



California State Board of Pharmacy

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: June 7-8, 2016

LOCATION:

June 7, 2016

Department of Consumer Affairs – Building Two
1747 North Market Blvd., Emerald Room
Sacramento, CA 95834

June 8, 2016

Department of Consumer Affairs
1625 North Market Blvd., First Floor Hearing Room
Sacramento, CA 95834

BOARD MEMBERS

PRESENT:

Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Gregory Lippe, Public Member (June 8th only)
Stanley Weisser, RPh
Albert Wong, PharmD
Allen Schaad, RPh (June 8th only)
Lavanza Butler, RPh
Ramon Castellblanch, Public Member
Ricardo Sanchez Public Member (June 7th only)

BOARD MEMBERS

NOT PRESENT:

Ryan Brooks, Public Member
Gregory Murphy, Public Member

STAFF

PRESENT:

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Lori Martinez, Staff Manager
Debbie Damoth, Staff Manager
Laura Hendricks, Staff Analyst

Tuesday, June 7, 2016

Call to Order

8:38 a.m.

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 8:38 a.m. Board members present: Amy Gutierrez, Debbie Veale, Victor Law, Albert Wong, Stanley Weisser and Lavanza Butler.

Note: Ramon Castellblanch arrived at 8:48 a.m. and Ricardo Sanchez arrived at 9:24 a.m.

Note: The meeting on June 7 was not webcast.

II. Strategic Planning Session (2017-2021)

Brianna Miller and Elisa Chohan from the department's SOLID unit facilitated the board's discussion to update its strategic plan for 2017-2021.

Below are the *draft* strategic objectives for each of the board's five goal areas.

Note: Following the conclusion of the meeting Ms. Miller and Ms. Chohan refined the draft objectives that will be brought to the board at its July meeting for further review and approval.

Goal Area: Legislation and Regulation

The Board pursues statutes, regulations and procedures that strengthen and support its mandate and mission.

- Educate the Board on national pharmacy initiatives impacting consumers and the future of pharmacy (i.e., pharmacists, pharmacy, technicians, distributors, etc.) to strategize the Board's efforts in alignment with where the profession is going to be in 2020.
- Execute efforts to coordinate a timely and effective process to achieve the work of the Board's committees and the goals of the Board to effectuate the work of the committees.
- Advocate for or against legislation that impacts the Board's mandate to achieve consumer protection.
- Establish a systemized review process of Board regulations on an ongoing manner (annually identified sections) to improve the ability to maintain clear, up-to-date and relevant regulations.

Holly Strom, former board member, stated that a goal of the board should be to ensure that every consumer gets an optimal result from their medication therapy.

Lugina Mendez, member of the New Mexico Board of Pharmacy, explained that their board allows consumers and licensees to submit requests to waive specific regulations

and the board uses these requests to determine what regulations the board should consider modifying.

The board recessed for a break at 10:45 a.m. and resumed at 11:03 a.m.

Goal Area: Licensing

The Board promotes licensing standards to protect consumers and allow appropriate access to the profession.

- Establish a statute or regulation that creates a Licensing process for alternate work sites and vendors in the pharmacy marketplace to maintain patient safety and health.
- Research and identify issues that result from unlicensed vendors in the marketplace to proactively maintain patient safety and health.
- Establish regulations for increased scope of practice for pharmacy technicians in specific practice settings, with inclusion of specialty areas, to increase access of pharmacists to patients.
- Update pharmacy technician qualifications in all practice settings for initial licensure and renewal in order to increase patient safety and patient access to care.
- Implement online application, license renewal, and fee payment for applicants and licensees in order to improve licensing conveniences and efficiencies that support applicants, licensees, and Board staff.
- Complete a comprehensive review of at least five licensure categories and update, if necessary, to ensure their relevancy and keep licensing requirements current with professional practices.
- Explore, and possibly implement, opportunities to utilize contracted organizations to administer the Board's California Pharmacists Jurisprudence Examination (CPJE) to increase access to the examination.
- Improve the license process for new licensees, including providing informational resources directed toward applicants, to offer more guidance about the licensing process and reduce processing times.

The board recessed for lunch at 12:33 p.m. resumed at 1:08 p.m.

Note: Mr. Sanchez left the meeting during the lunch break.

Goal Area: Outreach and Education

The Board informs consumers, licensees, and stakeholders about the practice and regulation of the profession.

- Develop and implement a communication plan for licensees and consumers to improve communication with licensees and consumers and keep them better informed.
- Identify and utilize additional resources for public and licensee outreach services to implement the communication plan.

- Establish a process to collect email addresses and, (if possible) mobile numbers for text messaging, from all licensees for better ability to improve communication.
- Publish summaries of all newly issued regulations that further explain implementation tactics to all licensees to provide education of the Board's regulations to licensees.
- Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in the practice setting.
- Communicate availability of specified pharmacy services and locations (e.g., new services that are consistent with SB 493*) so that the public is aware of pharmacies that meet their needs.
- Revise consumer-facing materials (e.g., posters, Point-to-Your-Language notice, television messages, etc.) to achieve better consumer understanding of their rights.

Goal Area: Enforcement

The Board protects consumers by preventing violations and effectively enforcing laws, codes, and standards when violations occur.

- Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse in order to provide assistance in recovery.
- Implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.
- Develop an enforcement plan to improve patient consultation compliance to improve patient outcomes and increase medication safety.
- Review and revise patient consultation regulations to improve access to and effectiveness of patient consultations.
- Collect data and report to board members about enforcement trends that are presented at case closures so the Board can better educate licensees about Board priorities.
- Evaluate industry technology trends to develop a future regulatory infrastructure that will further promote consumer safety.
- Evaluate the Board's disciplinary guidelines to assess the usefulness of the existing guideless and align them with the Board's priorities.
- Review (and amend, if needed) the policy utilized by Board Members that enables them to withhold disciplinary cases for group discussion in an effort to address inefficiencies in the disciplinary process.

Lori Hensic, representing Kaiser, stated that the board should do more than just identify resources to help pharmacy technicians with substance abuse problems. Ms. Hensic also spoke in support of the board working to improve patient consultations because studies show there is a positive correlation between consultation and patient safety.

The Board recessed for a break at 4:30 p.m. and resumed at 4:36 p.m.

Goal Area: Administration

The Board provides excellent customer service, effective leadership and responsible management.

- Schedule and conduct a full, annual review of the strategic plan by the Board to monitor progress and improve operational performance.
- Require managers to complete leadership training to obtain skills that will improve Board staff performance and allocate better use of resources.
- Conduct annual Individual Development Plans (IDPs) for all staff members to promote their growth and development and enhance performance.
- Collaborate with the Department of Consumer Affairs to explore the feasibility of procuring electronic management tools to increase efficiencies and reduce reliance on paper.
- Update and maintain procedure manuals in order to capture institutional knowledge and enable consistent operations.

