California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

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

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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 the July 2016 Board meeting, the board reviewed and approved the modified language as recommended by staff. A 15-day comment period was initiated on August 4, 2016 and ended August 19, 2016. The Board received numerous comments.

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. Two drafts of the language have been provided in **Attachment 1** as well as the comments received.

Attachment 1 contains:

1. *Draft 1* contains the modified text as approved by the board at the July 2016 Board Meeting, dated July 27, 2016.
2. *Draft 2* is the clean version of the modified text as approved by the board at the July 2016 Board Meeting, dated July 27, 2016 (this is provided for clarity). This draft does not contain any strike-outs or underlining.
3. A compilation document of the comments received during the 15-day comment period by Section number with Staff Recommendations.
4. The comments received during the 15-day comment period.

Attachment 1

Prescription Drug Take-Back

Modified Text

(As Approved at the July 2016 Board Meeting)

Title 16. Board of Pharmacy

Second Modified Text

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

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

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

Article 9.1. Prescription Drug Take-Back ~~Programs~~ Services

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

Section 1776 Prescription Drug Take-Back ~~Programs~~ Services: Authorization

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

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

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

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

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

Section 1776.1 Pharmacies

~~(a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.~~

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

~~(c)~~ (b) There are multiple federal, ~~and~~ state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.

~~(d)~~ (c) For purposes of this article, prescription drugs means dangerous drugs as defined by ~~California~~ Business and Professions Code section 4022, which includes ~~including~~ controlled substances. Controlled substances may be co~~m~~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 responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

(f) ~~(e)~~ Prescription drugs that are eligible for collection ~~in~~ as part of drug take-back ~~programs operated~~ services maintained by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a ~~patient or patient's agent~~ consumer. Dangerous drugs that have not been dispensed to ~~patients~~ consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected ~~in~~ as part of a pharmacy's drug take-back service ~~programs~~.

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

(1) ~~Pharmacy staff shall not r~~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 within 30 days~~ on a form designated by the board~~. ~~If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days.~~

(2) Any pharmacy ~~operating a mail back program or~~ maintaining a collection receptacle~~s~~ shall disclose ~~identify~~ to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.

(3) Any tampering with a ~~storage~~ collection receptacle or theft of deposited drugs shall be reported to the board in writing within 14 days.

(4) Any tampering, damage or theft of a removed liner shall be reported to the board in writing within 14 days.

~~(i)~~~~(h)~~(j) If the pharmacy ~~later~~ ceases to ~~operate~~ maintain ~~the~~ a registered collection receptacle, the pharmacy must notify the DEA ~~Drug Enforcement Administration~~ within 30 days.

~~(i)~~(k) A pharmacy shall not provide take-back services to consumers~~, as provided in sections 1776 – 1776.4,~~ if, in the professional judgment of the pharmacist-~~-~~in-~~-~~charge, the pharmacy cannot comply with the provisions of this article or the DEA ~~Drug Enforcement Administration~~ rules.

~~(i)~~(l) A pharmacy shall not provide take-back services to consumers~~, as provided in sections 1776 – 1776.4~~ if the pharmacy or the pharmacist-~~-~~in-~~-~~charge is on probation with the ~~B-~~board, and, if the pharmacy had previously provided take-back services, the pharmacist-~~-~~in-~~-~~charge shall notify the ~~B-~~board and the DEA ~~Drug Enforcement Administration~~ as required in subsections (h) and (i), above.

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

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

1776.2 Pharmacies Offering Mail Back Envelope or Package Services ~~Mail Back Package and Envelope Services from Pharmacies~~

(a) Pharmacies that provide prescription drug take-back services may do so by ~~establishing~~ providing ~~m~~ail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or package~~s~~ ~~containers~~ to allow a consumer to ~~for~~ return~~ing~~ 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 establish~~ing maintain a collection receptacle ~~in the pharmacy~~ whereby for the public to ~~may~~ deposit their unwanted prescription drugs for destruction. The

pharmacy is responsible for the management and maintenance of the receptacle. The receptacle shall be ~~securely locked and~~ substantially constructed, with a permanent outer container and a removable inner liner. The collection receptacle shall be locked at all times to prevent access to the inner liner. ~~In During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block the public patients from access to the collection receptacle by some means.~~

(b) ~~A The~~ pharmacy ~~operating~~ maintaining ~~the~~ a collection receptacle must securely ~~install~~ fasten the receptacle to a permanent structure so it cannot be ~~moved or~~ removed. The receptacle shall be installed in an inside location ~~within the pharmacy premise, where,~~ Except as provided in subsection (c), the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter.

(c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When 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.

(i) The liner may be removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner, ~~these pharmacy employees~~ ~~who~~ shall be immediately, without interruption, sealed and the pharmacy employees shall record ~~seal the liner and record~~, in a ~~written~~ log, their participation in the removal of each liner from a collection receptacle. ~~If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container.~~ Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.

(j) Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than ~~three~~ 14 days.

(k) The pharmacy shall make and keep the records specified in 1776.6. ~~maintain a written log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:~~

~~(1) The unique identification numbers of all unused liners in possession of the pharmacy,~~

~~(2) The unique identification number and dates a liner is placed in the collection receptacle,~~

~~(3) The date the liner is removed from the collection receptacle,~~

~~(4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and~~

~~(5) The date the liner was provided to a licensed DEA registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.~~

(l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.

(m) ~~The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not permissible to deposit any Schedule I drugs into the collection receptacle. Labeling The signage shall also identify informing the public that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.~~

The collection receptacle shall contain signage that includes:

(1) The name and phone number of the responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

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

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

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

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

1776.4 ~~Collection~~ Drug Take-Back Services in Skilled Nursing Facilities

A 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 collector~~s~~.

(2) ~~Any pharmacy or hospital/clinic with an onsite pharmacy that operates maintains a collection receptacle at a skilled nursing facility shall n~~ Notify the board in writing within 30 days of establishing a collection receptacle ~~on a form designated by the board~~.

(3) ~~Any pharmacy or hospital/clinic with an onsite pharmacy~~ Notify the board in writing within 30 days when they ~~that~~ cease~~s~~ 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 l~~ 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.~~

~~(e)~~ (d) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.

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

~~(g)~~ (f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be ~~moved or~~ removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.

~~(h)~~ (g) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.

(1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be ~~viewed,~~ removed, sorted, counted, or otherwise individually handled ~~counted~~.

(2) If the liner is not already itself rigid or already inside of a rigid container ~~as~~ when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation ~~for transport of medical waste~~. The rigid containers shall be capable of being sealed and be kept clean and in good repair.

~~(i)~~ (h) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

(1) The liner shall be waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing ~~or~~ and discourage removal of any contents once the liner has been removed from a collection receptacle. The liner shall

be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.

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

The collection receptacle shall contain signage that includes:

(1) The name and phone number of the responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

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

~~(l)~~ (k) The installation, removal, transfer and storage of inner liners shall be performed only by:

(1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or

(2) By or under the supervision of two employees of the authorized collector pharmacy.

~~(m)~~ (l) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.

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

~~(o)~~ (n) A pharmacy maintaining a collection receptacle in a skilled nursing facility shall make and keep the records as specified in 1776.6. ~~Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon,10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.~~

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

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

1776.5 Reverse Distributors

(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA ~~as a collector~~ may accept the sealed inner liners of collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's authorized collection location. Once received, the reverse distributor shall establish records required by this section.

(b) A licensed reverse distributor may not open, ~~or~~ survey, or otherwise analyze ~~count, inventory or otherwise sort or x-ray~~ the contents of inner liners. All liners shall be ~~incinerated~~ destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.

(c) 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

Prescription Drug Take-Back

Modified Text

(Clean Version)

(As Approved at the July 2016 Board Meeting)

Title 16. Board of Pharmacy
Second Modified (CLEAN) Text

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

Article 9.1. Prescription Drug Take-Back Services

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

Section 1776 Prescription Drug Take-Back Services: Authorization

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

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

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

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

Section 1776.1 Pharmacies

(a) Pharmacies may provide take-back services to the public. Retail pharmacies and hospital/clinics with onsite pharmacies may maintain collection receptacles in their facilities. Pharmacies may offer drug take-back services as specified in section 1776.4 in skilled nursing facilities licensed under Health and Safety Code section 1250(c).
(b) There are multiple federal, state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.
(c) For purposes of this article, prescription drugs means dangerous drugs as defined by Business and Professions Code section 4022, which includes controlled substances. Controlled substances may be 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 responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

(f) Prescription drugs that are eligible for collection as part of drug take-back services maintained by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected as part of a pharmacy's drug take-back service.

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

(1) Review, accept, count, sort, or otherwise individually handle any prescription drugs from consumers.

(2) Accept or possess prescription drugs 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 removed. The receptacle shall be installed in an inside

location. Except as provided in subsection (c), the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter.

(c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When 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 ~~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. 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 ~~three~~ 14 days.
(k) The pharmacy shall make and keep the records specified in 1776.6.
(l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.
(m) The collection receptacle shall contain signage that includes:
    (1) The name and phone number of the responsible pharmacy;
    (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
    (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

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

Reference: Section 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.60, 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 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 responsible pharmacy;

(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

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

(k) The installation, removal, transfer and storage of inner liners shall be performed only by:
(1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
(2) By or under the supervision of two employees of the authorized collector pharmacy.

(l) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.

(m) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

(n) A pharmacy maintaining a collection receptacle in a skilled nursing facility shall make and keep the records as specified in 1776.6.

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

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

1776.5 Reverse Distributors

(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA may accept the sealed inner liners of collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's authorized collection location. Once received, the reverse distributor shall establish records required by this section.

(b) A licensed reverse distributor may not open, survey, or otherwise analyze the contents of inner liners. All liners shall be destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.

(c) 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.

(e) For liners only, the information specified in subsection (e)(1)-(8) above shall be created at the time of receipt and at the time of destruction.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4005, Business and Professions Code and Section 1301.71, 1304.21, 1304.22, 1317.15, 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.

Prescription Drug Take-Back Second 15-Day Comment Compilation w/ Recommendations Comment Period Closed

August 19, 2016

Code Section	Commenter	Comment	Staff Recommendations
1776	Douglas Barcon	Dr. Barcon states that "mail-back" should be added to the second paragraph so they are not excluded.	Reject: Businesses do not need to be registered as a collector to distribute mail-back envelopes.
1776.1(c)	Douglas Barcon	Spelling correction - should be "commingled"	Accept: Spelling was correct. The DEA registered has the incorrect spelling.
1776.1(e)(2)	San Francisco Dept of Evironment	Commenter requested that the prohibition of sharps be removed as the DOT does not request separation for disposal or allow for preloaded devices to be deposited.	Reject: While it is possible that sharps may be deposited into the receptacle, sharps can easily be collected in a sharps container.
1776.1(h)	Douglas Barcon	Dr. Barcon states that "mail-back" should be added so they are not excluded.	Reject: Businesses do not need to be registered as a collector to distribute mail-back envelopes.
1776.1(i)	Douglas Barcon	Dr. Barcon states that "mail-back" should be added so they are not excluded.	Reject: While the Board needs to be aware of drug receptacles by a Board licensee, any business can provide mail-back envelopes. The Board does not need to be alerted to mail-back programs.

