



VII. Proposed Regulations to Add Title 16 CCR sections 1776 et seq, Related to Prescription Drug Take-Back

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).

The Board received numerous comments during the comment period and at the regulation hearings.

At this Meeting

The board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the January 2016 Board meeting.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.
3. Return the regulation to the enforcement committee for further discussion.

Attachment 1 contains the proposed regulation text as noticed on February 12, 2016.

Attachment 2 contains the comments from numerous stakeholders during the 45-day comment period and at the regulation hearings for review.

Attachment 3 contains the comments from several stakeholders at the regulation hearings for review.

Attachment 4 contains a comment received from 256 citizens from the San Francisco Bay Area.

Attachment 5 contains a compilation document containing the section specific comments received during the 45-day comment period.

Attachment 6 contains an article on drug disposal kiosks in hospitals.

**Prescription Drug
Take-Back
Attachment 1
Proposed Text**

**Title 16. Board of Pharmacy
Proposed Text**

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

Article 9.1. Prescription Drug Take-Back Programs

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

Section 1776 Prescription Drug Take-Back Programs: Authorization

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prescription drug take-back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs.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

All board-licensed authorized collectors should be vigilant to prevent 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: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.

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

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

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

Section 1776.1 Pharmacies

- (a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.
- (b) Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).
- (c) There are multiple federal and state 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) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.
- (e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's 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 shall be placed on collection receptacles as referenced in section 1776.3.
- (f) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.
 - (1) Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.
 - (2) A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
 - (3) A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock in a drug take-back collection receptacle. Instead the pharmacy must return these items to a reverse distributor.
- (g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back 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) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:
 - (1) Any pharmacy that ceases to operate a drug take-back program shall notify the board 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 collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
 - (3) Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board with 14 days.
 - (4) Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.
- (i) If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.

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

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

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

1776.2 Mail Back Package and Envelope Services from Pharmacies

- (a) Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.
- (b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.
- (c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.
- (d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.
- (e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.
- (f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.

- (g) Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.

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

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

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

1776.3 Collection Receptacles in Pharmacies

- (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In 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 patients from access to the collection receptacle by some means.
- (b) The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.
- (c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from 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.
- (e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.
- (f) A liner as used in this article shall be made of material that is certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
- (1) The liner shall waterproof, tamper evident and tear resistant.
- (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a

permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.

- (g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.
- (h) If the liner is not already itself rigid or already inside of a rigid container as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed and be kept clean and in good repair.
- (i) The liner may be removed from a locked receptacle only by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated.
- (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 days.
- (k) The pharmacy shall maintain a 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 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 Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed

cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.

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

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

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

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

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

- (a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.
- (b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.
 - (1) Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.
 - (2) Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
 - (3) Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
 - (4) Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy license.
- (c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.
- (d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.

- (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be 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.
- (h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.
 - (1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be viewed, removed or counted.
 - (2) If the liner is not already itself rigid or already inside of a rigid container as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.
- (i) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
 - (1) The liner shall waterproof, tamper evident and tear resistant.
 - (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.
- (j) The collection receptacle shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (k) Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.

- (l) The installation, removal, transfer and storage of inner liners shall be performed only by:
 - (1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
 - (2) By or under the supervision of two employees of the authorized collector pharmacy.
- (m) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.
- (n) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.
- (o) Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.

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 DEA as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.
- (b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately licensed DEA distributor.
- (c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (d) A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.
- (e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.

- (f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:
- (1) Date of acquisition;
 - (2) Number and the size (e.g., five 10-gallon liners, etc.);
 - (3) Inventory number of each liner or envelope/package;
 - (4) The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner;
 - (5) The date, place and method of destruction;
 - (6) Number of packages and inner liners received;
 - (7) Number of packages and inner liners destroyed;
 - (8) The number and signature of the two employees of the registrant that witnessed the destruction.

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

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

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

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

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records.

- (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) For pharmacies using collection receptacles, for each liner:
- (1) Date each unused liner is acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
 - (2) Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10- gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
 - (3) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
 - (4) Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
 - (5) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it and the signature of the driver.
- (f) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, 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).
 - (2) For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.

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

**Prescription Drug
Take-Back
Attachment 2
45-Day Comments**

Martinez, Lori@DCA

From: Brian Warren <bwarren@cpha.com>
Sent: Thursday, March 24, 2016 3:11 PM
To: Martinez, Lori@DCA
Subject: Comments on Drug Take-Back Regulations
Attachments: CPhA Support Letter for Drug Take-Back Regulations.docx

Good afternoon Lori,

Please find the attached comments to the Board's proposed regulations relating to prescription drug take-back programs. Thank you!

Brian Warren
Vice President, Center for Advocacy

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March 24, 2016

Amy Gutierrez, Pharm.D
President, California Board of Pharmacy
625 N. Market Blvd., Suite N-219
Sacramento, CA 95835

Dear Dr. Gutierrez:

The California Pharmacists Association (CPhA) writes in **support** of proposed regulations to add Article 9.1, Sections 1776 – 1776.6, to Title 16 of the California Code of Regulations, relating to the collection of prescription drugs from consumers.

These regulations provide necessary consistency between California law and federal law so that pharmacists have a uniform set of standards to comply with when providing drug collection services to their patients. The requirements contained in the proposed regulations will protect the public health and safety by ensuring the safe and secure collection of unwanted drugs from consumers. The regulations also provide that participation in “take-back” programs is voluntary for pharmacists and pharmacies. We strongly support this provision, as it furthers the Board’s consumer protection mandate by preventing pharmacies that cannot or should not collect prescription drugs from being required to do so.

CPhA supports comprehensive programs to provide patients with convenient disposal options for unused prescription drugs. Various disposal programs have existed at times throughout the state and many pharmacies have enthusiastically played a role by voluntarily hosting collection receptacles in their buildings. When pharmacies have the space, personnel, and resources to appropriately manage a collection receptacle, we support this role. However, if a pharmacy cannot host a collection receptacle due to limitations on space or personnel, or have other unique challenges that make it difficult to host a receptacle, we believe that those pharmacies should not participate in the collection of prescription drugs.

Accordingly, some pharmacies should be *prohibited* from hosting collection receptacles, such as pharmacies on probation with the Board. The regulations already require appropriate DEA registration and prohibit pharmacies from hosting collection receptacles if their DEA registration is on suspension or if they employ persons with a criminal background. **We recommend modifications**, attached, to prohibit pharmacies from hosting collection receptacles when the pharmacy or pharmacist in charge is on probation with the Board or, in the professional judgement of the pharmacist in charge, the pharmacy cannot comply with these regulations.

Much of the criticism of provisions in the proposed regulations that make hosting collection receptacles voluntary has come from organizations advocating for local ordinances to establish

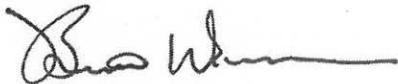
various designs of prescription drug disposal programs. These organizations say that the Board's regulations would preempt important local programs intended to benefit consumers. However, *the Board's regulations do not preempt any local program in which hosting a collection receptacle is voluntary for each individual pharmacy.* The vast majority of current and proposed local ordinances do not mandate pharmacies to host collection receptacles. Still others argue that the Board cannot, or should not, preempt a local ordinance that does mandate all pharmacies host collection receptacles. We strongly disagree with this contention.

The Board has been charged by the Legislature to protect California consumers via the licensing, regulating, and disciplining of pharmacists and pharmacies. It is the Board's responsibility to pursue regulations that it believes provide appropriate protections to consumers. Just as the Board has determined that pharmacies participating in prescription drug collection programs must follow the proposed regulations for the sake of consumer safety, this Board has the authority and responsibility to establish parameters on the decision to participate if it believes they are necessary—including ensuring that a PIC retains the ability to determine whether his or her pharmacy can adequately host a collection receptacle, as well as prohibiting some pharmacies from participating in collection programs at all.

Local ordinances that attempt to place requirements on pharmacies *related to their function as a pharmacy* go beyond attending to municipal affairs and inappropriately venture into regulating pharmacy practice. Local regulation of state-licensed professionals establishes dangerous precedent and usurps this Board's ability to effectively protect consumers. In the past, when local governments have attempted to limit or expand professionals' scopes of practice, the local ordinances have been overridden or preempted by state law. Similarly, this Board should not shy away from preempting a local ordinance that attempts to regulate pharmacists and pharmacies.

Thank you again for your leadership on this matter. If you have any questions, please do not hesitate to contact me at bwarren@cpha.com or (916) 779-4517.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian Warren", written in a cursive style.

Brian Warren
Vice President, Center for Advocacy



californiapharmacistsassociation

California Pharmacists Association Suggested Modifications to Take-Back Regulations

Section	Modification	Comment
1776.1	<p><u>(j) A pharmacy shall not provide take-back services to patients 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 Drug Enforcement Administration rules.</u></p>	<p>If a pharmacist in charge determines in their professional judgment that the pharmacy cannot comply with these regulations of the DEA rules, that pharmacy should not participate in take-back programs. Reasons a pharmacist in charge may make this determination include, but are not limited to, irregular store layout or lack of physical space that makes secure placement of collection receptacle problematic, past experience by pharmacy staff with difficulties hosting a collection receptacle, pharmacy location in a high crime area, and other problems.</p>
1776.1	<p><u>(k) A pharmacy shall not provide take-back services to patients as provided in sections 1776 - 1776.4 if the pharmacy or the pharmacist in charge is on probation with the Board, and, if the pharmacy had previously provided take-back services, the pharmacist in charge shall notify the Board and the Drug Enforcement Administration as required in subsections (h) and (i), above.</u></p>	<p>A pharmacy or pharmacist in charge on probation with the Board should not participate in take-back programs. Pharmacies and PICs are placed on probation for offenses such as diversion of controlled substance, failure to maintain secure drug inventory, and other pertinent violations of Pharmacy Law. Even if the probation is unrelated to inventory or diversion, a pharmacy or PIC on probation should focus on the essential responsibilities of operating a pharmacy and should not be involved in activities that could serve to distract pharmacy staff from that role.</p>

Martinez, Lori@DCA

From: Bill Worrell <bworrell@iwma.com>
Sent: Wednesday, March 23, 2016 10:11 AM
To: Martinez, Lori@DCA
Cc: 'Raymond A. Biering'
Subject: Prescription Drug take back regulations.
Attachments: Board of Pharmacy Letter.pdf

Hi Lori,

Attached is a letter from the San Luis Obispo County Integrated Waste Management Authority providing comments on the proposed Board of Pharmacy Prescription Drug take back Regulations. In addition, I am requesting that the letter be forwarded to all of the Board of Pharmacy Board Members.

Thank you.

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

San Luis Obispo County Integrated Waste Management Authority

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March 22, 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 for Prescription Drug Take-Back Programs

Dear California Board of Pharmacy Board Members:

Please consider the following comments regarding the proposed prescription drug take-back regulations (Proposed Regulations) being considered by the California Board of Pharmacy (BOP). The San Luis Obispo County Integrated Waste Management Authority (IWMA) agrees that "drug abuse is at epidemic levels." 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 will preempt 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. (see attachment 1).

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." For example, CalRecycle supported "streamlining, where possible, the collection, tracking and transportation process," including "not requiring mail-back programs to create and maintain a notification system." The BOP Proposed Regulations, however, creates such a system.

Both past and 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. (See attachment 2). The requirements in the BOP Proposed Regulations exceed the requirements in the DEA Regulations. Given the one-percent (1%) participation rate of pharmacies under the DEA Regulations, it is clear the BOP Proposed Regulations are overly burdensome on pharmacies and take-back programs will ultimately not be implemented.

The DEA Regulations only apply to programs which take back controlled substances. As such, some pharmacies have implemented take back programs for non-controlled substances. The

BOP Proposed Regulations, however, apply to any drug take back program regardless of whether it includes 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 in which the BOP estimates a participation rate of eight-percent (8%). However, none of these 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, many existing take back programs would be required to comply with the more stringent guidelines. 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.

Another reason that the ten-percent (10%) participation rate is unrealistic is that the BOP Proposed Regulations reduce the number of authorized locations of take-back programs. Currently in Alameda County, there are thirty (30) sites which have drug take-back kiosks. The Proposed Regulations would eliminate seventeen (17) of the current sites (see attachment 2) because they are not located at pharmacies, skilled nursing facilities or police stations. Since the national participation rate is about 1% of pharmacies under the DEA Regulations, and since BOP Proposed Regulations are more burdensome than the DEA Regulations, a ten-percent (10%) participation rate is highly improbable.

Attachment 3 is a detailed analysis of how the BOP Proposed Regulations are more burdensome than the existing DEA Regulations. If these additional requirements were resulting in a "better" program, than an argument could be made for adopting them; however, these regulations only increase the administrative and financial burden on the pharmacies and eliminate existing take back sites.

III. The BOP Proposed Regulations Will Preempt 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 BOP Proposed Regulations will preempt local programs, such as the one in San Luis Obispo County, because its take-back program is mandatory, while the BOP Proposed Regulations specifically provides any take-back programs to be voluntary. The BOP Regulations reference the take-back programs in Alameda County and San Francisco, as examples of successful programs. These programs, however, will be preempted by the BOP Proposed Regulations.

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 do not require pharmacies to maintain a drug take back program, but instead makes these programs purely voluntary. As discussed above, if implementing drug take back programs becomes voluntary, 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 facility with a kiosk in California will not be in compliance with the BOP Proposed Regulations. Existing locations will either have to comply with the new regulations or remove their kiosk. Since the BOP Proposed Regulations are overly burdensome and only make the drug take back programs voluntary, it is foreseeable that many kiosk locations will close.

Furthermore, under the BOP Proposed Regulations, all of the kiosks at collection locations, other than pharmacies, skilled nursing facilities, and police stations, would be prohibited. As noted above, in Alameda County, 17 of the 30 kiosk locations would be prohibited under the BOP Proposed Regulations and would be forced to 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 needles 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 (see attachment 3).

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 be delegated to DPH, not the BOP.

The BOP does not have the authority to preempt local programs without specific legislative authority. The BOP has taken the position that the Proposed Regulations preempt local programs. While local governments believe that any program must be in compliance with state and federal laws, the BOP does not have the legal authority to preempt a local program. In San Luis Obispo County every pharmacy must have a drug take-back program. The DEA regulations allow for either a kiosk in pharmacies or mail back envelopes. Thus, in San Luis Obispo County every pharmacy must have either a kiosk or mail back envelopes. Regardless of the selected method, the pharmacy must comply with the DEA regulations and applicable local ordinances adopted pursuant to the local entities' health, safety, and welfare powers under California law. There is no legal authority to support the assertion that the BOP, through an administrative regulation under its enabling legislation involving the efficacy of pharmacies and pharmacists, i.e. pharmaceutical safety, can preempt or intrude into the role of public entities' efforts to protect the environment or the general health, safety and welfare of their citizens.

Significantly, the BOP also does not have the authority to regulate waste once it leaves California, or the manner of which 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

California Board of Pharmacy
March 22, 2016
Page 8

the practice of pharmacy and thus the BOP would not have the authority to regulation 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,



Adam Hill
President
San Luis Obispo County Integrated Waste Management Board

CC: Raymond Biering, IWMA Counsel

- Attachment 1. Board of Pharmacy and CalRecycle comment letters on DEA Regulations
- Attachment 2. Article on 1% Participation Rate
- Attachment 3. Detailed analysis of BOP Proposed Regulations
- Attachment 4. IWMA CEQA notice of exemption



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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

February 19, 2013

Drug Enforcement Administration

Docket No. DEA-316

Submitted electronically to <http://www.regulations.gov>

Dear Drug Enforcement Administration:

The California State Board of Pharmacy is grateful for this opportunity to provide comments to the Drug Enforcement Administration on its proposal to establish parameters for the take back and destruction of unwanted controlled substances that have been dispensed to patients. We recognize the complexity of the task before the DEA in developing these regulations and we look forward to the enactment of the proposals, we hope with the several modifications we suggest below.

The California State Board of Pharmacy regulates nearly 140,000 licensees who dispense, store and ship prescription drugs and devices throughout, from and into California. This includes both individuals and firms including pharmacies, clinics, wholesalers, pharmacists and the designated representatives who are the licensed staff who work in wholesaler facilities. Under the general category of wholesaler, the board specifically licenses reverse distributors and brokers (who do not take possession but arrange for the sale of prescription medication).

California is the largest board of pharmacy in the US, and we work feverishly to secure our statutory mandate of consumer protection. In pursuit of this mandate, the board regulates the quality of the pharmaceutical products dispensed as well as the pharmacy services provided to patients. For a number of years, the appropriate disposal of prescription medication, coupled with escalating drug diversion and the growing prescription drug abuse problems have commanded the board's enforcement and educational efforts.

California is also at the forefront of issues surrounding the health of patients and possible jeopardy posed by unscrupulous "entrepreneurs," who buy and sell prescription drugs illegally and damage the state's (and nation's) drug supply. Patients and practitioners are ignorant of the potential for and presence of counterfeit or adulterated medication in the US pharmaceutical supply chain, and simply change therapy when a prescribed drug regimen no longer works.

Over the last decade, the board has aggressively undertaken innovative approaches to secure the quality of pharmaceuticals that are dispensed to patients in California. This includes:

- E-pedigree requirements to establish a comprehensive tracking system for the sale of each container of prescription medication dispensed to California patients, tracking and certifying ownership from the manufacturer, to the wholesaler, to the pharmacy or practitioner. Beginning in 2015 when the requirements become effective over a 2.5 year basis, e-pedigree requirements will permit the identification (and thus enable better investigation and prosecution) of suspect medication at the point it enters the pharmaceutical supply chain.

- Aggressive enforcement of financial sanctions for entities purchasing prescription medication from unlicensed sources (\$5,000 per invoice, resulting in fines of hundreds of thousands of dollars).
- Issuance of fines to pharmacies filling internet prescriptions illegally where there is no legitimate prescription for the transaction (\$25,000 per "prescription" dispensed, resulting of fines up to \$100 million).
- Identification and discipline of pharmacies purchasing drugs not for dispensing to patients but exclusively for resale to wholesalers. Despite a specific prohibition in California enacted in 2004 to prevent a pharmacy from reselling medication to any wholesaler except for returns to the wholesaler that sold the pharmacy the medication initially, the board continues to identify new pharmacy practices involving such sales. Often these sales transactions involve medication in short supply, for which desperate providers and patients will pay high amounts. Such manipulation by pharmacies and wholesalers documented by the board has resulted in price increases to patients exceeding 6,000 percent.
- Hosting educational forums, jointly with the Drug Enforcement Administration, to educate pharmacists about the dangers of prescription drug abuse, drug diversion issues, corresponding responsibility and pharmacy robberies.
- Cooperative joint investigations of board licensees with the Drug Enforcement Administration and other law enforcement agencies to identify and prosecute criminal drug diversion, particularly involving controlled substances.

California has a considerable stake in addressing the disposal of prescription medication. With over 12 percent of the nation's population, 650 million prescriptions were dispensed to patients in California in 2011 out of the total of 4 billion prescriptions dispensed nationally that year. Not all of these medications would have been consumed -- leaving California with likely the largest unwanted drug disposal problems and issues in the country.

Today, there is a considerable illegal movement of prescription medication, including controlled substances, that has been dispensed to patients but ends up being returned/resold to pharmacies and wholesalers. These entities refill manufacturers' containers, and then resell these drugs into the drug supply where they are re-dispensed to unknowing patients. In recent years, the board has encountered multiple cases of this "recycling" in multiple California pharmacies. Often these drugs are obtained from skilled nursing facilities, where the facility and patients no longer have use for them, and destruction would cost the facility money. Instead pharmacies take these drugs back, remove them from blister packs and redispense or resell them.

We have disciplined multiple pharmacies for doing this, but are certain we have not discovered all pharmacies performing such activities. Obtaining drugs from such sources is considerably cheaper than purchasing drugs from legitimate sources. However, identifying such practices is quite difficult for a regulator. In the last two years, the FDA and other law enforcement agencies have identified at least three large scale "recycling" operations, where patients and others have resold dispensed medication back to brokers who repackage into manufacturers' containers and resell the products to wholesalers and pharmacies. We know that two of these three cases involve prescription drugs in California.

Specifically:

- \$250m worth of HIV medications in New York, some of which were likely shipped to and dispensed in California by a pharmacy linked in ownership with the New York pharmacies indicted

- \$500m worth of HIV medications also in New York discovered by the NY AG's Office
- \$498m worth of prescription drugs collected from California patients in a federal indictment filed in late 2012.

In 2008, pursuant to legislation enacted in California, guidelines for drug take back programs were developed by several state agencies, including this board. These policies could not be mandated until the Drug Enforcement Administration completed its work on the take back and destruction of controlled substances. In many ways, the Drug Enforcement Administration's proposed federal regulations for destruction of previously dispensed controlled substances support these California guidelines for drug take back programs, which encourage voluntary ongoing collection programs, special event collection, and mail back programs.

Our recommendations are in the form of general comments:

1. 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.
2. We find no reference to brokering within the proposed regulations and believe that the proposed regulations do not permit brokering of previously dispensed controlled substances. However, we respectfully request that the DEA prohibit this activity specifically in these regulations. We believe that if left unchecked, the activities of brokers will complicate attempts to document and identify the activities of those entities handle the destruction of unwanted medication.
3. The board strongly supports the "commingling, do not sort" provisions of the proposed regulations. The sorting of pharmaceuticals collected in a drug take back program, when done by a pharmacy, reverse distributor or any entity poses a huge opportunity for diversion. In fact, we cannot envision another reason for sorting drugs except to secure a cache of specific drugs.
4. Regarding the non-retrievable method of destruction described in the general comments of the regulation package: we fully support commingling of prescription drugs with controlled drugs and even over the counter drugs at collection sites. We strongly support the prohibition against opening the collection devices and container linings, or sorting of collected pharmaceuticals.

However, the board now believes that the safest and surest way to ensure previously dispensed medication does not reenter the supply chain as a commercial product is to render the returned medication unusable: specifically to grind it up at the collection bin so that returned pharmaceuticals are nonsalable. As long as the medication can be differentiated as individual pills, it poses potential for being sorted and reintroduced into the supply chain. Grinders (like a coffee grinder or garbage disposal) could readily be added to collection bins at minimal expense to ensure no subsequent "recycling" occurs of the donation -- and in a manner that does not permit fingers to enter the grinding device.

With implementation of such grinders, regulators can be less concerned that the collected drugs will again become part of the nation's drug supply, permitting redirection of limited enforcement staff to other diversion activities.

5. We strongly urge that any pharmacy that agrees to accept drugs from nursing homes be required to similarly destroy and grind the medication at the time it is identified by the facility

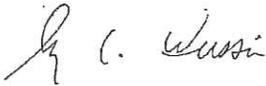
as unwanted waste. The attached photos taken during board investigations document issues we have discovered with drugs being returned to pharmacies where they are recycled to unknowing nursing home patients and other patients, principally from the large volume of medication targeted for destruction in these facilities.

Once a secure disposal system is developed, it could be made available to residential assisted living homes, where there is often no medical staff onsite, but drug disposal problems also exist.

Prescription drug abuse is a serious and growing problem in the US. We share the Drug Enforcement Administration's proposed requirements that reverse distributors, mail back programs, and collection programs offer the public options to dispose of unwanted pharmaceuticals, specifically the unique challenges of controlled substances. Yet from years of experience regulating pharmacies, wholesalers and reverse distributors, we do not want to see additional compromise in the quality of the state's and US pharmaceutical supply caused by opportunists who may pose as pharmacists, pharmacies, reverse distributors or others. The regulations proposed by the Drug Enforcement Administration are a good start. However, we respectfully assert that all drug take back programs involving previously dispensed medication should ensure the pulverization of medication returned so the remnants are worthless.

Thank you for this opportunity to comments on these important requirements. Please do not hesitate to contact the executive officer with questions.

Sincerely,



STAN WEISSER
President

Sincerely,



VIRGINIA HEROLD
Executive Officer

cc: Photos

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P.O. BOX 4025, SACRAMENTO, CALIFORNIA 95812

February 13, 2013

John W. Partridge
Drug Enforcement Administration
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Springfield, VA 22152
(202) 307-4654

Re: DEA's Proposed Rule for the Disposal of Controlled Substances, DEA Docket No. DEA-316,
<https://federalregister.gov/a/2012-30699>

Dear Mr. Partridge,

The California Department of Resources Recycling and Recovery (CalRecycle) appreciates the opportunity to provide comments regarding the Proposed Rule for the Disposal of Controlled Substances, Docket No. DEA-316. CalRecycle supports the efforts of the Drug Enforcement Agency (DEA) to promote the safe and effective disposal of controlled substances (CSs). We generally support the proposed regulations ("the proposed rule") and commend the DEA for carefully considering the many comments submitted on or before January 12, 2011, testimony at the public meeting held in Washington, D.C. on January 19-20, 2011, as well as the concerns of the hundreds of existing collection programs throughout the United States.

CalRecycle Responsibility and Experience

CalRecycle is responsible for establishing California solid waste diversion goals; overseeing all waste management activities including those at solid waste facilities; promoting better resource management by increasing waste prevention, reuse, composting, and recycling; and preventing illegal or inappropriate disposal of solid waste while mitigating any resulting hazards.

In 2007, the California Legislature enacted Senate Bill 966 (Simitan, Chapter 542, Statutes of 2007). The law directed CalRecycle, working with several other state, local, and federal agencies, to:

- 1) establish criteria and procedures for model collection programs for home-generated pharmaceutical waste;
- 2) evaluate the model programs for efficacy, safety, statewide accessibility, and cost-effectiveness;
- 3) consider the incidence, if any, of diversion of drugs for unlawful sale and use; and
- 4) provide the Legislature with recommendations for statutory changes and the potential implementation of a statewide program.

Pursuant to this legislation, CalRecycle established model program guidelines in 2008 (see <http://www.calrecycle.ca.gov/HomeHazWaste/Medications/ModelProgram/Criteria.pdf>). CalRecycle also submitted a report entitled "Recommendations for Home-Generated Pharmaceutical Collection Programs in California" to the Legislature in 2010 (see: <http://www.calrecycle.ca.gov/Publications/Documents/General/2011008.pdf>).

General Support

CalRecycle considers this version of the proposed rule to be a vast improvement over existing regulations and generally supports the proposed rule in the areas listed below.

- Streamlining, where possible, the collection, tracking, and transportation process by:
 - Allowing CSs to be commingled with non-controlled substances (non-CSs).
 - No longer requiring Form 41 in certain circumstances.
 - Not requiring mail-back programs to create and maintain a notification system.



ORIGINAL PRINTED ON 100% POST-CONSUMER CONTENT, PROCESS CHLORINE FREE PAPER

- Allowing common or contract carriers to transport CS waste (with further clarification requested below; see Comment #8).
- Expanding collection options by allowing:
 - Retail pharmacies and other authorized collectors (i.e., manufacturers, drug distributors, and reverse distributors) to collect CSs and distribute mail-back envelopes.
 - Mail-back programs to accept CSs if they have on-site destruction capabilities.
 - Collection at Long-Term Care Facilities (LTCFs) (with further clarification requested below; see Comment #2).
- Clarifying disposal requirements by:
 - Establishing a “non-retrievable” requirement (such as incineration or chemical digestion) without specifying the particular method.
 - Delineating that CS flushing and trash disposal does not meet the DEA’s “non-retrievable” standard.
- Allowing law enforcement agencies to continue current practices (i.e., it is not DEA’s intent to change established law enforcement agencies’ procedures).
- Authorizing individuals to handle a decedent’s CSs for collection and destruction.

Although CalRecycle generally supports the proposed rule, we respectfully submit the following concerns and requested clarifications.

Lessening Regulation-Induced Costs

- 1) *We support flexible storage options including pharmacy backhauling to a warehouse for storage consolidation.* The proposed rule states, “In accordance with section 1317.05(c)(2), upon removal of the inner liner of the collection receptacle, the authorized collector shall promptly: (1) destroy the inner liner and its contents; or (2) store the inner liner and its contents at the collector’s registered location in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur” (page 52 of the proposed rule). Existing Statute, CFR §1301.72(a) describes storage requirements, which would likely be costly for increased amounts of collected and commingled CSs and non-CSs especially at individual pharmacy locations. However, it could lessen the costs if the DEA allowed backhauling commingled drugs to a registered warehouse location for storage in a manner consistent with the security requirements for Schedule II CSs. We support backhauling consistent with the definition of a common or contract carrier using security standards such as those used in Washington State’s “PH:ARM Pilot” program¹, which has operated without diversion incidents for 3 ½ years.²
- 2) *We support any incentives available to encourage collection at LTCFs.* LTCFs currently flush pharmaceuticals. Prohibiting this practice while only allowing retail pharmacies at LTCFs to manage collection receptacles would likely increase costs, especially for those smaller LTCFs that lack retail pharmacies at their locations.
- 3) *We support best practice protocols that encourage ultimate users to remove pills from pill bottles before disposal.* The proposed rule is silent on this issue but we consider the following provision to be, in part, a cost-savings issue. CalRecycle’s Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs stated, “Home-generated pharmaceuticals should be emptied from [the] original container into the secured container at the collection location.” Reducing packaging would reduce the frequency required to empty collection receptacles, reduce the number of hauler pickups/shipments and associated transportation costs, and thereby improve the viability of any collection program. This CalRecycle provision also reduces environmental impacts from incinerating plastic pill bottles. Liquids, creams, powders, and related problematic medicines should remain in their packaging. In that case, signage can also advise consumers to remove personal information from the medicine containers but leave information as to the type of medication being deposited to ensure compliance with the Health Insurance Portability and Accountability Act (should any authorized inventories be performed as requested below; see Comment #6).

¹ Grasso, Cheri, et al., (2009) Secure Medicine Return in Washington State, The PH:ARM Pilot. www.medicinereturn.com/resources.

² Grasso, Cheri, Local Hazardous Waste Management Program, King County, WA., E-mail communication on August 16, 2010.

Providing Clarity Regarding Signage

- 4) *We seek clarity for non-CS collection programs.* CalRecycle suggests clarification be added to the proposed rule regarding programs that collect only non-CSs. These programs would be in violation of the law if they knowingly or intentionally collect a CS. However, with adequate signage prohibiting CSs, the program should be considered in compliance in the event that an ultimate user, who cannot easily identify the difference between CSs and non-CSs, unintentionally or unknowingly deposited CSs in the collection container. On behalf of hundreds of programs who may choose to continue to only collect non-CSs and seek assurances that they comply with the law, we request that DEA clarify its position on this issue.
- 5) *We support uniform signage/symbols.* CalRecycle supports using standard signage and symbols to indicate appropriate and inappropriate materials for collection receptacles or mailers. The proposed rule states, "...DEA is also proposing that the outer container prominently display a sign indicating that only non-controlled drugs and Schedule II, III, IV, or V controlled substances are acceptable for collection. DEA seeks comment on the value and utility of requiring that a specific, uniform symbol be placed on each collection receptacle" (page 51 of the proposed rule). As stated above, we agree "Members of the public cannot easily identify the difference between controlled and non-controlled substances" (page 27 of the proposed rule). Likewise, we suggest that standard symbols would improve the viability of any collection program if those symbols may currently be, or may become, easily recognizable nationwide.

Other Issues

- 6) *We support allowing inventories for carefully regulated studies.* We support provisions in the proposed rule that generally prohibit inventories for cost reduction and security reasons. However, we recommend the DEA include an exception provision in the proposed rule to allow for carefully-regulated studies to characterize and quantify the medicines returned through statistically valid sampling of returned medicines. Using the same type of authorizations allowed for research on Schedule I CSs, safe and secure protocols can be developed to allow research studies on the kinds and quantities of medicines disposed – providing important data for prescribers, health care systems, and environmental interests. This would provide a scientific basis for establishing better prescribing guidelines and verify if new prescribing guidelines have a measurable effect on source reduction.
- 7) *We support visual pre-screening for proper disposal.* CalRecycle supports allowing some flexibility to visually pre-screen waste. Existing collection programs have reported inappropriate materials deposited at events or in collection receptacles including chemotherapy drugs, iodine, sharps, or mercury-containing products such as thermometers. We recognize the importance of security at events where "Law enforcement officers...shall maintain control and custody of the collected substances from the time the substances are collected...until secure transfer, storage, or destruction of the controlled substance has occurred" [1317.65(b)]. However, we believe visual pre-screening by a pharmacist and/or other non-law enforcement officers would strike an appropriate balance between maintaining security and preventing certain materials from inappropriate disposal. Mail-back envelopes should also follow best practice protocols that clearly state such items are not accepted.
- 8) *We encourage defining common or contract carrier.* Regulations for effective collection programs must provide effective security measures that do not threaten the viability of those programs. CalRecycle suggests clarification is needed on the definition of common or contract carrier. We ask the DEA to consider the following definition, enacted in 2012 in California Assembly Bill 1442 (Wieckowski, Chapter 689, Statutes of 2012):

SECTION 1. Section 117637 is added to the Health and Safety Code, to read:

117637. "Common carrier" means either of the following:

(a) A person or company that has a United States Department of Transportation number issued by the Federal Motor Carrier Safety Administration and is registered with the Federal Motor Carrier Safety Administration as a for-hire property carrier.

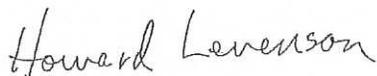
(b) A person or company that has a motor carrier of property permit issued by the Department of Motor Vehicles pursuant to the Motor Carriers of Property Permit Act (Division 14.85 (commencing with Section 34600) of the Vehicle Code) and, if applicable, a carrier identification number issued by the Department of the California Highway Patrol pursuant to Section 34507.5 of the Vehicle Code.

In comparison, the DEA proposes to authorize manufacturers, distributors, reverse distributors, and retail pharmacies as collectors because in part, they are accountable and they are subject to controls related to their DEA registration (page 35 of the proposed rule). To ensure the viability of all programs using common or contract carriers, CalRecycle considers this definition from AB 1442 to be closer to the DEA's standard of

accountable and subject to controls. We consider it important that standards for transportation should include using effective shipment tracking standards and high internal security measures as used with the United States Postal Service and other well-known contract carriers.

Thank you for the opportunity to provide comments. If you have any questions, please contact Mr. Burke Lucy of my staff at (916) 341-6592 or burke.lucy@calrecycle.ca.gov.

Sincerely,



Howard Levenson, Ph.D.
Deputy Director
Materials Management and Local Assistance Division

The New York Times | <http://nyti.ms/1VLfC9W>

U.S.

D.E.A. Effort to Curb Painkiller Abuse Falls Short at Pharmacies

By ALAN SCHWARZ OCT. 10, 2015

When the Drug Enforcement Administration announced last year that pharmacies nationwide could accept and destroy customers' unwanted prescription drugs, experts in substance abuse called it a significant step toward easing the painkiller and heroin epidemic.

One year later, however, the response has been insignificant, dismaying optimists and leaving communities searching for other strategies. Only about 1 percent of American pharmacies have set up disposal programs, with none of those belonging to the two largest chains, CVS and Walgreens, which have balked at the cost and security risks, according to government and industry data.

Countless unused prescription pills like oxycodone and Xanax linger in household medicine cabinets, in easy reach of addicted adults and experimenting adolescents. People who develop painkiller dependencies often move on to heroin, which is considerably cheaper and provides a stronger high. About 23,000 Americans died of prescription-drug overdoses in 2013, more than twice the number from 2001, according to the National Institute on Drug Abuse.

Flushing unwanted medications down the toilet is legal but discouraged because they can pollute water sources; throwing them in household garbage that eventually reaches landfills creates similar environmental concerns.

Alameda County Drug Drop-off Sites

-For Unwanted or Expired Medications-

February 2016

ALAMEDA

Alameda Police Department

1555 Oak Street (Lobby)
Alameda, CA
510-337-8340 8am-8pm daily

ALBANY

Albany Senior Center

846 Masonic Avenue
Albany, CA 94706

BERKELEY

Berkeley Transfer Station #3

1201 2nd Street
Berkeley, CA Mon-Sat. 8-4:30pm

United Pharmacy

2929 Telegraph Avenue
Berkeley, CA
510-843-3201

CASTRO VALLEY

Eden Medical Center (Emergency Entrance)

20103 Lake Chabot Road
Castro Valley, CA
510-537-1234

EMERYVILLE

Emeryville Senior Center

4321 Salmon Street
Emeryville, CA 94607

FREMONT

Alameda Co. Household Hazardous Waste Drop-Off Site -Fremont (For residents of Alameda County only)

41149 Bayview Road
Fremont, CA
1-877-STOP WASTE

Fremont Recycling & Transfer Station

41149 Bayview Road
Fremont, CA
510-252-0500

X = sites prohibited by Board of Pharmacy Regulations

Haller's Pharmacy and Medical Supply

37323 Fremont Boulevard
Fremont, CA
510-797-2772

Washington Township Medical Group at Warm Springs

46690 Mohave Drive
Fremont, CA
510-477-7621

Washington Hospital Community Health Resource Library

2500 McAvoy Avenue
Fremont, CA
510-477-7621

Washington Hospital Main Lobby

2000 McAvoy Avenue
Fremont, CA
510-797-1111

HAYWARD

Alameda Co. Household Hazardous Waste Drop-off Site - Hayward (For residents of Alameda County only)

2091 West Winton Avenue
Hayward, CA
1-800-606-6006

Ted's Drugs

27453 Hesperian Boulevard
Hayward, CA
510-782-6494

LIVERMORE

Alameda Co. Household Hazardous Waste Drop-Off Site – Livermore (For residents of Alameda County only)

5584 La Riviera Street
Livermore, CA
1-877-STOP WASTE

NEWARK

Haller's Pharmacy Newark

6170 Thornton Avenue
Newark, CA
510-797-4333

Washington Township Medical Group

6236 Thornton Avenue
Newark, CA
510-477-7621

OAKLAND

Alameda Co. Household Hazardous Waste Drop Off Site – Oakland (For residents of Alameda County only)

2100 East 7th Street
Oakland, CA
1-800-606-6006 Thurs. – Sat, 9-1pm

X = sites prohibited by Board of Pharmacy Regulations

Alta Bates Peralta Outpatient Pharmacy

3300 Webster Street, Ground Floor
Oakland, CA
510-869-8835

Medicine Drop-Off at the California State Building

1515 Clay Street
Oakland, CA
510-287-1657 Mon-Fri: 8-5pm

East Bay MJD Administration Bldg.

375 Eleventh Street
Oakland, CA 94607 Mon-Fri. 8-4:30pm

Oakland Fire Station #3

1445 14th Street @ Mandela Parkway
Oakland, CA (open 24 hrs a day)

Oakland Fire Station #20

1401 98th Avenue @ International Boulevard
Oakland, CA (open 24 hours a day)

PLEASANTON

Pleasanton Police Department

4833 Bernal Avenue
Pleasanton, CA
925-931-5100 (open 24 hours a day)

SAN LEANDRO

City of San Leandro Senior Center

13909 E. 14th Street
San Leandro, CA
510-577-7996

City of San Leandro Public Works

14200 Chapman Road
San Leandro, CA
510-577-3440

Davis Street Clinic

3081 Telegraph Street
San Leandro, CA
510-347-4620 Mon-Thurs: 8-8pm, Fri. 8-6pm

Medical Arts Pharmacy

13847 E. 14th Street
San Leandro, CA
510-357-1881

UNION CITY

Washington Township Medical Group

33077 Alvarado-Niles Road
Union City, CA
510-477-7621

X = sites prohibited by Board of Pharmacy Regulations

The following is the only site that can legally accept Controlled Substances:

Alameda County Sheriff's Office
15001 Foothill Boulevard
San Leandro, CA
510-667-7721 Mon-Fri: 7-5pm

Green type = *local independent pharmacy*

Comments from the San Luis Obispo County Integrated Waste Management Authority
on Title 16. Board of Pharmacy Proposed Text to add new Article 9.1 of Division 17 of
Title 16 of the California Code of Regulations

Section 1776 Prescription Drug Take-Back Programs: Authorization

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

Comment: This section requires every drug take back program to comply with the DEA regulations and the Board of Pharmacy (BOP) regulations. Most existing kiosks in California currently do not accept controlled substances and thus do not have to comply with the DEA regulations. By requiring every kiosk to comply with these regulations will result in most of them being closed.

The DEA recognized the value of having separate standards for programs that did not accept controlled substances. This is evident in the comment and response that was included in the Federal Register as part of adopting the DEA regulations.

“Page 53533. [7] Issue: One commenter stated that the collection receptacle design specifications will require current collection programs for non-controlled substances to install new collection receptacles if those programs wish to additionally collect pharmaceutical controlled substances. This commenter stated that such installations will be burdensome and will discourage participation for these programs.

DEA Response: The DEA deeply appreciates the concern and activism of local communities and other groups **currently conducting non-controlled substance drug take-back programs** and their wish to expand collection activities to pharmaceutical controlled substances. **Programs such as these are an important and vital component of the communities they serve.** The DEA understands that publication of this final rule may necessitate the need for some programs to implement new procedures and install new equipment in order to additionally collect pharmaceutical controlled substances. The DEA has not established the new requirements lightly or without considerable deliberation as to its impacts on existing programs. However, the risk of diversion for non-controlled substances is relatively low compared to the much higher risk of diversion, and the corresponding and associated risks to public health and safety, for pharmaceutical controlled substances. The DEA has been charged by Congress with the enforcement of the controlled substance laws of the United States, and must ensure that pharmaceutical controlled substances are properly secured and not easily susceptible to theft or diversion. Accordingly, the collection receptacle design specifications outlined in § 1317.75 will be implemented as proposed.”

Section 1776. Only California-licensed pharmacies and drug distributors (licensed wholesalers and third party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.

Comment: Many locations throughout California currently have kiosks to collect drugs. For example in Alameda County senior centers and a California State Office Building have kiosks. These kiosks do not accept controlled substances so are not subject to the DEA Regulations. If these regulations are adopted all of those locations would be forced to closed. In Alameda County that would result in the closure of 17 of the 30 existing sites.

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.

Comment: Local communities have take the lead to establish convenient drug take back programs. By preempting local programs, California will have very few drug take-back locations.

^(b)
^(c)

(d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances.

Comment: By including all prescription drugs in these regulations, the BOP has far exceeded the requirements of the DEA regulations. This will be a large burden on pharmacies that want to have kiosks for only non-controlled substances.

(e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's 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 shall be placed on collection receptacles as referenced in section 1776.3.

Comment: If the BOP is excluding certain drugs from the program, then the BOP should develop programs that allow the public to properly dispose of these drugs.

1776.3 Collection Receptacles in Pharmacies

(a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In 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 patients from access to the collection receptacle by some means.

Comment: The requirement to “physically block patients from access to the collection receptacle” is not needed since the kiosk is locked. This requirement will be a burden to a pharmacy trying to implement a take back program. Most of the other requirements match the DEA Regulations and thus do not need to be repeated. To the extent that they differ from the DEA Regulations, then it will require the pharmacy to meet both regulations.

1776.5 Reverse Distributors

Comment: This section should be totally eliminated. All reverse distributors involved in the drug take back program are located outside of California and thus not subject to California Law, but instead are governed by the DEA Regulations. For example (f) includes requirements on reverse distributors who receive liners from law enforcement under federal law. In addition this section includes requirements that are not consistent with DEA Regulations, such as (b) that requires incineration.