President Gutierrez adjourned the meeting at 5:30 p.m.

Wednesday, June 8, 2016

Call to Order

8:04 a.m.

III. Call to Order and Establishment of Quorum

President Gutierrez called the meeting to order at 8:04 a.m. Board members present: Amy Gutierrez, Debbie Veale, Victor Law, Allen Schaad, Greg Lippe, Stanley Weisser and Lavanza Butler.

Note: Albert Wong arrived at 8:07 a.m. and Ramon Castellblanch arrived at 8:19 a.m.

IV. Closed Session

President Gutierrez adjourned the meeting to closed session at 8:08 a.m.

V. Reconvene Open Session

President Gutierrez reconvened the meeting to open session at 9:05 a.m.

VI. Petitions for Early Termination of Probation

Administrative Law Judge Marcie Larson presided over the petitions for early termination of probation from Mary Fernandez (TCH 29486) and Tara Parks (RPH 58965).

VII. Closed Session

The board recessed into closed session at 11:10 a.m. to deliberate on disciplinary matters, including the above petitions.

The board returned to open session at 12:28 p.m.

President Gutierrez called a Special Board Meeting to order at 12:35 p.m. to discuss SB 1193 (related to automated drug delivery systems).

The minutes of the Special Board Meeting may be found on the board's website at: http://www.pharmacy.ca.gov/about/meetings_full.shtml

President Gutierrez adjourned the Special Board Meeting 2:04 p.m.

President Gutierrez returned to the Regular Board Meeting at 2:24 p.m.

VIII. Public Comment on Items Not on the Agenda/Items for Future Meetings

There were no comments from the board or from the public.

IX. Approval of the February 24-25 and April 27-28, 2016, Board Meeting Minutes

President Gutierrez noted that she has amendments to the February meeting minutes and asked that they be brought back to the July Board Meeting for approval.

There were no comments from the board or from the public.

Motion: Approve the April 27-28, 2016, Board Meeting minutes and bring the February minutes back to the July Board Meeting for approval.

M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Castellblanch	X			
Gutierrez	X			
Law	X			
Lippe	X			
Murphy				X
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong			X	

XV. Possible Reconsideration of the Adoption of Title 16 CCR section 1746.4 related to Immunizations

President Gutierrez reported that the board was recently asked a question about the board's immunization regulations that are nearing completion of the administration review process. This question is being brought to the board for clarification of the board's intent.

President Gutierrez explained that the issue is whether the board intended to draft the regulation to apply to all immunizations provided by pharmacists, or only those provided under the provisions of CA Business and Professions Code section 4052.8. She noted that pharmacists have been able to provide immunizations under a protocol with a physician under CA Business and Professions Code section 4052(a)(11). Any requirements on pharmacists providing immunizations under a physician's protocol would be established in the protocol.

President Gutierrez stated that the issue is whether the board wishes to have two standards of care for patients who receive immunizations from pharmacists, or whether it intended that all pharmacists who provide immunizations would be required to comply with the terms of proposed regulation section 1746.4.

President Gutierrez explained that if the board intended to have the protocol apply to all pharmacist-provided immunizations, the regulation would need to be amended and released for a 15-day comment period.

Note: The board's immunization regulation is provided below.

§1746.4 Pharmacists Initiating and Administering Vaccines.

- (a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.
- (b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
 - (1) Completion of an approved immunization training program, and
 - (2) Basic life support certification.This documentation shall be kept on site and available for inspection.
- (c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.
- (d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

- (e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient’s guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.
- (f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility’s normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy’s website.

Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4052 and 4052.8, Business and Professions Code.

Ms. Herold explained that in order for the regulation to apply to all pharmacists providing immunizations, the language would need to be modified as provided below.

(a) A pharmacist initiating and/or administering vaccines pursuant to sections 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

Dr. Jeff Goad, from Chapman University, spoke in support of the modified language.

Brian Warren, representing the California Pharmacists Association, supported the board’s approval of the protocol. However he asked the board to ensure that the language in the protocols created under SB 493 be not overly prescriptive and thereby having the unintended consequence of limiting a pharmacist using his or her professional judgement.

Motion: Modify the language as provided below and move the language to a 15-day comment period.

(a) A pharmacist initiating and/or administering vaccines pursuant to sections 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			

Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

XVI. Proposed Regulations to Add Title 16 CCR Sections 1776 et seq. Related to Prescription Drug Take-Back

Note: President Gutierrez explained that due to the number of parties interested in commenting on the drug take-back language, the board would have to limit public comment to two minutes per commenter.

President Gutierrez reported that 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. She noted that two regulation hearings were held on April 13, 2016 (one in Northern California and one in Southern California).

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

President Gutierrez explained that at this meeting the board would have the opportunity to discuss the regulation and the comments received and to determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the April 2016 Board meeting.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a second 15-day comment period.
3. Return the regulation to the enforcement committee for further discussion.
4. Review the comments received, determine the board's response and ask staff to modify the language to bring back to the July Board Meeting for review and approval.

It was clarified that for purposes of discussion the board would be using the language as approved by the board in April 2016 and released for comment on May 3, 2016 (Attachment 3 in the board meeting materials).

Note: The language (the April 2016 version of the regulation) used during the discussion has been provided following these minutes.

President Gutierrez recommended that the board review the comments received by code section and determine if the language in that section should be modified.

The board elected to review the comments received and determine if the language in that section should be modified. The modified language would then be brought to the July board meeting for further review and approval.

Note: The comments received during the May 3-18, 2016, comment period are provided following these minutes.

Motion: Review the comments received during the last 15-day comment period, make policy determinations based on the comments, and direct staff to modify the language based on the board’s discussion and bring it back to the July Board Meeting for further review and approval.

M/S: Lippe/Weisser

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Castellblanch	X			
Gutierrez	X			
Law	X			
Lippe	X			
Murphy				X
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

Below is a summary of the board’s discussion and policy decisions by code section.

Section 1776

The based on the comments received the board decided to remove the entire second paragraph of the language in 1776.

The board asked staff to amend the first paragraph to clarify that pharmaceutical take-back services are defined as both take-back receptacles as well as mail back envelopes.

There were no comments from the public.

Section 1776.1 (a)

President Gutierrez explained that previously the board removed 1776.1a. She noted that comments were received asking the board to add this section back into the language.

The board elected not to modify the language based on the comments (do not add back in

section a).

Joshua Room, Supervising Deputy Attorney General, explained that the board purposefully used the word “may” throughout the language as it is more permissive and will not create the same potential issue with preemption of local programs.

Mr. Weisser asked if the board is giving up its authority by allowing other entities to regulate what occurs in a pharmacy. Mr. Room explained that the language is silent on whether programs should be voluntary or mandatory. He added that the language is intended to provide the criteria that all pharmacies who participate in a take-back program (voluntary or mandatory) must follow.

