

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Prescription Drug Take-Back Programs

Sections Affected: Add Article 9.1 of Division 17 of Title 16, California Code of Regulations
Add Sections 1776 – 1776.6 of Article 9.1 of Division 17 of Title 16,
California Code Regulations

Specific Purpose of the Proposed Changes/Problems Addressed

The Board of Pharmacy (Board) proposes to add and adopt Article 9.1 and Sections 1776, 1776.1, 1776.2, 1776.3, 1776.4, 1776.5, and 1776.6 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of adding to the Board's regulations specific requirements for prescription drug take back programs as part of the Board's efforts to combat prescription drug abuse within California, as specified below.

In 2010, Congress passed the Secure and Responsible Drug Disposal Act (Act). The Act was passed to address the prescription medication epidemic in the United States. US residents had no legitimate way to dispose of their medications, so they would store them in their homes. This led to easy access, which made it difficult to combat the epidemic.

Until late 2014 when the federal Drug Enforcement Administration established requirements for the take back for destruction of controlled substances, there were few options for patients to discard unwanted controlled medications legally. Instead patients were directed to ask law enforcement agencies to destroy the drugs for them, or to make the medication unpalatable and discard in the trash or toilet. Increasingly public advocates have wanted additional options to destroy unwanted medication without using trash or toilet disposal. Recognizing the constraints of existing law, the DEA held biannual drug take back days since 2010 to provide another option. The take-back days have resulted in the collection of over 2,400 tons of pharmaceutical substances.

After the DEA requirements were finalized in late 2014, the board modeled its regulation requirements for prescription drug take back destruction programs after the federal requirements. This is necessary since pharmacies and reverse distributors are licensed by the Board as well as registered with the DEA to handle controlled substances. Failure to follow federal requirements could jeopardize a pharmacy's or reverse distributor's federal's DEA registration, which would make routine business transactions involving controlled substances illegal.

Most patients do not know which of their prescription medications are controlled substances. Thus, requiring patients to separate their medications for take back purposes would be a problem because patients often lack this knowledge. The federal requirements and the corresponding board-proposed requirements for drug take back assume that controlled substances will be part of the mix of unwanted medication mailed back or deposited into a collection receptacle for destruction. Not separating controlled substances out of a collection is part of the strategy for preventing the creation of a cache of controlled substances that could lead to misuse or diversion.

Effective October 2014, in response to the Act, the DEA promulgated regulations (Title 21, Code of Federal Regulations (CFR), sections 1300-1321) to specify the manner by which pharmaceuticals must be destroyed or disposed of by DEA registrants. The new regulations allow authorized manufactures, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect collected and non-controlled pharmaceutical drugs from ultimate users (e.g., patients) by voluntarily administering mail back programs and maintaining collection receptacles. Additionally, the regulations allow authorized hospitals/clinics with an on-site pharmacy and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities.

According to the Centers of Disease Control, Prescription drug abuse is at epidemic levels in the US according to the CDC. Every day in the US, 44 people die from an opioid overdose (opioids are a subset of controlled substances prescribed for pain that are highly addictive and tightly regulated, and command high prices on the street when illegally sold). In 2014, more individuals died from prescription drug overdoses than from motor vehicle accidents

Additionally, according to the Substance Abuse and Mental Health Administration, over 71 percent of prescription pain medications are obtained from family and friends. And 5 percent took the medication from a friend or relative without asking.

In order to address this epidemic, approved entities that are licensed by the Board are permitted to engage in the collection of pharmaceutical drugs from ultimate users if they comply with the DEA and the Board's regulations. While licensees are not being mandated to provide these services, these regulations are necessary to provide the statewide regulatory requirements should California licensees elect to do so.

The purpose of the Board's proposal makes the following additions:

Add Article 9.1 Prescription Drug Take-Back Programs. This article is added to establish a location within the CCR where the prescription drug take-back regulations will be defined. This will ensure accuracy and clarity within the regulations.

Add 16 CCR Section 1776 Prescription Drug Take-Back Programs: Authorization.

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

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

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

This section is necessary to define who may participate in the drug take-back program. Additionally, this section defines what is prohibited from being deposited into drug take-back receptacles. These drugs are prohibited due to environmental concerns with the disposal completed through incineration with this program. This section is also necessary to align the regulation with 21 CFR section 1317.

“Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations” was added to ensure compliance with the Administrative Procedures Act.

Add 16 CCR Section 1776.1 Pharmacies. This section is added to define the regulatory requirements as they relate specifically to licensed pharmacies.

Subdivision (a) specifies that “Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.” This section specifies that pharmacies may elect to provide prescription drug take-back services to patients; however, they are not mandated to do so. This section is necessary to provide clarity to pharmacies that participation in the take-back program is voluntary.

Subdivision (b) specifies that “Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).” This section specifies the CCR sections pharmacies must comply with if they provide take-back services. Additionally, this section specifies which skilled nursing facilities may provide take-back services. This information is necessary ensure that the regulated public is clear on the provision they must follow if they provide drug take-back services.

Subdivision (c) specifies that “There are multiple federal and state requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.” This section is necessary to ensure that those pharmacies electing to provide drug take-back services are properly educated on both the state and the federal requirements and overlapping jurisdiction. While the practice of pharmacy is regulated at the state level, the DEA does have the authority to investigate state licensed pharmacies for possible federal violations.