Code Section	Commenter	Comment	Staff Recommendations
1776.1(i)(1)	Douglas Barcon	Dr. Barcon states that "mail-back" should be added so they are not excluded.	Reject: While the Board needs to be aware of drug receptacles by a Board licensee, any business can provide mail-back envelopes. The Board does not need to be alerted to mail-back programs.
1776.1(i)	City of Santa Rosa	Commenter recommended that the language we changed from "pharmacies may offer drug take-back services" to "pharmacies may establish collection receptacles" because it is unclear why only a pharmacy can distribute mail-back envelopes in a skilled nursing facility. [Referenced 1317.70(c)]	Reject: This comment references an incorrect section. The correct section [1776.1(a)] states pharmacies may offer. A pharmacy can provide mail-back envelopes, a collection receptacle, or both.
1776.1(j)	Douglas Barcon	Dr. Barcon states that "mail-back" should be added so they are not excluded.	Reject: While the Board needs to be aware of drug receptacles by a Board licensee, any business can provide mail-back envelopes. The Board does not need to be alerted to mail-back programs.
1776.1(k)	San Francisco Dept of Evironment	Commenter recommends that this section be removed as it is unncessary because if they cannot comply with the DEA, then they cannot collect controlled substances.	Reject: The Board's regulations are slightly more detailed than the DEA's regulations. This section is necessary in the event that a pharmacy cannot comply with the regulations.

Code Section	Commenter	Comment	Staff Recommendations
1776.1(k)	City of Santa Rosa	Commenter recommended this section be changed to collection receptacle instead of "take-back services." They stated it was unclear why a pharmacy would not be able to comply with the regulations or DEA to hand out envelopes.	Policy Decision
1776.1(k)	Kaiser	Commenter recommended that this section be amended to collection receptacles only. They indicated there is no basis for a pharmacist to say they cannot comply with the DEA or the Board's regulations to not provide mail-back envelopes.	Policy Decision
1776.1(l)	City of Santa Rosa	Commenter recommended this section be changed to collection receptacle instead of "take-back services." They stated it was unclear why a pharmacy on probation could not hand out envelopes.	Policy Decision
1776.2(c)	Gordon Miller	Commenter recommended that this section be added back into the language as consumers should not have to pay the postage.	Reject: This section is in the regulation language. Commenter may have been looking at a previous version.
1776.3	City of Santa Rosa	Commenter expressed concern that the statement "shall be locked at all times" could be misunderstood to mean that the lock on the small deposit opening must be locked at all times.	Reject: The language states "locked at all times to prevent access to the inner liner." Consumers would not have access to the inner liner throught the small deposit opening.
1776.3(b)	City of Santa Rosa	Commenter indicated that it is confusing to have the stipulation for emergency areas in this section when it only applies to section (c).	Reject: Pharmacies may have an emergency exit door with the location. The collection receptacle should not be placed near that emergency area.
1776.3(b)	Fred Mayer, RPh	Commenter requested clarification as to who the DEA registrant is.	Reject: The DEA registrant is the location registered with the DEA.

Code Section	Commenter	Comment	Staff Recommendations
1776.3(b)	San Francisco Dept of Evironment	Commenter indicated that it is confusing to have the stipulation for emergency areas in this section when it only applies to section (c).	Reject: Pharmacies may have an emergency exit door with the location. The collection receptacle should not be placed near that emergency area.
1776.3(c)	City of Santa Rosa	Commenter expressed concern about the collection receptacle being locked when the responsible pharmacy is closed in a hospital. They indicated this will impact flexibilty on the operation of the receptacle.	Reject: Per 21 CFR 1317.75(f), the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees.
1776.3(d)	City of Santa Rosa	Commenter indicated that independant pharmacies should not have to lock the receptacle if they have closed and locked the entire building and the receptacle is not accessible to the public.	Reject: Per 21 CFR 1317.75(f), the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees.

Code Section	Commenter	Comment	Staff Recommendations
1776.3(d)	Alameda County Hazardous Waste	Commenter requested claification on the availability of the receptacle when a pharmacy is closed, but the store remains open.	Reject: Per 21 CFR 1317.75(f), the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees.
1776.3(d)	San Francisco Dept of Evironment	Commenter expressed concern that this section is not consistent with the DEA and recommended that the last two sentences be removed to prevent diversion.	Reject: Per 21 CFR 1317.75(f), the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees.
1776.3(d)	Kaiser	Kaiser recommends changing the word "slot" so as to not restrict the size of the deposit opening that would restrict the deposit of large vials or bags. They indicated "slot" implies a very narrow opening.	Reject: The term slot is used to limit the size. The receptacle should not have a large opening as people will be able to reach into the receptacle.

Code Section	Commenter	Comment	Staff Recommendations
1776.3(f)	Douglas Barcon	Dr. Barcon expressed concern about the ASTM bag requirement. He indicated that the bag requirements are not puncture resistance and could pose a safety issue for staff if sharps or broken glass in deposited. He recommend more stringent requirements or the use of personal protective equipment.	Reject: The ASTM bags biohazard bags that meet DOT standards for hazardous waste. They are commonly used. While sharps may inadvertantly be deposited into the receptacle, staff should still use caution.
1776.3(g)	Kaiser	Kaiser recommends adding "manually or with a tool" to the end of this section so to prevent the use of vacuums or tools from being used to remove the deposited drugs.	Reject: The regulation states that the deposited items should not be removed; this includes any method used to remove the drugs.
1776.3(h)	City of Santa Rosa	Commented expressed concern about the requirement of tight fitting covers and it would exclude the use of corrugated fiberboard.	Reject: Corrugated fiberboard does not meet US DOT standards. HMR 49 CFR 171-180
1776.3(i)	Alameda County Hazardous Waste	Recommended changing "pharmacy employees" to "pharmacy or DEA registrant employees" for consistency.	Agree with this change for consistency.
1776.3(i)	Douglas Barcon	Dr. Barcon suggested adding "personal protective equipment" to protect staff from needles or broken glass deposited into the receptacle. Protective gloves that meet ASTM F2878-10 for needles.	Reject: Personal protective equipment can be utilized; however, mandating the use of specific equipment as an added expense and may impact participation. Additionally, the Board does not anticipate an issue with punctures from the liners. The liners are to be immediately placed into a rigid container which will protect staff.

Code Section	Commenter	Comment	Staff Recommendations
1776.3(j)	San Francisco Dept of Evironment	Commenter expressed concern about the 14 day limitation and requested that it be changed to "promptly."	Reject comment. The use of the "promptly" is vague and subject to interpretation. The 14 day storage requirement sets a clear guideline and allows for sufficient flexibility.
1776.3(m)	San Francisco Dept of Evironment	Commenter requested that the prohibition of sharps be removed as the DOT does not request separation for disposal or allow for preloaded devices to be deposited.	Reject: While it is possible that sharps may be deposited into the receptacle, sharps can easily be collected in a sharps container.
1776.4(a)	San Francisco Dept of Evironment	Commenter requested that this section be removed as the DEA does not restrict who can distribute mail-back packages.	Policy Decision
1776.4(a)	City of Santa Rosa	Commenter states that a skilled nursing facility can partner with anyone to distribute envelopes, not just a pharmacy. [Reference 1317.70(c)]	Policy Decision
1776.4(c)	San Francisco Dept of Evironment	Commenter expressed concern that section (c) conflicts with section (k).	Reject: Staff does not agree that there is a conflict. Additionally, this section is outside the scope of the comment period.
1776.4(g)(2)	Kaiser	Kaiser recommends adding "manually or with a tool" to the end of this section so to prevent the use of vacuums or tools from being used to remove the deposited drugs.	Reject: The regulation states that the deposited items should not be removed; this includes any method used to remove the drugs.

Code Section	Commenter	Comment	Staff Recommendations
1776.4(g)(2)	Douglas Barcon	Dr. Barcon suggested adding a sentenced that allows pharmacy staff to wear ASTM F2878-10 protective gloves.	Reject: Personal protective equipment can be utilized; however, mandating the use of specific equipment as an added expense and may impact participation. Additionally, the Board does not anticipate an issue with punctures from the liners. The liners are to be immediately placed into a rigid container which will protect staff.
1776.4(g)(2)	City of Santa Rosa	Commented expressed concern about the requirement of tight fitting covers and it would exclude the use of corrugated fiberboard.	Reject: Corrugated fiberboard does not meet US DOT standards. HMR 49 CFR 171-180
1776.4(h)	City of Santa Rosa	Commenter indicated that the proposed text would prevent the reverse distributor was establishing the liner ID number.	Reject: Per the DEA response to comments (page 16 of 52), the unique identification number must be unique to the collector pharmacy and can be assigned by the manufacturer. If the reverse distributor assigns the numbers, they may not be unique to the pharmacy.
1776.4(i)(2)	San Francisco Dept of Evironment	Commenter requested that the prohibition of sharps be removed as the DOT does not request separation for disposal or allow for preloaded devices to be deposited.	Reject: While it is possible that sharps may be deposited into the receptacle, sharps can easily be collected in a sharps container.

Code Section	Commenter	Comment	Staff Recommendations
1776.4(l)	Douglas Barcon	Dr. Barcon suggested adding a sentenced that allows pharmacy staff to wear ASTM F2878-10 protective gloves.	Reject: Personal protective equipment can be utilized; however, mandating the use of specific equipment as an added expense and may impact participation. Additionally, the Board does not anticipate an issue with punctures from the liners. The liners are to be immediately placed into a rigid container which will protect staff.
1776.5(c)	City of Santa Rosa	Commenter expressed concern that only one reverse distributor employee needs to receive the liner at the reverse distrubtors location. Current language requires two employees.	Reject: Outside scope of the comment period.
1776.5(e)	Sharps	Commented recommended that the language be modified to read: "For each sealed liner or mail back envelope or package received pursuant to federal Title 21 CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/ or packages, including the: …" Commenter indicated that mail-back envelopes must be mailed to a reverse distributor and are not received from collectors or law enforcement.	Agree: Collector or Law enforcement is related to the sealed liners, not the mail back packages. The recommended language is clearer.
1776.5(e) - (f)	City of Santa Rosa	Commenter expressed concern that it is not possible to create the records for receipt and destruction at the same time because the events may not occur at the same time. They requested that the section be modified for consistency.	Reject: The appropriate records need to be created at the time of receipt and at the time of destruction. The regulation does not state that those times must occur at the same time.

