



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

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

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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. A 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 second 15-day comment period was initiated on August 4, 2016 and ended August 19, 2016.

At the September 2016 Board Meeting, the board approved a modified text to address concerns expressed during the second 15-day comment period. A third 15-day comment period was initiated on September 29, 2016 and ended on October 14, 2016.

At this Meeting

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

**The attachment contains:**

1. Draft 1 contains the modified text as approved by the board at the September 2016 Board Meeting, labeled September 22, 2016.
2. Draft 2 is the clean version of the modified text as approved by the board at the September 2016 Board Meeting, labeled September 22, 2016 CLEAN (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 third 15-day comment period by Section number with Staff Recommendations.
4. The comments received during the third 15-day comment period.

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**Staff Recommendation:** Adopt the regulatory language as approved on September 22, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

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# **Attachment 1**

# **Prescription Drug Take-Back**

**1776-1776.6**

**Prescription Drug  
Take-Back  
Modified Text  
(As Approved at the  
September 2016  
Board Meeting)**

**Title 16. Board of Pharmacy**  
**Third Modified Text**

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

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

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

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

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

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

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

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

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

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

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

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

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

### **Section 1776.1 Pharmacies**

- (a) ~~Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.~~
- (b) (a) Pharmacies may provide take-back services to the public patients ~~as provided in sections 1776 – 1776.4~~. Retail pharmacies and hospital/clinics with onsite pharmacies may establish-maintain collection receptacles in their facilities. Pharmacies may ~~operate collection receptacles~~ offer drug take-back services as specified ~~in~~ in section 1776.4 in skilled nursing facilities licensed under ~~California~~ Health and Safety Code section 1250(c).
- (c) (b) There are multiple federal, and state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.
- (d) (c) For purposes of this article, prescription drugs means dangerous drugs as defined by ~~California~~ Business and Professions Code section 4022, which includes including controlled substances. Controlled substances may be ~~commingled~~ in collection receptacles or mail back ~~packages or envelopes~~ or packages with other dangerous drugs.
- (d) Once drugs are deposited into a collection receptacle or mail back envelopes or packages by a consumer patient, they are not to be removed, counted, sorted or otherwise individually handled-separated by pharmacy staff or others.
- ~~(d) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's prescription drug take-back collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage informing the public that medical sharps and needles (e.g., insulin syringes) are of the items prohibited from being deposited shall be placed posted on collection receptacles as referenced in section 1776.3.~~
- The collection receptacle shall contain signage that includes:
- (1) The name and phone number of the responsible pharmacy;
  - (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
  - (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.
- (f) (e) Prescription drugs that are eligible for collection ~~in~~ as part of drug take-back ~~programs operated-services maintained~~ by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a patient or patient's agent-consumer. Dangerous drugs that have not been dispensed to patients consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in as part of a pharmacy's drug take-back service programs.
- (g) As part of its drug take-back services, a Pharmacy shall not:

- (1) ~~Pharmacy staff shall not~~ Review, accept, count, sort, or otherwise individually handle any prescription drugs ~~returned from the public consumers.~~
  - (2) ~~A pharmacy shall not a~~ Accept or possess prescription drugs returned to the pharmacy ~~by from~~ skilled nursing homes facilities, residential care homes, ~~other facilities~~, health care practitioners or any other entity entities in a collection receptacle.
  - (3) ~~A pharmacy shall not d~~ Dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock ~~in a drug take-back collection receptacle.~~ Instead the pharmacy must return these items to a reverse distributor.
- (g) ~~(g)(h)~~ A pharmacy must be registered with the federal ~~Drug Enforcement Administration~~ DEA as a collector for purposes of ~~operating~~ maintaining a prescription drug take-back collection receptacle program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.
- (h) ~~(g)(i)~~ Any pharmacy that ~~operates~~ maintains a drug take-back collection receptacle program as authorized in this article shall notify the board ~~in writing on a form designated by the board~~ within 30 days of establishing the collection program. Additionally:
- (1) Any pharmacy that ceases to ~~operate~~ maintain a drug take-back collection receptacle program shall notify the board in writing within 30 days ~~on a form designated by the board.~~ If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days.
  - (2) Any pharmacy operating a mail-back program or maintaining a collection receptacles shall disclose identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
  - (3) Any tampering with a storage collection receptacle or theft of deposited drugs shall be reported to the board in writing within 14 days.
  - (4) Any tampering, damage or theft of a removed liner shall be reported to the board in writing within 14 days.
- (i) ~~(h)(i)~~ If the pharmacy later ceases to ~~operate~~ maintain the a registered collection receptacle, the pharmacy must notify the ~~DEA Drug Enforcement Administration~~ within 30 days.
- (j) ~~(k)~~ A pharmacy shall not provide take-back services to consumers, ~~as provided in sections 1776 – 1776.4, if, in the professional judgment of the pharmacist in charge, the pharmacy cannot comply with the provisions of this article or the~~ DEA Drug Enforcement Administration rules.
- (k) ~~(l)~~ A pharmacy shall not provide take-back services to consumers, ~~as provided in sections 1776 – 1776.4~~ if the pharmacy or the pharmacist ~~in charge~~ is on probation with the B board, and, if the pharmacy had previously provided take-back services, the pharmacist ~~in charge~~ shall notify the B board and the DEA Drug Enforcement Administration as required in subsections (h) and (i), above.

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

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

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

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

- (a) Pharmacies that provide prescription drug take-back services may do so by ~~establishing providing~~ mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages ~~s containers~~ to allow a consumer to ~~for~~ returning prescription drugs to an authorized ~~DEA Drug Enforcement Administration~~ destruction location.
- (b) All envelopes and packages must be preaddressed to a location registered with the ~~DEA Drug Enforcement Administration~~ as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed ~~to be delivered for delivery~~ to facilities that comply with this section.
- ~~(c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.~~
- ~~(d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users that indicate the process to mail back drugs.~~
- ~~(e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.~~
- ~~(f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.~~
- ~~(g) (e) Once filled with unwanted prescription drugs, the A pharmacy shall not accept any mail back packages or envelopes that contain drugs unless they are registered as a collector and have an onsite method of destruction that complies with the DEA requirements. Instead, C consumers shall be directed to mail the envelopes or packages or deposit them into a pharmaceutical take-back receptacle, shall be mailed and not accepted by the pharmacy for return, processing or holding.~~

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

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

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

**1776.3 Collection Receptacles in Pharmacies**

- (a) ~~A pharmacy Pharmacies~~ may that provide prescription drug take-back services to the public may do so by ~~establishing~~ maintain a collection receptacle ~~in the pharmacy~~ whereby for the public to may deposit their unwanted prescription drugs for destruction. ~~The~~

- ~~pharmacy is responsible for the management and maintenance of the receptacle.~~ The receptacle shall be ~~securely locked and~~ substantially constructed, with a permanent outer container and a removable inner liner. ~~The collection receptacle shall be locked at all times to prevent access to the inner liner.~~ ~~In~~ During hours when the pharmacy is closed, the ~~collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block the public patients from access to the collection receptacle by some means.~~
- (b) ~~A~~ The pharmacy operating ~~maintaining the a~~ collection receptacle must securely ~~install~~ ~~fasten~~ the receptacle ~~to a permanent structure~~ so it cannot be ~~moved or~~ removed. The receptacle shall be installed in an inside location ~~within the pharmacy premise, where,~~ ~~Except as provided in subsection (c),~~ the receptacle is visible to pharmacy ~~or DEA~~ ~~registrant~~ employees, but not located in ~~or near~~ emergency areas, ~~nor behind the pharmacy's counter.~~
- (c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by ~~pharmacy or DEA registrant~~ employees and not in the proximity of ~~any~~ emergency or urgent care areas. ~~When no pharmacy or DEA registrant employees are present, the supervising responsible pharmacy is closed,~~ the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. ~~When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from public patient access by some means.~~
- (d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, ~~but does not allow for an individual to reach into the receptacle's contents.~~ ~~During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit~~ ~~opening slot~~ ~~on the collection receptacle.~~
- (e) ~~The pharmacy is responsible for the management and maintenance of the receptacle. A pharmacy shall direct consumers to directly deposit drugs into the collection receptacle. A Pharmacy staff shall not accept, count, sort or otherwise handle prescription drugs returned from the public consumers, but instead direct the public to deposit the drugs into the collection receptacle themselves.~~
- (f) A liner as used in this article shall be made of material that is certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
- (1) The liner shall ~~be~~ waterproof, tamper evident and tear resistant.
- (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.
- (g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, ~~or~~ ~~counted,~~ ~~sorted~~