Ms. Veale noted that if the board allows the PIC to determine if it is safe for their pharmacy to host a take-back receptacle, or if the board chooses to prohibit pharmacies on probation from hosting a take-back receptacle, there could be a conflict between the board’s regulations and a county that wants to mandate *all* pharmacies to participate. Mr. Room responded that this potential conflict would have to be litigated.

There were no comments from the public.

Section 1776.1 (b)

The board rejected the comment submitted by CHA that asked that "local" jurisdiction be removed, because their expertise may run counter to what is deemed appropriate by state and federal authorities.

Section 1776.1 (c)

The board rejected the comment submitted by Sharps that asked the board to further define “consumer.”

Section 1776.1 (d)

The board determined that signage should be posted informing the public that sharps are prohibited from being deposited in the receptacle.

There were no comments from the public.

Section 1776.1 (e)(2)

The board rejected the comment submitted by Doug Barcon requesting clarification of the definition of “other entities.”

The board accepted the comment submitted by SIRUM that recommended adding "in a collection receptacle" to the end of the section to ensure that pharmacies can continue to take back non-collected prescription drugs from facilities (ie. skilled nursing homes).

Section 1776.1(i)

President Gutierrez reviewed the comments submitted on 1776.1(i).

A representative from the California Association of Retired Americans (CARA) asked the board to remove the allowance for a PIC to determine if it is appropriate for their pharmacy to participate in a take-back program.

The board discussed the responsibilities of a PIC and the level of accountability the board places on PICs.

Angie Manetti, representing the California Retailers Association, asked if their members would be required to document the reason that the PIC determines that it is not appropriate for their pharmacy to participate in a take-back program. The board responded that it would be a good practice; however, it is not required in the board's regulations.

Lori Hensic, representing Kaiser, asked the board to allow the permit holder to determine if their pharmacy can safely participate in a take-back program. The board rejected the request from Kaiser to allow the permit holder to determine if a pharmacy can participate in a take-back program.

Tim Goncharoff, representing Santa Cruz, asked the board to remove 1776.1(i) in its entirety.

Heidi Sanborn, representing the California Product Stewardship Council, also asked the board to remove 1776.1(i).

Bill Worrell, from San Luis Obispo Integrated Waste Management Authority, recommended modifying the language to specifically state that PICs can only make the determination to host physical take-back bins.

Brian Warren asked the board to allow PICs to determine if they should provide take-back envelopes.

Dr. Wong asked who pays for pharmacies to provide take-back envelopes. President Gutierrez stated that the board should be focused on patient safety as opposed to who pays for take-back envelopes.

The board elected to modify the language to remove the reference to the code sections listed in 1771.1(i) and 1776.1(j).

Motion: Modify the language as provided below.

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

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

M/S: Law/Butler

Support: 8 Oppose: 1 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch		x		
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Section 1776.2

Based on the comments received the board elected to add back sections 1176.2 (c) and 1776.2(d) to make the language match the DEA requirements.

Maggie Johnson, with the San Francisco Department of the Environment, clarified that pharmacies cannot accept mail-back envelopes filled with unused drugs from consumers unless they are registered as a collector.

The board agreed with Ms. Johnson’s comment and agreed to modify 1776.2 (g) to specify that a pharmacy can take mail-back envelopes back if they are a collector and have onsite destruction.

Section 1776.3

The board reviewed the comments submitted on section 1776.3.

The board elected to remove the word “written” from sections 1776.3(i) and (k) in order to allow the use of electronic logs.

The board decided to remove the requirement to physically block the receptacle when the pharmacy is closed.

It was noted by a representative from Santa Rosa that there is some confusion as to whether the DEA requires the receptacle to be locked when the pharmacy is closed. It

was also noted by a representative from Santa Cruz that it is unclear if the DEA allows receptacle to be monitored and locked/unlocked by a non-pharmacy employee. The board asked Ms. Freedman to research the DEA requirements on these two points and report back to the board.

The board rejected the comment submitted by CHA recommending that verbiage should be added to explain what should occur if the deposit of inappropriate items is observed by staff and observed while transitioning the liner out of the receptacle.

The president of CARA asked the board to adopt the DEA regulations to prevent further delay of pharmacies participating in take-back programs. President Gutierrez stated that there is nothing that prohibits a pharmacy from participating in a take-back program; they would simply need to follow the DEA regulations.

Lori Hensic, representing Kaiser, recommended removing the phrase "in the pharmacy" from 1776.3(a). The board agreed with Ms. Hensic's recommendation.

The board decided to remove references "medical waste" from 1776.3(h).

The board accepted the comment from the City of Santa Rosa, which recommended modifying 1776.3(i) as follows: "The liner may only be removed from a locked collection receptacle either by two employees of the pharmacy or under the direct supervision of two employees of the pharmacy."

At the recommendation of Ms. Freedman, the board rejected the comment from San Francisco Department of the Environment that requested that the board change the 14 day storage requirement to "promptly."

The board removed the requirement to log unused liners in 1776.3(k)(1).

The board eliminated the requirement in 1776.3(K)(5) for the driver to sign to transport the liners.

Section 1776.4

The board removed the phrase "based upon a request by the resident patient" from 1776.4 (a). However, they asked Ms. Freedman to research if the removal of this phrase could have any unintended consequences.

The board accepted the comment submitted by the City of Santa Rosa on 1776.4(n) that recommended modifying the language as follows:

"Liners may be delivered to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up."

The board accepted the comment submitted by Sharps that recommended changing the language in 1776.4(o) as follows:

"Records which include the date, unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired, installed, removed and sealed, transferred to storage, and transferred for destruction; the address of the location where each receptacle with inner liner is maintained, the registration number of the collector, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the names and signatures of the two employees that witnessed each installation, removal, transfer to storage, and transfer for destruction; and if applicable, the names and signatures of the two reverse distributor drivers who transport each liner."

Section 1776.5

The board accepted the comment submitted by Sharps and Santa Rosa that recommended modifying 1776.5(a) as follows:

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

The board modified 1776.5(e) based on the comment from the City of Santa Rosa that expressed concern that the language references "incineration" when incineration is not required by the DEA. The board decided to replace the word "incineration" with "destruction."

Section 1776.6

The board rejected the comment from the San Francisco Department of the Environment to modify 1776.6 to use the phrase "all required records."

The board rejected the comments from Kaiser to modify 1776.6(d) and 1776.6(c) because the language in these sections are DEA requirements.

The board accepted the comments submitted by the City of Santa Rosa that recommended that the language be changed to: "...the method by which, the liner was delivered to the reverse distributor (e.g., shipping via common carrier, reverse distributor pick-up)."

Mr. Weisser thanked President Gutierrez and board staff for their work on this draft language.

Dr. Castellblanch thanked the consumer groups and city representatives for attending the meeting and providing comments.

President Gutierrez adjourned the meeting at 4:49 p.m.

