STEWARDSHIP PLAN FOR COVERED DRUGS

October 21, 2021

Version 4 (October 15, 2022)

Submitted by:
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Submitted to:
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Contents

I. Introduction

The Drug Take Back Solutions Foundation ("Foundation") submits this Stewardship Plan ("Plan") for Covered Drugs in compliance with California Senate Bill No. 212, Chapter 2 (commencing with Section 42030) to Part 3 of Division 30 of the Public Resources Code, relating to solid waste ("the Public Resource Code") and the California Code of Regulations Title 14 Division 7 Chapter 11, Article 4 ("the Regulation") collectively the "Drug Take-Back Laws" for the management, collection, transportation, and disposal of Covered Drugs from Ultimate Users. All capitalized terms not otherwise defined shall have the same meaning as in the Drug Take-Back Laws.

The Foundation's Plan provides a comprehensive Stewardship Program that includes compliant Covered Drug collection methods supported by outreach and education programs to increase awareness and participation by Ultimate Users. The Plan provides safe, secure, and convenient access on an ongoing basis for Ultimate Users and will be funded by participating Covered Entities. The Plan also provides reporting on collection metrics and results of Ultimate User education and outreach campaigns.

The Foundation is a 501(c)(3) organization and was formed in accordance with certain state Stewardship Program laws including the California SB-212 Solid Waste: Pharmaceutical and Sharps Waste Stewardship. The Foundation was formed by and for the purpose of creating a Stewardship Organization that represents the Covered Entities listed in Appendix E. The Foundation has a Governing Board composed of three members: Robert Carter, Susan Spier Jones and Joyce Ballack. The affairs and operations of the Foundation are managed by, or under the control of, the Governing Board on behalf of the Covered Entities. The Governing Board has elected three officers to manage day-to-day matters of the Foundation: Chris Smith, R.Ph, President, Lee Smith, Treasurer, and Jon Pierce, Secretary. The Foundation and the Covered Entities recognize they are ultimately responsible for the performance and execution of the services described in the Plan in accordance with the Drug Take-Back Laws.

To meet certain of those obligations, the Foundation has entered into a service agreement with Inmar Rx Solutions ("Inmar"), who will provide services that contribute to satisfying certain Program requirements. The Foundation has made a determination, based on good business judgment, that Inmar was a commercially reasonable choice for providing the needed services. These services include:

- Identifying and soliciting Authorized Collectors and managing Authorized Collector agreements
- Handling and disposal of Covered Drugs including transportation and destruction
- Oversight of alternative forms of collection:
    - Obtaining Mail-Back Distribution Sites
    - Sourcing and providing Mailers
    - Managing collection events
- Education and outreach, including Program website and toll-free number

Plan Outline

The Foundation's Stewardship Plan is designed to comply with CCR Title 14 Division 7 Chapter 11, Article 4. The requirements contained in the Regulation are enclosed in the gray boxes followed by the Foundation's response. Additional information requested in the Drug Take-Back Laws is also noted in the text, where relevant.

II. Definitions

"Authorized Collection Site" has the same definition as that in CA PRC Section 42030.

"Authorized Collector" has the same definition as that in CA PRC Section 42030.

"Collection Receptacle" means a secure repository into which Ultimate Users deposit Covered Drugs, which meets the requirements of 21 CFR Section 1317 and is compliant with all state laws and rules and federal laws and regulations governing the keeping of Covered Drugs in repositories.

"Collection Receptacle Collection Kit," "CRCK" means a Covered Drug collection kit comprised of the Container, a serialized collection liner that is opaque, waterproof, tamper resistant, either 18 or 35 gallons and an absorption pad for placement in the bottom of the Inner Liner bag.

"Collection Receptacle Supply Bundle," "CRSB" means a bundle consisting of three individual Collection Receptacle Collection Kits; each CRCK with its own unique serialized identification number.

"Combination Product Mail-Back Package" means a prepaid, pre-addressed, FDA-cleared sharps container and outer shipment package for the collection and disposal of drugs in a medical device, or a combination product containing a drug and a medical device.

"Covered Drug" has the same definition as that in CA PRC Section 42030. In accordance with CA PRC Section 42030(e)(1)(C) this includes, but is not limited to, a drug in a medical device, or a combination product containing a drug and a medical device.

"Covered Entity" has the same definition as that in CA PRC Section 42030.

"Covered Product" means a Covered Drug.

"Container" means the rigid cardboard box that both supports the Inner Liner inside the Collection Receptacle during Covered Drug collection and becomes the outer shipping package when the Inner Liner is full and/or removed from a Collection Receptacle. The rigid Container is leak resistant, has a sealable tight fitting cover and will be kept in clean and good repair as required by State Board Section 1776.3.

"Convenience Standard" means the minimum number of Authorized Collection Sites and reasonable geographic spread of Authorized Collection Sites, or Mail-Back Service covering any counties where there is not an authorized Retail

Pharmacy operating as an Authorized Collection Site, as described in clauses (i)-(iii) of subsection (1)(F) of subdivision (a) of Section 42032.2 of the PRC.

"DEA" means the U.S. Drug Enforcement Administration.

"DEA Rule" means the DEA Final Rule, "Disposal of Controlled Substances," 79 Fed. Reg. 53520 *et seq.* adopted on September 9, 2014 and codified at 21 CFR 1317.

"Department" means CalRecycle and successor agency.

"Departmental Administrative Fees" has the same definition as that in 14 CCR Section 18972.1.

"Distributor" means a wholesaler, as defined in Section 4043 of the Business and Professions Code.

"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the State Board.

"Drop-Door" means the door on the Collection Receptacle where Covered Drugs are deposited by Ultimate Users.

"Drug Take-Back Laws" means California Senate Bill No. 212, Chapter 2 (commencing with Section 42030) to Part 3 of Division 30 of the Public Resources Code, relating to solid waste and the California Code of Regulations Title 14 Division 7 Chapter 11, Article 4.

"Foundation" See Stewardship Organization.

"**Governing Board**" means a group of individuals that manages the affairs of the Drug Take Back Solutions Foundation.

"**Historically Underserved Communities**" means those who lack access to computers and the internet which typically includes Americans who have low incomes, live in rural communities, have limited education, and are members of racial or ethnic minorities.

"Homebound" has the same definition as that in 14 CCR Section 18972.1.

"Homeless" has the same definition as that in 14 CCR 18972.1.

“**Influencer Marketing**” means a content creation tactic used to drive awareness and education to a targeted audience through blogs and social media outlets.

“Inhaler Mail-Back Envelope” means a prepaid, pre-addressed envelope for the collection and disposal of inhalers.

“**Inner Liner**” means the liner maintained and shipped inside the Container which meets the requirements of 21 CFR Section 1317.60 and State Board Section 1776.3.

“**Local Jurisdiction**” has the same definition as that in 14 CCR 18972.1.

“**Mail-Back Service”** means a method of collecting Covered Products from Ultimate Users by using prepaid, pre-addressed Mailers as described in Section 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations.

“Mail-Back Distribution Site” or “Site” means a physical location providing Mail-Back Service for Ultimate Users.

“Mail-Back Starter Kit,” “MBSK” means 20 Standard Mail-Back Envelopes, 10 Inhaler Mail-Back Envelopes, and 10 Combination Product Mail-Back Packages with a visual reorder trigger, including instructions to Mail-Back Distribution Sites on how to reorder additional Mail-Back Starter Kits.

“Mailer” means a generic term that refers to all prepaid, pre-addressed Standard Mail-Back Envelopes, Inhaler Mail-Back Envelopes, and Combination Product Mail-Back Packages.

“Pharmacy” has the same definition as that in CA PRC Section 42030.

“Program Budget” means the initial Stewardship Program budget for the first five calendar years of operation required to be submitted with a Stewardship Plan pursuant to CA PRC 42033.

“Program Operator” has the same definition as that in CA PRC Section 42030.

“**Program Participants**” is a general term used to describe all the parties that contribute to or interface with the Stewardship Program including but not limited to Ultimate Users, Authorized Collectors, Covered Entities, Pharmacists, Authorized Collection Site employees, etc.

“Programmatic Advertising” means a data and technology-driven process by which buyers and sellers of digital advertising space purchase or sell that inventory in real time.

“PRC” means Public Resource Code.

“the Regulation” means the Pharmaceutical and Sharps Waste Stewardship Program, Title 14, Division 7, Chapter 11, Article 4.

“Retail Pharmacy” has the same definition as that in CA PRC Section 42030.

“Retail Pharmacy Chain” has the same definition as that in CA PRC Section 42030.

“**Serialization Tracking Form**” means a form provided by the Foundation to Authorized Collectors that must be completed and witnessed by two Authorized Collection Site employees at the time of on-site removal of Containers from Collection Receptacles during servicing.

“Service Provider” means a contracted vendor used to transport, process, and/or dispose of Covered Drugs collected through the Stewardship Program.

“**Standard Mail-Back Envelope**” means a prepaid and pre-addressed mailing envelope for the collection and disposal of all Covered Drugs except for those dispensed in an inhaler or drugs in a medical device, or a combination product containing a drug and a medical device.

“**State Board**” has the same definition as that in CA PRC Section 42030.

“Stewardship Organization” has the same definition as that in CA PRC Section 42030.

“Stewardship Plan” or “Plan” has the same definition as that in CA PRC Section 42030.

“Stewardship Program” or “Program” has the same definition as that in CA PRC Section 42030.

“Ultimate User” has the same definition as that in CA PRC Section 42030.

“Written Communication” means a formal method of communication in writing through letter, email, fax, memos, bulletins, etc.

III. Program Budget

14 CCR § 18973.2(f) Initial Program Budget and Program Funding. Demonstration of adequate funding for all administrative and operational costs of the stewardship program for the first five calendar years of operation, to be borne by participating covered entities pursuant to section 18973.6.