Subdivision (d) specifies that “For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.” Not allowing access prevents staff from seeing, and potentially taking, coveted drugs once deposited for disposal. This section is necessary to define the term “prescription drugs” and to ensure that pharmacy staff and others are not physically interacting with the returned drugs. As these drugs will not be inventoried, it is necessary to ensure that staff do not touch the drugs and inadvertently comingle the drugs with the current inventory for distribution to other patients.

Subdivision (e) specifies that “The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and

compressed cylinders or aerosols (e.g., asthma inhalers). Signage shall be placed on collection receptacles as referenced in section 1776.3.” This section defines what is prohibited from being accepted into drug take-back programs offered by pharmacies. These drugs are prohibited due to environmental concerns with the disposal completed through incineration with this program. Additionally, this section requires the use of appropriate signage as required in 21 CFR section 1317.75(e)(4).

Subdivision (f) specifies that “Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient’s agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.” This section is necessary to define what prescription drugs may be collected in the take-back programs. Additionally, it specifies that outdated pharmacy stock, drug samples, and medical waste cannot be collected as part of the drug take-back program as these items are addressed in other locations of law. Outdated pharmacy stock disposal and drug sample disposal is addressed in 16 CCR section 1780 and shall be returned to a reverse distributor for proper disposal and medical waste disposal is addressed in the Medical Waste Management Act.

Subdivision (f)(1) specifies that “Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.” This subdivision is necessary to ensure that pharmacy staff does not handle drugs returned from the public. This will ensure that returned drugs are not accidentally comingled with the pharmacy stock and that returned drugs are not diverted for misuse and abuse.

Subdivision (f)(2) specifies that “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.” This section is necessary to assure that pharmacies do not take-back drugs from other entities. This is necessary to align the regulation with 21 CFR section 1317.30.

Subdivision (f)(3) specifies that “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.” This section is necessary to assure that pharmacies do not dispose of pharmacy inventory in the drug take-back receptacles. Drug take-back is limited to drugs returned by patients and pharmacy inventory is to be returned to a reverse distributor as required in 16 CCR section 1780.

Subdivision (g) specifies that “A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.” This section is necessary to align the regulation with 21 CFR section 1301.71. It is necessary that valid licensees are registered as a “collector” for regulatory purposes and that those with drug related felonies are not working within a pharmacy collecting returned drugs. As the returned drugs will not be inventoried, it is important to restrict access to the receptacles.

Subdivision (h) specifies that “Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:” This section is necessary to ensure that the Board is notified timely that a pharmacy has elected to operate a drug take-back program. This is necessary for regulatory oversight and compliance review to be conducted at

the pharmacy. The 30 day requirement is established for clarity and consistency, and is aligned with other reporting deadline requirements within Title 21 of the CFR.

Subdivision (h)(1) specifies that “Any pharmacy that ceases to operate a drug take-back program shall notify the board within 30 days on a form designated by the board. If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days” This section is necessary to assure the Board is notified if a pharmacy ends their drug take-back program for regulatory purposes. Additionally, this also aligns the regulation with 21 CFR section 1317.40. The 30 day requirement is established for clarity and consistency, and is aligned with other reporting deadline requirements within Title 21 of the CFR.

Subdivision (h)(2) specifies that “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.” This section is necessary to ensure that the Board is routinely notified at the time of renewal that a pharmacy has elected to continue to operate a drug take-back program. This is necessary for regulatory oversight and compliance review to be conducted at the pharmacy.

Subdivision (h)(3) specifies that “Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board with 14 days.” This section is necessary to ensure the security of the drug take-back contents. The 14 day reporting time was selected to align with the loss of controlled substance reporting time line was defined in Business and Professions Code section 4104(c).

Subdivision (h)(4) specifies that “Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.” This section is necessary to ensure the security of the drug take-back contents. The 14 day reporting time was selected to align with the loss of controlled substance reporting time line was defined in Business and Professions Code section 4104(c).

Subdivision (i) specifies that “If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.” This is necessary to provide regulatory direction on what a pharmacy must do prior to beginning a drug take-back program. This also aligns the regulation with 21 CFR section 1317.40. The 30 day requirement is established for clarity and consistency, and is aligned with other reporting deadline requirements within Title 21 of the CFR.

“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” was added to ensure compliance with the Administrative Procedures Act.

Add 16 CCR Section 1776.2 Mail Back Package and Envelope Services from Pharmacies.

This section is added to define the regulatory requirements as they relate specifically to drug take-back services via mail back envelopes. Mail back services is an option for the drug take-back program and has different requirements than on-site receptacles will have because the envelope will be given to the patients to take with them to their residence for use.

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

a mail back program. This allows pharmacies that wish to participate, but do not wish to have a drug take-back receptacle, another option.

Subdivision (b) specifies that “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.” This section specifies that return shipping address requirements for mail back envelopes. This section is necessary to ensure that the prescription drugs are returned to collectors that are authorized to dispose of the returned drugs. Additionally, this section is necessary to align the regulation with 21 CFR sections 1317.70(c) and 1317.70(c)(3).