Title 16. Board of Pharmacy
Modified Text

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

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

Article 9.1. Prescription Drug Take-Back Programs

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

Section 1776 Prescription Drug Take-Back Programs: Authorization

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

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

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

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

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

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

Section 1776.1 Pharmacies

- ~~(a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.~~
- (b) (a) Pharmacies may provide take-back services to the public patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).
- ~~(c) (b) There are multiple federal, and state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.~~
- ~~(d) (c) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, which includes including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a consumer patient, they are not to be separated by pharmacy staff or others.~~
- (d) (d) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's prescription drug take-back collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage informing the public of the items prohibited from being deposited shall be placed posted on collection receptacles as referenced in section 1776.3.
- (e) (e) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a patient or patient's agent consumer. Dangerous drugs that have not been dispensed to patients consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in as part of a pharmacy's drug take-back programs.
- (1) Pharmacy staff shall not review, accept, count, sort, or handle any prescription drugs returned from the public.
- (2) A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
- (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.~~
- ~~(f) (f) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating maintaining a prescription drug take-back collection receptacle program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied,~~

surrendered or revoked.

- (h) (g) Any pharmacy that ~~operates~~ maintains a drug take-back collection receptacle program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:
- (1) Any pharmacy that ceases to ~~operate~~ maintain a drug take-back collection receptacle program shall notify the board within 30 days on a form designated by the board. ~~If the pharmacy later 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~~ collection receptacle or theft of deposited drugs shall be reported to the board with 14 days.
 - (4) Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.
- (h) (h) If the pharmacy ~~later ceases to operate~~ maintain ~~the~~ a registered collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.
- (i) A pharmacy shall not provide take-back services to consumers, as provided in sections 1776 - 1776.4, if, in the professional judgment of the pharmacist in charge, the pharmacy cannot comply with the provisions of this article or the Drug Enforcement Administration rules.
- (j) A pharmacy shall not provide take-back services to consumers, as provided in sections 1776 - 1776.4, if the pharmacy or the pharmacist in charge is on probation with the Board, and, if the pharmacy had previously provided take-back services, the pharmacist in charge shall notify the Board and the Drug Enforcement Administration as required in subsections (h) and (i), above.

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

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

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

1776.2 Mail Back Package and Envelope Services from Pharmacies

- (a) Pharmacies that provide prescription drug take-back services may do so by ~~establishing providing mail back services, whereby the public may obtain from the pharmacy~~ preaddressed mailing envelopes or packages containers to allow a consumer to for returning prescription drugs to an authorized Drug Enforcement Administration destruction location.
- (b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector ~~that has onsite a method appropriate to destroy the prescription drugs.~~ The pharmacy is responsible for ensuring that all preaddressed

envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.

- (c) ~~The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.~~
- (d) ~~The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.~~
- (e) ~~The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.~~
- (f) ~~Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.~~
- (g) ~~Once filled with unwanted prescription drugs, the A pharmacy shall not accept any mail back packages or envelopes that contain drugs. Consumers shall be directed to mail the envelopes or packages or deposit them into a pharmaceutical take-back receptacle. shall be mailed and not accepted by the pharmacy for return, processing or holding.~~

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

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

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

1776.3 Collection Receptacles in Pharmacies

- (a) Pharmacies ~~may~~ that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby ~~for~~ the public ~~to~~ may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. ~~In~~ During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block ~~the public patients~~ from access to the collection receptacle by some means.
- (b) The pharmacy ~~operating~~ maintaining the collection receptacle must securely install the receptacle so it cannot be moved or removed. The receptacle shall be installed in an inside location within the pharmacy premise, where the receptacle is visible to pharmacy employees, but not located in or near emergency areas.
- (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 any emergency or urgent care areas. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from public patient access by some means.

- (d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.
- (e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.
- (f) A liner as used in this article shall be made of material that is certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
- (1) The liner shall be waterproof, tamper evident and tear resistant.
- (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.
- (g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.
- (h) If the liner is not already itself rigid or already inside of a rigid container when as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed and be kept clean and in good repair.
- (i) The liner may be removed from a locked collection receptacle only by two employees of the pharmacy. Upon removal, these pharmacy employees ~~who~~ shall immediately seal the liner and record, in a written log, their participation in the removal of each liner from a collection receptacle. If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.
- (j) Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than ~~three~~ 14 days.
- (k) The pharmacy shall maintain a written log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:
- (1) The unique identification numbers of all unused liners in possession of the pharmacy,
- (2) The unique identification number and dates a liner is placed in the collection receptacle,
- (3) The date the liner is removed from the collection receptacle,

- (4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
- (5) The date the liner was provided to a licensed DEA-registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.
- (l) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.
- (m) The collection receptacle shall contain signage developed by the board advising the public that it is ~~permissible to deposit Schedule II-V drugs into the receptacle, but not permissible to deposit any~~ Schedule I drugs into the collection receptacle. ~~Labeling~~ The signage shall also identify 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~~ maintaining collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.

- (2) Any pharmacy or hospital/clinic with an onsite pharmacy that ~~operates~~ maintains a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
- (3) Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to ~~operate~~ maintain a collection ~~site~~ receptacle at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
- (4) Any pharmacy operating a collection receptacle ~~site~~ at a skilled nursing facility shall list all collection receptacles it ~~operates~~ maintains annually at the time of renewal of the pharmacy license.
- (c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.
- (d) Every pharmacy and hospital/clinic pharmacy that ~~operates~~ maintains a collection ~~site~~ receptacle at any skilled nursing facility shall notify the board within 14 days of any loss or theft from the collection receptacle or secured storage location for the storage of removed liners.
- (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be moved or removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.
- (h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.
- (1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be viewed, removed or counted.
- (2) If the liner is not already itself rigid or already inside of a rigid container ~~as~~ when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.
- (i) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact

resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

- (1) The liner shall be waterproof, tamper evident and tear resistant.
 - (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.
- (j) The collection receptacle shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (k) Once deposited, the prescription drugs shall not be handled, counted, inventoried or otherwise individually handled.
- (l) The installation, removal, transfer and storage of inner liners shall be performed only by:
- (1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
 - (2) By or under the supervision of two employees of the authorized collector pharmacy.
- (m) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.
- (n) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.
- (o) Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.

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

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

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

1776.5 Reverse Distributors

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

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

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

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

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

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

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

- ~~(a) When obtaining unused mail-back packages and envelopes for future distribution:~~
 - ~~(1) The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.~~
 - ~~(2) For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent,~~

and the number of unused packages sent with the corresponding unique identification number.

- ~~(b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.~~
- ~~(c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,~~
- ~~(d) For sealed mail-back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.~~
- (e) (a) For pharmacies using collection receptacles, the pharmacy shall maintain the following records for each liner:
 - (1) Date each unused liner is acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
 - (2) Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10- gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
 - (3) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
 - (4) Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
 - (5) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, and the signature of the driver.
- (b) For each reverse distributor (wholesaler or third-party logistics provider) accepting sealed mail-back packages: the date of receipt and the unique identification of the individual package or envelope.
- (c) For each reverse distributor that will destroy the mail-back packages: the number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.
- (d) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, the following records must be maintained, with recording taking place immediately upon receipt of a liner:
 - (1) The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the

reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier).