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.

(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.

Comment: DEA regulations have no record keeping requirements for pharmacies that distribute mail back envelopes. These BOP proposed regulations are an unnecessary burden on pharmacies.

CEQA NOTICE OF EXEMPTION

TO: Tommy Gong, County Clerk
County of San Luis Obispo
County Government Center
San Luis Obispo, CA 93401

(ENDORSED)
FILED

FROM: San Luis Obispo IWMA
870 Osos Street
San Luis Obispo, CA 93401

MAR 11 2015

TOMMY GONG, COUNTY CLERK

CONTACT: William Worrell, Manager
(805) 782-8530

TARBY BLANDFORD
DEPUTY CLERK

PROJECT TITLE: AN ORDINANCE ESTABLISHING A HOME-GENERATED UNWANTED PRESCRIPTION MEDICINE DISPOSAL PROGRAM

Project Description. This is an Ordinance which will provide options for the disposal of home-generated unwanted prescription medicine.

Public Agency Approving Project. The San Luis Obispo County Integrated Waste Management Authority (IWMA) approved this item at the IWMA Board Meeting held on March 11, 2015 at 1:30 p.m. in the Cold Canyon Landfall in San Luis Obispo County.

Environmental Determination. In this case it has been determined with certainty that there is no possibility that the project may have a significant environmental effect on the environment and therefore it is found to be exempt from CEQA pursuant to section 15061(b)(3) of the State Guidelines. The IWMA will file this Notice of Exemption upon approval of the Ordinance.

Reasons for Exemption. The opportunity for the public to dispose of unwanted medicine either at a pharmacy or through a mail back program instead of at local landfills or through the sewer system, will enhance and protect the environment. As a result, the proposed ordinance is not a project or it is subject to the "common sense" exemption within the meaning of the California Environmental Quality Act (CEQA) because it can be seen with certainty that there is no possibility that the new opportunity for the public to dispose of unwanted medicine may have a significant effect on the environment.

Even assuming the proposed ordinance were somehow considered to be a project under CEQA, it would be categorically exempt under CEQA as "Class 1 and 8 exemptions under Public Resources Code sections 21083 and 21084, and sections 15301 and 15308 (Actions by Regulatory Agencies for Protection of the Environment and actions at Existing Facilities) of the CEQA Guidelines (California Code of Regulations, Title 14, Division 6, Chapter 3. The categorical exemptions provide as follows:

Section 15301. Existing Facilities. Class 1 consists of activities mandated by the ordinance which will occur at existing retail establishments and, therefore, consist "of the operation, repair, maintenance, permitting, leasing, licensing or minor alteration of existing public or private structures, facilities, mechanical equipment, or topographical features, involving negligible or no expansion of use beyond that existing at the time of the lead agency's determination.... The key consideration is whether the project involves negligible or no expansion of an existing use."

Section 15308. Actions by Regulatory Agencies for Protection of the Environment. Class 8 consists of actions taken by regulatory agencies, as authorized by state or local ordinance, to assure the maintenance, restoration, enhancement, or protection of the environment where the regulatory process involves procedures for protection of the environment. Construction activities and relaxation of standards allowing environmental degradation are not included in this exemption.


William Worrell, Manager

3/11/15
Date

California Board of Pharmacy
March 22, 2016
Page 8

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,

Adam Hill
President
San Luis Obispo County Integrated Waste Management Board

CC: Raymond Biering, IWMA Counsel

Attachment 1. Board of Pharmacy and CalRecycle comment letters on DEA Regulations

Attachment 2. Article on 1% Participation Rate

Attachment 3. Detailed analysis of BOP Proposed Regulations

Attachment 4. IWMA CEQA notice of exemption

Martinez, Lori@DCA

From: Angie Manetti <amanetti@calretailers.com>
Sent: Monday, March 28, 2016 4:53 PM
To: Martinez, Lori@DCA
Subject: Comments on Drug Take Back Regulations
Attachments: CRA Comments#1 BOP Regs.pdf

Hi Lori,

On behalf of the California Retailers Association, please find our comment letter attached on the proposed drug take back regulations.

Thank you,

--

Angie Manetti
Director of Government Affairs
California Retailers Association
980 Ninth Street, Suite 2100
Sacramento, CA 95814
P: (916) 443-1975
F: (916) 443-4218
E: amanetti@calretailers.com



March 28, 2016

Amy Gutierrez, Pharm.D.
President, California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

RE: Proposed Regulations for Pharmacy Take Back of Prescription Medications

Dear Dr. Gutierrez,

The California Retailers Association (CRA) would like to thank the Board of Pharmacy for drafting regulations that provide our members with the necessary guidance to those participating in safe medication disposal programs. The services and medications we provide our patients serve a great purpose when used as prescribed, but they can pose serious dangers and may be especially harmful if they are used by someone other than the person the medicine was prescribed for. We acknowledge that sensible disposal options for unused or expired medications are important to make available to consumers.

Our members have been proactive on this issue by offering ways to provide safe drug disposal. We have participated in take-back events, made available mail-back envelopes to our customers, provided signage and consumer education on how to safely dispose medications, and partnered with organizations to help facilitate the donation of drug collection units. Many local municipalities have adopted local ordinances and many others are considering local requirements for drug take-back programs. In a number of cases these local entities are considering mandates for pharmacies to place take-back containers in their pharmacies.

Pharmacies face many challenges to participate in prescription drug take back programs, despite the Federal regulatory guidance. While most of the operational costs are covered by the product stewardship organizations created by the ordinances, there is an unquantifiable cost of liability pharmacies incur when participating, specifically as it relates to serving as a collection site. Furthermore, not every pharmacy is an adequate location to have a pharmaceutical waste receptacle for a host of reasons. Some do not have the physical floor space to offer and can take away space devoted to health care services like immunizations. Others don't have adequate staff to provide the level of monitoring required by the Federal

regulations. There are various safety concerns associated with bringing mass quantities of used or expired medications back into the retail environment which subject to maintaining compliance with existing health and food safety requirements depending on the pharmacy setting.

CRA certainly supports the spirit of the proposed regulations which preserve a pharmacy's ability to opt-in to a drug take back program, a decision well within the Board's scope and authority. Several counties and cities in California have expressed their desire to provide disposal options to their residents and have enacted extended producer responsibility ordinances for pharmaceuticals and over the counter medications. Except for 2 counties, local municipalities have acknowledged our concerns and, just as the proposed regulations do, have allowed pharmacy participation to be voluntary. CRA has made a deliberate effort to collaborate with these cities and counties to assist them in achieving their goals while using the flexibility they have provided our members to determine which disposal methods can work best for us. We believe the proposed regulations help perpetuate the collaborative process we've been a part of since the beginning of these local ordinances and gives our members the discretion to choose which collection method is most appropriate for each pharmacy.

As these regulations are on their way for final adoption, we ask the Board to offer clarification and revisit some of the provisions we have concerns over to ensure the terms of participation are clear for our members who choose to participate.

Mail-Back Envelopes

Some of our members that seek to provide mail-back envelopes as a way to participate in drug take back programs have raised concerns about the record-keeping requirements in the proposed regulations. The federal regulations state that an inventory of the mail back envelopes is only required for "Collectors" which would be those pharmacies that accept mail back envelopes in the pharmacy. The record keeping requirements in Section 1776.6 serve no purpose if these are made available to customers (either at no cost or for purchase) if mailed it back to the reverse distributor and not returned to the pharmacy. By leaving this section in, pharmacies are discouraged to utilize a mail-back option resulting in less locations willing to stock envelopes, limiting access to customers. We ask the Board remove these requirements for pharmacies that are only going to serve as envelope distributors.

Collection Receptacles

The proposed regulations provide guidance for pharmacies that choose to host collection receptacles. We understand that two pharmacy employees must handle the management of the receptacle which includes removing the liner when filled. There is confusion around Section 1776.5 (c), which specifies, "Two employees of the reverse distributor shall pickup or accept the receipt of inner liners from DEA registrants." It is not clear if this is interpreted to mean that reverse distributors are required to remove the liners from collection receptacles as it has been occurring in

practice. We ask the Board to provide clarification on this component as the current practice has significantly increased the costs associated with this collection method.

Your attention to addressing our remaining issues with the proposed regulations is greatly appreciated. The Board of Pharmacy's vision statement declares, "Healthy Californians through quality pharmacist's care." We share this vision. Our members' main focus as pharmacies is to serve our communities by providing quality health care services first. Disposal options are important to provide our customers, but it is imperative to preserve the flexibility for pharmacies to assess how participation and goals may be achieved. As these regulations are considered through the process, we urge the Board to maintain the to ensure pharmacy participation is voluntary. We appreciate the opportunity to be a part of this solution and look forward to the progress made on this issue. Thank you for your time and consideration

Sincerely,

A handwritten signature in black ink, appearing to read "A Manetti". The signature is fluid and cursive, with a large initial "A" and a stylized "M".

Angie Manetti
Director, Government Affairs

Martinez, Lori@DCA

From: Cathy Coyne <ccoyn@calsheriffs.org>
Sent: Monday, March 28, 2016 9:34 AM
To: Martinez, Lori@DCA
Cc: Martin Ryan (martinryan@amadorgov.org); Green, Carmen@calsheriffs.org; Cory Salzillo (cory@wpssgroup.com); WPSS (nick@wpssgroup.com); Martin Mayer; Asha Harris (asha@wpssgroup.com)
Subject: CSSA Comment Letter re Board of Pharmacy Proposed Regulations
Attachments: CSSALetterreBoardofPharmacyProposedRegulations032816.pdf

Dear Ms. Martinez:

Please accept the attached letter as written comment on the Board of Pharmacy's (BOP) pending regulations regarding prescription drug take back services that would add Article 9.1 of Division 17 of Title 16, to the California Code of Regulations and add Sections 1776– 1776.6 of Article 9.1 of Division 17 of Title 16, to the California Code of Regulations. In summary, and as noted in our letter, the California State Sheriffs' Association urges the BOP to abandon these proposed regulations as their adoption will preempt local drug take-back programs and likely leave law enforcement agencies with the responsibility to deal with the problem of disposing of unwanted, unused, and expired prescription drugs.

Thank you – Cathy Coyne, Deputy Executive Director
California State Sheriffs' Association
1231 I Street, Suite 200
Sacramento, CA 95814
916-375-8000 Phone / 916-375-8017 Fax
E-Mail: ccoyn@calsheriffs.org

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Organization Founded by the Sheriffs in 1894

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M. Carmen Green
Executive Director

Nick Warner
Policy Director

Martin J. Mayer
General Counsel

March 28, 2016

Ms. Lori Martinez
1625 N. Market Boulevard, N219
Sacramento, CA 95834
Via Facsimile ((916) 574-8618) and
E-Mail (Lori.Martinez@dca.ca.gov)

Re: Proposed Board of Pharmacy Regulations Governing Prescription Drug Take Back Services

Dear Ms. Martinez:

Please accept this letter as written comment on the Board of Pharmacy's (BOP) pending regulations regarding prescription drug take back services that would add Article 9.1 of Division 17 of Title 16, to the California Code of Regulations and add Sections 1776-1776.6 of Article 9.1 of Division 17 of Title 16, to the California Code of Regulations. In summary, and as noted below, the California State Sheriffs' Association urges the BOP to abandon these proposed regulations as their adoption will preempt local drug take-back programs and likely leave law enforcement agencies with the responsibility to deal with the problem of disposing of unwanted, unused, and expired prescription drugs.

Sheriffs are keenly aware of the dangers posed by the presence of unused prescription drugs. Abuse of these substances has grown dramatically in recent years and preventing access to them is a crucial part of the fight to stop illicit drug use. Facilitating the safe and efficient disposal of these drugs will limit the opportunities for abuse as well as accidental poisoning of children, a significant and growing problem.

Over the past several years, law enforcement agencies across California have been engaged in drug take back programs while federal efforts to regulate the disposal of unwanted prescription drugs were underway. These law enforcement programs were successful in keeping drugs away from users, children, and inappropriate environmental disposal (landfills and sewer systems). Now that federal law is in place, it is appropriate for pharmacies to assume the lead role in expediting drug disposal.

Unfortunately, the proposed regulations are likely to have the opposite effect. Inasmuch as they will preempt programs adopted by local governments, pharmacy participation is likely to plummet. These local programs can mandate that pharmacies undertake drug take back services and the importance of this is clear. In at least one jurisdiction that has a mandatory pharmacy take back program, 100% of pharmacies participate. Conversely, in areas where there is no local program, the average participation rate is 1%. By permitting, rather than requiring, pharmacy participation, law enforcement agencies will become the de facto recipients of the unwanted drugs that are not diverted for illegal use or inappropriately discarded.

Martinez, Lori@DCA

From: Lucy, Burke@CalRecycle <Burke.Lucy@CalRecycle.ca.gov>
Sent: Friday, March 25, 2016 2:40 PM
To: Martinez, Lori@DCA
Cc: Sodergren, Anne@DCA; Levenson, Howard@CalRecycle
Subject: CalRecycle comments on BoP Proposed Take-Back Regulations
Attachments: CalRecycle-comments-on-BoP-Proposed-Take-Back-Regs_032516.pdf

Ms. Martinez,

Please accept CalRecycle's attached comments on the Board of Pharmacy's proposed regulations to address prescription drug take back programs. Thank you for the opportunity to comment.

Mr. Burke Lucy
Environmental Scientist
Department of Resources Recycling and Recovery (CalRecycle)
1001 I Street, PO Box 4025
Sacramento, CA 95812
Burke.Lucy@CalRecycle.ca.gov
916.341.6592



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DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY

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P.O. BOX 4025, SACRAMENTO, CALIFORNIA 95812

March 25, 2016

Lori Martinez
1625 N. Market Blvd., N219
Sacramento, CA 95834
(916) 574-7917

Re: Board of Pharmacy's Proposed Regulations for Prescription Drug Take-Back Programs

Dear Ms. Martinez,

The California Department of Resources Recycling and Recovery (CalRecycle) supports the need to promote the safe and effective disposal of home-generated pharmaceutical waste and appreciates the opportunity to provide comments regarding the proposed regulations for prescription drug take-back programs. We commend the Board of Pharmacy (Board) for considering the testimony at the public meetings and the written comments presented by the key stakeholders who currently manage pharmacy collection programs throughout California.

CalRecycle supports the Board's overall approach in the proposed regulations to explicitly allow pharmacies to accept home-generated pharmaceutical waste for proper disposal as this would be an improvement over existing regulations. However, we respectfully submit the following concerns and requested clarifications for the Board's consideration. CalRecycle staff is primarily concerned with two overarching issues:

1. **Preemptive Language re: Local Government Mandates:** Any potentially preemptive language conflicting with local government ordinances that have proven effective in addressing pharmaceutical waste, such as those adopted in San Francisco, San Luis Obispo, and Santa Cruz Counties.
2. **Consistency with DEA Regulations:** The DEA has already adopted regulations for the most problematic pharmaceuticals and the Board should be consistent with those regulations.

Local Government Mandate Preemption:

- 1) *We request that the Board clearly state whether you intend to preempt local ordinances that mandate drug collection and reconsider any such preemptive language.* The Board's proposed voluntary language potentially conflicts with local ordinances mandating pharmacy drug take-back by saying "Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary" [§1776.1(a)]. In the January 19 Board meeting, the Board's Supervising Deputy Attorney General stated there is not a clear answer as to whether §1776.1(a) would preempt county ordinances and recommended that the Board clearly state if it intends to preempt county ordinances or if it wants to allow counties to mandate programs. Although the Board voted to retain language that potentially conflicts with local ordinance mandates, we request that the Board reconsider this and allow flexibility for local governments to enact ordinances that address issues specific to their jurisdictions.
- 2) *Consistent with the first point above, we request that the Board reconsider the language that would impact existing local mandates assisting patients with information to properly manage their drugs.* In particular, the Board's proposed regulations conflict with local ordinances such as San Francisco's Safe Drug Disposal Information Ordinance. This ordinance requires non-participating pharmacies to display signage promoting proper medicine disposal and listing participating pharmacies.



Consistency with DEA Regulations

- 3) ***We recommend revising the regulations to be consistent with DEA regulations by allowing more disposal flexibility beyond incineration.*** The proposed text states, “All liners shall be incinerated by an appropriately licensed DEA distributor” [§1776.5(b)]. Whereas, when asked to outline the DEA’s “non-retrievable” standard, the DEA indicated, “...that incineration and chemical digestion are some examples of current technology that may be utilized to achieve the non-retrievable standard.” The DEA also clarified its intent to encourage new technologies by writing, “The DEA believes that any actual or perceived endorsement or recommendation of a specific destruction method, beyond the provision of examples of current methods in the preamble, could suppress exploration and implementation of new technologies as people may assume that the endorsed or recommended methods are required at the exclusion of other methods.” Thus, we recommend that the regulations reflect the DEA’s non-retrievable standard, which may include incineration and chemical digestion.
- 4) ***We recommend revising the regulations to make them consistent with the DEA’s tracking requirements for collectors.*** The proposed text includes tracking requirements for pharmacies offering mail-back packages and envelopes to customers in §1776.6(a)-(d). While DEA regulations include pharmacies as potential collectors, a collector conducting a mail-back program must have a method of destruction at its registered location, thereby excluding pharmacies from associated recordkeeping requirements. The DEA regulations state, “The term collector means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized under this chapter to so receive a controlled substance for the purpose of destruction” [21 CFR §1300.01] and “A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with §1317.90 of this chapter” [21 CFR §1317.70].
- 5) ***We recommend revising the regulations to incorporate the DEA’s “promptly” standard for delivering drug waste instead of a more restrictive 3-day standard.*** The proposed text would require drugs removed from their containers to be stored no more than 3 days, whereas the DEA’s “promptly” standard allows for a wider variety of business models and activities and avoids *per se* violations. The proposed text states, “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 days” [§1776.3(j)]. The DEA regulations require registrants to, “...promptly deliver that controlled substance to a reverse distributor’s registered location...” [21 CFR §1317.05(a)(2)]. When asked to define “promptly,” the DEA stated, “The DEA considered imposing specific timelines (e.g., three days, five days); however, the wide variety of business models and activities made it impossible in most circumstances to set a specific deadline that would prevent diversion and diversion opportunities. Additionally, violations of specific timelines would be *per se* violations of the regulations, whereas violations of the flexible ‘prompt’ and ‘as soon as practicable’ standards would be considered under each registrant’s individual circumstances.” While we understand temporary storage outside the collection receptacle increases the chances of illegal drug diversion, three days is a very limited time to allow for any complications in a reverse distributor’s collection schedule or to reach more rural locations, resulting in a *per se* violation.
- 6) ***We recommend deleting/moving specific signage requirement language.*** The proposed text states, “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” [1776.4(j)]. The first sentence is redundant to DEA regulations [21 CFR §1317.75(e)(4)] and could be removed.
- 7) ***We recommend removing language redundant to DEA regulations.*** The following selected Board regulation sections under 1776.4 are redundant to DEA regulations under 21 CFR respectively, and could be removed, including: §1776.4(c) vs. §1317.80(b), §1776.4(f) vs. §1317.75(d)(2)(iii), §1776.4(g) and (h)(1) vs. §1317.75(e)(1) and (3). Many other sections are redundant to DEA regulations and may cause confusion.

Other Comments:

- 8) ***In an effort to increase drug disposal options, we recommend incorporating the US EPA incineration recommendations.*** The proposed text states, “All liners shall be incinerated by an appropriately licensed DEA distributor” [§1776.5(b)]. Yet, different incinerators have different standards depending on the type of waste

incinerated. In a 2012 memorandum titled, *Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs*, the U.S. Environmental Protection Agency (US EPA) recommended incineration at a "...permitted hazardous waste combustor, but when that is not feasible, at a minimum, they should be sent to a large or small municipal waste combustor." We recommend revising regulations to incorporate this and allow incineration at a permitted hazardous waste or a large or small municipal waste combustor.

- 9) *We recommend revising the regulations to address drugs potentially left beside a closed bin after hours with best management practices.* The proposed text states, "In 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 patients from access to the collection receptacle by some means" [§1776.3(a)]. We recognize that people have and will want to leave drugs next to locked collection receptacles in some cases, but we also consider one Board member's comment in the January 19 meeting to be key when he said people leave drugs in his pharmacy even though he doesn't have a collection receptacle. This suggests blocking a receptacle when locked still will not prevent the behavior from happening. Pharmacies are not prevented from blocking their receptacles when locked as needed but we consider this a training issue that should be left to best management practice guidelines, which should also emphasize the importance of effectively locating the receptacle within full view of pharmacy staff as required in DEA regulations.

Thank you for the opportunity to provide comments. If you have any questions, please contact Mr. Bob Fujii of my staff at (916) 341-6419 or bob.fujii@calrecycle.ca.gov.

Sincerely,



Howard Levenson
Deputy Director

Martinez, Lori@DCA

From: Ronda Fricke <rfricke@calhospital.org>
Sent: Monday, March 28, 2016 3:01 PM
To: Martinez, Lori@DCA
Subject: CHABOPDrugTakeBack032816
Attachments: CHABOPDrugTakeBack032816.docx

Lori – I am resubmitting this letter as I noticed the date on the first page indicated 2015. Please accept my apologies and use the letter attached in this email.

Thank you.



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

March 28, 2016

California State Board of Pharmacy
Attn: Lori Martinez
Lori.Martinez@dca.ca.gov
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

BY ELECTRONIC CORRESPONDENCE

RE: Prescription Drug Take-Back Programs, Adoption of New Article 9.1 and Sections 1776, 1776.1, 1776.2, 1776.3, 1776.4, 1776.5 and 1776.6 of Division 17 of Title 16 of the California Code of Regulations (CCR)

Dear Ms. Martinez:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments for consideration to the proposed adoption of the new Article 9.1 and Sections 1776, 1776.1, 1776.2, 1776.3, 1776.4, 1776.5 and 1776.6 of CCR Title 16, Division 17.

In light of the rising epidemic of opioid abuse, along with the need to protect the environment from hazardous waste disposal, the board of pharmacy has drafted salient regulations to enhance the availability of safe and effective drug take-back programs across the state. CHA applauds the intent, particularly with the proposed implementation of a voluntary pharmacy take-back program that will support all sites to individually and fully evaluate costs, security risks and benefit to their communities.

Opioid abuse continues to be a national health problem. From 1999-2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States. While other top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid abuse has increased significantly. In 2011, there were an estimated 420,000 emergency department visits related to abuse of narcotics (Drug Abuse Network). Clearly, CHA and its member hospitals are supportive of efforts to prevent death and decrease prescription drug related mortality and morbidity.

To combat the growing misuse of prescription drugs, the Office of the National Drug Control Policy (ONDCP) released a Prescription Drug Abuse Plan outlining a four pronged approach consisting of education, monitoring, proper medication disposal and enforcement. CHA and its corporate regional members, along with Cal ACEP have endorsed the San Diego Safe Pain Medicine Prescribing Guidelines and have worked to educate members over the past several

years on effectively managing pain issues with emergency and urgent care patients. CHA's Medication Safety Committee, developed and disseminated "Recommendations for Improving Safety of Opioid Use" tool, and also endorsed and worked closely with the Department of Justice to encourage the use of the state's prescription drug monitoring program, "CURES" (Controlled Utilization Review and Evaluation System). In an effort to work alongside stakeholders and the Board of Pharmacy to support the aforementioned four pronged approach to opioid drug abuse prevention, CHA is also committed to addressing proper medication disposal processes that make medication collection accessible, easy, cost effective and sustainable. The states "CalRecycle" program, has developed model programs for the collection and proper disposal of unused or expired home-generated pharmaceuticals. Minimum criteria includes those mentioned by the ONDCP along with additional criteria such as board reports on waste amounts, actions for compliance failure, etc.

Drug take-back programs can be classified as either "event based" or "ongoing", with the most notable example being the Drug Enforcement Agency (DEA) regularly scheduled collections on fixed dates. Other sporadic ongoing programs exist that offer a form of continuous medication collection, featuring either fixed drop off locations at pharmacies, police stations or mail back options. Drug take-back program initiation and implementation has been sluggish, even after the Drug Enforcement Administration (DEA) announced last year that pharmacies nationwide could accept and destroy unwanted prescription drugs. While over 9,000 drug take-back services exist across the state, safety, security and cost issues prevent pharmacies from willingly adding services. And CHA notes there is limited data on the impact and effectiveness of take-back programs and their effect on drug abuse. Nonetheless, CHA is firmly committed to public safety and prevention of opioid abuse and is supportive of drug take-back programs that meet model program criteria.

While CHA and its member hospitals do not see hospital/clinic pharmacies as the most appropriate site for establishing drug take-back programs, we support the draft regulations voluntary status for sites in these settings, as there may be unique community circumstances or programs where the hospital/clinic pharmacy is the most appropriate setting. Several of these hospital sites exist today as collection sites for licensed waste management services, components of larger county and district programs with comprehensive waste disposal services in multiple sites within a locale. Overall, however, CHA supports a multipronged approach with heavy emphasis on product stewardship where drug manufacturers play a lead role in funding and handling of their own environmentally harmful products.

CHA has three specific comments on the regulations listed below:

1. Proposed Section 16 CCR Section 1776.1 Pharmacies:
Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.

Recommendation: CHA reiterates its strong position on maintaining voluntary participation in these programs. CHA does not envision hospital/clinic pharmacies to be an appropriate site for establishing drug take back programs; however, there may be

unique community circumstances where the hospital/clinic pharmacy is an appropriate setting.

2. Proposed Section 16 CCR Section 1776.3 Collection Receptacles in Pharmacies:

In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from patient access by some means.

Recommendation: CHA recommends removing, “and not in the proximity of emergency or urgent care”. While CHA suspects that most hospital pharmacies will not participate in this program, there are several drug take-back programs in hospitals presently that have collection receptacles in their emergency departments. While emergency or urgent care departments may not be the most appropriate site for a collection receptacle, it may be the most appropriate area relative to regular employee monitoring and internal hospital safety and security.

3. Proposed Section 16 CCR Section 1776.3 Collection Receptacles in Pharmacies:

General Comment: As stated in 16 CCR Section 1776 Prescription Drug Take-Back Programs: Authorization, and throughout the proposed regulations: “Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following: medical sharps and needles (e.g. insulin syringes), iodine containing medications, mercury containing thermometers, radiopharmaceuticals, hazardous medications and compressed cylinders.” CHA offers, that inevitably, inappropriate items will end up in the containers even with appropriate signage, etc.

Recommendation: CHA suggests adding a section to address what processes occur when inappropriate items or damaged items are found in the transition of the sealed liners to the licensed DEA registered reverse distributor.

4. General Regulatory Comments: Costs

The Board of Pharmacy Initial Statement of Reason outlines costs for drug take-back services in pharmacies. While costs are outlined for liners and receptacles, there is underreporting of the actual costs to develop a hospital/clinic based drug take-back program.

Recommendation: Additional pharmacy and security labor costs, along with program development and maintenance costs need to be included to estimate actual costs.

5. General Regulatory Comments: Efficacy

While the severity of the prescription drug abuse problem continues to mount, there is no question that multiple approaches to combat the issue are warranted. Little data is

available on the impact and effectiveness of drug take-back programs. Obviously, drug take-back programs will reduce the available supply of prescription drugs; however, voluntary programs are unlikely to draw participation from individuals inclined towards diversion and non-medical use. A study done in 2012 showed that “most individuals diverting unused drugs originally obtain those drugs from a single doctor, highlighting doctors as the ultimate source of the drug surplus rather than the family medicine cabinet”. This is another reason why CHA and its member hospitals are heavily involved in the state’s prescription drug maintenance program, CURES, that proactively monitors prescribing behavior.

Recommendation: Pilot studies be performed to determine which medications are collected, assess take-backs true costs and link program elements to understand the relationship between prescription opioid abuse and take-back programs so that scarce resources can be targeted at the most appropriate arenas to prevent opioid drug abuse.

In conclusion, CHA appreciates the opportunity to comment on these regulations and provide an overview representative of its 400 member hospitals. We are especially appreciative of the overall theme of hospital/clinic pharmacy voluntary participation as these programs are not evidenced based and pose significant cost, security, and safety risks for our patients and communities.

Sincerely:



BJ Bartleson, RN, MS, NEA-BC
Vice President, Nursing and Clinical Services

BJB:rf

Martinez, Lori@DCA

From: Samantha Pellon <SPellon@cmanet.org>
Sent: Monday, March 28, 2016 3:18 PM
To: Martinez, Lori@DCA
Subject: Prescription Drug Take-Back Programs - Board of Pharmacy Proposed Regulations
Attachments: CMA Comments_BOP Prescription Drug Take Back Programs_03282016.pdf

Ms. Martinez:

On behalf of the California Medical Association, I am submitting the attached comments on the Board of Pharmacy's proposed regulations pertaining to Prescription Drug Take-Back Programs. Please let me know if there are any questions.

Thanks,

Samantha D. Pellón
Associate Director
California Medical Association
1201 J Street, Sacramento, CA 95814
P: 916.551.2887
F: 916.551.2044
E: spellon@cmanet.org



California Medical Association
Physicians dedicated to the health of Californians

March 28, 2016

VIA Email to Lori.Martinez@dca.ca.gov

Lori Martinez

Address: 1625 N. Market Blvd., N219

Sacramento, CA 95834

Phone No.: (916) 574-7917

Fax No.: (916) 574-8618

E-Mail Address: Lori.Martinez@dca.ca.gov

RE: Prescription Drug Take-Back Programs

Dear Ms. Martinez:

On behalf of our more than 40,000 physician and medical student members, the California Medical Association (CMA) would like to thank you for accepting comments on the California Board of Pharmacy's proposed regulations pertaining to prescription drug take-back programs. Our members support the establishment of drug take-back programs and believe they can help keep unused medications from being diverted or misused. The proposed regulations provides needed clarity and guidance to the pharmacies that elect to participate in these programs to ensure take-back programs are operated in a consistent manner that prioritizes public safety.

According to the Substance Abuse and Mental Health Administration, over 71 percent of prescription pain medications are obtained from family and friends. A significant component of the prescription drug abuse and diversion problem stems from misuse of unused drugs; as a result, increasing opportunities for the public to safely dispose of their unused prescription drugs may serve to reduce the misuse and diversion associated with these medications.

There is one suggested change to proposed language that may help improve clarity of the regulations. As worded, Section §1776.4(e) implies that the prescriber is the user who will be taking the medication. Rather, discontinuation of use of a medication is by the resident and may occur as a result of several options, one of which includes a prescriber's order. Rephrasing would resolve the issue:

(e) Within three business days after the ~~permanent~~ discontinuation of use of a medication by a ~~prescriber~~ the resident, as a result of an order by a prescriber, 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.

CMA appreciates the Board of Pharmacy's interest in establishing requirements for prescription drug take-back programs. If you have any questions, feel free to contact me at spellon@cmanet.org or 916.551.2887.

Sincerely,

Samantha D. Pellón
Associate Director, Center for Health Policy

Martinez, Lori@DCA

From: Christine Flowers <Christine@calpsc.org>
Sent: Monday, March 28, 2016 5:10 PM
To: Martinez, Lori@DCA
Cc: Heidi Sanborn; Sodergren, Anne@DCA
Subject: RE: Comment Letter for Proposed Regulations from CPSC
Attachments: CPSC BOP Letter Final 3-28-16.pdf

Importance: High

Ms. Martinez,

Please substitute this copy of our letter. The previous version still had the draft water mark on it. I have removed that on this copy.

Sincerely,

Christine Flowers

Christine Flowers-Assistant Director Christine@CalPSC.org
California Product Stewardship Council
1822 21st Street - Suite 100
Sacramento, CA 95811
(916) 706-3420 office (916) 454-9067 cell



From: Christine Flowers
Sent: Monday, March 28, 2016 5:04 PM
To: 'Lori.Martinez@dca.ca.gov' <Lori.Martinez@dca.ca.gov>
Cc: Heidi Sanborn <Heidi@calpsc.org>; 'Anne.Sodergren@dca.ca.gov' <Anne.Sodergren@dca.ca.gov>
Subject: Comment Letter for Proposed Regulations from CPSC

Ms. Martinez,

Please accept the attached letter as California Product Stewardship Councils' comments regarding the Proposed Regulations for Prescription Drug Take Back Programs.

Sincerely,

Christine Flowers

Christine Flowers-Assistant Director Christine@CalPSC.org

California Product Stewardship Council

1822 21st Street - Suite 100

Sacramento, CA 95811

(916) 706-3420 office (916) 454-9067 cell



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March 28, 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 regulations for prescription drug take-back programs. On behalf of CPSC, I am writing to provide our comments on the February 1, 2016 draft of the Prescription Drug Take Back Regulations. In short we do not know why the BoP is going beyond the Federal DEA's Final Rule on Disposal of Controlled Substances in several areas. Specific comments are below.

Section 1776 Prescription Drug Take-Back Programs: Authorization

"All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods."

Comment: It is challenging to reconcile the above statement with the Board's proposed regulation section 1776.1(f)(1) stating "Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public". It is inconsistent with the DEA Regulations. Specifically, it might be helpful to have direction regarding the extent to which pharmacies are required to vigilantly prevent items from being deposited in the collection receptacle, and how they might be able to meet this requirement without reviewing drugs returned from the public.

Recommendation: *modify text to read:* All board-licensed authorized collectors should to the extent that is practicable prevent patients or their agents from disposing of prohibited items through drug take-back collection methods.

Section 1776.1 Pharmacies

1776.1(a) ". . . *Provision of such services is voluntary*"

Comment:

CPSC is concerned that this wording might prohibit local jurisdictions from requiring pharmacies that are not themselves providing medicine take-back services to post signage directing their customers where they can go to safely dispose of their medications. For example, consider an ordinance that says, 'if a pharmacy is not participating in a drop off program, then the pharmacy must have a sign listing pharmacies that are participating.' An argument could be made that this ordinance mandates the pharmacy to 'assist patients seeking to destroy' which therefore violates

the voluntary provision of the state law. If this is not the intent of the Board, CPSC would welcome clarification of the proposed regulation.

Recommendation: *Remove the sentence " Provision of such services is voluntary" entirely, However if the BoP is unwilling to remove the language, at the very least modify the language to allow local jurisdictions to require pharmacies to post signage directing their customers where they can go to safely dispose of medications.*

1776.1(g) *"A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program."*

Comment: CPSC is concerned that this wording implies that if a pharmacy decides to participate in a mail-back program that they have to be registered as a collector; this is not a requirement per the DEA (see section 1776.6(a)(1)).

Recommendation: *modify text to read: A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for the purposes of operating a prescription drug take-back collection receptacle.*

1776.2(e) *"The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6".*

Comment: CPSC is concerned that adding these records requirements beyond what is required by the DEA could disincentivize participation in our medicine take-back program. This is needlessly burdensome. The packages and envelopes are already being tracked by the collector. Per the DEA, "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§ 1317.70)." See section 1776.6(a)(1) for more detail about collector status and requirements.

Recommendation: *Remove these record keeping requirements. Pharmacies do not need to be registered as a collector to provide this service.*

1776.3 Collection Receptacles in Pharmacies

1776.3(a) *". . . In 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 patients from access to the collection receptacle by some means."*

Comment:

CPSC is concerned that requiring pharmacies in retail stores to install a physical barrier something like an accordion style door might discourage them from participating in our medicine take-back program, which could in turn shift a larger burden to our local independent pharmacies. Additionally, it is unclear what exactly would constitute being physically blocked.

DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked goes beyond what the DEA requires. Staff is concerned that requiring a physical barrier

would not solve the intended problem, as it would be just as easy for members of the public to place medicine next to a physical barrier as it would be for them to place medicine next to a locked bin. It would also be easy for members of the public to place their medicines in the closest trash bin, as has been observed.

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

Recommendations: *Remove the language about physically blocking patient access and revert to DEA language in order to avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.*

1776.3(b) ". . . *The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.*"

Comment: CPSC is concerned that this section goes beyond the DEA regulation in a subtle but potentially significant way. As the DEA recognizes, hospitals can be unique in their design and need to have flexibility in the manner in which they participate in Safe Medicine Disposal Programs. The Board regulation as it is currently worded removes some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees" (Federal Register p. 53523). This implies that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. CPSC is concerned that the Board regulation as it is currently worded could discourage hospitals from participating in Safe Medicine Disposal programs by making it more difficult for them to do so.

Recommendation: Remove the word 'pharmacy' from 1776.3(b) so that it reads as the DEA: "visible to employees", not "visible to pharmacy employees".

1776.3(c) *In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from patient access by some means.*

Comment: As mentioned in the comment for section 1776.3(b), the DEA recognizes that hospitals can be unique in their design and need to have flexibility in the manner in which they participate in safe medicine disposal programs. Staff is concerned that the Board regulation as it is currently worded takes away some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees". This implies that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. This further implies that collection receptacles in hospitals do not need to be locked if the pharmacy is closed so long as hospital employees are still regularly monitoring the receptacle. Therefore, even if physical blockage is required in a retail store with a pharmacy, it should still not be necessary in a hospital setting.

CPSC is concerned that the Board regulation as it is currently worded could discourage hospitals from participating in our local medicine disposal program by making it more difficult for them to do so. Requiring hospitals to install something like an accordion style door could discourage them from participating. Additionally, it is unclear what exactly would constitute being physically blocked, and that alone could make it less likely for risk-averse hospitals with pharmacies to participate. The DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked goes beyond what the DEA requires.

Recommendation: *Modify text to read:* The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by an employee so that drugs may not be deposited into the collection receptacle.

1776.3(j) "location in the pharmacy *no longer than three days*"

Comment: It is CPSC's understanding that the DEA regulation only specifies a three day holding period in Long-Term Care Facilities. In the case of pharmacies, the DEA dictates only that liners be moved "promptly". The DEA specifically declined to clarify what would constitute a "prompt" action (Federal Register p. 53528). CPSC is concerned that more strictly defining the length of time inner liners can be stored could increase the burden on pharmacies thereby making it less likely that they would participate in our local medicine take-back program.

Recommendation: *Delete no longer than three days.* Revert to DEA language "liners be removed promptly."

1776.5(e) "*Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. . .*"

Comment: It is CPSC's understanding that incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable. One approved method of doing this is incineration. The DEA states that "the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration. . ." (Federal Register, p. 53536).

Recommendation: *modify text to read:* Each reverse distributor with a destruction site shall maintain a record of the destruction on DEA form 41.

In closing we understand that the BoP is proposing these regulations to align California's regulations with the DEA's Final Rule issued in 2014. Given the detailed nature of the DEA Final Rule, 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.

Sincerely,



Christine L. Flowers, Assistant Executive Director

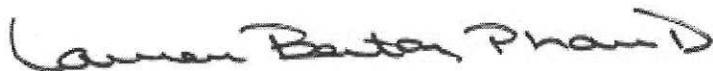
Martinez, Lori@DCA

From: Berton, Lauren N. <Lauren.Berton@CVSHealth.com>
Sent: Sunday, March 27, 2016 11:56 AM
To: Martinez, Lori@DCA
Subject: CVS Health Comments in Reference to Proposed Addition of § 1776 to 1776.6 Article 9.1 of Division 17 of Title 16 of the California Code of Regulations
Attachments: CVS Health Comments to Proposed Addition of Sections 1776 to 1776.6.pdf

Good Morning Lori,

Please find attached CVS comments in reference to proposed addition of § 1776 to 1776.6 for Prescription Drug Take Back Programs in Article 9.1 of Division 17 of Title 16 of the California Code of Regulations. Please feel free to reach out to me with any additional questions on the attached comments.

Thank you,



Lauren Berton, PharmD | Director, Pharmacy Regulatory Affairs
c 540-604-3661 | f 401-733-0479
CVS Health | One CVS Drive, Mail Code 2325, Woonsocket, RI 02895

CONFIDENTIALITY NOTICE: This communication and any attachments may contain confidential and/or privileged information for the use of the designated recipients named above. If you are not the intended recipient, you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please notify the sender immediately by email or telephone and destroy all copies of this communication and any attachments.



Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

March 27, 2016

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

Via email

Re: Proposed addition of Article 9.1 and Sections 1776 through 1776.6 of Division 17 of Title 16 of the California Code of Regulations Section

Dear Ms. Martinez:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies, subsidiaries and affiliates located throughout the State of California. CVS Health appreciates the opportunity to submit comments on the proposed addition of Article 9.1 and Sections 1776 through 1776.6 of Division 17 of Title 16 of the California Code of Regulations Section regarding specific requirements to allow pharmacies that wish to establish prescription drug take back services. We would like to thank the Board for their continued vigilance to continuously improve the laws and rules that guide pharmacists serving California patients and the Board's efforts to combat prescription drug abuse for greater public safety.

CVS Health supports and applauds the Board's current proposed regulations which allows for voluntary participation in drug take back services either via take back receptacles or mail back envelope programs because it allows pharmacies to provide the means they deem appropriate to successfully participate in drug take back services. By allowing law enforcement to use CVS parking lots to host drug take back events, events have improved visibility and foot traffic, patients can safely dispose of unused medication, and prescription waste is immediately removed from the location once the event is completed keeping both customers and employees safe.

CVS Health has teamed up with The Partnership at Drugfree.org to create an innovative community donation program through which local police departments can apply to receive a drug collection unit to help their communities safely dispose of unwanted medications, including controlled substances. Law enforcement drug collection programs help rid communities of unwanted medications that may otherwise be diverted, abused or contaminate our water supply. Since the program launched in April 2014, we have provided more than 500 bins that have collected more than 28 tons of unwanted medication, according to the police stations that have reported across the country. We also offer a mail back envelope for patients to purchase to dispose of unwanted medications in all our CVS locations.