- or otherwise individually handled.
- (h) If the liner is not already itself rigid or already inside of a rigid container when as it is removed from the collection receptacle, the liner must be immediately, without interruption, placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed and be kept clean and in good repair.~~
- (i) The liner may be removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner, these pharmacy employees who shall be immediately, without interruption, sealed and the pharmacy employees shall record seal the liner and record, in a written log, their participation in the removal of each liner from a collection receptacle. ~~If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container.~~ Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.
- (j) Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than three 14 days.
- (k) The pharmacy shall make and keep the records specified in 1776.6, maintain a written log to record information about all liners that have been placed into or removed from a collection receptacle. ~~The log shall contain:~~
- ~~(1) The unique identification numbers of all unused liners in possession of the pharmacy,~~
  - ~~(2) The unique identification number and dates a liner is placed in the collection receptacle,~~
  - ~~(3) The date the liner is removed from the collection receptacle,~~
  - ~~(4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and~~
  - ~~(5) The date the liner was provided to a licensed DEA registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.~~
- (l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.
- (m) ~~The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not permissible to deposit any Schedule I drugs into the collection receptacle. Labeling The signage shall also identify informing the public that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall~~

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

The collection receptacle shall contain signage that includes:

- (1) The name and phone number of the responsible pharmacy;
- (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
- (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

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

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

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

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

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

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

- (a) ~~(a) Skilled nursing facility personnel employees or person lawfully entitled to dispose of the resident decedent's property~~ may dispose of ~~a current resident's~~ unwanted or unused prescription drugs by using mail back ~~packages or envelopes and or packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. The pharmacy may allow skilled nursing facility employees to distribute mail back envelopes or packages to consumers. The pharmacy shall require~~ Records shall be kept by the skilled nursing facility employees to keep records noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.
- (b) ~~(b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a collection receptacle in a skilled nursing facility shall:~~
- ~~(1) Any pharmacy and hospital/clinic with an onsite pharmacy operating maintaining collection receptacles in skilled nursing facilities shall b-Be~~ registered and maintain registration with the DEA as a collectors.
  - ~~(2) Any pharmacy or hospital/clinic with an onsite pharmacy that operates maintains a collection receptacle at a skilled nursing facility shall n-Notify~~ the board in writing within 30 days of establishing a collection receptacle ~~on a form designated by the board.~~
  - ~~(3) Any pharmacy or hospital/clinic with an onsite pharmacy Notify the board in writing within 30 days when they that ceases to operate maintain a-the~~ collection site receptacle ~~at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.~~
  - (4) Notify the board in writing within 14 days of any tampering of the collection receptacle or theft of deposited drugs.

- (5) Notify the board in writing within 14 days of any tampering, damage or theft of a removed liner.
- (6) ~~Any pharmacy operating a collection receptacle site at a skilled nursing facility shall~~ list all collection receptacles it ~~operates~~ maintains annually at the time of renewal of the pharmacy license.
- ~~(c) (e) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.~~
- ~~(d) Every pharmacy and hospital/clinic pharmacy that operates maintains a collection site receptacle at any skilled nursing facility shall notify the board within 14 days of any loss or theft from the collection receptacle or secured storage location for the storage of removed liners.~~
- (e) (d) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (f) (e) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) (f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be ~~moved or~~ removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.
- (h) (g) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.
- (1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be ~~viewed,~~ removed, sorted, counted, or otherwise individually handled-counted.
- (2) If the liner is not already itself rigid or already inside of a rigid container as when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.~~
- (i) (h) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
- (1) The liner shall be waterproof, tamper evident and tear resistant.
- (2) The liner shall be opaque to prevent viewing ~~or~~ and discourage removal of any

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

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

~~The collection receptacle shall contain signage that includes:~~

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

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

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

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

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

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

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

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

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

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

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

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

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

**1776.5 Reverse Distributors**

- (a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA as a collector may accept the sealed inner liners of collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's authorized collection location. Once received, the reverse distributor shall establish records required by this section.
- (b) A licensed reverse distributor may not open, or survey, or otherwise analyze ~~count,~~ inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated ~~destroyed~~ by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.
- (c) If a reverse distributor picks up the sealed inner liners from the collector's authorized location, at least T two employees of the reverse distributor shall be present, pick up or accept the receipt of inner liners from DEA registrants. If the sealed inner liners are delivered to the reverse distributor via common or contract carrier, at least one employee of the reverse distributor shall accept the receipt of the inner liners at the reverse distributor's registered location.
- (d) A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.
- ~~(e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.~~
- ~~(f)~~(e) For each sealed liner or mail back envelopes or packages received ~~from collectors or law enforcement~~ pursuant to federal Title 21 CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes ~~or~~ packages, including the:
  - (1) Date of acquisition;
  - (2) Number and the size (e.g., five 10-gallon liners; etc.);
  - (3) Inventory-Unique Identification number of each liner or envelope/package;
  - (4) The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner;
  - (5) The date, place and method of destruction;
  - (6) Number of packages and inner liners received;
  - (7) Number of packages and inner liners destroyed;
  - (8) The number-name and signature of the two employees of the registrant that witnessed the destruction.
- (f) For liners only, the information specified in subsection (e)(1)-(8) above shall be created at the time of receipt and at the time of destruction.

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(2) Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., five-5 gallon, 10- gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.~~

~~(3) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each- the removal and sealing.~~

~~(4) Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5- gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.~~

~~(5) Date each sealed inner liner is transferred for destruction, the address and registration~~

number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique Identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading) and the signature of the driver.

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

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

**Prescription Drug  
Take-Back  
Modified Text  
(Clean Version)  
(As Approved at the  
September 2016  
Board Meeting)**

**Title 16. Board of Pharmacy**  
**Third Modified Text (CLEAN)**

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

**Article 9.1. Prescription Drug Take-Back Services**

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

**Section 1776 Prescription Drug Take-Back Services: Authorization**

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

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

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

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

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

**Section 1776.1 Pharmacies**

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

- (e) The collection receptacle shall contain signage that includes:
  - (1) The name and phone number of the responsible pharmacy;
  - (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
  - (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.
- (f) Prescription drugs that are eligible for collection as part of drug take-back services maintained by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected as part of a pharmacy's drug take-back service.
- (g) As part of its drug take-back services, a Pharmacy shall not:
  - (1) Review, accept, count, sort, or otherwise individually handle any prescription drugs from consumers.
  - (2) Accept or possess prescription drugs 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 no pharmacy or DEA registrant employees are present, the collection receptacle shall be locked so that

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

- (1) The name and phone number of the responsible pharmacy;
- (2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
- (3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

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

Reference: Section 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.60, 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 shall require skilled nursing facility employees to keep records noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.
- (b) Only pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a collection receptacle in a skilled nursing facility shall:
  - (1) Be registered and maintain registration with the DEA as a collector.
  - (2) Notify the board in writing within 30 days of establishing a collection receptacle.
  - (3) Notify the board in writing within 30 days when they cease to maintain the collection receptacle.
  - (4) Notify the board in writing within 14 days of any tampering of the collection receptacle or theft of deposited drugs.
  - (5) Notify the board in writing within 14 days of any tampering, damage or theft of a removed liner.
  - (6) List all collection receptacles it maintains annually at the time of renewal of the pharmacy license.
- (d) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (e) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.
- (g) The receptacle shall be securely locked and substantially constructed, with a permanent

outer container and a removable inner liner.

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

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

Reference: Sections 4005, Business and Professions Code and Sections 1304.22, 1317.05,

1317.40, 1317.60, 1317.75, 1317.80, and 1317.95, Title 21 Code of Federal Regulations

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

**1776.5 Reverse Distributors**

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

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

Reference: Sections 4005, Business and Professions Code and Section 1301.71, 1304.21, 1304.22, 1317.15, 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 number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
  - (3) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing.
  - (4) Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
  - (5) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique Identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading).