- (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

Attachment 2
Prescription Drug
Take-Back
15-Day Comment Table
and Staff
Recommendations

Code Section	Commenter	Comment	Staff Recommendations
1776	San Luis Obispo Integrated Waste	<p>Commenter expressed concern that not all drug take-back kiosks accept controlled substances and those that do not should be not have to comply with the regulations. They recommended adding an statement that the regs only apply to those programs that collect contolled substances.</p> <p>Commenter also expressed concern that the Board is restricting pharmaceutical receptacles to Board licensees, eliminating the ability for non-licensees (ie Law Enforcement) to have receptacles.</p>	<p>Reject comment. The Board only has jurisdiction over licensees; as such, these regulations would only apply to Board licensees. The Board does not want to limit collection to controlled vs non-controlled as there is not a way to prevent controlled drugs from begin deposited into the receptacles designed for Non-controlled only.</p>
1776	Doug Barcon, Pharm.D.	<p>Dr. Barcon requested clarification on Iodine products and requested the Board create a list. He indicated that the public may not be aware that a medication contains iodine. Dr. Barcon also indicated that the DEA allows collectors to view what is being deposited into the receptacles. He believes is is necessary to ensure prohibited items are not deposited. Finally, Dr. Barcon indicated that IV solutions and IV antibiotics should also be collected.</p>	<p>Modify List?</p>
1776	SF Dept of Environment and San Mateo Cty	<p>Commenter expressed concern that the language goes beyond DEA regulations and requested that the prohibited item list be removed from the regulation.</p>	<p>Modify List?</p>
1776	RxSafeMarin	<p>Commenter requested that "illicit drug" be removed as all drugs need to be removed from the street.</p>	<p>Reject Comment. The DEA regulations do not permit collection of Schedule 1 "illicit" drugs.</p>

Code Section	Commenter	Comment	Staff Recommendations
1776	Kaiser	Kaiser recommended removing the exclusion of chemo and cytotoxic drugs. They expressed concern that patients or caregivers may not know which medication is a chemo or cytotoxic drug.	Reject Comment. Cytotoxic drugs are required to be labeled on the container.
1776	City of Santa Rosa	Commenter expressed concern about the term "be vigilant" and recommended that the language be changed to "post clear and specific signage" or "to the extent feasible" because staff are not allowed to review what is being deposited.	Accept Comment. Staff recommends to add reference to signage as defined in 1776.3.
1776	LA County	<p>Commenter expressed concern about the term "vigilant" and requested that the language be changed to: "take reasonable steps in a manner consistent with this chapter to"</p> <p>Commenter expressed concern about the list of drugs as the list is not identified by the DEA. They requested that the list be removed or revised to only limit non-drug items (ie. mercury containing devices).</p>	<p>1. Accept Comment. Staff recommends to add reference to signage as defined in 1776.3.</p> <p>2. Modify List?</p>
1776	LA Waste	Commenter expressed concern about the term "vigilant" and requested that the language be changed to: "take reasonable steps in a manner consistent with this chapter to"	Accept Comment. Staff recommends to add reference to signage as defined in 1776.3.

Code Section	Commenter	Comment	Staff Recommendations
1776.1	Anthony Riley, MD	Dr. Riley recommends that Pharmacies be required to take back medications because patients routinely visit the pharmacy and pharmacies are equipped to handle the medication. He expressed that State Resources be offered to pharmacies to offset the cost.	Reject comment. The Board is not making participation mandatory as the Board is aware that some pharmacies will not be able to comply with the requirements of the regulations. Additionally, the Board does not have the authority to allocate State Resources.
1776.1(a)	Kaiser	Kaiser recommended that this section be added back in and read: 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.	Reject Comment. While the Board supports voluntary participation, it is not the Board's intention to preempt local jurisdiction mandatory programs.
1776.1(a)	CHA	CHA reiterated its position of non-mandatory participation and recommended that this remain for hospital/health systems.	Reject Comment. While the Board supports voluntary participation, it is not the Board's intention to preempt local jurisdiction mandatory programs.

Code Section	Commenter	Comment	Staff Recommendations
1776.1(b)	CHA	CHA recommended that "local" jurisdiction be removed as their expertise may run counter to what is deemed appropriate by state and federal authorities.	Reject Comment. The DEA specify states (53554 of the Federal Register) that all drug disposal must be conducted consistent with Federal, State, and Local laws.
1776.1(c)	Sharps	Commenter expressed concern about the term "consumer" and recommended that it be changed to "consumer or person lawfully entitled to dispose of the consumer's property" to allow for family members or nursing facility staff to dispose of medication.	Consumer's Agent?
1776.1(d)	LA County	Commenter expressed concern about the list of drugs as the list is not identified by the DEA. They requested that the list be removed or revised to only limit non-drug items (ie. mercury containing devices).	Modify List?
1776.1(d)	SF Dept of Environment	Commenter expressed concern that the language goes beyond DEA regulations and requested that the prohibited item list be removed from the regulation.	Modify List?
1776.1(d)	City of Santa Rosa	Commenter expressed concern about the list of prohibited drugs as the DEA does not provide a list. They request that the list be removed.	Modify List?
1776.1(d)	Kaiser	Kaiser recommended removing the exclusion of chemo and cytotoxic drugs. They expressed concern that patients or caregivers may not know which medication is a chemo or cytotoxic drug.	Reject Comment. Cytotoxic drugs are required to be labeled on the container.

Code Section	Commenter	Comment	Staff Recommendations
1776.1(e)(2)	Doug Barcon, Pharm.D.	Dr. Barcon requested clarification of "other entities"	Accept Comment. Staff recommends language to add "entities with commercial pharmaceutical waste"
1776.1(e)(2)	SIRUM	Commenter recommended adding "in a collection receptacle" to the end of the section to ensure that pharmacies can continue to take return non-collected prescription drugs from facilities (ie. skilled nursing homes).	Accept comment. Staff recommends this change.
1776.1(i)	SF Dept of Environment and San Mateo Cty	Commenter requested that this section be removed as it is unnecessary. They indicate that if a pharmacy cannot comply with the DEA, than it cannot collect controlled substances.	Reject Comment. The Board's regulations are more detailed than the DEA's regulations. This section is necessary in the event that a pharmacy cannot comply with the regulations.
1776.1(i)	Kaiser	Kaiser expressed concern that the pharmacy permit holder is not allowed to make the participation decisions when they may face civil action. Kaiser recommended that the language be modified to allow the permit holder authority to make the decision.	Reject Comment. The PIC is responsible for what occurs within the pharmacy.