14 CCR § 18973.6 A program operator must submit an initial stewardship program budget for the first five calendar years of operation and an annual budget, pursuant to sections 42033 and 42033.2 of Chapter 2, Part 3, Division 30 of the Public Resources Code.

14 CCR § 18973.6(b) through 14 CCR § 18973.6(f)

(b) Anticipated costs to implement the stewardship program

(c) Recommended reserve level amount and description justifying the reserve level amount indicated. The program operator shall maintain reserves in a prudent and responsible manner.

(d) Recommended funding level necessary to cover the stewardship plan's budgeted costs and to operate the stewardship program over a multi-year period in a prudent and responsible manner. Include a description of how costs are apportioned to and funds remitted from participating covered entities

(e) Description of the types of activities relative to each line-item cost category, identified pursuant to section 18973.6(b).

(f) An independent financial audit of the stewardship program funded by the member covered entities participating in the stewardship program or by a covered entity, if it operates its own stewardship program. The audit shall be performed at least once each calendar year. The audit shall be conducted in accordance with generally accepted auditing standards in the United States of America by a Certified Public Accountant.

A. The Foundation uses data on Covered Drugs to develop the Program Budget. Data sets from Covered Drugs sold include volume estimates, relative value, comparisons to states with similar populations, and actual historical data from the state.

B. The Foundation has researched Service Provider costs and made informed Program cost estimates based on experience. The Foundation's Service Providers have provided historical data for required Program costs such as Collection Receptacle servicing, disposal, outreach and education, signage, survey, start-up, and administration. The Foundation has secured long-term agreements with Service Providers with set fees for services required to operate the Program. The Program Budget includes the following activities for each line item:

1. Capital Expenses - $3,087,250: Items covered in this category include the purchasing of collection receptacles, installation of receptacles, signage for receptacles.
2. Education and Outreach - $555,000: Items under this category include social media materials (Twitter, Facebook, Instagram, blogs, programmatic media), printed marketing materials, printing, design, staff travel, traditional media outlets (television, newspaper & radio advertising).
3. Operational - $2,215,935: Items in this category consist of collection, transportation and disposal of liners and all types of covered drugs mail-back packages, website construction and design, maintenance, support.
4. Administrative - $1,175,731: Administrative overhead, postage and shipping, misc. supplies and funding for an annual independent financial audit.
5. Departmental Administrative Fees - $2,942,263: Fee owed to the Department by the Foundation pursuant to 14 CCR Section 18973.6(b)(3), PRC Section 42034 and PRC Section 42034.2.
6. Reserve Amount - $919,673: Anticipated amount to cover unexpected overages in operational expenses. Additional detail regarding the reserve amount is included below.

The Foundation has long-term commitments from the Covered Entities who will cover all costs associated with the Program. The Foundation uses data on Covered Drugs to inform the Program Budget. Data sets from Covered Drugs sold include volume estimates, relative value, comparisons to states with similar populations, and actual historical data from California. The Program Budget will be apportioned as fees among each participating Covered Entity pursuant to 14 CCR Section 18973.6 based upon the volume and value estimates above. Participating Covered Entities are invoiced and remit funds according to their contracts.

C. The Foundation has established a reserve in order to accommodate unplanned needs, and provide a cushion against unexpected events, losses of income or large unbudgeted expenses.

The Foundation has planned its Program Budget using a variety of factors to determine needs for capital, education, operational, and administrative costs throughout the year. Likewise, the Foundation has determined reserve levels that are sufficient to cover estimated impacts of unexpected cost variability including costs of collection, transportation, disposal, and other Program costs.

When considering unexpected costs or potential loss of income, the Foundation has determined that a reserve percentage that approximates 10% of additional Collection Receptacle needs to be sufficient for the Program year. Further, this reserve level would approximate ~3 months of education, operational, and administrative costs. This reserve amount will provide sufficient cash to respond to unexpected events throughout the Program year.

D. The Foundation will submit an initial Program Budget for the first five calendar years of operation of the Stewardship Program and will each year thereafter submit a written program budget for the upcoming Program year pursuant to PRC Section 42033.2 and 14 CCR Section 18973.6 of the Regulation. See Appendix A for the initial Program Budget.

E. An independent financial audit of the Stewardship Program will be performed at least once each calendar year in accordance with 14 CCR Section 18973.6(f) of the Regulation.

F. In accordance with 14 CCR Section 18973.2(a) and 14 CCR Section 18973.6(a) the contact information for the person responsible for submitting and overseeing the Stewardship Plan and Program Budget on behalf of the Program Operator is as follows:

Chris Smith, R.Ph.
Foundation President
Mailing: P.O. Box 997
Winston-Salem, NC 27102
Physical: Takeback Solutions Foundation
3929 West Point Blvd, Ste D
Winston-Salem NC 27103
Phone Number: (336) 631-7602
Email Address: Chris.Smith@takebackfoundation.org

www.takebackfoundation.org *Note: website is in final review and will be published soon.

Lee Smith
Treasurer
Mailing: P.O. Box 997
Winston-Salem, NC 27102
Physical: Takeback Solutions Foundation
3929 West Point Blvd, Ste D

Winston-Salem NC 27103
Phone Number: (336) 770-3550
Email Address: Lee.Smith@takebackfoundation.org

www.takebackfoundation.org *Note: website is in final review and will be published soon.

G. 14 CCR Section 18973.2(l) is not applicable.

IV. Contacts

A. Plan Oversight and Operations

14 CCR § 18973.2(a) Contact information of the corporate officer, or designee, responsible for submitting and overseeing the stewardship plan on behalf of the program operator.

Drug Takeback Foundation
Chris Smith, R.Ph., President
Mailing: P.O. Box 997
Winston-Salem, NC 27102
Physical: Takeback Solutions Foundation
3929 West Point Blvd, Ste D
Winston-Salem NC 27103
Phone Number: (336) 631-7602
Email Address: Chris.Smith@takebackfoundation.org

www.takebackfoundation.org *Note: website is in final review and will be published soon.

14 CCR § 18973.6(a) Contact information of the corporate officer, or designee, responsible for submitting and overseeing the Program Budget on behalf of the Program Operator.

Drug Takeback Solutions Foundation
Lee Smith, Treasurer
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www.takebackfoundation.org *Note: website is in final review and will be published soon.

B. Participating Covered Entities

14 CCR § 18973.2(b) Contact information for each covered entity participating in the stewardship plan.

See Appendix B for contact information related to participating Covered Entities.

C. Participating Authorized Collectors

14 CCR § 18973.2(d)(1) Authorized Collectors: Contact information for each participating authorized collector operating a collection site where covered drugs are collected.

See Appendix C for current contact information of participating Authorized Collectors.

D. Service Providers (Transport, Process and/or Disposal)

14 CCR § 18973.2(g)(5) Each service provider to be used to transport, process, or dispose of covered drugs collected through the stewardship program.

See Appendix D for current contact information for Service Providers to be used in the Stewardship Program.

V. Covered Drugs

14 CCR § 18973.2(c) List of each covered drug sold or offered for sale by each participating covered entity covered by the stewardship plan.

See Appendix E for the current list of Covered Drugs.

VI. Authorized Collectors

A. Potential Authorized Collectors Notification of Opportunity to Participate

14 CCR § 18973.2(d)(2) Pursuant to Section 42032.2(b)(1) of the Public Resources Code, list of potential authorized collectors, in the counties in which the program will operate, that were notified of the opportunity to serve as an authorized collector for the proposed stewardship program, and the method(s) by which each potential authorized collector was notified. The

notification shall occur at least 120 days before the stewardship plan is submitted to the department.

1. The Foundation identified and solicited potential Authorized Collectors and entered into agreements for the purpose of collecting Covered Drugs under the Program (See Appendix F). Local Jurisdictions that currently operate a Stewardship Program ordinance are excluded.

2. The Foundation used the following methods for identifying potential Authorized Collectors: (1) Analyzed a database of California-licensed Pharmacies, hospital/clinics with onsite Pharmacies who are eligible in accordance with the DEA Rule as Authorized Collectors and licensed in good standing with the State Board (2) Used DEA data to identify Pharmacies that could be considered as potential Authorized Collectors; and (3) Identified qualified law enforcement agencies.

3. These lists were combined and used in efforts to solicit potential Authorized Collectors. Where gaps in coverage exist, the Foundation additionally sought out potential Authorized Collectors in individual counties throughout California. The Foundation reached out to these potential Authorized Collectors prior to Plan submittal through US Postal Mail on February 7, 2021, notifying them of the opportunity to participate. Potential Authorized Collectors were contacted by phone or email, and discussions were undertaken to formalize agreements with those potential Authorized Collectors who expressed interest in participating in the Program. Please see Section VII, A for additional detail regarding the ongoing efforts to meet the Convenience Standard set forth in the Drug Take-Back Laws.

B. Retail Pharmacy and Retail Pharmacy Chains Engagement

14 CCR § 18973.2(d)(4) Description of efforts to work with retail pharmacies and retail pharmacy chains to fulfill the requirement in section 42032.2(b)(2) of the Public Resources Code, if applicable.

The Foundation completed detailed analysis to identify Retail Pharmacy and Retail Pharmacy Chains currently operating in the state of California. Virtual and/or face-to-face meetings were held throughout California with the identified Retail Pharmacies and Retail Pharmacy Chains to provide them with an overview of the newly adopted Drug Take-Back Laws and their obligations under the Drug Take-Back Laws. In addition to answering

questions about the Program details, the Foundation offered to assist them in satisfying their obligations under the Drug Take-Back Laws at no cost to them should they choose to participate in the Program.

Outreach to Retail Pharmacies and Retail Pharmacy Chains will continue throughout the life of the Program. Until the Convenience Standard is met, the Foundation will continuously solicit the participation of potential Authorized Collectors.

At least annually and as needed to continuously meet the Convenience Standard, outreach to potential Authorized Collectors will continue. All willing potential Authorized Collectors who meet the requirements set forth by the federal, state, and local laws and regulations will be permitted to participate.

