

Title 16. Board of Pharmacy
Third Modified Text

Changes made to the originally proposed language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Changes made to the first modified language are shown by ~~double-strikethrough~~ for deleted language and bold underline for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the second modified language are shown by ~~bold double-strikethrough and bold wavy underline~~ for deleted language and bold wavy underline for added language. (Additionally, the modified text is listed in purple for color printers.)

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 ~~Programs~~ 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 ~~Programs~~ Services: Authorization

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board ~~and licensed skilled nursing facilities~~ 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back envelopes or packages to the public to provide options for the public to ~~destroy discard~~ unwanted, unused or outdated prescription drugs. Each ~~of these entities~~ entity must comply with regulations of the federal Drug Enforcement Administration (DEA) and ~~the Board of Pharmacy regulations contained in~~ this article.

~~All board licensed authorized collectors should be vigilant to prevent the public patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following in pharmaceutical take-back receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), illicit drugs, and compressed cylinders or aerosols (e.g., asthma inhalers).~~

Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug distributors (licensed wholesalers and third-party logistics providers) who are registered with the Drug Enforcement Administration (DEA) as collectors and licensed in good standing with the board ~~and are also registered with the Drug Enforcement Administration as collectors~~ may host a pharmaceutical take-back receptacle as participate in drug take-back programs 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 assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.~~

~~(b) (a) Pharmacies may provide take-back services to the public patients as provided in sections 1776 – 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish-maintain collection receptacles in their facilities. Pharmacies may operate-collection-receptacles offer drug take-back services as specified ~~in~~ in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).~~

~~(c) (b) There are multiple federal, and 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.~~

~~(d) (c) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, which includes including controlled substances. Controlled substances may be commingled in collection receptacles or mail back ~~packages or 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 patient, they are not to be removed, counted, sorted or otherwise individually handled-separated by pharmacy staff or others.~~

~~(e) (d) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's prescription drug take-back collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage informing the public that medical sharps and needles (e.g., insulin syringes) are of the items prohibited from being deposited shall be placed posted on collection receptacles as referenced in section 1776.3.~~

~~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) (e) Prescription drugs that are eligible for collection ~~in~~ as part of drug take-back ~~programs operated-services maintained~~ by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a patient or patient's agent-consumer. Dangerous drugs that have not been dispensed to patients 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 in as part of a pharmacy's drug take-back service programs.~~

~~(g) As part of its drug take-back services, a Pharmacy shall not:~~

- (1) ~~Pharmacy staff shall not~~ Review, accept, count, sort, or otherwise individually handle any prescription drugs ~~returned from the public consumers.~~
 - (2) ~~A pharmacy shall not a~~ Accept or possess prescription drugs returned to the pharmacy ~~by from~~ skilled nursing homes facilities, residential care homes, ~~other facilities~~, health care practitioners or any other entity entities in a collection receptacle.
 - (3) ~~A pharmacy shall not d~~ Dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock ~~in a drug take-back collection receptacle.~~ Instead the pharmacy must return these items to a reverse distributor.
- (g) ~~(g)(h)~~ A pharmacy must be registered with the federal ~~Drug Enforcement Administration~~ DEA as a collector for purposes of ~~operating~~ maintaining a prescription drug take-back collection receptacle program. 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.
- (h) ~~(g)(i)~~ Any pharmacy that ~~operates~~ maintains a drug take-back collection receptacle program as authorized in this article shall notify the board ~~in writing on a form designated by the board~~ within 30 days of establishing the collection program. Additionally:
- (1) Any pharmacy that ceases to ~~operate~~ maintain a drug take-back collection receptacle program shall notify the board in writing within 30 days ~~on a form designated by the board.~~ If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days.
 - (2) Any pharmacy operating a mail-back program or maintaining a collection receptacles shall disclose identify 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 storage 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.
- (i) ~~(h)(i)~~ If the pharmacy later ceases to ~~operate~~ maintain the a registered collection receptacle, the pharmacy must notify the ~~DEA Drug Enforcement Administration~~ within 30 days.
- (j) ~~(k)~~ A pharmacy shall not provide take-back services to consumers, ~~as provided in sections 1776 – 1776.4, if, in the professional judgment of the pharmacist in charge, the pharmacy cannot comply with the provisions of this article or the~~ DEA Drug Enforcement Administration rules.
- (l) ~~(l)~~ A pharmacy shall not provide take-back services to consumers, ~~as provided in sections 1776 – 1776.4~~ if the pharmacy or the pharmacist ~~in charge~~ is on probation with the B board, and, if the pharmacy had previously provided take-back services, the pharmacist ~~in charge~~ shall notify the B board and the DEA Drug Enforcement Administration as required in subsections (h) and (i), 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-Mail Back Package and Envelope Services from Pharmacies~~

