

**STEWARDSHIP PLAN FOR
HOME-GENERATED SHARPS WASTE
SEPTEMBER 21, 2021
Version 4 (September 15, 2022)**

Submitted by:

The Drug Takeback Solutions Foundation
P.O. Box 997
Winston-Salem, NC 27102

Submitted to:

California Department of Resources Recycling and Recovery
Rachel Machi Wagoner, Director
P.O. Box 4025
Sacramento, CA 95812-4025

Table of Contents

I. Introduction	4
II. Definitions	6
III. Program Budget	9
IV. Contacts	12
A. Plan Oversight and Operations	12
B. Participating Covered Entities	13
C. Service Providers (Transport, Process and/or Disposal)	13
V. Sharps Sold and/or Offered for Sale by Covered Entities	13
VI. Collection, Transport, and Disposal	13
A. Collection	13
1. Ultimate User Collection	13
a) Distribution of Sharps Waste Containers to Point of Sale Locations	14
b) Distribution of Sharps Waste Containers to Ultimate Users	15
c) Instructions	17
d) Labeling and Packaging	18
2. Local Agency Requests	18
B. Transport	20
C. Disposal	20
VII. Tracking	20
VIII. Education and Outreach	21
A. Promotion	21
1. Printed Materials	21
2. Traditional Media	23
3. Programmatic Advertising	23
4. Influencer Marketing	23
5. Targeted Media	23
a) General Public and Historically Underserved Communities	23
b) Ultimate Users, Homeless Shelters, and CoC List	24
B. Website	24
C. Toll-Free Telephone Number	25

D. Education	26
IX. Coordination Efforts	26
X. Metrics	27
A. Sharps Waste Containers	27
B. Education and Outreach	28
XI. Records	29
A. Storage	29
B. Retention	30
XII. Plan Compliance	30
A. Monitoring	30
B. Non-Compliance Corrective Actions	30
XIII. Audits	31
XIV. Repeal of a Local Stewardship Program Ordinance	31
XV. Product Verification	32
XVI. Service Provider Selection Process	32
XVII. Annual Report	32
XVIII. Administrative and Operational Costs	32
XIX. State Agency Determinations	33
XX. Certification	40
XXI. Appendix A – Program Budget	41
XXII. Appendix B – Participating Covered Entities	42
XXIII. Appendix C – Service Providers	43
XXIV. Appendix D – Sharps Sold/Offered for Sale in California by Participating Covered Entities	44

I. Introduction

The Drug Takeback Solutions Foundation (“Foundation”) submits this Safe Drug Disposal Stewardship Plan (“Plan”) for Home-Generated Sharps Waste 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”) for the management, collection, transportation, and disposal of Home-Generated Sharps Waste from Ultimate Users. All capitalized terms not otherwise defined shall have the same meaning as in the Public Resource Code and the Regulation.

The Foundation’s Plan provides a comprehensive Stewardship Program that includes compliant Home-Generated Sharps Waste 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 which represents the Covered Entities listed in Appendix E. The Foundation has a Governing Board composed of three members: Robert Carter, Susan Speir 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, Inc. (“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:

- Handling and disposal of Home-Generated Sharps Waste including transportation and destruction.

- Sourcing and providing Sharps Waste Containers
- Education and outreach, including the Program’s website and toll-free call center

The Foundation’s and Inmar’s Experience

Members of the Foundation’s Governing Board and officers have extensive experience in healthcare, pharmaceutical industry, promotions services, population health, government services, environmental regulations, reverse logistics, and budgeting.

The Foundation entered into a service agreement with Inmar to provide certain services that contribute to satisfying Program requirements. As the Service Provider, Inmar will provide services only at the direction of the Foundation.

The Service Provider provides operational support for approved Stewardship Programs in several jurisdictions including the City and County of San Francisco, Santa Clara County, Santa Barbara County, Contra Costa County, Alameda County, Marin County, the Commonwealth of Massachusetts, the state of Oregon and the state of Washington, and is the leading provider of pharmaceutical reverse supply chain services in the nation. The Service Provider has helped state and local governments protect against drug diversion and negative environmental impacts by removing unused, expired, and surplus pharmaceutical products from communities. With the required legal, regulatory, and operations infrastructure in place, the Service Provider has placed over 4,100 Kiosks contracted in 49 states and has safely disposed of more than 400 tons of consumer returned medication to date.

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

“**Carrier**” means the Service Provider used to transport Home-Generated Sharps Waste.

“**Covered Entity**” has the same definition as that in CA PRC Section 42030.

“**Covered Product**” has the same definition as that in CA PRC Section 42030.

“**Department**” means CalRecycle and successor agency.

“**Departmental Administrative Fees**” has the same definition as that in 14 CCR Section 18972.1.

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

“**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**” means The Drug Takeback Solutions Foundation.

“**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 Section 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.

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

“**Mail-Back Unit**” means the combination of (1) a Mailer (see definition below) and (2) a Sharps Waste Container (see definition below) that can be filled with Covered Products that require disposal and are USPS approved.

“Mail-Back Program” 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.

“Mailer” means a cardboard package with a prepaid, pre-addressed label for shipping the Sharps Waste Container filled with Home-Generated Sharps Waste.

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

“Point of Sale” has the same definition as that in 14 CCR Section 18972.1.

“Point of Sale Location” means the Pharmacy, Retail Pharmacy, or other retailer including but not limited to an online retailer that provides for the purchase or distribution of Sharps.

“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 Section 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, Distribution Locations, Covered Entities, Pharmacists, Point of Sale Locations, etc.