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

# **Prescription Drug Take-Back**

**Third 15-day Comment  
Compilation w/ Recommendations**

**Comment Period Closed**

**October 14, 2016**

Code Section	Commenter	Comment	Staff Recommendations
1776.1(e)	SF Dept of Environment	Commenter expressed concern that unused self-injector devices are not allowed in collection receptacle. She indicated this conflicts with H&S code (118275(h)) and is not prohibited by the DEA. Commenter asked if a third take-back bin would be needed for these items to be accepted.	Reject comment as outside scope. However, while HS 118275(h) does permit commingling, B&P section 4146 specifies that a pharmacy may accept the return on needles and syringes from the public if contained in a sharps container, as defined is Health and Safety Code section 117750. Allowing for sharps to be deposited into a drug take-back receptacle would be in conflict with a CA statute.
1776.1(e)	LA County Legislative Affairs	Commenter expressed concern about sharps and needles not being accepted into drug take-back receptacles and the confusion consumers may have about how to dispose of these items. They indicated the exclusion is inconsistent with DEA, CA H&S, and Federal DOT regulations. They recommend that the Board allow "Unused" preloaded self injector devices to be deposited.	Reject comment as outside scope. However, while HS 118275(h) does permit commingling, B&P section 4146 specifies that a pharmacy may accept the return on needles and syringes from the public if contained in a sharps container, as defined is Health and Safety Code section 117750. Allowing for sharps to be deposited into a drug take-back receptacle would be in conflict with a CA statute.

Code Section	Commenter	Comment	Staff Recommendations
1776.1(k)	LA County Legislative Affairs	Commenter expressed concern that a pharmacist could decide not to host a bin and not have to provide any justification besides their professional judgement. They recommend that this section be removed.	Reject comment as outside scope. However, a pharmacist would need to have specific reasons to refuse to have a receptacle. They cannot simply state their "professional judgement"
1776.1(k)	SF Dept of Environment	Commenter indicated that is provision is not necessary and should be removed.	Reject comment as outside scope. However, a pharmacist would need to have specific reasons to refuse to have a receptacle. They cannot simply state their "professional judgement"
1776.1(k)	CA Product Stewardship	Commenter expressed concern about the ability for a pharmacist to use their professional judgement without having concrete requirements because it will be used to "usurps local governments" ability to enforce ordinances. They indicated if this language is retained "professional judgement" should be defined.	Reject comment as outside scope. However, a pharmacist would need to have specific reasons to refuse to have a receptacle. They cannot simply state their "professional judgement"
1776.1(l)	City of Santa Rose Water District	Commenter recommended that the language to be changed to: "A pharmacy shall not <u>host a pharmaceutical take-back receptacle</u> , if . . ." to allow the pharmacy to still distribute mail-back envelopes. While they understand that pharmacies on probation should not have a collectin receptacle, they do not understand why distributing mail-back envelopes in not permitted.	Reject comment as outside scope. However, if a pharmacy is on probation, they should not be involved in drug take-back.

Code Section	Commenter	Comment	Staff Recommendations
1776.2(b)	Sharps	Commenter expressed concern that the requirement for the preaddressed collector to have an onsite method of destruction is missing from this section and could cause confusion to those not familiar with the DEA requirements. They recommended that it be added back in.	Reject comment as outside scope. However, 21 CFR 1317.70(c)(3) does not specify "onsite method of destruction" as they can be mailed to a registered law enforcement location as well.
1776.2(b), (c), & (d)	Dr. Robert Stein, KGI	Dr. Stein recommended that this section be reorganized for clarity. He recommended that the prepaid postage requirement be moved from (c) to the end of (b). Then move the remaining portion of (c) to (d) and move the existing (d) to (c).	Reject comment as outside scope. Additionally, Board staff does not believe the change is necessary to improve clarity.
1776.3(b)	SF Dept of Environment	Commenter indicated that the emergency area provision is confusing in this section since it only applies to hospitals and clinics.	Reject comment as outside scope. However, this comment was previously submitted and rejected.
1776.3(b)	City of Santa Rosa Water District	Commenter expressed concern about the use of the term "near" in a pharmacy as it applies to an emergency door. They indicated that while the DEA uses the term "near" for a hospital and clinic, it shouldn't apply to a pharmacy.	Reject comment as outside scope. However, this comment was previously submitted and rejected.
1776.3(d)	SF Dept of Environment	Commenter expressed concern about the requirement to lock the collection receptacle when the pharmacy is closed as it is not consistent with DEA.	Reject comment as outside scope. However, this comment was previously submitted and rejected.
1776.3(h)	LA County Legislative Affairs	Commenter expressed concern about the requirement of a tight-fitting cover as it could exclude cardboard containers that are being used, have been tested, and approved to meet DOT standards.	Reject comment as outside scope. However, this comment was previously submitted and rejected.

Code Section	Commenter	Comment	Staff Recommendations
1776.1(m)	SF Dept of Environment	Commenter expressed concern that unused self-injector devices are not allowed in collection receptacle. She indicated this conflicts with H&S code (118275(h)) and is not prohibited by the DEA. Commenter asked if a third take-back bin would be needed for these items to be accepted.	Reject comment as outside scope. However, while HS 118275(h) does permit commingling, B&P section 4146 specifies that a pharmacy may accept the return on needles and syringes from the public if contained in a sharps container, as defined is Health and Safety Code section 117750. Allowing for sharps to be deposited into a drug take-back receptacle would be in conflict with a CA statute.
1776.3(m)	LA County Legislative Affairs	Commenter expressed concern about sharps and needles not being accepted into drug take-back receptacles and the confusion consumers may have about how to dispose of these items. They indicated the exclusion is inconsistent with DEA, CA H&S, and Federal DOT regulations. They recommend that the Board allow "Unused" preloaded self injector devices to be deposited.	Reject comment as outside scope. However, while HS 118275(h) does permit commingling, B&P section 4146 specifies that a pharmacy may accept the return on needles and syringes from the public if contained in a sharps container, as defined is Health and Safety Code section 117750. Allowing for sharps to be deposited into a drug take-back receptacle would be in conflict with a CA statute.
1776.4(a)	City of Santa Rosa Water District	Commenter recommended that the following provision be removed as it is unclear why a pharmacy should have authority in a skilled nursing facility to require records be kept. If the skilled nursing facility does not have a collection receptacle, who would oversee the records?	Reject comment as outside scope; however, the record requirement would be in place should the SNF have a collection receptacle.

Code Section	Commenter	Comment	Staff Recommendations
1776.4(a) & (c)	SF Dept of Environment	Commenter indicated that the record keeping requirements should be removed as the DEA does not require it.	Reject comment. Diversion from a skilled nursing facility through mail-back programs is a substantial risk without record keeping requirements in place.
1776.4(i)(2)	SF Dept of Environment	Commenter recommended that unused preloaded self-injectors be permitted.	Reject comment as outside scope. However, while HS 118275(h) does permit commingling, B&P section 4146 specifies that a pharmacy may accept the return on needles and syringes from the public if contained in a sharps container, as defined in Health and Safety Code section 117750. Allowing for sharps to be deposited into a drug take-back receptacle would be in conflict with a CA statute.
1776.5(f)	SF Dept of Environment	Commenter indicated that it is not possible to create records both at the time of receipt and time of destruction.	Reject comment as outside scope. However, this comment was previously submitted and rejected.
Overall	SF Dept of Environment	Commenter recommended that the Board adopt the federal DEA regulations.	Reject comment. The Board's regulation mirror the DEA's regulations with a few minor differences. The minor differences do not conflict with DEA, so programs can follow the Board's regulations and be compliant with the DEA.

Code Section	Commenter	Comment	Staff Recommendations
Overall	CA Product Stewardship	Commenter recommended that the Board adopt the federal DEA regulations.	Reject comment. The Board's regulation mirror the DEA's regulations with a few minor differences. The minor differences do not conflict with DEA, so programs can follow the Board's regulations and be compliant with the DEA.
Overall	Chapman University	A group of students and faculty at Chapman University recommend that hazardous drugs be added to the list of permitted substances to be deposited into the collection receptacle. They expressed concern about the lack of disposal guidelines for ambulatory, community, and home settings.	Reject comment. Board staff believe the commenter is looking at a prior text version as the list of permitted drugs has been removed from the regulation text.
Overall	Clean Water Action Org.	<p>The commenter expressed concern with the following:</p> <ol style="list-style-type: none"> <li>1. The need for Board regulations when there are federal and local measures in place.</li> <li>2. The Board is taking to long which has allowed pharmaceutical companies to delay implementation.</li> <li>3. The regulations add confusion in trying to figure out where the DEA regulation and Board regulations differ.</li> <li>4. The regulations do not reflect a wise, thought-out consideration of the benefits of drug collection.</li> </ol> <p>They recommend the Board abandon the regulations and adopt the federal DEA regulations.</p>	Reject comment. The Board's regulation mirror the DEA's regulations with a few minor differences. The minor differences do not conflict with DEA, so programs can follow the Board's regulations and be compliant with the DEA.
Overall	San Luis Obispo	Commenter indicated that the Board does not have legal authority to promulgate these regulations. Additionally, they indicated that the regulations are unnecessary, burdensome, allow for pharmacies to opt out, and will negatively impact the environment and require a CEQA review.	Reject. These comments have previously been submitted and rejected.