- (a) Pharmacies that provide prescription drug take-back services may do so by ~~establishing providing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages~~ containers to allow a consumer to for returning prescription drugs to an authorized DEA Drug Enforcement Administration destruction location.
- (b) All envelopes and packages must be preaddressed to a location registered with the DEA Drug Enforcement Administration as a collector ~~that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered 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 certain instructions for users that indicate the process to mail back drugs.
- ~~(e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.~~
- ~~(f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.~~
- ~~(g) (e) Once filled with unwanted prescription drugs, the 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, C consumers shall be directed to mail the envelopes or packages or deposit them into a pharmaceutical take back receptacle, shall be mailed and not accepted by the pharmacy for return, processing or holding.~~

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

Reference: Section 4005, Business and Professions Code and Sections 1317.70 and 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 ~~Pharmacies may~~ that provide prescription drug take-back services to the public may do so by ~~establishing~~ maintain a collection receptacle ~~in the pharmacy~~ whereby for the public to may deposit their unwanted prescription drugs for destruction. The

- ~~pharmacy is responsible for the management and maintenance of the receptacle.~~ The receptacle shall be ~~securely locked and~~ 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.~~ ~~In~~ 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 slot on the collection receptacle and physically block the public patients from access to the collection receptacle by some means.~~
- (b) ~~A~~ The pharmacy operating ~~maintaining the a~~ collection receptacle must securely ~~install~~ ~~fasten~~ the receptacle ~~to a permanent structure~~ so it cannot be ~~moved or~~ removed. The receptacle shall be installed in an inside location ~~within the pharmacy premise, where,~~ ~~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 supervising responsible pharmacy is closed,~~ the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. ~~When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from public patient access by some means.~~
- (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 slot~~ ~~on the collection receptacle.~~
- (e) ~~The pharmacy is responsible for the management and maintenance of the receptacle. A pharmacy shall direct consumers to directly deposit drugs into the collection receptacle. A Pharmacy staff shall not accept, count, sort or otherwise handle prescription drugs returned from the public consumers, but instead direct the public to deposit the drugs into the collection receptacle themselves.~~
- (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, ~~or~~ ~~counted,~~ ~~sorted~~

- or otherwise individually handled.
- (h) If the liner is not already itself rigid or already inside of a rigid container when as 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. ~~Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed 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, these pharmacy employees~~ who shall be immediately, without interruption, sealed and the pharmacy employees shall record seal the liner and record, in a written log, their participation in the removal of each liner from a collection receptacle. ~~If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container.~~ 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 three 14 days.
- (k) The pharmacy shall make and keep the records specified in 1776.6, ~~maintain a written log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:~~
- ~~(1) The unique identification numbers of all unused liners in possession of the pharmacy,~~
 - ~~(2) The unique identification number and dates a liner is placed in the collection receptacle,~~
 - ~~(3) The date the liner is removed from the collection receptacle,~~
 - ~~(4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and~~
 - ~~(5) The date the liner was provided to a licensed DEA registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.~~
- (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 developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not permissible to deposit any Schedule I drugs into the collection receptacle. Labeling The signage shall also identify informing the public that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall~~

~~also be affixed to the collection receptacle.~~

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.