Subdivision (c) specifies that “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.” This section specifies the requirements for mail back envelopes. This section is necessary to ensure that the mail back envelopes are secure for mailing and that users do not have to pay the shipping. This will encourage users to use the service if they do not have a financial burden for mailing. Additionally, this section is necessary to align the regulation with 21 CFR sections 1317.70(c)(1), 1317.70(c)(2), and 1317.70(c)(4).

Subdivision (d) specifies that “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.” This section is necessary to ensure that the mail back envelopes provide instructions to users on how to use the service and that the mail back envelopes have an identification number for tracking, as this will increase safety by discouraging theft. This will encourage users to use the service if they understand how to and that the envelopes can be tracked for security purposes. Additionally, this section is necessary to align the regulations with 21 CFR sections 1317.70(c)(5) and 1317.70(c)(6). The required instructions are defined in 21 CFR section 1317.70(c)(6).

Subdivision (e) specifies that “The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.” This section is necessary to ensure that the regulated public is clear on the provisions of the regulation they must follow in regards to record keeping if they provide drug mail back envelopes.

Subdivision (f) specifies that “Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.” This section is necessary to ensure that the public is clear that they do not need to provide identifying information when returning drugs via a mail back envelope. Additionally, this section is necessary to align the regulation with 21 CFR sections 1317.70(d).

Subdivision (g) specifies that “Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.” This section is necessary to ensure that authorized collectors do not accept mail back envelopes once sealed with drugs. For the purposes of tracking, it is necessary to ensure that the envelopes are in fact mailed for disposal.

“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” was added to ensure compliance with the Administrative Procedures Act.

Add 16 CCR Section 1776.3 Collection Receptacles in Pharmacies. This section is added to define the regulatory requirements as they relate specifically to drug take-back receptacles within pharmacies.

Subdivision (a) specifies that “Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block patients from access to the collection receptacle by some means.” This section is necessary to allow pharmacies to establish a collection receptacle within the pharmacy to collect unwanted drugs from the public. Additionally, this section is necessary to describe the security requirements for the receptacle to ensure that the receptacle is secure from unauthorized access and that patients do not have access to leave unwanted prescription drugs on top or next to the receptacle when it is locked. This section is also necessary to align the regulation with 21 CFR section 1317.75(e)(2).

Subdivision (b) specifies that “The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.” The section is necessary to provide the regulated public with the location and installation requirements for the collection receptacle to ensure security of the container. The receptacle needs to secure to prevent movement and theft of the container. Additionally, this section is necessary to align the regulation with 21 CFR sections 1317.75(d)(2), 1317.75(d)(2)(i), and 1317.75(e)(1).

Subdivision (c) specifies that “In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from patient access by some means.” The section is necessary to provide the regulated public with the location and installation requirements for the collection receptacle to ensure security of the container. The receptacle needs to secure to prevent movement and theft of the container. Additionally, this section is necessary to describe the security requirements for the receptacle to ensure that the receptacle is secure from unauthorized access and that patients do not have access to leave unwanted prescription drugs on top or next to the receptacle when it is locked. This section is also necessary to align the regulation with 21 CFR sections 1317.75(d)(2), 1317.75(d)(2)(i), and 1317.75(e)(1).

Subdivision (d) specifies that “The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner.” The section is necessary to provide the deposit opening requirements to ensure the safety and security of the drugs deposited into the receptacle for disposal. Additionally, this section is necessary to align the regulation with 21 CFR section 1317.75(e)(3).

Subdivision (e) specifies that “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.” This section is necessary to ensure that the regulated

public is clear that they are responsible for the receptacle within the pharmacy location. Additionally, this section provides additionally clarity that pharmacy staff shall not handle the returned drugs in anyway to reduce the possibility of theft. This section is also necessary to align the regulation with 21 CFR sections 1317.75(a) and 1317.75(c).

Subdivision (f) specifies that “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.” This section is necessary to specify the liner requirements for increased safety from access to the contents and to reduce the possibility of theft. These liner specifications are biohazard industry standards for disposal of medical waste.

Subdivision (f)(1) specifies that “The liner shall waterproof, tamper evident and tear resistant.” This section defines the liner security requirements. These requirements are necessary to prevent the liner from being compromised and the drugs accessed during storage and transport to reduce the possibility of theft. Additionally, this section is necessary to align the regulation with 21 CFR section 1317.60(a)(1).

Subdivision (f)(2) specifies that “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 manufacture.” This section further defines the security requirements. These are necessary to prevent the contents from being viewed by unauthorized third parties for security of the contents. Additionally, the size of the liner is necessary to determine the approximate amount of substances within the liner and the unique identification number for tracking purposes. This section is also necessary to align the regulation with 21 CFR sections 1317.60(a)(2), 1317.60(a)(3), 1317.60(a)(4), and 1317.60(a)(5).

Subdivision (g) specifies that “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.” This section is necessary to ensure that the regulated public is clear that deposited drugs should not be removed from the receptacle for any reason. This section also aligns the regulation with 21 CFR section 1317.75(e)(3).

Subdivision (h) specifies that “If the liner is not already itself rigid or already inside of a rigid container as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed and be kept clean and in good repair.” This section is necessary to define the storage requirements for the sealed liners. This is necessary to ensure the safety of the returned drugs, those handling the sealed liner, and those transporting the liner from exposure to dangerous chemicals or fumes. This also aligns the regulation with 21 CFR sections 1317.05(c)(2)(iv) and 1317.80(d); however, this section is more specific as to the requirements.