# **Prescription Drug Take-Back**

## **Third 15-day Comments**

### **Comment Period Closed**

### **October 14, 2016**

**Martinez, Lori@DCA**

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**From:** Michael Phan <phan146@mail.chapman.edu>  
**Sent:** Friday, October 14, 2016 12:57 PM  
**To:** Martinez, Lori@DCA  
**Cc:** Yang, Sun; Wong, Siu Fun; Ani Haroutunyan; Esther Shin; THIEN HUYNH  
**Subject:** Title 16 CCR § 1776-1776.6 - Comment on proposed modifications  
**Attachments:** Title 16 CCR § 1776-1777.6 - CUSP Comments.pdf

Dear Ms. Martinez,

Good afternoon -- my name is Michael Phan and I am a student pharmacist from Chapman University School of Pharmacy (CUSP). I write to you on behalf of a group of students and faculty from my school, and we would like to share some of our comments on the text of Title 16 CCR § 1776-1776.6.

We are strong proponents for Medication Take-Back Programs, and would appreciate any considerations that you would have with our comments. I've attached a document with our comments to this email.

Thank you for your time!

Kind Regards,

--

Michael Phan  
APhA-ASP President  
Pharm.D. Candidate 2018  
Chapman University School of Pharmacy  
[phan146@mail.chapman.edu](mailto:phan146@mail.chapman.edu)



To the California Board of Pharmacy;

We are students and faculty from the Chapman University School of Pharmacy (CUSP), and today we write to you about the recent modifications to Title 16 CCR 1776-1776.6. We believe that the current modifications are a monumental step forward to improving the public safety concerns related to disposal of medications. With that, we also urge you to reconsider including hazardous drugs, such as oral anticancer chemotherapy, to the list of medications that are accepted through the proposed Prescription Drug Take-Back programs.

The mechanisms of action of these agents make it harmful to any organism that comes into contact with it, especially the anticancer chemotherapeutic agents. Currently, there are standardized guidelines for the safe handling and disposal of these agents in the hospital setting, as outlined in USP <800>. However, there is a lack of standard guidelines in the U.S. for the ambulatory, community, and home settings. Approximately 25% of 400 novel chemotherapy agents in development are oral agents with multiple-day dosing regimens<sup>[1]</sup>. The increased availability of oral chemotherapy drugs has shifted drug administration from a supervised to a self-managed setting. Regimens using oral chemotherapy drugs provide the convenience for self-medication at home; however, they increase the risks of cross contamination of the patient's home environment, resulting in unintended exposure to family, caregivers, and visitors. In addition, patients have a lack of access to sites for safe disposal of oral anticancer chemotherapy and its empty containers, which may contain cytotoxic residues. These issues are exacerbated by the patient and caregiver's lack of awareness that these medications are hazardous, as well as the common misconception that oral anticancer chemotherapy are less toxic than parenteral anticancer agents<sup>[2]</sup>.

If non-hazardous prescription drugs already pose an issue to the environment when improperly disposed of, the potential damage from hazardous medications is monumental. As medication experts, it is our responsibility to be proactive to protect our patients, caregivers, and the public from potential harms caused by medications. We, as part of the American Pharmacists Association – Academy of Student Pharmacists (APhA-ASP), are currently proposing through the October 2016 APhA-ASP Midyear Regional Meeting to advocate for regional and federal legislations that will enhance the compliance of relevant stakeholders in the proper disposal of hazardous oral anti-cancer chemotherapy drugs, such as encouraging the Boards of Pharmacy to mandate proper identification of hazardous drugs through prescription labeling. We hope the proposed action will serve to address the concerns expressed in the current bill relating to the safe handling of the hazardous medication through the Medication Take-Back Program.

Thank you for your consideration.

Sincerely,

Michael Phan, PharmD Candidate 2018, CUSP

Ani Haroutunyan, PharmD Candidate 2018, CUSP

Siu Fun Wong, PharmD

Thien Huynh, PharmD Candidate 2018, CUSP

Esther Shin, PharmD Candidate 2018, CUSP

Sun Yang, BPharm, MS, PhD

References:

1. Patton J. Increased use of oral chemotherapy drugs spurs increased attention to patient compliance. *J Oncol Pract* 2008;4:175-177.
2. DeCardenas R, Helfrich JS. Oral therapies and safety issues for oncology practices. *Oncology Issues* 2010;(March/April):40-42.

**Martinez, Lori@DCA**

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**From:** aventura@cleanwater.org  
**Sent:** Friday, October 14, 2016 4:55 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Board of Pharmacy Proposed Regulations on Pharmaceutical Take-Back Programs  
**Attachments:** Board of pharmacy letter3.doc

Please find attached to this email, Clean Water Actions comments on the Board of Pharmacy's Third Modified Text.

\*\*\*\*\*

Andria Ventura  
Toxics Program Manager  
Clean Water Action/Clean Water Fund  
350 Frank H. Ogawa Plaza, Suite 200  
Oakland, CA 94612  
415-369-9166  
[www.cleanwateraction/ca.org](http://www.cleanwateraction/ca.org)  
*Visit us on Facebook at <https://www.facebook.com/CleanWaterActionCA/>*

October 14, 2016

Ms. Lori Martinez  
California State Board of Pharmacy  
1625 North Market Blvd, Suite N 219  
Sacramento, CA 95834  
*Submitted via email: [Lori.Martinez@dca.ca.gov](mailto:Lori.Martinez@dca.ca.gov)*

*Re: Proposed Article 9.1., Section 1776 - Prescription Drug Take-Back Programs*

Dear Ms. Martinez and Members of the Board of Pharmacy:

I am writing on behalf of Clean Water Action and its 50,000 members in California regarding the most recent modified text of the Board of Pharmacy's proposed regulations on pharmacy drug take-back programs. These comments are a follow-up to previous letters dated November 23, 2015 and May 16, 2016.

As we have indicated in the past, our members overwhelmingly support an extended producer responsibility (EPR) model that requires manufacturers of household medications to fund and implement collection programs of unused drugs, and surveys have shown that the most accessible sites for take-back bins are local pharmacies. Such programs in California, Mexico, and other nations, have proven to be safe, secure, and effective in keeping tons of pharmaceuticals out of the hands of those who may unintentionally misuse them and out of the aquatic environment.

The local ERP ordinances that have been passed by publicly elected officials with the support of their constituents all take the issue of safety seriously. For that reason, they require take-back programs for both prescription and over the counter drugs to comply with all Federal Drug Administration regulations and safety measures. While the Board of Pharmacy is not seeking to preempt these local ordinances, and has made some positive changes to their original proposed regulations, we continue to question why the Board feels obligated to promulgate regulations when both federal and local law require measures to ensure the programs are secure. Our members are frustrated by the Board's actions because:

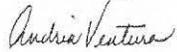
1. They have allowed pharmaceutical producers to delay progress on program implementation and passage of new ordinances by claiming that these unnecessary rules are still being developed. The industry, despite its many billions of dollars of profit each year, benefits from these delays, while the public continues to seek ways to dispose of unused medications in ways that are both safe and environmentally responsible.

2. They create added bureaucracy and confusion for pharmacies and other entities that wish to offer a public service by hosting collection receptacles as they struggle to understand what if anything the Board is requiring that federal regulations do not.
3. They seem to reflect an alarmist attitude by the Board, instead of a wise, thought-out consideration of the benefits of drug collection.

We wonder why the additional material accompanying this iteration of the proposed regulations includes stories of inappropriate behavior by a handful of law enforcement entities, and not on the successes and general lack of problems associated with drug collection. Our members agree with the Board that the security of drug takeback programs is paramount. However, they also see disposing medications in the trash or down the drain or stockpiling them because of a lack of proper disposal options as a greater threat to public safety, compliance with the law, and environmental quality.

For these reasons, we respectfully urge the Board to simply adopt a resolution confirming the necessity of complying with all federal regulations related to consumer drug collection and allow our communities to move forward with offering convenient disposal options to their residents.

Sincerely,



Andria Ventura

Toxics Program Manager

**Martinez, Lori@DCA**

---

**From:** Christopher Lester <chris@calpsc.org>  
**Sent:** Friday, October 14, 2016 5:06 PM  
**To:** Martinez, Lori@DCA  
**Cc:** Heidi Sanborn  
**Subject:** CPSC comments to the Board of Pharmacy's 3rd 15 day comment period on draft pharmacy take back regulations  
**Attachments:** image001.jpg; image002.jpg; image003.jpg; image004.jpg; image005.png; image006.png; CPSC BOP Letter 15 day comment period #3 10-14-2016 FINAL.pdf

Dear Ms. Martinez,

On behalf of the California Product Stewardship Council, I am submitting the attached written comments in regards to the California Board of Pharmacy' proposed regulations on Prescription Take Back Services as updated on September 22, 2016 and released for comment.