Code Section	Commenter	Comment	Staff Recommendations
1776.5(f)	San Francisco Dept of Evironment	Commenter expressed concern that it is not possible to create the records for receipt and destruction at the same time because the events may not occur at the same time. They requested that the section be modified for consistency.	Reject: The appropriate records need to be created at the time of receipt and at the time of destruction. The regulation does not state that those times must occur at the same time.
1776.6	City of Santa Rosa	Commenter expressed concern that the reference section quoted is not correct and requested that it be corrected.	Reject: The Authority and Refence citations will be confirmed upon approval of the final language.
1776.6(a)(1)	Alameda County Hazardous Waste	Recommended removing this section. Commenter believe it is excessively burdensome for the phamarcy. Additionally, they asked how the acquisiton date is to be determined and why the information is relevant.	Reject: This is a DEA requirement. See section 1304.22(f)(2)(i).
1776.6(a)(2)	Alameda County Hazardous Waste	Commenter believe it is excessively burdensome for the phamarcy and goes beyond the DEA requirements. Commenter suggested that the requirement for employees to sign off on the liner installation be removed and that the installation date be recorded on a sticker on the liner.	Reject: This is a DEA requirement. See section 1304.22(f)(2)(ii).
Overall	San Luis Obispo	Commenter states that the Board is exceeding its legal authority. Commenter states that the regulation do not protect the public and are beyond the scope of the Board's authority as the Board does not have authority over medical waste.	Reject: The Board has authority over prescription medication in a pharmacy, whether it is returned to the pharmacy or being sold out of the pharmacy.
Overall	San Luis Obispo	Commenter states that the regulations will have a negative impact on the evironment as kiosks will close instead of complying with the Board's regulations.	Reject: The Board's regulation mirror the DEA's regulations with a few minor differences. It the pharmacy kiosks are complying with the DEA regulations, they should not have an issue complying with the Board's regulations.

Code Section	Commenter	Comment	Staff Recommendations
Overall	San Francisco Dept of Evironment	Commenter recommends that the regs mirror the DEA regulations.	Reject: The Board's regulation mirror the DEA's regulations with a few minor differences.
1776	Gordon Miller	Commenter recommended that localities be allowed to use the DEA regulations to administer drug take-back programs.	Reject: Local governments can administer drug take-back programs. However, if the receptacles are in a pharmacy, the Board's regulations must also be followed.
		The Comments Below Were Received After the Closure of the Comment Period	
1776.6(a)(2)	County of Los Angeles	Add "number" after "identification"	While this comment was received late, the change is necessary for grammactical clarity.
1776.6(a)(4)	County of Los Angeles	Add "number" after "identification"	While this comment was received late, the change is necessary for grammactical clarity.
1776.6(a)(5)	County of Los Angeles	Add "liner" after "to whom the sealed inner" and before "was transferred"	While this comment was received late, the change is necessary for grammactical clarity.

Prescription Drug Take-Back Second 15-Day Comments Comment Period Closed August 19, 2016

Martinez, Lori@DCA

From: Pollock, Bill, Env. Health <bill.pollock@acgov.org>
Sent: Friday, August 19, 2016 4:58 PM
To: Martinez, Lori@DCA
Subject: comments om prescription drug takeback program draft regulations
Attachments: SKMBT_C284e16081917050.pdf

ALAMEDA COUNTY
HOUSEHOLD
HAZARDOUS WASTE

Alameda County Household Hazardous Waste Division, 1131 Harbor Bay Parkway, Mail Stop 30470, Alameda, California 94502-6540 • 510/670-6460

August 18, 2016

Ms. Lori Martinez, Staff Manager
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

COMMENTS ON BOARD OF PHARMACY PROPOSED REGULATIONS FOR PRESCRIPTION DRUG TAKE-BACK PROGRAMS DATED August 4th, 2016

Dear Ms. Martinez:

On behalf of the Alameda County Household Hazardous Waste program we recommend the following changes to the proposed regulations.

> *1776.6(a)(1) Date each unused liner is acquired, it's unique identification number and size (e.g.5 gallon, 10 Gallon). The pharmacy shall assign a unique identification number if the liner does not already contain one.*

We suggest deleting this section as keeping this record is excessively burdensome for the pharmacy and goes well beyond DEA requirements. If liners are supplied to the pharmacy in bulk with an accompanying label kit to be affixed on the liner with permanent adhesive before installation, how is the acquisition date to be determined and why is this information relevant or necessary?

> *1776.6(a)(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 signature of two employees that witnessed each installation.*

This is excessively burdensome for pharmacy staff and goes beyond DEA requirements

-We suggest removing the requirement for employees to sign off on installation of the liner and suggest requiring the installation date be recorded on the liner itself (e.g. using a sticker or label), as is standard practice in hazardous waste. (accumulation dates on hazardous waste drum labels)

With these changes and information on the liner it will be possible to satisfy all of the board's recordkeeping requirements with a copy of the shipping document by recording installation and removal dates (and transfer to storage date if applicable) on the shipping document, easing the recordkeeping burden on pharmacy staff.

1776.3(i)

We suggest replacing "pharmacy employees" with "pharmacy or DEA registrant employees" to maintain consistency with other references in the document and DEA rules.

> *1776.3 (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.*

This is unclear as to the availability of a kiosk in a drugstore when a pharmacy department is closed but the store is open.

In Email correspondence with Tom Prevoznik, Unit Chief Liaison Liaison & Policy Section
Office of Diversion Control (provided to Virginia Herold via email on 8/15/2016) on this exact subject.

" The DEA intended that when the "registered location" is closed, collectors shall lock or ensure that the collection receptacle is not accessible to the public. For example, if the pharmacy should close and the store (the registered location) remains open, the store employees, at the direction of the collector, are authorized to monitor and man the collection receptacle during the store's hours of operation. The DEA strongly encourages all collectors to continue to adhere to security controls and procedures that ensure that collected controlled substances are not diverted."

We suggest re-drafting that section to conform with DEA's intention.

Bill Pollock

Program Manager
Alameda County Household Hazardous Waste program
1131 Harbor Bay Parkway M/S51701 (mailing address only)
Alameda, CA 94502

Martinez, Lori@DCA

From: Doug Barcon <dougbarcon@gmail.com>
Sent: Thursday, August 11, 2016 3:27 PM
To: Martinez, Lori@DCA
Subject: Comments on Title 16 CCR 1776 et seq. Prescription Drug Take-Back
Attachments: Board of Pharm 1776 Drug Take-Back Comments Mod Aug-2016 Fin- Barcon.doc

Hi Lori.

Attached are my comments on Title 16 CCR 1776 et seq. on Prescription Drug Take-Back Programs. My comments may be within the scope of the current modified text or outside it, but they should be addressed before the regulation is finalized.

Thanks,

Douglas Barcon, Pharm.D.

Institution/Contact	Douglas Barcon, Pharm.D., Barcon & Associates, P.O. Box 5646, Diamond Bar, CA 91765	
Subdivision (e.g., a, b, c)	Proposed Language	Recommendation/Comments
Section 1776.3 Collection Receptacles in Pharmacies (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.	This paragraph is not part of the text modified in this revision but provides background information for another paragraph. The California Medical Waste Management Act (California MWMA) specifies the standard for a biohazard bag in section 117630 and the standard for a sharps container in section 117750. The standards (ASTM D1922 and ASTM D1709) are specific to a biohazard bag for tear and impact resistance, respectively. The standard for the inner liner for drug take-back as referenced by the DEA is specified in 49 CFR 173.197(e) under Pipeline and Hazardous Materials Safety Administration (PHMSA) and specifies the same ASTM D1922 and ASTM D1709 standards as the biohazard bag. Neither of these ASTM standards applies to sharps, which includes hypodermic needles or broken glass. Note that broken glass could be generated within the inner liner from direct impact from deposits onto glass containers. Commingling of sharps can pose a problem. The original intent of this comment was to suggest modification of the text to allow a pharmacy to use an inner liner that exceeded the specified ASTM standards to add optional sharps protection. However, modification of the flexible inner liner material to add sharps compliance, which is a more stringent regulation, would require new rulemaking by the U.S. Department of Transportation, a new special

		permit, or a waiver of preemption. Therefore, a pharmacy cannot use a flexible liner that exceeds the standards specified in 49 CFR 173.197(e). If a pharmacy wished to protect its employees or staff from the potential of a needle stick or laceration from broken glass within the inner liner, it would be necessary to use personal protective equipment (PPE), such as gloves. PPE is not addressed in the modified text and may be beyond the scope of the current modified text. ASTM Standard F2878-10 approved in January 2016 addresses hypodermic needle puncture resistance of protective clothing materials which may include: plastics or elastomeric films, coated fabrics, flexible materials, laminates, leathers or textile materials.
Section 1776.3 Collection Receptacles in Pharmacies (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. ~~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.	Personal protective equipment (PPE) or safety are not addressed in this section and there is no reference to policies and procedures. While needle sticks are unlikely when removing the liner, they cannot be ruled out. Injury from broken glass is also a possibility that cannot be ruled out. Protective gloves that meet the new ASTM F2878-10 standard for penetration by hypodermic needles are not inexpensive but afford a level of protection from needle sticks, and the materials also afford a level of employee protection against other sharps. The donning of such protective gloves by employees transferring a full inner liner to another rigid container should be addressed by this regulation as a recommended practice. Perhaps a sentence can be added that states the following or something similar: Protective gloves that

		meet the American Society for Testing Materials (ASTM) F2878-10 standard for protection from hypodermic needles may be worn by pharmacy employees when sealing inner liners and transferring filled liners to rigid containers.
Section 1776.1 Pharmacies (c)	Controlled substances may be co~~m~~mingled in collection receptacles or mail back ~~packages or~~ envelopes or packages with other dangerous drugs.	The correct spelling is *commingled* with two letters m. Acceptable spelling has also included *comingled* with a single m, but the correct spelling *commingled.*
Section 1776.4 Drug Take-Back Services in Skilled Nursing Facilities (g)(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.	This paragraph is partially within the modified text. Protective gloves that meet the new ASTM F2878-10 standard for penetration by hypodermic needles are not inexpensive but afford a level of protection from needle sticks, and the materials also afford a level of employee protection against other sharps. The donning of such protective gloves by employees transferring a full inner liner to another rigid container should be addressed by this regulation as a recommended practice. Perhaps a sentence can be added that states the following or something similar: Protective gloves that meet the American Society for Testing Materials (ASTM) F2878-10 standard for protection from hypodermic needles may be worn by pharmacy employees when sealing inner liners and transferring filled liners to rigid containers.
Section 1776.4 Drug Take-Back Services in Skilled Nursing Facilities (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	Protective gloves that meet the new ASTM F2878-10 standard for penetration by hypodermic needles are not inexpensive but afford a level of protection from needle sticks, and the materials also afford a level of employee protection against other sharps. The donning of such protective gloves by employees transferring a full inner

	to a reverse distributor for destruction.	liner to another rigid container should be addressed by this regulation as a recommended practice. Perhaps a sentence can be added that states the following or something similar: Protective gloves that meet the American Society for Testing Materials (ASTM) F2878-10 standard for protection from hypodermic needles may be worn by pharmacy employees when sealing inner liners and transferring filled liners to rigid containers.
Section 1776 Prescription Drug Take-Back ~~Programs~~ Services: Authorization	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.	Since this regulation also applies to the mail-back program, it should also include both the mail-back program and pharmaceutical take-back receptacles in this section. As written, it appears that a mail-back program is excluded. Suggest adding mail-back program to this paragraph.
Section 1776.1 Pharmacies (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.	Since this regulation also applies to the mail-back program, it should also include both the mail-back program and pharmaceutical take-back receptacles in this section. As written, it appears that a mail-back program is excluded. Suggest adding mail-back program to this paragraph.
Section 1776.1 Pharmacies (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.	Since this regulation also applies to the mail-back program, it should also include both the mail-back program and pharmaceutical take-back receptacles in this section. As written, it appears that a mail-back program is excluded. Suggest adding mail-back program to this paragraph.

