



## Frequently Asked Questions : DEA Rule on the Disposal of Controlled Substances (DEA-316)

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**Editor’s Note:** *As a result of ongoing conversations between ASHP and the Drug Enforcement Agency (DEA), the DEA released a letter clarifying how pharmaceutical wastage should be handled in light of the Final Rule discussed below. The FAQs were revised to take into account new information from the agency.*

### Summary

On September 9, 2014, the Drug Enforcement Agency (DEA) published its [Final Rule on the Disposal of Controlled Substances](#).<sup>1</sup> The Proposed Rule was published on December 21, 2012.<sup>2</sup> ASHP submitted comments on the Proposed Rule and identified a number of concerns that the organization had about the way the DEA proposed handling of controlled substances that were no longer wanted by patients or no longer useful to a hospital, health system, or clinic. Below are the answers to frequently asked questions from ASHP members. The effective date of the Final Rule is October 9, 2014.

### **May a hospital or clinic serve as a collection site for unwanted controlled substances?**

Yes. The DEA recognizes the benefits of increasing the number of collection sites for controlled substances. As such, the Agency has modified the rule to allow for any hospital or clinic with an on-site pharmacy to serve as a collection site. These sites may install collection receptacles at multiple locations within the hospital or clinic, but they must be in places that are regularly monitored by employees. In addition, no collection receptacle may be placed in or near an emergency room or urgent care area due to the chaotic nature and public access of these areas.

### **Wouldn’t it just be easier for hospital staff to collect unwanted drugs from patients or the public and then dispose of them according to DEA regulations?**

The DEA specifies that under no circumstances may pharmacy or hospital personnel collect controlled substances from ultimate users (patients) or other individuals authorized to handle

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<sup>1</sup> Federal Register, Vol. 79, No. 174, pp. 53520 – 53570.

<sup>2</sup> Federal Register, Vol, 77, No. 246, pp. 75784 – 75817.

controlled substances on a patient's behalf. These individuals must be the ones to deposit the substances directly into collection receptacles.

**My hospital has a contract with a long-term care (LTC) facility. Can they collect controlled substances too?**

Yes, provided the hospital or clinic has an on-site pharmacy, they may install and empty receptacles at LTC facilities, although the LTC facility cannot be responsible for the container nor can they dispose of anything in it. The sealed inner liners may be stored at the LTC facility for up to 3 days, prior to pick up by a reverse distributor, but they may not be transported by the hospital or clinic. The DEA encourages emptying of receptacles at the same time they are picked up by common carrier or reverse distributor.

LTC staff may assist residents who are unable to physically mail back or deposit the drugs, but the LTC staff cannot routinely collect and/or store controlled substances.

**Can pharmacists participate at a "takeback" event?**

The DEA clarifies that any takeback event must be held in partnership with law enforcement and that law enforcement must be present at the event. Pharmacists and other health professionals may assist law enforcement at these events and there are no restrictions on how law enforcement handles the collected substances as long as they maintain control and custody throughout the takeback event.

The DEA defines law enforcement to include law enforcement components of the Federal government as well.

**Can my hospital sort the collected drugs into controlled versus non-controlled substances? We're concerned about storage capacity if these two types of drugs are comingled.**

The DEA will not allow authorized collectors to sort collected medications after they have been deposited into a receptacle by the user (the patient who is prescribed the medication). The Agency has clarified that there is no requirement to comingled non-controlled and controlled substances, meaning that authorized collectors could instruct patients to deposit only controlled substances into a receptacle. However, authorized collectors may not handle the medications individually, although they may remove and immediately seal inner liners of the receptacles.

The exception to this prohibition is for law enforcement who may sort medications into controlled versus non-controlled substances after a takeback event and dispose/destroy the controlled substances in accordance with local, state, and federal guidelines and laws.