Thanks

**Chris Lester | Associate**



O: (916) 706-3420 | C: (530) 574-4683

[Chris@CalPSC.org](mailto:Chris@CalPSC.org)





October 14<sup>th</sup>, 2016

Dr. Amy Guterrez, President  
California Board of Pharmacy  
1625 N Market Blvd., N219  
Sacramento, CA 95834

**RE: Proposed Regulations for Prescription Drug Take-Back Programs**

Dear Dr. Guterrez and Members of the Board of Pharmacy:

The California Product Stewardship Council (CPSC) appreciates the opportunity to comment on the California Board of Pharmacy's (BoP) proposed Prescription Drug Take Back Regulations. On behalf of CPSC, we are providing comments on the September 22, 2016 draft of the regulations.

**1776.1 Pharmacies**

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.”*

**Comment:** Including this section allowing pharmacists to refuse to host a bin without any concrete requirements beyond the ill-defined “professional judgement” language is troublesome and will present a serious obstacle to recruiting pharmacies to host collection receptacles. Our experience with recruiting chain store pharmacies to participate in take-back programs is that not one pharmacist-in-charge at a chain store could make an independent decision without approval from their regional manager or other superior. This concern is increasingly problematic as we see more and more independent pharmacies being bought out by their chain competitors, leaving few options for placing bins.

Furthermore, this language usurps local government's ability to exercise their legitimate powers of local control and pass ordinances requiring that pharmacies provide take back services in instances where they cannot secure voluntary participation. Jurisdictions including the San Luis Obispo County Integrated Waste Management Authority and the County of Santa Cruz have existing ordinances that require participation of pharmacies and the regulations as proposed directly undermine the language and stated purpose of such legislation without specific requirements for why a pharmacist may refuse to participate. This conflict is sure to present legal challenges that will further delay the implementation of critically needed pharmacy take back programs.

**We suggest removing the language in 1776.1(k) entirely. Since the BoP appears determined to give the pharmacist some ability to refuse to host a bin, we suggest a compromise where clear, established criteria and/or a definition of “professional judgement” be provided, along with a requirement for verification that will help diffuse the potential for litigation.**

Apart from the one substantive change we propose above, we would like to reiterate our concern expressed both at public hearings and in previous comment letters that these proposed regulations in many cases go beyond the rules developed by the DEA and provide additional cumbersome requirements that not only impede our ability to recruit pharmacies to take back medicines, but present the real possibility for protracted litigation that will significantly delay the ability to place bins or require additional costs as CPSC and others have to revisit established programs to meet additional requirements imposed by the Board of Pharmacy regulations. In short, we recommend the **BoP not go beyond the Federal requirements** so that the public can benefit from the new opportunities for convenient and safe disposal of unwanted medicines in an expeditious manner. We strongly encourage the Board to adopt the text of the DEA Final Rule “as-is,” and without further elaboration. Fully harmonized rules will reduce confusion in the regulated community and reassure pharmacies that they are meeting both State and Federal requirements.

Sincerely,

A handwritten signature in cursive script that reads "Heidi Sanborn".

Heidi Sanborn, Executive Director

## Martinez, Lori@DCA

---

**From:** Tami Omoto-Frias <tomoto-frias@ceo.lacounty.gov>  
**Sent:** Friday, October 14, 2016 1:09 PM  
**To:** Martinez, Lori@DCA  
**Subject:** FW: Notice of Third Modified Text  
**Attachments:** Availability of Added Documents.pdf; Third Modified text (Board Approved) 9.22.2016.pdf; Third Notice of Modified Text.pdf; Board of Pharmacy Comments 10\_11\_2016.docx

Hi Ms. Martinez,  
Attached for your consideration are the comments from the County of Los Angeles.  
We appreciate the opportunity to weigh-in.  
Please let me know if you have any questions.  
Thanks.  
Tami

---

Tami Omoto-Frias  
County of Los Angeles  
Chief Executive Office  
Legislative Affairs and Intergovernmental Relations  
213/974-1192  
[tomoto-frias@ceo.lacounty.gov](mailto:tomoto-frias@ceo.lacounty.gov)  
Please consider the environment before printing this e-mail.

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**From:** Martinez, Lori@DCA [mailto:Lori.Martinez@dca.ca.gov]  
**Sent:** Thursday, September 29, 2016 2:01 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Notice of Third Modified Text

NOTICE IS HEREBY GIVEN that the Board of Pharmacy has proposed additional modifications to the text of Title 16 CCR § 1776-1776.6, related to Prescription Drug Take-Back Programs. Additionally, notice is hereby given that the Board of Pharmacy has added documents to the rulemaking record. Any person who wishes to comment on the proposed additional modifications to the text or the documents added to the record may do so by submitting written comments beginning September 29, 2016 and ending at 5pm on October 14, 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](mailto:Lori.Martinez@dca.ca.gov)  
Fax: (916) 574-8617

Any responses to comments directly concerning the proposed modifications to the text or added documents will be considered and responded to in the Final Statement of Reasons. *Please limit your comments to the 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](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

September 6, 2016

Ms. Lori Martinez  
California State Board of Pharmacy  
1625 North Market Blvd, Suite N219  
Sacramento, CA 95834

**COMMENTS ON BOARD OF PHARMACY PROPOSED REGULATIONS FOR  
PRESCRIPTION DRUG TAKE-BACK PROGRAMS DATED SEPTEMBER 22, 2016**

Dear Ms. Martinez:

Thank you for the opportunity to comment on the proposed Third Modified Text (Board Approved September 22, 2016) prescription drug take-back regulations being considered by the California Board of Pharmacy. We recommend the following changes to the proposed regulations.

1776.1 (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."*

**Comment:** Under Section 1776.1 subsection (e) sharps and needles are prohibited from being disposed in the collection receptacles. We believe this is an overreach of DEA Final Rule, and would be inconsistent with California Health and Safety Code and the Federal Department of Transportation Regulations. We have concerns about consumers not understanding how to dispose of items such as epipens that may be unused and in their original packaging. Therefore, we would like the BOP to allow disposal of unused preloaded self-injector devices still in their original packaging to be allowed to be disposed in pharmacy collection bins. This comment also impacts section 1776.3 subsection (m) that discusses the signage for the collection receptacle and the prohibition of sharps such as epi pens.

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."*

**Comment:** We have concern that a pharmacist could "decide" not to host a bin and provide no justification besides simply their "professional judgement". This could pose

serious challenges and may cause litigation for jurisdictions such as Santa Cruz who have ordinances and require participation by pharmacies. We strongly recommend this entire provision be removed from these regulations.

1776.3 (h) *“If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately, without interruption, placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair. All rigid containers must meet standards of the United States Department of Transportation”*

**Comment:** We have concerns about the possible exclusion of cardboard containers from the rule due to “tight-fitting covers”. We are aware companies such as Sharps Compliance, have had the liners they use tested and approved for medical waste by the Department of Transportation. Their liners have been tested with plastic bags inside the cardboard outer box and are tight-fitting while meeting all DOT specifications for medical waste. Therefore, we recommend the board remove the language regarding rigid containers needing a tight fitting cover.

## Martinez, Lori@DCA

---

**From:** Robert Stein <Robert\_Stein@kgi.edu>  
**Sent:** Thursday, September 29, 2016 2:45 PM  
**To:** Martinez, Lori@DCA  
**Subject:** RE: Notice of Third Modified Text

Hi Lori,

My one comment is non-substantive, but helps with clarity and flow.

In proposed 16 CCR 1776.2(b), (c) and (d) move the sentence regarding prepaid postage from 1776.2(c) to the end of 1776.2(b). This makes the subsection (c) describe the physical attributes of the envelope, while subsection (b) describes the addressing and prepaid postage requirements.

Move subsection (d) to become subsection (c) and (c) becomes (d). This results in the labeling, postage and end user instructions requirements being adjacent, with the required physical attributes clearly standing alone.

Best,  
Bob.

**Robert L. Stein**, Pharm.D., J.D.  
*Professor of Practice for Pharmacy Law & Ethics*



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[website](#) | [vCard](#) | [map](#) | [email](#)



This email may contain confidential and/or private information. If you received this email in error please delete and notify sender.

