



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Proposed Regulations to Add Title 16 California Code of Regulations (CCR) sections 1776 et seq., Related to Prescription Drug Take-Back

Attachment 1

Background:

At the January 2016 Board Meeting, the board approved proposed text to add Sections 1776 et seq of Title 16 CCR, related to Prescription Drug Take-Back Programs. The 45-day comment period began on February 12, 2016 and ended March 28, 2016. Two regulation hearings were held on April 13, 2016 (one in Northern California and one in Southern California).

At the April 2016 Board Meeting, the board approved a modified text to address concerns expressed during the 45-day comment period and at the regulation hearing. The 15-day comment period began on May 3, 2016 and ended May 18, 2016.

At the June 2016 Board Meeting, the board reviewed the comments received during the 15-day comment period. The board made policy decisions based on the 15-day comments, and instructed staff to make the recommended changes to the language and present the modified language to the board at the July 2016 Board Meeting.

At this Meeting

The board will have the opportunity to discuss the future of the regulation and determine what course of action it wishes to pursue. We are providing three drafts:

The attachment contains:

1. **Draft 1** contains the changes approved by the board during the June 2016 Board Meeting, dated June 8, 2016.
2. **Draft 2** is the staff recommended modified text, dated July 1, 2016. This draft contains changes made for clarity and consistency throughout the regulation text.
3. **Draft 3** is the clean version of the staff recommended modified text (this is provided for clarity). This draft does not contain any strike-outs or underlining.

Staff Recommendation: Adopt the staff recommended version, dated July 1, 2016, of the regulatory language and notice the language for a 15-day comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

Draft 1

Prescription Drug Take-Back Modified Text*

***As approved by the Board on June 8, 2016.**

Title 16. Board of Pharmacy
Board Approved Modified Text (6.8.2016)

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

Changes made to the modified language are shown by blue double strikethrough for deleted language and red double underline for added language

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

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: 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 mail back envelopes or packages to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration 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, 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 collection receptacles in their facilities. Pharmacies may operate collection receptacles 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 with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a consumer patient, they are not to be 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.
- (f) (e) Prescription drugs that are eligible for collection in drug take-back programs operated 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 programs.
 - (1) Pharmacy staff shall not review, accept, count, sort, or handle any prescription drugs returned from the public.
 - (2) A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities in a collection receptacle.
 - (3) A pharmacy shall not 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) (f) A pharmacy must be registered with the federal Drug Enforcement Administration 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) Any pharmacy that ~~operates~~ maintains a drug take-back collection receptacle program as authorized in this article shall notify the board 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 within 30 days on a form designated by the board. ~~If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the board within 30 days.~~
 - (2) Any pharmacy ~~operating a mail back program or~~ maintaining collection receptacles shall 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 with 14 days.
 - (4) Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.
- (i) (h) If the pharmacy ~~later ceases to operate~~ maintain the a registered collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.
- (i) 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 Drug Enforcement Administration rules.
- (i) 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 Board, and, if the pharmacy had previously provided take-back services, the pharmacist in charge shall notify the Board and the Drug Enforcement Administration as required in subsections (h) and (i), above.

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

Reference: Section 4005, 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 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 Drug Enforcement Administration destruction location.
- (b) All envelopes and packages must be preaddressed to a location registered with the 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 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) 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. 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) Pharmacies may that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby for the public to may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable 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) The pharmacy ~~operating~~ maintaining the collection receptacle must securely install the receptacle so it cannot be moved or removed. The receptacle shall be installed in an inside location ~~within the pharmacy premise~~, where the receptacle is visible to pharmacy employees, but not located in or near emergency areas.

[6.8.2016 Board Question: Legal Counsel confirmed that pharmacy employees must be present]

(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 employees and not in the

proximity of any emergency or urgent care areas. When the supervising 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.
- (e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, 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.
- (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 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 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.

[6.8.2016 Board Question: Legal Counsel confirmed that employees must be of the Pharmacy and that those employees may supervise the actions of another.]
- (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 sealed and the pharmacy employee 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 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.
- (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:

[6.8.2016 Board Requested Legal Counsel review and feedback on 1776.4(a). The changes below reflect Legal Counsel's review.]