C. Participation

1. Good Faith Negotiation

14 CCR § 18973.2(d)(3) Pursuant to Section 42032.2(b)(1) of the Public Resources Code, description of the process by which good faith negotiations with potential authorized collectors were and, if applicable, continue to be conducted. If a potential authorized collector expresses interest in participating in a stewardship program, the program operator shall commence good faith negotiations with the potential authorized collector within 30 days.

The Foundation has and will continue to follow up with any potential Authorized Collector that has expressed or expresses interest in participating in the Program. These conversations involve details including, but not limited to, the DEA requirements for proper placement, installation, and operation of the Collection Receptacle.

Once a clear understanding of all needs for the proper operation is reached, the Foundation confirms continued interest and proceeds with an agreement to establish the Pharmacy as an Authorized Collector. The Foundation begins working with the Authorized Collector towards modifying their DEA registration, where necessary, as well as provides materials for the training of their staff.

Upon notification of interest by a potential Authorized Collector, the Foundation will initiate good faith negotiations within 30 days as described in 14 CCR Section 18973.2(d)(3).

2. Written Offers to Participate

14 CCR § 18973.2 (d)(5) Description of the process to incorporate potential authorized collectors that submit a written offer to join the stewardship program, in accordance with section 42032.2(b)(3) of the Public Resources Code. A program operator shall include under its stewardship program any entity listed in subdivision (b) of section 42030 of the Public Resources Code that offers to participate in the stewardship program, in writing and without compensation, even if the minimum convenience standards set in clause (i) of subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code have been achieved. The program operator shall include the offering entity as an authorized collector in the stewardship program within 90 days of receiving the written offer to participate. A program operator shall not be required to respond to offers pursuant to this subsection until the program operator's stewardship plan has been approved by the department.

Potential Authorized Collectors may use Written Communication to request participation in the Stewardship Program. Upon receipt of a written offer to participate in the Stewardship Program, the Foundation will contact the potential Authorized Collector and complete the contract for inclusion and placement of the Collection Receptacle according to the below timeline and within 90 days of receiving the Written Communication as required by the Regulation. Authorized Collectors will be solicited for inclusion in the Program until the Convenience Standard is met. Inclusion in the Program and placement of the Collection Receptacle will be established within 90 days from when the Foundation receives the Written Communication offering to participate from the new Authorized Collector.

- 1-91 Days: Rollout for confirmed participating Authorized Collectors and contact Retail Pharmacies where the Convenience Standard is not met.
- 91-270 Days: Reach out to potential Authorized Collectors to meet the Convenience Standard.
- 150-270 Days: Reach out and establish additional Authorized Collectors to ensure that 90% of Ultimate Users would live within a 15 mile drive of an Authorized Collection Site or a Mail-Back Distribution Site in counties where an authorized Retail Pharmacy is not available.

- Ongoing: 90-day rolling request for new Authorized Collectors. At any time should an Authorized Collector provide the Foundation with a Written Communication offering to participate, the Authorized Collector will be included in the Program within 90 days.

3. Exclusion

14 CCR § 18973.2 (d)(6) Description of the reasons for excluding any potential authorized collectors, including those who request joining the program, as applicable.

14 CCR § 18973.2 (d)(7) Description of how the program operator will notify any potential authorized collectors of the reasons they were rejected from inclusion in the stewardship program and what changes the potential authorized collector can make in order to join the stewardship program.

The Foundation will include all potential Authorized Collectors who negotiate in good faith with the Foundation regarding the terms of agreement. However, a refusal to comply with the DEA and/or State Board rules would disqualify a potential Authorized Collector from participating in the Program.

If a potential Authorized Collector is rejected from being included in the Stewardship Program for the reason stated above, the Foundation will provide the potential Authorized Collector the reason(s) in Written Communication and provide a process for the potential Authorized Collector to resolve the outstanding items to be able to be included in the Stewardship Program.

VII. Collection, Transport, and Disposal

14 CCR § 18973.2(g) Collection, Transportation, and Disposal System. Descriptions of the following:
(1) Processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal.

A. Policies and Procedures

1. Collection

a) Products Accepted

The Foundation's Plan provides for the acceptance of all Covered Drugs, regardless of manufacturer, labeler, or

producer. The Program will not apply to Covered Drugs or Sharps within a Local Jurisdiction that is subject to a Stewardship Program pursuant to an ordinance.

b) Collection Receptacle Specifications

i) Collection Receptacles used in the Program are made in the USA and designed to be safe and secure. Collection Receptacles are produced from 16-gauge cold-rolled steel and with an easy-to-use, Americans with Disabilities Act (ADA)-compliant design.

ii) The Container is a 275 lb.-rated box with a 6-mil, DEA-compliant Inner Liner. Inner Liners are either 18 gallons or 35 gallons dependent upon geographical location and population density of the Authorized Collection Site. This volume rating is printed directly onto the 6-mil DEA-compliant Inner Liners and has passed the tests prescribed in accordance with 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.

iii) Collection Receptacles comply with all state laws and rules and federal laws and regulations governing the keeping of Covered Drugs in repositories. The top of the Collection Receptacle is sloped, limiting the ability to stack items on top. In addition, the Drop-Door features an extended metal tongue that lowers into the Container to detect when capacity is reached. The Drop-Door shall be locked when the Pharmacy is not open and shall remain unlocked during Pharmacy operating hours.

iv) When the tongue encounters resistance within the Collection Receptacle, it is an indication that it is time to change the Container. Lastly, the Collection Receptacle access door is reversible to allow for convenient placement in any appropriate location in the Authorized Collection Site. The access door shall be locked at all

times to prevent access to the Inner Liner with the exception of when removing or adding the Container.

v) Per DEA requirements, the Collection Receptacle will be installed in the line of sight of the Pharmacy or DEA registrant employees, but not behind the Pharmacy counter pursuant to the State Board Section 1776.3(b-c) regulation, and bolted to the floor or a permanent fixture. The Collection Receptacle has pre-drilled holes in the bottom for easier installation. For enhanced security, it also features a 4-point locking system with steel projections in two center locations and the top and bottom of the door that are activated when locked. Top and bottom deadbolt locations are hidden from the outside to prevent break-ins.

vi) There will be signage on the Collection Receptacles that include the Authorized Collector's name and phone number in accordance with the State Board Section 1776.1(e)(1) regulation.

vii) The Collection Receptacle will include signage in English and Spanish. Signage will also be translated into languages based on those offered by the California Online Voter Registration website by the California Secretary of State (Hindi, Chinese, Japanese, Khmer, Korean, Tagalog, Thai, and Vietnamese) and will be available to Ultimate Users on their mobile devices via a QR code that will be placed on the Collection Receptacle. Signage includes communication representing items allowed (all Covered Drugs including inhalers and schedule II - V controlled substances) and prohibited (drugs in a medical device, or a combination product containing a drug and a medical device such as auto-injectors) for deposit into the Collection Receptacle as well as readily recognizable images to communicate how to safely deposit Covered Drugs into the Collection Receptacle. The signage will communicate how Ultimate Users can request Combination Product Mail-Back Packages for the disposal of drugs in a medical device, or a combination product containing a drug and a

medical device. The signage will also feature the Program's website and toll-free number, so Ultimate Users can ask questions and find more information. Collection Receptacle signage will be designed for consistency with that of existing approved Program Operators.

c) Mailer Specifications

i) Standard Mail-Back Envelopes and Inhaler Mail-Back Envelopes

The Standard Mail-Back Envelopes and Inhaler Mail-Back Envelopes will meet DEA Rule requirements under § 1317.70(c)(2), specifically:

- Pre-addressed, postage paid
- Nondescript and does not indicate what may be inside
- Waterproof, spill proof, tamper-evident, tear-resistant, and sealable; the Mailers also contain an absorbent pad
- Contain a unique ID number that allows for tracking
- Include instructions for the Ultimate User that indicate the process for mailing the Mailers, Covered Products that can be sent, notice that Mailers can only be mailed in the US customs territory and notice that only Mailers provided by the Authorized Collector will be accepted
- No personally identifiable information will be required

ii) Combination Product Mail-Back Packages

In accordance with 49 CFR 173.197 the Combination Product Mail-Back Package is rigid, leak resistant, impervious to moisture, strong enough to prevent tearing or bursting during normal conditions of transport, and puncture resistant.

The Combination Product Mail-Back Package is a red in color, 1.4 quart container with petal access and hinge cap (dimensions: 7.5 X 3.6 X 3.6 inches). The Combination Product Mail-Back Package displays the universal biohazard symbol and comes with a liquid-absorbing pad.

All Mailers provide written instructions for returning Covered Drugs including clear instructions as to what can and cannot be included in the Mailers.

2. Transport

Collection Receptacle contents will be sent by the Authorized Collector using the Service Provider's Department of Transportation (DOT) Special Permit #20499, from the Authorized Collector via FedEx to the Plan's licensed DEA Reverse Distributor-Collector Service Provider.

The Authorized Collector will properly seal, securely store, and arrange for pickup of the Container (including Inner Liner) from the registered location in a manner consistent with DEA regulations. The Container (including Inner Liner) will include a pre-addressed and prepaid shipping label. The FedEx representative will take possession of the Container and deliver it to the Service Provider for witnessed transportation to witnessed incineration. All Mailers received at the Service Provider will also be taken via witnessed transportation to witnessed incineration.

3. Documentation and Tracking

a) Collection Receptacles

Containers and Inner Liners will have a unique, serialized identification number to enable tracking at all stages of the return process.

Tracking is well documented using the Serialization Tracking Form. This Form must be completed and witnessed by two Authorized Collection Site employees.

The purpose of the Serialization Tracking Form is to document the use of the serialized Container throughout the

collection process and to help the Authorized Collector meet record keeping requirements. The Foundation will require each Authorized Collector to understand and comply with all federal, state, and local regulatory requirements pertaining to collection of Covered Drugs applicable at the Authorized Collection Site.