Subdivision (i) specifies that “A liner may be removed from a locked receptacle by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated.” This section defines the requirements when removing a liner from a receptacle. Two employees are required for security purposes. This section also defines that two employees must place the sealed liner into a rigid container. This is necessary for security. Additionally, the contents of the liner are not to be inspected in any manner and the liner shall not be opened for security of the returned drugs. This section also aligns the regulation with 21 CFR sections 1304.22(f)(2)(iii), 1317.60(c), and 1317.75(g).

Subdivision (j) specifies that “Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than three days.” This section is necessary to ensure that sealed liners are transferred for disposal in a timely manner. This section is also necessary to align the regulation with 21 CFR sections 1317.05(c)(2)(iv) and 1317.80(d).

Subdivision (k) specifies that “The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:.” This section is necessary to require that a record be maintained of the liners for tracking and security proposes. This is also necessary to align the regulation with 21 CFR section 1304.22(f)(2).

Subdivision (k)(1) specifies that “The unique identification numbers of all unused liners in possession of the pharmacy,” This section is necessary to require that the unique identification number be recorded of the liners for tracking and security proposes to reduce the possibility of theft. This is also necessary to align the regulation with 21 CFR section 1304.22(f)(2)(i).

Subdivision (k)(2) specifies that “The unique identification number and dates a liner is placed in the collection receptacle,” This section is necessary to require that the use date and unique identification number of each liner be recorded for tracking and security proposes to reduce the possibility of theft. This is also necessary to align the regulation with 21 CFR section 1304.22(f)(2)(ii).

Subdivision (k)(3) specifies that “The date the liner is removed from the collection receptacle and placed in a rigid container,” This section is necessary to require that the removal date and unique identification number of each liner be recorded for tracking and security proposes to reduce the possibility of theft. This is also necessary to align the regulation with 21 CFR section 1304.22(f)(2)(iii).

Subdivision (k)(4) specifies that “The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and.” This section is necessary to require that pharmacy staff involved in removing the full liner be identified and recorded for tracking and security proposes to reduce the possibility of theft. This is also necessary to align the regulation with 21 CFR section 1304.22(f)(2)(iii).

Subdivision (k)(5) specifies that “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.” This section is necessary to require that pharmacy staff involved in transferring the full liner be identified and recorded for tracking and

security proposes. Additionally, the date of the transfer is necessary for tracking and security and to confirm compliance with the three day storage limit. The three day limit will prevent the amount of deposited drugs being stored from stock piling and reduce the possibility of theft. The identification of the common carrier, driver, and paperwork are necessary for tracking and security and to document the chain of custody. This is also necessary to align the regulation with 21 CFR section 1304.22(f)(2)(v).

Subdivision (l) specifies that “The pharmacy shall ensure the sealed inner liners and their contents are shipped to a distributor’s registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by a licensed distributor pick-up at the licensed pharmacy’s premises.” This section is necessary to require appropriate shipping information and ensure that the full, sealed liners are picked up at the pharmacy. This is necessary to ensure that the liners are not be removed from the pharmacy and taken to an unauthorized location for shipping. This section is also necessary to align the regulation with 21 CFR section 1317.05(a)(3).

Subdivision (m) specifies that “The collection receptacle shall contain signage developed by the board advising to the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.” This section defines what is prohibited from being accepted into drug take-back receptacles offered in pharmacies. These drugs are prohibited due to environmental concerns with the disposal completed through incineration with this program. Additionally, this section requires the use of appropriate signage as defined in 21 CFR section 1317.75(e)(4).

Subdivision (n) specifies that “The board shall develop signage to appear on the collection receptacle to provide consumer information the collection process.” This section is necessary to require board developed signage to appear on the collection receptacle to educate consumers about drug take-back services.

“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” was added to ensure compliance with the Administrative Procedures Act.

Add 16 CCR Section 1776.4 Collection in Skilled Nursing Facilities.

This section specifies that “Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article” and is added to define the regulatory requirements as they relate specifically to skilled nursing facilities.

Subdivision (a) specifies that “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.” This section specifies that requirements for mail back services at skilled nursing facilities. This section authorizes skilled nursing facilities to use mail back services at the request of a resident if the skill nursing location does not have a collection

receptacle on site. This section is necessary to ensure compliance and tracking of mail back envelopes from skilled nursing facilities. This section requires that same data recordation as pharmacies utilizing mail back services.

Subdivision (b) specifies that “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.” This section specifies who may operate a collection receptacle at a skilled nursing facility. This section is necessary to prevent unauthorized access to skilled nursing facilities and returned drugs. Additionally, this section aligns the regulation with 21 CFR section 1317.80(b).

Subdivision (b)(1) specifies that “Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.” This section is necessary to ensure that only authorized “collectors” have access to the skilled nursing facility and the returned drugs. Additionally, this section is necessary to ensure that only licensees authorized by the DEA are performing drug collection services. This section also aligns the regulation with 21 CFR section 1317.80(e).

