

Client Alert

Special Matters and Government Investigations Practice Group

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DEA's Proposed New Regulations Regarding the Disposal of Controlled Substances

The Drug Enforcement Administration (DEA) recently issued a notice of proposed rulemaking with regard to the disposal of controlled substances. These regulations seek to implement the Secure and Responsible Drug Disposal Act of 2010 (the Disposal Act, Pub. L. 111-273, 124 Stat. 2858), which amended the Controlled Substances Act (CSA) and authorized DEA to develop permanent, ongoing, and responsible methods for the disposal of controlled substances that have been dispensed to an end-user.

Background

Prior to the passage of the Disposal Act, the CSA's closed system for controlled substance distribution did not account for circumstances in which a controlled substance was lawfully dispensed to an ultimate user (*i.e.*, a patient) but was not fully consumed. Under the prior regulatory scheme, an end user was not authorized to transfer a controlled substance to another person, even for the purpose of disposal.

Without the ability to return unwanted controlled substance medications, an end user had extremely limited disposal options. The patient could dispose of the drugs by throwing them away or flushing them down a toilet, options which present environmental concerns, or he could surrender the drugs to law enforcement. Opportunities to return drugs to law enforcement have only recently been readily available, however, as the DEA began to sponsor national "Take-Back Days." DEA has sponsored a total of only five Take-Back Days from 2010 through 2012. As a result of the limited options for disposal, controlled substances have tended to accumulate in household medicine cabinets where they are susceptible to abuse or diversion.

The Disposal Act has amended the CSA by allowing ultimate users to deliver their controlled substances to another person for the purpose of disposal, with the return and disposal being conducted in accordance with the regulations now being promulgated by the DEA.

Overview of Proposed Regulations

The proposed rule deletes 21 CFR §1307.12 on "Distribution to supplier or manufacturer" and 21 CFR § 1307.21 on "Disposal of controlled substances" and promulgates a new part 1317 that sets forth a comprehensive set of

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regulations on controlled substance disposal. DEA's proposed regulations expand the disposal options available to end users¹ to include three voluntary options for ultimate user disposal: take-back events, mail-back programs, and collection receptacle programs.²

- Take-back events -- The proposed regulations specifically authorize federal, state, tribal, and local law enforcement agencies, either independently or in partnership with private entities or community groups, to voluntarily hold take-back events. Take-back events must be overseen by a full-time law enforcement officer, and law enforcement officers must maintain control and custody over the controlled substances from the time the substances are collected until secure transfer, storage, or destruction has occurred. The regulations specify that no person other than an ultimate user and a law enforcement officer may handle the controlled substances during a take-back event.
- Mail-back programs -- The proposed regulations authorize law enforcement agencies to conduct mail-back programs. Mail-back programs may also be conducted by DEA-registered manufacturers, distributors, reverse distributors, or retail pharmacies if the registrant is authorized as a "collector" and utilizes an on-site method of destruction at their registered location. The law enforcement agency or collector conducting the mail-back program must produce and provide secure, pre-addressed, postage paid packages to ultimate users who can then return controlled substances through the mail. The agency or collector conducting the mail-back program may partner with third parties for various purposes, including making the packages available to the public. For example, a DEA-registered reverse distributor that is authorized as a collector and will destroy the controlled substances at its facility may partner with another business, such as a retail pharmacy, that can provide the packages to its customers.
- Collection receptacles -- Under the proposed regulations, a law enforcement agency may maintain a secure collection receptacle at the agency's physical location. The regulations also authorize any DEA-registered manufacturer, distributor, reverse distributor, or retail pharmacy authorized as a collector to maintain a collection receptacle at their DEA-registered location. Collection receptacles may not be placed at non-registered locations such as libraries or community centers. The regulations also allow collection receptacles to be placed at Long Term Care facilities under certain circumstances.³

Requirements for DEA Registrants to Participate in New Controlled Substance Disposal Options

Some of the key requirements for registrant participation in mail-back and collection receptacle disposal programs are outlined below:

General Requirements

- **Modification of registration** -- In order to offer a mail-back or collection receptacle program, a DEA-registered manufacturer, distributor, reverse distributor, or retail pharmacy must apply for a modification to its DEA registration and obtain authorization from DEA to be a "collector."
- **Employee restrictions** -- A collector may not allow an employee who has been convicted of a felony offense relating to controlled substances or who has had a DEA registration revoked or suspended or had an application for registration denied to have access to or influence over the controlled substances acquired by collection.