The serial numbers, date received, and signatures of the Authorized Collection Site employee must be completed upon receipt of the Container. The date-in-use is to be completed with the Authorized Collection Site employee's signature upon installation of the Container into the Collection Receptacle. The date the Container is removed and the date the Container is shipped must be noted by the Authorized Collection Site employees on the Serialization Tracking Form. Once the Container arrives at the destruction facility, the serial number will be noted before final disposition. Authorized Collectors must maintain a copy of the completed Serialization Tracking Form, and other records as applicable, on file at the Authorized Collection Site for at least three (3) years.

This tracking process will allow the Foundation to report the number of Authorized Collection Site Containers distributed and returned in the annual reporting as required. The tracking process is also described in detail in Section VII.

b) Mailers

All Mailers will have a unique, serialized identification number. Mailers are tracked through receipt by the Service Provider to final destruction at the destruction facility.

4. Disposal

Please refer to section VII.D.5 below for all details regarding the policies and procedures for disposal of Covered Drugs.

B. Convenience Standard

14 CCR § 18973.2(g)(2) How convenience standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code will be met for each county, including the following:

14 CCR § 18973.2(g)(2)(A) How reasonable geographic spread is determined, including all factors applied to develop the determination. Population considerations shall use the most recent publicly available population calculations from the State of California Department of Finance.

14 CCR § 18973.2(g)(2)(B) How frequently the convenience standards will be re-evaluated to ensure compliance with the convenience standards, including updating population estimates.

14 CCR § 18973.2(g)(6)(C) Pursuant to section 42032.2(c)(2) of the Public Resources Code, description of any mail-back program or alternative form of collection and disposal system that complies with applicable local, state, and federal laws and regulations including, but not limited to, United States Drug Enforcement Administration regulations that will be used as a supplemental service for any county that does not have the minimum number of authorized collection sites due to circumstances beyond the program operator's control.

1. Pursuant to the PRC Section 42032.2(a)(1)(F)(i-iii), the Foundation shall establish a minimum of five (5) Authorized Collection Sites in each county in which the Program is implemented, or one (1) Authorized Collection Site per 50,000 people in the county, whichever is greater. The Foundation used the E-1 population data released in May 2021 by the State of California Department of Finance ("E-1") as a base for its required number of Authorized Collectors. As of Plan submission, there are six (6) counties where the Foundation has executed agreements with sufficient participating Authorized Collection Sites to meet or exceed the Convenience Standard. The Foundation has also secured close to 50% of all the required Authorized Collectors across the state needed in order to meet the Convenience Standard based upon the May 2021 E-1 population data. The Foundation has identified where additional participating Authorized Collectors are required in order to meet the Convenience Standard. In those locations, the Foundation is making additional outreach efforts to secure Authorized Collectors. Pursuant to PRC Section 42032.2(a)(1)(F)(iii), the Foundation will provide Mail-Back Service for any counties where there is not an authorized Retail Pharmacy operating as an Authorized Collection Site. The Foundation shall be fully operational within 270 days of Plan approval.

2. The Foundation is using the E-1 population data in order to determine the geographic spread of the population within each

county. Tableau, a data visualization tool, is used to map the Authorized Collection Sites with population data to calculate the geographic spread and determine the number and location of Collection Receptacles needed per county. The tool identifies population density shading by county whereby the calculation method of 1 for 50,000 is used to determine the appropriate number of Authorized Collection Sites. The data is being used to create targeted Authorized Collection Sites in order to ensure that at least 90% of Ultimate Users live within a 15 mile drive of an Authorized Collection Site or a Mail-back Distribution Site in counties where an authorized Retail Pharmacy is not available to be consistent with other existing Local Jurisdictions. The Foundation continues to reach out to these targeted Authorized Collectors in order to meet this standard.

3. The Foundation will continue working with all interested Authorized Collectors to secure agreements, establish Authorized Collection Sites, and install Collection Receptacles regardless of location or status of Convenience Standard. The Foundation will continue to solicit potential Authorized Collectors and evaluate annually the need for additional Authorized Collection Sites based on the most current E-1 population data as required by the Regulation. Additionally, the Foundation will review each yearly release from the Department of Finance to make adjustments as necessary to the Convenience Standard due to population changes.

4. The Foundation will meet the Convenience Standard set forth in PRC Section 42032.2(a)(1)(F)(i-ii) using only Authorized Collection Sites. As required by PRC Section 42032.2(a)(1)(F)(iii), the Foundation will provide Mail-Back Service in counties where there is not an authorized Retail Pharmacy operating as an Authorized Collection Site Additionally, to increase access to Covered Drug disposal options for the Homeless population and the underserved, Mail-Back Distribution Sites will be utilized. The Foundation will place Mail-Back Distribution Sites that are readily available and accessible to Ultimate Users.

C. Collection Receptacle Procedures

14 CCR § 18973.2(g)(7) Description of a service schedule that meets the needs of each authorized collection site. Process by which collection receptacles will be monitored,

explanation of how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached. The service schedule must meet the needs of each authorized collection site to ensure that collected covered drugs are transported to final disposal in a timely manner.

1. Initial Set-up

   Each Authorized Collector is issued a Collection Receptacle, two (2) sets of three (3) keys each, instructions for the installation, removal, and shipping of Covered Drugs collected in the Collection Receptacle and a Collection Receptacle Supply Bundle (CRSB).

2. Replenishment

   Each Collection Receptacle Collection Kit (CRCK) within a CRSB is marked with a unique serialized identification number for use in automatically replenishing the Authorized Collection Site and for the tracking of each CRCK shipped from the Authorized Collection Site to the Service Provider's facility for disposal/destruction.

   Upon receipt of the second CRCK within a CRSB, a new CRSB is generated and provided to the Authorized Collection Site. Automatic replenishment of CRSBs ensures the necessary supplies for the collection of Covered Drugs are continuously available at Authorized Collection Sites without requiring Authorized Collectors to store a large supply of CRCKs.

   CRSBs have been specifically designed to facilitate the packaging, removal, shipping, and resupply of the Collection Receptacle as efficiently as possible.

3. Collection Receptacle Service Schedules

   The Foundation will train Authorized Collectors on how to identify when a Collection Receptacle has reached capacity, how to replace the Container, and schedule a pick-up to ensure collected Covered Drugs are transported for destruction in a timely manner. The Authorized Collector will be responsible for scheduling the pick-up once a Collection Receptacle is full and the Container has been replaced. Authorized Collectors can monitor capacity by checking the Collection Receptacle's Drop-Door. Containers that have been filled and removed from a Collection Receptacle must be stored in a secured, locked location in the Pharmacy no longer than 14 days.

D. Mail-Back

14 CCR § 18973.2(g)(6) Mail-back services or an alternative form of collection and disposal system to be provided to ultimate users, pursuant to sections 42032.2(a)(1)(G) and 42032.2(c) of the Public Resources Code.

14 CCR § 18973.2(g)(6)(A) List of locations and/or description of mechanisms to provide ultimate users with preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system that would render the covered drug inert, or applicable.

1. Upon Request Service

a) The Foundation will provide prepaid, pre-addressed Mailers to Authorized Collectors, Ultimate Users, in-home hospice providers, and homeless shelters at no cost. The Mailers provide written instructions for returning Covered Drugs including clear instructions as to what can and cannot be included in the Mailers.

b) The Foundation will offer Mail-Back Service at multiple retail sites throughout the State. Unless otherwise requested by an Authorized Collector, Standard Mail-Back Envelopes will only be distributed at Sites that are not already Authorized Collection Sites.

c) Standard Mail-Back Envelopes, Inhaler Mail-Back Envelopes, and Combination Product Mail-Back Packages will be available directly from the Foundation via the Program's website and toll-free number. Mailers will be shipped directly to the Ultimate User and can then be returned with the Covered Drug free of charge. Appendix G provides a list of Sites the Foundation has secured to offer Mail-Back Service.

d) Ultimate Users will be able to request up to three (3) Standard Mail-Back Envelopes, three (3) Inhaler Mail-Back Envelopes, and three (3) Combination Products Mail-Back Packages at a time via the Program's website or toll-free number. Ultimate Users will receive the Mailers no later than ten (10) business days from the date of request.

e) The Standard Mail-Back Envelopes, Inhaler Mail-Back Envelopes, and Combination Product Mail-Back Packages meet DEA Rule requirements under § 1317.70(c).

f) Implementation Timeline for Mail-Back Service:

- 1-91 Days: Rollout for confirmed Mail-Back Distribution Sites
- 91-270 Days: Reach out to additional potential Mail-Back Distribution Sites to meet the Convenience Standard set forth in PRC Sections 42032.2(a)(1)(F)(iii) where there is not an authorized Retail Pharmacy operating as an Authorized Collection Site.
- 150-270 Days: Continue to reach out to additional Sites to ensure that 90% of Ultimate Users would live within 15 miles of either an Authorized Collection Site or a Mail-Back Distribution Site.