“The future isn’t what it used to be.” – Y. Berra

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**From:** Martinez, Lori@DCA [mailto:Lori.Martinez@dca.ca.gov]  
**Sent:** Thursday, September 29, 2016 2:01 PM  
**To:** Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>  
**Subject:** Notice of Third Modified Text

NOTICE IS HEREBY GIVEN that the Board of Pharmacy has proposed additional modifications to the text of Title 16 CCR § 1776-1776.6, related to Prescription Drug Take-Back Programs. Additionally, notice is hereby given that the Board of Pharmacy has added documents to the rulemaking record. Any person who wishes to comment on the proposed additional modifications to the text or the documents added to the record may do so by submitting written comments beginning September 29, 2016 and ending at 5pm on October 14, 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](mailto:Lori.Martinez@dca.ca.gov)  
Fax: (916) 574-8617

Any responses to comments directly concerning the proposed modifications to the text or added documents will be considered and responded to in the Final Statement of Reasons. *Please limit your comments to the 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](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

## Martinez, Lori@DCA

---

**From:** Herold, Virginia@DCA  
**Sent:** Tuesday, October 04, 2016 4:19 AM  
**To:** Jackson, Jen (ENV)  
**Cc:** Dabney, Alison (CDPH-DDWEM); Johnson, Margaret (ENV); Leung, Eileen (ENV); Heidi Sanborn; Martinez, Lori@DCA  
**Subject:** RE: Comments on Drug Take Back Regulations

Hi Jen,

Thanks for your comment. Because we are in a 15-day notice period, we will treat this as a written comment regarding the regulation.

The board will see your comment at the end of the month during our board meeting and determine a course of action. I greatly appreciate your efforts in making certain the board has this information.

Thanks. I hope things are well.

Giny

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**From:** Jackson, Jen (ENV) [mailto:cynthia.jackson@sfgov.org]  
**Sent:** Thursday, September 29, 2016 6:07 PM  
**To:** Herold, Virginia@DCA  
**Cc:** Dabney, Alison (CDPH-DDWEM); Johnson, Margaret (ENV); Leung, Eileen (ENV); Heidi Sanborn  
**Subject:** FW: Comments on Drug Take Back Regulations

Hi Ginny,

I hope you're well. I understand that you received the below comment from CADPH, which was read into the record last week at the public meeting. In addition, our agency also commented that at a minimum the draft regulations should be changed to at least allow unused auto injectors to go into a take-back bin. However, I noted in the just-released third version of Board of Pharmacy's draft regs, there is no change to the language on prohibition of medical sharps. I am wondering how your regulations can be reconciled with the apparent conflict with the Health & Safety Code. Auto injectors with medicine in them can't be autoclaved and need to be treated as would other pharmaceuticals. Therefore, are you proposing that anyone wishing to properly dispose of unused epipens containing drugs would have to have a third, separate bin, even though the contents of that additional bin would go to the same place as all other collected pharmaceuticals? This will take valuable drugstore floor/counter space and will cause confusion and additional disposal costs. There is no provision in DEA regulations that prohibits the commingling and the Health & Safety Code specifically allows for it.

Thanks in advance for any clarification you can provide.

Jen

**Jen Jackson**

**Toxics Reduction & Healthy Ecosystems Programs Manager**

San Francisco Department of the Environment  
1455 Market Street, Suite 1200, San Francisco, CA 94103  
[jen.jackson@sfgov.org](mailto:jen.jackson@sfgov.org) T: (415) 355-3758 C: (415) 629-0446

Begin forwarded message:

**From:** "Dabney, Alison (CDPH-DDWEM)" <[Alison.Dabney@cdph.ca.gov](mailto:Alison.Dabney@cdph.ca.gov)>  
**Date:** September 21, 2016 at 2:28:15 PM PDT

**To:** "Martinez, Lori@DCA" <Lori.Martinez@dca.ca.gov>

**Cc:** "Jackson, Jen (ENV) (cynthia.jackson@sfgov.org)" <cynthia.jackson@sfgov.org>

**Subject:** Comments on Drug Take Back Regulations

Hello Lori,

I was reviewing your draft regulations. I noticed that §1776.1 (e) states that medical sharps and needles should not be placed in the containers. Then, a comment noted that Epipens could be placed into sharps waste containers. I would like to point out that most sharps waste collection containers for the public are treated by autoclave (250° F for 30 mins.) not incineration. Therefore, there are some unused, pre-filled syringes and Epipens that are full of medication or have residual/remaining medication that should NOT be placed into a container intended only for sharps waste.

Please add a qualifier to this section that allows these items (unused, prefilled items, i.e. Epipens) to be placed in a drug collection container. To further educate the consumer, labels can be placed on each container or kiosk instructing what items should not be placed in them.

I have found that having a clear and specific direction in regulations for this is necessary, since consumers find disposal of many items very confusing.

Sincerely,  
Alison

Alison Dabney, Chief  
Medical Waste Management Program  
California Department of Public Health  
P O Box 997377 MS 7405  
Sacramento, CA 95899-7377  
916-449-5692  
fax 916-449-5665

[www.cdph.ca.gov/certlic/medicalwaste](http://www.cdph.ca.gov/certlic/medicalwaste)

<image002.jpg>

**Martinez, Lori@DCA**

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**From:** Bill Worrell <bworrell@iwma.com>  
**Sent:** Friday, October 14, 2016 2:21 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Comments on the Drug take back regulations  
**Attachments:** SLO County IWMA Comments 10-14-16.pdf

Hi Lori,  
Attached is a letter commenting on the drug take back 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

## IWMA BOARD MEMBERS

Jeff Lee, President  
City of Grover Beach

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October 14, 2016

California Board of Pharmacy  
1625 N. Market Blvd., N219  
Sacramento, CA 95834  
Subject: Prescription Drug Take-Back

Attn: Ms. Lori Martinez

RE: Proposed Regulations (Third Modified Text Board Approved  
September 22, 2016) for Prescription Drug Take-Back Programs

Dear California Board of Pharmacy Board Members:

Thank you for the opportunity to comment on the third modified text (Board Approved September 22, 2016) proposed prescription drug take-back regulations (Proposed Regulations) being considered by the California Board of Pharmacy (BOP). During the process of reviewing these Proposed Regulations, the San Luis Obispo County Integrated Waste Management Authority (IWMA) has commented on the various drafts. With this letter the IWMA has reiterated all the previous comments that were made and still apply. The IWMA recognized that some of these comments have already been considered and rejected by the BOP at previous meetings. However, with the change in Board Membership on the BOP and the future review of comments by other agencies, the IWMA believes that it would be helpful to reiterate its previous comments that still apply to the Proposed Regulations.

IWMA agrees that "drug abuse is at epidemic levels." However, the IWMA 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.

The IWMA offers the following comments:

- I. The BOP Proposed Regulations are Unnecessary
- II. The BOP Proposed Regulations are Burdensome
- III. The BOP Proposed Regulations allows pharmacies to opt out of successful local programs
- IV. The BOP Proposed Regulations will have a negative impact on the environment and require CEQA review
- V. The BOP is exceeding its legal authority

#### **I. The BOP Proposed Regulations are Unnecessary**

The Proposed Regulations are unnecessary because of existing DEA Regulations. As stated in the BOP Initial Statement of Reasons, pharmacies must comply with DEA Regulations. On September 9, 2014, the DEA published its Final Rule for drug take-back programs (DEA Regulations). *See* 21 CFR 1300 *et. seq.* The Final Rule was the result of a 4-year process that started with the passage of the Secure and Responsible Drug Disposal Act of 2010. During the development of the DEA regulations both the BOP and CalRecycle commented on and generally supported the proposed regulations.

The BOP provided five recommendations in the form of general comments. The first comment was: "We generally support the framework for the return and destruction of controlled substances as provided for in these proposed regulations. The growing prescription drug abuse and diversion issues in the US require action and such a regulatory framework." The next 3 comments are consistent with the DEA regulations. The only comment that was not incorporated into the final DEA regulations was a requirement making drugs unusable by, "specifically to grind it up at the collection bin". The current BOP Proposed Regulations do not include a requirement to grind drugs up at collection bins.

CalRecycle also provided comments during the DEA rule making process and "generally supported the proposed rule."

The current DEA Regulations are sufficient to insure a safe and efficient drug disposal program. California had already recognized this through the California Health and Safety Code which states in Section 118275 (6) (A) that pharmaceutical wastes classified by the DEA regulations as "controlled substances" shall be disposed of in compliance with DEA requirements.

#### **II. The BOP Proposed Regulations are Burdensome**

When the DEA Regulations were prepared, many comments centered on how burdensome they were on the pharmacies. Since September of 2014, when the DEA Regulations were put in place, only one-percent (1%) of eligible pharmacies have implemented take back programs for controlled substances.