CVS Health appreciates the opportunity to submit comments for the proposed addition of these regulations. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,



Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health

Martinez, Lori@DCA

From: Ppsi Ppsi <ppsi@aol.com>
Sent: Wednesday, February 17, 2016 6:09 PM
To: Herold, Virginia@DCA; ramonc@qhconcepts.com; Martinez, Lori@DCA
Cc: heidi@calpsc.org; jreid@californiaalliance.org; henekelly@aol.com; ksmith@californiaalliance.org
Subject: RE: Title 16 BoP hearing April 13, 2016 10 AM-USC, Irvine, California

Ginny:

re: Title 16 BoP hearing April 13, 2016 10 AM-USC, Irvine, California

PPSI just received the above notice for the april 13 hearing on takeback of drugs and the only thing I can see after reading the entire proposal **"YOU GOT TO BE KIDDING" !!! ??**

PPSI, a 501(c)(3) nonprofit, public health, consumer, pharmacy, education organization has the following concerns, regarding your proposed takeback program and would like them introduced into the official record, since we cannot attend the USC Orange County campus on April 13 at 10 AM, in Irvine, as follows:

1. Why are you having this hearing in Orange County, instead of Sacramento ?
2. Can we have a second hearing in Sacramento for those people who cannot make it to Orange County, due to the high cost of travel and expenses ?
3. Your proposal that employee pharmacists pay for takebacks is ludicrous.
4. In no other industry, including paint, batteries, light bulbs, computers, fluorescent lights or needle exchange takebacks, does the employee cover the cost of removing hazardous material that is causing public health harm.
5. In all other civilized countries of the world, bug PhRMA pays for takeback of outdated, unwanted, unused, expired prescription medications, including Canada, Mexico and the UK and EU countries.
6. Your economic figures of charging the employee pharmacists for takebacks is outrageous, especially the 10% who would participate, if any at all would, in fact, participate !! **WOULD YOU KICKBACK MONEY FROM YOUR BUREAUCRATIC SALARY TO PAY FOR PRESCRIPTION DRUGS, SINCE YOU ARE THE CONSUMER USER OF THESE LIFE SAVING MEDICATIONS ? WHO DREAMT UP THIS PROPOSAL ?**
7. Marin county, a model program for takebacks, has instituted, since 2004, a program where pharmacies collect the unwanted, outdated, expired RX's, patients put the pills only in unmarked baggies, with no labels, bring them into the pharmacies without labels and put in a bin, where the Marin County Department of Health then picks them up once a month and incinerates them. . **THIS PROGRAM HAS WORKED FOR 11 YEARS. YOUR NEW PROPOSAL WOULD KINOTHING IS FLUSHED DOWN THE DRAIN OR PUT IN THE GARBAGE TO END UP IN THE WATER SUPPLY OR LANDFILL, WHEN IT RAINS !!**
8. Walgreens has just come out with kiosks and bins in 500 pharmacies in the USA, including 68 in California, which they are paying for out of their own pocket. However, Walgreens is the first of the chains to do this.
QUESTION-- IF WALGREENS, WHICH IS WORTH OVER \$400 BILLION CAN AFFORD TO DO THIS, WHY CANNOT THE REST OF THE CHAINS IN CALIFORNIA DO THIS, THROUGH 12-15% OF THEIR PHARMACIES STATEWIDE ? WHAT DOES WALGREENS KNOW OR DO THAT CVS, RITE AID, SAFEWAY, ETC. SHOULD BE DOING ?
9. Kaiser Permanente put in 4 bins for takeback of drugs in the San Rafael area of Marin County and they have currently removed these bins for some strange reason. if Walgreens can put in 68 bins for takebacks in California,. why cannot kaiser permanente have at least 150 bins in their 54 facilities in California, since they made over \$4 billion in profits last year and account for over 25% of the California population, with over 10 million patients enrolled ?

10. Your idea of pharmacies volunteering to do this is ludicrous!! Big PhRMA did 5 billion prescriptions in prescriptions last year and over 700 million RX's were filled in California alone. why aren't they paying the bill and also for the incineration and the cost of doing business, similar to paint, batteries, light bulbs, computers, fluorescent lights or needle exchange takebacks, does the employee cover the cost of removing hazardous material that is causing public health harm.

Pharmacists are stressed out now, being overworked and underpaid and many, many of them, including my Touro pharmacy intern students have loans to pay back, exceeding \$300,000 on their costs of education. **AND THE CALIFORNIA BOP WANTS PHARMACISTS TO PAY FOR TAKEBACKS FROM THIS \$3 TRILLION BIG PhRMA INDUSTRY..... YOU GOTTA BE KIDDING ME, GINNY !! WHAT WAS YOUR GROUP SMOKING WHEN YOU PUT THE ONUS ON THE EMPLOYEE PHARMACIST TO PAY FOR THIS RIDICULOUS SCHEME ?**

I have discussed this all over the telephone with your expert contact person, Lori Martinez, Pharm.D., email above and have expressed our consumer, public health issues.

In the name of consumer and public health safety, the CA BOP needs to get these drugs out of the medicine cabinets and incinerated to prevent teens from their "RAVE" parties and deaths by overdose.

WE IN MARIN COUNTY HAVE HAD 27 DEATHS FROM OPIOID OVERDOSES, RAVE PARTIES AND IS THE HIGHEST IN CALIFORNIA, PER CAPITA, OF ANY OF THE 58 CALIFORNIA COUNTIES.

see: "Marin officials want drug companies to fund disposal of expired meds"

link: <http://www.marinij.com/article/NO/20150326/NEWS/150329860>

Time to put the onus on big PhRMA and make them pay. We are only talking about 1 cent per prescription, which is peanuts to this industry, which spends billions of dollars on lobbying and last year spent over 3 trillion dollars on advertising or some ridiculous amount.

Please introduce this before your April 13 hearing and PPSI formally requests another hearing in the Sacramento area, in addition to the April 13, Orange County, Irvine hearing.

Best,

Fred

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

Martinez, Lori@DCA

From: George Wang <george_wang@sirum.org>
Sent: Monday, March 28, 2016 3:47 PM
To: Martinez, Lori@DCA
Cc: Herold, Virginia@DCA
Subject: Proposed Text: Prescription Drug Take-Back Programs, Section 1776

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

We request the following amendments to the proposed text for Prescription Drug Take-Back Programs, Section 1776 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations.

Our intent for these amendments is to ensure that pharmacies can continue to lawfully receive returned non-controlled prescription drugs from facilities such as skilled nursing homes. We believe this issue should not be commingled with drug take-back programs.

The scope of the DEA promulgated regulations (Title 21, Code of Federal Regulations (CFR), sections 1300-1321) for drug take-back programs is limited to controlled substances. We ask that with regard to long-term care facilities, the scope of Section 1776 match the DEA's regulations and be limited to controlled substances. While we understand that patients may not be able to differentiate between controlled and non-controlled substances as outlined in the Board's Initial Statement of Reasons, in long-term care facilities, health care professionals -- not patients -- can/must differentiate between controlled and non-controlled substances as part of their duties. It is therefore unnecessary to treat controlled and non-controlled substances as the same in these settings.

1776.1 (f) (2) A pharmacy shall not accept or possess controlled substances prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities unless authorized to operate a drug take-back collection program.

1776.4 (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 controlled substances prescription drugs.

1776.4 (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded controlled substances 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.

Without these amendments, regulations proposed for Section 1776 change the practice of long-term care pharmacies for example to credit unused, non-controlled medication for private and public health plans, which would have a significant business impact to these pharmacies and long-term care facilities. We strongly urge you to accept our amendments.

Thank you,
George

--
George Wang, PhD
Co-Founder & Director
SIRUM | Saving Medicine : Saving Lives

Martinez, Lori@DCA

From: Buffum, John <John.Buffum@ucsf.edu>
Sent: Wednesday, February 17, 2016 8:36 PM
To: Ppsi Ppsi; Herold, Virginia@DCA; ramonc@qhconcepts.com; Martinez, Lori@DCA
Cc: heidi@calpsc.org; jreid@californiaalliance.org; henekelly@aol.com; ksmith@californiaalliance.org
Subject: RE: Title 16 BoP hearing April 13, 2016 10 AM-USC, Irvine, California

I agree with Fred. This would propose to undo all our progress towards getting unused drugs off the streets and out of landfills. It almost sounds like the drug companies, having lost in court, are trying a new tactic. Just who does the BOP represent?

John Buffum, PharmD, BCPP
Clinical Professor of Pharmacy, UCSF
Vice President, Marin County Pharmacists Association

From: Ppsi Ppsi [ppsi@aol.com]
Sent: Wednesday, February 17, 2016 6:09 PM
To: virginia.herold@dca.ca.gov; ramonc@qhconcepts.com; lori.martinez@dca.ca.gov
Cc: heidi@calpsc.org; jreid@californiaalliance.org; henekelly@aol.com; ksmith@californiaalliance.org
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Best,

Fred

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

Martinez, Lori@DCA

From: Janne Campbell <glasgowe@comcast.net>
Sent: Tuesday, February 16, 2016 10:06 AM
To: Martinez, Lori@DCA
Subject: Don't Obstruct Pharmacy-based Drug Take-Back Programs

Dear Dr. Gutierrez and Fellow Board Members

I am deeply concerned with the impacts unused medications have on water quality and public health, as well as the Board of Pharmacy's proposed rules that will actually discourage pharmacies from hosting medicine collection bins. Pharmacies provide an important public health service to the community and studies show that they are where the public wants to be able to safely dispose of medicines.

Because pharmacies have been shown to be the most effective collection sites, the U.S. Drug Enforcement Agency has established common sense rules that allow pharmacies to support drug takeback in a safe and secure manner. Pharmacies who volunteer to host bins in California have not experienced serious problems or legal issues and many of the fears expressed by some pharmacy interests are unsubstantiated.

The Board of Pharmacy does NOT need to develop extensive regulations. Instead it should simply acknowledge that California pharmacies can host safe medicine disposal bins if they follow the DEA rules. By proposing additional regulations and deliberating over a lengthy period of time, the Board has scared pharmacies that wish to host take-back bins now from doing so. In addition, by attempting to preempt those few ordinances that require pharmacy participation in manufacturer supported programs, you are interfering with the actions of elected officials who are acting on behalf of the public to protect public health. That is inappropriate for an unelected Board.

Instead of obstructing what are mostly voluntary actions by publicly responsible pharmacies, the Board of Pharmacy should promote such programs as a means of protecting public and environmental health. California pharmacies distribute medications and are the perfect and safe location to return them. I urge you to simply endorse the Drug Enforcement Agency's rules for pharmacy-based collection programs with all expediency and to desist from any effort to preempt local laws. Just because we cannot see the medicines washing up on the shore doesn't mean there is no danger to fish and us. We have in place laws to collect medical sharps why not medicines. Years ago we were also told by grocery stores and bottling companies that recycling would not work and guess what? people recycle bottles, cans, paper, metal and anything else that can be recycled. Throwing these medicines into the general trash is immoral. This is just the first step. The next will be finding a way to get it out of the water when it goes through the water and sewage treatment plants. We know it is having an effect on wild life and that too is immoral. Get a grip.

Janne Campbell
20 Berkeley Ave.
San Anselmo, CA 94960

Martinez, Lori@DCA

From: Mukhar, John <John.Mukhar@CityofPaloAlto.org>
Sent: Monday, March 28, 2016 4:26 PM
To: Martinez, Lori@DCA
Cc: Herold, Virginia@DCA; Williams, David@@bacwa.org; Heidi Sanborn; Bobel, Phil; North, Karin
Subject: City of Palo Alto Comments on the Proposal to add Article 9.1 "Prescription Drug Take-Back Programs"
Attachments: City of Palo Alto--Comments on the Proposal to add Article 9.1-Prescription Drug Take-Back Programs.pdf

Hello Ms. Martinez,

Attached you will find the City of Palo Alto's comments on the Proposal to add Article 9.1 ("Prescription Drug Take-Back Programs") to Division 17 of Title 16 of the California Code of Regulations.

The City of Palo Alto appreciates this opportunity to comment on the California Board of Pharmacy's (BOP) Proposed Regulations for Prescription Drug Take-Back Programs by adding Sections 1776 through 17776.6 to Article 9.1, Division 17 of Title 16 of the California Code of Regulations (Regulations).

The City of Palo Alto owns and operates the Palo Alto Regional Water Quality Control Plant (RWQCP), a wastewater treatment plant that serves a population of approximately 230,000 in the East Palo Alto Sanitary District and the cities of Los Altos, Los Altos Hills, Mountain View, Palo Alto, and Stanford University. Our agency is tasked with protecting water quality for our communities by collecting and treating wastewater. The City of Palo Alto has been a leader in developing pollution prevention and source control efforts, making it more convenient for the public to safely dispose of unwanted medications which reduces drug abuse, poisonings, medication mistakes, and water contamination. We have set-up and manage multiple drugs drop off locations around the City of Palo Alto and partner agencies, including at the Palo Alto Police Department, RWQCP, and Palo Alto Household Hazardous Waste Center.

If you have any questions, I could be reached via email or by phone on 650-329-2285

Regards
John Mukhar, P.E.
Department of Public Works – Environmental Service
City of Palo Alto



PUBLIC WORKS

CITY OF
**PALO
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March 25, 2016

Board of Pharmacy – attn. Lori Martinez
1625 North Market Ste. N-219
Sacramento, CA 95834
lori.martinez@dca.ca.gov

Subject: Comments on the Proposal to add Article 9.1 (“Prescription Drug Take-Back Programs”) to Division 17 of Title 16 of the California Code of Regulations

Dear Ms. Martinez:

The City of Palo Alto appreciates this opportunity to comment on the California Board of Pharmacy’s (BOP) Proposed Regulations for Prescription Drug Take-Back Programs by adding Sections 1776 through 17776.6 to Article 9.1, Division 17 of Title 16 of the California Code of Regulations (Regulations).

The City of Palo Alto owns and operates the Palo Alto Regional Water Quality Control Plant (RWQCP), a wastewater treatment plant that serves a population of approximately 230,000 in the East Palo Alto Sanitary District and the cities of Los Altos, Los Altos Hills, Mountain View, Palo Alto, and Stanford University. Our agency is tasked with protecting water quality for our communities by collecting and treating wastewater. The City of Palo Alto has been a leader in developing pollution prevention and source control efforts, making it more convenient for the public to safely dispose of unwanted medications which reduces drug abuse, poisonings, medication mistakes, and water contamination. We have set-up and manage multiple drugs drop off locations around the City of Palo Alto and partner agencies, including at the Palo Alto Police Department, RWQCP, and Palo Alto Household Hazardous Waste Center.

The City of Palo Alto submits the following feedback and recommendations for your consideration, organized as follows:

- Requirement for Incineration Limits Alternative Destructive Technologies
- Several Collection Requirements Appear to be More Stringent Than DEA Requirements, Which May Lead to Reduced Safe Collection
- Suggested Clarifying Language

Requirement for Incineration Limits Alternative Destructive Technologies

1776.5(b) “A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately licensed DEA distributor.”

1776.5(e) “Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. . .”



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Incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable. One such method is incineration. Future alternatives may include plasma or pyrolysis technologies which ionize wastes without the air emissions associated with incineration. The DEA explicitly states:

"the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration . . ." (Federal Register, p. 53536).

We are requesting that you do not further restrict what is required in the DEA regulation and leave Title 16 open to future destruction technologies. Please delete references to incineration and replace with statements such as "rendered non-retrievable" or a "destruction site" (rather than "incineration site").

II. Several Collection Requirements Appear to be More Stringent Than DEA Requirements, Which May Lead to Reduced Safe Collection

The Secure and Responsible Drug Disposal Act of 2010 and the United States Drug Enforcement Agencies (DEA) Regulations, which implemented the Act, were established in order to provide citizens with increased access to properly dispose of medications classified as controlled substances. In several instances, the proposed Regulations are more stringent than the DEA Regulations. This may have the unfortunate outcome of reducing consumer access to proper medication disposal. Below we identify such instances, along with suggested revisions:

1776.2(e) "The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6".

1776.6(a)(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."

1776.6(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."

These three provisions require a pharmacy to create and maintain these records; meanwhile a non-pharmacy retailer can conduct a mail back program without this requirement. Further, these envelopes and packages are already being tracked by the collector, and do not need to be additionally tracked. Per the DEA, "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§ 1317.70)."

As for 1776.6(a)(1), pharmacies are not collectors with regard to mail-back envelopes. Rather, the collector is the reverse distributor to which the envelopes are mailed from the ultimate user. These recordkeeping duties should not be required for pharmacies which simply hand out the envelopes because they are already required for the reverse distributors accepting them for destruction. Requiring them for pharmacies would make it too onerous for many pharmacies to participate in drug take-back programs as providers of mail-back envelopes.

We recommend that the language be removed that requires pharmacies participating in a mail-back program to maintain records beyond what is required by the DEA and remove language that suggests that pharmacies participating in mail-back programs need to be registered as collectors.

1776.3(a) and (c) ". . . In 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 patients from access to the collection receptacle by some means."

Restricting the placement of collection receptacles in pharmacies may diminish pharmacy participation. The DEA clearly states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked serves no benefit since it would be just as easy to place unwanted drugs next to a physical barrier as it would be to place medicine next to a locked bin.

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

We recommend removing language about physically blocking access, and reverting to DEA language in order to avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.

1776.3(b) ". . . The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas."

This provision goes beyond the DEA regulation in a subtle but potentially significant way. As the DEA recognizes, hospitals can be unique in their design and need to have flexibility in the manner in which they participate in Safe Medicine Disposal Programs. The DEA regulations imply that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. We do not want to discourage hospitals from participating in Safe Medicine Disposal programs by making it more difficult for them to do so. Please simply delete the word 'pharmacy' from 1776.3(b) so that it reads as the DEA: "visible to employees", not "visible to pharmacy employees."

1776.3(h) ". . . A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. 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." (Note: similar language is also included in 1776.4(h)(2)).

Requiring rigid containers to "meet standards of the USDOT for transport of medical waste" exceeds the requirements of the DEA regulation, which does not mention medical waste. There is a lot of confusion around the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste. HSC §117700 says, "Medical waste does not include . . . (e) Hazardous waste, radioactive waste, or household waste . . ." Moreover, it appears that home-generated pharmaceutical waste is still considered household waste once it's collected and consolidated. Alison Dabney, Chief of the California Department of Public Health's Medical Waste Management Program wrote on November 18, 2015, "A waste-to-energy facility's permit that prohibits it from accepting medical waste in California does not prohibit the facility from accepting consolidated home-generated pharmaceutical waste, since the current law (Health and Safety Code, §§117600-118360) does not prohibit it. However, any local ordinances regarding the disposal of these items should also be reviewed."

One of the reasons that we are concerned about using medical waste transport regulations is that there are a lot of exemptions that surround the regulation of medical waste transport, and this makes it very difficult to determine what is required. For example, while the definition of medical waste in the Health and Safety Code does include pharmaceutical waste, they exempt pharmaceutical wastes that are being hauled by a reverse distributor (Health and Safety Code Section 117690). It is unclear if this exemption might nullify the otherwise applicable DOT regulations.

Moreover, it is not clear what exactly would qualify as meeting the USDOT standards. It is unclear whether a cardboard box, currently an industry standard, would meet the requirements (tight-fitting cover, rigid...). Or would a cardboard box in combination with a plastic bag combine to fulfill the requirements of the "inner liner" as the inner liner is already required to be waterproof? Dis-allowing cardboard boxes would cause the price of disposal to substantially increase.

One approach could be to modify text to read: "A rigid container may be disposable, reusable, or recyclable (example: cardboard box). Rigid containers shall be capable of being sealed and be kept clean and in good repair. Rigid containers may be of any color. All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations."

1776.3(j) "location in the pharmacy no longer than three days"

It is our understanding that the DEA regulation only specifies a three day holding period in Long-Term Care Facilities. In the case of pharmacies, the DEA dictates only that liners be moved "promptly". The DEA specifically declined to clarify what would constitute a "prompt" action (Federal Register p. 53528). Strictly defining the length of time inner liners can be stored could increase the burden on pharmacies and thereby decrease their participation in medicine take-back programs.

1776.4 Collection in Skilled Nursing Facilities

We would like to avoid restricting which types of facilities are permitted to participate in medicine take-back programs. DEA defines Long-Term Care Facilities on page 53540 of the Federal Register as "a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients." This appears to have a broader meaning than the Skilled Nursing Facility referred to by the Board and defined in the Health and Safety Code section 1250(c) as "a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis."

We request that you expand the referenced definition of Skilled Nursing Facilities to include language from the Health and Safety Code section 1418 would more clearly and consistently reflect DEA language; this could be accomplished by including California's definition of Long Term Health Care Facilities.

1776.4(n) "Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility."

The DEA regulation allows "the installation, removal, transfer, and storage of inner liners...by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility" in addition to allowing these activities to occur under the supervision of two pharmacy employees (§1317.80(c)). We are asking that you do not restrict any of the allowable activities to just two pharmacy employees.

The BOP language above appears to state that pharmacy employees can themselves directly deliver sealed inner liners to a reverse distributor. However, the DEA says: "...the practitioner may destroy the collected substances by delivering the sealed inner liners to a reverse distributor or distributor's registered location by common or contract carrier, or a reverse distributor or distributor may pick-up sealed inner liners at the LTCF" (Federal Register p. 53543 and §1317.05). Per our interpretation this does not allow pharmacy employees to transport the sealed inner liners themselves. Please clarify.

1776.6(a)(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."

According to the DEA, this is the record that the collector is required to keep (§ 1304.22(f)). Per our previous comments, please clarify that this applies only to the collector, which in this case is the reverse distributor, not the pharmacy. These recordkeeping duties should not be required for pharmacies who simply hand out the envelopes because they are already required for the reverse distributors accepting them for destruction. Requiring them for pharmacies may make it too onerous for pharmacies to participate in drug take-back programs.

III. Suggested Clarifying Language

There are a few locations in the proposed Regulation in which it appears that the language could be slightly modified to clarify the intent. We provide our feedback below.

Section 1776: Authorization: *All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods.*"

Vigilance on the part of authorized collectors is inconsistent with the DEA's Regulations that prohibit authorized collectors from handling and/or sorting through collected drugs. Moreover, the Board's own proposed regulation section 1776.1(f)(1) stating "Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public."

We recommend the following clarification: "All board-licensed authorized collectors should, to the extent that is practicable, be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods."

Section 1776: Authorization: *"Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article."*

This provision would remove the ability for entities that choose to not serve as authorized collectors but would choose to distribute mail-back envelopes to customers from partnering with authorized collectors to provide mail-back envelopes and thus significantly reduce the number of locations that would provide mail-back envelopes to consumers with no perceivable benefit. The DEA has determined such in Section § 1317.70 (c) of their Regulations which states "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section."

We recommend that the text be rephrased so it is clear that pharmacies can participate in drug take-back programs by providing mail-back envelopes without being registered as a collector. If the Board wishes to require pharmacies to be licensed and in good standing in order to offer mail-back envelopes, the following text could suffice. "Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board may participate in drug take-back programs authorized under this article."

1776.1(e) *"The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers..."*

As currently worded, this section implies that pharmacies are not permitted to have a separate bin for sharps

collection. Therefore, we recommend that the text be modified to specify this provision is specific to drug collection receptacles.

1776.1(g) "A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program."

This provision implies that if a pharmacy decides to partner with an authorized collector to provide mail-back envelopes, they must be registered as an authorized collector; this is not a requirement per DEA Regulation. We recommend a minor edit to provide clarification: "A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for the purposes of operating a prescription drug take-back collection receptacle."

1776.2(a) "Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location."

This could be a good place to say that pharmacies could participate in this way without registering as collectors. For instance, the text could be modified to say: "Pharmacies that would like to provide prescription drug take-back services without registering as a collector may do so by establishing mail back services, whereby ..."

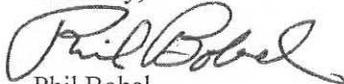
1776.5(a) "A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered DEA as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section."

The DEA-registered Reverse Distributor is not the collector except in the case of mail-backs. Consider modifying the text to read "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. Once received, the reverse distributor shall establish records required by this section."

The City of Palo Alto appreciates the difficult task the Board has undertaken to develop the proposed Regulations. Given that the purpose of drug take-back programs is to provide increased convenience for proper disposal, we hope you will seek to have the Regulations align closely with the DEA Regulations while providing flexibility for local ordinances and future destruction technologies.

Should you have any questions about our feedback, please feel free to contact Karin North the Watershed Protection Manager at 650-329-2104.

Sincerely,



Phil Bobel
Assistant Director
Environmental Services – Public Works
City of Palo Alto

cc: Executive Director of the Board of Pharmacy
Bay Area Clean Water Agencies (BACWA)
California Product Stewardship Council

Martinez, Lori@DCA

From: Steve.W.Gray@kp.org
Sent: Monday, March 28, 2016 3:22 PM
To: Martinez, Lori@DCA
Cc: Perry.Flowers@kp.org
Subject: KP Response to Proposed Take Back Regulation 1760
Attachments: Final KP Response to BOP Proposed Take Back Regulations 1760 Mar 28 2016 dk.doc

Thank you for the opportunity to submit comments to the Board's Proposed Take Back Regulation 1760
Please accept our comments and please confirm receipt

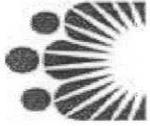
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March 28, 2016

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

c/o California Board of Pharmacy

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

On behalf of the Pharmacy Operations department of Kaiser Foundation Hospitals, and Kaiser Foundation Health Plan, we respectfully submit in "Attachment 1", recommendations to the Board of Pharmacy's proposal to change Title 16 CCR Articles 4.5, 7 and 7.5. We ask for your careful review and consideration of our recommendations. We believe that changes to what has been published are necessary to promote optimal safety and access to high quality, affordable care. We respectfully request that if the Board of Pharmacy disagrees with one or more of our proposals, that the rationale for that disagreement be clearly stated.

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

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

Attachment 1

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

Introductory Comments:

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

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

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

Proposed Board of Pharmacy Regulations	Recommended Changes and Rationale and Impact Statements
<p>Section 1776 Prescription Drug Take-Back Programs: Authorization <i>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 to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.</i> <i>All board-licensed authorized collectors should be vigilant to prevent 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: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer</i></p>	<p>Section 1776 Prescription Drug Take-Back Programs: Authorization <u>Recommended Change</u> <i>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 to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.</i> <i>All board-licensed authorized collectors should be vigilant to prevent 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: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers,</i></p>

<p>chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).</p> <p>Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.</p> <p>Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.</p>	<p>radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate conduct in drug take back programs authorized under this article.</p> <p>Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.</p> <p>Rationale</p> <p>The use of the word “participate” is confusing. For clarity the Board should use the same terminology as the federal DEA regulations – which is to “conduct” and it means that the pharmacies, etc. are registered with the DEA to “conduct” programs with take back receptacles, either on site in the pharmacy or hospitals or certain nursing facilities, etc. A pharmacy, hospital or other entity, licensed by the Board or otherwise, does not have to “conduct” a program with take back receptacles. They may partner with a program to only dispense mail-back envelopes or packages.</p> <p>Impact</p> <p>Unless changed, the wording could confuse pharmacies that desire to dispense properly addressed and constructed postage prepaid mail-back envelopes or packages. The result would be a diminished effectiveness of the Safe Drug/Medication Disposal programs throughout California.</p>
<p>Section 1776.1 Pharmacies</p> <p>(a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.</p> <p>(b) Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section</p>	<p>Section 1776.1 Pharmacies</p> <p>Recommended Change</p> <p>(a) <i>Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary. No pharmacy may be mandated by any State regulation or local ordinance to participate as a collector of dangerous drugs, including but not limited to controlled substances.</i></p> <p>Rationale</p> <p>The proposed regulation statement is NOT clear about the Board’s intent. It</p>

1250(c).
 (c) There are multiple federal and state 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) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.
 (e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's 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 shall be placed on collection receptacles as referenced in section 1776.3.
 (f) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.
 (1) Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.
 (2) A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
 (3) A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock in a drug take-back collection receptacle. Instead the pharmacy must return these items to a reverse distributor.

could mean that the Board considers participation and voluntary but would allow local County and City ordinances to mandate "collection receptacle" participation.

Impact

Without the clarification many pharmacies that are neither designed, equipped nor staffed to adequately protect the public, their patients or their employees may be forced into "collection receptacle" participation or lengthy and expensive court situations that distract from patient care and clog the court system. These include, but are not limited to, pharmacies, hospitals and clinics that may be on probation, have lost critical personnel, are in high risk areas or are literally "closed door" pharmacies that are not open to the public and whose mandatory participation is kept undisclosed to the public for security purposes. Allowing other agencies or jurisdictions to mandate "collection receptacle" participation may cause some pharmacies in some critical access areas to cease operations and thus decrease patient and public access to pharmacy care and services. Further, subsection (c) requires all pharmacies that do participate with "collection receptacles" to follow DEA regulations and other federal law. Those requirements mandate close supervision and security of the "collection receptacles" at all times. A mandate to participate with "collection receptacles" would require a substantial increase in staffing in many pharmacies especially during "extended hours", weekends and holidays, thus it would likely require such pharmacies to reduce their hours of service, thus also reducing the patients, consumers and the public in their communities access to pharmacy care and service.

Recommended Change

(d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including products classified as either federal or State controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.

<p><i>(g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back 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.</i></p> <p><i>(h) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:</i></p> <p><i>(1) Any pharmacy that ceases to operate a drug take-back program shall notify the board within 30 days on a form designated by the board. If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the board within 30 days.</i></p> <p><i>(2) Any pharmacy operating a mail back program or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.</i></p> <p><i>(3) Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board within 14 days.</i></p> <p><i>(4) Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.</i></p> <p><i>(i) If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.</i></p> <p><i>Note: Authority cited: Section 4005, Business and Professions Code.</i></p> <p><i>Reference: Section 4005, Business and Professions Code and Sections 1301.71, 1317.30, 1317.40, Title 21 Code of Federal Regulations.</i></p>	<p>Rationale</p> <p>The proposed language is unclear because some products listed as “controlled substances” under State law are not necessarily “controlled substances” under federal law. Conversely, some products that are listed as “controlled substances” under federal law are not “dangerous drugs” under State law. States have the authority to classify products as “controlled substances” that are commonly prescribed and dispensed products that are not controlled substances under federal law. For example, Fioricet is an analgesic that is a “controlled substance” under State law but not under federal law. Section 4021 of the California Business and Professions Code defines generally for pharmacy practice to items listed in California Health and Safety Code’s Chapter 2 of Division 10, not in any federal statute or regulation. However, subsection (c) of the proposed regulation requires compliance with “federal and state requirements governing the collection and destruction of dangerous drugs”.</p> <p>Impact</p> <p>Both the professional obligations of pharmacists and pharmacies as well as their criminal and civil obligations will be confused if they participate in these programs intended to benefit the safety of patients, the public and the environment. It will discourage participation.</p> <p>Recommended Change</p> <p>(e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s 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 shall be placed on collection receptacles as referenced in section 1776.3.</p> <p>Rationale</p> <p>Subsection “(e)” is unclear, vague and inconsistent with the Board’s findings and intent. Section 1776.3(m) already has a requirement to post a sign on a collection receptacle informing patients, consumers and the public in general that the specified types of products (e.g. syringes and needles, antineoplastic</p>
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agents, etc.) are not to be placed in the receptacles. However, it is common knowledge that very often laypersons do not know to which products these descriptions apply. -The Board [see subsection "(f)(1)]as well as the federal DEA regulations prohibit pharmacists or pharmacy personnel from handling or sorting products before they are put in the receptacles.

Impact

Thus it is very likely that consumers, patients and especially their family, caregivers and agents will place those prohibited items in the receptacles. Thus subsection "(e)" "expressly prohibited" language will subject pharmacies, hospitals and other entities governed by these regulations to regulatory and civil liability. While it is understandable why such items "should not" be placed in the receptacles, the Board's and the DEA's have removed the only method of assuring that they are not placed in the receptacles.

Recommended Change

(f)(2) *A pharmacy shall not ~~accept or possess~~ use prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities as part of programs for disposal of drugs possessed by consumers, patients, their caregivers of agents for redistribution, dispensing or compounding.*

Rationale

Other California law allows the collection of unused pharmaceuticals that have not been out of the possession and control of health care personnel and that have been properly stored and protected for purposes of redistribution and dispensing to other needy patients.

Impact

Pharmacies participating as collectors in programs for consumers, patients, etc. to dispose of unwanted drugs will be discouraged from participating in other programs established by the State for the care of financially needy patients and for the avoidance of waste and pollution which are core public motives for such programs and the establishment of unwanted drug collection programs.

Recommended Change

(g) *A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone prohibited from pharmacy employment by the DEA or the State because of a conviction convicted of a felony related to controlled substances, or anyone who is prohibited from pharmacy employment by the DEA or the State because he or she has had a DEA registration or State pharmacy permit denied, surrendered or revoked.*

Rationale

The State and the DEA have processes where by prior convictions and prior denials, surrenders, or revocations of pharmacy permits and registrations, respectively, can be excused.

Impact

Such a strict prohibition would frustrate the intent of public policy to diminish the potential harm to patients, their families, the public and the environment by reducing the number of pharmacies that could participate as collectors even though such transgressions, for various purposes under the control of the State and the DEA, had been forgiven.

Recommended Change

(h) (2) *Any pharmacy operating a mail back program under which the drugs are mailed to the pharmacy or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.*

Rationale

The provision as written is misleading and inconsistent with current practices, the Board's intent or DEA regulations regarding DEA controlled substances. Pharmacies may be involved in two distinct types of programs by which "mail back" envelopes or packages are distributed or dispensed. If the pharmacy is distributing or dispensing envelopes or packages that have the pharmacy's address preprinted on the envelope or package, then the pharmacy is acting as

a "collector". But if the pharmacy is distributing or dispensing envelopes or packages that are addressed to an entity that is properly registered with the Board of Pharmacy and the DEA then the pharmacy is NOT a "collector" for either the purposes of this regulations or the DEA regulations. Pharmacies and other entities not under the Board's jurisdiction are currently and have long been involved in distributing envelopes and packages for the disposal of prescription drugs, including controlled substances. Most of the time such envelopes are "sold" to the consumers or patients to cover the cost of postage and collection and disposal at the DEA authorized "collector" location. Some pharmacies and other entities distribute/dispense the envelopes at NO COST to the consumers and patients. These programs have been moderately successful at furthering the intent of public policy about improving public and patient safety as well as protecting the environment. It is envisioned that the "mail back" programs will be even more successful if and/or when the cost of the envelopes as well as their collection and disposal are covered so they can be dispensed and distributed to consumers and patients without charge.

Impact

If this subsection is not clarified, many pharmacies that could and would be convenient and proper outlets for the "mail back" envelopes and packages will not participate. Pharmacies that merely participate in these public-benefit programs are only "partners" with the registered collectors. This is a recognized relationship in 21 CFR 1317.70(c) that states; "*Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection of controlled substances by common or contract carrier. Any person may **partner with a collector** or law enforcement to make such packages available in accordance with this section.*" [emphasis added]

Though the Board could also require the "partner" pharmacies to register with the Board and provide other notices as specified, the Board should not confuse pharmacies and others about the two distinct types of "mail back" participation. The Board should also re-consider the necessity of having the "partner" pharmacies register with the Board and its potential for discouraging their participation. The Board heard many reasons why "mail back" is and

<p>should be the public's preferred methodology.</p> <p><u>Recommended Change</u> <i>(i) If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the Board and the Drug Enforcement Administration within 30 days.</i></p> <p><u>Rationale</u> Since previous subsection requires such pharmacies to register with the Board of pharmacy, it seems there should be a similar requirement to notify the Board when that situation ceases. Otherwise the Board will have inaccurate data and may be advising the public or other entities erroneously and potentially using resources less efficiently.</p> <p><u>Impact</u> Without this change there will be significant confusion, at least.</p>	
<p>1776.2 Mail Back Package and Envelope Services from Pharmacies</p> <p><u>Recommended Changes</u> <i>(a) Pharmacies that provide prescription drug take-back services may also do so by establishing either conducting their own or partnering with another entity for mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.</i></p> <p><u>Rationale</u> This subsection is misleading as worded. Under California and federal law a pharmacy or any other entity does not have to be either licensed with the Board of Pharmacy nor Registered with the DEA to distribute properly addressed postage pre-paid mail-back envelopes and packages that are addressed to an entity, e.g. Reverse Distributor, that is properly licensed and Registered.</p> <p><u>Impact</u> Unless changed, this provision will discourage of many, perhaps most, pharmacies from at trying to address the goals of the Safe Drug/Medicine Disposal programs by dispensing, free or otherwise, DEA approved mail-back envelopes/packages.</p>	<p>1776.2 Mail Back Package and Envelope Services from Pharmacies</p> <p><i>(a) Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.</i></p> <p><i>(b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate for ensuring the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.</i></p> <p><i>(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.</i></p> <p><i>(d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.</i></p> <p><i>(e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.</i></p>

(f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.

(g) Once filled with unwanted prescription drugs, the mail back packages or envelopes 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.

Recommended Changes

(b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ~~ensuring~~ checking upon receipt of mail-back envelopes or packages that the preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that are listed on official Board and DEA sites to comply with this section.

Rationale

The current wording implies and unreasonable and impractical standard to verify the address against a government listing every time one envelope or package received from a partner entity is dispensed to a patient.

Impact

Such an unreasonable and impractical standard will discourage of many, perhaps most, pharmacies from at trying to address the goals of the Safe Drug/Medicine Disposal programs by dispensing, free or otherwise, DEA approved mail-back envelopes/packages.

Recommended Changes

(d) ~~The~~ If a pharmacy is a collector and distributes or dispenses preaddressed envelopes ~~and~~ or packages that are addressed to that pharmacy, the envelopes or packages shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.

Rationale

This provision is unclear and confusing because it does not distinguish be pharmacies that are collectors that have the "mail back" envelopes and packages addressed back to that pharmacy and other pharmacies that may be collectors but do not have "mail back" envelopes and packages addressed back to that pharmacy. It even confuses situations regarding pharmacies that are NOT collectors but merely dispense or distribute "mail back" envelopes or packages as a "partner" (see above) with a collector. "Since it is possible, though unlikely, that a pharmacy will be a collector if it only dispenses or distributes "mail back" envelopes or packages as a "partner" (see above) the

subsection should be modified.

Also, collectors that are not under the Board's jurisdiction are not required by the DEA to have serial numbers on their "mail back" envelopes and packages. Current and long-standing practice regarding such "mail back" envelopes and packages without serial has apparently not been a concern of the DEA. Such packages are handled through federal employees of the US Postal department until they reach the collector's site where they are properly disposed of as part of operations that are approved and inspected by the DEA.

Impact

If this subsection is not clarified, many pharmacies that could and would be convenient and proper outlets for the "mail back" envelopes and packages will not participate. The "partner" collectors will simply not send the serial numbered "mail back" envelopes and packages. Pharmacies that merely participate in these public-benefit programs are only "partners" with the registered collectors. This is a recognized relationship in 21 CFR 1317.70(c) that states; "Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection of controlled substances by common or contract carrier. Any person may **partner with a collector** or law enforcement to make such packages available in accordance with this section." [emphasis added]

Recommended Changes

(e) The A collector pharmacy that registers with the DEA to conduct programs with receptacles for collecting unwanted controlled substances and for distributing it own mail back envelopes and packages shall create and maintain records verifications required by section 4776.6-1776.2(b) or by the DEA.

Rationale

The DEA does not require the recordkeeping records for mail-back envelopes and packages as proposed in section 1776. For reasons stated below, the Board should not require individual serial numbers on mail-back envelope or recordkeeping per each serial number. The Board could require a record of the verification per 1776.2(b).

<p>Impact</p> <p>If this subsection is not so limited or omitted, many pharmacies that could and would be convenient and proper outlets for the “mail back” envelopes and packages will not participate. The “partner” collectors will simply not send the serial numbered “mail back” envelopes and packages. Pharmacies that merely participate in these public-benefit programs are only “partners” with the registered collectors. This is a recognized relationship in 21 CFR 1317.70(c) that states; “Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section.”</p>	<p>1776.3 Collection Receptacles in Pharmacies</p> <p>(a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In 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 patients from access to the collection receptacle by some means.</p> <p>(b) The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.</p> <p>(c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the</p>
<p>1776.3 Collection Receptacles in Pharmacies</p> <p>Recommended Change</p> <p>(d) The receptacle shall include a small opening that allows deposit of most of the original containers in which the drugs were dispensed into the inside of the receptacle and directly into the inner liner without the ability for a consumer to retrieve the drugs or drug containers once they are deposited into the receptacle.</p> <p>Rationale</p> <p>It has been noted by Poison Control center experts in government and other such centers, that some “Safe Drug/Medicine” program “collection receptacles” only have narrow slots through which consumers and patients cannot insert typical prescription vials. Some of such programs ask the consumers and patients to empty the unwanted prescription drugs in to plastic bags to bring to the collection site without the original containers so that the “pills” can be inserted directly into the receptacle through a narrow slot. Unfortunately, it has been noted that this can have significant potentially dangerous and other consequences. First, if the drugs are taken from the original “child resistant” prescription vials at the patient’s residence, the protection of children is diminished. Apparently such plastic bags are innocently started but not necessarily promptly taken to the site for disposal,</p>	

collection receptacle is also physically blocked from 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.

(e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.

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

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

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

(g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.

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

or they are taken only to find the intended receptacle not available/closed and are taken back home or disposed of in nearby trash.

Another consequence is that such drugs, which often do include controlled substances, when removed from their original dispensed containers present, at best, situations of confusion if law enforcement challenges the patient's, or the patient's family member's or caregiver's legitimate ability to possess the drugs.

Further, drugs, especially for the seriously infirm or elderly or for those who need help with adherence scheduling, are often removed from their original containers and put in "calendar pill trays" and other similar containers that cannot be inserted through narrow slots.

Lastly, there have been reports of receptacles used by programs that had narrow slots used to encourage the deposit of loose pills without their containers have been accessed via narrow vacuum hoses that simply sucked out the loose pills – thus foiling the intended security.

Common so called "justifications" for a narrow slot, is that the program does not want the expense of disposal of the containers, and, the patient's privacy would be violated if the original Rx containers were included. Neither is valid. The first should be a part of the program. The second ignores that the receptacles are to be destroyed as a whole with human inspection of the contents.

Impact

Without this specification change to the receptacles, much of the safety value of the "Safe Drug/Medicine Disposal" programs will be missed, with children and the infirm being the most vulnerable.

Recommended Change

(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 Schedule I drugs. Labeling shall also identify 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

<p>in good repair.</p> <p>(i) The liner may be removed from a locked receptacle only by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated.</p> <p>(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 days.</p> <p>(k) The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:</p> <p>(1) The unique identification numbers of all unused liners in possession of the pharmacy,</p> <p>(2) The unique identification number and dates a liner is placed in the collection receptacle,</p> <p>(3) The date the liner is removed from the collection receptacle,</p> <p>(4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and</p> <p>(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.</p> <p>(l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a 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.</p> <p>(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 Schedule I drugs. Labeling shall also identify that medical</p>	<p>receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.</p> <p>(n) The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process. <u>The signage should also indicate the available options for disposal of sharps. The pharmacy or other involved entities shall not be liable for adverse consequences if consumers violate the prohibitions indicated on the signage. The signage shall indicate that the person placing the items into the receptacle shall be responsible for violation of the prohibitions listed on the signage.</u></p> <p>Rationale</p> <p>The fact simply is that the vast majority of consumers do not know which drugs or substances are Schedule I or which products are “antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs)”. Consumers are highly likely to put Schedule I drugs/substances or “antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs)” into the receptacles anyway. Or, they will try to engage the pharmacy staff into helping them determine which are Schedule I and to sort through the drugs/substances they intend to deposit – which would be a violation of both this regulation and the DEA regulations. Further it seems that one of the significant public safety benefits of the “Safe Drug Disposal Programs” is to provide a convenient means to dispose of all drugs, perhaps especially any Schedule 1 drugs.</p> <p>A significant number of prescription drugs are dispensed to consumers in syringes and other products that would be listed as “sharps”. Experience with existing and pilot programs has shown that such sharps products, with and without drug residue are disposed of in these receptacles. Attempts to discourage this, such as providing receptacles with only narrow slots, have not been effective and have resulted in the dangerous handling of sharps in attempts to get them through the narrow slot and/or the leaving of the sharp near the receptacles or in nearby trash containers.</p>
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<p>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.</p> <p>(n) The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process.</p> <p>Note: Authority cited: Section 4005, Business and Professions Code.</p> <p>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.</p>	<p>1776.4 Collection in Skilled Nursing Facilities</p> <p>Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.</p> <p>(a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.</p> <p>(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.</p> <p>(1) Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.</p> <p>(2) Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.</p> <p>(3) Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board</p>
<p>1776.4 Collection in Skilled Nursing Facilities</p> <p>Recommended Change</p> <p>Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate with a <u>pharmacy in drug take-back programs involving controlled substances as authorized by this article.</u></p> <p>Rationale</p> <p>As stated, this regulation provision is confusing. The ability of the Board of Pharmacy to regulate an SNF about operating a drug take back program that does NOT involve controlled substances may be challenged as beyond the Board's scope of authority vs. the authority of the California Department of Public Health.</p> <p>Impact</p> <p>Without this or a similar change, the implementation of the regulation may be delayed with corresponding delay in public benefit.</p>	

within 30 days on a form designated by the board.