Section 1776.1 Pharmacies (i)(1)	Any pharmacy that ceases to ~~operate~~ maintain a drug take-back collection receptacle program shall notify the board in writing within 30 days ~~on a form designated by the board~~. ~~If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days.~~	Since this regulation also applies to the mail-back program, it should also include both the mail-back program and pharmaceutical take-back receptacles in this section. As written, it appears that a mail-back program is excluded. Suggest adding mail-back program to this paragraph.
Section 1776.1 Pharmacies (j)	If the pharmacy ~~later~~ ceases to operate maintain ~~the~~ a registered collection receptacle, the pharmacy must notify the DEA ~~Drug Enforcement Administration~~ within 30 days.	Since this regulation also applies to the mail-back program, it should also include both the mail-back program and pharmaceutical take-back receptacles in this section. As written, it appears that a mail-back program is excluded. Suggest adding mail-back program to this paragraph.

Martinez, Lori@DCA

From: PPSI@aol.com
Sent: Saturday, August 13, 2016 9:11 AM
To: Martinez, Lori@DCA
Cc: heidi@calpsc.org
Subject: Fwd: Who is registrant??? Santa Rosa's BOP draft comment letter
Attachments: image001.jpg; SantaRosaWaterBOP_2nd_15day_Letter_Aug12.docx; SantaRosaWaterBOP_2nd_15day_Attachment_Aug12.docx

Lori:

Is the hospital the DEA
Registrant??? or the Hospital Pharmacy?? or whom??

Please clarify??

best.....confusing,no??

Fred
MCPhA,Sec'ty

Frederick S, Mayer, R.Ph. MPH,FACA
PPSI CEO, Gray Panthers
300 Deer Valley Road, Suite 2 F
San Rafael, CA 94903
415-302-7351 ppsi@aol.com www.ppsinc.org

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From: THare@srcity.org
Reply-to: cpsc-pharmaceuticals-listserv@googlegroups.com
To: cpsc-pharmaceuticals-listserv@googlegroups.com
Sent: 8/13/2016 7:49:54 A.M. Pacific Daylight Time
Subj: Santa Rosa's BOP draft comment letter

-

Hi all,

I am attaching the draft version of Santa Rosa's BOP comment letter.

The comments we are choosing to submit are very nit-picky at this point, so this will definitely not make for exciting reading, but I wanted to provide them to everyone just in case they could be of use.

One thing I am not entirely sure of is whether the Board is correct that the hospital is the DEA registrant. If in fact the pharmacy within the hospital is the DEA registrant, and not the hospital itself, that comment section needs to be re-written.

Best,

Thomas

Thomas Hare | Environmental Compliance Inspector II

Santa Rosa Water |4300 Llano Rd. | Santa Rosa, CA 95407

Tel. (707) 543-3396 | Fax (707) 543-3398 | THare@srcity.org

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August 12, 2016

Ms. Lori Martinez, Staff Manager
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

RE: COMMENTS ON BOARD OF PHARMACY PROPOSED REGULATIONS FOR PRESCRIPTION DRUG TAKE-BACK SERVICES DATED JULY 27, 2016

Dear Ms. Martinez:

City of Santa Rosa Water Department staff would like to thank the Board of Pharmacy (Board) for the changes made to the draft regulations dated April 25, 2016. After reviewing the current draft dated July 27, 2016, the Board is asked to consider the attached list of comments and suggested text modifications when deciding how to move forward with proposed draft regulations regarding pharmaceutical take-back programs. The Santa Rosa Water Department co-leads a regional Safe Medicine Disposal Program which has collected more than 100,000 pounds of unused and/or unwanted medications since its inception in 2007. Staff is concerned that these proposed Board regulations may further restrict what is allowable for take back programs in comparison to the Drug Enforcement Agency (DEA) regulations. This could diminish the participation of pharmacies in medicine take-back programs, result in more medications being inappropriately flushed, and, ultimately, increase pharmaceutical pollutant loads entering wastewater treatment facilities.

The attachment includes excerpts from the proposed regulations by section and includes potential text modifications with comments that describe our concerns in detail.

City of Santa Rosa staff is very appreciative of the Board's willingness to delve into the details of the DEA regulations in order to establish a shared understanding and to promote beneficial Board of Pharmacy regulations of pharmaceutical take-back programs in California.

If you would like to discuss any of our concerns or need any additional details, please feel free to contact Thomas Hare at (707) 543-3396.

Thank you for your consideration.

Linda Reed,
Acting Director Santa Rosa Water

Attachment

Attachment – City of Santa Rosa Water Department Comments on Proposed Board of Pharmacy Regulations for Prescription Drug Take-back Services dated July 27, 2016

Section 1776.1 Pharmacies

1776.1(i) *"Pharmacies may offer drug take-back services as specified in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c)"*

Proposed text change: Pharmacies may establish collection receptacles as specified in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).

Comment: Per staff interpretation of the DEA regulations, any person or entity may distribute mail-back envelopes or packages. It is unclear why the pharmacy would be the entity offering any take-back service other than collection receptacles in skilled nursing facilities.

§ 1317.70 (c) . . . Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. . .

1776.1 (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."*

Proposed text change: A pharmacy shall not host a pharmaceutical take-back receptacle if, . . .

Comment: The phrase "take-back services" applies to both collection receptacles and mail-back envelopes. It is unclear what would prevent a pharmacy from being capable of complying with provisions governing the distribution of mail-back envelopes or packages.

1776.1 (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 board. . ."*

Proposed text change: A pharmacy shall not host a pharmaceutical take-back receptacle, as provided in section 1776.3 if . . .

Comment: The phrase "take-back services" applies to both collection receptacles and mail-back envelopes. It is unclear why it would be problematic for a pharmacy on probation to provide mail-back envelopes or packages to their customers.

1776.3 Collection Receptacles in Pharmacies

1776.3(a) *"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."*

Proposed text change: The receptacle shall be substantially constructed, with a permanent outer container kept securely locked to prevent the removal of the inner liner's contents.

Comment: It is possible to interpret the statement "*the collection receptacle shall be locked at all times to prevent access to the inner liner*" as meaning that all of the locks on the collection receptacle, including the lock on the small opening that allows deposits, must be kept locked at all times.

1776.3(b) *"A pharmacy maintaining a collection receptacle must securely fasten the receptacle to a permanent structure so it cannot be removed. The receptacle shall be installed in an inside location. Except as provided in subsection (c), the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter."*

Proposed text change: . . . the receptacle must be visible to pharmacy or DEA registrant employees, but not located behind the pharmacy's counter.

Comment: It is confusing to repeat the stipulation about emergency areas in subsection (b) as it only applies to subsection (c).

1776.3(c) *"In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When the responsible pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle."*

Proposed text change: The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by pharmacy or DEA registrant employees so that drugs may not be deposited into the collection receptacle.

Comment: As discussed in recent Board meetings, the DEA recognizes that hospitals can be unique in their design and need to have flexibility in the manner in which they participate in safe medicine disposal programs. The proposed Board regulation may remove some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees". This implies, as the Board recently agreed, that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. This further implies that collection receptacles in hospitals do not need to be locked even if the pharmacy is closed so long as registrant employees are still regularly monitoring the receptacle.

1776.3(d) *"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."*

Proposed text change: During hours when the pharmacy is closed, the collection receptacle shall be locked or made otherwise inaccessible to the public so that drugs may not be deposited into the collection receptacle.

Comment: For independent pharmacies that lock the entire building when they close the pharmacy, it is unclear what benefit would result from requiring them to lock the top of the bin when they close the pharmacy as locking the building fulfills the DEA requirement of making the receptacle 'otherwise inaccessible to the public'. If the Board chooses to revert to the DEA language they could avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.

1776.3(h) "*. . . 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.*"

Proposed text change: A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, capable of being sealed, and be kept clean and in good repair. All rigid containers must meet standards of the United States Department of Transportation.

Comment: Staff is concerned that requiring rigid containers to have tight-fitting covers might exclude the use of corrugated fiberboard. Combining the duplicative sentences above as proposed would alleviate this concern.

1776.4 Drug Take-Back Services in Skilled Nursing Facilities

1776.4(a) "*. . . 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.*"

Proposed change: Delete this provision.

Comment: The phrase "take-back services" applies to both collection receptacles and mail-back envelopes. It is unclear why a pharmacy would be the entity offering any take-back service other than collection receptacles in skilled nursing facilities.

§ 1317.70 (c) . . . Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. . .

1776.4(g)(2) "*. . . 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.*"

Proposed text change: A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, capable of being sealed, and be kept clean and in good repair. All rigid containers must meet standards of the United States Department of Transportation.

Comment: As mentioned in the comment for 1776.3 (h), staff is concerned that requiring rigid containers to have tight-fitting covers might exclude the use of corrugated fiberboard. Combining the duplicative sentences above as proposed would alleviate this concern.

1776.4(h) *"The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer."*

Proposed text change: The liner shall bear a permanent, unique identification number established by the pharmacy, established by the reverse distributor, or pre-entered onto the liner by the liner's manufacturer.

Comment: The existing text precludes the possibility of the reverse distributor being the entity that establishes the permanent, unique identification number on the liner.

1776.5 Reverse Distributors

1776.5(c) *"Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants."*

Proposed text change: Reverse distributors picking up inner liners from DEA registrants must have two employees present while handling or transporting the inner liners.

Comment: Reverse distributors that are receiving inner liners from DEA registrants via common or contract carrier need only do so with one employee:

§ 1317.15 (b)(2)(ii) "All controlled substance deliveries to a reverse distributor shall be personally received by an employee of the reverse distributor at the registered location."

1776.5(e) and 1776.5(f)

1776.5(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."

1776.5(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."*

Proposed change: Modify subsections (e) and (f) to render them internally consistent.

Comment: It is not possible to create all of the information in subsection (e) both at the time of receipt and at the time of destruction. For example, it is not possible to provide the name and signature of the two employees of the registrant that witnessed the destruction at the time of receipt as the destruction has not yet occurred.

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

1776.6(Note) "*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*"

Proposed change: Correct reference to cited sections.

Comment: Staff looked for this section 1317.22 but were unable to find it; please note most other authority cited references were not checked.

Martinez, Lori@DCA

From: Gordon Miller <gmiller@astound.net>
Sent: Friday, August 19, 2016 11:52 AM
To: Martinez, Lori@DCA
Subject: Feedback on the Proposed 16 CCR § 1776

In regards to the proposed 16 CCR § 1776, specifically the deletion of 16 CCR § 1776.2(c), I am concerned that having the consumer pay postage to send off the mail-back package will be burdensome and severely reduce use of the mail-back option. Consumers will need to go to the post office and stand in line to have their packages weighed and stamped, a potentially inconvenient and time-consuming process. Consumers will be tempted to resort to previous alternatives - flushing or disposing in the trash.

There is also a philosophical issue about 16 CCR § 1776. The tenth amendment to the US Constitution states, "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." States and localities were intended to be laboratories of democracy. But I have seen the federal government pre-empt states and localities on the behalf of businesses worried about the proliferation of state and local regulations. Pharmacy chains and pharmaceutical manufacturers are apparently worried about drug take back programs, possibly for ideological (how dare they, the public, tell us what to do) reasons. The Board of Pharmacy appears to be caught in such a struggle. The DEA has regulations about drug take back. Why not allow localities to cite those regulations as they develop and try out administrative procedures?