2. Mail-Back Distribution Sites Service

14 CCR § 18973.2(g)(6)(A) List of locations and/or description of mechanisms to provide ultimate users with preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system that would render the covered drug inert, if applicable.

a) The Foundation will offer Mail-Back Service to Mail-Back Distribution Sites throughout the state in addition to the required Authorized Collection Sites. The Foundation recognizes that such Mail-Back Distribution Sites are not included in the requirement to meet the Convenience Standard as required by the Regulation. The Foundation continues to work with each Site who has agreed to offer Mail-Back Service to become an Authorized Collection Site.

b) The Foundation obtains signed order forms where Mail-Back Distribution Sites will be established. Each Site will agree to maintain compliance with the Drug Take-Back Law and will remain in compliance to that end. Each Site is required to provide access to Ultimate Users during normal business hours, display signage and instructions that are Americans with Disabilities Act (ADA) compliant regarding proper use of all Mailers and comply with all applicable state and federal laws. The Foundation will provide each Mail-Back Distribution Site with educational information to disseminate to Ultimate Users regarding the safe disposal of Covered Drugs.

c) Once a location has been accepted as a Mail-Back Distribution Site, the Foundation will send a Mail-Back Starter Kit (MBSK). The MBSK will include twenty (20) serialized Standard Mail-Back Envelopes, ten (10) serialized Inhaler Mail-Back Envelopes, and ten (10) serialized Combination Product Mail-Back Packages. Records logging which serial numbers have been distributed to which Mail-Back Distribution Site will be retained by the Program Operator.

d) Standard Mail-Back Envelopes will accept all Covered Drugs, including pills, creams and liquids, and schedule II-V controlled substances except inhalers, drugs in a medical device, or a combination product containing a drug and a medical device which have their own individual Mailers (Inhaler Mail-Back Envelopes, Combination Product Mail-Back Packages). Inhaler Mail-Back Envelopes and Combination Product Mail-Back Packages are included in the MBSK in a quantity of ten and allow for Mail-Back Service for drugs in a medical device, or combination products containing a drug and a medical device.

e) The MBSK is a countertop display that comes pre-assembled. The front of the box displays information about what can and cannot be included in the Mailers and how the Site may request more Mailers via the Program's website or toll-free number. There is currently no limit on the number of Mailers that an Ultimate User may take from a Mail-Back Distribution Site. The Mailers provide written instructions for returning Covered Drugs.

f) The Foundation is committed to providing all Authorized Collectors an option to supply Ultimate Users with information regarding Mail-Back Service options. The Foundation will provide both Mail-Back Distribution Sites and Authorized Collectors with promotional brochures.

3. Homeless Distribution

14 CCR § 18973.2(g)(6)(B) Pursuant to section 42032.2(a)(1)(G)(i) of the Public Resources Code, mechanism to provide preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system requested by ultimate users who are homeless, homebound, or disabled through the program operator's internet website and toll-free telephone number.

The Foundation and Service Provider will work with the California Department of Social Services (CDSS) and local Continuum of Care (CoC) offices to identify locations appropriate to serve as Mail-Back Distribution Sites to serve the Homeless community throughout the state. The Foundation will provide the CDSS and CoC with educational materials that emphasize that all populations, including the Homeless, have access to no-cost safe drug disposal through the Program.

All types of Mailers will be available to ensure adequate access for the return of Covered Drugs from the Homeless. Additionally, as an option for Ultimate Users without an address, the Foundation will use United States Postal Service (USPS) General Delivery. Educational materials communicating the availability and process for using this service will be provided to Ultimate Users, Authorized Collectors and Mail-Back Distribution Sites.. Using this service, Mailers are delivered to the post office of choice according to USPS policies.

4. Transport

a) Collection Receptacle-Collected Covered Drugs

Covered Drugs collected by way of Collection Receptacles will be sent using the Service Provider's Department of Transportation (DOT) Special Permit #20499, from the Authorized Collector via FedEx to the Program Operator's licensed DEA Reverse Distributor-Collector Service Provider.

b) Mail-Back Collected Covered Drugs

All Mailers will be transported via the United States Postal Service (USPS) to the Program Operator's licensed DEA Reverse Distributor-Collector Service Provider.

5. Disposal

All collected Covered Drugs received by the Program Operator's licensed DEA Reverse Distributor-Collector Service Provider will be transported by the Service Provider to the appropriate disposal facility. Transport to the disposal facility will be quick, secure, and in accordance with all DEA requirements.

All Service Providers participating in the Program will be required to comply with all local, state, and federal laws and regulations surrounding the transportation/disposal of Covered Drugs.

VIII. Tracking

14 CCR § 18973.2(g)(3) Tracking mechanism(s) for collection, transportation, and disposal.

A. Collection Receptacle

1. Tracking of Covered Drugs from Collection Receptacles begins with the shipment of the CRSB to the Authorized Collector and concludes with the destruction of the collected Covered Drugs at the destruction facility.

2. Authorized Collectors will be required to maintain a Serialization Tracking Form for each CRCK received at their Authorized Collection Site. The purpose of this Form is to document the use of the serialized Container and Inner Liner throughout the collection process and to help the Authorized Collector meet the Regulation record keeping requirements.

3. To ensure compliance with safety policies and Plan operating procedures, the Serialization Tracking Form is validated with the names and signatures of a minimum of two Authorized Collection Site employees and reviewed by the Program Operator and the Authorized Collector.

4. Authorized Collectors will retain a copy of the Serialization Tracking Form, a copy of the FedEx tracking information, and any other records as applicable on file at the Authorized Collection Site for a minimum of three (3) years.

5. Serialization Tracking Form data elements tracked include but are not limited to the following:
    - Name and address of the Authorized Collector
    - Size of Inner Liner
    - Pharmacy DEA # (if applicable)
    - Name and address of Reverse Distributor/Disposal Site
    - Reverse Distributor/Disposal Site DEA#
    - Serial Number of CRCK
    - Date CRCK received (i.e., date Inner Liner acquired)

- Date Container installed in Collection Receptacle
- Date Container removed from Collection Receptacle
- Date Container transferred to storage
- FedEx tracking number
- Date Container shipped to the licensed DEA Reverse Distributor-Collector Service Provider.

6. Upon receipt of CRCK(s) shipped from an Authorized Collector, the licensed DEA Reverse Distributor-Collector Service Provider will record and track the following data elements for each CRCK:
    - Date received
    - Number and size of Containers received and destroyed
    - Serialized barcode label information
    - Serialization Container tracking number
    - Method of delivery, signature of individuals delivering Containers and employees who received the Container
    - Weight
    - Date transported to destruction facility
    - Place and method of destruction
    - Destruction date
    - Manifest number (if applicable)
    - Name and signature of the two employees of the DEA registrant that witnessed the destruction

7. All information recorded will be transferred to the Program Operator daily. Any discrepancies observed by the licensed DEA Reverse Distributor-Collector Service Provider will be recorded on discrepancy reports and corrective action will be taken according to Program procedures.

B. Mail-Back

1. Tracking of Mailers containing Covered Drugs begins with the distribution of MBSKs to the Mail-Back Distribution Sites and concludes with the destruction of the collected Covered Drugs at the destruction facility.

2. Upon receipt of a Mailer shipped from an Ultimate User, the licensed DEA Reverse Distributor-Collector Service Provider will record and track the following data elements for each Mailer:
    - Date received

- Number and type of Mailer received and destroyed
- Serialized barcode label information
- Serialization Mailer tracking number
- Method of delivery, signature of individuals delivering Mailers and employees who received the sealed Mailers
- Weight
- Date transported to destruction facility
- Place and method of destruction
- Destruction date
- Manifest number (if applicable)
- Name and signature of the two employees of the DEA registrant that witnessed the destruction.

3. All information recorded will be transferred to the Program Operator daily for tracking of the Mailers returned using the MBSK's distribution system.

IX. Education and Outreach

14 CCR § 18973.2(j) Education and Outreach. Description of a comprehensive education and outreach program

The Foundation is committed to the education and outreach for all Ultimate Users affected by the Program. The Program Operator will execute a comprehensive and measurable public education and outreach strategy to drive awareness of the Program and maximize participation. In addition to preventative education, the education and outreach strategy is designed to ensure that where and how to return Covered Drugs is widely understood by Ultimate Users, Authorized Collectors and other parties that may be interested in the Program.

A. Promotion

The Foundation will develop a strategy for education and outreach intended to promote Ultimate User awareness and maximize Ultimate User participation. The promotion strategy will include a creative brief that outlines goals, target audience, messaging, and calls to action. Promotional materials, including signage, will be provided free of charge to hospitals, Pharmacies, and other locations, as necessary. Content for all methods of promotion will focus on an array of topical themes based on the Program requirements, and would be one, or a combination of, the following:

- Tips for safe storage of Covered Drugs in the home prior to disposal
- Education about the implications of improper drug disposal
- Guidance on separation of Covered Drugs from non-Covered Drugs
- Promotion of the Program, including directions on where and how to participate

Upon the Plan's approval and subsequent implementation, the Foundation will promote the Program using various promotion methods including but not limited to the following:

1. Printed Materials

> *14 CCR § 18973.2(j)(1) Any activities to promote awareness and maximize ultimate user participation in the stewardship program, including, but not limited to, provision of educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others as necessary.*
>
> *14 CCR § 18973.2(j)(2) Materials to be utilized that are distributed in languages suited to local demographics, consistent with section 7295 of the Government Code. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary. Signage or labeling for secure collection receptacles shall be designed with explanatory graphics which are readily understandable by all ultimate users.*

Easily consumable educational materials will be developed for dissemination to residents, pharmacists, retailers, and health care practitioners that will be translated into the languages based on those offered by the California Online Voter Registration website by the California Secretary of State (Spanish, Hindi, Chinese, Japanese, Khmer, Korean, Tagalog, Thai, and Vietnamese) in addition to English.

Whenever notice of availability of materials explaining services offered under the Program is given either orally or in writing, it will be given in English and in the non-English language(s) in which the materials have been translated.

Printed materials will be easily understandable with varying levels of English proficiency, will leverage explanatory graphics to aid in comprehension, and will promote the disposal of Covered Drugs consistent with the services offered by the Program.

2. Traditional Media

General awareness media campaigns about the Stewardship Program will be deployed across traditional media outlets to all demographics. General awareness campaigns will be ongoing and will run at various intervals throughout the life of the Program.

3. Programmatic Advertising

Programmatic advertising will leverage the Foundation's network of transparent retail audiences to serve behaviorally targeted display and/or video ads on browser sites on internet capable devices (smart phones, computers, tablets, etc.). These campaigns will continue for a minimum of two (2) years and will be evaluated for effectiveness and continuation beginning in the third year of Program operation and annually thereafter as needed.

4. Influencer Marketing

The Foundation uses a Service Provider to execute robust, data-driven Influencer Marketing that activates shoppers and Ultimate Users alike.