Subdivision (b)(2) specifies that “Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.” This section is necessary to ensure that the Board is notified timely that a pharmacy or hospital/clinic has elected to operate a drug take-back program within a skilled nursing facility. This is necessary for regulatory oversight and compliance review to be conducted at the location. The 30 day requirement is established for clarity and consistency, and is aligned with other reporting deadline requirements within Title 21 of the CFR.

Subdivision (b)(3) specifies that “Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.” This section is necessary to ensure the Board is notified if a drug take-back programs ends at a skilled nursing facility for regulatory purposes. Additionally, this also aligns the regulation with 21 CFR section 1317.40. The 30 day requirement is established for clarity and consistency, and is aligned with other reporting deadline requirements within Title 21 of the CFR.

Subdivision (b)(4) specifies that “Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy license.” This section is necessary to ensure that the Board is routinely notified at the time of renewal that a pharmacy has elected to continue to operate a drug take-back program. This is necessary for regulatory oversight and compliance review to be conducted at the pharmacy.

Subdivision (c) specifies that “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.” This section is necessary to ensure that only specific personnel have access to the returned drugs. This section also aligns the regulation with 21 CFR section 1317.80(b).

Subdivision (d) specifies that “Every pharmacy and hospital/clinic pharmacy that operates a collection site at any skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.” This section is necessary to ensure the security of the drug take-back contents. The 14 day reporting

time was selected to align with the loss of controlled substance reporting time line was defined in Business and Professions Code section 4104(c) to investigate losses in a timely manner.

Subdivision (e) specifies that “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.” This section is necessary to allow for unused medication to be deposited into a collection receptacle and ensure accurate record keeping of the disposal of unused medication at a skill nursing facility. Accurate record keeping is necessary to prevent misuse and abuse of unused medication by staff. Additionally, this section aligns the regulation with 21 CFR section 1317.80(a).

Subdivision (f) specifies that “A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.” This section is necessary to define the location of a collection receptacle. For security of the drugs deposited, it is necessary that the receptacle be placed in a visible and monitored location. This section also aligns the regulation with 21 CFR section 1317.75(d)(2)(iii).

Subdivision (g) specifies that “The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed.” The section is necessary to provide the regulated public with the location and installation requirements for the collection receptacle to ensure security of the container. The receptacle needs to secure to prevent movement and theft of the container or its contents. This section is also necessary to align the regulation with 21 CFR section 1317.75(e)(1).

Subdivision (h) specifies that “The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removal inner liner.” This section is necessary to describe the security requirements for the receptacle to ensure that the receptacle is secure from unauthorized access. This section is also necessary to align the regulation with 21 CFR section 1317.75(e)(2).

Subdivision (h)(1) specifies that “The liner shall comply with provisions in this section. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.” This section is necessary to ensure that the regulated public is clear that deposited drugs should not be removed from the receptacle for any reason to protect the security and safety of the public. This section also aligns the regulation with 21 CFR section 1317.75(e)(3).

Subdivision (h)(2) specifies that “If the liner is not already itself rigid or already inside of a rigid container as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.” This section is necessary to define the storage requirements for the sealed liners. This is necessary to ensure the safety of the returned drugs, those handling the sealed liner, and those transporting the liner from exposure to dangerous chemicals or fumes and to prevent theft of the contents. This also aligns the regulation with 21 CFR sections 1317.05(c)(2)(iv) and 1317.80(d); however, this section is more specific as to the requirements of the rigid containers.

Subdivision (i) specifies that “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.” This section is necessary to specify the liner requirements to ensure safety of those handling liners and prevent loss of drugs through damaged liners. These liner specifications are biohazard industry standards for disposal of medical waste.

Subdivision (i)(1) specifies that “The liner shall waterproof, tamper evident and tear resistant.” These requirements are necessary to prevent the liner from being compromised and the drugs accessed during storage and transport. Additionally, this section is necessary to align the regulation with 21 CFR section 1317.60(a)(1).

Subdivision (i)(2) specifies that “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 manufacturer.” This section further defines the security requirements. These are necessary to prevent the contents from being viewed by unauthorized third parties for security of the contents. Additionally, the size of the liner is necessary to determine the approximate amount of substances within the liner and the unique identification number for tracking purposes. This section is also necessary to align the regulation with 21 CFR sections 1317.60(a)(2), 1317.60(a)(3), 1317.60(a)(4), and 1317.60(a)(5).

Subdivision (j) specifies that “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.” This section is necessary to require appropriate signage be placed on the collection receptacle to make it clear to the public which drugs may be deposited for disposal. Additionally, this section aligns the regulation with 21 CFR section 1317.75(e)(4).

Subdivision (k) specifies that “Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.” This section is necessary to ensure that deposited drugs are not handled in any manner after being deposited into the receptacle. This is for safety and security to remove the possibility of theft and misuse and abuse by others. This section aligns the regulation with 21 CFR section 1317.75(c).

Subdivision (l) specifies that “The installation, removal, transfer and storage of inner liners shall be performed only by:.” This section is necessary to restrict access to the collection receptacle for security purposes. It is important to ensure the security of the liners and the contents in used liners from unauthorized access to prevent misuse and abuse of the returned drugs.