(4) Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy license.

(c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.

(d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.

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

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

(g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be 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.

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

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

(2) If the liner is not already itself rigid or already inside of a rigid container as

it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.

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

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

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

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

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

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

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

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

(m) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked,

<p>substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.</p> <p>(n) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.</p> <p>(o) Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.</p> <p>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</p>	
<p>1776.5 Reverse Distributors</p> <p>(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered DEA as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.</p> <p>(b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately licensed DEA distributor.</p> <p>(c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.</p> <p>(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.</p> <p>(e) Each reverse distributor with an incineration site shall maintain a record of</p>	<p>1776.5 Reverse Distributors</p> <p>Recommended Change</p> <p>(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered <u>with the DEA</u> as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.</p> <p>Rationale</p> <p>A clerical correction.</p> <p>Impact</p> <p>N/A</p> <p>Recommended Change</p> <p>(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, <u>except that if such person has had such conviction</u></p>

the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.

(f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:

- (1) Date of acquisition;
- (2) Number and the size (e.g., five 10-gallon liners, etc.);
- (3) Inventory number of each liner or envelope/package;
- (4) The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner;
- (5) The date, place and method of destruction;
- (6) Number of packages and inner liners received;
- (7) Number of packages and inner liners destroyed;
- (8) The number and signature of the two employees of the registrant that witnessed the destruction.

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

reversed or officially forgiven or who is eligible by the DEA now for registration shall be eligible for employment. Pharmacies participating with a Reverse Distributor in good faith shall not be liable for a violation by such Reverse Distributor.

Rationale

The statement about "who has access to or influence over controlled substances" is so vague and overly broad that it has no meaning within the industry. All Reverse Distributors that are registered with the DEA, are likely to legitimately handle controlled substances. Therefore the statement would seem to include all persons that determine the policies, procedures and practices for the Reverse Distributor. Pharmacies are not likely to be intimately involved in the hiring or personnel practices of any Reverse Distributor with whom it shares a relationship. Therefore it needs to be clear that such pharmacies are not liable for the specified transgressions of such Reverse Distributors.

Impact

If not changed, the provision will cause confusion among all entities the Board licenses. Further, the DEA has processes where past incidences that could have prevented an entity or person from being a "Registrant", or even past regulatory violations, can be forgiven or expunged. Similar processes exist for the Board of Pharmacy. If not changed, the provision would unnecessarily limit the number of persons or entities from which the public could now benefit from their participation.

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.

- (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

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

Recommended Change

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records.

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

(1) The collector or partner pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy; the number of

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) For pharmacies using collection receptacles, for each liner:

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

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

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

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

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

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 to a 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 envelopes or packages, date sent, and the number of unused envelopes or 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) (e) For sealed mail-back envelopes or packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope;

(d) (f) For sealed mail back envelopes or packages destroyed onsite by the reverse distributor collector: number of sealed mail-back envelopes or 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.

[Note: re-numbering of remaining sub-paragraphs would be required]

Rationale

There is no requirement under the DEA regulations for each mail-back envelope or package to be produced with a "unique identification number". Consequently, the current producers of such DEA approved envelopes do not put such identification number on their envelopes/packages.

If the intent of this regulation is to require pharmacies that participate in a Mail Back program to add a unique serial number from all such envelopes distributed by pharmacies nation-wide, WITHOUT duplication, it would be a huge undertaking that would delay the implementation of such mail-back programs and delay or diminish the important public protection purposes of the programs. This reality is similar to the Board's learning when it was involved in attempting to create a system of unique serial numbers for each pack of prescription pharmaceutical for the Track-and-Trace provisions of a "Pedigree" program.

<p>The apparent purpose of each envelope/package having a “unique” serial number from all other envelopes/packages, would be to potentially identify any envelopes/packages that went “a stray”. The regulation is void of what would be expected, and by of whom, if such was suspected. Even then the intended receiving entity would not know if any envelope/package is missing, still in the pharmacy, still in the possession of some patient or consumer, was discarded by a patient/consumer or....? There is, rightly so, no requirement for the pharmacy to record even the name of the consumer to which it was dispensed. FURTHER MORE, there is no requirement under federal regulations for any entity, even a pharmacy, that dispenses DEA mail-back envelopes/packages to be licensed by any government entity, including the California Board of Pharmacy, or Registered with the DEA, AS LONG AS THE ENTITY TO WHICH THE POSTAGE PRE-PAID ENVELOPE/PACKAGE IS ADDRESSED TO A PROPERLY LICENSED AND REGISTERED ENTITY, e.g. a Reverse Distributor that properly disposes of the un-wanted drugs.</p> <p>Impact</p> <p>This regulatory provision is, at least, vague and unclear, because it does not indicate what the pharmacy is to do if it receives mail-back envelopes without a unique identification number. Unfortunately, as written it will vastly increase the likelihood that few pharmacies will participate and thus the purpose of the programs will be diminished.</p>	<p>registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it and the signature of the driver.</p> <p>(f) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, immediately upon receipt of a liner:</p> <p>(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).</p> <p>(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</p> <p>Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1317.22, Title 21 Code of Federal Regulations</p>
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Martinez, Lori@DCA

From: Taskforce <taskforce@dpw.lacounty.gov>
Sent: Monday, March 21, 2016 4:16 PM
To: Martinez, Lori@DCA
Cc: Dan Lafferty; Carlos Ruiz; Bahman Hajialiakbar; mikemohajer@yahoo.com
Subject: Comments: Board of Pharmacy Proposed Regulations for Prescription Drug Take-Back Programs – February 1, 2016
Attachments: BoPProposedRegulations.pdf



TO: Ms. Lori Martinez, Staff Manager
California State Board of Pharmacy

Please see the attached correspondence from the Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force regarding Comments: Board of Pharmacy Proposed Regulations for Prescription Drug Take-Back Programs – February 1, 2016.

If you have any questions regarding the subject matter, please contact Mr. Mike Mohajer of the Task Force at MikeMohajer@yahoo.com or at (909) 592-1147. For questions regarding the Task Force, please contact Ms. Kristin Keating at (626) 458-2505 or kkeating@dpw.lacounty.gov.



GAIL FARBER, CHAIR
MARGARET CLARK, VICE - CHAIR

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March 21, 2016

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

Dear Ms. Martinez:

**COMMENTS: BOARD OF PHARMACY PROPOSED REGULATIONS FOR
PRESCRIPTION DRUG TAKE-BACK PROGRAMS – FEBRUARY 1, 2016**

The Los Angeles County Integrated Waste Management Task Force (Task Force) appreciates this opportunity to comment on the California Board of Pharmacy's (BOP) February 1, 2016 Proposed Regulations for Prescription Drug Take-Back Programs by adding Sections 1776 through 17776.6 to Article 9.1, Division 17 of Title 16 of the California Code of Regulations (Regulations), copy enclosed. Protecting the health and safety of residents is the most important responsibility for all levels of government and the proposed Regulations should help in addressing the prescription drug abuse epidemic which plagues California and the nation. The Secure and Responsible Drug Disposal Act of 2010 and the United States Drug Enforcement Agencies (DEA) Regulations, which implemented the Act, were established in order to provide citizens with increased access to properly dispose of medications classified as controlled substances. Unfortunately, in many instances, the proposed Regulations are needlessly more stringent than the DEA Regulations and will in all likelihood actually reduce access for residents to properly dispose of unwanted medications. Accordingly, the Task Force submits the following comments for your consideration:

Pursuant to the California Integrated Waste Management Act of 1989 (Assembly Bill 939) and Chapter 3.67 of the Los Angeles County Code, the Task Force is responsible for coordinating the development of all major solid waste planning documents prepared for the County of Los Angeles and the 88 cities in Los Angeles County with a combined population in excess of ten million. Consistent with these responsibilities and to ensure a coordinated cost-effective and environmentally sound solid waste management system in Los Angeles County, the Task Force also addresses issues impacting the system on a countywide basis. The Task Force membership includes

representatives of the League of California Cities-Los Angeles County Division, County of Los Angeles Board of Supervisors, City of Los Angeles, the waste management industry, environmental groups, the public, and a number of other governmental agencies.

A. Section 1776 Prescription Drug Take-Back Programs: Authorization

"All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods."

Comment: Vigilance on the part of authorized collectors is inconsistent with the DEA's Regulations that prohibit authorized collectors from handling and/or sorting through collected drugs. Moreover, the Board's own proposed regulation section 1776.1(f)(1) stating "Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public."

Recommendation: *modify text to read:* All board-licensed authorized collectors should to the extent that is practicable prevent patients or their agents from disposing of prohibited items through drug take-back collection methods.

"Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article."

Comment: This provision would remove the ability for entities that choose to not serve as authorized collectors but would choose to distribute mail-back envelopes to customers from partnering with authorized collectors to provide mail-back envelopes and thus significantly reduce the number of locations that would provide mail-back envelopes to consumers with no perceivable benefit. The DEA has determined such in Section § 1317.70 (c) of their Regulations which states "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section."

Recommendation: Rephrase text so it is clear that pharmacies can participate in drug take-back programs by providing mail-back envelopes without being registered as a collector. If the Board wishes to require pharmacies to be licensed and in good standing in order to offer mail-back envelopes, the following text could suffice.

Modify text to read: Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board may participate in drug take-back programs authorized under this article.

Those pharmacies wishing to host a prescription drug take-back collection receptacle must be registered with the Drug Enforcement Administration as collectors.

B. Section 1776.1 Pharmacies

1776.1(a) *Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.*

Comment: The nature of this statement would preempt local ordinances that require pharmacy participation in any form including providing information to consumers of location that accept unwanted drugs.

Recommendation: Remove the sentence "Provision of such services is voluntary" entirely, however, if the Board is unwilling to remove the language, at the very least modify the language to allow local jurisdictions to require pharmacies to post signage directing their customers where they can go to safely dispose of their medicines.

1776.1(e) *"The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, . . ."*

Comment: As currently worded, this section implies that pharmacies are not permitted to have a separate bin for sharps collection.

Recommendation: Modify text to specify this provision is specific to drug collection receptacles.

1776.1(g) *"A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program."*

Comment: This provision implies that if a pharmacy decides to partner with an authorized collector to provide mail-back envelopes, they must be registered as an authorized collector; this is not a requirement per DEA Regulation.

Recommendation: Modify text to read: "A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for the purposes of operating a prescription drug take-back collection receptacle."

C. Section 1776.2 Mail Back Package and Envelope Services from Pharmacies

1776.2(a) *“Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.”*

Comment: This could be a good place to say that pharmacies could participate in this way without registering as collectors.

Recommendation: Modify text to read: Pharmacies that would like to provide prescription drug take-back services without registering as a collector may do so by establishing mail back services, whereby

1776.2(e) *“The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6”.*

Comment: This is needlessly burdensome. Why would a pharmacy have to create and maintain all of these records when a non-pharmacy retailer can do so without this requirement? These envelopes and packages are already being tracked by the collector, and do not need to be additionally tracked. The BOP is overstepping the requirements in the DEA regulation and making it too onerous to participate in medicine take-back programs. Per the DEA, “Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§ 1317.70).” See section 1776.6(a)(1) for a full explication.

Recommendation: Remove these record-keeping requirements, as pharmacies do not need to be registered as a collector to provide this service.

D. 1776.3 Collection Receptacles in Pharmacies

1776.3(a) and (c) *“. . . In 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 patients from access to the collection receptacle by some means.”*

Comment: The proposal is further restricting the placement of collection receptacles in pharmacies in a way that will significantly diminish the participation of pharmacies in medicine take-back programs. The DEA clearly states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be ‘physically blocked’ in addition to being locked goes beyond what the DEA requires. This provision serves no benefit since it would be just

as easy to place unwanted drugs next to a physical barrier as it would be to place medicine next to a locked bin.

Recommendations:

- 1) Remove language about physically blocking patient access, and
 - 2) Revert to DEA language in order to avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.
-

1776.3(b) “. . . The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.”

Comment: This section goes beyond the DEA regulation in a subtle but potentially significant way. As the DEA recognizes, hospitals can be unique in their design and need to have flexibility in the manner in which they participate in Safe Medicine Disposal Programs. The BOP regulation as it is currently worded removes that flexibility. The DEA regulations imply that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. We do not want to discourage hospitals from participating in Safe Medicine Disposal programs by making it more difficult for them to do so.

Recommendation: Remove the word ‘pharmacy’ from 1776.3(b) so that it reads as the DEA: “visible to employees”, not “visible to pharmacy employees”.

1776.3(h) “. . . A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. 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.”

Comment: Stating specifically that rigid containers must “meet standards of the USDOT for transport of medical waste” exceeds the requirements of the DEA regulation, which does not mention medical waste. There is a lot of confusion around the definition of medical waste; especially home-generated pharmaceutical defined in the HSC §117700.

It would be very helpful if the BOP would say the equivalent of: “It is not within the DEA’s expertise or authority to opine on the applicability of DOT regulations.” However, “All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.” (Federal Register p53554)

Moreover, it is not clear what exactly would qualify as meeting the USDOT standards. It would be helpful to establish that a cardboard box could meet the requirements specified, as this is currently an industry standard. Dis-allowing cardboard boxes would cause the price of disposal to substantially increase. Do cardboard boxes have tight-fitting covers? Are they rigid? Do they qualify as leak resistant? Or would a cardboard box in combination with a plastic bag combine to fulfill the requirements of the "inner liner" as the inner liner is already required to be waterproof? Please make this clear.

Recommendation: *modify text to read:* A rigid container may be disposable, reusable, or recyclable (example: cardboard box). Rigid containers shall be capable of being sealed and be kept clean and in good repair. Rigid containers may be of any color. It is not within the BOP's expertise or authority to opine on the applicability of DOT regulations. However, all drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.

E. 1776.4 Collection in Skilled Nursing Facilities

1776.4(h)(2) – See Section 1776.3(h) for comments

1776.4(n) *"Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility."*

Comment: The DEA regulation allows "the installation, removal, transfer, and storage of inner liners . . . by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility" in addition to allowing these activities to occur under the supervision of two pharmacy employees (§1317.80(c)). Please do not restrict any of the allowable activities to just two pharmacy employees.

The BOP language above appears to state that pharmacy employees can themselves directly deliver sealed inner liners to a reverse distributor. However, the DEA says: ". . . the practitioner may destroy the collected substances by delivering the sealed inner liners to a reverse distributor or distributor's registered location by common or contract carrier, or a reverse distributor or distributor may pick-up sealed inner liners at the LTCF" (Federal Register p. 53543 and §1317.05). Per our interpretation this does not allow pharmacy employees to transport the sealed inner liners themselves. Please clarify.

F. 1776.5 Reverse Distributors

1776.5(a) *“A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered DEA as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.”*

Comment: The DEA-registered Reverse Distributor is not the collector except in the case of mail-backs (see section 1776.6(a)(1) for full references).

Recommendation: Modify text to read: 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. Once received, the reverse distributor shall establish records required by this section.

1776.5(b) *“A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately licensed DEA distributor.”*

Comment: Incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable. One such method is incineration. The DEA explicitly states, “the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration . . .” (Federal Register, p. 53536). Please do not further restrict what is required in the DEA regulation.

Recommendation: Modify text to read: A licensed reverse distributor may not count, inventory or otherwise sort or x-rays the contents of inner liners. All liners shall be rendered non-retrievable by an appropriately licensed DEA distributor in compliance with applicable Federal, State, tribal, and local laws and regulations.

1776.5(e) *“Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. . .”*

Comment: As mentioned in the comment for 1776.5(b), incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable. One approved method of doing this is incineration. The DEA explicitly states that “the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration. . .” (Federal Register, p. 53536). Please do not further restrict what is required in the DEA regulation.

Recommendation: *modify text to read:* Each reverse distributor with a destruction site shall maintain a record of the destruction on DEA form 41.

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

1776.6(a)(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.”*

Comment: Pharmacies are not collectors with regard to mail-back envelopes. Rather, the collector is the reverse distributor to which the envelopes are mailed from the ultimate user. These recordkeeping duties should not be required for pharmacies which simply hand out the envelopes because they are already required for the reverse distributors accepting them for destruction. Requiring them for pharmacies would make it too onerous for many pharmacies to participate in drug take-back programs as providers of mail-back envelopes.

Recommendation: Remove language requiring pharmacies participating in a mail-back program to maintain burdensome records beyond what is required by the DEA.

1776.6(a)(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.”*

Comment: According to the DEA, this is the record that the collector is required to keep (§ 1304.22(f)). Please clarify that this applies only to the collector, which in this case is the reverse distributor, not the pharmacy. These recordkeeping duties should not be required for pharmacies who simply hand out the envelopes because they are already required for the reverse distributors accepting them for destruction. Requiring them for pharmacies would make it too onerous for many pharmacies to participate in drug take-back programs. See section 1776.6(a)(1) for a full explication.

Recommendation: Clarify that the record-keeping requirements in 1776.6(a)(2) only apply to collectors, not to pharmacies distributing mail-back envelopes.

Ms. Martinez
March 21, 2016
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1776.6(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.”*

Comment: This burdensome nature of this provision is beyond DEA Regulation and does not provide a clear benefit. The collector, the reverse distributor in the case of mail-backs, is responsible for keeping detailed records. See section 1776.6(a)(1) for a full explication.

Recommendation: Remove this item entirely.

The Task Force appreciates the difficult task the Board has undertaken to develop the proposed Regulations. The general purpose of these comments are intended to bring to light provisions in the proposed Regulations which the Task Force believes afford no added benefit to the health and safety of residents and in most cases make it more difficult to provide convenient access for residents to properly dispose of unwanted drugs. It is hoped that the Board consider the purpose of drug take-back programs, which is to provide increased convenience for proper disposal and revise the Regulations to be as closely aligned with the DEA Regulations as possible.

If you have any questions, please contact Mr. Mike Mohajer of the Task Force at MikeMohajer@yahoo.com or (909) 592-1147.

Sincerely,



Margaret Clark, Vice-Chair
Los Angeles County Solid Waste Management Committee/
Integrated Waste management Task Force and
Mayor Pro Tem, City of Rosemead

GA:kk

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Enc.

cc: Each member of the California Board of Pharmacy
Executive Director of the Board of Pharmacy
California State Association of Counties
League of California Cities, Los Angeles Division
California Product Stewardship Council

Ms. Martinez
March 21, 2016
Page 10

Each member of the Los Angeles County Board of Supervisors
San Gabriel Valley Council of Governments
South Bay Cities Council of Governments
Gateway Cities Council of Governments
Westside Cities Council of Governments
Each City Mayor and City Manager in the County of Los Angeles
Each City Recycling Coordinator in Los Angeles County
Each Member of the County Sanitation Districts of Los Angeles County
Each Member of the Los Angeles County Integrated Waste Management Task Force

Martinez, Lori@DCA

From: Johnson, Margaret (ENV) <margaret.johnson@sfgov.org>
Sent: Thursday, March 24, 2016 5:06 PM
To: Martinez, Lori@DCA; Sodergren, Anne@DCA
Subject: Comments on Proposed Text, Prescription Drug Take-Back, February 1, 2016
Attachments: San Francisco comments to BOP on Prescription Drug Take-Back reg proposal 3-25-16.docx

Hello Lori and Anne. Thank you for the opportunity to comment. Our comments are attached.

**Maggie Johnson, Senior Residential Toxics
Reduction Coordinator**
San Francisco Department of the Environment
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Edwin M. Lee
Mayor



SF Environment
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A Department of the City and County of San Francisco

Deborah O. Raphael
Director

March 25, 2016

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

Comments on Proposed Text, Prescription Drug Take-Back, February 1, 2016

Dear Ms. Martinez:

The San Francisco Department of the Environment appreciates the opportunity to comment on the Board of Pharmacy's proposal to add Article 9.1, Prescription Drug Take-Back Programs, to Division 17 of Title 16 of the California Code of Regulations. In 2015, the City and County of San Francisco passed the San Francisco Safe Drug Disposal Stewardship Ordinance which requires pharmaceutical manufacturers to fund and implement a permanent medicine take-back program for residents to properly dispose of their unwanted medicines. A successful program calls for voluntary participation from pharmacies to host a collection receptacle. Many pharmacies are waiting for the California Board of Pharmacy (CABOP) to pass regulations before they decide whether or not they are able to host a collection receptacle. We urge the CABOP to pass regulations as quickly as possible so there is no delay in implementing our stewardship program.

In general, we understand that CABOP is proposing these regulations to align California's regulations with the Federal DEA's Final Rule on Disposal of Controlled Substances issued in 2014. The DEA Final Rule was issued to expand the options available to the public to properly dispose of controlled substances, while ensuring that disposal is done in a safe and secure manner. The DEA Final Rule was passed after careful consideration and review of many public comments submitted by a range of stakeholders. Given the detailed nature of the DEA Final Rule, we recommend that the Board not go beyond the Federal requirements. We believe it is in the best interest of the public, who will benefit from the new opportunities for convenient and safe disposal

San Francisco Department of the Environment
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of unwanted medicines, to have California’s regulation follow the DEA Final Rule as closely as possible. 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.

We offer the following specific comments on the February 1, 2016 proposed regulations.

Section 1776 Prescription Drug Take-Back Programs: Authorization

- **“Pharmacies, hospital/clinics with onsite pharmacies...and licensed skilled nursing facilities may offer, under the requirements in this article...”**

Comment: The DEA does not use the term “skilled nursing facilities,” but rather “long term care facilities.” Long term care facility (LTCF) “means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.” “Skilled nursing facility,” as defined in CA Health and Safety Code Section 1250(c) has a narrower meaning than the DEA’s LTCF.

Recommendation: Change “skilled nursing facilities” to “long term care facilities” to match the DEA term here and throughout the proposed regulations. This will provide consistency and avoid confusion between the State and Federal regulations.

- **“Federal, state, and other laws prohibit the deposit in drug take-back receptacles of the following...”**

Comment: We are unaware of any laws which establish prohibitions related to drug take-back receptacles for the specific items listed when they are generated in the home. We are concerned this language goes beyond the scope of the DEA Final Rule, will cause confusion, and overreaches CABOP’s purview by interpreting other agencies’ law.

Recommendation: Please remove this provision from the final regulations or list the applicable laws in the Initial or Final Statement of Reasons.

- **“Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs...”**

Comment: Pharmacies who solely provide mail-back packages to the public, with or without a fee, are not required to register with the DEA. The DEA regulations require only those pharmacies or reverse distributors who operate a mail-back program, by receiving and destroying sealed mail-back packages, to register as a collector. In contrast, the proposed regulations would require any

pharmacy that provides mail-back packages to the public to register with the DEA and CABOP as a collector.

Recommendation: Clarify that pharmacies which solely offer mail-back packages to the public do not have to be registered with the DEA or with CABOP. Change the text to “Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may operate collection receptacles. California-licensed pharmacies may provide empty, unused mail-back packages to the public under the provisions of Section 1776.2.”

Section 1776.1 Pharmacies

- **(a): “Pharmacies may assist patients ...”**

Comment: The DEA regulations use the term “non-registrant persons,” which includes ultimate users and others who are lawfully entitled to dispose of controlled substances.

Recommendation: Replace “patients” with “non-registrant persons” or “the public.”

- **(a): “... Provision of such services is voluntary”**

Comment: This statement may be interpreted to preempt local government ordinances that require retail pharmacies to provide a drug take-back program. To intentionally preempt local governments on this issue is not consistent with the CABOP’s mission statement to protect and promote the health and safety of Californians.

Recommendation: Change text to: “Provision of such services, under these regulations, is voluntary.

Section 1776.2 Mail Back Package and Envelope Services from Pharmacies

General Comment: This section needs to be reworked to clarify that it does not apply to pharmacies which solely provide empty unused mail-back envelopes or packages to the public. If CABOP’s intention is to mirror the DEA Final Rule, these regulations should only be applicable to pharmacies which are actually **operating** a mail-back program (i.e. receiving and destroying on-site sealed mail-back envelopes or packages). We do not believe CABOP should extend the scope of this section to pharmacies that solely provide empty, unused mail-back envelopes or packages to the public and do not operate an on-site destruction facility.

- **(e) “The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.”**

Comment: The DEA Final Rule does not require pharmacies (or other entities) to maintain records on empty unsealed mail-back packages they give to the public. Requiring pharmacies who solely distribute empty mail-back units to the public to create and maintain records for mail-back packages would be an unnecessary burden. Furthermore, in San Francisco’s pilot mail-back program, we found that many mail-back envelopes that we distributed to the public were never used; therefore there is little utility to maintaining such records.

Recommendation: Delete subpart (e) of 1776.2.

Section 1776.3 Collection Receptacles in Pharmacies

- **(a) “... In 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 patients from access to the collection receptacle by some means.”**

Comment: This requirement goes beyond the DEA regulations, and could be a large burden to pharmacies. The DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Furthermore, in the case of independent pharmacies where the collection receptacle is already inaccessible to the public when the pharmacy is closed, it is not necessary for them to lock the top of the bin.

Recommendation: Replace above text with: “The receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present.”

- **(b) “The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.”**

Comment: The DEA does not specify that employees must be employed in the pharmacy. The reference to “emergency areas,” is likely only applicable to pharmacies located within a hospital or clinic and is proposed in the following paragraph.

Recommendation: Delete “pharmacy,” and “but not located in emergency areas.”

- **(c) “When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from patient access by some means.”**

Recommendation: Change above text to read: The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by an employee so that drugs may not be deposited into the collection receptacle.

- **(h) “All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste.”**

Comment: There is a lot of confusion around the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste (see CA Health & Safety Code Section 117700).

Recommendation: Delete “for transport of medical waste.”

- **(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 days.”**

Comment: The DEA does not specify how many days a pharmacy can store full liners before transporting for destruction, only specifying “promptly” (see Section 1317.05 (c)). We do not believe three days is a reasonable time frame that will work for all pharmacies in the state of California.

Recommendation: Delete ”no longer than three days.”

- **(k)(5) “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 paper (invoice, bill of lading) must be recorded.”**

Comment: The DEA does not require any of these records when registrants use a common carrier to transport inner liners to a reverse distributor. We foresee some possible issues with obtaining the signature of the common carrier driver, in the case where some companies may prohibit their drivers from signing anything or the driver does not feel comfortable signing any forms.

Recommendation: Delete “the signature of the driver.”

- **(m) “... Labeling shall also identify that...may not be deposited into the receptacle.” ...”**

Comment: As noted above, we are not aware of any laws that specifically bar certain materials from being deposited into drug take-back receptacles.

Recommendation: Delete this section except for the last sentence.

Section 1776.4 Collection in Skilled Nursing Facilities

- **(h)(2) “All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste.”**

Comment: As noted above, there is a lot of confusion about the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste (see CA Health & Safety Code Section 117700).

Recommendation: Delete “for transport of medical waste.”

- **(n) “Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor’s registered location...”**

Comment: The DEA limits disposal of sealed inner liners to on-site destruction, delivery to a reverse distributor’s registered location by common carrier, or by reverse distributor pick-up at the authorized collector’s location. Collectors are not allowed to self-transport.

Recommendation: Replace “two pharmacy employees delivering” with “common carrier or reverse distributor pickup of ...”

Section 1776.5 Reverse Distributors

- **“A licensed reverse distributor registered DEA as a collector...”**

Comments: Reverse distributors are required to be registered with the DEA as a reverse distributor. They would be registered with the DEA as a collector only if they are operating a mail-back program.

Recommendation: Modify text to read, “A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA may accept...”

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

- **(a) “When obtaining unused mail-back packages ...”**
- **(a)(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.”**

- **“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.”**

Comment: These records are not required by the DEA of pharmacies which are solely providing unused, empty mail-back envelopes or packages to the public. These records are required of the



reverse distributor who is operating the mail-back program. It is burdensome and unnecessary to require this level of recordkeeping of pharmacies that are solely providing unused mail back envelopes to the public.

Recommendation: Delete sections 1776.6(a) and 1776.6(b). If CABOP envisions a pharmacy that may also operate an on-site destruction facility, then we suggest that this section be reworked to only pertain to those pharmacies.

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

Sincerely,

Jen Jackson

Toxics Reduction Program Manager

San Francisco Department of the Environment

Martinez, Lori@DCA

From: Mary Rose <mrose1126@aol.com>
Sent: Monday, February 15, 2016 3:44 PM
To: Martinez, Lori@DCA
Subject: Don't Obstruct Pharmacy-based Drug Take-Back Programs

Dear Dr. Gutierrez and Fellow Board Members

I am deeply concerned with the impacts unused medications have on water quality and public health, as well as the Board of Pharmacy's proposed rules that will actually discourage pharmacies from hosting medicine collection bins. Pharmacies provide an important public health service to the community and studies show that they are where the public wants to be able to safely dispose of medicines.

Because pharmacies have been shown to be the most effective collection sites, the U.S. Drug Enforcement Agency has established common sense rules that allow pharmacies to support drug takeback in a safe and secure manner. Pharmacies who volunteer to host bins in California have not experienced serious problems or legal issues and many of the fears expressed by some pharmacy interests are unsubstantiated.

The Board of Pharmacy does NOT need to develop extensive regulations. Instead it should simply acknowledge that California pharmacies can host safe medicine disposal bins if they follow the DEA rules. By proposing additional regulations and deliberating over a lengthy period of time, the Board has scared pharmacies that wish to host take-back bins now from doing so. In addition, by attempting to preempt those few ordinances that require pharmacy participation in manufacturer supported programs, you are interfering with the actions of elected officials who are acting on behalf of the public to protect public health. That is inappropriate for an unelected Board.

Instead of obstructing what are mostly voluntary actions by publicly responsible pharmacies, the Board of Pharmacy should promote such programs as a means of protecting public and environmental health. California pharmacies distribute medications and are the perfect and safe location to return them.

It is hard enough already to properly dispose of drugs, with pharmacies and city and county recycling centers each having different rules and criteria for turning in drugs. It should be made easier, clearer and simpler for people to dispose of drugs. Pharmacies are based on dispensing drugs and could easily take the lead in securing a safe and clear way for the public to dispose of drugs.

I urge you to simply endorse the Drug Enforcement Agency's rules for pharmacy-based collection programs with all expediency and to desist from any effort to preempt local laws.

Mary Rose
1370 Delaware Street
Berkeley, CA 94702

Martinez, Lori@DCA

From: Merry Selk <merryselk@gmail.com>
Sent: Monday, February 15, 2016 4:39 PM
To: Martinez, Lori@DCA
Subject: SUPPORT for Pharmacy-based Drug Take-Back Programs

Dear Dr. Gutierrez and Fellow Board Members

Unused medications hurt water quality and public health, and the Board of Pharmacy's proposed rules will discourage pharmacies from hosting medicine collection bins.

Please endorse Drug Enforcement Agency rules for pharmacy-based collection programs and stop attempts to preempt local laws.

Because pharmacies have been shown to be the most effective collection sites, the U.S. Drug Enforcement Agency has established common sense rules that allow pharmacies to support drug takeback in a safe and secure manner.

By proposing additional regulations and deliberating over a lengthy period of time, the Board has scared pharmacies that wish to host take-back bins now from doing so.

The Board of Pharmacy should promote such programs as a means of protecting public and environmental health. California pharmacies distribute medications and are the perfect and safe location to return them.

Merry Selk
1016 Evelyn Ave.
Albany, CA 94706

Martinez, Lori@DCA

From: Mary Staples <mstaples@NACDS.org>
Sent: Monday, March 28, 2016 12:24 PM
To: Amy Guittierez
Cc: Herold, Virginia@DCA; Martinez, Lori@DCA; Sodergren, Anne@DCA
Subject: NACDS Comments on the California Board of Pharmacy Proposed Rule Article 9.1, Prescription Drug Take-Back Programs, Section 1776
Attachments: CA NACDS Cmts RxTB 3-28-2016.pdf

Please accept these comments for the record.

Mary Staples
Director, State Government Affairs

NACDS
1560 E. Southlake Blvd., Suite 230
Southlake, TX 76092
817.442.1155
817.442.1140 Fax
817.308.2103 Cell
mstaples@nacds.org

March 28, 2016

Amy Gutierrez, Pharm.D.
President, California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

Re: NACDS Comments on the California Board of Pharmacy Proposed Rule Article 9.1, Prescription Drug Take-Back Programs, Section 1776

Dear Dr. Gutierrez:

On behalf of our members that operate pharmacies throughout the state of California, the National Association of Chain Drug Stores (NACDS) supports the Board of Pharmacy's proposed drug take-back regulations with some requests for clarification and modification. Specifically, we urge the Board to make clear in the Final Rule that pharmacies that merely distribute another entity's mail-back envelopes are not "collectors" within the drug take-back program and that pharmacy participation in drug-take back programs is voluntary. We also request that the Board ensure that the Final Rule mirror the Drug Enforcement Agency's ("DEA") 2014 Final Rule regarding drug take-back programs as much as possible.

Voluntary Pharmacy Participation

As we have previously outlined to the Board in our January, 2016 drug take-back program comments, we believe that pharmacy participation in any state or municipal take-back program should be voluntary. In our January letter, we outlined the public health concerns, operational concerns and flexibility rationale for why we oppose mandatory participation. We have attached a copy of that letter for more detail.

Section 1776.1 of the Proposed Rule states that "provision of [drug take-back] services is voluntary." We applaud the Board for including such language, but we also encourage the Board to make clear that such language also preempts any municipality-based programs to the contrary. In other words, the Final Rule should clarify that no municipality intending to set up a drug take-back program can mandate pharmacy participation. We seek consistency across the state and ask the Board to help us achieve that goal by clarifying the preemptive effect of the Final Rule on municipal take-back programs.

Definition of Collectors

While the Proposed Rule does not specifically define the term "collector," we believe that a plain reading of the Proposed Rule demonstrates that a pharmacy that merely distributes mail-back envelopes to be sent directly to another entity with whom it has partnered for the receipt and destruction of the envelopes ("Partner") is not a "collector" for purposes of the rule. Section 1776.2(b) contemplates a process in which pharmacies distribute preaddressed envelopes that will be returned to a "collector" with onsite capabilities for destruction. The recipient of the filled envelope is the "collector," not the pharmacy. To further emphasize this point, Section 1776.2(g) states that "once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding." We believe that read together, these two provisions make clear that pharmacies that distribute mail-back envelopes are not "collectors" within the Proposed Rule.

In the DEA Final Rule on drug take-back programs, the DEA, in 21 CFR 1317.70(a) states that a collector, must have, at their registered location a method of destruction for returned envelopes. Moreover, 21 CFR

NACDS Regional Office

1560 East Southlake Boulevard, Suite 230 • Southlake, TX 76092 • 817.442.1155 • www.NACDS.org

1317.70(c) states that:

Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section.

This language makes clear that the recipient of the returned envelope, the Partner, is a "collector" for drug take-back purposes and that a pharmacy that distributes such envelopes is not the collector, merely facilitating distribution of the envelopes. To maintain consistency with the federal regulation, we urge the Board to take the same approach. Again, we believe that Board has already done so, as described above. However, to the extent that the Board's Proposed Rule does not track the federal language, we urge the Board to clarify that pharmacies, in California, who merely distribute take-back envelopes in partnership with collectors need not register as collectors themselves.

Inconsistencies with the DEA Final Rule

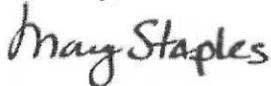
While the Proposed Rule generally tracks the DEA Final Rule in establishing a drug take-back program, there are several areas of inconsistency. More specifically, Section 1776.6(a) and (b) include record keeping requirements for pharmacies that are not included in the federal regulation. These two provisions would require pharmacies to keep records of the date an unused mail-back envelope was obtained by the pharmacy, the serial number of each package or envelope distributed and the date distributed. We do not understand the justification for such added requirements. These two requirements impose additional administrative burdens and costs on participating pharmacies without a justification or rationale. Accordingly, we ask the Board to delete these two requirements. While these two requirements are of greatest concern to NACDS, we also ask the Board to take efforts to ensure that all of the provisions of the Proposed Rule are consistent with the DEA's federal regulation.

Conclusion

For the reasons outlined above, we urge the Board to finalize its proposed drug take-back regulations with the requested changes and clarifications. Most importantly, the Board should make clear that the Final Rule preempts municipality-based mandatory drug take-back programs. Pharmacy participation in drug take-back programs should remain voluntary consistent with federal law.

Thank you for consideration of our comments. If you have any questions or need additional information, please contact me at mstaples@nacds.org, or 817-442-1155.

Sincerely,



Mary Staples
Director, Government Affairs

cc: Virginia Herold, Executive Officer, California Board of Pharmacy

Attachment

January 15, 2016

Amy Gutierrez, Pharm.D.
President
California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

Dear Dr. Gutierrez:

On behalf of our 19 members that operate more than 3,400 pharmacies throughout the state of California, the National Association of Chain Drug Stores (NACDS) supports the Board of Pharmacy's proposed drug take-back regulations. Importantly, the proposed regulations maintain consistency between federal drug take-back law and state's drug take-back law by preempting local county efforts that would otherwise mandate that pharmacies serve as collection sites for drug take-back programs. We are not urging the Board prohibit pharmacies from participating in take-back programs. Rather, we believe the Board should make clear to the municipalities that the statewide policy is voluntary participation, as mandatory participation raises security, liability, public health and safety concerns, as well as practical operational concerns.

Background

Effective October 9, 2014, the Drug Enforcement Administration (DEA) issued final regulations that implemented the federal Secure and Responsible Drug Disposal Act ("Act"). The Act and these DEA regulations allow entities, which are DEA registered and authorized by the DEA, to voluntarily set up programs for disposal of consumers' unwanted controlled substances. The law and regulations apply to a variety of DEA registrants, including retail pharmacies, and provide for a variety of disposal options, including allowing registrants to setup mail-back and collection receptacles. In short, the DEA regulations allow a voluntary approach with each DEA registrant deciding if and how they want to set up a program. We appreciate the fact that the Board's proposed regulations track with the federal law and regulations through clarifying that pharmacy participation in California drug take-back programs must be voluntary in nature. As we have previously stated in comments to the Board, there are several reasons why pharmacy participation should be voluntary in drug take-back programs.

Security and Liability Concerns

First, if the Board were to allow municipalities to mandate pharmacy take back programs centered upon retail pharmacy take back receptacles, it would inadvertently create security risks for pharmacies, as well as for their staff and customers. More precisely, if bad actors learn that pharmacies are now required to house take back receptacles that hold addictive drugs with high value on the black market, then such bad actors, with little difficulty, could charge into a pharmacy armed with weapons and steal the collection receptacle.

Public Health Concerns

Second, voluntary take-back programs are necessary to avoid public health concerns. The DEA rule, which is controlling on this issue, provides that only consumers are permitted to deposit their unwanted medications into collection receptacles. The regulations do not allow pharmacists or pharmacy staff to touch or handle them in any manner. While consumers are expected to place their unwanted medications into collection receptacles, this may not always occur. Instead, a consumer might dispose of their drugs next to or on top of

the collection receptacle where another consumer could pick them up, which is particularly worrisome if a child were to pick up and ingest such a drug.

Practical Operational Concerns

Third, municipality-based mandatory take-back participation is problematic as not every pharmacy is the same in design, space and structure, and each pharmacy must consider its own space limitations to take back consumers' returned drugs in mandated receptacles. Space is becoming even more limited as pharmacists increasingly provide more and more health services to patients. Pharmacies need space to provide such services and housing taking back receptacles may interfere with pharmacies ability to effectively offer their patients other health care services.

The Need for Flexibility

Finally, municipality-based mandatory take-back programs interfere with the development of safer and more feasible take-back options that would otherwise be precluded by such mandates. For example, the DEA regulations allow DEA registered entities to voluntarily decide to operate a mail-back program for consumers to return their unwanted prescribed medications (both controlled and non-controlled) via the mail to locations where they are destroyed. Consumers may collect their unwanted medications and place their unwanted medications in the envelope at a time and place convenient for them, and then mail it when it is full. However, if municipalities mandate take-back receptacles at pharmacies, then such programs may preclude pharmacies from offering innovative mail-back programs.

Conclusion

For the reasons outlined above, we urge the Board to finalize its proposed regulations that clearly preempt municipality-based mandatory drug take-back programs. Pharmacy participation in drug take-back programs should remain voluntary consistent with federal law. Please do not hesitate to contact me for further information or assistance on this issue. I can be reached at 817-442-1155 or at mstaples@nacds.org.

Sincerely,

A handwritten signature in black ink that reads "Mary Staples". The signature is written in a cursive, slightly slanted style.

Mary Staples

cc: Virginia Herold, Executive Officer, California Board of Pharmacy

Martinez, Lori@DCA

From: Nickie Amerius-Sargeant <namersarg@yahoo.com>
Sent: Monday, February 15, 2016 9:20 PM
To: Martinez, Lori@DCA
Subject: Don't Obstruct Pharmacy-based Drug Take-Back Programs

Dear Dr. Gutierrez and Fellow Board Members

I am deeply concerned with the impacts unused medications have on water quality and public health, as well as the Board of Pharmacy's proposed rules that will actually discourage pharmacies from hosting medicine collection bins. Pharmacies provide an important public health service to the community and studies show that they are where the public wants to be able to safely dispose of medicines.

Because pharmacies have been shown to be the most effective collection sites, the U.S. Drug Enforcement Agency has established common sense rules that allow pharmacies to support drug takeback in a safe and secure manner. Pharmacies who volunteer to host bins in California have not experienced serious problems or legal issues and many of the fears expressed by some pharmacy interests are unsubstantiated.

The Board of Pharmacy does NOT need to develop extensive regulations. Instead it should simply acknowledge that California pharmacies can host safe medicine disposal bins if they follow the DEA rules. By proposing additional regulations and deliberating over a lengthy period of time, the Board has scared pharmacies that wish to host take-back bins now from doing so. In addition, by attempting to preempt those few ordinances that require pharmacy participation in manufacturer supported programs, you are interfering with the actions of elected officials who are acting on behalf of the public to protect public health. That is inappropriate for an unelected Board.