The Service Provider has a network of more than 12,000 highly vetted influencers who are experts at creating authentic, compelling content that can drive awareness and inspire participation among Ultimate Users. The Service Provider utilizes sophisticated influencer selection, data-driven content distribution, and audience re-engagement tactics to ensure that content is hyper-relevant and that the Ultimate Users receiving the content are the ones most inclined to act.

Influencer Marketing content will be deployed every four (4) weeks and support the user-generated content with targeted media as outlined in the next section.

5. Targeted Media

a) General Public and Historically Underserved Communities

Targeted outreach to Historically Underserved Communities and the public will be done through semi-annual direct mail campaigns. Here, the Foundation is defining Historically Underserved Communities as those who lack access to

computers and the internet. Historically, this has included Americans who have low incomes, live in rural communities, have limited education, and are members of racial or ethnic minorities. This semi-annual direct mail campaign will continue for a minimum of two (2) years and will be evaluated for effectiveness and continuation beginning in the third year of Program operation and annually thereafter as needed.

b) Ultimate Users, Homeless Shelters, and CoC List

Targeted outreach to Ultimate Users, homeless shelters, and the CoC list will be done through semi-annual direct mail Public Service Announcement (PSA) postcard campaigns. This semi-annual direct mail campaign will continue for a minimum of two (2) years and will be evaluated for effectiveness and continuation beginning in the third year of Program operation and annually thereafter as needed.

B. Website

14 CCR § 18973.2(j)(3) Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, consistent with section 7295 of the Government Code, and maintained to ensure all information is up to date and accurate. The internet website's digital content and navigability must be accessible to disabled individuals. The internet website shall include, but is not limited to, the following:
(A) Authorized collection site physical addresses
(B) Authorized collection site contact telephone numbers
(C) Authorized collection site days and hours of operation
(D) Mechanism to accept requests for mail-back materials from ultimate users who are homeless, homebound, or disabled
(E) Information to promote the stewardship program, including, but not limited to, instructions for safe handling and proper disposal of covered drugs and information on collection options

The Foundation will provide a mobile-optimized website using Web Content Accessibility Guidelines (WCAG) 2.0 with language options suited to local demographics consistent with section 7295 of the Government Code. The website will publicize collection options and educate all affected parties, including individuals with limited English proficiency, on proper disposal practices. The Foundation will use enhanced search engine optimization to ensure easy location and access.

Specifically, the website will:

- Be available in all the Google Translate languages.
- Integrate with Google Maps to allow Ultimate Users to find the nearest Authorized Collection Site or Mail-Back Distribution Site via an interactive map. The list of locations will be updated monthly to ensure accuracy.
- Display a list of Authorized Collection Site physical addresses, telephone numbers, and hours of operation. The list will be inclusive of all Collection Receptacles located in the state, including those operated by other Program Operators.
- Integrate with Google for updates on hours of operation.
- Accept requests for Mailers from Ultimate Users including those who are Homeless, Homebound, or disabled.
- Clearly indicate what Covered Drugs are and are not accepted. Graphics of non-Covered Drugs are provided for additional clarity.
- Include educational and outreach materials on safe storage and disposal of Covered Drugs.
- Feature links to social media pages for more useful content.

Potential Authorized Collectors interested in participating in the Program will be able to request more information through the website. In addition, participating Authorized Collectors will have access to resources for compliant Collection Receptacle and Container management (including installation, tracking, and shipping) and will be able to request on-site Collection Receptacle maintenance and support.

C. Toll-Free Number

14 CCR § 18973.2(j)(4) Establishment of a toll-free telephone number to accept requests for mail-back materials from ultimate users who are homeless, homebound, or disabled, and to provide disposal options and other program information to ultimate users without access to the internet. The toll-free telephone number shall offer language options suited to local demographics, accept calls via human representative, and provide services for hearing-impaired and speech-impaired individuals.

The Foundation will operate a toll-free call center that interested parties can call to learn more about the Program and drug disposal best practices. Ultimate Users will be able to request information about the nearest Authorized Collection Sites or Mail-Back Distribution Sites, or request that a Mailer be sent to them. The call center is operated with live operators and will be staffed with a third-party service to assist with live translation. Live translation will be available in the languages based on those offered by the California Online Voter Registration website by the

California Secretary of State (Spanish, Hindi, Chinese, Japanese, Khmer, Korean, Tagalog, Thai, and Vietnamese) in addition to English. Live translation works according to the following process:

- Non-English speaking Ultimate Users will be given the option to select between English and Spanish (e.g. “Select 1 for English; Para continuar en español, presione dos; For other language needs, please stay on the line”)
- All Ultimate Users will be routed to a live human operator who can help direct and answer all inquiries
- Live translators will be available for language needs outside of English and Spanish. A live human operator will assist Ultimate Users in establishing the preferred language and re-routing appropriately.

The call center is equipped with Text Telephone/Typewriter Relay Service (TTY) to receive and manage calls from Ultimate Users who are hearing or speech-impaired. Additionally, the call center will accommodate requests from Homeless, Homebound, and disabled Ultimate Users. All operators are trained to assist and answer any and all questions related to the Program including but not limited to Authorized Collector Collection Receptacle support and service requests.

Callers with medical emergencies will be directed to call 911. Ultimate Users with medication-related questions will be directed to contact their health care provider(s).

D. Education

14 CCR § 18973.2(j)(6) How ultimate users will be encouraged to separate products that are not covered products from covered products, when appropriate, before submitting the covered products to an authorized collection site or mail-back program.

14 CCR § 18973.2(j)(7) How the program operator will comply with the requirement in section 42031.6(b) of the Public Resources Code.

1. The Foundation will execute a comprehensive and measurable public education strategy to drive awareness of the Program and maximize participation. In addition to preventative education, the Foundation's strategy is designed to ensure that where and how to return unwanted Covered Drugs is widely understood by California Ultimate Users and Authorized Collectors, hospitals, Pharmacies and other locations. Authorized Collection Sites will receive training material that clearly communicates items allowed (all Covered Drugs including inhalers and Schedule II - V Controlled Substances) and prohibited (drugs in a medical device, or a combination product containing a drug and a medical device such as auto-injectors/epi-pens) for deposit into the Collection Receptacle and instructions for how Ultimate Users can obtain Combination Product Mail-Back Packages.

2. All education key messages will include, but not be limited to, the following:

    - Promote the safe and secure storage of Covered Drugs by Ultimate Users.
    - Awareness of the inherent risks of improperly storing or disposing of opioids or opiates and other Covered Drugs.
    - Discourage the disposal of Covered Drugs in the garbage or sewer system.
    - Promote the disposal of Covered Drugs using the Program including Authorized Collection Site locations, hours of operation, and Mail-Back Service.
    - Encourage Ultimate Users to separate Covered Drugs from non-Covered Drugs, when appropriate, before disposing of Covered Products via Authorized Collection Sites or Mail-Back Service.

3. The Foundation will coordinate to ensure that Ultimate Users clearly understand the logistics, safety, and educational components of the Program.

X. Coordination Efforts

14 CCR § 18973.2(k) Coordination Efforts. Description of how the program operator will coordinate with other program operators to avoid confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.

Should there be multiple approved Program Operators, the Foundation will work with all approved Program Operators to ensure that the public and all Program Participants do not encounter confusion. The Foundation proposes the Program Operators establish one website and one toll-free number for use by the public and all Program Participants.

The Foundation proposes to coordinate specifically on the following elements:

- Jointly agree on a neutrally branded website name
- Jointly agree on toll-free telephone number
- Jointly agree to fund the website and toll-free number fairly
- Jointly agree to provide a joint document to CalRecycle detailing the Plan
- Jointly agree to meet immediately to discuss any confusion that arises by the public and all Program participants and take action to address.

Additionally, the Foundation proposes the approved Program Operators design a state-wide Program logo that will be readily recognizable for use on Collection Receptacles, educational materials, the website and other materials for the public and all Program participants. The state-wide Program logo will alleviate confusion to the public and all Program participants by identifying participating Collection Receptacles though receptacles may vary by size, color, or configuration.

Lastly, the Foundation will individually meet all education and outreach requirements but is willing to coordinate with other Program Operators to ensure consistent messaging regarding safe drug disposal, statistics regarding the dangers of drug disposal in the waste-stream, drug abuse statistics, and other Program advocacy.

XI. Metrics

14 CCR § 18973.2(g)(4) Metrics that will be used to measure the amount, including, but not limited to, weight, of covered drugs collected from ultimate users at each authorized collection site.

A. Collected Covered Drugs

1. Collection Receptacles

a) Accessibility

The Foundation requires that all Collection Receptacles be unlocked and accessible to the public during all operating hours. Per 14 CCR Section 18973.4 (c)(4)(E), the Foundation requires an Authorized Collection Site to document the amount of time a Collection Receptacle is unavailable to the public during operating hours. Authorized Collection Sites are also required to provide a description of the cause leading to the lack of availability. This documentation is to be retained by the Authorized Collection Sites for as long as they are operational. Authorized Collector documentation will be utilized by the Foundation to help remediate any issues that affect Collection Receptacle availability.

b) Content Measuring

i) Weight measures of collected Covered Drugs are taken throughout the collection, transport and disposal stages and compared to historical standard average collection weights.

ii) The Foundation will use average collection weight metrics to determine when an Authorized Collection Site needs additional outreach efforts to increase collection utilization or if additional CRCKs are needed beyond the standard allocation.

2. Mail-Back Envelopes

14 CCR § 18973.2(g)(6)(E) Metrics that will be used to measure the amount of preaddressed, prepaid mail-back materials distributed or alternative form of collection and disposal system provided, and the metrics used to measure the amount of material returned.

Quantity of Mailers distributed is measured against the quantity of Mailers returned via the Mailer's unique tracking number and distribution location identifier. This measurement includes the type of Mailers distributed (Standard Mail-Back Envelopes, Inhaler Mail-

Back Envelopes or Combination Mail-Back Packages) and Mailers distributed by Mail-back Distribution Site, website and toll-free number. The Foundation will use Mailer return metrics to adjust the number of Mailers distributed to meet the needs of each location.

