**Summary of the** **Drug Enforcement Administration’s**

**Final Rule for the Disposal of Controlled Substances**

Final Rule: <https://federalregister.gov/a/2014-20926>

DEA’s Drug Disposal website: <http://www.deadiversion.usdoj.gov/drug_disposal/>

**The Drug Enforcement Administration (“DEA”) released a final regulation (“the rule”) on September 9, 2014 to implement the Secure and Responsible Drug Disposal Act of 2010 by expanding options to collect controlled substances from ultimate users for secure destruction.**

**Effective date** = October 9, 2014 (30 days after official publication in the Federal Register).

This summary highlights key provisions of the DEA’s regulation, with references to sections of the final rule and to statements in the explanatory text of the Federal Register document. The final rule contains many more details than can be provided in this detailed summary. Stakeholders seeking to comply with this regulation should review the entire rule carefully, and contact the DEA to resolve any questions.

***Key definitions in existing law:*
Controlled substances** (“CSs”) are drugs or other materials that, because of their potential for abuse, are closely regulated by the federal government and are classified according to Schedules I-V;
“**Schedule I**” CSs are illegal drugs such as cocaine and heroin that are not legal to possess or use; “**Schedule II through V**” CSs are legal pharmaceuticals; the rule addresses the collection and destruction of Schedule II – V CSs.
In the controlled substance universe, “**registrants**” are those entities that are registered with DEA to handle controlled substance drugs from the point of manufacture, through distribution, to retail pharmacy sale, or administration in a hospital.
“**Reverse distributors**” are registrant companies authorized to accept unsold controlled substances from other registrants or law enforcement for purposes of return-for-credit and/or for destruction.

An “**Ultimate user**” is “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household” (21 U.S.C. 802, see <http://www.deadiversion.usdoj.gov/21cfr/21usc/802.htm>).
DEA proposes slightly different requirements for authorized collectors that are “**Practitioners**” (i.e., retail pharmacies and hospitals/clinics with on-site pharmacies) and those that are “**Non-practitioners**” (i.e., manufacturers, distributors, reverse distributors, narcotic treatment centers).

**General background**

Collection methods for controlled substances in the final rule include:

1. **Take-back events** – conducted by law enforcement.
2. **Mail-back programs** – administered by authorized manufacturers, distributors, reverse distributors, retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment centers, or law enforcement.
3. **Collection receptacles (i.e., permanent drop-off boxes)** – operated by authorized manufacturers, distributors, reverse distributors, retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment centers, or by law enforcement.
Authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may also operate collection receptacles at long-term care facilities (“LTCFs”).

The proposed regulations also reorganize and consolidate existing regulations on disposal, including clarifying the role of reverse distributors. Definitions and other details are amended in Parts § 1300, 1301, 1304, 1305, 1307 of Title 21 of the *Code of Federal Regulations* (“CFR”). A whole new Part § 1317, labeled “Disposal,” is added. We reference specific sections of the proposed CFR citations throughout this summary.

The Secure & Responsible Drug Disposal Act of 2010 defines that the rule applies to controlled substances (Schedule II – V) accepted for disposal from:

* An **ultimate user** (i.e., the person to whom the drug is prescribed, or a member of the person’s household, or an animal owned by the person) [§ 1317.30(b)(1)]; or
* **Individuals legally authorized to dispose of ultimate user decedent’s property** (i.e., when a person dies, a person authorized to dispose of their property may return their drugs for disposal) [§ 1307.30(b)(2)]; or
* **Long-term care facilities**, on behalf of an ultimate user who resides, or has resided, at the LTCF [§ 1317.30(b)(3)], only **via a collection receptacle on the premises maintained by a retail pharmacy** or a hospital/clinic with an on-site pharmacy [§ 1317.80]. (LTCF is defined in§ § 1300.01(b) and “means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.”)