Instead of obstructing what are mostly voluntary actions by publicly responsible pharmacies, the Board of Pharmacy should promote such programs as a means of protecting public and environmental health. California pharmacies distribute medications and are the perfect and safe location to return them. I urge you to simply endorse the Drug Enforcement Agency's rules for pharmacy-based collection programs with all expediency and to desist from any effort to preempt local laws.

Keep water quality safe and have drug manufacturers collect unused drugs.

Nickie Amerius-Sargeant
7170 F Street
Tres PINOS, CA 95075

NIPOMO COMMUNITY

BOARD MEMBERS

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MICHAEL W. SEITZ, GENERAL COUNSEL

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March 15, 2016

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

Dear Mrs. Martinez:

SUBJECT: CALIFORNIA BOARD OF PHARMACY PROPOSED REGULATIONS

On behalf of the Board Members of Nipomo Community Services District (NCSD), I am writing to provide comment regarding the California Board of Pharmacy proposed regulations to section 1776.1 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations. It is NCSD's opinion that the proposed regulations will significantly limit the options for the public to dispose of their unwanted medicine. The reasons are twofold.

1. The California Board of Pharmacy proposed regulations are more burdensome than the federal regulations adopted by the Department of Justice on September 9, 2014. For example, the proposed regulations increase the record keeping requirements without any apparent benefit. There are also additional requirements and restrictions on how unwanted medicine can be collected and disposed of.

2. The California Board of Pharmacy proposed regulations will preempt local programs. In San Luis Obispo County there is a requirement that every pharmacy provides the public with an option to disposal of unwanted medicine. If this requirement is preempted, many of these pharmacies will no longer provide the public with a method of disposal of unwanted medicine.

NCSD oversees two wastewater treatment plants (WWTP). As with most wastewater treatment facilities, the WWTPs are not designed to and therefore not effective in removing pharmaceuticals from the waste stream.

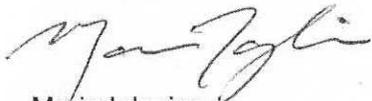
Keeping pharmaceuticals out of the groundwater to the extent possible should be a priority. This objective is more effectively and efficiently achieved by addressing the problem at the point of entry. California should be looking to enhance the collection of unwanted medicine at facilities that are capable of managing disposal of these products. Too often the option people are left with when faced with discarding unwanted medicines is to flush them down the drain.

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CALIFORNIA BOARD OF PHARMACY

One solution to preventing pharmaceuticals from entering the groundwater is to provide the public with easy access to designated disposal sites. Residents of California would be better served if the California Board of Pharmacy were to adopt the Department of Justice regulations issued on September 9, 2014.

Sincerely,

NIPOMO COMMUNITY SERVICES DISTRICT



Mario Iglesias
General Manager

c: NCSD Board Members

Martinez, Lori@DCA

From: PHuntzinger <pehuntedalycity@yahoo.com>
Sent: Friday, February 12, 2016 9:54 AM
To: Martinez, Lori@DCA
Subject: Take Back Programs

Good Day,

Regarding med take back programs I think it is important to have guidance regarding the deposition of prohibited products. Primarily, pharmacies have no control on what is deposited by the public in such receptacles and shouldn't be held accountable for prohibited items that are deposited in them.

Sincerely,

Paul Huntzinger, RPh 44650

Sent from my iPhone

Martinez, Lori@DCA

From: Ryan Schmidt <ryanschmidt24@yahoo.com>
Sent: Tuesday, February 16, 2016 10:18 AM
To: Martinez, Lori@DCA
Subject: Don't Obstruct Pharmacy-based Drug Take-Back Programs

Dear Dr. Gutierrez and Fellow Board Members

I trust that the Board will not unnecessarily overlap the common sense regulations already in place to encourage pharmaceutical re-cycling. This is an important issue to our water quality, and once in which progress is needed to further and promote successful recycling programs.

I am deeply concerned with the impacts unused medications have on water quality and public health, as well as the Board of Pharmacy's proposed rules that will actually discourage pharmacies from hosting medicine collection bins. Pharmacies provide an important public health service to the community and studies show that they are where the public wants to be able to safely dispose of medicines.

Because pharmacies have been shown to be the most effective collection sites, the U.S. Drug Enforcement Agency has established common sense rules that allow pharmacies to support drug takeback in a safe and secure manner. Pharmacies who volunteer to host bins in California have not experienced serious problems or legal issues and many of the fears expressed by some pharmacy interests are unsubstantiated.

The Board of Pharmacy does NOT need to develop extensive regulations. Instead it should simply acknowledge that California pharmacies can host safe medicine disposal bins if they follow the DEA rules. By proposing additional regulations and deliberating over a lengthy period of time, the Board has scared pharmacies that wish to host take-back bins now from doing so. In addition, by attempting to preempt those few ordinances that require pharmacy participation in manufacturer supported programs, you are interfering with the actions of elected officials who are acting on behalf of the public to protect public health. That is inappropriate for an unelected Board.

Instead of obstructing what are mostly voluntary actions by publicly responsible pharmacies, the Board of Pharmacy should promote such programs as a means of protecting public and environmental health. California pharmacies distribute medications and are the perfect and safe location to return them. I urge you to simply endorse the Drug Enforcement Agency's rules for pharmacy-based collection programs with all expediency and to desist from any effort to preempt local laws.

Ryan Schmidt
30 Wool St.
San Francisco, CA 94110

Martinez, Lori@DCA

From: Robert Stein <Robert_Stein@kgi.edu>
Sent: Tuesday, March 01, 2016 4:08 PM
To: Martinez, Lori@DCA
Subject: Proposed CCR 1715.65

Hi Lori,

I am the designated reviewer of this proposed regulation for CSHP. Please put me on the list to be notified of any changes to the text of the regulation.

Thanks,
Bob.

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



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

Martinez, Lori@DCA

From: Paige Dulberg <pdulberg@westyost.com>
Sent: Monday, March 28, 2016 3:14 PM
To: Martinez, Lori@DCA
Cc: Andy Rodgers; Daria Isupov
Subject: RRWA BOP Take-Back Regulation Comments
Attachments: BOP-1776_RRWA-Comments.pdf

Dear Ms Martinez,

Attached, please a letter from the Russian River Watershed Association: "Comments on Board of Pharmacy Proposed Regulations for Prescription Drug Take Back Programs." Thank you for sharing our comments with the Board. Please let Andy Rodgers know if you have any questions.

Regards,

Paige Dulberg

Russian River Watershed Association Staff

West Yost Associates

pdulberg@westyost.com

(707) 508-3677



Executive Director: Andy Rodgers

300 Seminary Ave, Ukiah, CA 95482

(707) 508-3672

www.rrwatershed.org



SENT VIA: EMAIL

March 28, 2016

Lori Martinez
California State Board of Pharmacy
1625 North Market Boulevard, Suite N 219
Sacramento, California 95834

Lori.Martinez@dca.ca.gov

**SUBJECT: COMMENTS ON BOARD OF PHARMACY
PROPOSED REGULATIONS FOR PRESCRIPTION DRUG TAKE-
BACK PROGRAMS**

Dear Ms Martinez and Members of the Board,

I write on behalf of the Russian River Watershed Association (RRWA) and Sonoma County's Safe Medicine Disposal Collaborative to respectfully express our opposition to the draft proposed text of Section 1776 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations.

RRWA formed in 2003 and is a coalition of eleven cities, counties, and agencies within the Russian River Watershed that work together for clean water, fisheries restoration, and watershed enhancement. Our collective concern of household hazardous waste led to the creation of our Safe Medicine Disposal (SMD) Program in 2007. RRWA partners with local government agencies, pharmacies, and law enforcement offices to provide safe medicine disposal options to our community. Residents can bring their unused, unwanted, or outdated medicines to any of our thirty-seven secure drug take-back locations. The SMD Program has collected over 95,000 pounds of pharmaceutical waste since 2007 and is currently funded by local governments. A collaboration of active stakeholders has worked together for years to maintain and expand the SMD Program. Regional collection programs like ours keep medications out of the wrong hands, protect young children from accidental poisonings, and protect the environment.

Collectively, we request that the Board please consider the following comments when deciding how to move forward with the proposed draft regulations regarding pharmaceutical take back programs:

- As written, Section 1776.1(e) may be interpreted as prohibiting collection of medical sharps and needles in *any* collection receptacle in a pharmacy. However, sharps may be safely collected in *sharps-specific* collection receptacles. Please do not prohibit the placement of sharps-specific collection receptacles in pharmacies; consider clarifying the wording of Section 1776.1(e) to prohibit sharps and

MEMBER AGENCIES

- City of Cloverdale
- City of Cotati
- City of Healdsburg
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- City of Santa Rosa
- City of Sebastopol
- City of Ukiah
- County of Mendocino
- County of Sonoma
- Sonoma County Water Agency
- Town of Windsor

ANDY RODGERS
Executive Director

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(707) 666 - 4857

www.rrwatershed.org

other dangerous drugs from prescription drug collection receptacles only.

- The Drug Enforcement Agency (DEA) states that drug receptacles shall be locked or made otherwise inaccessible to the public when an employee is not present. The Board's proposed requirement to "lock the deposit slot on the collection receptacle and physically block patients from access to the collection receptacle by some means" is confusing. Requiring the receptacle itself to be physically blocked goes beyond the DEA requirements and does not necessarily increase public safety. Furthermore, the security requirements, as written, could be misinterpreted. Is this a requirement to install a physical barrier around all collection receptacles? Requiring this would likely consume more pharmacy floor space and deter pharmacies from installing collection receptacles. Please consider clarifying the security requirements in Sections 1776.3(a) and 1776.3(c).
- In the case of pharmacies, the DEA regulations only state that liners must be removed "promptly." Please consider updating Section 1776.3(j) to be consistent with the DEA by removing the "three day" removal requirement and replacing it with a "prompt" removal.
- A pharmacy that distributes mail-back envelopes does not come into contact with the collected, unwanted medications. Instead, the unwanted medications are mailed directly to a reverse distributor. The reverse distributor is responsible for recording information about the collected medications including the date and unique identification number.

Simply having mail-back envelopes on site does not mean that the pharmacy is actively collecting unwanted prescription drugs at their location. Accordingly, please consider eliminating the requirement for pharmacy retailers to be registered with the DEA as a collector if they participate in drug take-back programs only by distributing empty envelopes to patients.

Furthermore, the DEA does not require retailers that sell or otherwise distribute mail-back envelopes to or maintain records of the mail-back envelopes *before they are used to collect unwanted medications*. Please remove the burdensome recordkeeping requirements for empty mail back envelopes outlined in Sections 1776.2(e), 1776.6(a), and 1776.6(b).

- Please consider revising the language of Section 1776.1(a) to allow local jurisdictions to require pharmacy participation in regional

programs. In some cases, local jurisdictions may consider mandating pharmacies to participate in a regional drug take-back program, so long as the pharmacies are not *financially responsible* for providing the service. To avoid any potential dispute regarding the Board's preemption of local jurisdictions, we request the removal of the sentence "Provision of such services is voluntary." from Section 1776.1(a).

RRWA and the SMD Collaborative agree that pharmacies should be able to assist patients seeking to destroy unwanted medications. In our community, participants have shown a preference for disposing of their unwanted medications at pharmacy take-back locations. RRWA and the SMD Collaborative hope to grow the number of pharmacies that participate in the SMD Program. As written, the Board's regulations are confusing, open to misinterpretation and could deter pharmacy participation in SMD Programs. Because of this, we request that you revise and clarify Section 1776.

If you have any questions or concerns about RRWA's position, please contact me at 707-508-3672.

Sincerely,



Andy Rodgers, RRWA Executive Director

Cc: RRWA Board of Directors
Safe Medicine Disposal Ordinance Collaborative
Heidi Sanborn, California Product Stewardship Council

Martinez, Lori@DCA

From: Jan Harris <jharris@sharpsinc.com>
Sent: Monday, March 28, 2016 4:56 PM
To: Martinez, Lori@DCA
Cc: Sodergren, Anne@DCA
Subject: Sharps Compliance Comments to Draft Regulations 1776
Attachments: Sharps Compliance CABOP Proposed Draft 1776 Comments.pdf; Sharps Compliance CABOP Proposed Draft 1776 Letter.pdf

Hello Ms. Martinez,

Please accept comments on proposed draft regulations 1776 submitted by Sharps Compliance for the Board's review and consideration.

Thank you,

Jan Harris

Jan Harris | Director, Environmental Health & Safety

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

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

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. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

Section 1776 Prescription Drug Take-Back Programs: Authorization

Paragraph 1:

“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 to the public to provide options **for the public to destroy** unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.”

Proposed change:

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and **licensed long-term healthcare facilities** may offer, under the requirements in this article, specified prescription drug take-back services to the public to provide options **for the public to have their unused or outdated prescription drugs collected for destruction**. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article

Comments:

- By changing from “**Licensed Skilled Nursing Facilities**” to “**Licensed Long-Term Healthcare Facilities**”, the regulations will be more inclusive in the collection and disposal rather than restricting only to skilled nursing facilities. Thousands of pounds of unused medications in Residential Care Facilities for the Elderly/Assisted Living (RCFE/AL) will continue to be sewered or placed into the trash if not included in this regulation. By incorporating California’s definition of long-term healthcare facilities (LTCF) as defined in the Health and Safety Code section 1418, the definition will better reflect the language in the DEA rule. In the DEA language (page 53540), long-term care includes facilities which provide extended healthcare to resident patients. In addition, EPA’s proposed rule on management standard for hazardous waste pharmaceuticals includes clear language including all long-term care. Upon the finalization of this rule, inclusion of RCFE/AL facilities in California will simplify the disposal process and potentially increase the usage of receptacles in LTCF.
- For clarification, we propose wording changed from “**for the public to destroy**” to “**for the public to have their unused or outdated prescription drugs collected for destruction**.”

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

Paragraph 2:

“All board-licensed **authorized collectors** should **be vigilant** to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods.”

Proposed change:

“All board-licensed **authorized collectors with collection receptacles** should, **through signage and other feasible methods, reduce the chance of** the patients or their agents of disposing of prohibited items through drug take-back collection methods.”

Comments:

- Both DEA and the Board’s proposed rules state that drugs returned for collection shall not be reviewed, accepted, counted, sorted, or handled. Since the pharmacy employees cannot inspect the drugs being placed into a receptacle, we believe the term vigilant could be confusing.
- Since employees of authorized collectors of mail-back envelopes/packages are not aware of what is placed into the envelopes/packages, we believe there should be clarification by adding receptacle. Note that the DEA rule requires that detailed instructions be included with mail-back envelopes/packages as to what can and cannot be placed in the mail-back.

Paragraph 3:

“Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration **as collectors** may participate in drug take-back programs authorized under this article.”

Proposed change:

“Only California-licensed pharmacies placing a drug take-back collection receptacle at their registered location, or at a LTCF; and drug distributors/reverse distributors (licensed wholesalers and third-party logistics providers) conducting a mail-back collection program who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take-back programs authorized under this article.”

Comments:

The DEA states that “A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector.” A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction (1317.90).

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713-927-9956

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

Pharmacies are not the collector of mail-backs because the mail-backs do not come back to them; and in addition, they do not have the required onsite method of destruction.

On the other hand, reverse distributors cannot register as a collector for receptacles since the receptacle has to be located at the registered collectors' place of business. The pharmacy is the registered collector for the receptacle collection.

We would request that the differences in "collectors" be clarified throughout the regulations to harmonize with the DEA rule and to reduce confusion.

Section 1776.1 Pharmacies

General comment for this section: Since pharmacies are not collectors for mail-back programs, we suggest changing all language in this section from "drug take-back program" to "drug take-back collection receptacle program"

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

Proposed change:

Pharmacies may assist patients **or their authorized agents seeking to have their unused or outdated prescription drugs collected for destruction.**

Comments:

- Patients aren't destroying the drugs, and therefore we believe the proposed change will help clarify that this is collection for destruction.
- We suggest removing "Provision of such services is voluntary." By placing this language into the rule, it could pre-empt local jurisdictions' ordinances.

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

Proposed change:

...operated by pharmacies or distributors/reverse distributors are only...

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Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

Comment:

Since pharmacies are collectors for receptacles and reverse distributors are collectors for mail-back programs, we suggest including distributors/reverse distributors when using terminology that may indicate all take-back programs, including mail-backs.

(g) “A pharmacy must be registered with the federal Drug Enforcement Administration as a collector **for purposes of operating a prescription drug take-back program.**”

Proposed change:

“A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for **the purposes of operating a prescription drug take-back collection receptacle.**”

Comment:

The draft wording may be interpreted that if a pharmacy chooses to participate with a reverse distributor in providing mail-back envelopes/packages, they must register as a mail-back collector. And as previously indicated, the reverse distributor, not the pharmacy is the collector for mail-backs.

Section 1776.2 Mail Back Package and Envelope Services from Pharmacies

Proposed change:

Recommend removing from the Section title, the words “from Pharmacies” since mail-back program collectors (reverse distributors) can partner with other organization as well.

(a) “Pharmacies that provide prescription drug take-back services may do so by establishing **mail-back services**, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.”

Proposed change:

“Pharmacies may participate with DEA-registered collectors that are reverse distributors with onsite destruction to provide preaddressed mail-back envelopes or packages to the public for the return and destruction of prescription drugs.”

Comment:

Proposed change would clarify that pharmacies could participate in this way without registering as collectors.

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

(e) “The pharmacy distributing mail-back envelopes/packages shall create and maintain records required by section 1776.6”.

Proposed change:

Delete.

Comment:

Since the pharmacy would be participating with the reverse distributor registered as a mail-back collector to provide mail-backs, and is not the collector itself, (e) is only applicable to the collector of the mail-back, not the pharmacy and is therefore not applicable. This comment would also apply to 1776.4(h)(2).

1776.3 Collection Receptacles in Pharmacies

(a) “Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. **In 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 patients from access to the collection receptacle by some means.**”

Proposed change:

“...In 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 or make otherwise inaccessible to the public when an employee is not present, e.g., when the pharmacy is closed.”

Comment:

This language harmonizes with the requirements of the DEA without causing confusion in interpreting what “physically blocked” could mean. The language as drafted could deter pharmacies from placing receptacles due to the perception that additional construction or barriers must be placed.

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

(b) “The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, **where the receptacle is visible to pharmacy employees, but not located in emergency areas.**”

Proposed change:

...where the receptacle is visible to employees, and not located in emergency areas.

Comment:

Receptacles in hospitals/clinics with onsite pharmacies need to be monitored, but would not necessarily be placed where pharmacy employees could monitor. In addition, receptacles in LTCF would need to be monitored by facility employees. Therefore, using employee instead of pharmacy employee would harmonize with the DEA rule and not discourage hospitals/clinics or LTCF from participating in a take-back receptacle program. This comment will also apply to 1776.3(c).

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

Proposed change:

“...A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, and **capable of being sealed** and 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 and other applicable state and federal regulations for this waste type.**”

Comment:

- Since a rigid container may be a cardboard box designed to be sealed, the term “tight-fitting covers” could result in the interpretation of an actual cover/lid being required on the cardboard box/inner liner. Therefore, the commonly used term of sealed, which could apply to a variety of container types, is recommended.
- Since medical waste does not include household waste, requiring that transport containers meet the packaging requirements of medical waste exceeds the requirements of the DEA and DOT regulations for the transport of this waste type.

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

(k)(5) “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.”

Proposed change:

“If a common carrier is used to transport the liner to the reverse distributor, the company used, and any related paperwork (invoice, bill of lading) must be recorded.”

Comment:

DEA does not require a driver’s signature. In addition, a common carrier would not be able to sign such a document. By adding this language, it would preclude the use of common carrier and therefore result in 2-driver pick-up where this would not be cost-effective; and would limit the number of pharmacies participating in the take-back program.

1776.4 Collection in Skilled Nursing Facilities

Proposed change:

Expanding the referenced definition of Skilled Nursing Facilities to include language from the Health and Safety Code section 1418 would more clearly and consistently reflect DEA language; this would be accomplished by including California’s definition of Long Term Health Care Facilities.

Comment:

Additional information on this proposed change in this document under 1776 Authorization, Paragraph 1, Proposed Change

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

(a) “. . . Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.”

Proposed change:

Delete.

Comment:

This recordkeeping requirement goes beyond DEA requirements. Additional recordkeeping burdens beyond that required by DEA will lead to a reduced number of facilities utilizing the mail-back option.

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

Proposed change:

“Sealed inner liners that are placed in a container may be stored at the long-term healthcare 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 DEA-registered reverse distributor by common or contract carrier pick-up or by distributor pick-up at the collector’s authorized collection location.”

Comment:

This proposed change is intended to clarify that the transfer from the facility is to a common carrier or pickup from the facility to transport the liner to a reverse distributor. This should help to clarify that the DEA regulations do not allow the collector pharmacy to take the inner liners themselves for disposal.

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

(o) Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.

Proposed change:

Records of the acquisition, installation and removal from collection receptacle, transfer to storage, and transfer for destruction for each collection receptacle sealed liner must include the dates, addresses of the locations where each liner is installed, unique identification numbers and sizes (e.g. 5-gallon, 10-gallon, etc.), registration number of the collector, the names and signatures of the two employees involved in these processes, and the name of the reverse distributor to whom each sealed inner liner was transferred.

Comment:

In order to harmonize with DEA, 1304.22(f)

1776.5 Reverse Distributors

(a) “A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) **registered DEA as a collector** may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.”

Proposed change:

“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. Once received, the reverse distributor shall establish records required by this section.”

Comment:

The DEA-registered reverse distributor is not the collector in the case of collection receptacles.

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

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

(a)(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.”

Proposed change:

Delete.

Comment:

Pharmacies cannot be the collector of mail-back envelopes under the DEA Regulations because the mail-back envelopes do not come back to them; furthermore, pursuant to the DEA Regulations they are prohibited from being the collector as they do not have the required onsite method of destruction. Rather, the collector is the reverse distributor to which the envelopes are mailed from the ultimate user. DEA 1317.70 A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter. DEA 1317.70 (c) states that “any person may partner with a collector or law enforcement to make such packages available in accordance with this section.”

1304.22(f) of the DEA regulations states, “For unused packages provided to a third party to make available to ultimate users and other authorized non-registrants: 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 numbers”. Since the reverse distributor is the mail-back collector, this requirement would not be applicable to pharmacies. By placing this additional recordkeeping burden on pharmacies, it will reduce those willing to participate with reverse distributor collectors in providing mail-backs to the public.

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

(a)(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.”

Proposed change:

Delete.

Comment:

DEA requires only a collector to keep, as that term is interpreted under the DEA regulations 1304.22(f) as indicated previously.

(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.”

Proposed change:

Delete.

Comment:

DEA requires only a collector to keep, as that term is interpreted under the DEA regulations 1304.22(f) as indicated previously.

Sharps Compliance, Inc. Comments on Board of Pharmacy Regulations Regarding Pharmaceutical Take-back Programs

March 28, 2016

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

RE: Comments on California Board of Pharmacy proposed regulations for prescription drug take-back programs.

Dear Ms. Martinez:

Please accept the attached comments and recommended modifications to the Board's proposed draft regulations regarding pharmaceutical take-back programs.

Sharps Compliance, Inc. (Sharps) is a DEA-registered reverse distributor and collector with onsite destruction that has collected non-controlled medications through collection boxes and a USPS-authorized mail-back program since 2009. In 2014, Sharps adapted our programs to meet the DEA rule for disposal and has collaborated with 3rd parties to provide thousands of envelopes and receptacles for the collection of controlled and non-controlled drugs from ultimate users at retail pharmacies, long-term care communities, law enforcement facilities, narcotic treatment centers, hospitals and clinics with onsite pharmacies, and the military in California and throughout the United States. Mail-backs as well as inner liners removed from collection receptacles are transported to Sharps' onsite DEA-registered destruction facility via common carrier. Sharps has prevented over 1 million pounds of pharmaceuticals from contaminating our waters and potentially ending up in the wrong hands.

Sharps appreciates the effort the Board has put into developing this rule. Sharps is also concerned that the regulations as drafted may reduce the number of California pharmacies agreeing to become collectors due to the added perceived burden and differences with the DEA regulations. This could reduce the convenience for ultimate users, resulting in potential diversion from expired drugs in the home and continued sewerage and trash disposal in both homes and in long-term care facilities.

Again, Sharps appreciates the Board's work and looks forward to continued efforts to develop a rule that harmonizes with the DEA regulations. Sharps is available to answer any questions regarding our programs or these comments/recommendations.

Thank you,

Jan Harris, MPH
Director, Environmental, Health and Safety, Sharps Compliance

Attachment

jharris@sharpsinc.com
www.sharpsinc.com
713-927-9956

Martinez, Lori@DCA

From: Tim Goncharoff <Tim.Goncharoff@santacruzcounty.us>
Sent: Thursday, February 18, 2016 8:11 AM
To: Herold, Virginia@DCA; 'ramonc@qhconcepts.com'; Martinez, Lori@DCA
Subject: Proposed Regulations on Pharmaceutical Takeback

Dear Ginny and Members of the Board,

I write to take strong exception to your proposed regulations on pharmaceutical takeback programs. Rather than protecting the health and safety of Californians, as your Board is charged, this proposed regulation would make proper disposal of unused pharmaceuticals less likely, leading to further environmental damage, more drugs poisoning children and the elderly, and more drugs finding their way to the illicit black market. I urge you to reconsider.

Good models for the proper disposal of unused medications exist. They are common in Europe and Canada, and are now appearing in California. These approaches work. They are safe, proven, inexpensive and convenient for consumers. Placing unnecessary obstacles in the path of these proven programs is exactly the wrong stance to take. Your Board should be encouraging such programs.

I have particular concerns with the sections cited below:

“Only California-licensed pharmacies and drug distributors (licensed wholesalers and third- party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.” Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.

While it is good to see an authority cited as required by law, a quick read makes it clear that the authority claimed is nowhere in the code. The Board may regulate pharmacies. It has no authority to permit or prohibit the activities of any other business or entity.

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

The Board seeks to arrogate to itself powers that are contained nowhere in the law. The recorded discussions of the Board make it clear that the intent of declaring participation voluntary is to supersede local ordinances mandating participation. The Board has no such authority under the law. Similarly, the Board’s attempt to regulate skilled nursing facilities and other non-pharmacy locations is clearly beyond their authority.

“e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s 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 shall be placed on collection receptacles as referenced in section 1776.3.”

This section is bound to lead to confusion. As your Board knows, specific collection programs for medical sharps are in place in many locations, including pharmacies, and more are on the way. This section would seem to prohibit such efforts, leaving improper disposal of medical sharps the only option. This is severely misguided.

“A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.”

An obvious question is “How will they know?” Are pharmacy staff supposed to quiz customers about whether they come from any of the prohibited locations? Beyond that, the sections seems to force such facilities into a twilight zone without any legal disposal options. You would prohibit them from participating in takeback programs on their own, and prohibit them from participating in those located at pharmacies. What then are they to do with their leftover medications?

“1776.3 Collection Receptacles in Pharmacies

Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In 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 patients from access to the collection receptacle by some means.”

This is a tangled section that will only have the effect of creating the very problem it intends to avoid. Why shouldn't receptacles inside stores be accessible to the public when the pharmacy is closed? They are sturdy, securely bolted down, and tamper-proof without the use of power tools. In fact they are far more secure than the drugs on the pharmacy's shelves. If we lock the bins people will leave drugs on top of or next to them. If we create physical barriers, the drugs will be left next to the barriers. This is silly. Leave the darn bins unlocked so people can use them whenever the store is open. This is how it currently works in many places, and it works well.

“(c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from patient access by some means.”

Where does your Board find the legal authority to regulate hospitals? Many medical facilities, including hospitals, now host bins for the collections of leftover medicines and sharps. Why would you want to interfere with this?

“(i) The liner may be removed from a locked receptacle only by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle.”

This is poorly thought out. What busy pharmacy can spare two staff members to handle this duty? It is more properly performed by a duly licensed collector. You are making this burdensome for pharmacies, and as you insist on making such programs voluntary, making it unlikely that they will participate.

“(k) The pharmacy shall maintain a 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.”

Again, unnecessarily burdensome, and an obstacle to participation. Collectors are already required to keep meticulous records. Let them provide copies to the pharmacy or the Board if needed, but don't expect busy pharmacists to undertake this unnecessary duty.

“(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 Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
(n) The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process.”

This is well-intentioned, but I encourage you to look at the signs and other materials already in use where such programs are active. Many consumers do not know what a Schedule I or Schedule II drug is. Signage needs to be designed for consumers, not for pharmacists.

In summary, while I think the proposed regulations are well-intended, they will have the effect of encouraging improper disposal of drugs and sharps by making safe and proper disposal programs difficult, inconvenient, expensive and scarce. I strongly encourage you to withdraw the proposed regulations, carry out a serious study of the many effective disposal programs already up and running, and then approach this subject again with better information and a clearer intent.

Thank you,

Tim Goncharoff
County of Santa Cruz

Martinez, Lori@DCA

From: Hare, Thomas <THare@srcity.org>
Sent: Friday, March 25, 2016 3:18 PM
To: Martinez, Lori@DCA
Subject: Santa Rosa Water BOP 45 Day Comment Drug Take-Back
Attachments: Santa Rosa Water BOP Letter.pdf; Santa Rosa Water BOP Comments.docx

RE: COMMENTS ON BOARD OF PHARMACY PROPOSED REGULATIONS FOR PRESCRIPTION DRUG TAKE-BACK PROGRAMS DATED FEBRUARY 1, 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 comments specific to sections of the proposed Board of Pharmacy Regulations are to be found in the ten 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 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



March 23rd, 2016

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

RE: COMMENTS ON BOARD OF PHARMACY PROPOSED REGULATIONS FOR PRESCRIPTION DRUG TAKE-BACK PROGRAMS DATED FEBRUARY 1, 2016

Dear Ms. Martinez:

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

The attachment includes excerpts from the proposed regulations by section and includes potential modifications with comments that describe our concerns in detail. There is some duplication within the sections in order that they might still be coherent if separated for review. However, in the case of comments regarding the status of pharmacies participating in mail-back programs, the full comment is too lengthy to duplicate in each relevant section.

City of Santa Rosa staff is very appreciative of the Board of Pharmacy staff's willingness to delve into the details of the DEA regulations in order to establish a shared understanding and to promote beneficial Board of Pharmacy regulations of pharmaceutical take-back programs in California. If you would like to discuss any of our concerns or need any additional details, please feel free to contact Thomas Hare at (707) 543-3396.

Thank you for your consideration.

Linda Reed,
Acting Director Santa Rosa Water

Attachment

Attachment – City of Santa Rosa Water Department Comments on Board of Pharmacy Regulations regarding Pharmaceutical Take-back Programs

Section 1776 Prescription Drug Take-Back Programs: Authorization

“All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods.”

Proposed text change: “All board-licensed authorized collectors should to the extent feasible prevent patients or their agents from disposing of prohibited items through drug take-back collection methods.”

Comment: Considering that the Board’s proposed regulation section 1776.1(f)(1) states “Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public”, it will be difficult for pharmacies to vigilantly prevent items from being deposited in the collection receptacle without reviewing drugs returned from the public. Suggest the term “vigilant” be changed as noted above.

Section 1776 Prescription Drug Take-Back Programs: Authorization

“Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.”

Proposed text change: “Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board may participate in drug take back programs authorized under this article. Those pharmacies wishing to host a prescription drug take-back collection receptacle must be registered with the Drug Enforcement Administration as collectors.”

Comment: The DEA states that “A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter (§ 1317.70).”

As confirmed 3/18/2016 by Ruth Carter, Chief of the Liaison & Policy Section of the DEA, pharmacies are not the collector of mail-backs because the mail-backs do not come back to them; furthermore, they are prohibited from being the collector as they do not have the required onsite method of destruction (see section 1776.6(a)(1) for full explication).

It would be helpful to rephrase the text to make it clear that pharmacies can participate in drug take-back programs by providing mail-back envelopes without being registered as a collector with the DEA. If the Board wishes to require pharmacies to be licensed and in good standing in order to offer mail-back envelopes, the above suggested text would still accomplish this.

Section 1776.1 Pharmacies

1776.1(a) “. . . *Provision of such services is voluntary*”

Proposed change(s):

- 1) Remove voluntary language entirely, or as a minimum:
- 2) Clarify Board intent regarding pre-emption, and:
- 3) Specify that local jurisdictions are allowed to require non-participating pharmacies to post signs informing the public of participating pharmacy locations, and/or as an intermediate step:
- 4) Avoid precluding local jurisdictions from requiring pharmacies to provide mail-back envelopes so long as the pharmacies are not financially responsible for the associated costs.

Comment: Staff is concerned that the current wording might be construed as prohibiting local jurisdictions from requiring pharmacies that are not themselves providing medicine take-back services to post signage directing their customers where they can go to safely dispose of their medications or from requiring pharmacies to provide mail-back envelopes where they are not responsible for the associated costs. Staff is concerned that local ordinances such as these could be construed as mandating the pharmacy to ‘assist patients seeking to destroy’ in conflict with the voluntary provision of the state law. If this is not the intent of the Board, staff would welcome clarification of the proposed regulation. In doing so, staff would hope to avoid any potential dispute regarding the scope of preemption of local jurisdictions.

In order to address potential financial concerns, staff would welcome the Board to consider allowing local jurisdictions to require pharmacies to provide mail-back envelopes so long as the pharmacy is not mandated to be financially responsible for the cost of providing the envelopes.

1776.1(e) *“The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s 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). . .”*

Proposed text change: “The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s prescription drug collection receptacle: . . .<list with footnotes giving regulatory references for each prohibited item> . . .”

Comment: The way this section is currently worded implies that pharmacies are not permitted to have a separate bin for sharps collection. The origin of each of these prohibitions is unclear; please identify the source regulation in each case. Staff asks that the Board avoid making the regulation more restrictive than necessary in order that local medicine take-back programs may enjoy robust participation from local pharmacies and the general public.

1776.1(g) *"A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program."*

Proposed text change: "A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for the purposes of operating a prescription drug take-back collection receptacle."

Comment: The proposed wording may imply that if a pharmacy decides to participate in a mail-back program that they have to be registered as a collector; as elsewhere discussed, this is not a requirement per the DEA (see section 1776.6(a)(1) for full explication).

Section 1776.2 Mail Back Package and Envelope Services from Pharmacies

1776.2(a) *"Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location."*

Proposed text change: "Pharmacies that would like to provide prescription drug take-back services without registering as a collector may do so by establishing mail back services, whereby . . ."

Comment: Suggested change would clarify that pharmacies could participate in this way without registering as collectors.

1776.2(e) *"The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6".*

Proposed change: Delete this provision.

Comment: Staff is concerned that adding records requirements beyond DEA requirements could de-incentivize participation in medicine take-back programs. Per the DEA, "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§ 1317.70)." See section 1776.6(a)(1) for more detail about collector status and requirements.

1776.3 Collection Receptacles in Pharmacies

1776.3(a) *" . . . In 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 patients from access to the collection receptacle by some means."*

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

Comment: Staff is concerned that requiring pharmacies in retail stores to install a physical barrier something like an accordion style door might discourage them from participating in medicine take-back programs and shift a larger burden to local independent pharmacies. Additionally, it is unclear what

exactly would constitute being physically blocked, and that alone could make it less likely for risk-averse pharmacies to participate.

DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked goes beyond what the DEA requires. Moreover, it would be just as easy for members of the public to place medicine next to a physical barrier as it would be for them to place medicine next to a locked bin. It would also be easy for members of the public to place their medicines in the closest trash bin, as has been observed. Staff has heard comments that even in pharmacies that do not have any sort of sharps or medicine take-back program, members of the public have left things like syringes on the counter of the pharmacy while the pharmacy is closed. It is unreasonable to expect that this regulation can completely prevent improper disposal from occurring.

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

1776.3(b) ". . . *The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.*"

Proposed change: Remove the word 'pharmacy' from 1776.3(b) so that it reads as the DEA: "visible to employees", not "visible to pharmacy employees".

Comment: Staff is concerned that this section goes beyond the DEA regulation in a subtle but potentially significant way. As the DEA recognizes, hospitals can be unique in their design and need to have flexibility in the manner in which they participate in Safe Medicine Disposal Programs. The Board regulation as it is currently worded removes some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees" (Federal Register p. 53523). This implies that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. Staff is concerned that the Board regulation as it is currently worded could discourage hospitals from participating in Safe Medicine Disposal programs by making it more difficult for them to do so.

1776.3(c) *In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from patient access by some means.*

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

Comment: As mentioned in the comment for section 1776.3(b), the DEA recognizes that hospitals can be unique in their design and need to have flexibility in the manner in which they participate in safe medicine disposal programs. The proposed Board regulation may remove some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees". This implies that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. This further implies that collection receptacles in hospitals do not need to be locked if the pharmacy is closed so long as hospital employees are still regularly monitoring the receptacle. Therefore, even if physical blockage is required in a retail store with a pharmacy, it should still not be necessary in a hospital setting.

Staff is concerned that the Board regulation as it is currently worded could discourage hospitals from participating in medicine disposal programs by making it more difficult for them to do so. Requiring hospitals to install something like an accordion style door could discourage them from participating. Additionally, it is unclear what exactly would constitute being physically blocked, and that alone could make it less likely for risk-averse hospitals with pharmacies to participate. The DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked goes beyond what the DEA requires. Moreover, it would be just as easy for members of the public to place medicine next to a physical barrier as it would be for them to place medicine next to a locked bin. It would also be easy for members of the public to place their medicines in the closest trash bin, as has been observed.

DEA section 1317.75(e):

"Except at a narcotic treatment program, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees."

Federal Register p. 53523:

"The DEA recognizes that hospitals/clinics with an on-site pharmacy can be unique in their design and it may be more effective to install collection receptacles at various locations within the hospital/clinic, depending on factors such as security, convenience, and accessibility. As such, it would be challenging for authorized hospitals/clinics to adhere to the general rule to place collection receptacles in the immediate proximity of where controlled substances are stored and at which an employee is present. Accordingly, the DEA is requiring hospitals/clinics that are collectors to place collection receptacles in locations that are regularly monitored by employees."

1776.3(h) ". . . A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. 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."

Proposed text change: "A rigid container may be disposable, reusable, or recyclable (example: cardboard box). Rigid containers shall be capable of being sealed and be kept clean and in good repair.

Rigid containers may be of any color. All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.”

Comment: Requiring rigid containers to “meet standards of the USDOT for transport of medical waste” exceeds the requirements of the DEA regulation, which does not mention medical waste. There is a lot of confusion around the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste. HSC §117700 says, “Medical waste does not include . . . (e) Hazardous waste, radioactive waste, or *household waste* . . .” Moreover, it appears that home-generated pharmaceutical waste is still considered household waste once it’s collected and consolidated. Alison Dabney, Chief of the California Department of Public Health’s Medical Waste Management Program wrote on November 18, 2015, “A waste-to-energy facility’s permit that prohibits it from accepting medical waste in California does not prohibit the facility from accepting consolidated home-generated pharmaceutical waste, since the current law (Health and Safety Code, §§117600-118360) does not prohibit it. However, any local ordinances regarding the disposal of these items should also be reviewed.”

One of the reasons that staff is concerned about using medical waste transport regulations is that there are a lot of exemptions that surround the regulation of medical waste transport, and this makes it very difficult to determine what is required. For example, while the definition of medical waste in the Health and Safety Code does include pharmaceutical waste, they exempt pharmaceutical wastes that are being hauled by a reverse distributor (Health and Safety Code Section 117690). It is unclear if this exemption might nullify the otherwise applicable DOT regulations.

In order to avoid confusion, it could be helpful for the Board to replicate the DEA’s statements in this matter: “All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.” (Federal Register p53554)

It is not clear what exactly would qualify as meeting the USDOT standards. Staff would welcome guidance from the Board clearly establishing that a cardboard box could meet the requirements specified as cardboard boxes are currently an industry standard. Dis-allowing cardboard boxes would cause the price of disposal to substantially increase. Do cardboard boxes have tight-fitting covers? Are they rigid? Do they qualify as leak resistant? Or would a cardboard box in combination with a plastic bag combine to fulfill the requirements of the “inner liner” as the inner liner is already required to be waterproof? Clarification would be beneficial.

1776.3(j) “location in the pharmacy *no longer than three days*”

Proposed change: Delete specific time provision, replace with requiring “prompt” removal.

Comment: It is staff’s understanding that the DEA regulation only specifies a three day holding period in Long-Term Care Facilities. In the case of pharmacies, the DEA dictates only that liners be moved “promptly”. The DEA specifically declined to clarify what would constitute a “prompt” action (Federal Register p. 53528). Strictly defining the length of time inner liners can be stored could increase the burden on pharmacies and thereby decrease their participation in medicine take-back programs.

1776.4 Collection in Skilled Nursing Facilities

Proposed change: Expanding the referenced definition of Skilled Nursing Facilities to include language from the Health and Safety Code section 1418 would more clearly and consistently reflect DEA language; this would be accomplished by including California's definition of Long Term Health Care Facilities.

Comment: DEA defines Long-Term Care Facilities on page 53540 of the Federal Register as "a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients." This appears to have a broader meaning than the Skilled Nursing Facility referred to by the Board and defined in the Health and Safety Code section 1250(c) as "a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis". Staff would like to avoid further restricting which types of facilities are permitted to participate in medicine take-back programs.

1776.4(a) ". . . Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent."

Proposed change: Delete this provision.

Comment: This provision goes beyond DEA record-keeping requirements. Staff asks that the Board avoid making the regulation more restrictive than necessary in order that local medicine take-back programs may enjoy robust participation from local pharmacies, Long-Term Care Facilities, and the general public.

1776.4(h)(2) ". . . A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. 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."

Proposed text change: "A rigid container may be disposable, reusable, or recyclable (example: cardboard box). Rigid containers shall be capable of being sealed and be kept clean and in good repair. Rigid containers may be of any color. It is not within the Board's expertise or authority to opine on the applicability of DOT regulations. However, all drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations."

Comment: As mentioned in the comment for 1776.3(h), staff is concerned that stating specifically that rigid containers must "meet standards of the USDOT for transport of medical waste" exceeds the requirements of the DEA regulation, which does not mention medical waste. There is a lot of confusion around the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste. HSC §117700 says, "Medical waste does not include . . . (e) Hazardous waste, radioactive waste, or household waste . . ." Moreover, it appears that home-generated pharmaceutical waste is still considered household waste once it's collected and consolidated. Alison Dabney, Chief of the California Department of Public Health's Medical Waste Management Program wrote on November 18, 2015, "A waste-to-energy facility's permit that prohibits it from accepting medical waste in California does not prohibit the facility from accepting consolidated home-generated pharmaceutical waste, since the current law (Health and Safety Code, §§117600-

118360) does not prohibit it. However, any local ordinances regarding the disposal of these items should also be reviewed.”

1776.4(n) *“Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor’s registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.”*

Proposed change: Make consistent with DEA language.

Comment: The DEA regulation allows “the installation, removal, transfer, and storage of inner liners . . . by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility” in addition to allowing these activities to occur under the supervision of two pharmacy employees (§1317.80(c)). Staff is concerned that the BOP regulation as it is currently worded may restrict some of the listed allowable activities to just two pharmacy employees where the DEA regulation allows more flexibility.