Subdivision (l)(1) specifies that “One employee of the authorized collector and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or.” As the collection receptacle is not maintained by the skilled nursing facility staff, it is necessary to require at least one employee of the authorized collector to access the collection receptacle. This is for security of the receptacle and the contents on the liner. Additionally, one of the two staff accessing the receptacle can be a supervisor at the skilled nursing facility. This allows for on-site staff to be utilized when accessing the receptacle. This section also aligns the regulation with 21 CFR section 1317.80(c).

Subdivision (l)(2) specifies that “By or under the supervision of two employees of the authorized collector pharmacy.” This section allows for the removal of the liner and contents using two employees of the authorized collector. This allows for a secondary option for available staff when removing the liner and contents from the receptacle. This section also aligns the regulation with 21 CFR section 1317.80(c).

Subdivision (m) specifies that “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.” This section is necessary to ensure the security of sealed liners prior to transferring for disposal and reduce the likelihood of theft. Additionally, the three business day requirement is specified in the CFR and this section is necessary to align the regulation with 21 CFR section 1317.80(d).

Subdivision (n) specifies that “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 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.” This section is necessary to provide clarification on how the sealed liners are to be transported to the reverse distributor for disposal. As with pharmacies, the sealed liners can be picked up from the skilled nursing facility. Additionally, as the receptacle is maintained by an authorized collector, two employees of the authorized collector may transport the sealed liner directly to a disposal site. This section also aligns the regulation with 21 CFR sections 1317.05(a)(3), 1317.95(b)(1) and 1317.95(b)(2).

Subdivision (p) specifies that “Records of the 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 transferred each liner.” This section is necessary to ensure adequate tracking and security of liners sent for disposal. The potential for theft/diversion of controlled substances is high with drug take-back because the drugs are not subject to inventory and exchange hands prior to disposal. It is necessary to record this information to trace the liner from the site to disposal and those staff that are involved in the handling. This section also aligns the regulation with 21 CFR 1304.22(f)(2)(v).

“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” was added to ensure compliance with the Administrative Procedures Act.

Add 16 CCR Section 1776.5 Reverse Distributors.

This section is added to define the regulatory requirements as they relate specifically to reverse distributors. Reverse distributors are responsible for the disposal of returned drugs and have different responsibilities than the individuals collecting direct from the public.

Subdivision (a) specifies that “A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.” This section identifies the meaning of “reverse distributor” and is necessary to authorize reverse distributors to take possession of sealed liners. Additionally, this section

establishes the record keeping requirement for the tracking of the liners. This section also aligns the regulation with 21 CFR sections 1317.15 and 1317.55.

Subdivision (b) specifies that “A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately DEA-licensed distributor.” This section is necessary to ensure the security of the returned drugs to prevent misuse and abuse. This section maintains the same security and handling requirements that apply to registered collectors and is consistent with federal DEA requirements.

Subdivision (c) specifies that “Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.” This section is necessary to ensure the security of the returned drugs to prevent misuse and abuse. This section maintains the same two person security and handling requirements that apply to registered collectors and is consistent with federal DEA requirements.

Subdivision (d) specifies that “A reverse distributor shall not employ as an agent or employee 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.” This section is necessary to align the regulation with 21 CFR section 1301.71. It is important that those with drug related felonies do not have access to non-inventoried returned drugs to prevent theft and misuse. Additionally, those without a DEA registration cannot participate as the DEA and Board would not know who was performing the service and who to monitor and inspect for compliance.

Subdivision (e) specifies that “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.” This section is necessary to align the regulation with 21 CFR 1304.21(e) and ensure comprehensive and accurate records are maintained. Records assist the Board in determining that laws are complied with and the product is handled appropriately.

Subdivision (f) specifies that “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:”

Subdivision (f)(1) specifies “Date of acquisition.”

Subdivision (f)(2) specifies “Number and the size (e.g., five 10-gallon liners, etc.);”

Subdivision (f)(3) specifies “Inventory number of each liner or envelope/package;”

Subdivision (f)(4) specifies “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;”

Subdivision (f)(5) specifies “The date and place and method of destruction;”

Subdivision (f)(6) specifies “Number of packages and inner liners received;”

Subdivision (f)(7) specifies “Number of packages and inner liners destroyed;”

Subdivision (f)(8) specifies “The number and signature of the two employees of the registrant that witnessed the destruction.”

Subdivisions (f) – (f)(8) are necessary to align the regulation to 21 CFR section 1304.22(e)(4)(ii). This entire subdivision specifies the record keeping requirements for reverse distributors. These requirements are necessary to ensure the security and tracking of the returned drugs. Records keeping assists the Board in monitoring and makes it more likely that product is handled appropriately.

“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” was added to ensure compliance with the Administrative Procedures Act.

Add 16 CCR Section 1776.6 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services.

This section specifies “Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records.” This section is necessary to define the record keeping requirements for Board licensees participating in drug take-back. Records are necessary for tracking and security of the supplies and drugs.

Subdivision (a) specifies that “When obtaining unused mail-back packages and envelopes for future distribution.” It is necessary to define the requirements for the mail back packaging as the requirements are slightly different than those for collection receptacles.

Subdivision (a)(1) specifies that “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.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(1)(i) and ensure adequate tracking of unused envelopes for security.

Subdivision (a)(2) specifies that “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.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(1)(ii) and ensure adequate tracking of unused envelopes for security. Additionally, record keeping allows for better monitoring of licensees.