General provisions that apply to all collection methods:

* According to the provisions of the Secure & Responsible Drug Disposal Act of 2010:
	+ all proposed collection methods are **voluntary**. Nothing in the rule requires anyone to serve as a collector.
	+ **no funding** mechanism is provided for CS disposal, collection or destruction.
* Controlled substances and non-controlled medicines can be **comingled**, but this is not required [§ 1317.65(d), § 1317.70(b) and § 1317.75(b)].
* The rule is silent on the issue of **collection of loose pills** separated from their packaging (e.g., plastic pill bottles or blister packs). This practice is not required, but is allowable at the discretion of the collector. [addressed in rule document on page 53532, third column, issue 4] [Note: as a best practice, individuals should only separate their medicines from packaging at the collection point. Anyone transporting controlled substances may need to prove they are authorized to possess the medicine by showing name on prescription label.]
* **Controlled substances cannot be counted** **separately or inventoried** once collected into a sealed inner liner in a collection receptacle or a sealed mail-back package. Sealed inner liners from collection receptacles and sealed mail-back packages cannot be opened, x-rayed, analyzed, or otherwise penetrated.[§ 1317.60(c) and § 1317.70(f)]. The **only exception is that law enforcement are not required to follow all the same security protocols as other collectors and therefore may conduct or allow sorting or inventorying** of controlled substances and other medicines they collect under appropriate law enforcement supervision. In addition, the rule does not prohibit visual screening of medicines prior to placement in a collection receptacle or polling of residents about the medicines they are disposing of. [Federal Register 79 (174) on page 53534, column 2, Issue 16; on page 53538, second column, Issue 5; and on page 53539, column 2, issue 3.]
* Employee of a registrant is as defined under the general common law of agency. [§ 1300.05(b)] There are specific prohibitions against collectors employing anyone with access to controlled substances that has a felony conviction or that has had a DEA license denied/revoked/suspended. [§ 1301.71(f)]
* Law enforcement officer has a specific definition, see Law Enforcement section or see § 1300.05(b).
* The rule is silent on methods to **protect confidentiality of patient information** on packaging (i.e., HIPAA protections), therefore best practices already in place at existing take-back programs can be utilized. Provisions prohibiting any inventorying of collected medicines also serve to protect patient information.

**Collectors who may be authorized by the DEA** (excludes Law Enforcement, see below)

* The following **existing DEA registrants** can amend their registration with the DEA to become a “collector” [§ 1300.01(b) and § 1317.40] of CSs:
	+ **drug manufacturers**,
	+ **drug distributors**,
	+ **reverse distributors**,
	+ **narcotic treatment program,**
	+ **hospital/clinic with an on-site pharmacy,** i.e. a pharmacy located on the physical premises of the registrant’s registered location [§ 1300.05(b)(3)].
	+ **retail pharmacies**.
* A registrant listed above may send a written request to DEA to modify its existing registration to be designated as a collector No fee is required. Authorized collectors must also provide written notification to DEA if they stop collecting controlled substances. Written notification may be provided online at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov) or by mail. [§ 1301.51].
* In addition, as noted below, law enforcement is already authorized to handle CSs and therefore are not included in the “collector” definition. See Law Enforcement section below for separate requirements for law enforcement programs.
* Only specific existing DEA registrants can be authorized to serve as collectors. Non-registrants such as government entities, HHW collection facilities, and community centers, cannot serve as authorized collectors for controlled substances. [Federal Register 79 (174): on page 53530, column 1, Issue 1.]
* DEA’s rule narrative notes the current number of potential collectors as follows:
	+ Manufacturers – 536
	+ Distributors – 829
	+ Reverse Distributors – 60
	+ Narcotic Treatment Programs – 1332
	+ Hospitals/clinics with an On-Site Pharmacy – 15,953
	+ Retail Pharmacies – 69,026