Separately, staff is concerned that the Board language may differ from DEA regulations which say: “. . . the practitioner may destroy the collected substances by delivering the sealed inner liners to a reverse distributor or distributor’s registered location by common or contract carrier, or a reverse distributor or distributor may pick-up sealed inner liners at the LTCF” (Federal Register p. 53543 and §1317.05). It appears DEA language prohibits pharmacy employees from transporting the sealed inner liners themselves; staff would welcome clarification from the Board on this matter.

1776.5 Reverse Distributors

1776.5(a) *“A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered DEA as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.”*

Proposed text change: “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. Once received, the reverse distributor shall establish records required by this section.”

Comment: Per Ruth Carter, Chief of the Liaison & Policy Section of the DEA, the DEA-registered Reverse Distributor is not the collector except in the case of mail-backs (see section 1776.6(a)(1) comment).

1776.5(b) *“A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately licensed DEA distributor.”*

Proposed text change: “A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be rendered non-retrievable by an appropriately licensed DEA distributor in compliance with applicable Federal, State, tribal, and local laws and regulations.”

Comment: Incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable. One approved method is incineration. Actually, “the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration. . .” (Federal Register, p. 53536).

1776.5(e) *“Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. . .”*

Proposed text change: “Each reverse distributor with a destruction site shall maintain a record of the destruction on DEA form 41.”

Comment: As mentioned in the comment for 1776.5(b), incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable.

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

1776.6(a)(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.”*

Proposed change: Preserve the DEA requirement that these records are required only for the reverse distributors accepting these envelopes for destruction.

Comment: Pharmacies cannot be the collector of mail-back envelopes under the DEA Regulations because the mail-back envelopes do not come back to them; furthermore, pursuant to the DEA Regulations they are prohibited from being the collector as they do not have the required onsite method of destruction. Rather, the collector is the reverse distributor to which the envelopes are mailed from the ultimate user.

In order to seek clarification in this matter from the DEA, staff sent an email on 18 March 2016 to Ruth Carter, Chief of the Liaison & Policy Section of the DEA. On March 18, 2016, Ruth Carter from the DEA staff sent a response which confirmed that under the DEA Regulations the reverse distributor is the collector when it comes to mail-back packages, not the pharmacy providing the mail-back packages. A copy of the email exchange can be provided upon request.

Staff is concerned that if these recordkeeping duties are required for pharmacies who simply hand out the envelopes it will discourage pharmacies from participating in a medicine mail-back program. Staff respectfully submits for the Board’s consideration that they preserve the DEA requirement that these records are required only for the reverse distributors accepting these envelopes for destruction.

DEA: § 1317.70 Mail-back programs:

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

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

Federal Register, page 53536, Issue [3] and its response: ". . . A commenter also asked the DEA to clarify whether unregistered retail pharmacies working with a registered authorized collector would be permitted to make mail-back packages available to patients. Response: As discussed in the NPRM, authorized collectors who conduct mail-back programs are encouraged to collaborate to operate mail-back programs by partnering with other entities to assist with the dissemination of mail-back packages to ultimate users, in order to minimize costs. . ."

1776.6(a)(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."*

Proposed change: Preserve the DEA requirement that these records are required only for the reverse distributors accepting these envelopes for destruction.

Comment: Per Ruth Carter, Chief of the Liaison & Policy Section of the DEA, this is the record that the DEA requires only a collector to keep, as that term is interpreted under the DEA regulations (§ 1304.22(f)). Staff would welcome clarification from the Board that this applies only to the collector, which in this case is the reverse distributor, not the pharmacy. See preceding section 1776.6(a)(1) for more detail.

1776.6(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."*

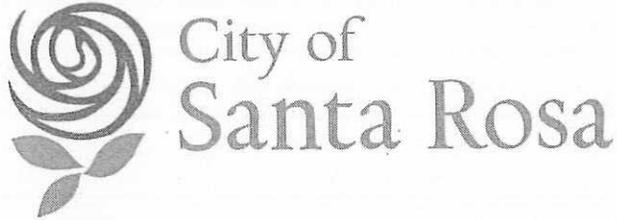
Proposed change: Preserve the DEA requirement that these records are required only for the reverse distributors accepting these envelopes for destruction.

Comment: Per Ruth Carter, Chief of the Liaison & Policy Section of the DEA, this is the record that the DEA requires the collector to keep (§ 1304.22(f)). Staff would welcome clarification from the Board that this applies only to the collector, which in this case is the reverse distributor, not the pharmacy. See section 1776.6(a)(1) for more detail.

1776.6(Note) *"Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1317.22, Title 21 Code of Federal Regulations"*

Proposed change: Confirm cited sections.

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



March 25th, 2016

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

RE: COMMENTS ON BOARD OF PHARMACY PROPOSED REGULATIONS FOR PRESCRIPTION DRUG TAKE-BACK PROGRAMS DATED FEBRUARY 1, 2016

Dear Ms. Martinez:

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

The attachment includes excerpts from the proposed regulations by section and includes potential modifications with comments that describe our concerns in detail. There is some duplication within the sections in order that they might still be coherent if separated for review. However, in the case of comments regarding the status of pharmacies participating in mail-back programs, the full comment is too lengthy to duplicate in each relevant section.

City of Santa Rosa staff is very appreciative of the Board of Pharmacy staff's willingness to delve into the details of the DEA regulations in order to establish a shared understanding and to promote beneficial Board of Pharmacy regulations of pharmaceutical take-back programs in California. If you would like to discuss any of our concerns or need any additional details, please feel free to contact Thomas Hare at (707) 543-3396.

Thank you for your consideration.

Linda Reed
Acting Director Santa Rosa Water

Attachment

Martinez, Lori@DCA

From: Laurie Ion <ion@templetoncsd.org>
Sent: Thursday, March 17, 2016 1:48 PM
To: Martinez, Lori@DCA
Cc: Jeff Brittz; tlm@templetoncsd.org; Bill Worrell (bworrell@iwma.com)
Subject: Letter of Protest - Concerning Section 1776 of Article 9.1 of Division 17 of Title 16 - Prescription Drug Take Back Programs
Attachments: CALIFORNIA-BRD-OF-PHARMACY-CORRES-MAR172016.pdf

03/17/16

Dear Ms. Martinez,
Attached please find a letter from the Templeton Community Services District Board of Directors concerning the above matter. As a wastewater and water utility the Templeton CSD Board of Directors believes it is imperative that we keep controlled substances from being disposed of by being flushed down the toilet or thrown out in the trash, where the drugs could contaminate local lakes, rivers, streams and soil. Our wastewater is a critical source of our water supply.

Thank you,
Laurie Ion, Assistant to the General Manager

p.s. The hard copy of this letter is being mailed to you.

Laurie Ion

Assistant to General Manager/Board Secretary
Templeton Community Services District
PHONE: (805) 434-4900
FAX: (805) 434-4820

CONFIDENTIALITY NOTICE: This email and any documents, files or previous email messages attached to it may contain information that is confidential or legally privileged and is for the sole use of the intended recipient(s). If you are not the intended recipient, do not read, print, or save this email. Any unauthorized review, use, disclosure or distribution of this email, its contents or the attachments, is strictly prohibited. If you are not the intended recipient, please contact the sender by telephone or reply email and destroy the original, any attachments and all copies without reading or saving.

BOARD OF DIRECTORS

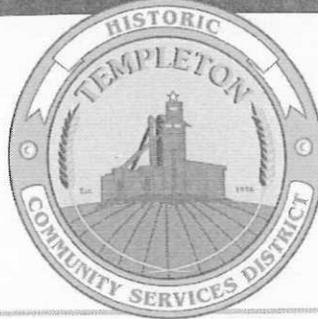
David LaCaro
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Bettina L. Mayer, P.E.
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Laurie A. Ion
*Assistant to General Manager/
Board Secretary*

Jay Short
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Finance Officer

Melissa Johnson
Recreation Supervisor

Bill White
Fire Chief

TEMPLETON COMMUNITY SERVICES DISTRICT

P.O. BOX 780 • 420 CROCKER STREET • TEMPLETON, CA 93465 • (805) 434-4900 • FAX: (805) 434-4820 • www.templetoncsd.org

March 16, 2016

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

RE: Letter of Protest - Concerning § 1776 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations regarding the Prescription Drug Take Back Programs

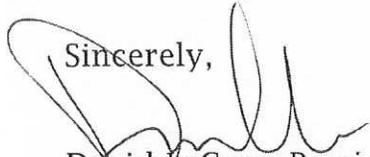
Dear Ms. Martinez,

Our agency is opposed to the California Board of Pharmacy's proposal to add § 1776 of Article 9.1 of Division 17 of title 16 of the California Code of Regulations regarding the prescription drug take-back programs. Since 2011 our agency has worked with the Integrated Waste Management Authority, law enforcement, health and safety, substance abuse prevention, and environmental organizations to provide safe medication drop-off locations for expired or leftover prescription medicines. As a wastewater and water utility it is imperative that we keep controlled substances from being disposed of by being flushed down the toilet or thrown out in the trash, where the drugs could contaminate local lakes, rivers, streams and soil. Our wastewater is a critical source of our water supply.

We believe that the public should have as many safe disposal options for the disposal of their unwanted medicines as possible. It only makes sense that returning expired or leftover prescriptions medicines to a local pharmacy would be acceptable and promoted, particularly in a rural community. The proposed Board of Pharmacy regulations, by preempting local programs and adding burdensome requirements to the Department of Justice regulations, will result in fewer take back locations.

Given the national drug abuse problems, California should be looking to enhance, not inhibit, the collection of unwanted medicine. The solution is to regulate the collection and disposal of unwanted medicine in accordance with the Department of Justice regulations issued on September 9, 2014.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. LaCaro', written over the word 'Sincerely,'.

David LaCaro, President
Board of Directors

Prescription Drug

Take-Back

Attachment 3

Regulation Hearing Comments

Code Section	Commenter	Comment
1776	LA County of Public Works	<p>Comment: This provision would remove the ability for entities that choose to not serve as authorized collectors but would choose to distribute mail-back envelopes to customers from partnering with authorized collectors to provide mail-back envelopes and thus significantly reduce the number of locations that would provide mail-back envelopes to consumers with no perceivable benefit. The DEA has determined such in Section § 1317.70 (c) of their Regulations which states "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section."</p> <p>Recommendation: Rephrase text so that it is clear that pharmacies can participate in drug take-back programs by providing mail-back envelopes without being registered as a collector. If the Board wishes to require pharmacies to be licensed and in good standing in order to offer mail-back envelopes, the following text could suffice:</p> <p>"Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board may participate in drug take-back programs authorized under this article. Those pharmacies wishing to host a prescription drug take-back collection receptacle must be registered with the Drug Enforcement Administration as collectors."</p>
1776.1(a)	LA County of Public Health	<p>Comment:</p> <p>Given that pharmacy participation is voluntary, and the Board of Pharmacy clearly states that the protection of the public is its function of highest priority, recommend language requiring that pharmacies that elect not to offer drug take back options (either receptacles or mail back envelopes) to their customers should, at a minimum, provide a listing of alternative locations that offer drug take-back options. This recommendation is similar to the requirement that physicians who are opposed to offering certain medical services on religious grounds must provide information about local area physicians who are able to offer those services in order to preserve access to those services.</p>
1776.1(e)	LA County of Public Health	<p>Comment:</p> <p>Recommend clarifying that pharmacies are permitted to offer separate bins for sharps and needles, even if these proposed regulations prohibit those items from being placed in the drug take back receptacles. The current language may lead to confusion about if pharmacies are permitted to collect sharps and needles at all.</p>
1776.1(g)	LA County of Public Health	<p>Comment</p> <p>Recommend clarifying whether pharmacies that are not registered with the DEA as collectors can operate a prescription drug take-back program via mail back services.</p>

Code Section	Commenter	Comment
1776.2(a)	LA County of Public Works	<p>Comment: This could be a good place to say that pharmacies could participate in this way without registering as collectors.</p> <p>Recommendation: Modify text to read: Pharmacies that <u>would like to</u> provide prescription drug take-back services <u>without registering as a collector</u> may do so by establishing mail back services, whereby....</p>
1776.2(e)	LA County of Public Works	<p>Comment: This is needlessly burdensome. Why would a pharmacy have to create and maintain all of these records when a non-pharmacy retailer can do so without this requirement? These envelopes and packages are already being tracked by the collector, and do not need to be additionally tracked. The BOP is overstepping the requirements in the DEA regulation and making it too onerous to participate in medicine take-back programs. Per the DEA, "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§1317.70)." See section 1776.6(a)(1) for a full explication.</p> <p>Recommendation: Remove these record-keeping requirements, as pharmacies do not need to be registered as a collector to provide this service.</p>
1776.3(a) & (c)	LA County of Public Works	<p>Comment: The proposal is further restricting the placement of collection receptacles in pharmacies in a way that will significantly diminish the participation of pharmacies in medicine take-back programs. DEA clearly states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked goes beyond what the DEA requires. This provision serves no benefit since it would be just as easy to place unwanted drugs next to a physical barrier as it would be to place medicine next to a locked bin.</p> <p>Recommendations:</p> <ol style="list-style-type: none"> 1) Remove language about physically blocking patient access, and 2) Revert to DEA language in order to avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.
1776.6(a)(1)	LA County of Public Health	<p>Comment: Similar comment as above from Section 1776.1(g). If pharmacies are only providing the drug mail back envelopes and their customers are mailing them to the disposal site, which we understand is often not the pharmacy, then requiring this record keeping seems unnecessary given that pharmacies will not have this information and thus will be unable to perform this required record keeping.</p>

Code Section	Commenter	Comment
1776.6(b)	LA County of Public Works	<p>Comment: This burdensome nature of this provision is beyond DEA Regulation and does not provide a clear benefit. The collector, the reverse distributor in the case of mail-backs, is responsible for keeping detailed records. See section 1776.6(a)(1) for a full explication.</p> <p>Recommendation: Remove this item entirely.</p>
Overall Comment	Stan Goldenberg	<p>The regulation address Skilled Nursing Facilities, but Long Term Care Pharmacies (Community Care Facilities, Small 6-bed facilities) also face problems with drug destruction. These facilities also need to be addressed. Currently using Rx Destroyer product to destroy of drugs and the Board wishes that those containers should be destroyed of as biohazard; however, the small facilities do not have the resourses to do that. The Board should allow that those be returned to the Pharmacies to be destroyed.</p>
Overall Comment	Christine Flowers	<p>Written Comments Submitted: Board is proposing to go beyond final rule of DEA and preempt local counties. Proposing languaging without a legal opinion on preemption is inviting a challenge and will further delay the regulations. The State has an drug abuse epidemic. The Board should not go beyond the DEA rule and there has been to much delay.</p> <p>A newspaper was provided and will be provided to Board members at the Board meeting.</p>
Overall Comment	Lauren Berton	<p>Also provided written comments.</p> <p>CVS supports the Board efforts and the work done. CVS supports and applauds the Board's efforts to make participation voluntary. Allow pharmacies to determine how the wish to participate (drug take-back bin or mail back program).</p>

Prescription Drug

Take-Back

Attachment 4

**Comments received from 256
citizens in the San Francisco Bay
Area**

Martinez, Lori@DCA

From:
Sent: Sunday, February 21, 2016 1:41 PM
To: Martinez, Lori@DCA
Subject: Don't Obstruct Pharmacy-based Drug Take-Back Programs

Dear Dr. Gutierrez and Fellow Board Members

I am deeply concerned with the impacts unused medications have on water quality and public health, as well as the Board of Pharmacy's proposed rules that will actually discourage pharmacies from hosting medicine collection bins. Pharmacies provide an important public health service to the community and studies show that they are where the public wants to be able to safely dispose of medicines.

Because pharmacies have been shown to be the most effective collection sites, the U.S. Drug Enforcement Agency has established common sense rules that allow pharmacies to support drug takeback in a safe and secure manner. Pharmacies who volunteer to host bins in California have not experienced serious problems or legal issues and many of the fears expressed by some pharmacy interests are unsubstantiated.

The Board of Pharmacy does NOT need to develop extensive regulations. Instead it should simply acknowledge that California pharmacies can host safe medicine disposal bins if they follow the DEA rules. By proposing additional regulations and deliberating over a lengthy period of time, the Board has scared pharmacies that wish to host take-back bins now from doing so. In addition, by attempting to preempt those few ordinances that require pharmacy participation in manufacturer supported programs, you are interfering with the actions of elected officials who are acting on behalf of the public to protect public health. That is inappropriate for an unelected Board.

Instead of obstructing what are mostly voluntary actions by publicly responsible pharmacies, the Board of Pharmacy should promote such programs as a means of protecting public and environmental health. California pharmacies distribute medications and are the perfect and safe location to return them. I urge you to simply endorse the Drug Enforcement Agency's rules for pharmacy-based collection programs with all expediency and to desist from any effort to preempt local laws.

**Prescription Drug
Take-Back
Attachment 5
Section Specific
Comment Compilation**

Code	Commenter	Comment
1776	City of Palo Alto; Los Angeles Waste Management	<p>Vigilance on the part of authorized collectors is inconsistent with the DEA's Regulations that prohibit authorized collectors from handling and/or sorting through collected drugs. Moreover, the Board's own proposed regulation section 1776.1(f)(1) stating "Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public."</p> <p>We recommend the following clarification: "All board-licensed authorized collectors should, <u>to the extent that is practicable</u>, be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods."</p>
1776	City of Santa Rosa	<p>Proposed text change: "All board-licensed authorized collectors should <u>to the extent feasible</u> prevent patients or their agents from disposing of prohibited items through drug take-back collection methods."</p> <p>Comment: Considering that the Board's proposed regulation section 1776.1(f)(1) states "Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public", it will be difficult for pharmacies to vigilantly prevent items from being deposited in the collection receptacle without reviewing drugs returned from the public. Suggest the term "vigilant" be changed as noted above.</p>
1776	City of Santa Rosa	<p>Proposed text change: "Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board may participate in drug take back programs authorized under this article. Those pharmacies wishing to host a prescription drug take-back collection receptacle must be registered with the Drug Enforcement Administration as collectors."</p> <p>Comment: The DEA states that "A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter (§ 1317.70)."</p> <p>As confirmed 3/18/2016 by Ruth Carter, Chief of the Liaison & Policy Section of the DEA, pharmacies are not the collector of mail-backs because the mail-backs do not come back to them; furthermore, they are prohibited from being the collector as they do not have the required onsite method of destruction (see section 1776.6(a)(1) for full explication).</p> <p>It would be helpful to rephrase the text to make it clear that pharmacies can participate in drug take-back programs by providing mail-back envelopes without being registered as a collector with the DEA. If the Board wishes to require pharmacies to be licensed and in good standing in order to offer mail-back envelopes, the above suggested text would still accomplish this.</p>

Code	Commenter	Comment
1776	Sharps	<p>Proposed change: Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and <u>licensed long-term healthcare facilities</u> may offer, under the requirements in this article, specified prescription drug take-back services to the public to provide options <u>for the public to have their unused or outdated prescription drugs collected for destruction</u>. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.</p> <p>Comments: By changing from “Licensed Skilled Nursing Facilities” to “Licensed Long-Term Healthcare Facilities”, the regulations will be more inclusive in the collection and disposal rather than restricting only to skilled nursing facilities. Thousands of pounds of unused medications in Residential Care Facilities for the Elderly/Assisted Living (RCFE/AL) will continue to be sewerred or placed into the trash if not included in this regulation. By incorporating California's definition of long-term healthcare facilities (LTCF) as defined in the Health and Safety Code section 1418, the definition will better reflect the language in the DEA rule. In the DEA language (page 53540), long-term care includes facilities which provide extended healthcare to resident patients. In addition, EPA's proposed rule on management standard for hazardous waste pharmaceuticals includes clear language including all long-term care. Upon the finalization of this rule, inclusion of RCFE/AL facilities in California will simplify the disposal process and potentially increase the usage of receptacles in LTCF.</p> <p>For clarification, we propose wording changed from “for the public to destroy” to “for the public to have their unused or outdated prescription drugs collected for destruction.</p>
1776	Tim Goncharoff County of Santa Cruz	<p>“Only California-licensed pharmacies and drug distributors (licensed wholesalers and third- party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.” Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.</p> <p>While it is good to see an authority cited as required by law, a quick read makes it clear that the authority claimed is nowhere in the code. The Board may regulate pharmacies. It has no authority to permit or prohibit the activities of any other business or entity.</p>

Code	Commenter	Comment
1776	Sharps	<p>Proposed change: “All board-licensed <u>authorized collectors with collection receptacles</u> should, <u>through signage and other feasible methods, reduce the chance of</u> the patients or their agents of disposing of prohibited items through drug take-back collection methods.”</p> <p>Comments: <input type="checkbox"/> Both DEA and the Board’s proposed rules state that drugs returned for collection shall not be reviewed, accepted, counted, sorted, or handled. Since the pharmacy employees cannot inspect the drugs being placed into a receptacle, we believe the term vigilant could be confusing. <input type="checkbox"/> Since employees of authorized collectors of mail-back envelopes/packages are not aware of what is placed into the envelopes/packages, we believe there should be clarification by adding receptacle. Note that the DEA rule requires that detailed instructions be included with mail-back envelopes/packages as to what can and cannot be placed in the mail-back.</p>
1776	Sharps	<p>Proposed change: “Only California-licensed pharmacies placing a drug take-back collection receptacle at their registered location, or at a LTCF; and drug distributors/reverse distributors (licensed wholesalers and third-party logistics providers) conducting a mail-back collection program who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take-back programs authorized under this article.”</p> <p>Comments: The DEA states that “A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector.” A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction (1317.90). Pharmacies are not the collector of mail-backs because the mail-backs do not come back to them; and in addition, they do not have the required onsite method of destruction. On the other hand, reverse distributors cannot register as a collector for receptacles since the receptacle has to be located at the registered collectors’ place of business. The pharmacy is the registered collector for the receptacle collection. We would request that the differences in “collectors” be clarified throughout the regulations to harmonize with the DEA rule and to reduce confusion.</p>

Code	Commenter	Comment
1776	City of Palo Alto; Los Angeles Waste Management	<p>This provision would remove the ability for entities that choose to not serve as authorized collectors but would choose to distribute mail-back envelopes to customers from partnering with authorized collectors to provide mail-back envelopes and thus significantly reduce the number of locations that would provide mail-back envelopes to consumers with no perceivable benefit. The DEA has determined such in Section § 1317.70 (c) of their Regulations which states "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section."</p> <p>We recommend that the text be rephrased so it is clear that pharmacies can participate in drug take-back programs by providing mail-back envelopes without being registered as a collector. If the Board wishes to require pharmacies to be licensed and in good standing in order to offer mail-back envelopes, the following text could suffice. "Only California-licensed pharmacies and drug distributors (licensed wholesalers and thirdparty logistics providers) who are licensed in good standing with the board may participate in drug takeback programs authorized under this article."</p>
1776	San Francisco Dept of Environment	<p>Comment: The DEA does not use the term "skilled nursing facilities," but rather "long term care facilities." Long term care facility (LTCF) "means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients." "Skilled nursing facility," as defined in CA Health and Safety Code Section 1250(c) has a narrower meaning than the DEA's LTCF.</p> <p>Recommendation: Change "skilled nursing facilities" to "long term care facilities" to match the DEA term here and throughout the proposed regulations. This will provide consistency and avoid confusion between the State and Federal regulations.</p> <p>Comment: We are unaware of any laws which establish prohibitions related to drug take-back receptacles for the specific items listed when they are generated in the home. We are concerned this language goes beyond the scope of the DEA Final Rule, will cause confusion, and overreaches CABOP's purview by interpreting other agencies' law.</p> <p>Recommendation: Please remove this provision from the final regulations or list the applicable laws in the Initial or Final Statement of Reasons.</p>

Code	Commenter	Comment
1776	San Francisco Dept of Environment	<p>Comment: Pharmacies who solely provide mail-back packages to the public, with or without a fee, are not required to register with the DEA. The DEA regulations require only those pharmacies or reverse distributors who operate a mail-back program, by receiving and destroying sealed mail-back packages, to register as a collector. In contrast, the proposed regulations would require any pharmacy that provides mail-back packages to the public to register with the DEA and CABOP as a collector.</p> <p>Recommendation: Clarify that pharmacies which solely offer mail-back packages to the public do not have to be registered with the DEA or with CABOP. Change the text to “Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may operate collection receptacles. California-licensed pharmacies may provide empty, unused mail-back packages to the public under the provisions of Section 1776.2.”</p>
1776	Kaiser	<p>Only California-licensed pharmacies and drug distributors (licensed wholesalers and third- party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate <u>conduct</u> in drug take back programs authorized under this article.</p> <p>Rationale The use of the word “participate” is confusing. For clarity the Board should use the same terminology as the federal DEA regulations – which is to “conduct” and it means that the pharmacies, etc. are registered with the DEA to “conduct” programs with take back receptacles, either on site in the pharmacy or hospitals or certain nursing facilities, etc. A pharmacy, hospital or other entity, licensed by the Board or otherwise, does not have to “conduct” a program with take back receptacles. They may partner with a program to only dispense mail-back envelopes or packages.</p> <p>Impact Unless changed, the wording could confuse pharmacies that desire to dispense properly addressed and constructed postage prepaid mail-back envelopes or packages. The result would be a diminished effectiveness of the Safe Drug/Medication Disposal programs throughout California.</p>

Code	Commenter	Comment
1776	CA Product Stewardship	<p>“All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods.”</p> <p>Comment: It is challenging to reconcile the above statement with the Board’s proposed regulation section 1776.1(f)(1) stating “Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public”. It is inconsistent with the DEA Regulations. Specifically, it might be helpful to have direction regarding the extent to which pharmacies are required to vigilantly prevent items from being deposited in the collection receptacle, and how they might be able to meet this requirement without reviewing drugs returned from the public.</p> <p>Recommendation: modify text to read: All board-licensed authorized collectors should <u>to the extent that is practicable</u> prevent patients or their agents from disposing of prohibited items through drug take-back collection methods.</p>
1776	San Luis Obispo County Integrated Waste Management	<p>This section requires every drug take back program to comply with the DEA regulations and the Board of Pharmacy (BOP) regulations. Most existing kiosks in California currently do not accept controlled substances and thus do not have to comply with the DEA regulations. By requiring every kiosk to comply with these regulations will result in most of them being closed.</p> <p>The DEA recognized the value of having separate standards for programs that did not accept controlled substances. This is evident in the comment and response that was included in the Federal Register as part of adopting the DEA regulations.</p>
1776	San Luis Obispo County Integrated Waste Management	<p>Comment: Many locations throughout California currently have kiosks to collect drugs. For example in Alameda County senior centers and a California State Office Building have kiosks. These kiosks do not accept controlled substances so are not subject to the DEA Regulations. If these regulations are adopted all of those locations would be forced to closed. In Alameda County that would result in the closure of 17 of the 30 existing sites.</p>

Code	Commenter	Comment
1776.1	Tim Goncharoff County of Santa Cruz	<p>“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) Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).”</p> <p>The Board seeks to arrogate to itself powers that are contained nowhere in the law. The recorded discussions of the Board make it clear that the intent of declaring participation voluntary is to supersede local ordinances mandating participation. The Board has no such authority under the law. Similarly, the Board’s attempt to regulate skilled nursing facilities and other non-pharmacy locations is clearly beyond their authority.</p> <p>“e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s 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 shall be placed on collection receptacles as referenced in section 1776.3.”</p> <p>This section is bound to lead to confusion. As your Board knows, specific collection programs for medical sharps are in place in many locations, including pharmacies, and more are on the way. This section would seem to prohibit such efforts, leaving improper disposal of medical sharps the only option. This is severely misguided.</p> <p>“A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.”</p> <p>An obvious question is “How will they know?” Are pharmacy staff supposed to quiz customers about whether they come from any of the prohibited locations? Beyond that, the sections seems to force such facilities into a twilight zone without any legal disposal options. You would prohibit them from participating in takeback programs on their own, and prohibit them from participating in those located at pharmacies. What then are they to do with their leftover medications?</p>
1776.1	CVS	<p>CVS Health supports and applauds the Board’s current proposed regulations which allows for voluntary participation in drug take back services either via take back receptacles or mail back envelope programs because it allows pharmacies to provide the means they deem appropriate to successfully participate in drug take back services.</p>

Code	Commenter	Comment
1776.1	CHA	<p>Recommendation: CHA reiterates its strong position on maintaining voluntary participation in these programs. CHA does not envision hospital/clinic pharmacies to be an appropriate site for establishing drug take back programs; however, there may be unique community circumstances where the hospital/clinic pharmacy is an appropriate setting.</p>
1776.1	CPhA	<p>Addition:</p> <p>(j) A pharmacy shall not provide take-back services to patients 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 Drug Enforcement Administration rules.</p> <p>If a pharmacist in charge determines in their professional judgment that the pharmacy cannot comply with these regulations of the DEA rules, that pharmacy should not participate in take-back programs. Reasons a pharmacist in charge may make this determination include, but are not limited to, irregular store layout or lack of physical space that makes secure placement of collection receptacle problematic, past experience by pharmacy staff with difficulties hosting a collection receptacle, pharmacy location in a high crime area, and other problems.</p>
1776.1	CPhA	<p>Addition:</p> <p>(k) A pharmacy shall not provide take-back services to patients as provided in sections 1776 - 1776.4 if the pharmacy or the pharmacist in charge is on probation with the Board, and, if the pharmacy had previously provided take-back services, the pharmacist in charge shall notify the Board and the Drug Enforcement Administration as required in subsections (h) and (i), above.</p> <p>A pharmacy or pharmacist in charge on probation with the Board should not participate in take-back programs. Pharmacies and PICs are placed on probation for offenses such as diversion of controlled substance, failure to maintain secure drug inventory, and other pertinent violations of Pharmacy Law. Even if the probation is unrelated to inventory or diversion, a pharmacy or PIC on probation should focus on the essential responsibilities of operating a pharmacy and should not be involved in activities that could serve to distract pharmacy staff from that role.</p>

Code	Commenter	Comment
1776.1(a)	City of Santa Rosa	<p>Proposed change(s):</p> <ol style="list-style-type: none"> 1) Remove voluntary language entirely, or as a minimum: 2) Clarify Board intent regarding pre-emption, and: 3) Specify that local jurisdictions are allowed to require non-participating pharmacies to post signs informing the public of participating pharmacy locations, and/or as an intermediate step: 4) Avoid precluding local jurisdictions from requiring pharmacies to provide mail-back envelopes so long as the pharmacies are not financially responsible for the associated costs. <p>Comment: Staff is concerned that the current wording might be construed as prohibiting local jurisdictions from requiring pharmacies that are not themselves providing medicine take-back services to post signage directing their customers where they can go to safely dispose of their medications or from requiring pharmacies to provide mail-back envelopes where they are not responsible for the associated costs. Staff is concerned that local ordinances such as these could be construed as mandating the pharmacy to ‘assist patients seeking to destroy’ in conflict with the voluntary provision of the state law. If this is not the intent of the Board, staff would welcome clarification of the proposed regulation. In doing so, staff would hope to avoid any potential dispute regarding the scope of preemption of local jurisdictions.</p> <p>In order to address potential financial concerns, staff would welcome the Board to consider allowing local jurisdictions to require pharmacies to provide mail-back envelopes so long as the pharmacy is not mandated to be financially responsible for the cost of providing the envelopes</p>
1776.1(a)	Sharps	<p>Proposed change: <u>Pharmacies may assist patients or their authorized agents seeking to have their unused or outdated prescription drugs collected for destruction.</u></p> <p>Comments:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Patients aren’t destroying the drugs, and therefore we believe the proposed change will help clarify that this is collection for destruction. <input type="checkbox"/> We suggest removing “Provision of such services is voluntary.” By placing this language into the rule, it could preempt local jurisdictions’ ordinances.

Code	Commenter	Comment
1776.1(a)	NACDS	<p>As we have previously outlined to the Board in our January, 2016 drug take-back program comments, we believe that pharmacy participation in any state or municipal take-back program should be voluntary. In our January letter, we outlined the public health concerns, operational concerns and flexibility rationale for why we oppose mandatory participation. We have attached a copy of that letter for more detail.</p> <p>Section 1776.1 of the Proposed Rule states that “provision of [drug take-back] services is voluntary.” We applaud the Board for including such language, but we also encourage the Board to make clear that such language also preempts any municipality-based programs to the contrary. In other words, the Final Rule should clarify that no municipality intending to set up a drug take-back program can mandate pharmacy participation. We seek consistency across the state and ask the Board to help us achieve that goal by clarifying the preemptive effect of the Final Rule on municipal take-back programs.</p>
1776.1(a)	San Francisco Dept of Environment	<ul style="list-style-type: none"> • (a): “Pharmacies may assist patients ...” <p>Comment: The DEA regulations use the term “non-registrant persons,” which includes ultimate users and others who are lawfully entitled to dispose of controlled substances.</p> <p>Recommendation: Replace “patients” with “non-registrant persons” or “the public.”</p> <ul style="list-style-type: none"> • (a): “... Provision of such services is voluntary” <p>Comment: This statement may be interpreted to preempt local government ordinances that require retail pharmacies to provide a drug take-back program. To intentionally preempt local governments on this issue is not consistent with the CABOP’s mission statement to protect and promote the health and safety of Californians.</p> <p>Recommendation: Change text to: “Provision of such services, under these regulations, is voluntary.”</p>

Code	Commenter	Comment
1776.1(a)	Kaiser	<p>Recommended Change (a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary. No pharmacy may be mandated by any State regulation or local ordinance to participate as a collector of dangerous drugs, including but not limited to controlled substances.</p> <p>Rationale The proposed regulation statement is NOT clear about the Board's intent. It could mean that the Board considers participation and voluntary but would allow local County and City ordinances to mandate "collection receptacle" participation.</p> <p>Impact Without the clarification many pharmacies that are neither designed, equipped nor staffed to adequately protect the public, their patients or their employees may be forced into "collection receptacle" participation or lengthy and expensive court situations that distract from patient care and clog the court system. These include, but are not limited to, pharmacies, hospitals and clinics that may be on probation, have lost critical personnel, are in high risk areas or are literally "closed door" pharmacies that are not open to the public and whose mandatory participation is kept undisclosed to the public for security purposes. Allowing other agencies or jurisdictions to mandate "collection receptacle" participation may cause some pharmacies in some critical access areas to cease operations and thus decrease patient and public access to pharmacy care and services. Further, subsection (c) requires all pharmacies that do participate with "collection receptacles" to follow DEA regulations and other federal law. Those requirements mandate close supervision and security of the "collection receptacles" at all times. A mandate to participate with "collection receptacles" would require a substantial increase in staffing in many pharmacies especially during "extended hours", weekends and holidays, thus it would likely require such pharmacies to reduce their hours of service, thus also reducing the patients, consumers and the public in their communities access to pharmacy care and service.</p>

Code	Commenter	Comment
1776.1(a)	CalRecycle	<p>We request that the Board clearly state whether you intend to preempt local ordinances that mandate drug collection and recomider any such preemptive language. The Board' s proposed voluntary language potentially conflicts with local ordinances mandating pharmacy drug take-back by saying "Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article.</p> <p>Provision of such services is voluntary"[§1776.1(a)). In the January 19 Board meeting, the Board' s Supervising Deputy Attorney General stated there is not a clear answer as to whether §1776.1(a) would preempt county ordinances and recommended that the Board clearly state if it intends to preempt county ordinances or if it wants to allow counties to mandate programs. Although the Board voted to retain language that potentially conflicts with local ordinance mandates, we request that the Board reconsider this and allow flexibility for local governments to enact ordinances that address issues specific to their jurisdictions.</p> <p>Consistent with the first point above, we request that the Board reconsider the language that would impact existing local mandates assisting patients with information to properly manage their drugs. In particular, the Board's proposed regulations conflict with local ordinances such as San Francisco's Safe Drug Disposal Information Ordinance. This ordinance requires non-participating pharmacies to display signage promoting proper medicine disposal and listing participating pharmacies.</p>
1776.1(a)	CA Product Stewardship	<p>Comment: CPSC is concerned that this wording might prohibit local jurisdictions from requiring pharmacies that are not themselves providing medicine take-back services to post signage directing their customers where they can go to safely dispose of their medications. For example, consider an ordinance that says, 'if a pharmacy is not participating in a drop off program, then the pharmacy must have a sign listing pharmacies that are participating.' An argument could be made that this ordinance mandates the pharmacy to 'assist patients seeking to destroy' which therefore violates the voluntary provision of the state law. If this is not the intent of the Board, CPSC would welcome clarification of the proposed regulation.</p> <p>Recommendation: Remove the sentence " Provision of such services is voluntary" entirely, However if the BoP is unwilling to remove the language, at the very least modify the language to allow local jurisdictions to require pharmacies to post signage directing their customers where they can go to safely dispose of medications.</p>
1776.1(a)	Nipomo Community	<p>The California Board of Pharmacy proposed regulations will preempt local programs. In San Luis Obispo County there is a requirement that every pharmacy provides the public with an option to disposal of unwanted medicine. If this requirement is preempted, many of these pharmacies will no longer provide the public with a method of disposal of unwanted medicine.</p>

Code	Commenter	Comment
1776.1(a)	San Luis Obispo County Integrated Waste Management	Comment: Local communities have take the lead to establish convenient drug take back programs. By preempting local programs, California will have very few drug take-back locations.
1776.1(a)	Los Angeles Waste Management	<p>Comment: The nature of this statement would preempt local ordinances that require pharmacy participation in any form including providing information to consumers of location that accept unwanted drugs.</p> <p>Recommendation: Remove the sentence "Provision of such services is voluntary" entirely, however, if the Board is unwilling to remove the language, at the very least modify the language to allow local jurisdictions to require pharmacies to post signage directing their customers where they can go to safely dispose of their medicines.</p>
1776.1(a)	Russian River Watershed	Please consider revising the language of Section 1776.1(a) to allow local jurisdictions to require pharmacy participation in regional programs. In some cases, local jurisdictions may consider mandating pharmacies to participate in a regional drug take-back program, so long as the pharmacies are not financially responsible for providing the service. To avoid any potential dispute regarding the Board's preemption of local jurisdictions, we request the removal of the sentence "Provision of such services is voluntary." from Section 1776.1(a).