The DEA does not believe that storage should be an issue and that shipments of discarded medications can be arranged in such a way to reduce the chances that large amounts of

controlled substances will be sitting in a secured room. The Agency has allowed for an increase in the amount of time between when an authorized reverse distributor takes possession of controlled substances and when they must destroy them from a proposed 14 days to 30 days in the Final Rule.

**What methods does the DEA allow for destruction of unwanted or discarded controlled substances?**

The DEA makes clear that they will not be recommending a list of methods of destruction and that their main focus is to define “non-retrievable” which is to mean permanently rendering the drug into an unusable state through physical or chemical change, for example. The DEA will not evaluate, review, or approve the processes by which drugs are rendered non-retrievable. The Agency does state, however, that methods such as “sewering” (i.e., flushing) or mixing with cat litter/coffee grounds do not satisfy these requirements for DEA registrants. Ultimate users (patients) may dispose of controlled substances in accordance with the product label and local laws which may include sewerage.

**Will the DEA provide a grace period to phase out “sewering” and/or specifically exempt transdermal or skin patches?**

The DEA states that the technology currently exists to render controlled substances “non-retrievable” and that there will be no grace period beyond the October 9, 2014 effective date of the rule. FDA approved labels may allow ultimate users to sewer narcotic transdermal products as they are not DEA registrants, nor are they bound by the Final Rule.

**When do I have to use a DEA Form 41?**

The DEA is modifying the Form 41 to be the single document used by both closed systems (e.g., health systems) as well as by reverse distributors. The Agency requires that the record of destruction include two signatures of employees that witness the destruction of the controlled substance and the method by which it was destroyed. These records must be kept for a minimum of 2 years. The DEA reaffirms that this documentation must occur every time controlled substances are destroyed.

**What are we supposed to do with leftover drug from an IV administration or an injection?**

As a result of ongoing discussions between the DEA and ASHP, the agency posted a “[Dear Practitioner](#)” letter on their website on Friday, October 17, 2014 clarifying how the final rule applies to pharmaceutical wastage. The DEA states that the new disposal requirements as implemented by the Final Rule is intended to apply to the disposal of practitioner inventory, as opposed to pharmaceutical wastage.

The DEA further clarifies that:

*...once a controlled substance has been dispensed to a patient by an institutional practitioner on the basis of an order for immediate administration to a patient at the registrant's registered location, the substance is no longer in the practitioner's inventory. For example, after a pre-filled syringe or a single-dose vial or syringe is administered to a patient, any remaining substance in the syringe or vial is not required to be destroyed in accordance with new Part 1317. However, the remaining substance should be destroyed in accordance with applicable Federal, State, tribal, and local laws and regulations.*

**What about drugs left in my hospital or site by patients who forget to take them, don't want them anymore, or pass away while at my institution?**

The law that this Final Rule is implementing only allows for three types of entities who may deliver controlled substances for disposal: 1) ultimate users (patients), 2) those who are legally entitled to dispose of controlled substances in the event of death of the ultimate user, and 3) LTC facilities.

The DEA states that for long-term-care facilities, a staff member may act on behalf of the patient by placing it in a container or mail back container, but that they cannot routinely collect these meds and store them. In cases where a patient has intentionally left the meds there, they are considered "unwanted" and the LTC facility may put them in a collection receptacle.

The DEA also states that they are bound by the law and cannot authorize additional individuals or entities (including hospitals/health systems and their staff) to deliver controlled substances for disposal, and therefore, if no next of kin is available, they are advised to contact local law enforcement or the local DEA office for guidance on disposal.

**Additional Information and Resources**

- [October 17, 2014 DEA "Dear Practitioner" Letter](#)
- [DEA Final Rule](#)
- [September 9, 2014 DEA "Dear Registrant" Letter](#)

For general inquiries about DEA's Final Rule, please contact Christopher Topoleski, Director of Federal Regulatory Affairs at 301-664-8692 or via e-mail at [ctopoleski@ashp.org](mailto:ctopoleski@ashp.org).

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