Gordon Miller
925/938-1758
cell 925/324-6881
gmiller@astound.net
1340 Las Juntas Way
Apartment B
Walnut Creek, CA 94597-2069

Martinez, Lori@DCA

From: Steve.W.Gray@kp.org
Sent: Friday, August 19, 2016 4:19 PM
To: Martinez, Lori@DCA
Cc: Perry.Flowers@kp.org
Subject: California Board of Pharmacy Proposed Changes to Pharmacy Regulations, Title 16 CCR , Article 9, Section 1776, et seq
Attachments: Final KP Response to BOP Proposed Take Back Regulations 1776 et seq Aug 19 2016.doc

Importance: High

We respectfully submit comments re California Board of Pharmacy Proposed Changes to Pharmacy Regulations, Title 16 CCR, Article 9, Section 1776, et seq

Please acknowledge receipt. Thanks.

Steven Gray, PharmD, JD
Pharmacy Professional Affairs Leader

Kaiser Permanente
National Pharmacy Programs and Services
12254 Bellflower Blvd
Downey, CA 90242

562.658.3663 (office)
320 (tie-line)
562.658.3665 (fax)
909.548.9774 (mobile phone)
Wendy E Rosa (assistant)

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kp.org/thrive

KAISER PERMANENTE®
Pharmacy Professional Affairs
12254 Bellflower Blvd, Downey, CA 90242
Office 562-658-3510 Fax 562-658-3512

August 19, 2016
To: Lori Martinez
Lori Martinez@dca.ca.gov
Fax: 916.574.8618

1625 N. Market Blvd., N219
Sacramento, CA 95834

c/o California Board of Pharmacy

Re: California Board of Pharmacy Proposed Changes to Pharmacy Regulations, Title 16 CCR _____

On behalf of the Pharmacy Operations department of Kaiser Foundation Hospitals, and Kaiser Foundation Health Plan, we respectfully submit in "Attachment 1", recommendations to the Board of Pharmacy's proposal to change Title 16 CCR **Article 9, Section 1776, et. seq.)**. We ask for your careful review and consideration of our recommendations. We believe that changes to what has been published are necessary to promote optimal safety and access to high quality, affordable care. We respectfully request that if the Board of Pharmacy disagrees with one or more of our proposals, that the rationale for that disagreement be clearly stated.

s/s Steven Gray, PharmD, JD
Pharmacy Professional Affairs Leader

Cc: W. Perry Flowers, M.S., R.Ph.
Vice President – Acute and Transitional Care

Attachment 1
Kaiser Pharmacy Operation's Recommendations and Concerns about California Board of Pharmacy Proposed changes to Pharmacy Regulations (16 CCR, Article 9, Section 1776, et. seq.)

Introductory Comments:
Kaiser Foundation Health Plan and Kaiser Foundation Hospitals California Pharmacy Operations sections of is submitting this document on behalf of California Kaiser's 35 hospital pharmacies, eight licensed home infusion pharmacies, 29 ambulatory oncology pharmacies that have California Board of Pharmacy-issued licenses and over 250 outpatient pharmacies.

We prepared the grid below to clearly show the language that we believe to be problematic or unclear; the rationale for our recommendations to improve the language, and an- assessment of the impact to the public, to patients and perhaps our organization (and many others) if the language is not changed.

For further information, please contact Steve Gray at steve.w.gray@kp.org

Proposed Board of Pharmacy Regulations	Recommended Changes and Rationale and Impact Statements
	Underline = Additions Strikethroughs = Omissions
Section 1776.1 Pharmacies ~~(i)~~ (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 Drug Enforcement Administration rules.	**Section 1776.1 Pharmacies** **Recommended Change** (k) A pharmacy shall not provide collection receptacles for 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 Drug Enforcement Administration rules. **Rationale** The language is confusing and not consistent with stated concerns of the DEA or the Board of Pharmacy. The concern expressed by the Board of Pharmacy is about the *collection* of unwanted drugs by pharmacies and the potential diversion and quality hazards that such service could pose to the public, including the re-use of drugs collected by pharmacy. The DEA allows any pharmacy or other entity, WITHOUT being registered with the DEA as a Take Back provider, to participate in the dispensing of mail-back envelopes or packages if those envelopes or packages are part of a program that is conducted by an entity *that is Registered with the DEA* and whose mail back envelopes and packages meet all specified requirements. Such mail back envelopes or packages, once dispensed to a patient or other person, are NOT mailed back to and UN-registered pharmacy. They are postage prepaid and

	pre-addressed to be mailed back to an entity that is properly Registered with the DEA for subsequent proper destruction of the drugs. Thus a pharmacy that is participating *only as a dispenser* of another Registered entity's envelopes or packages does not present a hazard to the public of diversion or re-use of those drugs because the unwanted drugs are never in the pharmacy's possession. Consequently there is no basis for a Pharmacist-In-Charge to determine that merely allowing the pharmacy to dispense appropriate mail back envelopes or packages presents a hazard or does not comply with Board of Pharmacy or DEA requirements. Further, this change would be consistent with the language or proposed regulation section 1776.2, which clearly makes it option for a pharmacy to participate by dispensing mail back envelopes and packages. **Impact** If this wording is not changed it will confuse who, the PIC or the Pharmacy Permit holder, has the authority to allow or require that the pharmacy to participate in the public service of dispensing mail back envelopes or packages that are properly a part of a registered entity's mail back program. Consequently the public policy will be frustrated by not having as broad availability as possible to resolve the problems that retention in households of unwanted prescription drugs and controlled substance present. Further, this proposed wording of the regulation, if not changed, will cause confusion and potential labor relations problems that may unnecessarily have to be resolved by the courts.
1776.3 Collection Receptacles in Pharmacies (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.	**1776.3 Collection Receptacles in Pharmacies** **Recommended Change** **(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 access mechanism on the collection receptacle. Rationale The use of the word "slot" implies a very narrow opening that would not allow some vials, or bags or packages of vials, to be deposited. Worse, it may mean to some consumers that the "pills", etc. have to be emptied from prescription vials and bottles to be placed into the collection receptacle loose. That would require the opening and handling of loose tablets, capsules and other dosage forms. It would increase the risk of spillage near the receptacle and the

	contamination of the area and the consumer's hands etc. It may also cause injury as the consumer tries to put his/her hand far enough into the receptacle to meet the sub-section "(g)" requirement that the pills, tablets, capsules, etc. go directly into the receptacle's liner. Some already approved collection receptacles have an access opening that is not a "slot" but a wider opening and a mechanism that are designed to allow larger vials and bags to be deposited directly into the receptacle's line but still prevent anyone from retrieving the deposited vials, etc. once deposited. Such receptacles with the larger access meet the requirements of sub-section "(g)" of this proposed regulation. Impact Not making this change would cause potential contamination and injury and mislead participating organizations about what is allowed. Some organizations already have receptacles with mere narrow slots because they do not want the cost of having to transport and destroy the vials, etc. along with the drugs. Experience with these types of receptacles has already demonstrated the hazards described above.
(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.	(g) Recommended Change (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 manually or with a tool. Rationale Experience has shown that with the use of a tool or vacuum apparatus, receptacles with small "slots" or openings can still be have deposited drugs removed. Having receptacles like US Mail Boxes that use a double access mechanism will prevent such illicit access and removal. Impact Without this small but important change in the specifications of the point of deposit access for collection receptacles, diversion and contamination and their dangers to patients, staff and the public will unnecessarily occur.
1776.4 Collection in Skilled Nursing Facilities ~~(h)~~ (g) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.	**1776.4 Collection in Skilled Nursing Facilities** Recommended Change ~~(h)~~ (g) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.

(1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be ~~viewed~~, removed, sorted, counted, or otherwise individually handled ~~counted~~.	(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~~, viewed, removed, sorted, counted, or otherwise individually handled ~~counted~~ manually or with a tool. Rational and Impact (See above)

Martinez, Lori@DCA

From: Bill Worrell <bworrell@iwma.com>
Sent: Thursday, August 18, 2016 3:40 PM
To: Martinez, Lori@DCA
Subject: Prescription Drug Take Back Program Proposed Regulations
Attachments: SLO IWMA comments.pdf

Hi Lori,
Attached are comments on the Prescription Drug Take Back Program Proposed Regulations.

Bill Worrell
San Luis Obispo County
Integrated Waste Management Authority
870 Osos Street
San Luis Obispo, CA 93401
805-782-8530

"Computers are useless. They can only give you answers." Pablo Picasso

San Luis Obispo County
Integrated Waste Management Authority

870 Osos Street
San Luis Obispo, CA 93401

805/782-8530
FAX 805/782-8529
E-mail: iwma@iwma.com

Recycling, Compost & Haz.
Waste Info. 800/400-0811
School Programs Information
805/782-8424

August 18, 2016

California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Subject: Prescription Drug Take-Back

Attn: Ms. Lori Martinez

RE: Proposed Second Modified Text (Board Approved July 27, 2016) for Prescription Drug Take-Back Programs

Dear California Board of Pharmacy Board Members:

Thank you for the opportunity to once again formally comment on the proposed Second Modified Text (Board Approved July 27, 2016) prescription drug take-back regulations (Proposed Regulations) being considered by the California Board of Pharmacy (BOP).

The San Luis Obispo County Integrated Waste Management Authority (IWMA) agrees that "drug abuse is at epidemic levels." While the Proposed Regulations are significantly improved compared to the initial proposed regulations, the IWMA still disagrees that the Proposed Regulations will help solve this epidemic, and, in fact, will frustrate solutions to the problem. If these Proposed Regulations are adopted, almost all of the existing unwanted drug take back locations in California will close and it will be difficult to open new ones. Thus, the public will have almost no opportunity to properly dispose of unwanted prescription drugs. Because of the reasons discussed below, the IWMA recommends that the BOP abandon its Proposed Regulations and instead allow the applicable Drug Enforcement Administration (DEA) Regulations and appropriate State and local programs to govern drug take back solutions in California.

Many of the comments in the March 22, 2016 IWMA comment letter still apply to the Proposed Regulations. For example:

I. The BOP is exceeding its legal authority

II. The BOP Proposed Regulations will have a negative impact on the environment and require CEQA review

I. The Board of Pharmacy is Exceeding Its Legal Authority

The general rulemaking authority granted the Board of Pharmacy by section 4005 of the Business and Professions Code is admittedly broad in scope. The section provides, in part: "The board may make such rules and regulations, not inconsistent with the laws of this State as may be necessary for the protection of the public. Included therein shall be the right to make rules and regulations as follows: " . . . pertaining to the practice of pharmacy . . . pertaining to establishments wherein any drug is compounded, prepared or sold. . . ." Bus. & Prof. Code § 4005(a).

The substantive breadth of such rulemaking power is limited, however, by the purpose and scope of the authorizing legislation. Government Code section 11342.2 provides, in part: "Whenever . . . a state agency has authority to adopt regulations . . . no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute." 1967 Cal. AG LEXIS 51, 49 Ops. Cal. Atty. Gen. 27.