Code Section	Commenter	Comment	Staff Recommendations
1776.1(i)	CA Product Stewardship	Commenter recommends that this section be removed as it allows for an exemption without having to justify it.	Reject comment. The Pharmacist is utilizing their professional judgment to determine if they can comply with the DEA or Board's regulations.
1776.1(i)	Clean Water Action	Commenter recommends that this section be removed as it will discourage pharmacies from participating or confuse pharmacists.	Reject Comment. The Pharmacist is utilizing their professional judgment to determine if they can comply with the DEA or Board's regulations. Not all pharmacies may have the resources or pharmacy space to have a receptacle.
1776.1(i)	San Luis Obispo Integrated Waste	Commenter recommends changing "1776-1776.4" to "1776.3" so that if pharmacies do not have a collection bin, they can still provide mail back services.	Reject Comment. Staff recommends changing "services" to "collection receptacle" to clearly identify that the pharmacy can still provide mail-back envelopes if they cannot provide a receptacle.

Code Section	Commenter	Comment	Staff Recommendations
1776.1(i)	City of Santa Rosa	Commenter requested that the reference sections be changed to 1776.3 only so that pharmacies who cannot have a receptacle, can still provide mail back services.	Reject Comment. Staff recommends changing "services" to "collection receptacle" to clearly identify that the pharmacy can still provide mail-back envelopes if they cannot provide a receptacle.
1776.1(i)	CRA	CRA expressed concern that the justification to not have a receptacle creates a burdensome administrative process. They recommended that the Board only require justification for pharmacies subject to a local mandate.	Reject Comment. The regulation does not require paperwork be completed to not participate; however, if questioned by a mandatory local jurisdiction, the Pharmacist may have to explain their reasoning.
1776.2	RxSafeMarin	Commenter recommended that mailers be pre-printed for postage because the public should not have to pay the postage.	Accept Comment. Pre-Paid Postage is a DEA requirement.

Code Section	Commenter	Comment	Staff Recommendations
1776.2	LA County & LA Waste & SF Dept of Environment	<p>Commenter expressed concern that the language in this section is confusing and could be misconstrued. They recommended the following language:</p> <p>(a) Register with the DEA and the board as a collector.</p> <p>(b) Utilize mail-back envelopes and packages which meet the requirements of 21 CFR 1317.70(c) and make them available, for sale or for free, to the public directly or through another entity, including, but not limited to other pharmacies.</p> <p>(c) Follow the requirements of 21 CFR 1317.70(e) in conducting a mail-back program.</p> <p>(d) Have and utilize at their registered location a method of destruction which shall render the contents of the mail-back envelopes and packages non-retrievable.</p> <p>1776.2.2 Requirements for Pharmacies Which Distribute Mail-Back Envelopes and Packages</p> <p>(a) Ensure that any mail-back envelopes or packages made available to the public are preaddressed to a location that complies with DEA and board requirements.</p> <p>(b) Direct the public to take mail-back envelopes or packages and their contents to common carrier or contract carrier indicated on the envelope or package.</p>	Reject Comment. Staff disagrees that the section is confusing; however, minor changes were made to text
1776.2(a)	Sharps	<p>Commenter expressed concern about the term "consumer" and recommended that it be changed to "consumer or person lawfully entitled to dispose of the consumer's property" to allow for family members or nursing facility staff to dispose of medication.</p> <p>Additionally, commenter requested that "destruction location" be changed to " with onsite destruction" to comply with 21 CFR 1317.70.</p>	<p>1. Consumer's Agent?</p> <p>2. Reject Comment. Staff believes that authorized DEA destruction location is sufficient for the Board's regulations. Board inspectors will not know if the site has onsite destruction.</p>
1776.2(c)	Doug Barcon, Pharm.D.	Dr. Barcon expressed concern that the requirement for mail-back envelopes to be tear resistant was removed. He recommended that the requirement be added back in because of the odd shape of prescription containers.	Accept comment. This is a DEA requirement.
1776.2(d)	Doug Barcon, Pharm.D.	Dr. Barcon expressed concern that the requirement for preaddressed envelopes to have a unique ID number was removed when this is a requirement of the DEA.	Accept comment. This is a DEA requirement.

Code Section	Commenter	Comment	Staff Recommendations
1776.2(g)	Sharps	Commenter expressed concern about the term "consumer" and recommended that it be changed to "consumer or person lawfully entitled to dispose of the consumer's property" to allow for family members or nursing facility staff to dispose of medication.	Accept comment. This is permitted by DEA. Staff recommended adding this to the language.
1776.3	CRA	CRA recommended that "written" log be removed to allow for alternative record keeping systems.	Accept comment. Staff recommends this change.
1776.3	CHA	CHA recommended that verbage should be added to explain what should occur if the deposit of inappropriate items is observed by staff and observed while transitioning the liner out of the receptacle.	
1776.3(a) & (c)	LA County	Commenter expressed concern that the physical barrier will add additional costs and provides little to no safety benefit. They recommended that the requirement be removed.	Accept comment. Staff recommends that the language be changed to "locked or made inaccessible"
1776.3(a)	Sharps	Commenter expressed concern about the requirement to physically block the receptacle. Commenter believes it will discourage participation and requested that the requirement be removed.	Accept comment. Staff recommends that the language be changed to "locked or made inaccessible"
1776.3(a)	CRA	CRA recommended that the requirement to physically block the public from access be removed. They recommended that the language be changed to: During hours when the pharmacy is closed, the collection receptacle shall be locked or made otherwise inaccessible not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block the public patients from access to the collection-receptacle by some means.	Accept comment. Staff recommends that the language be changed to "locked or made inaccessible"

Code Section	Commenter	Comment	Staff Recommendations
1776.3(a)	SF Dept of Environment and San Mateo Cty	Commenter expressed concern that the requirement to block the receptacle goes beyond the DEA regulations. They recommended that the language be changed to "The receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present."	Accept comment. Staff recommends that the language be changed to "locked or made inaccessible"
1776.3(a)	Clean Water Action	Commenter recommended that the requirement to physically block the public from access be removed. They indicated that even if the receptacle is blocked, people may still leave medication next to the barrier.	Accept comment. Staff recommends that the language be changed to "locked or made inaccessible"
1776.3(a)	San Luis Obispo Integrated Waste	Commenter recommended that the requirement to physically block the public from access be removed. They indicated that the requirement exceeds Federal Requirements and could result in pharmacies not participating.	Accept comment. Staff recommends that the language be changed to "locked or made inaccessible"
1776.3(a)	LA Waste	Commenter expressed concern that the language goes beyond DEA regulations and requested that the language to be modified to use the DEA language.	Accept comment. Staff recommends that the language be changed to "locked or made inaccessible"
1776.3(a)	CA Product Stewardship & City of Santa Rosa	<p>Commenter recommends that the text be changed 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> <p>They indicated that requirement exceeds DEA requirements and could result in pharmacies not participating.</p>	Accept comment. Staff recommends that the language be changed to "locked or made inaccessible"