Subdivision (b) specifies that “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.” This section is necessary to ensure adequate tracking of unused envelopes for security. It is necessary to identify the packages being distributed to confirm with packages being disposed of. This is to ensure proper use of the drug take-back program and the safety and security of the service and drugs.

Subdivision (c) specifies that “For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(1)(iii) and ensure adequate tracking of envelopes for accountability and security.

Subdivision (d) specifies that “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.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(1)(iv) and ensure adequate tracking of envelopes for accountability and security. Additionally, it is necessary to ensure that the sealed packages are being disposed of properly and in a timely manner.

Subdivision (e) specifies that “For pharmacies using collection receptacles, for each liner:” It is necessary to define the requirements for the receptacle liner as the requirements are slightly different than those for mail back packaging.

Subdivision (e)(1) specifies that “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.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(2)(i) and ensure adequate tracking of receptacle liners for accountability and security.

Subdivision (e)(2) specifies that “Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(2)(ii) and ensure adequate tracking of receptacle liners for accountability and security.

Subdivision (e)(3) specifies that “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.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(2)(iii) and ensure adequate tracking of receptacle liners for tracking, accountability, and security.

Subdivision (e)(4) specifies that “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.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(2)(iv) and ensure adequate tracking of receptacle liners for tracking, accountability, and security.

Subdivision (e)(5) specifies that “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.” This section is necessary to align the regulation with 21 CFR section 1304.22(f)(2)(v) and ensure adequate tracking of receptacle liners for tracking, accountability, and security.

Subdivision (f) specifies that “For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, immediately upon receipt of a liner:” It is necessary to define the requirements for reverse distributor as the requirements are slightly different. As reverse distributors are the last contact prior to disposal, sufficient tracking and security is important to prevent theft and diversion.

Subdivision (f)(1) specifies that “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).” This section is necessary to align the regulation with 21 CFR section 1304.22(e)(4)(i) and ensure adequate tracking of receptacle liners for tracking, accountability, and security.

Subdivision (f)(2) specifies that “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.” This section is necessary to align the regulation with 21 CFR section 1304.22(e)(4)(ii) and ensure adequate tracking of receptacle liners for tracking, accountability, and security.

“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” was added to ensure compliance with the Administrative Procedures Act.

Factual Basis/Rationale

Business and Professions Code (B&P) section 4001.1 specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy (Board) in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 generally authorizes the Board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

B&P section 4022 generally defines “dangerous drug” or “dangerous device” as any drug or device unsafe for self-use in humans or animals. California Health and Safety Code, Division 10, the California Uniform Controlled Substances Act, dealing with “controlled substances,” a subset of dangerous and illicit drugs. There are five categories: Schedule 1 drugs are generally considered illicit and are rarely prescribed. Schedule II-V list controlled substances that are prescribed to patients with specific controls on the prescribing and refilling of these substances because these substances are also more often abused than other medications. Controlled Substances in Schedules II-V are a subset of “dangerous drugs.”

B&P section 4037 generally defines “pharmacy” as any place licensed by the Board in which the practice of pharmacy is practiced.

B&P section 4110 generally defines the California licensing requirements to operate a pharmacy.

B&P section 4160 generally defines the California licensing requirements for wholesalers (distributors) and third-party logistics providers (reverse distributors).

Title 21, Code of Federal Regulations Section 1317 defines the Federal requirements for disposal of controlled substances.

This proposal will allow pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities to offer drug take-back services. This proposal will provide the public with options to destroy unwanted, unused, or outdated prescription drugs. This will reduce the supply of controlled substances available for misuse and abuse without denying patient access for the medication. Approved entities that are licensed by the Board are permitted to engage in the collection of pharmaceutical drugs from ultimate users if they comply with the DEA and the Board's regulations. Participation in the drug take-back program is voluntary. While licensees are not being mandated to provide these services, these regulations are necessary to provide regulatory oversight should the licensees elect to do so.

Underlying Data

1. Relevant Meeting Minutes from Board of Pharmacy Meeting held October 28-30, 2015 (Pages 8-9).
2. Relevant Meeting Minutes from Board of Pharmacy Committee Meeting held September 9, 2015 (Pages 3-6).
3. Relevant Meeting Minutes from Board of Pharmacy Meeting held July 27-29, 2015 (Pages 9-10).
4. Relevant Meeting Minutes from Board of Pharmacy Committee Meeting held June 24, 2015 (Pages 2-8).
5. Relevant Meeting Minutes from Board of Pharmacy Committee Meeting held March 26, 2015 (Pages 7-8).
6. Relevant Meeting Minutes from Board of Pharmacy Committee Meeting held December 17, 2014 (Pages 2-4).
7. Ohio State Board of Pharmacy: Frequently Asked Questions: Drug Enforcement Administration Releases New Rules on Pharmaceutical Drug Collection. Updated December 18, 2014
8. Centers for Disease Control and Prevention, Increase in Drug and Opioid Overdose – United States, 2000-2014, Morbidity and Mortality Weekly Report, Early Release, Vol. 64 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>
9. Substance Abuse and Mental Health Services Administration <http://www.samhsa.gov/prescription-drug-misuse-abuse>
10. Secure and Responsible Drug Disposal Act of 2010, United States Congress (http://www.deadiversion.usdoj.gov/drug_disposal/non_registrant/s_3397.pdf)
11. Title 21, Code of Federal Regulations, Sections 1300 – 1317 (<http://www.gpo.gov/fdsys/pkg/CFR-2015-title21-vol9/pdf/CFR-2015-title21-vol9-chap11.pdf>)
12. Federal Register, Vol. 79, No. 174. Published September 9, 2014, Drug Enforcement Administration Final Rule, *Disposal of Controlled Substances*. (http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf)

Business Impact

The Board has made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. The Board has made an initial determination that the proposed regulatory action may affect approximately 1,000 business licensees consisting of pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board.