**General Procedures for all Collectors** (excludes Law Enforcement, see below)

* Collectors may only accept Schedule II-V controlled substances, not Schedule I drugs [§ 1317.70(b) and § 1317.75(b)]. Collectors cannot dispose of inventory or stock of controlled substances in the collection receptacles or mail-back packages. [§ 1317.05 and § 1317.75(b)]
* **Collectors cannot handle the controlled substances returned by ultimate users** before they are placed in the collection receptacle or mail-back package. Only law enforcement can directly accept a controlled substance from an ultimate user. [§ 1317.75(c)] [Federal Register 79 (174) on page 53535, column 2, Issue 21; page 53540, column1, Issue 6; and page 53539, column 2, issue 3.]
* **Sealed inner liners and mail-back packages containing collected drugs must be stored securely by authorized collectors [§ 1301.75(c)].** Practitioners and long-term care facilities must use a securely locked, substantially constructed cabinet or a securely locked room with controlled access [§ 1301.75(c) and § 1317.80(d)], and non-practitioners must use a storage area at a security level appropriate for Schedule II CSs[§ 1317.05(c)(1)(ii) and (c)(2)(ii)].
* Collectors shall either **destroy the collected drugs on-site** [§ 1317.05(c)(1)(i) and § 1317.05(c)(2)(i)] **or transfer the drugs for final disposal** in one of the following ways:
	+ Practitioners, i.e. retail pharmacies and hospitals/clinics with on-site pharmacy, may transfer collected drugs for destruction [§ 117.05(c)(2)(iv)]:
		- By prompt delivery using common or contract carrier to a reverse distributor’s or a distributor’s authorized location; or
		- By pick-up at the authorized collection location by a reverse distributor or a distributor; or
		- Request assistance from the DEA Special Agent in Charge in the practitioner’s area.
	+ Non-practitioners, i.e. manufacturers, distributor, reverse distributors, and narcotic treatment centers, may transfer collected drugs for destruction [§ 1317.05(c)(2)(v)]:
		- By prompt delivery, using common or contract carrier to a reverse distributor’s or a distributor’s authorized location; or
		- By pick-up at the authorized collection location by a reverse distributor or a distributor.
		- By prompt transportation by the authorized collector's own means to a reverse distributor or location for destruction. Transportation by a collector’s own means shall include two authorized employees at all stages: loading, transport, unloading, handling. [§ 1317.05(b)(4)]
		- Freight forwarding facilities may not be used to transfer sealed inner liners.
* **Record-keeping for all collectors** [§ 1304.22(f)].Collectors must keep an inventory of all inner liners and all mail-back packages and maintain records on use and destruction to account for disposal of CSs.
* **Timing of disposal of collected medicines.** Reverse distributors must destroy controlled substances received for the purposes of destruction within 30 days of receipt [§ 1317.15(d)]. Long-term care facilities cannot store sealed inner liners longer than 3 business days. [§ 1317.80(d)] Otherwise, collectors must dispose of drugs in the sealed mail-back packages or inner liners “promptly”, which is not precisely defined by DEA to allow flexibility. [Federal Register 79 (174):on page 53528, column 3, Issue 12]

**Collection by Law Enforcement [§ 1317.35]**

* Law enforcement can operate **take-back events**, **mail-back** or **collection receptacles** to collect CSs from ultimate users. Law enforcement is the only entity who may operate take-back events.
* The rule is not intended to change established law enforcement agency procedures for handling, storage and transfer of CSs. Law enforcement are not required to meet all the same requirements of other collectors for mail-back or collection receptacles.
* Take-back events and mail-back programs provided by law enforcement must be overseen by a **law enforcement officer**, which is defined in § 1300.05(b) as:
	+ An employee of a law enforcement agency or law enforcement component of a federal agency who is (1) under the discretion of a Federal, State, tribal, or local government, (2) acting in course of official duty, and (3) duly sworn to carry firearms, execute and serve warrants, make arrests without a warrant, and make seizures of property; or
	+ A Veterans Health Administration (VHA) police officer authorized by Dept. of Veterans Affairs to participate in VHA collection activities; or
	+ A Dept. of Defense (DOD) police officer authorized by DOD to participate in DOD collection activities.
* Record-keeping and storage by law enforcement should be consistent with the agencies’ storage and record-keeping procedures for illicit (Schedule I) CSs, such as evidence.
* **Destruction of controlled substances collected by law enforcement.** Law enforcement can transport collected CSs to a destruction location as long as the transfer is done in a manner that prevents diversion [§ 1317.35(d)]. Or the law enforcement agency can transfer collected CSs to a reverse distributor for destruction with specific record-keeping requirements [§ 1317.35(e)].