The DEA Regulations only apply to programs which take back controlled substances. As such, a significantly greater number of pharmacies have implemented take back programs for non-controlled substances. The BOP Proposed Regulations eliminates the option of a take back program for non-controlled substances and instead requires every take back program to include controlled substances.

The BOP predicts that ten-percent (10%) of the pharmacies in California will voluntarily participate in the drug take-back program with an in-store kiosk. This is based on the Alameda County and San Francisco drug take back programs. However, with the exception of a few Walgreen pharmacies, none of currently participating pharmacies take controlled substances and, thus, are not currently governed by the DEA Regulations. In addition, the pharmacies do not pay to participate in the program. If the BOP Proposed Regulations are adopted, the stricter rules and the added cost of participating means that most, if not all, pharmacies would drop out of the drug take back program.

### **III. The BOP Proposed Regulations allows pharmacies to opt out of successful local programs.**

Local communities throughout California, such as San Francisco and the Counties of Alameda, Santa Cruz, and San Luis Obispo, have implemented drug take back programs to protect the health and welfare of its citizens and the environment. These local programs were implemented to increase the number of take back locations and/or provide funding for pharmacies that participate in a take back programs. In adopting these programs, local governments included the requirement that any program be consistent with Federal and State regulations.

The Proposed Regulations Section 1776.1(k) states "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." While the IWMA recognizes there could be a situation where a take-back receptacle is not practical in a pharmacy, the IWMA believes that any pharmacy could provide mail-back envelopes to its customers. This Section will allow pharmacies to opt out of a local program.

### **IV. 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. SLO County's IWMA mandatory retail drug take program ordinance created "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.

On March 11, 2015, the IWMA Board of Directors adopted Ordinance 2015-1 establishing a mandatory retail drug take back program. At the time of the adoption of Ordinance 2015-1, no pharmacies in San Luis Obispo County had a drug take back program. Currently, every pharmacy in San Luis Obispo County (45 pharmacies) has a drug take back program. Due to Ordinance 2015-1, consumers in San Luis Obispo County now have a safe and environmentally sound means of disposing of unwanted prescription medication. Ordinance 2015-1 has reduced the quantity of prescription medication in landfills and our water supplies. These are the physical conditions that currently exist in San Luis Obispo County and what must be considered as the "baseline" in the environmental impact analysis of the proposed regulations. In addition, similarly situated jurisdictions with existing take-back ordinances or policies must also be considered.

The Proposed Regulations under Section 1776.1(k) allow pharmacies to opt out of take back services. As discussed above, if pharmacies can opt out, the participation rate by pharmacies will likely mirror the national rate of one-percent (1%). Both in San Luis Obispo County and throughout California, this will result in a significant reduction in the number of locations where the public can safely dispose of unwanted prescription medication. This will have a significant impact on the environment because, instead of being safely disposed of, the unwanted prescription medication will be flushed down toilets or end up in landfills.

In addition to the impact in San Luis Obispo County, almost every existing take back kiosk in California excludes controlled substances and thus are not required to comply with the DEA regulations. The Proposed Regulations will require these existing kiosks to also accept controlled substances. Since the Proposed Regulations which require compliance with DEA regulations, it is foreseeable that many kiosk locations will close. These closures will have a significant impact on the environment because, just as in San Luis Obispo County, 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.

## **V. The Board of Pharmacy is Exceeding Its Legal Authority**

### **A. Legal Standard.**

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.

**B. The BOP Regulations Are Not Necessary and Are Beyond the Scope of the BOP's Authority**

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

**i. 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. The DPH is already responsible for the disposal of hypodermic needs through its sharps take back program. *See* Health & Safety Code § 118286. In addition, 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.

**ii. 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)."

Regulations already exist 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.

Another example of DPH responsibility for the disposal of medical waste is the sharps take back program. Under California Health and Safety Code 118286 (management of home-generated sharps waste), the DPH is responsible for this program. In many ways, it is a parallel program to the home-generated drug drop off program.

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 been delegated to DPH, not the BOP.

The Proposed Regulations will also create a "dual" regulatory system. For example, in Alameda County there are Fire Stations, Public Works offices, senior centers and the State of California State Building in Oakland that all have pharmaceutical take-back receptacles. These receptacles would not be in compliance with the Proposed Regulations. However, since these receptacles are not at a pharmacy, they would not be subject to the Proposed Regulations instead they are in compliance with the California Department of Health Services regulations.

Significantly, the BOP also does not have the authority to regulate waste once it leaves California, or the manner in which it is disposed of by reverse distributors inside or outside of California. The Proposed Regulations include additional requirements on reverse distributors who are not located in California. Section 1776.5 Reverse Distributors attempts to place numerous requirements on reverse distributors. These reverse distributors are not located in California and, thus, would be subject to federal laws and the laws of their state. In addition, reverse distributors are neither pharmacists, pharmacies or engaged in the practice of pharmacy and thus the BOP would not have the authority to regulate them even if they were located in California.

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 Worrell

Manager

CC: Raymond Biering, IWMA Counsel

**Martinez, Lori@DCA**

---

**From:** Hare, Thomas <THare@srcity.org>  
**Sent:** Thursday, October 13, 2016 5:14 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Santa Rosa Water Comment Letter October 2016  
**Attachments:** image001.jpg; BOP\_SantaRosa\_Oct13.pdf; Santa Rosa Water BOP\_3rd\_15day\_Attachment\_Oct7b.docx

**RE: COMMENTS ON BOARD OF PHARMACY PROPOSED REGULATIONS FOR PRESCRIPTION DRUG TAKE-BACK PROGRAMS DATED SEPTEMBER 22, 2016**

Dear Ms. Martinez,

Please find attached the official comments on behalf of Santa Rosa Water Department staff.

The one page pdf Letter attachment is the cover letter for our comments, and is signed by the acting director of the Santa Rosa Water Department. The detailed comments specific to individual sections of the proposed Board of Pharmacy Regulations are to be found in the two page Word document.

Please verify receipt of these comments.

If anyone at the Board of Pharmacy has any questions about our letter or our comments, please contact me at [thare@srcity.org](mailto:thare@srcity.org) or (707) 543-3396.

Thank you,

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](mailto:THare@srcity.org)



**Attachment – City of Santa Rosa Water Department Comments on Proposed Board of Pharmacy Regulations for Prescription Drug Take-back Services dated September 22, 2016**

**Section 1776.1 Pharmacies**

1776.1 (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. . .”*

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

**Comment:** The Board in its September meeting did not discuss specifically whether a pharmacy on probation with the Board could still distribute mail-back envelopes. It is unclear to staff why it would be problematic for a pharmacy on probation to provide mail-back envelopes or packages to their customers.

The phrase “take-back services” applies to both collection receptacles and mail-back envelopes; changing the text to ‘take-back receptacle’ would allow a pharmacy on probation to still provide mail-back envelopes or packages.

**1776.3 Collection Receptacles in Pharmacies**

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 shall be visible to pharmacy or DEA registrant employees, but not located behind the pharmacy’s counter.**

**Comment:** It is unclear what “near emergency areas” would mean in the context of a pharmacy; “near” is a vague term, and could be especially problematic in small pharmacies where any potential location in the pharmacy could be deemed “near” to an emergency exit door.

While the DEA uses the term “near” in the context of hospitals/clinics, expanding the use of “near” to include pharmacies poses a larger problem. In § 1317.75 (d)(2)(i) the DEA makes it clear that subsection (i) only applies to hospitals and clinics. Additionally, as quoted below, the DEA describes their rationale for excluding the placement of receptacles in emergency areas, and that rationale does not apply to pharmacies. Staff would very much like to avoid adding an unnecessary layer of complexity to the placement of collection receptacles in pharmacies.

*§ 1317.75 (d)(2)(i) At a hospital/clinic: A collection receptacle shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided.*

*Federal Register Vol. 79, No. 174 p. 53523: "...[T]he DEA is requiring hospitals/clinics that are collectors to place collection receptacles in locations that are regularly monitored by employees... In addition, the DEA is prohibiting such collectors from placing collection receptacles in the proximity of any area where emergency or urgent care is provided. In the DEA's experience, the risk of diversion is particularly high in areas where emergency or urgent care is provided because of the often chaotic environment and the extended amounts of time persons spend in such areas."*

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#### **1776.4 Drug Take-Back Services in Skilled Nursing Facilities**

*1776.4(a) ". . . 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:** At the September Board meeting this section was significantly improved. However, staff believes that it is still problematic to leave the above sentence in place. As acknowledged by the Board, skilled nursing facilities do not need to partner with pharmacies to use mail-back envelopes and packages. It is therefore unclear what authority pharmacies have over the records skilled nursing facility employees must keep. Why would the pharmacy be the entity charged with this oversight of skilled nursing facility employees? Would this only apply to pharmacies that are maintaining a collection receptacle in a skilled nursing facility? Who would oversee this requirement in skilled nursing facilities that do not have a collection receptacle?