As of June 30, 2015, the Board issued licenses to approximately 9,100 pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors. The Board estimates that approximately 10% of business licensees will voluntarily participate in the drug take-back program. There are currently several drug take-back programs within California, two of those are programs in San Francisco County and Alameda County. Based on the number of licensees in those counties and the number of licensees participating in the county drug take-back programs, the Board determined that 8% of licensees are participating in those counties. Using this information, the Board made the estimate that a 10% participation rate is reasonable for determining the number of licensees that may voluntarily participate statewide.

In order to assess the cost impact that pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors may incur to comply with the proposed regulations to participate in the drug take-back program, the Board contacted a few businesses that sell the equipment necessary to comply with the proposed regulation and the DEA's regulations.

If a licensee electing to participate in the drug take-back services selected the option to have a collection receptacle on site, it is estimated that the receptacle, the liners, and the shipment for destruction would cost between \$20.00 and \$200.00 a month depending on the frequency of the shipment of liners for the receptacle. There is no initial cost for the receptacle as it is included in the cost of the liners. This is an annual expense of between \$240.00 and \$2,400.00.

If a licensee electing to participate in the drug take-back services selected the mail back option, the cost of the envelopes to provide to patients, which includes a pre-paid shipping label, will vary depending on the how much advertising is done to the public, how densely populated is the area around the store, how many other medication collection locations are there in the area, and where the envelopes are displayed in the store. The estimated cost of a box of 250 envelopes is \$1,050.00. A large pharmacy may require 1,000 envelopes a year, at a cost of \$4,200.00. While a small pharmacy may only require 250 envelopes a year.

In order to keep a pharmacy, hospital/clinic with onsite pharmacy open, a pharmacist is required to be present. According to the United States Bureau of Labor Statistics' May 2012 National Occupational Employment and Wage Estimates, the annual average salary for a pharmacist in California is \$125,800. The estimated annual costs for this regulation range from \$240 to \$4,200. The estimated amount is less than 3% of the annual average pharmacist salary. The Board does not consider this to be a significant expense because pharmacies are not required to participate.

Economic Impact Assessment

This regulatory proposal will have the following effects:

It will not create or eliminate jobs within the State of California because the licensed businesses can choose whether or not to provide drug take-back services. The proposed regulation defines the requirements for participating in drug take-back services should the business elect to do so.

It will not create new business or eliminate businesses within the State of California because licensed businesses can choose whether or not to provide drug take-back services. The proposed regulation defines the requirements for participating in drug take-back services should the business elect to do so.

It will not affect the expansion of businesses currently doing business within the State of California because licensed businesses can choose whether or not to provide drug take-back

services. The proposed regulation defines the requirements for participating in drug take-back services should the business elect to do so.

This regulatory proposal benefits the health and welfare of California residents because the proposed regulation will facilitate the safe reduction of controlled substances available in California residences which will reduce the amount of drugs being misused and abused. This will result in improved health for Californians. Additionally, if fewer people are misusing and abusing controlled substances, there may be a corresponding reduction in crime seeking prescription medication.

This regulatory proposal benefits worker safety because the proposed regulation will reduce the amount of controlled substances available in California residences which will reduce the amount of drugs being misused and abused. On the job accidents will decrease if fewer employees and/or co-workers are working under the influence of a controlled substance. Individuals handling discarded drugs through proper means should be protected by the regulations.

The regulatory proposal benefits the state's environment because the proposed regulation will reduce the amount of controlled substances available in California residences which will reduce the amount of drugs being misused and abused. Providing drug take-back services will reduce the amount of controlled substances being disposed of by being flushed down the toilet or thrown out in the trash, where the drugs could contaminate lakes, rivers, streams, and soil.

Specific Technologies or Equipment

This regulation does mandate the use specific equipment, including that as required in Title 21, Code of Federal Regulations sections 1317.70, 1317.75, and 1317.80, as indicated in the Underlying Data. The types of mail back program packaging and collection receptacles outlined in the above referenced documents are industry and performance standards for the practice and profession of disposing of controlled substances. Individuals are not, however, required to provide drug take-back services and therefore need not use these technologies.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law begin implemented or made specific. Without the proposed regulation, licensees would be required to follow the DEA's regulations, which are difficult for board licensees and the public to understand. The Board's regulations consolidate the DEA's requirements into Article 9.1 and add several requirements to facilitate collection and provide safeguards for the removal of drugs collected. Additionally, as the regulatory agency, the board would not be aware of the drug take-back service available in California without the notification requirements within the regulation.