

**Title 16. Board of Pharmacy
Order of Adoption**

Proposal to add new Article 9.1 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 9.1. Prescription Drug Take-Back Services

Proposal to add § 1776 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

Section 1776 Prescription Drug Take-Back Services: Authorization

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board may offer, under the requirements in this article, specified prescription drug take-back services through collection receptacles and/or mail back envelopes or packages to provide options for the public to discard unwanted, unused or outdated prescription drugs. Each entity must comply with regulations of the federal Drug Enforcement Administration (DEA) and this article.

Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug distributors (licensed wholesalers and third-party logistics providers) who are registered with the DEA as collectors and licensed in good standing with the board may host a pharmaceutical take-back receptacle as authorized under this article.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, 4026.5, and 4301, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.

Proposal to add § 1776.1 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

Section 1776.1 Pharmacies

- (a) Pharmacies may provide take-back services to the public. Retail pharmacies and hospital/clinics with onsite pharmacies may maintain collection receptacles in their facilities. Pharmacies may offer drug take-back services as specified in section 1776.4 in skilled nursing facilities licensed under Health and Safety Code section 1250(c).
- (b) There are multiple federal, state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.
- (c) For purposes of this article, prescription drugs means dangerous drugs as defined by Business and Professions Code section 4022, which includes controlled substances. Controlled substances may be commingled in collection receptacles or mail back envelopes or packages with other dangerous drugs.
- (d) Once drugs are deposited into a collection receptacle or mail back envelopes or packages by a consumer, they are not to be removed, counted, sorted or otherwise individually handled.

- (e) The collection receptacle shall contain signage that includes:
 - (1) The name and phone number of the responsible pharmacy;
 - (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
 - (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.
- (f) Prescription drugs that are eligible for collection as part of drug take-back services maintained by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected as part of a pharmacy's drug take-back service.
- (g) As part of its drug take-back services, a pharmacy shall not:
 - (1) Review, accept, count, sort, or otherwise individually handle any prescription drugs from consumers.
 - (2) Accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity.
 - (3) Dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock.
- (h) A pharmacy must be registered with the federal DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.
- (i) Any pharmacy that maintains a drug take-back collection receptacle as authorized in this article shall notify the board in writing within 30 days of establishing the collection program. Additionally:
 - (1) Any pharmacy that ceases to maintain a drug take-back collection receptacle shall notify the board in writing within 30 days.
 - (2) Any pharmacy maintaining a collection receptacle shall disclose to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
 - (3) Any tampering with a collection receptacle or theft of deposited drugs shall be reported to the board in writing within 14 days.
 - (4) Any tampering, damage or theft of a removed liner shall be reported to the board in writing within 14 days.
- (j) If the pharmacy ceases to maintain a registered collection receptacle, the pharmacy must notify the DEA within 30 days.
- (k) A pharmacy shall not provide take-back services to consumers if, in the professional judgment of the pharmacist-in-charge, the pharmacy cannot comply with the provisions of this article or the DEA rules.
- (l) A pharmacy shall not provide take-back services to consumers if the pharmacy or the pharmacist-in-charge is on probation with the board, and, if the pharmacy had previously provided take-back services, the pharmacist-in-charge shall notify the board and the DEA as required in subsections (i) and (j), above.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005 and 4022, Business and Professions Code and Sections 1301.71, 1317.30, 1317.40, Title 21 Code of Federal Regulations.

Proposal to add § 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.2 Pharmacies Offering Mail Back Envelope or Package Services

- (a) Pharmacies that provide prescription drug take-back services may do so by providing preaddressed mailing envelopes or packages to allow a consumer to return prescription drugs to an authorized DEA destruction location.
- (b) All envelopes and packages must be preaddressed to a location registered with the DEA as a collector. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed for delivery to facilities that comply with this section.
- (c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.
- (d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and instructions for users that indicate the process to mail back drugs.
- (e) A pharmacy shall not accept any mail back packages or envelopes that contain drugs unless they are registered as a collector and have an onsite method of destruction that complies with the DEA requirements. Instead, consumers shall be directed to mail the envelopes or packages.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code and Section 1317.70, Title 21 Code of Federal Regulations.

Proposal to add § 1776.3 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.3 Collection Receptacles in Pharmacies

- (a) A pharmacy may maintain a collection receptacle for the public to deposit their unwanted prescription drugs for destruction. The pharmacy is responsible for the management and maintenance of the receptacle. The receptacle shall be substantially constructed, with a permanent outer container and a removable inner liner. The collection receptacle shall be locked at all times to prevent access to the inner liner.
- (b) A pharmacy maintaining a collection receptacle must securely fasten the receptacle to a permanent structure so it cannot be removed. The receptacle shall be installed in an inside location. Except as provided in subsection (c), the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter.
- (c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle shall be locked so that

