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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 <u>be vigilant</u> 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 dugs. 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 <u>to the extent that is practicable</u> 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 <u>as collectors</u> 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 <u>may be delivered</u> to a reverse distributor for destruction by <u>two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location,</u> 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.

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

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

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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

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 Cordinator 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

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