Code Section	Commenter	Comment	Staff Recommendations
1776.3(b)	CA Product Stewardship & City of Santa Rosa	<p>Commenter recommends that the text be changed to read: "In non-hospital locations, the receptacle shall be installed in an inside location such that it can be seen from the pharmacy counter."</p> <p>They indicated that language appears to apply to both hospital and non-hospital locations and limits the flexibility for locations within hospitals.</p>	Accept comment. Staff Recommends that "pharmacy" be removed so that it reads licensed premise and visible to employees.
1776.3(b)	SF Dept of Environment	The commenter expressed concern that the DEA does not require the receptacle be visible to "pharmacy" employees and requested that the language be changed to: "The receptacle shall be installed in an inside location, where the receptacle is visible to employees."	Accept comment. Staff Recommends that "pharmacy" be removed so that it reads licensed premise and visible to employees.
1776.3(b)	LA County	The commenter expressed concern that the DEA does not require the receptacle be visible to "pharmacy" employees and requested that this requirement be changed.	Accept comment. Staff Recommends that "pharmacy" be removed so that it reads licensed premise and visible to employees.
1776.3(b)	LA Waste	Commenter requested that "pharmacy," "within the pharmacy premises," and "but not located in emergency areas" be removed as the DEA regulations do not specify this.	Reject comment. The DEA specifically states "At a hospital/clinic: "A collection receptacle shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided."

Code Section	Commenter	Comment	Staff Recommendations
1776.3(b)	CHA	CHA recommends allowing drug take-back receptacles near a emergency/urgent care area if deemed safe and appropriate by the PIC and hospital administration.	Reject comment. The DEA specifically states "At a hospital/clinic: "A collection receptacle shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided."
1776.3(c)	Sharps	Commenter expressed concern that the regulations require supervision of pharmacy employees within the hospital; however, the DEA regulation is not that restrictive and only states "monitored by employees." They recommended that the language be modified to: "When the supervising employees are not available for regular monitoring, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle."	Reject Comment. The Pharmacy within the Hospital is responsible for the receptacle.
1776.3(c)	CA Product Stewardship and San Mateo Cty and City of Santa Rosa	Commenter recommends that the text be changed 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." They indicated that requirement exceeds DEA requirements and do not allow flexibility for hospitals.	Reject Comment. The Pharmacy within the Hospital is responsible for the receptacle.
1776.3(c)	LA Waste	Commenter requested that the language be changed to: "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."	Reject Comment. The Pharmacy within the Hospital is responsible for the receptacle.
1776.3(c)	SF Dept of Environment	Commenter expressed concern that the requirement to block the receptacle goes beyond the DEA regulations. They recommended that the language be changed to "The receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by an employee."	Reject Comment. The Pharmacy within the Hospital is responsible for the receptacle.

Code Section	Commenter	Comment	Staff Recommendations
1776.3(f)(1)	Doug Barcon, Pharm.D.	Dr. Barcon recommended that the liners be puncture proof as sharps could be deposited.	Reject comment. The Liners are required to meet ASTM D1709 standard for impact and ASTM D12922 standard for tear resistance. These standards would reduce the chance for a needle puncture.
1776.3(h)	Sharps	<p>Commenter expressed concern that the USDOT standards exceed DEA requirements and are overly burdensome. They recommended that the language be modified to: "If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair."</p> <p>OR</p> <p>"If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. All rigid containers must meet Department of Transportation testing for leak resistance, imperviousness to moisture, burst, tear and break resistance, and must be sealed to prevent leaks.</p>	Reject comment. The DEA specify states (53554 of the Federal Register) that all drug disposal must be conducted consistent with Federal, State, and Local laws. The DEA rule does not exempt from compliance with the USDOT.

Code Section	Commenter	Comment	Staff Recommendations
1776.3(h)	City of Santa Rosa	Commenter expressed concern that the USDOT standards exceed DEA requirements. They recommended that the language be modified to: “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. 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.”	Reject comment. The DEA specify states (53554 of the Federal Register) that all drug disposal must be conducted consistent with Federal, State, and Local laws. The DEA rule does not exempt from compliance with the USDOT.
1776.3(h)	LA County	Commenter requested the the DOT medical waste container requirement be removed as it is not included in the DEA regs.	Reject Comment
1776.3(h)	LA Waste and SF Dept of Environment	Commented indicated that home-generated pharmaceutical waste is not medical waste and requested that the "transport of medical waste" requirement be removed.	Reject Comment.
1776.3(i)	City of Santa Rosa	Commenter requested that two employees of the pharmacy be permitted to "supervise" the removal of the liner. They recommended the following text: "The liner may only be removed from a locked collection receptacle either by two employees of the pharmacy or under the direct supervision of two employees of the pharmacy."	Reject Comment. The Pharmacy within the Hospital is responsible for the receptacle.
1776.3(i)	Doug Barcon, Pharm.D.	Dr. Barcon recommended that needle sticks be reported to the Board and that the Board compile statistics on the frequency of needle sticks to modify the regulations in the future.	Reject Comment. At this time staff does not recommend that pharmacies be required to report needle sticks due to the administrative concerns for both the site and the Board.

Code Section	Commenter	Comment	Staff Recommendations
1776.3(i)	SF Dept of Environment	Commented requested that the 14 day storage requirement be changed to "promptly" to allow for greater flexibility.	Reject comment. The use of the "promptly" is vague and subject to interpretation. The 14 day storage requirement sets a clear guideline and allows for sufficient flexibility.
1776.3(k)(1)	City of Santa Rosa	Commenter recommends that the requirement to log unused liners be removed as it could lead is misplaced packages.	Accept comment. Board staff recommends that the recording of unused liners be removed.
1776.3(k)(1)	San Luis Obispo Integrated Waste	Commenter recommends that the requirement to log unused liners be removed as it serves no useful purpose.	Accept comment. Board staff recommends that the recording of unused liners be removed.
1776.3(k)(4)	City of Santa Rosa	Commenter requested that "and" be changed to "or" to be consistent with DEA regulations.	Reject Comment. The DEA specifically requires the name and signature for removal 1304.22(f)(2)(iii)
1776.3(k)(5)	LA County & LA Waste & SF Dept of Environment	Commenter requested that the requirement to have a driver sign to transport the liner to the reverse distributor as some common carriers do not permit the drivers to sign.	Accept comment. Staff Recommends deleting the driver signature.