Code	Commenter	Comment
1776.1(d)	Kaiser	<p>(d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including <u>products classified as either federal or State</u> controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.</p> <p>Rationale The proposed language is unclear because some products listed as “controlled substances” under State law are not necessarily “controlled substances” under federal law. Conversely, some products that are listed as “controlled substances” under federal law are not “dangerous drugs” under State law. States have the authority to classify products as “controlled substances” that are commonly prescribed and dispensed products that are not controlled substances under federal law. For example, Fioricet is an analgesic that is a “controlled substance” under State law but not under federal law. Section 4021 of the California Business and Professions Code defines generally for pharmacy practice to items listed in California Health and Safety Code’s Chapter 2 of Division 10, not in any federal statute or regulation. However, subsection (c) of the proposed regulation requires compliance with “federal and state requirements governing the collection and destruction of dangerous drugs”.</p> <p>Impact Both the professional obligations of pharmacists and pharmacies as well as their criminal and civil obligations will be confused if they participate in these programs intended to benefit the safety of patients, the public and the environment. It will discourage participation.</p>
1776.1(d)	San Luis Obispo County Integrated Waste Management	By including all prescription drugs in these regulations, the BOP has far exceeded the requirements of the DEA regulations. This will be a large burden on pharmacies that want to have kiosks for only non-controlled substances.
1776.1(e)	City of Santa Rosa	<p>Proposed text change: “The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s <u>prescription drug</u> collection receptacle: . . .<list with footnotes giving regulatory references for each prohibited item> . . .”</p> <p>Comment: The way this section is currently worded implies that pharmacies are not permitted to have a separate bin for sharps collection. The origin of each of these prohibitions is unclear; please identify the source regulation in each case. Staff asks that the Board avoid making the regulation more restrictive than necessary in order that local medicine take-back programs may enjoy robust participation from local pharmacies and the general public.</p>

Code	Commenter	Comment
1776.1(e)	Russian River Watershed	As written, Section 1776.1(e) may be interpreted as prohibiting collection of medical sharps and needles in any collection receptacle in a pharmacy. However, sharps may be safely collected in sharps-specific collection receptacles. Please do not prohibit the placement of sharps-specific collection receptacles in pharmacies; consider clarifying the wording of Section 1776.1(e) to prohibit sharps and other dangerous drugs from prescription drug collection receptacles only.
1776.1(e)	San Luis Obispo County Integrated Waste Management	Comment: If the BOP is excluding certain drugs from the program, then the BOP should develop programs that allow the public to properly dispose of these drugs.
1776.1(e)	City of Palo Alto; Los Angeles Waste Management	As currently worded, this section implies that pharmacies are not permitted to have a separate bin for sharps collection. Therefore, we recommend that the text be modified to specify this provision IS specific to drug collection receptacles.
1776.1(e)	Kaiser	<p>(e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's 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 shall be placed on collection receptacles as referenced in section 1776.3.</p> <p>Rationale Subsection "(e)" is unclear, vague and inconsistent with the Board's findings and intent. Section 1776.3(m) already has a requirement to post a sign on a collection receptacle informing patients, consumers and the public in general that the specified types of products (e.g. syringes and needles, antineoplastic agents, etc.) are not to be placed in the receptacles. However, it is common knowledge that very often laypersons do not know to which products these descriptions apply. The Board [see subsection "(f)(1)]as well as the federal DEA regulations prohibit pharmacists or pharmacy personnel from handling or sorting products before they are put in the receptacles.</p> <p>Impact Thus it is very likely that consumers, patients and especially their family, caregivers and agents will place those prohibited items in the receptacles. Thus subsection "(e)" "expressly prohibited" language will subject pharmacies, hospitals and other entities governed by these regulations to regulatory and civil liability. While it is understandable why such items "should not" be placed in the receptacles, the Board's and the DEA's have removed the only method of assuring that they are not placed in the receptacles.</p>

Code	Commenter	Comment
1776.1(f)	Sharps	<p>Proposed change: ...operated by pharmacies or distributors/reverse distributors are only...</p> <p>Comment: Since pharmacies are collectors for receptacles and reverse distributors are collectors for mail-back programs, we suggest including distributors/reverse distributors when using terminology that may indicate all take-back programs, including mail-backs.</p>
1776.1(f)	SIRUM	<p>The scope of the DEA promulgated regulations (Title 21, Code of Federal Regulations (CFR), sections 1300-1321) for drug take-back programs is limited to controlled substances. We ask that with regard to long-term care facilities, the scope of Section 1776 match the DEA's regulations and be limited to controlled substances. While we understand that patients may not be able to differentiate between controlled and non-controlled substances as outlined in the Board's Initial Statement of Reasons, in long-term care facilities, health care professionals -- not patients -- can/must differentiate between controlled and non-controlled substances as part of their duties. It is therefore unnecessary to treat controlled and non-controlled substances as the same in these settings.</p> <p>1776.1 (f) (2) A pharmacy shall not accept or possess <u>controlled substances</u> prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities unless <u>authorized to operate a drug take-back collection program</u>.</p>
1776.1(f)(2)	Kaiser	<p>(f)(2) A pharmacy shall not accept or possess use prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities <u>as part of programs for disposal of drugs possessed by consumers, patients, their caregivers of agents for redistribution, dispensing or compounding</u>.</p> <p>Rationale Other California law allows the collection of unused pharmaceuticals that have not been out of the possession and control of health care personnel and that have been properly stored and protected for purposes of redistribution and dispensing to other needy patients.</p> <p>Impact Pharmacies participating as collectors in programs for consumers, patients, etc. to dispose of unwanted drugs will be discourage from participating in other programs established by the State for the care of financially needy patients and for the avoidance of waste and pollution which are core public motives for such programs and the establishment of unwanted drug collection programs.</p>

Code	Commenter	Comment
1776.1(g)	City of Santa Rosa	<p>Proposed text change: "A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for the purposes of operating a prescription drug take-back collection receptacle."</p> <p>Comment: The proposed wording may imply that if a pharmacy decides to participate in a mail-back program that they have to be registered as a collector; as elsewhere discussed, this is not a requirement per the DEA (see section 1776.6(a)(1) for full explication).</p>
1776.1(g)	Sharps	<p>Proposed change: "A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for the purposes of operating a prescription drug take-back collection receptacle."</p> <p>Comment: The draft wording may be interpreted that if a pharmacy chooses to participate with a reverse distributor in providing mail-back envelopes/packages, they must register as a mail-back collector. And as previously indicated, the reverse distributor, not the pharmacy is the collector for mail-backs.</p>
1776.1(g)	Kaiser	<p>(g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone <u>prohibited from pharmacy employment by the DEA or the State because of a conviction</u> convicted of a felony related to controlled substances, or anyone who <u>is prohibited from pharmacy employment by the DEA or the State because he or she has had a DEA registration or State pharmacy permit denied, surrendered or revoked.</u></p> <p>Rationale The State and the DEA have processes where by prior convictions and prior denials, surrenders, or revocations of pharmacy permits and registrations, respectively, can be excused.</p> <p>Impact Such a strict prohibition would frustrate the intent of public policy to diminish the potential harm to patients, their families, the public and the environment by reducing the number of pharmacies that could participate as collectors even though such transgressions, for various purposes under the control of the State and the DEA, had been forgiven.</p>

Code	Commenter	Comment
1776.1(g)	City of Palo Alto; Los Angeles Waste Management	<p>This provision implies that if a pharmacy decides to partner with an authorized collector to provide mail-back envelopes, they must be registered as an authorized collector; this is not a requirement per DEA Regulation.</p> <p>We recommend a minor edit to provide clarification: "A pharmacy must be registered with the federal Drug Enforcement Administration as a collector <u>for the purposes of operating a prescription drug take-back collection receptacle.</u></p>
1776.1(g)	CA Product Stewardship	<p>Comment: CPSC is concerned that this wording implies that if a pharmacy decides to participate in a mail-back program that they have to be registered as a collector; this is not a requirement per the DEA (see section 1776.6(a)(1)).</p> <p>Recommendation: modify text to read: A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for the purposes of <u>operating a prescription drug take-back collection receptacle.</u></p>

Code	Commenter	Comment
1776.1(h)(2)	Kaiser	<p>(h) (2) Any pharmacy operating a mail back program <u>under which the drugs are mailed to the pharmacy</u> or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.</p> <p>Rationale The provision as written is misleading and inconsistent with current practices, the Board's intent or DEA regulations regarding DEA controlled substances. Pharmacies may be involved in two distinct types of programs by which "mail back" envelopes or packages are distributed or dispensed. If the pharmacy is distributing or dispensing envelopes or packages that have the pharmacy's address preprinted on the envelope or package, then the pharmacy is acting as a "collector". But if the pharmacy is distributing or dispensing envelopes or packages that are addressed to an entity that is properly registered with the Board of Pharmacy and the DEA then the pharmacy is NOT a "collector" for either the purposes of this regulations or the DEA regulations. Pharmacies and other entities not under the Board's jurisdiction are currently and have long been involved in distributing envelopes and packages for the disposal of prescription drugs, including controlled substances. Most of the time such envelopes are "sold" to the consumers or patients to cover the cost of postage and collection and disposal at the DEA authorized "collector" location. Some pharmacies and other entities distribute/dispense the envelopes at NO COST to the consumers and patients. These programs have been moderately successful at furthering the intent of public policy about improving public and patient safety as well as protecting the environment. It is envisioned that the "mail back" programs will be even more successful if and/or when the cost of the envelopes as well as their collection and disposal are covered so they can be dispensed and distributed to consumers and patients without charge.</p> <p>CONTINUED ON NEXT ROW</p>

Code	Commenter	Comment
1776.1(h)(2)	Kaiser	<p>Impact</p> <p>If this subsection is not clarified, many pharmacies that could and would be convenient and proper outlets for the “mail back” envelopes and packages will not participate. Pharmacies that merely participate in these public-benefit programs are only “partners” with the registered collectors. This is a recognized relationship in 21 CFR 1317.70(c) that states; “<i>Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section.</i>” [emphasis added]</p> <p>Though the Board could also require the “partner” pharmacies to register with the Board and provide other notices as specified, the Board should not confuse pharmacies and others about the two distinct types of “mail back” participation. The Board should also re-consider the necessity of having the “partner” pharmacies register with the Board and its potential for discouraging their participation. The Board heard many reasons why “mail back” is and should be the public’s preferred methodology.</p>
1776.1(i)	Kaiser	<p>(i) If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the <u>Board and the Drug Enforcement Administration</u> within 30 days.</p> <p>Rationale</p> <p>Since previous subsection requires such pharmacies to register with the Board of pharmacy, it seems there should be a similar requirement to notify the Board when that situation ceases. Otherwise the Board will have inaccurate data and may be advising the public or other entities erroneously and potentially using resources less efficiently.</p> <p>Impact</p> <p>Without this change there will be significant confusion, at least.</p>

Code	Commenter	Comment
1776.2	NACDS	<p>While the Proposed Rule does not specifically define the term “collector,” we believe that a plain reading of the Proposed Rule demonstrates that a pharmacy that merely distributes mail-back envelopes to be sent directly to another entity with whom it has partnered for the receipt and destruction of the envelopes (“Partner”) is not a “collector” for purposes of the rule. Section 1776.2(b) contemplates a process in which pharmacies distribute preaddressed envelopes that will be returned to a “collector” with onsite capabilities for destruction. The recipient of the filled envelope is the “collector,” not the pharmacy. To further emphasize this point, Section 1776.2(g) states that “once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.” We believe that read together, these two provisions make clear that pharmacies that distribute mail-back envelopes are not “collectors” within the Proposed Rule.</p> <p>In the DEA Final Rule on drug take-back programs, the DEA, in 21 CFR 1317.70(a) states that a collector, must have, at their registered location a method of destruction for returned envelopes. Moreover, 21 CFR 1317.70(c) states that: Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section.</p> <p>This language makes clear that the recipient of the returned envelope, the Partner, is a “collector” for drug take-back purposes and that a pharmacy that distributes such envelopes is not the collector, merely facilitating distribution of the envelopes.</p> <p>To maintain consistency with the federal regulation, we urge the Board to take the same approach. Again, we believe that Board has already done so, as described above. However, to the extent that the Board’s Proposed Rule does not track the federal language, we urge the Board to clarify that pharmacies, in California, who merely distribute take-back envelopes in partnership with collectors need not register as collectors themselves.</p>
1776.2	San Francisco Dept of Environment	<p>General Comment: This section needs to be reworked to clarify that it does not apply to pharmacies which solely provide empty unused mail-back envelopes or packages to the public. If CABOP’s intention is to mirror the DEA Final Rule, these regulations should only be applicable to pharmacies which are actually operating a mail-back program (i.e. receiving and destroying on-site sealed mail-back envelopes or packages). We do not believe CABOP should extend the scope of this section to pharmacies that solely provide empty, unused mail-back envelopes or packages to the public and do not operate an on-site destruction facility.</p>
1776.2	Sharps	<p>Proposed change: Recommend removing from the Section title, the words “from Pharmacies” since mail-back program collectors (reverse distributors) can partner with other organization as well.</p>

Code	Commenter	Comment
1776.2(a)	Sharps	<p>Proposed change: “Pharmacies may participate with DEA-registered collectors that are reverse distributors with onsite destruction to provide preaddressed mail-back envelopes or packages to the public for the return and destruction of prescription drugs.”</p> <p>Comment: Proposed change would clarify that pharmacies could participate in this way without registering as collectors.</p>
1776.2(a)	City of Santa Rosa	<p>Proposed text change: “Pharmacies that <u>would like to</u> provide prescription drug take-back services <u>without registering as a collector</u> may do so by establishing mail back services, whereby . . .”</p> <p>Comment: Suggested change would clarify that pharmacies could participate in this way without registering as collectors.</p>
1776.2(a)	Kaiser	<p>1776.2 Mail Back Package and Envelope Services from Pharmacies Recommended Changes (a) Pharmacies that provide prescription drug take-back services may <u>also</u> do so by establishing <u>either conducting their own or partnering with another entity for</u> mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.</p> <p>Rationale This subsection is misleading as worded. Under California and federal law a pharmacy or any other entity does not have to be either licensed with the Board of Pharmacy nor Registered with the DEA to distribute properly addressed postage pre-paid mail-back envelopes and packages that are addressed to an entity, e.g. Reverse Distributor, that is properly licensed and Registered.</p> <p>Impact Unless changed, this provision will discourage of many, perhaps most, pharmacies from at trying to address the goals of the Safe Drug/Medicine Disposal programs by dispensing, free or otherwise, DEA approved mail-back envelopes/packages.</p>

Code	Commenter	Comment
1776.2(a)	City of Palo Alto; Los Angeles Waste Management	This could be a good place to say that pharmacies could participate in this way without registering as collectors. For instance, the text could be modified to say: "Pharmacies that <u>would like to</u> provide prescription drug take-back services <u>without registering as a collector</u> may do so by establishing mail back services, whereby ... "
1776.2(b)	Kaiser	<p>(b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring <u>checking upon receipt of mail-back envelopes or packages</u> that all the preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities <u>that are listed on official Board and DEA sites to comply with this section.</u></p> <p>Rationale The current wording implies an unreasonable and impractical standard to verify the address against a government listing every time one envelope or package received from a partner entity is dispensed to a patient.</p> <p>Impact Such an unreasonable and impractical standard will discourage many, perhaps most, pharmacies from trying to address the goals of the Safe Drug/Medicine Disposal programs by dispensing, free or otherwise, DEA approved mail-back envelopes/packages.</p>

Code	Commenter	Comment
1776.2(d)	Kaiser	<p>(d) The If a pharmacy is a collector and distributes or dispenses preaddressed envelopes and or packages that are addressed to that pharmacy, the envelopes or packages shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.</p> <p>Rationale This provision is unclear and confusing because it does not distinguish be pharmacies that are collectors that have the “mail back” envelopes and packages addressed back to that pharmacy and other pharmacies that may be collectors but do not have “mail back” envelopes and packages addressed back to that pharmacy. It even confuses situations regarding pharmacies that are NOT collectors but merely dispense or distribute “mail back” envelopes or packages as a “partner” (see above) with a collector. ”Since it is possible, though unlikely, that a pharmacy will be a collector if it only dispenses or distributes “mail back” envelopes or packages as a “partner” (see above) the subsection should be modified.</p> <p>Also, collectors that are not under the Board’s jurisdiction are not required by the DEA to have serial numbers on their “mail back” envelopes and packages. Current and long-standing practice regarding such “mail back” envelopes and packages without serial has apparently not been a concern of the DEA. Such packages are handled through federal employees of the US Postal department until they reach the collector’s site where they a properly disposed of as part of operations that are approved and inspected by the DEA.</p> <p>Impact If this subsection is not clarified, many pharmacies that could and would be convenient and proper outlets for the “mail back” envelopes and packages will not participate. The “partner” collectors will simply not send the serial numbered “mail back” envelopes and packages. Pharmacies that merely participate in these public-benefit programs are only “partners” with the registered collectors. This is a recognized relationship in 21 CFR 1317.70(c) that states; “Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section.” [emphasis added]</p>
1776.2(e)	Sharps	<p>Proposed change: Delete.</p> <p>Comment: Since the pharmacy would be participating with the reverse distributor registered as a mail-back collector to provide mail-backs, and is not the collector itself, (e) is only applicable to the collector of the mail-back, not the pharmacy and is therefore not applicable. This comment would also apply to 1776.4(h)(2).</p>

Code	Commenter	Comment
1776.2(e)	City of Santa Rosa	<p>Proposed change: Delete this provision.</p> <p>Comment: Staff is concerned that adding records requirements beyond DEA requirements could de-incentivize participation in medicine take-back programs. Per the DEA, "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§ 1317.70)." See section 1776.6(a)(1) for more detail about collector status and requirements.</p>
1776.2(e)	Russian River Watershed	<p>A pharmacy that distributes mail-back envelopes does not come into contact with the collected, unwanted medications. Instead, the unwanted medications are mailed directly to a reverse distributor. The reverse distributor is responsible for recording information about the collected medications including the date and unique identification number.</p> <p>Simply having mail-back envelopes on site does not mean that the pharmacy is actively collecting unwanted prescription drugs at their location. Accordingly, please consider eliminating the requirement for pharmacy retailers to be registered with the DEA as a collector if they participate in drug take-back programs only by distributing empty envelopes to patients.</p> <p>Furthermore, the DEA does not require retailers that sell or otherwise distribute mail-back envelopes to or maintain records of the mail-back envelopes before they are used to collect unwanted medications. Please remove the burdensome recordkeeping requirements for empty mail back envelopes outlined in Sections 1776.2(e), 1776.6(a), and 1776.6(b).</p>

Code	Commenter	Comment
1776.2(e)	Kaiser	<p>(e) The <u>A collector pharmacy that registers with the DEA to conduct programs with receptacles for collecting unwanted controlled substances and for distributing its own mail back envelopes and packages shall create and maintain records verifications required by section 1776.6 1776.2(b) or by the DEA.</u></p> <p>Rationale The DEA does not require the recordkeeping records for mail-back envelopes and packages as proposed in section 1776. For reasons stated below, the Board should not require individual serial numbers on mail-back envelope or recordkeeping per each serial number. The Board could require a record of the verification per 1776.2(b).</p> <p>Impact If this subsection is not so limited or omitted, many pharmacies that could and would be convenient and proper outlets for the “mail back” envelopes and packages will not participate. The “partner” collectors will simply not send the serial numbered “mail back” envelopes and packages. Pharmacies that merely participate in these public-benefit programs are only “partners” with the registered collectors. This is a recognized relationship in 21 CFR 1317.70(c) that states; “Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section.”</p>
1776.2(e)	San Francisco Dept of Environment	<p>Comment: The DEA Final Rule does not require pharmacies (or other entities) to maintain records on empty unsealed mail-back packages they give to the public. Requiring pharmacies who solely distribute empty mail-back units to the public to create and maintain records for mail-back packages would be an unnecessary burden. Furthermore, in San Francisco’s pilot mail-back program, we found that many mail-back envelopes that we distributed to the public were never used; therefore there is little utility to maintaining such records.</p> <p>Recommendation: Delete subpart (e) of 1776.2.</p>

Code	Commenter	Comment
1776.2(e)	Los Angeles Waste Management	<p>Comment: This is needlessly burdensome. Why would a pharmacy have to create and maintain all of these records when a non-pharmacy retailer can do so without this requirement? These envelopes and packages are already being tracked by the collector, and do not need to be additionally tracked. The BOP is overstepping the requirements in the DEA regulation and making it too onerous to participate in medicine take-back programs. Per the DEA, "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§ 1317.70)." See section 1776.6(a)(1) for a full explication.</p> <p>Recommendation: Remove these record-keeping requirements, as pharmacies do not need to be registered as a collector to provide this service.</p>
1776.2(e)	CA Product Stewardship	<p>Comment: CPSC is concerned that adding these records requirements beyond what is required by the DEA could disincentivize participation in our medicine take-back program. This is needlessly burdensome. The packages and envelopes are already being tracked by the collector. Per the DEA, "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§ 1317.70)." See section 1776.6(a)(1) for more detail about collector status and requirements.</p> <p>Recommendation: Remove these record keeping requirements. Pharmacies do not need to be registered as a collector to provide this service.</p>
1776.3	CHA	<p>Recommendation: CHA recommends removing, "and not in the proximity of emergency or urgent care". While CHA suspects that most hospital pharmacies will not participate in this program, there are several drug take-back programs in hospitals presently that have collection receptacles in their emergency departments. While emergency or urgent care departments may not be the most appropriate site for a collection receptacle, it may be the most appropriate area relative to regular employee monitoring and internal hospital safety and security.</p> <p>Recommendation: CHA suggests adding a section to address what processes occur when inappropriate items or damaged items are found in the transition of the sealed liners to the licensed DEA registered reverse distributor.</p>

Code	Commenter	Comment
1776.3	Tim Goncharoff County of Santa Cruz	<p>“1776.3 Collection Receptacles in Pharmacies Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In 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 patients from access to the collection receptacle by some means.”</p> <p>This is a tangled section that will only have the effect of creating the very problem it intends to avoid. Why shouldn't receptacles inside stores be accessible to the public when the pharmacy is closed? They are sturdy, securely bolted down, and tamper-proof without the use of power tools. In fact they are far more secure than the drugs on the pharmacy's shelves. If we lock the bins people will leave drugs on top of or next to them. If we create physical barriers, the drugs will be left next to the barriers. This is silly. Leave the darn bins unlocked so people can use them whenever the store is open. This is how it currently works in many places, and it works well.</p>
1776.3	CalRecycle	<p>We recommend revising the regulations to incorporate the DEA's "promptly" standard for delivering drug waste instead of a more restrictive 3-day standard. The proposed text would require drugs removed from their containers to be stored no more than 3 days, whereas the DEA's "promptly" standard allows for a wider variety of business models and activities and avoids per se violations. The proposed text states, "Linens and their rigid containers that have been tilted and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than three days" [§1776.30)]. The DEA regulations require registrants to, "...promptly deliver that controlled substance to a reverse distributor's registered location ..." (21 CFR §1317.05(a)(2)). When asked to define "promptly," the DEA stated, "The DEA considered imposing specific timelines (e.g., three days, five days); however, the wide variety of business models and activities made it impossible in most circumstances to set a specific deadline that would prevent diversion and diversion opportunities. Additionally, violations of specific timelines would be per se violations of the regulations, whereas violations of the flexible 'prompt' and 'as soon as practicable' standards would be considered under each registrant's individual circumstances." While we understand temporary storage outside the collection receptacle increases the chances of illegal drug diversion, three days is a very limited time to allow for any complications in a reverse distributor's collection schedule or to reach more rural locations, resulting in a per se violation.</p>

Code	Commenter	Comment
1776.3(a)	CalRecycle	<p>We recommend revising the regulations to address drugs potentially left beside a closed bin after hours with best management practices. The proposed text states, "In 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 patients from access to the collection receptacle by some means" [§1776.3(a)]. We recognize that people have and will want to leave drugs next to locked collection receptacles in some cases, but we also consider one Board member's comment in the January 19 meeting to be key when he said people leave drugs in his pharmacy even though he doesn't have a collection receptacle. This suggests blocking a receptacle when locked still will not prevent the behavior from happening. Pharmacies are not prevented from blocking their receptacles when locked as needed but we consider this a training issue that should be left to best management practice guidelines, which should also emphasize the importance of effectively locating the receptacle within full view of pharmacy staff as required in DEA regulations.</p>
1776.3(a)	City of Santa Rosa	<p>Proposed text change: "The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by an employee so that drugs may not be deposited into the collection receptacle."</p> <p>Comment: Staff is concerned that requiring pharmacies in retail stores to install a physical barrier something like an accordion style door might discourage them from participating in medicine take-back programs and shift a larger burden to local independent pharmacies. Additionally, it is unclear what exactly would constitute being physically blocked, and that alone could make it less likely for risk-averse pharmacies to participate.</p> <p>DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked goes beyond what the DEA requires. Moreover, it would be just as easy for members of the public to place medicine next to a physical barrier as it would be for them to place medicine next to a locked bin. It would also be easy for members of the public to place their medicines in the closest trash bin, as has been observed. Staff has heard comments that even in pharmacies that do not have any sort of sharps or medicine take-back program, members of the public have left things like syringes on the counter of the pharmacy while the pharmacy is closed. It is unreasonable to expect that this regulation can completely prevent improper disposal from occurring.</p> <p>Separately, for independent pharmacies that lock the entire building when they close the pharmacy, it is unclear what benefit would result from requiring them to lock the top of the bin when they close the pharmacy as locking the building fulfills the DEA requirement of making the receptacle 'otherwise inaccessible to the public'. If the Board chooses to revert to the DEA language they could avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.</p>

Code	Commenter	Comment
1776.3(a)	Sharps	<p>Proposed change: "...In 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 or make otherwise inaccessible to the public when an employee is not present, e.g., when the pharmacy is closed."</p> <p>Comment: This language harmonizes with the requirements of the DEA without causing confusion in interpreting what "physically blocked" could mean. The language as drafted could deter pharmacies from placing receptacles due to the perception that additional construction or barriers must be placed.</p>
1776.3(a)	San Luis Obispo County Integrated Waste Management	<p>Comment: The requirement to "physically block patients from access to the collection receptacle" is not needed since the kiosk is locked. This requirement will be a burden to a pharmacy trying to implement a take back program. Most of the other requirements match the DEA Regulations and thus do not need to be repeated. To the extent that they differ from the DEA Regulations, then it will require the pharmacy to meet both regulations.</p>
1776.3(a)	San Francisco Dept of Environment	<p>Comment: This requirement goes beyond the DEA regulations, and could be a large burden to pharmacies. The DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Furthermore, in the case of independent pharmacies where the collection receptacle is already inaccessible to the public when the pharmacy is closed, it is not necessary for them to lock the top of the bin.</p> <p>Recommendation: Replace above text with: "The receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present."</p>
1776.3(a) & (c)	Russian River Watershed	<p>The Drug Enforcement Agency (DEA) states that drug receptacles shall be locked or made otherwise inaccessible to the public when an employee is not present. The Board's proposed requirement to "lock the deposit slot on the collection receptacle and physically block patients from access to the collection receptacle by some means" is confusing. Requiring the receptacle itself to be physically blocked goes beyond the DEA requirements and does not necessarily increase public safety. Furthermore, the security requirements, as written, could be misinterpreted. Is this a requirement to install a physical barrier around all collection receptacles? Requiring this would likely consume more pharmacy floor space and deter pharmacies from installing collection receptacles. Please consider clarifying the security requirements in Sections 1776.3(a) and 1776.3(c).</p>

Code	Commenter	Comment
1776.3(a) & (c)	City of Palo Alto; Los Angeles Waste Management	<p>Restricting the placement of collection receptacles in pharmacies may diminish pharmacy participation. The DEA clearly states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be ‘physically blocked’ in addition to being locked serves no benefit since it would be just as easy to place unwanted drugs next to a physical barrier as it would be to place medicine next to a locked bin. Separately, for independent pharmacies that lock the entire building when they close the pharmacy, it is unclear what benefit would result from requiring them to lock the top of the bin when they close the pharmacy as locking the building fulfills the DEA requirement of making the receptacle ‘otherwise inaccessible to the public’. If the Board chooses to revert to the DEA language they could avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.</p> <p>We recommend removing language about physically blocking access, and reverting to DEA language in order to avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.</p>
1776.3(b)	Sharps	<p>Proposed change: ...where the receptacle is visible to employees, and not located in emergency areas.</p> <p>Comment: Receptacles in hospitals/clinics with onsite pharmacies need to be monitored, but would not necessarily be placed where pharmacy employees could monitor. In addition, receptacles in LTCF would need to be monitored by facility employees. Therefore, using employee instead of pharmacy employee would harmonize with the DEA rule and not discourage hospitals/clinics or LTCF from participating in a take-back receptacle program. This comment will also apply to 1776.3(c).</p>
1776.3(b)	City of Palo Alto; Los Angeles Waste Management	<p>This provision goes beyond the DEA regulation in a subtle but potentially significant way. As the DEA recognizes, hospitals can be unique in their design and need to have flexibility in the manner in which they participate in Safe Medicine Disposal Programs. The DEA regulations imply that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. We do not want to discourage hospitals from participating in Safe Medicine Disposal programs by making it more difficult for them to do so. Please simply delete the word ‘pharmacy’ from 1776.3(b) so that it reads as the DEA: “visible to employees”, not “visible to pharmacy employees.”</p>

Code	Commenter	Comment
1776.3(b)	City of Santa Rosa	<p>Proposed change: Remove the word 'pharmacy' from 1776.3(b) so that it reads as the DEA: "visible to employees", not "visible to pharmacy employees".</p> <p>Comment: Staff is concerned that this section goes beyond the DEA regulation in a subtle but potentially significant way. As the DEA recognizes, hospitals can be unique in their design and need to have flexibility in the manner in which they participate in Safe Medicine Disposal Programs. The Board regulation as it is currently worded removes some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees" (Federal Register p. 53523). This implies that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. Staff is concerned that the Board regulation as it is currently worded could discourage hospitals from participating in Safe Medicine Disposal programs by making it more difficult for them to do so.</p>
1776.3(b)	San Francisco Dept of Environment	<p>Comment: The DEA does not specify that employees must be employed in the pharmacy. The reference to "emergency areas," is likely only applicable to pharmacies located within a hospital or clinic and is proposed in the following paragraph.</p> <p>Recommendation: Delete "pharmacy," and "but not located in emergency areas."</p>
1776.3(c)	City of Santa Rosa	<p>Proposed text change: "The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by an employee so that drugs may not be deposited into the collection receptacle."</p> <p>Comment: As mentioned in the comment for section 1776.3(b), the DEA recognizes that hospitals can be unique in their design and need to have flexibility in the manner in which they participate in safe medicine disposal programs. The proposed Board regulation may remove some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees". This implies that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. This further implies that collection receptacles in hospitals do not need to be locked if the pharmacy is closed so long as hospital employees are still regularly monitoring the receptacle. Therefore, even if physical blockage is required in a retail store with a pharmacy, it should still not be necessary in a hospital setting.</p> <p>CONTINUED ON NEXT ROW</p>

Code	Commenter	Comment
1776.3(c)	City of Santa Rosa	<p>Staff is concerned that the Board regulation as it is currently worded could discourage hospitals from participating in medicine disposal programs by making it more difficult for them to do so. Requiring hospitals to install something like an accordion style door could discourage them from participating. Additionally, it is unclear what exactly would constitute being physically blocked, and that alone could make it less likely for risk-averse hospitals with pharmacies to participate. The DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked goes beyond what the DEA requires. Moreover, it would be just as easy for members of the public to place medicine next to a physical barrier as it would be for them to place medicine next to a locked bin. It would also be easy for members of the public to place their medicines in the closest trash bin, as has been observed.</p> <p>DEA section 1317.75(e): "Except at a narcotic treatment program, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees."</p> <p>Federal Register p. 53523: "The DEA recognizes that hospitals/clinics with an on-site pharmacy can be unique in their design and it may be more effective to install collection receptacles at various locations within the hospital/clinic, depending on factors such as security, convenience, and accessibility. As such, it would be challenging for authorized hospitals/clinics to adhere to the general rule to place collection receptacles in the immediate proximity of where controlled substances are stored and at which an employee is present. Accordingly, the DEA is requiring hospitals/clinics that are collectors to place collection receptacles in locations that are regularly monitored by employees."</p>
1776.3(c)	Tim Goncharoff County of Santa Cruz	<p>"(c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from patient access by some means."</p> <p>Where does your Board find the legal authority to regulate hospitals? Many medical facilities, including hospitals, now host bins for the collections of leftover medicines and sharps. Why would you want to interfere with this?</p>
1776.3(c)	San Francisco Dept of Environment	<p>Recommendation: Change text to read: The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by an employee so that drugs may not be deposited into the collection receptacle.</p>

Code	Commenter	Comment
1776.3(c)	CA Product Stewardship	<p>Comment: As mentioned in the comment for section 1776.3(b), the DEA recognizes that hospitals can be unique in their design and need to have flexibility in the manner in which they participate in safe medicine disposal programs. Staff is concerned that the Board regulation as it is currently worded takes away some of that flexibility. The DEA states that "it may be more effective to install collection receptacles at various locations . . ." so long as they are "in an area regularly monitored by employees". This implies that employees of the hospital can monitor the collection receptacle, not just employees of the pharmacy specifically. This further implies that collection receptacles in hospitals do not need to be locked if the pharmacy is closed so long as hospital employees are still regularly monitoring the receptacle. Therefore, even if physical blockage is required in a retail store with a pharmacy, it should still not be necessary in a hospital setting CPSC is concerned that the Board regulation as it is currently worded could discourage hospitals from participating in our local medicine disposal program by making it more difficult for them to do so. Requiring hospitals to install something like an accordion style door could discourage them from participating. Additionally, it is unclear what exactly would constitute being physically blocked, and that alone could make it less likely for risk-averse hospitals with pharmacies to participate. The DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be 'physically blocked' in addition to being locked goes beyond what the DEA requires.</p> <p>Recommendation: Modify text to read: The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by an employee so that drugs may not be deposited into the collection receptacle.</p>

Code	Commenter	Comment
1776.3(d)	Kaiser	<p>(d) The receptacle shall include a small an opening that allows deposit of most of the original containers in which the drugs were dispensed into the inside of the receptacle and directly into the inner liner without the ability for a consumer to retrieve the drugs or drug containers once they are deposited into the receptacle.</p> <p>Rationale It has been noted by Poison Control center experts in government and other such centers, that some “Safe Drug/Medicine” program “collection receptacles” only have narrow slots through which consumers and patients cannot insert typical prescription vials. Some of such programs ask the consumers and patients to empty the unwanted prescription drugs in to plastic bags to bring to the collection site without the original containers so that the “pills” can be inserted directly into the receptacle through a narrow slot. Unfortunately, it has been noted that this can have significant potentially dangerous and other consequences.</p> <p>First, if the drugs are taken from the original “child resistant” prescription vials at the patient’s residence, the protection of children is diminished. Apparently such plastic bags are innocently started but not necessarily promptly taken to the site for disposal, or they are taken only to find the intended receptacle not available/closed and are taken back home or disposed of in nearby trash.</p> <p>Another consequence is that such drugs, which often do include controlled substances, when removed from their original dispensed containers present, at best, situations of confusion if law enforcement challenges the patient’s, or the patient’s family member’s or caregiver’s legitimate ability to possess the drugs.</p> <p>CONTINUED ON NEXT ROW</p>

Code	Commenter	Comment
1776.3(d)	Kaiser	<p>Further, drugs, especially for the seriously infirm or elderly or for those who need help with adherence scheduling, are often removed from their original containers and put in “calendar pill trays” and other similar containers that cannot be inserted through narrow slots.</p> <p>Lastly, there have been reports of receptacles used by programs that had narrow slots used to encourage the deposit of loose pills without their containers have been accessed via narrow vacuum hoses that simply sucked out the loose pills – thus foiling the intended security.</p> <p>Common so called “justifications” for a narrow slot, is that the program does not want the expense of disposal of the containers, and, the patient’s privacy would be violated if the original Rx containers were included. Neither is valid. The first should be a part of the program. The second ignores that the receptacles are to be destroyed as a whole with human inspection of the contents.</p> <p>Impact Without this specification change to the receptacles, much of the safety value of the “Safe Drug/Medicine Disposal” programs will be missed, with children and the infirm being the most vulnerable.</p>
1776.3(e)	CA Product Stewardship	<p>CPSC is concerned that requiring pharmacies in retail stores to install a physical barrier something like an accordion style door might discourage them from participating in our medicine take-back program, which could in turn shift a larger burden to our local independent pharmacies. Additionally, it is unclear what exactly would constitute being physically blocked.</p> <p>DEA states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present. Requiring the receptacle to be ‘physically blocked’ in addition to being locked goes beyond what the DEA requires. Staff is concerned that requiring a physical barrier would not solve the intended problem, as it would be just as easy for members of the public to place medicine next to a physical barrier as it would be for them to place medicine next to a locked bin. It would also be easy for members of the public to place their medicines in the closest trash bin, as has been observed.</p> <p>Separately, for independent pharmacies that lock the entire building when they close the pharmacy, it is unclear what benefit would result from requiring them to lock the top of the bin when they close the pharmacy as locking the building fulfills the DEA requirement of making the receptacle ‘otherwise inaccessible to the public’. If the Board chooses to revert to the DEA language they could avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.</p> <p>Recommendations: Remove the language about physically blocking patient access and revert to DEA language in order to avoid requiring independent pharmacies to lock the collection receptacle when they lock the building.</p>

Code	Commenter	Comment
1776.3(h)	Sharps	<p>Proposed change: “...A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, and <u>capable of being sealed</u> and kept clean and in good repair. Rigid containers may be of any color. <u>All rigid containers must meet standards of the United States Department of Transportation and other applicable state and federal regulations for this waste type.</u>”</p> <p>Comment: <input type="checkbox"/> Since a rigid container may be a cardboard box designed to be sealed, the term “tight-fitting covers” could result in the interpretation of an actual cover/lid being required on the cardboard box/inner liner. Therefore, the commonly used term of sealed, which could apply to a variety of container types, is recommended. <input type="checkbox"/> Since medical waste does not include household waste, requiring that transport containers meet the packaging requirements of medical waste exceeds the requirements of the DEA and DOT regulations for the transport of this waste type.</p>
1776.3(h)	San Francisco Dept of Environment	<p>Comment: There is a lot of confusion around the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste (see CA Health & Safety Code Section 117700).</p> <p>Recommendation: Delete “for transport of medical waste.”</p>

Code	Commenter	Comment
1776.3(h)	City of Palo Alto	<p>Requiring rigid containers to “meet standards of the USDOT for transport of medical waste” exceeds the requirements of the DEA regulation, which does not mention medical waste. There is a lot of confusion around the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste. HSC §117700 says, “Medical waste does not include . . . (e) Hazardous waste, radioactive waste, or household waste” Moreover, it appears that home-generated pharmaceutical waste is still considered household waste once it’s collected and consolidated. Alison Dabney, Chief of the California Department of Public Health’s Medical Waste Management Program wrote on November 18, 2015, “A wasteto-energy facility’s permit that prohibits it from accepting medical waste in California does not prohibit the facility from accepting consolidated home-generated pharmaceutical waste, since the current law (Health and Safety Code, §§117600-118360) does not prohibit it. However, any local ordinances regarding the disposal of these items should also be reviewed.”</p> <p>One of the reasons that we are concerned about using medical waste transport regulations is that there are a lot of exemptions that surround the regulation of medical waste transport, and this makes it very difficult to determine what is required. For example, while the definition of medical waste in the Health and Safety Code does include pharmaceutical waste, they exempt pharmaceutical wastes that are being hauled by a reverse distributor (Health and Safety Code Section 117690). It is unclear if this exemption might nullify the otherwise applicable DOT regulations. Moreover, it is not clear what exactly would qualify as meeting the USDOT standards. It is unclear whether a cardboard box, currently an industry standard, would meet the requirements (tight-fitting cover, rigid...). Or would a cardboard box in combination with a plastic bag combine to fulfill the requirements of the “inner liner” as the inner liner is already required to be waterproof? Dis-allowing cardboard boxes would cause the price of disposal to substantially increase. One approach could be to modify text to read: “A rigid container may be disposable, reusable, or recyclable (example: cardboard box). Rigid containers shall be capable of being sealed and be kept clean and in good repair. Rigid containers may be of any color. All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.”</p>

Code	Commenter	Comment
1776.3(h)	City of Santa Rosa	<p>Proposed text change: "A rigid container may be disposable, reusable, or recyclable (example: cardboard box). Rigid containers shall be capable of being sealed and be kept clean and in good repair. Rigid containers may be of any color. All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations."</p> <p>Comment: Requiring rigid containers to "meet standards of the USDOT for transport of medical waste" exceeds the requirements of the DEA regulation, which does not mention medical waste. There is a lot of confusion around the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste. HSC §117700 says, "Medical waste does not include . . . (e) Hazardous waste, radioactive waste, or household waste . . ." Moreover, it appears that home-generated pharmaceutical waste is still considered household waste once it's collected and consolidated. Alison Dabney, Chief of the California Department of Public Health's Medical Waste Management Program wrote on November 18, 2015, "A waste-to-energy facility's permit that prohibits it from accepting medical waste in California does not prohibit the facility from accepting consolidated home-generated pharmaceutical waste, since the current law (Health and Safety Code, §§117600-118360) does not prohibit it. However, any local ordinances regarding the disposal of these items should also be reviewed."</p> <p>CONTINUED TO NEXT ROW</p>
1776.3(h)	City of Santa Rosa	<p>One of the reasons that staff is concerned about using medical waste transport regulations is that there are a lot of exemptions that surround the regulation of medical waste transport, and this makes it very difficult to determine what is required. For example, while the definition of medical waste in the Health and Safety Code does include pharmaceutical waste, they exempt pharmaceutical wastes that are being hauled by a reverse distributor (Health and Safety Code Section 117690). It is unclear if this exemption might nullify the otherwise applicable DOT regulations.</p> <p>In order to avoid confusion, it could be helpful for the Board to replicate the DEA's statements in this matter: "All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations." (Federal Register p53554)</p> <p>It is not clear what exactly would qualify as meeting the USDOT standards. Staff would welcome guidance from the Board clearly establishing that a cardboard box could meet the requirements specified as cardboard boxes are currently an industry standard. Dis-allowing cardboard boxes would cause the price of disposal to substantially increase. Do cardboard boxes have tight-fitting covers? Are they rigid? Do they qualify as leak resistant? Or would a cardboard box in combination with a plastic bag combine to fulfill the requirements of the "inner liner" as the inner liner is already required to be waterproof? Clarification would be beneficial.</p>

Code	Commenter	Comment
1776.3(h)	Los Angeles Waste Management	<p>Comment: Stating specifically that rigid containers must “meet standards of the USDOT for transport of medical waste” exceeds the requirements of the DEA regulation, which does not mention medical waste. There is a lot of confusion around the definition of medical waste; especially home-generated pharmaceutical defined in the HSC §117700.</p> <p>It would be very helpful if the BOP would say the equivalent of: “It is not within the DEA’s expertise or authority to opine on the applicability of DOT regulations.” However, “All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.” (Federal Register p53554).</p> <p>Moreover, it is not clear what exactly would qualify as meeting the USDOT standards. It would be helpful to establish that a cardboard box could meet the requirements specified, as this is currently an industry standard. Dis-allowing cardboard boxes would cause the price of disposal to substantially increase. Do cardboard boxes have tightfitting covers? Are they rigid? Do they qualify as leak resistant? Or would a cardboard box in combination with a plastic bag combine to fulfill the requirements of the “inner liner” as the inner liner is already required to be waterproof? Please make this clear.</p> <p>Recommendation: modify text to read: A rigid container may be disposable, reusable, or recyclable (example: cardboard box). Rigid containers shall be capable of being sealed and be kept clean and in good repair. Rigid containers may be of any color. It is not within the BOP’s expertise or authority to opine on the applicability of DOT regulations. However, all drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.</p>
1776.3(i)	Tim Goncharoff County of Santa Cruz	<p>“i) The liner may be removed from a locked receptacle only by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle.”</p> <p>This is poorly thought out. What busy pharmacy can spare two staff members to handle this duty? It is more properly performed by a duly licensed collector. You are making this burdensome for pharmacies, and as you insist on making such programs voluntary, making it unlikely that they will participate.</p>

Code	Commenter	Comment
1776.3(j)	City of Palo Alto	It is our understanding that the DEA regulation only specifies a three day holding period in Long-Term Care Facilities. In the case of pharmacies, the DEA dictates only that liners be moved “promptly”. The DEA specifically declined to clarify what would constitute a “prompt” action (Federal Register p. 53528). Strictly defining the length of time inner liners can be stored could increase the burden on pharmacies and thereby decrease their participation in medicine take-back programs.
1776.3(j)	San Francisco Dept of Environment	<p>Comment: The DEA does not specify how many days a pharmacy can store full liners before transporting for destruction, only specifying “promptly” (see Section 1317.05 (c). We do not believe three days is a reasonable time frame that will work for all pharmacies in the state of California.</p> <p>Recommendation: Delete “no longer than three days.”</p>
1776.3(j)	City of Santa Rosa	<p>Proposed change: Delete specific time provision, replace with requiring “prompt” removal.</p> <p>Comment: It is staff’s understanding that the DEA regulation only specifies a three day holding period in Long-Term Care Facilities. In the case of pharmacies, the DEA dictates only that liners be moved “promptly”. The DEA specifically declined to clarify what would constitute a “prompt” action (Federal Register p. 53528). Strictly defining the length of time inner liners can be stored could increase the burden on pharmacies and thereby decrease their participation in medicine take-back programs.</p>
1776.3(j)	CA Product Stewardship	<p>Comment: It is CPSC’s understanding that the DEA regulation only specifies a three day holding period in Long-Term Care Facilities. In the case of pharmacies, the DEA dictates only that liners be moved “promptly”. The DEA specifically declined to clarify what would constitute a “prompt” action (Federal Register p. 53528). CPSC is concerned that more strictly defining the length of time inner liners can be stored could increase the burden on pharmacies thereby making it less likely that they would participate in our local medicine take-back program.</p> <p>Recommendation: Delete no longer than three days. Revert to DEA language “liners be removed promptly.</p>
1776.3(j)	Russian River Watershed	In the case of pharmacies, the DEA regulations only state that liners must be removed “promptly.” Please consider updating Section 1776.3(j) to be consistent with the DEA by removing the “three day” removal requirement and replacing it with a “prompt” removal.

Code	Commenter	Comment
1776.3(k)	Tim Goncharoff County of Santa Cruz	Again, unnecessarily burdensome, and an obstacle to participation. Collectors are already required to keep meticulous records. Let them provide copies to the pharmacy or the Board if needed, but don't expect busy pharmacists to undertake this unnecessary duty.
1776.3(k)(5)	Sharps	<p>Proposed change: "If a common carrier is used to transport the liner to the reverse distributor, the company used, and any related paperwork (invoice, bill of lading) must be recorded."</p> <p>Comment: DEA does not require a driver's signature. In addition, a common carrier would not be able to sign such a document. By adding this language, it would preclude the use of common carrier and therefore result in 2-driver pick-up where this would not be cost-effective; and would limit the number of pharmacies participating in the take-back program.</p>
1776.3(k)(5)	San Francisco Dept of Environment	<p>Comment: The DEA does not require any of these records when registrants use a common carrier to transport inner liners to a reverse distributor. We foresee some possible issues with obtaining the signature of the common carrier driver, in the case where some companies may prohibit their drivers from signing anything or the driver does not feel comfortable signing any forms.</p> <p>Recommendation: Delete "the signature of the driver."</p>
1776.3(m)	San Francisco Dept of Environment	<p>Comment: As noted above, we are not aware of any laws that specifically bar certain materials from being deposited into drug take-back receptacles.</p> <p>Recommendation: Delete this section except for the last sentence.</p>
1776.3(m) & (n)	Tim Goncharoff County of Santa Cruz	This is well-intentioned, but I encourage you to look at the signs and other materials already in use where such programs are active. Many consumers do not know what a Schedule I or Schedule II drug is. Signage needs to be designed for consumers, not for pharmacists.