Weight measure data will be captured by the Foundation's Service Provider for all Mailers returned through the Mailer process and provided to the Foundation's operations support team for use in metric reporting.

B. Education and Outreach

14 CCR § 18973.2(j)(5) Metrics to evaluate performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility.

The Foundation will conduct an annual survey of Ultimate Users, pharmacists, and healthcare professionals in the state of California who interact with Ultimate Users. The goal of the survey is to measure public awareness of the Program such as through measuring the percentage of Ultimate Users, pharmacists, and healthcare professionals who are aware of the Program.

The survey will measure how the above groups assess the convenience and accessibility of Collection Receptacles and other collection methods, and assess knowledge and attitudes regarding the risks, such as abuse, poisoning, and overdose from improperly storing and improperly discarding or abandoning Covered Drugs. The Foundation will design survey questions to evaluate the effectiveness of different messaging for raising awareness of the Program and for increasing knowledge of or changing attitudes towards risks posed by improper storage or disposal of Covered Drugs. The Foundation commits to provide survey responses to the Department for review in the Annual Report that will describe the following data points:

- Overall number of survey respondents and methods of contact
- Percentage of survey respondents that are aware of the Program
- Percentage of survey respondents that were exposed to any forms of outreach provided by the Program
- Percentage of survey respondents that have used the Program and which collection method was used
- The percentage of survey respondents that believe the Program is convenient and accessible.

Results from the survey will be used by the Foundation to improve the effectiveness of the Foundation's Plan. Examples of such improvements could include adjusting the number or location of Authorized Collection Sites, providing additional services in Historically Underserved Communities, improving outreach to and education for Ultimate Users, including Historically Underserved Communities, and/or identifying other methods for improving service and outreach.

XII. Records

14 CCR § 18973.2(h) Collection, Transportation, and Disposal System Records. Description of how and where the records generated during the collection, transportation, and disposal of collected covered drugs will be maintained. These records include, but are not limited to: collection manifests, mailer distributions, receipts of returned covered drugs, return mailings, and final disposal of covered drugs, as applicable.

A. Storage

The Foundation will utilize a document repository to manage records. There will be a role-based security system in place to ensure access is limited. Record keeping will be managed by the Foundation's Service Provider's operations and regulatory teams. Records will include items related to incident reporting, waste files, weights, serial numbers, etc. The Foundation will maintain records for collection services, process reviews, and audits and inspections of Service Providers and Authorized Collectors.

B. Retention

Pursuant to 14 CCR Section 18974 (a), (b), and (c), records generated throughout Program processes and/or required under this Regulation and Chapter 2 of Part 3 of Division 30 of the Public Resource Code procedures will be retained and made available for at least three (3) years or for the period required by applicable federal or state laws, whichever is longer. The Foundation will retain records for a longer period of time upon the Department's request and will provide records or copies of records to the Department upon request.

XIII. Plan Compliance

14 CCR § 18973.2(g)(8) What corrective actions will be taken if a program operator discovers critical instances of noncompliance with stewardship plan policies and procedures.

A. Monitoring

- Formalized reviews/audits of required tracking/reporting documentation.
- Random/unscheduled on-site visits.
- Scheduled on-site audits of Authorized Collection Sites for compliance with the Controlled Substances Act, 21 USC Sections 801-971 and 21 CFR Section1317; United States Department of Transportation Hazardous Materials Regulation, 49 CFR Sections100-185; State Board and all applicable state of California statutes and regulations.

B. Non-Compliance Corrective Actions

If issues of non-compliance are identified via Program monitoring procedures and/or reported by both Program and/or non-Program Participants, the following corrective actions will be taken immediately:

- Risk analysis of non-compliance will be done to ensure no public health hazards exist.
- As needed, notifications to impacted internal teams, clients and/or local law enforcement agencies will be done through a formalized notification process.
- Plan process/procedure gap analysis will be done for each non-compliant event with appropriate Program Participants and oversight/operations staff. Where a gap has been identified, processes/procedures will be modified to address the gap and reduce/eliminate repetition of the same non-compliant event.
- Training material and communication of Plan process/procedure changes will be provided to all participants via a series of video recorded sessions or live sessions.

XIV. Safety and Security

14 CCR § 18973.2(g)(10) Standard operating procedures that will address incidents related to safety and security, including processes to ensure that the department and applicable local, state, and federal agencies are notified of the incident. This description shall also explain the actions that will be taken to change policies, procedures, and tracking mechanisms to alleviate the problems with safety and security and improve safety and security.

A. Protecting Ultimate User information during processing, collection, transportation, and disposal of medications

The Foundation provides significant training to participating Authorized Collectors and strictly follows the DEA Rule for the proper handling of Collection Receptacles and Inner Liners. This begins with the proper training of the Authorized Collector in the compliant operation of Collection Receptacles and proper preparation, removal, and packaging of Containers. It also involves the training of staff that may come into contact with the packaged Containers to ensure proper handling. The Foundation will ensure that Authorized Collectors strictly comply with state and federal statutes and regulations, including but not limited to the DEA regulations cited below as well as all relevant provisions of 16 CCR Section 1776.

According to the DEA, as provided in 21 CFR Sections 1317.60(c) and 1317.70(f), Inner Liners shall be sealed immediately upon removal from the Collection Receptacle; sealed Inner Liners and Mailers shall not be opened, x-rayed, analyzed, or otherwise penetrated. Accordingly, their contents shall not be sorted or inventoried after being placed into Collection Receptacles or Mailers. To clarify this, 21 CFR Section 1317.75(c) was modified to add the prohibition against individually handling Covered Drugs after they have been deposited into Collection Receptacles.

The Foundation, contracted Service Providers, and Authorized Collectors will comply with all regulations regarding the protection of Ultimate User privacy and will be HIPAA and Protected Healthcare Information (PHI) compliant. All Ultimate User information on Covered Drug packaging will be promptly destroyed in the unlikely event of exposure.

B. Authorized Collector agreements ensuring compliance with laws and registration with the State Board.

Authorized Collectors--except for law enforcement agencies being considered by the Foundation for the Stewardship Program--must be registered with the State Board. Authorized Collector agreements specifically require Authorized Collectors' commitment to compliant operation of the Collection Receptacle and shipping of Containers in accordance with the DEA and State Board rules, specifically 16 CCR Section 1776. A refusal to sign the agreement or comply with the DEA and State Board rules would result in an Authorized Collector being excluded from the Program. These rules include but are not limited to:

- An Authorized Collector shall not:
    - Review, accept, count, sort, or otherwise individually handle any Covered Drugs from Ultimate Users
    - Accept or possess Covered Drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity.
    - Dispose of quarantined, recalled or outdated Covered Drugs from pharmacy stock.
- An Authorized Collector must be registered with the federal DEA as a Collector for purposes of maintaining a Collection Receptacle. Authorized Collectors cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.
    - Any Authorized Collector that maintains a Collection Receptacle shall notify the State Board in writing within 30 days of establishing the Authorized Collection Site. Additionally:
        - Any Authorized Collector that ceases to maintain a Collection Receptacle shall notify the State Board in writing within 30 days.
        - Any Authorized Collector maintaining a Collection Receptacle shall disclose to the State 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.
        - Any tampering with a Collection Receptacle or theft of Covered Drugs shall be reported to the State Board in writing within 14 days.
        - Any tampering, damage or theft of a removed Container or Inner Liner shall be reported to the State Board in writing within 14 days.
- If the Authorized Collector ceases to maintain a registered Collection Receptacle, they must notify the DEA within 30 days.
- An Authorized Collector shall not provide Stewardship Program services to Ultimate Users if, in the professional judgment of the pharmacist-in-charge, the Authorized Collector cannot comply with the provisions of 16 CCR Section 1776.1 or the DEA rules.
- An Authorized Collector shall not provide Stewardship Program services to Ultimate Users if the Pharmacy or the pharmacist-in-charge is on probation with the State Board, and, if the Pharmacy

had previously provided Program services, the pharmacist-in-charge shall notify the State Board and the DEA as required in 16 CCR Sections 1776.1 (i) and (j) and (l).

C. Reverse distributor compliance with laws and registration with the State Board

Reverse distributors are required to be compliant with the DEA and State Board rules, specifically 16 CCR Section 1776.5(a-f). These rules include but are not limited to:

- A licensed reverse distributor may not open, survey, or otherwise analyze the contents of Inner Liners. All sealed liners shall be destroyed by an appropriately licensed and registered DEA reverse distributor in a manner that makes the Covered Drugs irretrievable.
- 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.
- For each sealed Container and Mailer received pursuant to federal Title 21 CFR Section 1317.55, the reverse distributor shall maintain records of the number of sealed Containers or Mailers in accordance with 16 CCR Section 1776.5(e).

The individual parties (Authorized Collectors and Reverse Distributors) have the overarching responsibility for compliance with all applicable DEA and State Board Regulations.

D. Security Incidents

1. Standard Procedure

a) The Foundation is ready and willing to assist Authorized Collectors should there be any unplanned event such as a natural disaster or any type of security incident. Personnel will respond to assist only when the situation is deemed safe. This could mean safe for travel or safe for personnel to be on-site due to current natural or unplanned events. Should the integrity and security of Authorized Collection Sites be compromised, the Foundation will work with the Authorized Collector to develop a

strategy to ensure that the Collection Receptacles and Authorized Collection Sites are safe and secure.

b) Should an Authorized Collector need to report an incident that would require special intervention, the Authorized Collector can contact the Foundation via the provided toll-free number or website. Authorized Collectors are also given access to a direct line of communication with the Foundation where these types of incidents are able to be reported. The Foundation will work to mitigate any potential issue with its Authorized Collectors.

c) Should the Foundation deem that a security incident or unplanned event warrants notification to the Department, the Foundation will notify the Department as well as any and all relevant local and state agencies in writing no later than thirty (30) days after the event has safely concluded. Should the event be labeled catastrophic, the Foundation will notify the Department as well as any and all relevant local and state agencies as soon as reasonably possible or as required under any local, state or federal regulations.