- drugs may not be deposited into the collection receptacle.
- (d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit opening on the collection receptacle.
 - (e) A pharmacy shall direct consumers to directly deposit drugs into the collection receptacle. A pharmacy shall not accept, count, sort or otherwise handle prescription drugs from consumers.
 - (f) A liner as used in this article shall be made of material that is certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
 - (1) The liner shall be waterproof, tamper evident and tear resistant.
 - (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.
 - (g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted or otherwise individually handled.
 - (h) If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately, without interruption, placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair.
 - (i) The liner may be removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner shall be immediately, without interruption, sealed and the pharmacy employees shall record, in a log, their participation in the removal of each liner from a collection receptacle. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.
 - (j) Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than 14 days.
 - (k) The pharmacy shall make and keep the records specified in 1776.6.
 - (l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.
 - (m) The collection receptacle shall contain signage that includes:
 - (1) The name and phone number of the responsible pharmacy;

- (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
- (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.60, and 1317.75, Title 21 Code of Federal Regulations.

Proposal to add § 1776.4 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.4 Drug Take-Back Services in Skilled Nursing Facilities

A pharmacy may offer drug take-back services in skilled nursing facilities licensed under Health and Safety Code section 1250(c) as authorized by this article.

- (a) Skilled nursing facility employees or person lawfully entitled to dispose of the resident decedent's property may dispose of unwanted or unused prescription drugs by using mail back envelopes or packages. The pharmacy shall require skilled nursing facility employees to keep records noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.
- (b) Only pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a collection receptacle in a skilled nursing facility shall:
 - (1) Be registered and maintain registration with the DEA as a collector.
 - (2) Notify the board in writing within 30 days of establishing a collection receptacle.
 - (3) Notify the board in writing within 30 days when they cease to maintain the collection receptacle.
 - (4) Notify the board in writing within 14 days of any tampering of the collection receptacle or theft of deposited drugs.
 - (5) Notify the board in writing within 14 days of any tampering, damage or theft of a removed liner.
 - (6) List all collection receptacles it maintains annually at the time of renewal of the pharmacy license.
- (d) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (e) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.
- (g) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.

- (1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled.
 - (2) If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair.
- (h) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
- (1) The liner shall be waterproof, tamper evident and tear resistant.
 - (2) The liner shall be opaque to prevent viewing and discourage removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number.
- (i) The collection receptacle shall contain signage that includes:
- (1) The name and phone number of the responsible pharmacy;
 - (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
 - (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.
- (j) Once deposited, the prescription drugs shall not be counted, sorted or otherwise individually handled.
- (k) The installation, removal, transfer and storage of inner liners shall be performed only by:
- (1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
 - (2) By or under the supervision of two employees of the authorized collector pharmacy.
- (l) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.
- (m) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.
- (n) A pharmacy maintaining a collection receptacle in a skilled nursing facility shall make and keep the records as specified in 1776.6.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.40, 1317.60, 1317.75, 1317.80, and 1317.95, Title 21 Code of Federal Regulations

Proposal to add § 1776.5 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.5 Reverse Distributors

- (a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA may accept the sealed inner liners of collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's authorized collection location. Once received, the reverse distributor shall establish records required by this section.
- (b) A licensed reverse distributor may not open, survey, or otherwise analyze the contents of inner liners. All liners shall be destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.
- (c) If a reverse distributor picks up the sealed inner liners from the collector's authorized location, at least two employees of the reverse distributor shall be present. If the sealed inner liners are delivered to the reverse distributor via common or contract carrier, at least one employee of the reverse distributor shall accept the receipt of the inner liners at the reverse distributor's registered location.
- (d) A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.
- (e) For each sealed liner or mail back envelopes or packages received pursuant to federal Title 21 CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes or packages, including the:
 - (1) Date of acquisition;
 - (2) Number and the size (e.g., five 10-gallon liners, etc.);
 - (3) Unique Identification number of each liner or envelope/package;
 - (4) The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner;
 - (5) The date, place and method of destruction;
 - (6) Number of packages and inner liners received;
 - (7) Number of packages and inner liners destroyed;
 - (8) The name and signature of the two employees of the registrant that witnessed the destruction.
- (e) For liners only, the information specified in subsection (e)(1)-(8) above shall be created at the time of receipt and at the time of destruction.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, Business and Professions Code and Section 1301.71, 1304.21, 1304.22, 1317.15, 1317.55, and 1317.95, Title 21 Code of Federal Regulations.

Proposal to add § 1776.6 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

1776.6 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services

Each entity authorized by this article to collect unwanted prescription drugs from consumers shall maintain the records required by this article for three years.

(a) For pharmacies maintaining collection receptacles, the pharmacy shall make and keep the following records for each liner:

- (1) Date each unused liner is acquired, its unique identification number and size (e.g., 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 number and size (e.g., 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 the removal and sealing.
- (4) Date each sealed inner liner is transferred to storage, the unique identification number 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 liner 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).

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1304.22, Title 21 Code of Federal Regulations