**Take-back events [§ 1317.65]**

* Only **law enforcement** can run take-back events, but other entities can partner or co-sponsor such events [§ 1317.65(a)].
* Take-back events must be overseen by a **law enforcement officer** as defined in [§ 1300.05(b)], see above.
* **No other person besides the ultimate user and the law enforcement officer may handle CSs** at any time during the event (e.g., community volunteers or pharmacists may not handle CSs) [§ 1317.65(e)].
* The rule recommends that there should be at least one secure receptacle at take-back events to achieve optimal security [§ 1317.65(c)]. Law enforcement have discretion on the use or type of the secure receptacle for events.

**Mail-back [§ 1317.70]**

* **Law enforcement** and **collectors who have on-site destruction capabilities** (e.g., reverse distributors) can run mail-back services.
* Any other entity (e.g., retail pharmacy, government agency, sponsoring company) can **partner** with an authorized collector or law enforcement agency to make mail-back packages available to ultimate users [§ 1317.70(c)].
* **Specifications of mail-back packages** [§ 1317.70(c)(1-6)]:
	+ Provided either at no cost or a fee;
	+ Nondescript, tamper-evident, tear-resistant, water-proof, spill-proof and sealable;
	+ Postage paid and pre-addressed to authorized mail-back location (i.e., collector’s registered location with on-site method of destruction or to law enforcement agency’s physical address);
	+ Each mail-back package must have a unique ID number so that each package can be tracked;
		- Collector must keep inventory of mail-back packages created and record the unique ID number of each package received;
		- Collector is not responsible for tracking mailers that were disseminated but never returned.
	+ Each package must include instructions for the user that indicate process for mailing back the package, the permitted substances that can be sent, and related information;
* No personal information from the ultimate user shall be required.
* **Only law enforcement officers** as defined in § 1300.05(b), see above, shall handle mail-back packages for a law enforcement program. Only employees as defined in § 1300.05(b) shall handle mail-back packages for a mail-back program administered by an authorized collector.
* Collectors administering a mail-back program may not open, x-ray, or analyze the packages.
* **Destruction of mail-back packages.**
	+ Authorized collectors must render returned mail-back package non-retrievable on-site, by a method consistent with § 1317.90.
	+ Law enforcement are not required to destroy mail-back packages on-site and may continue to transfer collected CSs in mail-back packages to reverse distributors for destruction [§ 1317.35(d) and (e)].
* DEA recognizes that proposed requirements may limit the number of companies authorized to conduct a mail-back program; however, it notes that a single authorized mail-back program would be capable of receiving packages from any location within the U.S.

**Collection receptacles** [**§ 1317.75]**

* Registered **collectors** may maintain a collection receptacle at a DEA registered physical location. **Law enforcement** may also maintain a collection receptacle at their registered locations.
	+ Receptacles cannot be placed at non-registered locations such as libraries or community centers.
* **Collection receptacle placement and requirements** [§ 1317.75(d) and (e)]:
	+ Receptacles must be securely placed and maintained within a collector’s or law enforcement’s physical location or at an authorized long-term care facility. The receptacle must be in a location where an employee is present, except that:
		- A hospital/clinic collector may place the receptacle in an area regularly monitored by employees, but not in ER or urgent care area;
		- A narcotic treatment program collector must locate the receptacle in a securely locked room, with limited access, that does not contain any other controlled substances; and
		- A long-term care facility must place the receptacle in a secured area that is regularly monitored by employees.
	+ Permanent, “substantially-constructed,” securely locked outer container with removable inner liner;
	+ Small opening must be baffled or otherwise constructed so that contents can be added but not removed through it;
	+ Opening must be locked or otherwise inaccessible to the public when an employee is not present (unless receptacle is located in a secured area of a narcotic treatment center);
	+ Outer container must be securely fastened to a permanent structure so that it cannot be moved;
	+ Signage requirements must indicate that only Schedule II – V CSs and non-CSs are accepted (i.e., no illegal drugs – Schedule I – are accepted);
* **Inner Liner requirements** [§ 1317.60]
	+ Inner liner must be waterproof, tamper-evident, tear-resistant, opaque and sealable, with the size clearly marked.
	+ Inner liner must have permanent identification number for tracking that is unique to each collector;
	+ Removal of inner liner shall be performed by or under the supervision of at least two employees of the authorized collector.
	+ Inner liner must be immediately sealed, and cannot be opened, x-rayed, analyzed, or otherwise penetrated.
	+ The DEA rule does not create a definition for “inner liner”, and the Federal Register document explains this by saying the requirements of inner liners are described in § 1317.60.