2. Changes to Standard Procedures

If problems are identified with existing safety and/or security procedures, the following actions will be taken to change policies, procedures, and tracking mechanisms to alleviate identified problems:

- Risk analysis of identified problems will be done to ensure no health hazards exist to both Authorized Collectors and Ultimate Users.
- Program safety and security process/procedure gap analysis will be done with appropriate Authorized Collectors and oversight/operations staff. Where a gap has been identified, processes/procedures will be modified to address the gap and reduce/eliminate repetition of the safety/security problem.
- Training material and communication of Program process/procedure changes will be provided to all Authorized Collectors via a series of video recorded sessions or live sessions.

XV. Audits

14 CCR § 18973.2(h) Collection, Transportation, and Disposal System Records. Description of how and where the record generated during the collection, transportation, and disposal of collected covered drugs will be maintained. These records include, but are not limited to: collection manifests, mailer distributions, receipts of returned covered drugs, return mailings, and final disposal of covered drugs, as applicable.

The Foundation follows a process for auditing Service Providers. A formalized plan includes annually:

- Review of documentation used by Service Providers
- Periodic on-site audits of facilities
- Review of processes and procedures for compliance with relevant regulatory agencies
- Review of processes and procedures to ensure satisfactory service levels are in place to ensure the secure collection and disposal of Covered Drugs

XVI. Repeal of a Local Stewardship Program Ordinance

14 CCR § 18973.2(i) Ordinance Repeals. Pursuant to subdivision (e) of section 42032.2 of the Public Resources Code, description of processes, logistics, and timing of implementation that will be necessary for the stewardship program to expand into jurisdictions not previously included in the stewardship plan, in the event of the repeal of a local stewardship program ordinance. The description shall include an explanation of how the stewardship program will meet the convenience standards, pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code.

Should any Local Jurisdiction (e.g., city or county) repeal their Stewardship Program ordinance, the Foundation would work with the Local Jurisdiction to incorporate the statewide Program into their jurisdiction within 270 days of the effective date of their repeal. The Foundation will consistently monitor the Local Jurisdictions to remain aware of any program changes or repeals. Steps for incorporating any Local Jurisdiction who has repealed their ordinance include:

1. Identifying any differences in the Programs such as convenience standards, reporting, education and outreach.
2. The Foundation will transition any of the existing Authorized Collectors in the Local Jurisdiction as well as any other existing or potential Authorized Collectors wanting to participate.
3. Develop a project schedule that details the following:

a. Updating existing Authorized Collection Sites with new Collection Receptacle signage, training materials, and educational materials if necessary.
b. Installation of any new Collection Receptacles at Authorized Collection Sites.
c. Expanding the education and outreach program into the Local Jurisdiction.
d. Notification and/or necessary reporting to the Department.

XVII. Product Verification

14 CCR § 18974.3(a) through § 18974.3(b)

(a) Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or dispenses a covered product shall: successfully log onto the department's internet web site to determine if covered products to be sold, offered for sale, or dispensed are in compliance with the law, by verifying that the covered entities providing the covered product(s) are in compliance with the law.

(b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated responsible party for any of the foregoing identify a noncompliant covered entity or stewardship organization, the distributor, wholesaler, pharmacy, other retailer, or designated responsible party for any of the foregoing shall report the discovery to the department within 30 days.

Pursuant to 14 CCR Section 18974.3, Program procedures will require each distributor, wholesaler, Pharmacy, and retailer that sells, offers for sale, or dispenses a Covered Drug to log on to the Department's website to determine and verify that the Covered Entity providing the Covered Drug follows the law. Any discovery of non-compliance will be reported to the Department within 30 days of discovery.

XVIII. Service Provider Selection Process

14 CCR § 18973.2(m) Process for selecting service providers, including a description of any competitive procedure used, if applicable.

The Foundation contracts with Inmar to conduct a formalized Service Provider selection process. The Foundation selects Service Providers based upon a competitive pricing analysis, regulatory compliance, security, safety and services standards. Because of the Foundation's relationships with multiple Providers across a broad range of businesses that operate in the space of pharmaceutical waste, regulated transport and disposal, etc., they are able to obtain accurate and competitive pricing from potential Service Providers.

XIX. Annual Report

14 CCR § 18973.4 Annual Report for Covered Drugs

The Foundation will submit its annual report for Covered Drugs for the 2022 calendar year on or before March 31, 2023, and each subsequent year thereafter. The annual report will provide all required elements pursuant to 14 CCR Section 18973.4 of the Regulation.

XX. Administrative and Operational Costs

14 CCR § 18974.1(a) Administrative and Operational Costs - Each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products.

Pursuant to 14 CCR Section 18974.1, all administrative and operational costs associated with establishing and implementing the Stewardship Program will be paid by each participating Covered Entity including costs for collecting, transporting, and disposing of Covered Drugs.

XXI. State Agency Determinations

Provided below are the Foundation's Covered Drug Stewardship Plan determinations by the State Board dated 1) September 14, 2021 and 2) November 18, 2021.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

VIA REGULAR MAIL AND EMAIL

Sept. 14, 2021

Kristin S. Alstad
Sr. Manager, Regulatory Compliance
635 Vine Street
Winston Salem, NC, 27101
kristin.alstad@inmar.com

Dear Ms. Alstad,

Pursuant to Section 42032(b) of the Public Resources Code, the Board is obligated to respond to the Take Back Foundation's plan for covered drugs you submitted to the Board on June 18, 2021 entitled "Stewardship Plan for Covered Drugs" (Plan). Your other stewardship plan submitted to the Board covering sharps will be analyzed in a separate letter within 90 days of the date you submitted the sharps stewardship plan.

Pursuant to our telephone conversation today in which we discussed certain issues with the Plan, you stated that you intended to submit a revised Plan to the Board to address one issue that was unresolved. Accordingly, the Board of Pharmacy will not respond with substantive comments to the Plan submitted and instead will respond to the revised Plan that you stated today that you intended to re-submit to the Board. Please understand that the Board's failure to provide substantive comments to the original Plan today cannot be viewed as its determination that your Plan, as originally submitted, complies with California Pharmacy Law. If you have any questions, please feel free to contact me.

Sincerely,

Lyle Matthews, Pharm.D., MAM
Inspector
California State Board of Pharmacy

Cc: Jason Smyth – CalRecycle

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

VIA EMAIL AND MAIL

November 18, 2021

Kristin S. Alstad
Sr. Manager, Regulatory Compliance
635 Vine Street
Winston Salem, NC, 27101
kristin.alstad@inmar.com

Dear Ms. Alstad,

Pursuant to Section 42032(b) of the Public Resources Code, this letter constitutes the California Board of Pharmacy's (Board) response to the updated Drug Takeback Solution Foundation's plan for covered drugs you submitted to the Board on November 17, 2021 entitled "STEWARDSHIP PLAN FOR COVERED DRUGS October 21, 2021 Version 2 (November 17, 2021)"(Plan) that has the name, "FINAL CA_STATE_COV_DRUG_PLAN_CALRECYCLE_SUBMISSION_V0107082021 10-21-21(3)-KK EDITS 11-17-21" in the header of the document. We believe that your Plan complies with pharmacy law of California.

Our review was based solely on California pharmacy law. In evaluating your Plan for compliance with pharmacy law, the Board relied upon the facts and details contained in the Plan. Please note that any different or additional facts in the design or operation of your Plan could result in a different conclusion.

Please note: For certain facilities or pharmacies overseen by other agencies or boards, there could be additional requirements for those types of facilities. As such, the Board's determination of compliance should not be interpreted as a determination of full compliance with all legal provisions.

Sincerely,

Lilly Fang, Pharm.D. Xin Fang (Lilly)
Inspector
California State Board of Pharmacy

Cc: Jason Smyth – CalRecycle

XXII. Certification

As required by 14 CCR Section 18973(e), I hereby declare, under penalty of perjury, that the information provided in this document is true and correct, to the best of my knowledge.

Additionally, as required by 14 CCR Section 18973.2(e)(2), I hereby certify that, at the time of submission to the Department, the Stewardship Plan, including all aspects of the Plan related to the collection, transportation, and disposal of Covered Drugs is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to the United States Drug Enforcement Administration regulations.

Chris Smith, R.Ph.
Foundation President
P.O. Box 997
Winston-Salem, NC 27102
Phone Number: (336) 631-7602

Email Address: Chris.Smith@takebackfoundation.org

XXIII. Appendix A: Program Budget

The Foundation provided the Program Budget in a separate, accessible Excel spreadsheet with the Plan.

XXIV. Appendix B: Participating Covered Entities

The Foundation provided the list of participating Covered Entities in a separate, accessible Excel spreadsheet with the Plan.

XXV. Appendix C: Participating Authorized Collectors

The Foundation provided the list of participating Authorized Collectors in a separate, accessible Excel spreadsheet with the Plan.

XXVI. Appendix D: Service Providers

The Foundation provided the list of Service Providers in a separate, accessible Excel spreadsheet with the Plan.

XXVII. Appendix E: Covered Drugs Sold/Offered for Sale in California by Participating Covered Entities

The Foundation provided the list of Covered Drugs sold/offered for sale in California by participating Covered Entities in a separate, accessible Excel spreadsheet with the Plan.

XXVIII. Appendix F: Contacted Potential Authorized Collectors

The Foundation provided the list of contacted potential Authorized Collectors in a separate, accessible Excel spreadsheet with the Plan.

XXIX. Appendix G: Participating Mail-Back Distribution Locations

The Foundation provided the list of participating Mail-Back Distribution Locations in a separate, accessible Excel spreadsheet with the Plan.