Code Section	Commenter	Comment	Staff Recommendations
1776.3(m)	City of Santa Rosa	Commenter expressed concern that the language in this section is inconsistent with 1776.4(j) and requested that the language be changed to: "The collection receptacle shall prominently display a sign indicating that only Schedule II – V controlled and non-controlled substances may be deposited."	Modify List?
1776.3(m)	Doug Barcon, Pharm.D.	Dr. Barcon recommends that pictograms be used in addition to text on receptacle signage.	Reject Comment. The meaning of pictograms may be unclear or confusing to the public.
1776.3(m)	SF Dept of Environment and San Mateo Cty	Commenter expressed concern about the list of prohibited drugs as the DEA does not provide a list. They request that the list be removed.	Modify List?
1776.4(a)	Sharps	Commenter expressed concern about the limitation placed with "skilled nursing facility personnel" and requested that the language be modified to add: Mail back envelopes and packages may also be provided to residents in Assisted Living/Retirement Communities for the Elderly in accordance to DEA 1370 to allow assisted living and residential care facilities to participate.	Reject comment. These regulations do not address assisted living facilities. The use of mail back envelopes is not restricted.
1776.4(a)	City of Santa Rosa	Commenter states that this section is more restrictive than the DEA requirements and requested that the language be deleted.	Reject Comment. Board staff disagrees that the language is more restrictive.

Code Section	Commenter	Comment	Staff Recommendations
1776.4(h)(2)	Sharps	<p>Commenter expressed concern that the USDOT standards exceed DEA requirements and are overly burdensome. They recommended that the language be modified to: "If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair."</p> <p>OR</p> <p>"If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. All rigid containers must meet Department of Transportation testing for leak resistance, imperviousness to moisture, burst, tear and break resistance, and must be sealed to prevent leaks.</p>	<p>Reject comment. The DEA specify states (53554 of the Federal Register) that all drug disposal must be conducted consistent with Federal, State, and Local laws. The DEA rule does not exempt from compliance with the USDOT.</p>
1776.4(h)(2)	City of Santa Rosa	<p>Commenter expressed concern that the USDOT standards exceed DEA requirements. They recommended that the language be modified to: "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. 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>Reject comment. The DEA specify states (53554 of the Federal Register) that all drug disposal must be conducted consistent with Federal, State, and Local laws. The DEA rule does not exempt from compliance with the USDOT.</p>
1776.4(h)(2)	SF Dept of Environment	<p>Commented indicated that home-generated pharmaceutical waste is not medical waste and requested that the "transport of medical waste" requirement be removed.</p>	<p>Reject Comment.</p>

Code Section	Commenter	Comment	Staff Recommendations
1776.4(n)	SF Dept of Environment	Commenter expressed concern that the DEA regulations do not allow Pharmacy employees to delivery liners for destruction. They requested that the language be changed to eliminate "two pharmacy employees delivering"	Accept Comment. The DEA allows for delivery by common/contract carrier (1317.02(c)(2)(iv)) Staff recommended a language change.
1776.4(n)	City of Santa Rosa	Commenter expressed concern that this section differs from the DEA regulation and recommends that the language be changed to: "Liners may be delivered to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up."	Accept Comment. The DEA allows for delivery by common/contract carrier (1317.02(c)(2)(iv)) Staff recommended a language change.
1776.4(n)	Sharps	Commenter expressed concern that the language allows pharmacy employees to deliver liners to the a reverse distributor; however, this is not allowed by the DEA. They recommended that this language be removed.	Accept Comment. The DEA allows for delivery by common/contract carrier (1317.02(c)(2)(iv)) Staff recommended a language change.
1776.4(o)	Sharps	Commenter expressed concern that the record keeping requirements are not specific enough and need to be modified to: "Records which include the date, unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired, installed, removed and sealed, transferred to storage, and transferred for destruction; the address of the location where each receptacle with inner liner is maintained, the registration number of the collector, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the names and signatures of the two employees that witnessed each installation, removal, transfer to storage, and transfer for destruction; and if applicable, the names and signatures of the two reverse distributor drivers who transport each liner."	Accept comment. Board staff recommends using the language provided by Sharps.

Code Section	Commenter	Comment	Staff Recommendations
1776.5(a)	Sharps	Commenter expressed concern that a reverse distributor is only registered as a collector for mail back services and not for liners. They recommended that the language be changed to: " A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA, may accept the sealed inner liners of collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's authorized collection location. Once received, the reverse distributor shall establish records required by this section. "	Accept comment. However, staff recommends that the "as a collector" be removed instead of comments language.
1776.5(a)	City of Santa Rosa	Commenter expressed concern that a reverse distributor is only registered as a collector for mail back services and not for liners. They recommended that the language be changed to: " 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. "	Accept comment. Staff recommends using this language.
1776.5(e)	City of Santa Rosa	Commenter expressed concern that the language references "incineration" however, incineration is not required by the DEA. They recommended that the term be changed to "destruction"	Accept Comment. Staff recommends changing "incineration" to "destruction."
1776.6	SF Dept of Environment	Commenter states that there are no records specified following the beginning statement and request that the language be changed to "all required records"	Reject comment. The records are defined within the section.
1776.6(b) & (c)	Kaiser	Kaiser expressed concern that the language in 1776.2 removed the unique identifier requirement for mail-back envelopes, but reverse distributors are still required to record it. Additionally, Kaiser states that the DEA regs do not require a unique identification number.	Reject comment. The unique ID is required in the DEA regulations. (1317.70)
1776.6(d)(1)	City of Santa Rosa	Commenter expressed concern that this section differs from the DEA regulation and recommends that the language be changed to: " . . . the method by which the liner was delivered to the reverse distributor (e.g., shipping via common carrier, reverse distributor pick-up) "	Accept Comment. The liners cannot be delivered by pharmacy staff.

Code Section	Commenter	Comment	Staff Recommendations
Overall	San Luis Obispo Integrated Waste	Commenter indicated that the Board does not have the authority to regulate "pharmaceutical waste" and recommended that a legislative amendment to HS 118275 be pursued.	
Overall	Clean Water Action	Commenter expressed concern that the regulation limits drug take-back to prescription medication. This would eliminate the ability to dispose of OTC in pharmacy collection receptacles. They recommended that the reference to "prescription drugs" be removed from the entire regulation or add reference to OTCs.	Reject comment. The Board only has jurisdiction over prescription drugs. Additionally, the DEA regulations only apply to unused prescription drugs.
Overall	CA Product Stewardship	Commenter expressed concern that the regulation limits drug take-back to prescription medication. This would eliminate the ability to dispose of OTC in pharmacy collection receptacles. They recommended that the reference to "prescription drugs" be removed from the entire regulation or add reference to OTCs.	Reject comment. The Board only has jurisdiction over prescription drugs. Additionally, the DEA regulations only apply to unused prescription drugs.
Overall	LA Waste	Commenter expressed concern that the regulation limits drug take-back to prescription medication. This would eliminate the ability to dispose of OTC in pharmacy collection receptacles. They recommended that the reference to "prescription drugs" be removed from the entire regulation or add reference to OTCs.	Reject comment. The Board only has jurisdiction over prescription drugs. Additionally, the DEA regulations only apply to unused prescription drugs.