**Long-Term Care Facilities (LTCFs)**

* + LTCF is defined at § 1300.01(b) and “means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.”
* Only authorized **retail pharmacy registrants or hospital/clinic registrants with an on-site pharmacy** may operate a collection receptacle at a LTCF [§ 1317.80(b)].
* LTCF staff may dispose of CSs on behalf of resident ultimate users into an authorized collection receptacle managed on-site by an authorized collector [§ 1317.80(a)].
* Such disposal must occur within 3 business days after the discontinuation of use by the ultimate user [§ 1317.80(a)]. LTCFs may store sealed inner liners for up to 3 business days in a controlled access room. [§ 1317.80(d)]
* Only the authorized collector (retail pharmacy or hospital/clinic registrant) may manage the collection receptacle at the LTCF, including removal of the inner liner, following protocols as noted above [§ 1317.80(b)]. The inner liner may be removed by one employee of the collector and one supervisory-level employee of the LTCF [§ 1317.80(c)].
* Each physical location of a LTCF collection receptacle must be included in a retail pharmacy’s or a hospital/clinic with an on-site pharmacy’s application to modify its DEA registration [§1301.51(b)(2)].
* All disposal options are available to ultimate users who reside in, or resided in, LTCFs; for example, mail-back packages can be used [Federal Register 79 (174): page 53541].
* Without a collection receptacle, the LTCF is not permitted to dispose of a CS on behalf of an ultimate user. The ultimate user residing in the LTCF, or persons lawfully entitled to dispose of a decedent’s property, may dispose of the CS using the methods available to any ultimate user outside of the LTCF. [Federal Register 79 (174): page 53542]

**Role of reverse distributors and distributors**

* The rule modifies the definition of reverse distributor and modifies some requirements for reverse distributors. [§ 1300.01(b) and § 1317.15]
* The rule adds a definition for the term “reverse distribute” in § § 1300.01(b). “Reverse distribute” for destruction can apply to both reverse distributors and other registrants authorized by the Disposal Act to accept controlled substances for destruction, e.g. forward distributors.
* Reverse distributors can accept CSs that have been collected by law enforcement and other authorized collectors through collection receptacles and mail-back programs [§ 1317.55(a)].
* Distributors can also accept CSs from authorized collectors through collection receptacles [§ 13§ § 1317.55(b)].
* Reverse distributors must destroy CSs no later than 30 days from pick-up or receipt. [§ 1317.15(d)]
* Reverse distributors must keep records of receipt, storage, transfer and destruction of CS mail-back packages and inner liners [§ 1304], but cannot open or inventory the contents of packages [§ 1317.70(f)] or liners [§ 1317.75(c)].
* Authorized collectors, including reverse distributors and distributors, are exempt from reporting through the ARCOS system for controlled substances collected through collection receptacles and mail-back programs. [§ 1304.33(g)]

**Disposal**

* **Destruction** means that collected CSs must be rendered “**non-retrievable**” – to permanently alter any controlled substance’s physical and/or chemical condition or state through irreversible means in order to render that controlled substance unavailable and unusable for all practical purposes [§ 1317.90(a) and § 1300.05(b)].
* The destruction standard is not prescribed otherwise. Examples of current technology that may achieve the non-retrievable standard are incineration and chemical digestion. “The DEA will not evaluate, review, or approve the processes or methods utilized to render a controlled substance non-retrievable, as long as the desired result is achieved.” [Federal Register 79 (174): page 53547, column 3, Issue 1]
* **“…[S]ewering (disposal by flushing down a toilet or drain) and landfill disposal (mixing controlled substances with undesirable items such as kitty litter or coffee grounds and depositing in a garbage collection) are examples of current methods of disposal that do not meet the non-retrievable standard.”** [*Federal Register* 79 (174): 53548].
* **Destruction methods must meet all applicable federal, state, tribal, and local laws and regulations** [§ 13§ § 1317.90(a)].
* These standards apply to controlled substances collected by authorized collectors and law enforcement, but not to ultimate users who may also continue to use the disposal guidance provided by Food & Drug Administration and the Office of National Drug Control Policy [Federal Register 79 (174): page 53547].