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- Recordkeeping requirements -- Collectors are required to maintain inventory records for used and unused mail-back packages and collection receptacle inner liners. Authorized collectors are exempt from ARCOS reporting requirements for controlled substances received through mail-back programs or collection receptacles. Schedule II controlled substances collected through mail-back programs and collection receptacles also are exempt from DEA 222 form requirements.

Specific Requirements for Mail-back Programs

- Packages used for mail-back programs must be postage prepaid and preaddressed to a collector's registered location with on-site destruction capabilities. Packages must be nondescript, tamper-evident, waterproof and tear-resistant. Packages must also include instructions for the user that indicate the process for mailing the package back and other information. Each package must have a unique identification number so that the package can be tracked from collection to destruction.
- Ultimate users shall not be required to provide any personally identifiable information when mailing back controlled substances to an authorized collector.
- A collector can only accept for destruction those packages that the collector made available. If a collector receives an unauthorized package, the collector must notify DEA within 3 business days and must store the package securely until the collector receives further instructions from DEA.
- Upon receipt of a sealed mail-back package, the package shall not be opened, x-rayed, analyzed or otherwise penetrated. The collector must destroy the package using an on-site method of destruction or must securely store the package in a manner consistent with the security requirements for Schedule II controlled substances until prompt on-site destruction can occur. A collector operating a mail-back program is not authorized to deliver or transfer controlled substances collected through a mail-back program to a reverse distributor or distributor.

Specific Requirements for Collection Receptacle Programs

- In general, collection receptacles may only be placed at the registered location of the collector
- A collection receptacle must be securely fastened to a permanent structure so that it cannot be removed and must be located in the immediate proximity of a designated area in which controlled substances are stored and at which an authorized employee is present. At a retail pharmacy, this means that the receptacle must be in a position from which it can be seen from the pharmacy counter.
- The receptacle must meet certain design specifications, which include having a permanent outer shell and removable inner liner. The outer shell must have an opening that allows contents to be added to the inner liner while preventing removal of contents. The outer shell must be locked or otherwise inaccessible when an authorized employee is not present. Each inner liner must be waterproof, tamper-evident, tear-resistant and immediately sealable. Each liner must have a unique identification number so that it can be properly tracked from collection to destruction.
- The installation and removal of the inner liner is to be performed by or under the supervision of two or more authorized employees. The inner liner must be sealed immediately upon removal from the outer shell, and the sealed inner liner shall not be opened, x-rayed, analyzed or otherwise penetrated.

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- After the inner liner is removed from the collection receptacle and sealed, the collector must promptly destroy the sealed inner liner and its contents or store the sealed liner and its contents in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur. A collector may destroy the liner and contents on-site in accordance with the regulations or can promptly deliver the liner and contents to a reverse distributor or distributor. A collector may also request assistance from the DEA by submitting a copy of DEA Form 41 to the Special Agent in Charge in the collector's area listing the controlled substances to be disposed of.

Conclusion

These regulations are still in proposed form. King & Spalding plans to issue a further Client Alert when DEA finalizes the controlled substance disposal regulations.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.

¹ The proposed regulations also allow disposal of a deceased ultimate user's controlled substance medications by persons lawfully entitled to disposed of the deceased ultimate user's property and allows Long Term Care Facilities to dispose of controlled substance medications on behalf of current or former residents.

² In addition to expanding the disposal options available to ultimate users, the proposed rule also modifies existing regulations governing reverse distributors and the return and recall of controlled substances. These changes are outside the scope of this article.

³ Under the proposed regulations, only a registered retail pharmacy may manage and maintain a collection receptacle at a Long Term Care facility. A retail pharmacy registrant that plans to operate a collection receptacle at a LTC facility must apply for a modification to its DEA registration and include in the application for modification the physical location of each LTC facility at which the pharmacy intends to operate a collection receptacle. At a LTC facility, a collection receptacle must be located in a secure area monitored by LTC facility personnel. Only authorized employees of the pharmacy registrant may have access to the inner liner of the receptacle.