- (n) ~~The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process.~~

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

Reference: Section 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.60, 1317.75, and 1317.80 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 ~~Collection-Drug Take-Back Services~~ in Skilled Nursing Facilities

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

- (a) (a) Skilled nursing facility ~~personnel employees or person lawfully entitled to dispose of the resident decedent's property~~ may dispose of a current resident's unwanted or unused prescription drugs by using mail back ~~packages or envelopes and or packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. The pharmacy may allow skilled nursing facility employees to distribute mail back envelopes or packages to consumers. The pharmacy shall require~~ Records shall be kept by the 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) (b) Only ~~retail~~ 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) ~~Any pharmacy and hospital/clinic with an onsite pharmacy operating maintaining collection receptacles in skilled nursing facilities shall b~~ Be registered and maintain registration with the DEA as a collectors.
 - (2) ~~Any pharmacy or hospital/clinic with an onsite pharmacy that operates maintains a collection receptacle at a skilled nursing facility shall n~~ Notify the board in writing within 30 days of establishing a collection receptacle ~~on a form designated by the board.~~
 - (3) ~~Any pharmacy or hospital/clinic with an onsite pharmacy~~ Notify the board in writing within 30 days when they that ceases to operate maintain a the collection site receptacle ~~at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.~~
 - (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) ~~Any pharmacy operating a collection receptacle site at a skilled nursing facility shall~~ list all collection receptacles it ~~operates~~ maintains annually at the time of renewal of the pharmacy license.
- ~~(c) (e) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.~~
- ~~(d) Every pharmacy and hospital/clinic pharmacy that operates maintains a collection site receptacle at any skilled nursing facility shall notify the board within 14 days of any loss or theft from the collection receptacle or secured storage location for the storage of removed liners.~~
- (e) (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.
- (f) (e) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) (f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be ~~moved or~~ 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.
- (h) (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 ~~viewed,~~ removed, sorted, counted, or otherwise individually handled-counted.
- (2) If the liner is not already itself rigid or already inside of a rigid container as 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. ~~Rigid containers may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation ~~for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.~~
- (i) (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 ~~or~~ 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 ~~established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.~~

- (j) ~~(i) The collection receptacle shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II—V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.~~

~~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.~~

- (k) ~~(j) Once deposited, the prescription drugs shall not be handled, counted, inventoried, sorted or otherwise individually handled.~~

- (l) ~~(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.~~

- (m) ~~(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.~~

- (n) ~~(m) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.~~

- (o) ~~(n) A pharmacy maintaining a collection receptacle in a skilled nursing facility shall make and keep the records as specified in 1776.6. Records of the pickup, delivery and destruction shall be maintained that provide the 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 if applicable, the names and signatures of the two employees who transported each liner.~~

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 as a collector 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, or survey, or otherwise analyze ~~count,~~ inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated ~~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 T two employees of the reverse distributor shall be present, pick up or accept the receipt of inner liners from DEA registrants. 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) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.~~
- ~~(f)~~(e) For each sealed liner or mail back envelopes or packages received ~~from collectors or law enforcement~~ 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) Inventory-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 number-name and signature of the two employees of the registrant that witnessed the destruction.
- (f) 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, and 1317.55 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 patients shall maintain the ~~following~~ records required by this article for three years.

~~(a) When obtaining unused mail-back packages and envelopes for future distribution:~~

~~(1) The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.~~

~~(2) For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.~~

~~(b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.~~

~~(c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,~~

~~(d) For sealed mail-back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.~~

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

~~(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 number 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 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) and the signature of the driver.

- ~~(b) For each reverse distributor (wholesaler or third-party logistics provider) accepting sealed mail-back packages: the date of receipt and the unique identification of the individual package or envelope;~~
- ~~(c) For each reverse distributor that will destroy the mail-back packages: the number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction;~~
- ~~(f) (d) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, the following records must be maintained, with recording taking place immediately upon receipt of a liner:~~
- ~~(1) The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier or pick-up by reverse distributor);~~
 - ~~(2) For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction;~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section ~~1317.22~~ 1304.22, Title 21 Code of Federal Regulations