Code	Commenter	Comment
1776.3(m) & (n)	Kaiser	<p>(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 Schedule I drugs. Labeling shall also identify 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.</p> <p>(n) The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process. The signage should also indicate the available options for disposal of sharps. The pharmacy or other involved entities shall not be liable for adverse consequences if consumers violate the prohibitions indicated on the signage. The signage shall indicate that the person placing the items into the receptacle shall be responsible for violation of the prohibitions listed on the signage.</p> <p>CONTINUED ON NEXT ROW</p>
1776.3(m) & (n)	Kaiser	<p>The fact simply is that the vast majority of consumers do not know which drugs or substances are Schedule I or which products are “antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs)”. Consumer are highly likely to put Schedule I drugs/substances or “antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs) into the receptacles anyway. Or, they will try to engage the pharmacy staff into helping them determine which are Schedule I and to sort through the drugs/substances they intend to deposit – which would be a violation of both this regulation and the DEA regulations. Further it seems that one of the significant public safety benefits of the “Safe Drug Disposal Programs” is to provide a convenient means to dispose of all drugs, perhaps especially any Schedule 1 drugs. A significant number of prescription drugs are dispensed to consumers in syringes and other products that would be listed as “sharps”. Experience with existing and pilot programs has shown that such sharps products, with and without drug residue are disposed of in these receptacles. Attempts to discourage this, such as providing receptacles with only narrow slots, have not been effective and have resulted in the dangerous handling of sharps in attempts to get them through the narrow slot and/or the leaving of the sharp near the receptacles or in nearby trash containers.</p>

Code	Commenter	Comment
1776.4	Kaiser	<p>Recommended Change Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate <u>with a pharmacy</u> in drug take-back programs <u>involving controlled</u> substances as authorized by this article.</p> <p>Rationale As stated, this regulation provision is confusing. The ability of the Board of Pharmacy to regulate an SNF about operating a drug take back program that does NOT involve controlled substances may be challenged as beyond the Board's scope of authority vs. the authority of the California Department of Public Health.</p> <p>Impact Without this or a similar change, the implementation of the regulation may be delayed with corresponding delay in public benefit.</p>
1776.4	City of Santa Rosa	<p>Proposed change: Expanding the referenced definition of Skilled Nursing Facilities to include language from the Health and Safety Code section 1418 would more clearly and consistently reflect DEA language; this would be accomplished by including California's definition of Long Term Health Care Facilities.</p> <p>Comment: DEA defines Long-Term Care Facilities on page 53540 of the Federal Register as "a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients." This appears to have a broader meaning than the Skilled Nursing Facility referred to by the Board and defined in the Health and Safety Code section 1250(c) as "a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis". Staff would like to avoid further restricting which types of facilities are permitted to participate in medicine take-back programs.</p>
1776.4	City of Palo Alto	<p>We would like to avoid restricting which types of facilities are permitted to participate in medicine take-back programs. DEA defines Long-Term Care Facilities on page 53540 of the Federal Register as "a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients." This appears to have a broader meaning than the Skilled Nursing Facility referred to by the Board and defined in the Health and Safety Code section 1250(c) as "a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis."</p> <p>We request that you expand the referenced definition of Skilled Nursing Facilities to include language from the Health and Safety Code section 1418 would more clearly and consistently reflect DEA language; this could be accomplished by including California's definition of Long Term Health Care Facilities.</p>

Code	Commenter	Comment
1776.4	Sharps	<p>Proposed change: Expanding the referenced definition of Skilled Nursing Facilities to include language from the Health and Safety Code section 1418 would more clearly and consistently reflect DEA language; this would be accomplished by including California's definition of Long Term Health Care Facilities.</p> <p>Comment: Additional information on this proposed change in this document under 1776 Authorization, Paragraph 1, Proposed Change.</p>
1776.4	CalRecycle	<p>We recommend deleting/moving specific signage requirement language. The proposed text states, "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" [1776.40)). The first sentence is redundant to DEA regulations [21 CFR §1317.75(e)(4)) and could be removed.</p>
1776.4	CalRecycle	<p>We recommend removing language redundant to DEA regulations. The following selected Board regulation sections under 1776.4 are redundant to DEA regulations under 21 CFR respectively, and could be removed, including: §1776.4(c) vs. §1317.80(b), §1776.4(t) vs. §1317.75(d){2}(iii), §1776.4(g) and (h)(l) vs. §1317.75(e)(l) and (3). Many other sections are redundant to DEA regulations and may cause confusion.</p>
1776.4(a)	City of Santa Rosa	<p>Proposed change: Delete this provision.</p> <p>Comment: This provision goes beyond DEA record-keeping requirements. Staff asks that the Board avoid making the regulation more restrictive than necessary in order that local medicine take-back programs may enjoy robust participation from local pharmacies, Long-Term Care Facilities, and the general public.</p>
1776.4(a)	Sharps	<p>Proposed change: Delete.</p> <p>Comment: This recordkeeping requirement goes beyond DEA requirements. Additional recordkeeping burdens beyond that required by DEA will lead to a reduced number of facilities utilizing the mail-back option.</p>

Code	Commenter	Comment
1776.4(b)	SIRUM	1776.4 (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 <u>controlled substances</u> prescription drugs .
1776.4(e)	SIRUM	<p>1776.4 (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded <u>controlled substances</u>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.</p> <p>Without these amendments, regulations proposed for Section 1776 change the practice of long-term care pharmacies for example to credit unused, non-controlled medication for private and public health plans, which would have a significant business impact to these pharmacies and long-term care facilities. We strongly urge you to accept our amendments</p>
1776.4(e)	CMA	<p>There is one suggested change to proposed language that may help improve clarity of the regulations. As worded, Section §1776.4(e) implies that the prescriber is the user who will be taking the medication. Rather, discontinuation of use of a medication is by the resident and may occur as a result of several options, one of which includes a prescriber's order. Rephrasing would resolve the issue:</p> <p>(e) Within three business days after the permanent discontinuation of use of a medication by a prescriber <u>the resident</u>, as a result of <u>an order by a prescriber</u>, 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.</p>

Code	Commenter	Comment
1776.4(h)(2)	City of Santa Rosa	<p>Proposed text change: "A rigid container may be disposable, reusable, or recyclable (example: cardboard box). Rigid containers shall be capable of being sealed and be kept clean and in good repair. Rigid containers may be of any color. It is not within the Board's expertise or authority to opine on the applicability of DOT regulations. However, all drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations."</p> <p>Comment: As mentioned in the comment for 1776.3(h), staff is concerned that stating specifically that rigid containers must "meet standards of the USDOT for transport of medical waste" exceeds the requirements of the DEA regulation, which does not mention medical waste. There is a lot of confusion around the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste. HSC §117700 says, "Medical waste does not include . . . (e) Hazardous waste, radioactive waste, or household waste . . ." Moreover, it appears that home-generated pharmaceutical waste is still considered household waste once it's collected and consolidated. Alison Dabney, Chief of the California Department of Public Health's Medical Waste Management Program wrote on November 18, 2015, "A waste-to-energy facility's permit that prohibits it from accepting medical waste in California does not prohibit the facility from accepting consolidated home-generated pharmaceutical waste, since the current law (Health and Safety Code, §§117600-118360) does not prohibit it. However, any local ordinances regarding the disposal of these items should also be reviewed."</p>
1776.4(h)(2)	Los Angeles Waste Management	Same comments as 1776.3(h).
1776.4(h)(2)	San Francisco Dept of Environment	<p>Comment: As noted above, there is a lot of confusion about the definition of medical waste; significantly, home-generated pharmaceutical waste is not currently defined as medical waste (see CA Health & Safety Code Section 117700).</p> <p>Recommendation: Delete "for transport of medical waste."</p>

Code	Commenter	Comment
1776.4(m)	Sharps	<p>Proposed change: “Sealed inner liners that are placed in a container may be stored at the long-term healthcare 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 DEA-registered reverse distributor by common or contract carrier pick-up or by distributor pick-up at the collector’s authorized collection location.</p> <p>Comment: This proposed change is intended to clarify that the transfer from the facility is to a common carrier or pickup from the facility to transport the liner to a reverse distributor. This should help to clarify that the DEA regulations do not allow the collector pharmacy to take the inner liners themselves for disposal.</p>
1776.4(n)	San Francisco Dept of Environment	<p>Comment: The DEA limits disposal of sealed inner liners to on-site destruction, delivery to a reverse distributor’s registered location by common carrier, or by reverse distributor pick-up at the authorized collector’s location. Collectors are not allowed to self-transport.</p> <p>Recommendation: Replace “two pharmacy employees delivering” with “common carrier or reverse distributor pickup of ...”</p>
1776.4(n)	City of Santa Rosa	<p>Proposed change: Make consistent with DEA language.</p> <p>Comment: The DEA regulation allows “the installation, removal, transfer, and storage of inner liners . . . by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility” in addition to allowing these activities to occur under the supervision of two pharmacy employees (§1317.80(c)). Staff is concerned that the BOP regulation as it is currently worded may restrict some of the listed allowable activities to just two pharmacy employees where the DEA regulation allows more flexibility.</p> <p>Separately, staff is concerned that the Board language may differ from DEA regulations which say: “. . . the practitioner may destroy the collected substances by delivering the sealed inner liners to a reverse distributor or distributor’s registered location by common or contract carrier, or a reverse distributor or distributor may pick-up sealed inner liners at the LTCF” (Federal Register p. 53543 and §1317.05). It appears DEA language prohibits pharmacy employees from transporting the sealed inner liners themselves; staff would welcome clarification from the Board on this matter.</p>

Code	Commenter	Comment
1776.4(n)	City of Palo Alto; Los Angeles Waste Management	<p>The DEA regulation allows “the installation, removal, transfer, and storage of inner liners...by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility” in addition to allowing these activities to occur under the supervision of two pharmacy employees (§1317.80(c)). We are asking that you do not restrict any of the allowable activities to just two pharmacy employees.</p> <p>The BOP language above appears to state that pharmacy employees can themselves directly deliver sealed inner liners to a reverse distributor. However, the DEA says: “...the practitioner may destroy the collected substances by delivering the sealed inner liners to a reverse distributor or distributor’s registered location by common or contract carrier, or a reverse distributor or distributor may pick-up sealed inner liners at the LTCF” (Federal Register p. 53543 and §1317.05). Per our interpretation this does not allow pharmacy employees to transport the sealed inner liners themselves. Please clarify.</p>
1776.4(o)	Sharps	<p>Proposed change: Records of the acquisition, installation and removal from collection receptacle, transfer to storage, and transfer for destruction for each collection receptacle sealed liner must include the dates, addresses of the locations where each liner is installed, unique identification numbers and sizes (e.g. 5-gallon, 10-gallon, etc.), registration number of the collector, the names and signatures of the two employees involved in these processes, and the name of the reverse distributor to whom each sealed inner liner was transferred.</p> <p>Comment: In order to harmonize with DEA, 1304.22(f)</p>
1776.5	San Francisco Dept of Environment	<p>Comments: Reverse distributors are required to be registered with the DEA as a reverse distributor. They would be registered with the DEA as a collector only if they are operating a mail-back program.</p> <p>Recommendation: Modify text to read, “A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA may accept...”</p>

Code	Commenter	Comment
1776.5	City of Palo Alto; Los Angeles Waste Management	<p>Incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable. One such method is incineration. Future alternatives may include plasma or pyrolysis technologies which ionize wastes without the air emissions associated with incineration.</p> <p>The DEA explicitly states: “the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration . . .” (Federal Register, p. 53536).</p> <p>We are requesting that you do not further restrict what is required in the DEA regulation and leave Title 16 open to future destruction technologies. Please delete references to incineration and replace with statements such as “rendered non-retrievable” or a “destruction site” (rather than “incineration site”).</p>
1776.5	San Luis Obispo County Integrated Waste Management	<p>Comment: This section should be totally eliminated. All reverse distributors involved in the drug take back program are located outside of California and thus not subject to California Law, but instead are governed by the DEA Regulations. For example (f) includes requirements on reverse distributors who receive liners from law enforcement under federal law. In addition this section includes requirements that are not consistent with DEA Regulations, such as (b) that requires incineration.</p>
1776.5(a)	Sharps	<p>Proposed change: “A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) <u>registered with the DEA</u> may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.”</p> <p>Comment: The DEA-registered reverse distributor is not the collector in the case of collection receptacles.</p>
1776.5(a)	Kaiser	<p>(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. Once received, the reverse distributor shall establish records required by this section.</p> <p>Rationale A clerical correction.</p> <p>Impact N/A</p>

Code	Commenter	Comment
1776.5(a)	City of Santa Rosa	<p>Proposed text change: "A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) <u>registered with the DEA</u> may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section."</p> <p>Comment: Per Ruth Carter, Chief of the Liaison & Policy Section of the DEA, the DEA-registered Reverse Distributor is not the collector except in the case of mail-backs (see section 1776.6(a)(1) comment).</p>
1776.5(a)	City of Palo Alto; Los Angeles Waste Management	<p>The DEA-registered Reverse Distributor is not the collector except in the case of mail-backs. Consider modifying the text to read "A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) <u>registered with the DEA</u> may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section."</p>
1776.5(b)	City of Santa Rosa	<p>Proposed text change: "A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be rendered non-retrievable by an appropriately licensed DEA distributor in compliance with applicable Federal, State, tribal, and local laws and regulations."</p> <p>Comment: Incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable. One approved method is incineration. Actually, "the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration. . ." (Federal Register, p. 53536).</p>
1776.5(b)	CalRecycle	<p>We recommend revising the regulations to be consistent with DEA regulations by allowing more disposal flexibility beyond incineration. The proposed text states, "All liners shall be incinerated by an appropriately licensed DEA distributor" [§1776.5(b)]. Whereas, when asked to outline the DEA's "non-retrievable" standard, the DEA indicated, "...that incineration and chemical digestion are some examples of current technology that may be utilized to achieve the non-retrievable standard." The DEA also clarified its intent to encourage new technologies by writing, "The DEA believes that any actual or perceived endorsement or recommendation of a specific destruction method, beyond the provision of examples of current methods in the preamble, could suppress exploration and implementation of new technologies as people may assume that the endorsed or recommended methods are required at the exclusion of other methods." Thus, we recommend that the regulations reflect the DEA's non-retrievable standard, which may include incineration and chemical digestion.</p>

Code	Commenter	Comment
1776.5(b)	CalRecycle	<p>In an effort to increase drug disposal options, we recommend incorporating the US EPA incineration recommendations. The proposed text states, "All liners shall be incinerated by an appropriately licensed DEA distributor" [§1776.5(b)]. Yet, different incinerators have different standards depending on the type of waste incinerated. In a 2012 memorandum titled, Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs, the U.S. Environmental Protection Agency (US EPA) recommended incineration at a "...permitted hazardous waste combustor, but when that is not feasible, at a minimum, they should be sent to a large or small municipal waste combustor." We recommend revising regulations to incorporate this and allow incineration at a permitted hazardous waste or a large or small municipal waste combustor.</p>
1776.5(c)	CRA	<p>The proposed regulations provide guidance for pharmacies that choose to host collection receptacles. We understand that two pharmacy employees must handle the management of the receptacle which includes removing the liner when filled. There is confusion around Section 1776.5 (c), which specifies, "Two employees of the reverse distributor shall pickup or accept the receipt of inner liners from DEA registrants." It is not clear if this is interpreted to mean that reverse distributors are required to remove the liners from collection receptacles as it has been occurring in practice. We ask the Board to provide clarification on this component as the current practice has significantly increased the costs associated with this collection method.</p>

Code	Commenter	Comment
1776.5(d)	Kaiser	<p>(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, <u>except that if such person has had such conviction reversed or officially forgiven or who is eligible by the DEA now for registration shall be eligible for employment.</u> <u>Pharmacies participating with a Reverse Distributor in good faith shall not be liable for a violation by such Reverse Distributor.</u></p> <p>Rationale The statement about “who has access to or influence over controlled substances” is so vague and overly broad that it has no meaning within the industry. All Reverse Distributors that are registered with the DEA, are likely to legitimately handle controlled substances. Therefore the statement would seem to include all persons that determine the policies, procedures and practices for the Reverse Distributor. Pharmacies are not likely to be intimately involved in the hiring or personnel practices of any Reverse Distributor with whom it shares a relationship. Therefore it needs to be clear that such pharmacies are not liable for the specified transgressions of such Reverse Distributors.</p> <p>Impact If not changed, the provision will cause confusion among all entities the Board licenses. Further, the DEA has processes where past incidences that could have prevented an entity or person from being a “Registrant”, or even past regulatory violations, can be forgiven or expunged. Similar processes exist for the Board of Pharmacy. If not changed, the provision would unnecessarily limit the number of persons or entities from which the public could now benefit from their participation.</p>
1776.5(e)	City of Santa Rosa	<p>Proposed text change: “Each reverse distributor with <u>a destruction</u> site shall maintain a record of the destruction on DEA form 41.”</p> <p>Comment: As mentioned in the comment for 1776.5(b), incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable.</p>

Code	Commenter	Comment
1776.5(e)	Los Angeles Waste Management	<p>As mentioned in the comment for 1776.5, incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances nonretrievable. One approved method of doing this is incineration. The DEA explicitly states that “the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration. . .” (Federal Register, p. 53536). Please do not further restrict what is required in the DEA regulation.</p> <p>Recommendation: modify text to read: Each reverse distributor with a destruction site shall maintain a record of the destruction on DEA form 41.</p>
1776.5(e)	CA Product Stewardship	<p>Comment: It is CPSC’s understanding that incineration is not specifically required by the DEA (§1317.90); rather, it is required to render the substances non-retrievable. One approved method of doing this is incineration. The DEA states that “the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration. . .” (Federal Register, p. 53536).</p> <p>Recommendation: modify text to read: Each reverse distributor with a destruction site shall maintain a record of the destruction on DEA form 41.</p>
1776.6	CalRecycle	<p>We recommend revising the regulations to make them consistent with the DEA's tracking requirements for collectors. The proposed text includes tracking requirements for pharmacies offering mail-back packages and envelopes to customers in §1776.6(a)-(d). While DEA regulations include pharmacies as potential collectors, a collector conducting a mail-back program must have a method of destruction at its registered location, thereby excluding pharmacies from associated recordkeeping requirements. The DEA regulations state, "The term collector means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized under this chapter to so receive a controlled substance for the purpose of destruction" [21 CFR §1300.01) and "A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail- back program shall have and utilize at their registered location a method of destruction consistent with §1317.90 of this chapter" [21 CFR §1317.70].</p>

Code	Commenter	Comment
1776.6	San Francisco Dept of Environment	<p>Comment: These records are not required by the DEA of pharmacies which are solely providing unused, empty mail-back envelopes or packages to the public. These records are required of the reverse distributor who is operating the mail-back program. It is burdensome and unnecessary to require this level of recordkeeping of pharmacies that are solely providing unused mail back envelopes to the public.</p> <p>Recommendation: Delete sections 1776.6(a) and 1776.6(b). If CABOP envisions a pharmacy that may also operate an on-site destruction facility, then we suggest that this section be reworked to only pertain to those pharmacies</p>
1776.6	San Luis Obispo County Integrated Waste Management	<p>Comment: DEA regulations have no record keeping requirements for pharmacies that distribute mail back envelopes. These BOP proposed regulations are an unnecessary burden on pharmacies.</p>
1776.6	CRA	<p>Some of our members that seek to provide mail-back envelopes as a way to participate in drug take back programs have raised concerns about the recordkeeping requirements in the proposed regulations. The federal regulations state that an inventory of the mail back envelopes is only required for "Collectors" which would be those pharmacies that accept mail back envelopes in the pharmacy. The record keeping requirements in Section 1776.6 serve no purpose if these are made available to customers (either at no cost or for purchase) if mailed it back to the reverse distributor and not returned to the pharmacy. By leaving this section in, pharmacies are discouraged to utilize a mail-back option resulting in less locations willing to stock envelopes, limiting access to customers. We ask the Board remove these requirements for pharmacies that are only going to serve as envelope distributors.</p>

Code	Commenter	Comment
1776.6	Kaiser	<p>(a) When obtaining unused mail-back packages and envelopes for future distribution:</p> <p>(1) The collector <u>or partner</u> 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.</p> <p>(2) For unused packages and envelopes provided to a skilled nursing facility or <u>to</u> a 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 <u>envelopes or packages</u>, date sent, and the number of unused <u>envelopes or packages</u> sent with the corresponding unique identification number.</p> <p>(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.</p> <p>(c) (b) For sealed mail-back <u>envelopes or packages</u> received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,</p> <p>(d) (c) For sealed mail back <u>envelopes or packages</u> destroyed onsite by the reverse distributor collector: number of sealed mail-back <u>envelopes or packages</u> 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.</p> <p>[Note: re-numbering of remaining sub-paragraphs would be required]</p> <p>CONTINUED ON NEXT ROW</p>

Code	Commenter	Comment
1776.6	Kaiser	<p>Rationale</p> <p>There is no requirement under the DEA regulations for each mail-back envelope or package to be produced with a “unique identification number”. Consequently, the current producers of such DEA approved envelopes do not put such identification number on their envelopes/packages.</p> <p>If the intent of this regulation is to require pharmacies that participate in a Mail Back program to add a unique serial number from all such envelopes distributed by pharmacies nation-wide, WITHOUT duplication, it would be a huge undertaking that would delay the implementation of such mail-back programs and delay or diminish the important public protection purposes of the programs. This reality is similar to the Board’s learning when it was involved in attempting to create a system of unique serial numbers for each pack of prescription pharmaceutical for the Track-and-Trace provisions of a “Pedigree” program.</p> <p>The apparent purpose of each envelope/package having a “unique” serial number from all other envelopes/packages, would be to potentially identify any envelopes/packages that went “a stray”. The regulation is void of what would be expected, and by of whom, if such was suspected. Even then the intended receiving entity would not know if any envelope/package is missing, still in the pharmacy, still in the possession of some patient or consumer, was discarded by a patient/consumer or....? There is, rightly so, no requirement for the pharmacy to record even the name of the consumer to which it was dispensed. FURTHER MORE, there is no requirement under federal regulations for any entity, even a pharmacy, that dispenses DEA mail-back envelopes/packages to be licensed by any government entity, including the California Board of Pharmacy, or Registered with the DEA, AS LONG AS THE ENTITY TO WHICH THE POSTAGE PRE-PAID ENVELOPE/PACKAGE IS ADDRESSED TO A PROPERLY LICENSED AND REGISTERED ENTITY, e.g. a Reverse Distributor that properly disposes of the un-wanted drugs.</p> <p>Impact</p> <p>This regulatory provision is, at least, vague and unclear, because it does not indicate what the pharmacy is to do if it receives mail-back envelopes without a unique identification number. Unfortunately, as written it will vastly increase the likelihood that few pharmacies will participate and thus the purpose of the programs will be diminished.</p>

Code	Commenter	Comment
1776.6(a)(1)	City of Santa Rosa	<p>Proposed change: Preserve the DEA requirement that these records are required only for the reverse distributors accepting these envelopes for destruction.</p> <p>Comment: Pharmacies cannot be the collector of mail-back envelopes under the DEA Regulations because the mail-back envelopes do not come back to them; furthermore, pursuant to the DEA Regulations they are prohibited from being the collector as they do not have the required onsite method of destruction. Rather, the collector is the reverse distributor to which the envelopes are mailed from the ultimate user.</p> <p>In order to seek clarification in this matter from the DEA, staff sent an email on 18 March 2016 to Ruth Carter, Chief of the Liaison & Policy Section of the DEA. On March 18, 2016, Ruth Carter from the DEA staff sent a response which confirmed that under the DEA Regulations the reverse distributor is the collector when it comes to mail-back packages, not the pharmacy providing the mail-back packages. A copy of the email exchange can be provided upon request.</p> <p>Staff is concerned that if these recordkeeping duties are required for pharmacies who simply hand out the envelopes it will discourage pharmacies from participating in a medicine mail-back program. Staff respectfully submits for the Board's consideration that they preserve the DEA requirement that these records are required only for the reverse distributors accepting these envelopes for destruction.</p> <p>CONTINUED TO NEXT ROW</p>
1776.6(a)(1)	City of Santa Rosa	<p>DEA: § 1317.70 Mail-back programs:</p> <p>§ 1317.70 (a) A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter.</p> <p>§ 1317.70 (c) . . . Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. . .</p> <p>Federal Register, page 53536, Issue [3] and its response: ". . . A commenter also asked the DEA to clarify whether unregistered retail pharmacies working with a registered authorized collector would be permitted to make mail-back packages available to patients. Response: As discussed in the NPRM, authorized collectors who conduct mail-back programs are encouraged to collaborate to operate mail-back programs by partnering with other entities to assist with the dissemination of mail-back packages to ultimate users, in order to minimize costs. . ."</p>

Code	Commenter	Comment
1776.6(a)(1)	Sharps	<p>Proposed change: Delete.</p> <p>Comment: Pharmacies cannot be the collector of mail-back envelopes under the DEA Regulations because the mail-back envelopes do not come back to them; furthermore, pursuant to the DEA Regulations they are prohibited from being the collector as they do not have the required onsite method of destruction. Rather, the collector is the reverse distributor to which the envelopes are mailed from the ultimate user. DEA 1317.70 A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter. DEA 1317.70 (c) states that “any person may partner with a collector or law enforcement to make such packages available in accordance with this section.”</p> <p>1304.22(f) of the DEA regulations states, “For unused packages provided to a third party to make available to ultimate users and other authorized non-registrants: 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 numbers”. Since the reverse distributor is the mail-back collector, this requirement would not be applicable to pharmacies. By placing this additional recordkeeping burden on pharmacies, it will reduce those willing to participate with reverse distributor collectors in providing mail-backs to the public.</p>
1776.6(a)(1)	City of Palo Alto; Los Angeles Waste Management	<p>As for 1776.6(a)(1), pharmacies are not collectors with regard to mail-back envelopes. Rather, the collector is the reverse distributor to which the envelopes are mailed from the ultimate user. These recordkeeping duties should not be required for pharmacies which simply hand out the envelopes because they are already required for the reverse distributors accepting them for destruction. Requiring them for pharmacies would make it too onerous for many pharmacies to participate in drug take-back programs as providers of mail-back envelopes.</p> <p>We recommend that the language be removed that requires pharmacies participating in a mail-back program to maintain records beyond what is required by the DEA and remove language that suggests that pharmacies participating in mail-back programs need to registered as collectors.</p>

Code	Commenter	Comment
1776.6(a)(2)	City of Santa Rosa	<p>Proposed change: Preserve the DEA requirement that these records are required only for the reverse distributors accepting these envelopes for destruction.</p> <p>Comment: Per Ruth Carter, Chief of the Liaison & Policy Section of the DEA, this is the record that the DEA requires only a collector to keep, as that term is interpreted under the DEA regulations (§ 1304.22(f)). Staff would welcome clarification from the Board that this applies only to the collector, which in this case is the reverse distributor, not the pharmacy. See preceding section 1776.6(a)(1) for more detail.</p>
1776.6(a)(2)	Sharps	<p>Proposed change: Delete.</p> <p>Comment: DEA requires only a collector to keep, as that term is interpreted under the DEA regulations 1304.22(f) as indicated previously.</p>
1776.6(a)(2)	City of Palo Alto; Los Angeles Waste Management	<p>According to the DEA, this is the record that the collector is required to keep (§ 1304.22(f)). Per our previous comments, please clarify that this applies only to the collector, which in this case is the reverse distributor, not the pharmacy. These recordkeeping duties should not be required for pharmacies who simply hand out the envelopes because they are already required for the reverse distributors accepting them for destruction.</p> <p>Requiring them for pharmacies may make it too onerous for pharmacies to participate in drug take-back programs.</p>
1776.6(a) & (b)	NACDS	<p>While the Proposed Rule generally tracks the DEA Final Rule in establishing a drug take-back program, there are several areas of inconsistency. More specifically, Section 1776.6(a) and (b) include record keeping requirements for pharmacies that are not included in the federal regulation. These two provisions would require pharmacies to keep records of the date an unused mail-back envelope was obtained by the pharmacy, the serial number of each package or envelope distributed and the date distributed. We do not understand the justification for such added requirements. These two requirements impose additional administrative burdens and costs on participating pharmacies without a justification or rationale. Accordingly, we ask the Board to delete these two requirements. While these two requirements are of greatest concern to NACDS, we also ask the Board to take efforts to ensure that all of the provisions of the Proposed Rule are consistent with the DEA's federal regulation.</p>

Code	Commenter	Comment
1776.6(a) & (b)	Russian River Watershed	<p>A pharmacy that distributes mail-back envelopes does not come into contact with the collected, unwanted medications. Instead, the unwanted medications are mailed directly to a reverse distributor. The reverse distributor is responsible for recording information about the collected medications including the date and unique identification number.</p> <p>Simply having mail-back envelopes on site does not mean that the pharmacy is actively collecting unwanted prescription drugs at their location. Accordingly, please consider eliminating the requirement for pharmacy retailers to be registered with the DEA as a collector if they participate in drug take-back programs only by distributing empty envelopes to patients.</p> <p>Furthermore, the DEA does not require retailers that sell or otherwise distribute mail-back envelopes to or maintain records of the mail-back envelopes before they are used to collect unwanted medications. Please remove the burdensome recordkeeping requirements for empty mail back envelopes outlined in Sections 1776.2(e), 1776.6(a), and 1776.6(b).</p>
1776.6(b)	City of Santa Rosa	<p>Proposed change: Preserve the DEA requirement that these records are required only for the reverse distributors accepting these envelopes for destruction.</p> <p>Comment: Per Ruth Carter, Chief of the Liaison & Policy Section of the DEA, this is the record that the DEA requires the collector to keep (§ 1304.22(f)). Staff would welcome clarification from the Board that this applies only to the collector, which in this case is the reverse distributor, not the pharmacy. See section 1776.6(a)(1) for more detail.</p>
1776.6(b)	Sharps	<p>Proposed change: Delete.</p> <p>Comment: DEA requires only a collector to keep, as that term is interpreted under the DEA regulations 1304.22(f) as indicated previously.</p>

Code	Commenter	Comment
1776.6(b)	Los Angeles Waste Management	<p>Comment: This burdensome nature of this provision is beyond DEA Regulation and does not provide a clear benefit. The collector, the reverse distributor in the case of mail-backs, is responsible for keeping detailed records. See section 1776.6(a)(1) for a full explication.</p> <p>Recommendation: Remove this item entirely</p>
Overall	CPhA	Supports the Proposed Regulation. Strongly supports "Voluntary" participation.
Overall	CRA	CRA certainly supports the spirit of the proposed regulations which preserve a pharmacy's ability to opt-in to a drug take back program, a decision well within the Board's scope and authority. As these regulations are considered through the process, we urge the Board to maintain the to ensure pharmacy participation is voluntary.
Overall	CA Sheriff's Assoc.	<p>The California State Sheriffs' Association urges the BOP to abandon these proposed regulations as their adoption will preempt local drug take-back programs and likely leave law enforcement agencies with the responsibility to deal with the problem of disposing of unwanted, unused, and expired prescription drugs. By permitting, rather than requiring, pharmacy participation, law enforcement agencies will become the de facto recipients of the unwanted drugs that are not diverted for illegal use or inappropriately discarded.</p> <p>The fact that the proposed BOP regulations are more restrictive than existing DEA regulations will add to the burden imposed on potential participants and make it less likely that pharmacies will voluntarily participate.</p>

Code	Commenter	Comment
Overall	CHA	<p>CHA applauds the intent, particularly with the proposed implementation of a voluntary pharmacy take-back program that will support all sites to individually and fully evaluate costs, security risks and benefit to their communities.</p> <p>The Board of Pharmacy Initial Statement of Reason outlines costs for drug take-back services in pharmacies. While costs are outlined for liners and receptacles, there is underreporting of the actual costs to develop a hospital/clinic based drug take-back program.</p> <p>Recommendation: Additional pharmacy and security labor costs, along with program development and maintenance costs need to be included to estimate actual costs.</p>
Overall	CHA	<p>While the severity of the prescription drug abuse problem continues to mount, there is no question that multiple approaches to combat the issue are warranted. Little data is available on the impact and effectiveness of drug take-back programs. Obviously, drug take-back programs will reduce the available supply of prescription drugs; however, voluntary programs are unlikely to draw participation from individuals inclined towards diversion and non-medical use. A study done in 2012 showed that “most individuals diverting unused drugs originally obtain those drugs from a single doctor, highlighting doctors as the ultimate source of the drug surplus rather than the family medicine cabinet”. This is another reason why CHA and its member hospitals are heavily involved in the state’s prescription drug maintenance program, CURES, that proactively monitors prescribing behavior.</p> <p>Recommendation: Pilot studies be performed to determine which medications are collected, assess take-backs true costs and link program elements to understand the relationship between prescription opioid abuse and take-back programs so that scarce resources can be targeted at the most appropriate arenas to prevent opioid drug abuse</p>
Overall	CA Product Stewardship	<p>Given the detailed nature of the DEA Final Rule, 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.</p>

Code	Commenter	Comment
Overall	City of Palo Alto	<p>1776.2(e) "The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6".</p> <p>1776.6(a)(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."</p> <p>1776.6(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."</p> <p>These three provisions require a pharmacy to create and maintain these records; meanwhile a non-pharmacy retailer can conduct a mail back program without this requirement. Further, these envelopes and packages are already being tracked by the collector, and do not need to be additionally tracked. Per the DEA, "Any person may partner with a collector or law enforcement to make such packages available in accordance with this section (§ 1317.70)."</p>
Overall	San Francisco Dept of Environment	<p>A successful program calls for voluntary participation from pharmacies to host a collection receptacle. Many pharmacies are waiting for the California Board of Pharmacy (CABOP) to pass regulations before they decide whether or not they are able to host a collection receptacle. We urge the CABOP to pass regulations as quickly as possible so there is no delay in implementing our stewardship program.</p> <p>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.</p>
Overall	NACDS	<p>Most importantly, the Board should make clear that the Final Rule preempts municipality-based mandatory drug take-back programs. Pharmacy participation in drug take-back programs should remain voluntary consistent with federal law.</p>
Overall	Nipomo Community	<p>The California Board of Pharmacy proposed regulations are more burdensome than the federal regulations adopted by the Department of Justice on September 9, 2014. For example, the proposed regulations increase the record keeping requirements without any apparent benefit. There are also additional requirements and restrictions on how unwanted medicine can be collected and disposed of.</p>

Code	Commenter	Comment
Overall	Paul Huntzinger	Regarding med take back programs I think it is important to have guidance regarding the deposition of prohibited products. Primarily, pharmacies have no control on what is deposited by the public in such receptacles and shouldn't be held accountable for prohibited items that are deposited in them.
Overall	Templeton Community	The proposed Board of Pharmacy regulations, by preempting local programs and adding burdensome requirements to the Department of justice regulations, will result in fewer take back locations. The solution is to regulate the collection and disposal of unwanted medicine in accordance with the Department of justice regulations issued on September 9, 2014.

**Prescription Drug
Take-Back
Attachment 6
Drug Kiosks Article**

Drug disposal kiosks help hospitals serve their community

Patients who need to dispose of unwanted controlled substances and other medications are embracing the convenience of drug disposal kiosks managed by their local health-system pharmacies.

“We’ve collected a little over two tons, in the last year, of unwanted medications,” said Buck Stanford, community pharmacy operations director for Intermountain Healthcare in Utah.

“I’m a little surprised at how much medicine we’re taking in. So that just goes to show that we have an abundance of medication that’s out there that needs to be disposed of,” he said.

Stanford said all 25 of Intermountain Healthcare’s community pharmacies have a way for patients to dispose of their medicines.

The health system last February installed drug disposal kiosks in 21 of its outpatient pharmacies. At the 4 facilities that lack space for a kiosk, patients are given preaddressed envelopes that they can use to mail some unwanted medications—though not controlled substances—for incineration.

On the other side of the country, Kristina L. McGill, director of pharmacy at Beth Israel Deaconess Hospital–Plymouth, said the hospital last fall became the second in Massachusetts to set up a drug disposal kiosk and the first to install one outside of the pharmacy.

McGill said the 155-bed community hospital has shipped off medications from the 38-gallon kiosk twice since the unit was installed.

Both health systems obtained their kiosks, known as MedSafe units, from Sharps Compliance Inc. of Houston. The steel kiosks are double padlocked and contain an inner receptacle consisting of sturdy inner and outer cardboard boxes plus plastic liners and absorbent pads. The inner boxes double as a shipping container for sending the medications away for incineration.

Stanford said pharmacists and technicians, working in pairs, are able to unlock the kiosks and seal up the contents for shipping and disposal. Replacement liners are shipped to the pharmacies at regular intervals. When a new liner arrives, the staff collects the old one and sends it out to be incinerated regardless of how full it is.

Stanford said most of his pharmacies were on a quarterly liner replacement plan when the program started. But the kiosks have proved so popular that most sites now get replacement liners every month or two.

McGill said she and her chief of security open their unit about every two weeks to make sure the inner receptacle

isn’t overflowing and to “fish out” anything readily visible that doesn’t belong in the kiosk.

“Although it says very clearly on the MedSafe not to put any sharps in it, people put in their unopened insulin pens and [enoxaparin syringes]. I take those out, and we dispose of that in our pharmacy trash,” she said.

Instructions on the units describe substances that are not acceptable for deposit, including liquid medications in volumes greater than 4 ounces.

The Drug Enforcement Administration (DEA) in October 2014 implemented a regulation that allows pharmacies and other healthcare entities to register as collection sites for controlled substances and other unwanted medications [see November 15, 2014, *AJHP News*]. Healthcare entities must apply to have the “authorized collector” status added, at no cost, to their DEA registration before obtaining a drug disposal kiosk from a vendor.

A DEA spokeswoman said that as of February 29, a total of 882 DEA registrants had been designated as collectors.

The Utah and Massachusetts health systems obtained their kiosks for the same reason: to help stem the epidemic of opioid abuse in their community.

“Here at our hospital in Plymouth, we probably see somewhere between two and five overdoses a week,” McGill said.

She said the hospital’s response to the opioid abuse epidemic has included moving to an electronic prescribing system to prevent the fraudulent use of paper prescription pads. The hospital also supports a multipronged abuse-prevention initiative led by the Massachusetts Hospital Association.

“We, as a hospital, have spent the last year and a half really focusing on how we can use fewer narcotics,” McGill said. “So we use a lot of i.v. acetaminophen, i.v. ibuprofen, i.v. ketorolac. We use a lot of multimodal therapy, and then we try and reserve actual narcotics if that doesn’t work. We’ve redone all our order sets, and so it’s a pretty big deal.”

The association recommends that, unless there is a clinical need, hospital emergency departments prescribe no more than a five-day supply of an opioid to a patient. That recommendation is intended, in part, to reduce the supply of excess opioids in communities.

After McGill discovered that another hospital in the state had set up a drug disposal kiosk in an outpatient pharmacy, she approached her chief executive officer about getting one for the hospital. His response was, “Yes, get it right away,” McGill recalled.

McGill said the kiosk is a valuable service to the community, and the lobby location is convenient for dropping



Kristina L. McGill

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Continued from page 510

off unwanted medications. She said people can even use the hospital's free valet parking service while they go inside to place medicines in the unit.

"And we have a lot of volunteers, and they're excited to just be able to bring their stuff in as they come in to volunteer and just drop it in there. Even my staff has made use of it" for personal medications, McGill said.

Stanford said he's used Intermountain's kiosks to dispose of unwanted medicines from his home. He said that making the kiosks available in the pharmacies is "an extension of what we are already doing to try to protect the health of the people in our state."

In Utah, according to the most recent data from the state's department of health, 49 people die each month from drug poisoning, and about 75% of the deaths are related to opioid use.

McGill said she had to demonstrate, before obtaining the kiosk, that the lobby location was monitored and secure.

"We had to make sure that it was under camera surveillance. Not that we want to see who is putting something in our kiosk; we wanted to make sure nobody is trying to take it away," she said.

But she said thieves would have a difficult time removing or breaking into her hospital's locked kiosk.

"It probably weighs about 300 or 400 pounds, and it's bolted to the floor," she said.

Stanford likewise said there were concerns, before the kiosks were installed, that they could be targets for theft. "But we haven't had any issues yet," he said, adding that the kiosks are under video surveillance.

Stanford said he's considered placing kiosks at locations outside the pharmacy, such as outpatient clinics for patients with behavioral health and substance abuse problems.

"But so far, we haven't needed to do that because of the amount of locations that we have with the MedSafes already," Stanford said. "They're already really convenient."

Both pharmacists were enthusiastic about the units and have recommended kiosks to their colleagues.

"I think everybody should do it," McGill said, though she cautioned that some planning is necessary before setting up a kiosk.

"You need to have a space for it and you need to be committed to it, because it doesn't take care of itself," she said.

Walgreens in February announced that it plans to install drug disposal kiosks in more than 500 of the drugstore chain's locations. Some police stations have also installed drug disposal kiosks or established other programs for the collection of unwanted medications.

ASHP policy 0614, Safe Disposal of Patients' Home Medications, encourages pharmacists to develop patient-oriented medication disposal options that minimize the risk of accidental poisoning, drug diversion, and adverse effects on the environment.

—Kate Traynor

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Substances doubtful for bulk drug substances list could be INDs

Pharmacists, physicians, and advocacy groups that want patients to use substances unlikely to be on the upcoming "bulk drug substances list" for compounders should consider submitting "treatment" investigational new drug (IND) applications, FDA personnel recently suggested.

FDA-cleared treatment IND applications, they explained, offer a legal workaround that can benefit many patients.

"An interested party, whether it be an advocacy group, a treatment center, or a compounding pharmacy, could submit a treatment IND, which once that was in place could be expanded to treat a large number of patients," said Jonathan Jarow, from the Center for Drug Evaluation and Research (CDER) Office of the Center Director.

The suggestion arose during the discussion of quinacrine hydrochloride at the March 8–9 meeting of the Pharmacy Compounding Advisory Committee in Silver Spring, Maryland.

It was the fourth time that FDA had convened a meeting of the committee to discuss possible entries on the bulk drug substances list.

Substances on that list can be used by pharmacy compounders to prepare patient-specific products despite not being the subject of a *United States Pharmacopeia* or *National Formulary* monograph or a component of an FDA-approved drug product.

Quinacrine hydrochloride is among the 61 substances that FDA announced in October 2015 may continue to be a component of compounded products while FDA works on the regulation concerning the bulk drug substances list.

Commercial products containing quinacrine hydrochloride left the U.S. market more than a decade ago for undetermined reasons, Jane Axelrad, head of FDA's compounding oversight activities, told the committee.

Yet physicians still prescribe the drug.

Some 15,500 prescriptions for quinacrine hydrochloride products were compounded and dispensed by com-