Subsequent Attorney General Opinions and California Supreme Court cases have made clear that an enabling statute does not have to expressly authorize an agency to regulate a specific aspect of the subject matter under its jurisdiction. 1978 Cal. AG LEXIS 88, 61 Ops. Cal. Atty. Gen. 24; *Ralphs Grocery Co. v. Reimel*, 69 Cal. 2d 172, 176 (1968). California Courts have held, however, that "the [Board] has no power to vary or enlarge the terms of an enabling statute, or to issue regulations which conflict with this or any other statute." *Credit Ins. Gen. Agent Assn. v. Payne,* 16 Cal. 3d 651, 656 (1976).

A review of the legislative intent of these statutes reveals that the Board of the Pharmacy, as a board under California's Department of Consumer Affairs, was established in order to protect the people of California. A review of the relevant Business & Professions code sections makes clear the legislative purpose is one of insuring that drugs and related items furnished to the public are of adequate purity and quality and are dispensed from sanitary facilities by competent personnel pursuant to proper authorization. The regulations adopted to implement these statutory goals are of the same tenor and are intended to insure the health and safety of citizens that use the services of a pharmacist. 1967 Cal. AG LEXIS 51, 49 Ops. Cal. Atty. Gen. 27.

Courts have held that "[i]n order for the regulation to be within the delegated authority, it must appear that it is necessary and reasonably designed to protect the public within the meaning of its enabling statute. A board's responsibility is to follow the statutory language and decide whether the proposed regulation is **necessary to protect the public.** Additionally, the board should determine whether the proposed regulation is **reasonable in its scope and effect.** *Credit Ins. Gen. Agent Assn., supra* 16 Cal. 3d 651 at 657 emphasis added; 1978 Cal. AG LEXIS 88, 61 Ops. Cal. Atty. Gen. 24. In this case, the BOP is clearly exceeding its regulatory authority by attempting to extend its authority into other environmental and public health concerns beyond the scope of its enabling statute.

After a review, it is clear the BOP Proposed Regulations are neither *necessary* to protect the public nor *reasonable* in their scope and effect.

A. The BOP Proposed Regulations are not Necessary to Protect the Public

As discussed previously, the BOP Proposed Regulations are not necessary to protect the public because there are already several federal and state, statutory and regulatory schemes in place governing the disposal of medical waste, including pharmaceuticals. California's Department of Public Health (DPH) regulates the generation, handling, storage, treatment and disposal of medical waste through the Medical Waste Management Program within its Environmental Management Branch. California's Health & Safety Code § 118275(6)(A) states that "[pharmaceutical waste classified by DEA regulations as controlled substances shall be disposed of in compliance with DEA requirements." The DEA has already established regulations that address the disposal of unwanted prescription medication. The Proposed Regulations are not consistent with DEA regulations.

B. The BOP Proposed Regulations are Beyond the Scope of the BOP's Authority

Even if the Proposed Regulations were necessary to protect the public, they are not *reasonable* in their scope and effect and, in fact, go far beyond the scope of the BOP's authority. The scope of the BOP's regulatory authority is confined to the regulation of pharmacists and the practice of pharmacy. The Proposed Regulations do not, however, merely regulate pharmacies or pharmacists. The Proposed Regulations intrude into an environmental issue by governing the management and disposal of medical waste. Environmental regulation is beyond the scope of the Board of Pharmacy's authority. Allowing the Board of Pharmacy to regulate an aspect of environmental concern, would effectively enlarge the terms of its enabling statute. The Proposed Regulations are not reasonably designed because they do not aid the statutory objective of ensuring the health and safety of citizen that use the services of a pharmacist. The Proposed Regulations attempt to govern matters outside the concern of the Board's purview.

The Board of Pharmacy (BOP) does not have the authority to regulate a "pharmaceutical waste", rather that authority is vested with the California Department of Public Health (DPH). According to the DPH "the Medical Waste Management Program (Program), in the Environmental Management Branch, regulates the generation, handling, storage, treatment, and disposal of medical waste by providing oversight for the implementation of the Medical Waste Management Act (MWMA)."

The authority under the Medical Waste Management Act is further recognized in the recently passed Senate Bill 1229 by Senator Jackson. The LEGISLATIVE COUNSEL'S DIGEST for SB 1229 states, "Under existing law, the Medical Waste Management Act, the State Department of Public

Health regulates the management and handling of medical waste, including pharmaceutical waste, as defined. The act generally prohibits a person from transporting, storing, treating, disposing, or causing the treatment of medical waste in a manner not authorized by the act. A violation of that provision is a crime."

As previously stated, regulations already exist in California to manage the disposal of medical waste. California Health and Safety Code Section 118275 (6) (A) states "Pharmaceutical wastes classified by the DEA regulations as controlled substances shall be disposed of in compliance with DEA requirements." The BOP Proposed Regulations are not consistent with DEA regulations.

The BOP, under the California Business and Professions Code, does provide for the regulation of pharmacists and the practice of pharmacy. The disposal of unwanted drugs is outside of this responsibility. The DEA Regulations only requires that "two employees" of the pharmacy remove and dispose of the drugs. There is no requirement that these employees be pharmacists or be engaged in the practice of pharmacy. It is clear that the management of medical waste has already be delegated to DPH, not the BOP.

II. The BOP Regulations will have a Significant Environmental Effect and Require CEQA Review.

The Board of Pharmacy proposed regulations constitute a "project" that will have a significant environmental effect. Therefore, under CEQA, the preparation of an environmental impact report ("EIR") is required prior to adopting the BOP Proposed Regulations.

A. Legal Standard.

The California Environmental Quality Act, Pub. Res. Code §§ 21000 et seq. ("CEQA") applies to discretionary "projects" to be carried out or approved by public agencies. See Pub. Res. Code § 21080(a). An activity is a "project" covered by CEQA if it is directly undertaken by a public agency, supported by a public agency, or involved issuance of entitlement for use by a public agency and has potential to result in a physical change to the environment, directly or ultimately. CEQA applies when a public agency proposes to "approve" a project. RiverWatch v. Olivehain Mun. Water Dist., 170 Cal. App. 4th 1186 (2009). The term "approval" refers to a public agency decision that "commits the agency to a definite course of action in regard to a project. 14 CCR § 15352(a). Existing law clearly provides that a "project" may include ordinances, rules and regulations, general plans, specific plans, and similar legislative and quasi legislative actions.

Proposed regulations that result in a direct or reasonably foreseeable indirect change to the physical environment are subject to CEQA review. If there is substantial evidence that proposed

regulations will have a significant environmental effect, an environmental impact report (EIR) must be prepared. A "significant effect on the environment" is a substantial adverse change in the physical environment in the area affected by the project. In determining whether a project's impacts are significant, an EIR compares those impacts with existing environmental conditions, which are referred to as the "baseline" for the impact analysis. CEQA guidelines specify that the "baseline" normally consists of the physical conditions that exist in the area affected by the project at the time the EIR process begins. 14 CCR § 15125(a).

B. The BOP Proposed Regulations and Their Effect on the Environment.

The BOP Proposed Regulations are a discretionary activity undertaken by a public agency that has a potential to result in a physical change to the environment. Therefore, the proposed regulations are a "project" under CEQA requiring environmental review. There are currently drug take-back programs in California that created a "baseline" physical conditions by which the Board of Pharmacy must compare the effect of its proposed regulations on that baseline and determine whether the impact is significant.

Almost every existing pharmacy take back program with a kiosk in California, which are currently in compliance with DEA regulations, will not be in compliance with the BOP Proposed Regulations. Existing locations will either have to comply with the BOP Proposed Regulations or remove their kiosk. Since the BOP Proposed Regulations are overly burdensome and allow the pharmacist-in-charge to opt out of mandatory programs, it is foreseeable that many existing kiosk locations will close. These closures will have a significant impact on the environment because consumers will no longer have a convenient and safe means of disposing of unwanted prescription medication. This will lead to more prescription medication ending up in landfills or water supplies. Therefore, the BOP must comply with CEQA and conduct an environmental review of their Proposed Regulations.

For all the above reasons, the San Luis Obispo County Integrated Waste Management Authority respectfully urges the Board of Pharmacy to abandon the Proposed Regulations and, instead, allow the existing DEA Regulations and local environmental programs to govern the pharmaceutical drug take back efforts in California.

Sincerely,

William A. Worrell
Manager

C:\IWMA\Correspondence\2016\Board of Pharmacy 8-18-2016.wpd

Martinez, Lori@DCA

From: Gundy, Renae <RGundy@srcity.org>
Sent: Thursday, August 18, 2016 2:50 PM
To: Martinez, Lori@DCA
Subject: Section 1176 Prescription Drug Take-Back Services-comments
Attachments: Board of Pharmacy-letter and comments 8.2016-Final.pdf

Dear Ms. Martinez,

Please consider the attached comments on Board of Pharmacy proposed regulations for prescription drug take-back services.

Thank you,

Renae Gundy | Environmental Compliance Inspector
Santa Rosa Water |4300 Llano Road | Santa Rosa, CA 95407
Tel. (707) 543-4368 | Fax (707) 543-3398 | rgundy@srcity.org

City of Santa Rosa

August 12, 2016

Ms. Lori Martinez, Staff Manager
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

RE: COMMENTS ON BOARD OF PHARMACY PROPOSED REGULATIONS FOR PRESCRIPTION DRUG TAKE-BACK SERVICES DATED JULY 27, 2016

Dear Ms. Martinez:

City of Santa Rosa Water Department staff would like to thank the Board of Pharmacy (Board) for the changes made to the draft regulations for prescription drug take-back services dated April 25, 2016.

By way of background, Santa Rosa Water co-leads a regional Safe Medicine Disposal Program which has collected more than 100,000 pounds of expired, unused and/or unwanted medications since its inception in 2007. Staff is concerned that the proposed Board regulations may further restrict what is allowable for take back programs in comparison to the Drug Enforcement Agency (DEA) regulations. This could diminish the participation of pharmacies in take-back programs, result in more medications being inappropriately flushed, and, ultimately, increase pharmaceutical pollutant loads entering wastewater treatment facilities. Considering the potential impacts of improperly disposed of pharmaceuticals to public health, safety and the environment, Santa Rosa Water has substantial interest in the Board's proposed regulations regarding prescription drug take-back services.

After reviewing the current draft dated July 27, 2016, the Board is asked to consider the attached list of comments and suggested text modifications when deciding how to move forward with proposed draft regulations regarding pharmaceutical take-back programs. The attachment includes excerpts from the proposed regulations by section and includes potential text modifications with comments that describe our concerns in detail.

City of Santa Rosa staff is very appreciative of the Board's willingness to delve into the details of the DEA regulations in order to establish a shared understanding and to promote beneficial Board of Pharmacy regulations of pharmaceutical take-back programs in California.

If you would like to discuss any of our concerns or need any additional details, please feel free to contact Thomas Hare at (707) 543-3396.

Thank you for your consideration.