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

**Martinez, Lori@DCA**

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**From:** Leung, Eileen (ENV) <eileen.leung@sfgov.org>  
**Sent:** Friday, October 14, 2016 4:13 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Comments for BOP Drug Take-Back Regulations  
**Attachments:** October 14 2016 SFE comments to BOP on Drug Take-Back reg proposal.pdf

Hi Lori,

Please see attached for comments the San Francisco Department of the Environment is submitting regarding the third version of the BOP Drug Take-Back Regulations.

Thank you,

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

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Please consider the environment before printing this email.

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

October 14, 2016

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

RE: Comments on Third Modified Text, Proposed Prescription Drug Take-Back Rule (Board Approved September 22, 2016)

Dear Ms. Martinez:

The San Francisco Department of the Environment appreciates the opportunity to comment on the Board of Pharmacy's September 22, 2016 Third Modified Text, which is proposed 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. *We urge the CABOP to pass regulations as quickly as possible so there is no delay in implementing our stewardship program.* To that end, we provide the following comments:

### **1. Address Sharps Containing Medication**

CABOP's Third Modified Text is inconsistent with California Health and Safety Code and the Federal Department of Transportation with regard to medical sharps and needles. Certain medications are commonly dispensed in pre-loaded self-injection devices, such as "epi-pens." 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.

California Health & Safety Code Section 118275(h) rightly anticipated the need to address sharps containing medication and 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.

San Francisco Department of the Environment  
1455 Market Street, Suite 1200, San Francisco, CA 94103  
Telephone: (415) 355-3700 • Fax: (415) 554-6393

Email: [environment@sfgov.org](mailto:environment@sfgov.org) • [SFEnvironment.org](http://SFEnvironment.org)

Printed on 100% post-consumer recycled paper.

Comments from the California Department of Public Health submitted to CABOP on September 21, 2016, point to regulations that sharps containing medication should not be autoclaved. Therefore, approval of these draft regulations as currently written could result in pharmacies needing a completely separate disposal system for unused epi-pens containing medication. This action by CABOP could have a damaging effect on pharmacy participation in take-back programs.

We recommend that CABOP allow preloaded self-injection devices in their original packaging to be allowed in collection kiosks.

## **2. Point to DEA Rule**

As other State Boards of Pharmacy have done, we recommend that instead of developing its own regulations, that CABOP regulations should simply 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.

## **3. Change Language**

Should CABOP proceed with its own regulations, we offer the following specific language changes to the Third Modified Text to reduce confusion and remedy inconsistencies.

### Section 1776.1 Pharmacies

- (e)(1) “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, July 27, and September 22 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 is 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 opening 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 even when the store’s pharmacy area is closed, because consumers may leave unwanted medication adjacent to the bin, offering a potential diversion opportunity.

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

- (m) “Medical sharps and needles...shall not be deposited”

Comment: Unused medication, dispensed to a consumer, 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. This change will support compliance with California Department of Public Health’s directive to incinerate pharmaceuticals instead of steam sterilizing (autoclaving) treatment.

Recommendation: Insert a 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: Although we appreciate the CABOP’s deletion of the third sentence of this paragraph (“The pharmacy may allow...”) in the third modified text, we continue to believe that the CABOP is unnecessarily going beyond DEA requirements by including this paragraph (a) at all. The DEA does not authorize, require or restrict the simple distribution of mail back envelopes or packages at skilled nursing facilities or any other potential distribution points. The DEA requirements apply to receipt and destruction of mail back envelopes or packages. It is clear from the DEA rule commentary that the DEA wished to make it possible for **any**

location to distribute mail-back packages to ultimate users and it is disappointing that CABOP intends to require this one type of distribution point (skilled nursing facilities) to maintain unnecessary recordkeeping.

Recommendation: Delete Section 1776.4(a), 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: 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 exempt from the prohibition on co-disposal in collection receptacles maintained under this regulation. This exemption will promote compliance with the CA Dept of Public Health's requirement that pharmaceuticals be incinerated, not steam sterilized (autoclaved) as treatment.

Recommendation: 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 appreciate 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](mailto:Margaret.Johnson@sfgov.org).

Sincerely,



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

## Martinez, Lori@DCA

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**From:** Jan Harris <jharris@sharpsinc.com>  
**Sent:** Friday, October 14, 2016 2:06 PM  
**To:** Martinez, Lori@DCA  
**Subject:** RE: Notice of Third Modified Text  
**Attachments:** Sharps Compliance CA 1776 comments 101416.docx

Good afternoon Lori. Please find attached Sharps' comments for the Third Modified Text. We are grateful for being included in this important endeavor and appreciate the Board's hard work.

Thanks as always,

Jan Harris  
Sharps Compliance  
[www.sharpsinc.com](http://www.sharpsinc.com)  
713-927-9956

Jan Harris | Director, Environmental Health & Safety

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[jharris@sharpsinc.com](mailto:jharris@sharpsinc.com) | <http://www.sharpsinc.com>

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**From:** Martinez, Lori@DCA [mailto:Lori.Martinez@dca.ca.gov]  
**Sent:** Thursday, September 29, 2016 4:01 PM  
**To:** Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>  
**Subject:** Notice of Third Modified Text

NOTICE IS HEREBY GIVEN that the Board of Pharmacy has proposed additional modifications to the text of Title 16 CCR § 1776-1776.6, related to Prescription Drug Take-Back Programs. Additionally, notice is hereby given that the Board of Pharmacy has added documents to the rulemaking record. Any person who wishes to comment on the proposed additional modifications to the text or the documents added to the record may do so by submitting written comments beginning September 29, 2016 and ending at 5pm on October 14, 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](mailto:Lori.Martinez@dca.ca.gov)  
Fax: (916) 574-8617

Any responses to comments directly concerning the proposed modifications to the text or added documents will be considered and responded to in the Final Statement of Reasons. *Please limit your comments to the 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](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.**

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**SHARPS**  
Compliance, Inc.  
**Pharmaceutical Waste Solutions**

October 14, 2016

Lori Martinez, Staff Manager  
California State Board of Pharmacy  
1625 North 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 – Third Modified Text

Dear Ms. Martinez:

Please accept the attached comment and recommended modification 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 destroyed 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 packages; and with collectors to provide 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.

We appreciate the hard work the Board has put into 1776 to help clarify the DEA regulations and help with the removal of controls from homes and the waters and landfills of California.

Thank you,

Jan Harris, MPH  
Director Environmental, Health and Safety  
Sharps Compliance, Inc.  
[jharris@sharpsinc.com](mailto:jharris@sharpsinc.com)  
[www.sharpsinc.com](http://www.sharpsinc.com)  
713-927-9956

**Sharps Compliance, Inc.**  
9220 Kirby Drive, Suite 500  
Houston, Texas 77054  
(713) 432-0300

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

Sharps Compliance offers the following comment and suggested language change for your consideration:

**1776.2 Pharmacies Offering Mail Back Envelope or Package Services**

**Current Language:**

(b) All envelopes and packages must be preaddressed to a location registered with the DEA as a collector.

**Comments:**

The Board has proposed the removal of the continuation of the above sentence which reads: "...*that has onsite a method appropriate to destroy the prescription drugs.*" Even though the Board DID include the requirement for any pharmacy registered as a collector for envelopes/packages to have onsite treatment, the Board has eliminated the need for any other registered DEA collector of envelopes/packages to have onsite destruction. The DEA requires envelopes/packages to be addressed to the DEA envelope/package collector's registered location...and that location must have onsite treatment. In our opinion, if a 3<sup>rd</sup> party distributing the envelopes/packages is not familiar with the DEA rule, this could be confusing and lead to envelopes being distributed that are addressed to a 3<sup>rd</sup> party that does not have onsite destruction. This would also place the distributing pharmacy or other 3<sup>rd</sup> party out of compliance with the DEA rule. Envelopes/packages are, at this point, provided only by reverse distributors registered with the DEA as a mailback (envelope/package) collector. This is because, typically, the reverse distributor is the only collector that has onsite treatment as required by DEA.

**Recommended Language Change:**

In order to clarify and harmonize with the DEA, we recommend the Board change the previous language to read:

(b) All envelopes and packages must be preaddressed to a location registered with the DEA as a collector that has an onsite method of destruction that complies with the DEA requirements.