the nursing units for wastage. In addition, if any controlled substances in the pharmacy’s inventory become a Resource Conservation and Recovery Act (RCRA) hazardous waste, cartridges or bottles used for sequestration will contain these wastes and must be managed as hazardous waste. This includes using appropriate sequestration devices. If there is difficulty in ensuring compliant segregation of hazardous and non-hazardous controlled substance wastage in the nursing units, all sequestration devices should be managed as if they contain hazardous waste.

## Application for administration of controlled substances

### Inventory

If there are expiring controlled substances in the nursing unit, or those that have not been dispensed to a patient by an institutional practitioner on the basis of an order for immediate administration to the patient, the controlled substances remain in inventory. Coordination with pharmacy or other appropriate staff should take place to ensure these items that remain in inventory are appropriately addressed.

### Wastage

It is important to remember a few basic but critical rules. The same security, recordkeeping, and recording must continue to be adhered to. Any remaining drugs taken from inventory pursuant to an order for medication are not covered under Part 1317 and do not have to be recorded on DEA Form 41 but must be disposed in accordance with other federal, state, tribal, and local laws and regulations as applicable. In addition, a best management approach is to handle the wastage in a manner that should not allow for access by unauthorized parties.

## Steps in managing controlled substances

The flow chart that follows shows the steps under the non-retrievable standard in identifying and managing controlled substances from inventory to disposal

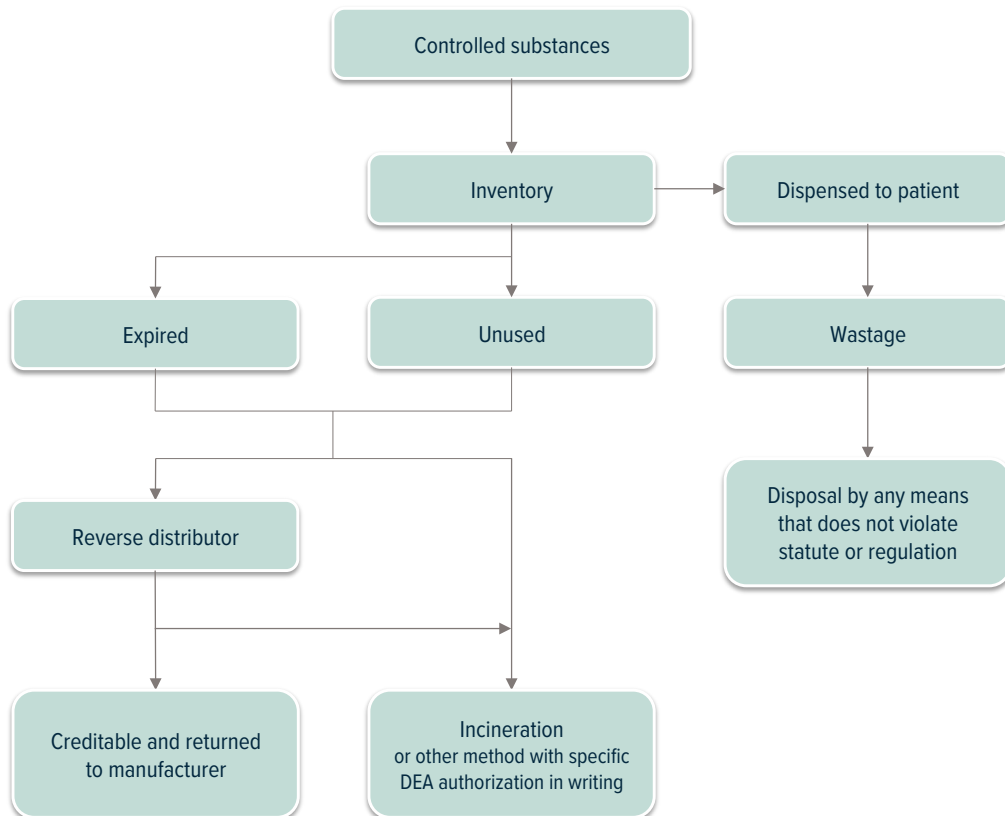
**BEST PRACTICES FOR DISPOSAL OF CONTROLLED SUBSTANCES**

through destruction. All controlled substances received are entered into inventory. As the chart shows, there are two ways to remove drugs from inventory: 1) through reverse distribution or 2) dispensing or administering to the patient. The DEA is not concerned with hazardous and nonhazardous waste designation, as long as regulatory compliance in those areas is maintained. Unless RCRA hazardous wastes are included, any incinerator permitted to handle non-hazardous pharmaceutical waste, including waste-to-energy facilities or medical waste incinerators, may be used for destruction purposes.

In some states and municipalities, wastewater discharge is still available, although this practice is highly discouraged from an environmental perspective. Therefore, an analysis of the different disposal options on a site-specific basis is advisable to choose the most suitable alternative from an environmental and a security standpoint, and also considering local disposal rules.

The flow chart also shows the steps in managing the waste from administration of controlled substances to disposal of the wastage. The administration of a controlled substance will invariably leave a residual amount, either because the medication is not fully consumed, or small amounts remain in the delivery device. Either way, what remains from a dispensed medication is wastage.

A protocol should be in place that stipulates how wastage will be managed to prevent unauthorized access. As an alternative security measure, the wastage can be placed in commercially available collection/ solidification products that minimize diversion risk. Several commercial options are available that may be reviewed by facilities for consideration based upon their particular protocols and needs. Products that are used should then be transferred to appropriate hazardous or non-hazardous waste vendors for disposal via incineration. This flow chart demonstrates an analysis a facility should take.



As of this publication, incineration is the only destruction and disposal method the DEA recognizes as meeting the non-retrievable standard. Should a registrant desire to use any other method that proposes or documents meeting that standard, the registrant should have written approval from the DEA.

## Summary

Enforcement of the Controlled Substances Act is the responsibility of the Department of Justice Drug Enforcement Administration's Office of Diversion Control. That office's primary mission is the prevention of the illegal use of controlled substances.

The DEA's 2014 Final Rule (Part 1317) differentiates between controlled substances in the pharmacy's inventory versus any wastage remaining after dispensing or administering. Outdated, unused, and unwanted controlled substances in the pharmacy's inventory must be reverse distributed as a transfer between DEA registrants or managed in accordance with regional DEA authorization. The DEA requires that recording of specific information must accompany "wasting" procedures, states the need for two witnesses, and requires efforts to prevent diversion. It is important to consider that any disposal option for wastage must take into account both environmental and security concerns to ensure the waste is not only kept from being diverted but also that ultimate disposal provides the least impact to the environment. The use of a sequestration device followed by incineration is a reasonable option. Any questions regarding the disposal of any controlled substances, whether from inventory or wastage, should be directed to either the hospital's director of pharmacy or other appropriate designated person.

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