Linda Reed,
Interim Director Santa Rosa Water

Attachment

Santa Rosa Water
69 Stony Circle • Santa Rosa, CA 95401
Tel: (707) 543-4200 • Fax: (707) 543-3936

Attachment – City of Santa Rosa Water Department Comments on Proposed Board of Pharmacy Regulations for Prescription Drug Take-back Services dated July 27, 2016

Section 1776.1 Pharmacies

1776.1(i) *"Pharmacies may offer drug take-back services as specified in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c)"*

Proposed text change: Pharmacies may establish collection receptacles as specified in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).

Comment: Per staff interpretation of the DEA regulations, any person or entity may distribute mail-back envelopes or packages. It is unclear why the pharmacy would be the entity offering any take-back service other than collection receptacles in skilled nursing facilities.

§ 1317.70 (c) . . . Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. . .

1776.1 (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."*

Proposed text change: A pharmacy shall not host a pharmaceutical take-back receptacle if, . . .

Comment: The phrase "take-back services" applies to both collection receptacles and mail-back envelopes. It is unclear what would prevent a pharmacy from being capable of complying with provisions governing the distribution of mail-back envelopes or packages.

1776.1 (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 board. . ."*

Proposed text change: A pharmacy shall not host a pharmaceutical take-back receptacle, as provided in section 1776.3 if . . .

Comment: The phrase "take-back services" applies to both collection receptacles and mail-back envelopes. It is unclear why it would be problematic for a pharmacy on probation to provide mail-back envelopes or packages to their customers.

1776.3 Collection Receptacles in Pharmacies

1776.3(a) *"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."*

Proposed text change: The receptacle shall be substantially constructed, with a permanent outer container kept securely locked to prevent the removal of the inner liner's contents.

Comment: It is possible to interpret the statement "*the collection receptacle shall be locked at all times to prevent access to the inner liner*" as meaning that all of the locks on the collection receptacle, including the lock on the small opening that allows deposits, must be kept locked at all times.

1776.3(b) "*A pharmacy maintaining a collection receptacle must securely fasten the receptacle to a permanent structure so it cannot be removed. The receptacle shall be installed in an inside location. Except as provided in subsection (c), the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter.*"

Proposed text change: . . . the receptacle must be visible to pharmacy or DEA registrant employees, but not located behind the pharmacy's counter.

Comment: It is confusing to repeat the stipulation about emergency areas in subsection (b) as it only applies to subsection (c).

1776.3(c) "*In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When the responsible pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle.*"

Proposed text change: The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by pharmacy or DEA registrant employees so that drugs may not be deposited into the collection receptacle.

Comment: As discussed in recent Board meetings, the DEA recognizes that hospitals can be unique in their design and need to have flexibility in the manner in which they participate in safe medicine disposal programs. The proposed Board regulation may remove some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees". This implies, as the Board recently agreed, that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. This further implies that collection receptacles in hospitals do not need to be locked even if the pharmacy is closed so long as registrant employees are still regularly monitoring the receptacle.

1776.3(d) "*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.*"

Proposed text change: During hours when the pharmacy is closed, the collection receptacle shall be locked or made otherwise inaccessible to the public so that drugs may not be deposited into the collection receptacle.

Comment: For independent pharmacies that lock the entire building when they close the pharmacy, it is unclear what benefit would result from requiring them to lock the top of the bin when they close the pharmacy as locking the building fulfills the DEA requirement of making the receptacle 'otherwise inaccessible to the public'. If the Board chooses to revert to the DEA language they could avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.

1776.3(h) "*. . . 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.*"

Proposed text change: A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, capable of being sealed, and be kept clean and in good repair. All rigid containers must meet standards of the United States Department of Transportation.

Comment: Staff is concerned that requiring rigid containers to have tight-fitting covers might exclude the use of corrugated fiberboard. Combining the duplicative sentences above as proposed would alleviate this concern.

1776.4 Drug Take-Back Services in Skilled Nursing Facilities

1776.4(a) "*. . . 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.*"

Proposed change: Delete this provision.

Comment: The phrase "take-back services" applies to both collection receptacles and mail-back envelopes. It is unclear why a pharmacy would be the entity offering any take-back service other than collection receptacles in skilled nursing facilities.

§ 1317.70 (c) . . . Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. . .

1776.4(g)(2) "*. . . 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.*"

Proposed text change: A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, capable of being sealed, and be kept clean and in good repair. All rigid containers must meet standards of the United States Department of Transportation.

Comment: As mentioned in the comment for 1776.3 (h), staff is concerned that requiring rigid containers to have tight-fitting covers might exclude the use of corrugated fiberboard. Combining the duplicative sentences above as proposed would alleviate this concern.

1776.4(h) *"The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer."*

Proposed text change: The liner shall bear a permanent, unique identification number established by the pharmacy, established by the reverse distributor, or pre-entered onto the liner by the liner's manufacturer.

Comment: The existing text precludes the possibility of the reverse distributor being the entity that establishes the permanent, unique identification number on the liner.

1776.5 Reverse Distributors

1776.5(c) *"Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants."*

Proposed text change: Reverse distributors picking up inner liners from DEA registrants must have two employees present while handling or transporting the inner liners.

Comment: Reverse distributors that are receiving inner liners from DEA registrants via common or contract carrier need only do so with one employee:

§ 1317.15 (b)(2)(ii) "All controlled substance deliveries to a reverse distributor shall be personally received by an employee of the reverse distributor at the registered location."

1776.5(e) and 1776.5(f)

1776.5(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."

1776.5(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."*

Proposed change: Modify subsections (e) and (f) to render them internally consistent.

Comment: It is not possible to create all of the information in subsection (e) both at the time of receipt and at the time of destruction. For example, it is not possible to provide the name and signature of the two employees of the registrant that witnessed the destruction at the time of receipt as the destruction has not yet occurred.

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

1776.6(Note) "*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*"

Proposed change: Correct reference to cited sections.

Comment: Staff looked for this section 1317.22 but were unable to find it; please note most other authority cited references were not checked.

Martinez, Lori@DCA

From: Leung, Eileen (ENV) <eileen.leung@sfgov.org>
Sent: Friday, August 19, 2016 4:21 PM
To: Martinez, Lori@DCA
Cc: Johnson, Margaret (ENV); Jackson, Jen (ENV)
Subject: SFE Comments Regarding BOP Drug Take-Back Regulations
Attachments: SFE Comments to BOP on Drug Take-Back - August 2016.pdf

Hi Lori,

The San Francisco Department of the Environment is submitting the attached comments in regards to the CABOP proposed Prescription Drug Take-Back Regulations. We thank you for the opportunity to submit these comments and appreciate all your hard work on these regulations. Feel free to contact us if you have any questions.

Have a good weekend!

Eileen Leung
Safe Medicine Disposal Project Coordinator
San Francisco Department of the Environment
eileen.leung@sfgov.org
T: (415) 355-3705

Edwin M. Lee
Mayor

SF Environment
Our home. Our city. Our planet.
A Department of the City and County of San Francisco

Deborah O. Raphael
Director

August 19, 2016

Lori Martinez
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Comments on Second Modified Text, Proposed Prescription Drug Take-Back Rule (Board Approved July 27, 2016)

Dear Ms. Martinez:

The San Francisco Department of the Environment appreciates the opportunity to comment on the Board of Pharmacy's July 27, 2016 Second Modified Text, which proposes to add Article 9.1, Prescription Drug Take-Back Programs, to Division 17 of Title 16 of the California Code of Regulations.

As you are aware, the City and County of San Francisco passed the San Francisco Safe Drug Disposal Stewardship Ordinance in 2015 which requires pharmaceutical manufacturers to fund and implement a permanent medicine take-back program in San Francisco. Many pharmacies are waiting for the California Board of Pharmacy (CABOP) to pass regulations before they decide whether to host a collection receptacle. We urge the CABOP to pass regulations as quickly as possible so there is no delay in implementing our stewardship program.

We appreciate the effort and attention CABOP staff and board members have devoted to developing this proposed rule and to incorporating stakeholder comments. However, we recommend that instead of developing its own regulations, that **CABOP regulations should point to or mirror Federal Drug Enforcement Administration in 21 CFR 1317 et seq** ("DEA Final Rule"). The DEA Final Rule was passed after careful consideration and review of many public comments submitted by a range of stakeholders. We believe it is in the best interest of the public, who will benefit from the new opportunities for convenient and safe disposal of unwanted medicines, to have California's regulation follow the DEA Final Rule as closely as possible. Rather than clarifying the DEA Final Rule, we believe CABOP regulations, as they are currently written, may cause further confusion.

In addition to causing confusion, we believe that CABOP's Second Modified Text inappropriately overreaches the DEA Final Rule, and is inconsistent with California Health and Safety Code and the Federal Department of Transportation Regulations, with regard to medical sharps and needles. As the CABOP is aware, certain medications are commonly dispensed in pre-loaded self-injection devices, such as "epi-pens." These devices are dispensed in sturdy and puncture-proof packaging which is designed to be carried by the consumer in purses and back-packs. These devices have expiration dates and commonly go unused by the expiration date. As a result, consumers routinely need to dispose of a medication which is packaged in combination with a sharp.

The California Health & Safety Code rightly anticipated the need to address sharps containing medication. Section 118275(h) of the Health & Safety Code allows for the consolidation of sharps waste and pharmaceutical waste in a common container, so long as the consolidated waste is managed as a pharmaceutical waste – that is, it is incinerated and not only autoclaved. In addition, the Federal Department of Transportation Special Permit DOT-SP 20255 issued on June 10, 2016 does not require segregation of sharps from other materials collected for the purpose of disposal under the DEA Final Rule.

Therefore, we respectfully request that CABOP remove the prohibition on medical sharps. At a minimum, CABOP should allow pre-loaded self-injection devices which are unused and in their original packaging to be disposed in collection receptacles.

In addition to the above general comments, we offer the following specific recommended language changes to the Second Modified Text of the proposed regulation.

Section 1776.1 Pharmacies

- **(e)(2) "Medical sharps and needles...shall not be deposited"**

Comment: At a minimum, unused medication which is packaged in combination with a sharp and which is still in its original puncture-proof packaging should be allowed to be disposed in collection receptacles maintained under this regulation.

Recommendation: Either remove this line completely, or at a minimum insert new paragraph immediately following Section 1776.1(e) as follows: For the purposes of this Article 9.1, "medical sharps and needles" do not include preloaded self-injection devices that are unused and in their original packaging.

- **(k) "A pharmacy shall not provide take-back services to consumers if, in the professional judgement of the pharmacist in charge, the pharmacy cannot comply with the provisions of this article or the Drug Enforcement Administration rules."**

General Comment: This paragraph was discussed extensively at the April 27 and July 27 meetings of the full CABOP. If a pharmacy cannot comply with the DEA rules, under Federal law, it cannot collect controlled substances from ultimate users. This paragraph is unnecessary.

Recommendation: Remove this paragraph.

Section 1776.3 Collection Receptacles in Pharmacies

- **(b) "A pharmacy maintaining a collection receptacle must securely fasten the receptacle to a permanent structure so it cannot be removed. The receptacle shall be installed in an inside location. Except as provided in subsection (c), the receptacle [shall be] visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter."**

Comment: It is confusing to include the stipulation about emergency areas in subsection (b) as it only applies to subsection (c).

Recommendation: Change text of third sentence to: The receptacle must be visible to employees, but not located behind the pharmacy's counter.