1776.4 Collection in Skilled Nursing Facilities

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) 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. Records shall be kept by the skilled nursing facility 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 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.
- (1) Any pharmacy and hospital/clinic with an onsite pharmacy ~~operating~~ maintaining collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.
- (2) Any pharmacy or hospital/clinic with an onsite pharmacy that ~~operates~~ maintains a collection receptacle at a skilled nursing facility shall notify the board 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 that ceases to ~~operate~~ maintain a collection ~~site~~ receptacle at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
- (4) 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) 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) 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) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) 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) 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 or

- 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 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) 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 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) 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.
- (k) Once deposited, the prescription drugs shall not be handled, counted, inventoried or otherwise individually handled.
- (l) 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) 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) 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) ~~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.~~ Records which include the date, unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired, installed, removed and sealed, transferred to storage, and transferred for destruction; the address of the

location where each receptacle with inner liner is maintained, the registration number of the collector, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the names and signatures of the two employees that witnessed each installation, removal, transfer to storage, and transfer for destruction; and if applicable, the names and signatures of the two reverse distributor drivers who transport 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~~ 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) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (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) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:
- (1) Date of acquisition;
 - (2) Number and the size (e.g., five 10-gallon liners, etc.);
 - (3) Inventory 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 and signature of the two employees of the registrant that witnessed the 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 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 collection receptacles, the pharmacy shall maintain the following records for each liner:
 - (1) Date each unused liner is acquired, its unique identification number and size (e.g., five 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 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

removal.

- (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, 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, Title 21 Code of Federal Regulations

Draft 2

Prescription Drug Take-Back Staff Recommended Modified Text*

*Contains changes made for clarity and consistency through the regulation text.

Title 16. Board of Pharmacy
Staff Recommended Modified Text (7.1.2016)

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Staff recommended changes are shown by ~~green double strikethrough~~ for deleted language and purple bold underline for added language.

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 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 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 ~~com~~mingled 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 collector pharmacy;
 - (2) No medical sharps and needles (e.g., insulin syringes); and
 - (3) Consumers may deposit prescription drugs including Schedule II-IV 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)(f)~~ (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 on a form designated by the board~~ within 30 days. 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~~ in writing within 14 days.
 - (4) Any tampering, damage or theft of a removed liner shall be reported to the board ~~in writing within~~ 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~~ DEA within 30 days.
- ~~(j)(k)~~ (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~~ DEA Drug Enforcement Administration rules.
- ~~(j)(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~~ 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 the receptacle is visible to pharmacy employees, but not located in or near emergency areas, nor behind the pharmacy's counter.

[6.8.2016 Board Question: Legal Counsel confirmed that pharmacy employees must be present]

- (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 employees and not in the proximity of any emergency or urgent care areas. When 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 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 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.

[6.8.2016 Board Question: Legal Counsel confirmed that employees must be of the Pharmacy and that those employees may supervise the actions of another.]

- (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 collector pharmacy;
- (2) No medical sharps and needles (e.g., insulin syringes); and
- (3) Consumers may deposit prescription drugs including Schedule II-IV 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:

[6.8.2016 Board Requested Legal Counsel review and feedback on 1776.4(a). The changes below reflect Legal Counsel's review.]

1776.4 ~~Collection~~ 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) ~~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.~~ 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) (c) 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.~~

(d) (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) (e) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.

(f) (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.

(g) (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 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.

(h) (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.
- (f) ~~(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 collector pharmacy;
 - (2) No medical sharps and needles (e.g., insulin syringes); and
 - (3) Consumers may deposit prescription drugs including Schedule II-IV 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. Records which include the date, unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired, installed, removed and sealed, transferred to storage, and transferred for destruction; the address of the location where each receptacle with inner liner is maintained, the registration number of the collector, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the names and signatures of the two employees that witnessed each installation, removal,~~

~~transfer to storage, and transfer for destruction; and if applicable, the names and signatures of the two reverse distributor drivers who transport 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) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (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 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.
- ~~(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, Title 21 Code of Federal Regulations

Draft 3

Prescription Drug Take-Back Staff Recommended Clean Text*

*Contains no strike-outs or underscore.

Title 16. Board of Pharmacy
Staff Recommended Clean Text (7.1.2016)

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 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 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 comingled 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 collector pharmacy;
 - (2) No medical sharps and needles (e.g., insulin syringes); and
 - (3) Consumers may deposit prescription drugs including Schedule II-IV 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 returned to the pharmacy 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 (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

- (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 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 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 moved or removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy 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 employees and not in the

- proximity of any emergency or urgent care areas. When the responsible pharmacy is closed, 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 slot 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 tight-fitting covers, and be kept clean and in good repair. All rigid containers must meet standards of the United States Department of Transportation. 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 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 collector pharmacy;
 - (2) No medical sharps and needles (e.g., insulin syringes); and
 - (3) Consumers may deposit prescription drugs including Schedule II-IV 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, 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 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 may allow skilled nursing facility employees to distribute mail back envelopes or packages to consumers. 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.
- (c) 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) 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 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.
 - (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 tight-fitting covers, and be kept clean and in good repair. All rigid containers must meet standards of the United States Department of Transportation. The rigid containers shall be capable of being sealed 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 established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.
 - (i) The collection receptacle shall contain signage that includes:
 - (1) The name and phone number of the collector pharmacy;
 - (2) No medical sharps and needles (e.g., insulin syringes); and
 - (3) Consumers may deposit prescription drugs including Schedule II-IV 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) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (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 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) 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.

- (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 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 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 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).

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