



Drug Take-Back Program

Frequently Asked Questions (4/30/19)

Q: Does this program conform to the Federal Drug Enforcement Administration (DEA) rules and California State Board of Pharmacy (Board of Pharmacy) guidelines for collecting waste pharmaceuticals?

A: Yes, this program follows the [DEA Final Rule on Disposal of Controlled Substances](#). On June 8, 2017, the Board of Pharmacy adopted their [Prescription Drug Take-Back Services](#) regulations. The Board of Pharmacy regulations language largely parallels that of the DEA Final Rule, but in some cases has additional requirements that Board regulated entities must follow in order to comply. Furthermore, any pharmacy that provides take-back services must notify the Board of Pharmacy in writing within 30 days of establishing the collection program, and annually at the time of renewal of the pharmacy license along with where the collection receptacle is located. A pharmacy shall not provide take-back services if the pharmacy or pharmacist-in-charge is on probation with the Board.

Q: Can Controlled Substances be collected under this program?

A: Yes. The [DEA Final Rule on Disposal of Controlled Substances](#) (DEA Rule) – effective October 9, 2014 – authorizes pharmacies, hospitals with an on-site pharmacy, and other entities to modify their DEA registration to become “collectors” and lawfully accept Schedule II through V controlled substance medications from ultimate users for disposal. Modifying one’s registration is easy, free-of-charge, and can be completed in no more than ten minutes through the DEA’s online [CSA Collector Status Request/Update portal](#).

Q: Is it the collector’s responsibility to contract with a California Board of Pharmacy registered reverse distributor and pay the costs of pharmaceutical waste removal?

A: No, the receptacle disposal costs will be covered until August 31, 2020 from the time of installation. CPSC will coordinate with the reverse distributor to service the receptacle. The grant will also cover the costs of the collection receptacle and public education. The collector will be responsible for paying the disposal costs from September 1, 2020 until the statewide producer-funded program required by SB 212 is implemented, expected for June 2022, unless CPSC is able to secure funding to cover the disposal costs during that period.

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Medical Waste Receptacles:

Internal Capacity: **38 gallons**

Exterior Color: **Stainless steel with primarily white stickers** (example provided, although branding will be significantly different)

Dimensions: **23" W x 20.5" D x 52" H**



Q: How are the receptacles installed?

A: A controlled substance collection receptacle at a pharmacy, skilled nursing facility and hospital/health clinic with an on-site pharmacy must meet the following criteria under the DEA Rule and/or Board of Pharmacy regulations:

1. Inside a collector's registered location
2. In the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter)
3. Be securely fastened to a permanent structure so that it cannot be removed
4. Not located in or near emergency areas, nor behind the pharmacy's counter

The collection receptacle is set up to be easily anchored to a permanent structure and will be installed by CPSC.

Q: Will the collection receptacles be placed in a customer/patient area or behind the pharmacy counter? How do you ensure narcotics or sharps do not end up in the container?

A: The collection receptacle cannot be placed behind the pharmacy counter per the Board of Pharmacy regulation. It is intended to be self-service in the customer area, but visible to the pharmacist so they may screen material being dropped off. Signage on the receptacles will clearly state that sharps and other prohibited items are not allowed in the container, and will also include the name and phone number of the responsible pharmacy as required by the Board of Pharmacy. Another element of this program is the outreach/education campaign, which will teach consumers how to properly use the collection receptacles.

Q: Is there any paperwork or tracking that the pharmacies, skilled nursing facilities and hospitals/health clinics with on-site pharmacies must do for incoming or outgoing pharmaceutical waste?

A: Under the DEA Rule, the installation and removal of the inner liner of the collection receptacle shall be performed by or be carried out under the supervision of at least two employees of the authorized collector and the collector will be provided two keys to unlock the collection receptacle.

The adopted Board of Pharmacy [Prescription Drug Take Back Services](#) regulations require that a pharmacy, skilled nursing facility and hospital/health clinic with on-site pharmacy with a collection receptacle maintain the following records for each pharmaceutical waste collection liner for three years:

1. Date each unused liner is acquired, its unique identification number and size (e.g., five 5 gallon, 10 gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.

2. Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each the removal and sealing.
4. Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique Identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading) and the signature of the driver.

Q: Will the pharmacist have potential civil and criminal liability associated with providing this service to the public?

A: [SB 1229](#), Home-generated pharmaceutical waste: secure drug take-back receptacles, was signed by Governor Jerry Brown on **August 29, 2016** and provides that “*Any collector that maintains a secure drug take-back receptacle shall not be liable in a civil action, or be subject to criminal prosecution, for any injury or harm that results from the collector maintaining a secure drug take-back receptacle on its premises provided that the collector, not for compensation, acts in good faith to take all of the following steps to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the home-generated pharmaceutical waste contained in a secure drug take-back receptacle, unless the injury or harm results from the collector’s gross negligence or willful and wanton misconduct:*

- (1) Complies with all applicable state and federal laws and regulations relating to the collection of home-generated pharmaceutical waste for disposal in secure drug take-back receptacles, including, but not limited to, the federal Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273).*
- (2) Notifies local law enforcement and any local environmental health department as to the existence and location of any secure drug take-back receptacle on the collector’s premises and the status of the collector’s registration as a collector with the federal Drug Enforcement Administration.*
- (3) Ensures that the secure drug take-back receptacle is placed in a location that is regularly monitored by employees of the registered collector.*
- (4) Ensures that conspicuous signage is posted on the secure drug take-back receptacle that clearly notifies customers as to what controlled and noncontrolled substances are and are not acceptable for deposit into the receptacle, as well as the hours during which collection is allowed.*
- (5) Ensures that public access to the secure drug take-back receptacle is limited to hours in which employees of the registered collector are present and able to monitor the operation of the secure drug take-back receptacle.*

(6) Regularly inspects the area surrounding the secure drug take-back receptacle for potential tampering or diversion. Record logs of those inspections shall be maintained and retained for two years, reflecting the date and time of the inspection, and the initials of the employee inspecting the area. The logs shall be maintained in writing or electronically and may be combined with logs required by state or federal regulations. The logs may be used to demonstrate regular inspection of the area. Other records or reports mandated by federal or state regulations shall also be retained for a minimum of two years unless regulations mandate a longer period.

(7) Notifies local law enforcement authorities of any suspected or known tampering, theft, or significant loss of controlled substances, within one business day of discovery. If the collector maintains daily business hours, this notification shall be made within one calendar day.

(8) Notify local law enforcement as to any decision to discontinue its voluntary collection of controlled substances and provide documentation of its written notification to the federal Drug Enforcement Administration's Registration Unit as otherwise required under federal laws and regulations."

Q: Does my city or county have additional registration requirements?

A: Your city or county jurisdiction may have special med bin or medicine collection registration requirements, so we encourage you to contact your city and/or county Household Hazardous Waste facility and Environmental Services Department to ask about registration requirements.

CPSC greatly appreciates your commitment to safe medicine disposal by hosting a collection receptacle and are here to offer you any support needed. Please contact Nate Pelczar via email (Nate@calpsc.org) or by phone (916) 706-3420 with questions or feedback.