- **(d) "... 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."**

Comment: This is not consistent with the DEA Final Rule. The DEA has communicated to local government officials that the collection receptacle should not be locked during store hours because store consumers may leave unwanted medication adjacent to the bin, offering a potential diversion opportunity.

Recommendation: Delete last two sentences from Section 1776.3(d).

- **(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."**

Comment: The DEA does not specify how many days a pharmacy can store full liners before transporting for destruction, only specifying "promptly" (see Section 1317.05 (c). While we appreciate the CABOP increasing the storage time in the April 25 modified text from three to 14 days, we still believe the DEA language allows for adequate flexibility for all pharmacies in the state of California, while ensuring that full liners are not stored indefinitely.

Recommendation: Replace "no longer than 14 days" with "promptly."

- **(m) "Medical sharps and needles...shall not be deposited"**

Comment: At a minimum, unused medication which is packaged in combination with a sharp and which is still in its original puncture-proof packaging should be allowed to be disposed in collection receptacles maintained under this regulation.

Recommendation: Either remove this line completely, or at a minimum insert new paragraph immediately following Section 1776.3(m) as follows: For the purposes of this Article 9.1, "medical sharps and needles" do not include preloaded self-injection devices that are unused and in their original packaging.

Section 1776.4 Collection in Skilled Nursing Facilities

- **(a) Skilled nursing facility employees or person[s] 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 ..."**

Comment: The DEA does not authorize, require, or restrict the simple distribution of mail back envelopes or packages at skilled nursing facilities or other potential distribution points. The DEA record-keeping requirements apply to the receipt and destruction of mail back envelopes or packages. This section is confusing and unnecessary.

Recommendation: Delete Section 1776.4(a).

- **(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..."**

Comment: This paragraph conflicts with Section 1776.4(k).

Recommendation: Delete Section 1776.4(c) and retain Section 1776.4(k) which follows the DEA Final Rule.

- **(i)(2) "Medical sharps and needles...shall not be deposited"**

Comment: At a minimum, unused medication which is packaged in combination with a sharp and which is still in its original puncture-proof packaging should be allowed to be disposed in collection receptacles maintained under this regulation.

Recommendation: Either remove this line completely, or at a minimum insert new paragraph immediately following Section 1776.4(i)(2) as follows: For the purposes of this Article 9.1, "medical sharps and needles" do not include preloaded self-injection devices that are unused and in their original packaging.

Section 1776.5 Reverse Distributors

- **(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."**

Comment: It is not possible to create all of the information in subsection (e) both at the time of receipt and at the time of destruction. For example, it is not possible to provide the name and signature of the two employees of the registrant that witnessed the destruction at the time of receipt as the destruction has not yet occurred.

Recommendation: Modify subsections (e) and (f) to render them internally consistent.

We remain very appreciative of the time and effort that CABOP staff have spent to bring these regulations forward, and of staff's willingness to consider the viewpoints of all stakeholders. If you have questions about our comments or need additional information, please do not hesitate to contact Maggie Johnson of my staff at 415-355-5006 or via email to Margaret.Johnson@sfgov.org.

Sincerely,

Jen Jackson
Toxics Reduction Program Manager
San Francisco Department of the Environment

Martinez, Lori@DCA

From: Jan Harris <jharris@sharpsinc.com>
Sent: Friday, August 19, 2016 3:33 PM
To: Martinez, Lori@DCA
Subject: RE: Notice of Modified Text - Drug Take-Back
Attachments: Sharps Compliance CA 1776 comments 081916.pdf

Hi Lori. Here are Sharps' comments. Thanks again for the opportunity to comment. Have a wonderful weekend.

Jan

Jan Harris, MPH
Sharps Compliance
713-927-9956

Jan Harris | Director, Environmental Health & Safety

Sharps Compliance, Inc.
d- 713-927-9956 | o- 800-772-5657 | f- 713-660-3596

jharris@sharpsinc.com | http://www.sharpsinc.com

From: Martinez, Lori@DCA [mailto:Lori.Martinez@dca.ca.gov]
Sent: Thursday, August 04, 2016 4:36 PM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: Notice of Modified Text - Drug Take-Back

NOTICE IS HEREBY GIVEN that the Board of Pharmacy has proposed modifications to the text of Title 16 CCR § 1776 et seq., related to Prescription Drug Take-Back Programs. Any person who wishes to comment on the proposed modifications may do so by submitting written comments beginning August 4, 2016 and ending at 5pm on August 19, 2016, to the following:

Contact Person:	Lori Martinez
Agency Name:	California State Board of Pharmacy
Address:	1625 North Market Blvd, Suite N 219 Sacramento, CA 95834
Email:	Lori.Martinez@dca.ca.gov
Fax:	(916) 574-8617

Any responses to comments directly concerning the proposed modifications to the text of the regulations will be considered and responded to in the Final Statement of Reasons. Please limit your comments to the most current modifications of the text.

All information and documents related to this and other pending regulations can be found on the Board's website: http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

Lori Martinez
Administration and Regulations Manager
California Board of Pharmacy
1625 N Market Blvd., Ste. N219
Sacramento, CA 95834
PH: 916.574.7900
FX: 916.574.8618

As a leader in healthcare waste management, Sharps Compliance strives to reduce, recycle and repurpose treated materials for a better and sustainable environment.

SHARPS
Compliance, Inc.

Pharmaceutical Waste Solutions

August 19, 2016

Lori Martinez, Staff Manager
California State Board of Pharmacy
1625North Market Blvd, Suite N 219
Sacramento, CA 95834

RE: Sharps Compliance, Inc. Comments on Board of Pharmacy Proposed Regulations Regarding Section 1776 Prescription Drug Take-Back – Second Modified Text

Dear Ms. Martinez:

Please accept the attached comments and recommended modifications to the Board's modified proposed regulations regarding prescription drug take-back programs adding to Article 9.1, Prescription Drug Take-Back Programs, to Division 17 of Title 16 of the California Code of Regulations. Sharps appreciates the Boards' continued work to provide clear guidance for both the Board and DEA rules.

Sharps Compliance, Inc. (Sharps) is a DEA-registered reverse distributor and collector with onsite destruction that has collected medications through collection boxes and a USPS-authorized mailback program since 2009, with updates to comply with the DEA Disposal of Controlled Substances rule in 2014. As a DEA-registered reverse distributor, and a DEA-registered collector for mailbacks, Sharps has collaborated with 3rd parties to provide thousands of envelopes and receptacles for the collection of controlled and non-controlled drugs from ultimate users at retail pharmacies, long-term care communities, law enforcement facilities, narcotic treatment centers, hospitals and clinics with onsite pharmacies, and the military in California and throughout the United States. Sharps has prevented over one million pounds of pharmaceuticals from contaminating our waters and potentially ending up in the wrong hands.

Sharps is available to answer any questions regarding our programs or these comments.

Thank you,

Jan Harris, MPH
Director Environmental, Health and Safety
Sharps Compliance, Inc.
jharris@sharpsinc.com
www.sharpsinc.com
713-927-9956

Sharps Compliance offers the following comments and suggested language changes of 1776.5(e) for your consideration:

Sharps Compliance, Inc. Comments on Board of Pharmacy Proposed Regulations Regarding Section 1776 Prescription Drug Take-Back – Second Modified Text August 19, 2016

1776.5 Reverse Distributors

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: ...

Comments:

In 1776.5(e), the underlined verbiage above would indicate that mailbacks are received from collectors. If by "collector", the Board is referring to a pharmacy which could be a registered collector responsible for a receptacle, or can work with a DEA-registered collector (reverse distributor) to provide mailbacks to consumers, receiving mailbacks from the pharmacy collector would be non-compliant with the DEA rule since the pharmacy, if they are handing out or selling mailbacks to consumers, cannot take them back. DEA-registered "mailback collectors" (reverse distributors), unlike "receptacle collectors" (pharmacies) must have onsite destruction.

The DEA-registered mailback collector (the reverse distributor) would instead RECEIVE mailbacks directly from consumers at the collector's registered location for destruction. They would not receive mailbacks from other collectors.

To further clarify, DEA 1317.70 (a) and (e) state, "A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter.

In addition, the DEA rule allows for mailbacks to be sold by DEA-registered mailback collectors (reverse distributor with onsite treatment) to anyone to provide to consumers, including pharmacies, long-term care facilities, hospice, and law enforcement who partners with that collector. Therefore, we would recommend leaving out "received from collectors or law enforcement", since the mailbacks may be received from ultimate users directly, skilled nursing facilities, and others, but not other collectors.

Recommended language change:

1776.5(e)
e) For each sealed liner or mail back envelope or package received pursuant to federal Title 21 CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/ or packages, including the: ...

Martinez, Lori@DCA

From: Tami Omoto-Frias <tomoto-frias@ceo.lacounty.gov>
Sent: Monday, August 22, 2016 8:26 AM
To: Martinez, Lori@DCA
Cc: Angela Ovalle
Subject: RE: Notice of Modified Text - Drug Take-Back
Attachments: County of Los Angeles Comments.docx

Good morning Ms. Martinez,
Please find the attached comments from the County of Los Angeles that reflect minor changes.
Thank you.
Tami

From: Martinez, Lori@DCA [mailto:Lori.Martinez@dca.ca.gov]
Sent: Thursday, August 04, 2016 2:36 PM
To: Martinez, Lori@DCA
Subject: Notice of Modified Text - Drug Take-Back

NOTICE IS HEREBY GIVEN that the Board of Pharmacy has proposed modifications to the text of Title 16 CCR § 1776 et seq., related to Prescription Drug Take-Back Programs. Any person who wishes to comment on the proposed modifications may do so by submitting written comments beginning August 4, 2016 and ending at 5pm on August 19, 2016, to the following:

Contact Person:	Lori Martinez
Agency Name:	California State Board of Pharmacy
Address:	1625 North Market Blvd, Suite N 219 Sacramento, CA 95834
Email:	Lori.Martinez@dca.ca.gov
Fax:	(916) 574-8617

Any responses to comments directly concerning the proposed modifications to the text of the regulations will be considered and responded to in the Final Statement of Reasons. Please limit your comments to the most current modifications of the text.

All information and documents related to this and other pending regulations can be found on the Board's website: http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

Lori Martinez
Administration and Regulations Manager
California Board of Pharmacy
1625 N Market Blvd., Ste. N219
Sacramento, CA 95834
PH: 916.574.7900

FX: 916.574.8618

Comments on California Board of Pharmacy Proposed Regulations on Pharmaceutical Take-Back Programs

The comments below are based on the July 27, 2016 Modified text

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

Section 1776.6(a) (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..."*

Section 1776.6(a) (4) *"Date each sealed liner is transferred to storage, the unique identification and size..."*

Comment: In both sections above, the word "number" should follow the word "identification".

Suggested revisions:

> **1776.6(a) (2)** *"Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size..."*
>
> **1776.6(a) (4)** *"Date each sealed liner is transferred to storage, the unique identification number and size..."*

Section 1776.6(a) (5) *"Date each sealed liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred...*

Comment: The word "liner" should follow the word "inner".

Suggested revisions:

> ***Section 1776.6(a) (5)*** *"Date each sealed liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred...*