“Programmatic Advertising” means 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 Waste Stewardship Program, Title 14, Division 7, Chapter 11, and Article 4

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

“Service Provider” means a contracted vendor used to transport, process, and/or dispose of Home-Generated Sharps Waste collected through the Stewardship Program.

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

“Home-Generated Sharps Waste” has the same definition as that in CA PRC Section 42030.

“Sharps Waste Container” means a secure repository into which Ultimate Users deposit Sharps that is FDA approved, meets the requirements of Section 501(k) clearance, and is compliant with all state laws and rules and federal laws and regulations governing the keeping of Sharps in repositories.

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

“Mail-Back Unit Distribution Location” or “Distribution Location” means a location at which Ultimate Users can pick up a Mail-Back Unit to use for the collection of Home-Generated Sharps.

“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.

III. Program Budget

14 CCR Section 18973.3(e) 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 Section 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 Section 18973.6(b) through 14 CCR Section 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) A 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 Home-Generated Sharps Waste to develop the Program Budget. Data sets from Home-Generated Sharps 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 Budget estimates based on experience. The Foundation's Service Providers have provided historical data for required Program costs such as 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 amounts and activities:
 - 1. Capital Expenses - The Foundation has contracted with a Service Provider to support the collection, transportation, and destruction of all Home-Generated Sharps Waste. The costs associated with this contract do not qualify as a capital cost/expenditure, and there are no other capital,

fixed or one-time costs that the Foundation is aware of at this time other than website development work that is included in the "operational costs" section of the Program Budget.

2. Operational - \$17,727,173: Items in this category consist of collection, transportation, and disposal of Home-Generated Sharps Waste, website construction, design, maintenance, and support.
3. Education and Outreach - \$674,127: 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 and radio advertising)
4. Administrative - \$1,226,164: Administrative overhead, postage and shipping, miscellaneous supplies, funding of an annual independent audit of the Stewardship Program.
5. Departmental Administrative Fees - \$2,942,263: Fee due to the Department pursuant to 14 CCR Section 18973.6(b)(3) and PRC Section 42034 and PRC Section 42034.2.
6. Reserve Amount - \$1,767,017: Anticipated amount to cover unexpected overages in Program operational expenses. Additional details regarding the reserve amount are included below.

The Foundation has long-term commitments from the Covered Entities who will cover all costs associated with the Program Budget. 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 cushion against unexpected events, losses of income or large unbudgeted expenses.

The Foundation has planned its annual 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 operational costs.

When considering unexpected costs or potential loss of income, the Foundation has determined that a reserve percentage that approximates 10% of additional Mail-Back Units 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 (5) calendar years of operation of the Stewardship Plan and will each year thereafter submit a written program budget for the upcoming 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 and be in accordance with 14 CCR Section 18973.6(f) of the Regulation.
- F. In accordance with 14 CCR Section 18973.3(a) and 14 CCR Section 18973.6(a) the contact information 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 18973.3(k) is not applicable.

IV. Contacts

- A. Plan Oversight and Operations

14 CCR Section 18973.3(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 Section 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
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.

B. Participating Covered Entities

14 CCR Section 18973.3(b) Contact information for each covered entity participating in the stewardship plan

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

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

14 CCR Section 18973.3(f)(4) Each service provider to be used to transport, process, or dispose of home-generated sharps waste collected through the stewardship program

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

V. Sharps Sold and/or Offered for Sale by Covered Entities

14 CCR Section 18973.3(c) List of sharps sold or offered for sale by each participating covered entity covered by the stewardship plan.

See Appendix D for the current list of Sharps sold and/or offered for sale in California by each participating Covered Entity covered by this Program.

VI. Collection, Transport, and Disposal

14 CCR Section 18973.3(f) 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 home-generated sharps waste from collection through final disposal.

A. Collection

1. Ultimate User Collection

The Foundation will establish a Mail-Back Program for the collection and management of Home-Generated Sharps Waste by distributing Mail-Back Units to Ultimate Users throughout the state of California. Pursuant to PRC Section 42032.2(d)(1)(F) and CCR Section 18973.3(f)(5), any supplemental collection methods are provided in addition to, but not in lieu of, the Mail-Back Program.

- The Mail-Back Program will:

- Be free of charge to the Ultimate User. At no point will an Ultimate User be charged for a Sharps Waste Container or Mailer, or for the shipping/handling and destruction of Sharps.
- Provide Mail-Back Units at all Points of Sale where Covered Products are sold. The Foundation is willing to jointly coordinate with other approved Program Operators on Sharps Waste Container distribution as further described in Section VIII: Coordination Efforts.
- Arrange, at the Point of Sale or prior, for a Mail-Back Unit to be sent to the Ultimate User and arrive to the Ultimate User within five (5) business days of the request.
- Ensure that a toll-free 24/7 telephone number and website are operating and able to assist Ultimate Users with the ordering of Mail-Back Units. All Mail-Back Units ordered via the website or over the telephone will be delivered within five (5) business days of the request.
- Provide the option for an ordering portal for all Point of Sale Locations that are distributing Sharps whereby employees have the ability to order Mail-Back Units for Ultimate Users with no additional inconvenience to the Ultimate User. For more information see section b) Distribution of Sharps Waste Containers to Ultimate Users below.

a) Distribution of Sharps Waste Containers to Point of Sale Locations

The Foundation will work with existing partners in the state of California to provide education on the appropriate laws and regulations for Sharps Waste Container distribution. The Foundation will use the below outreach phases to inform all Point of Sale Locations of the Program in the state of California:

- Phase 1 - The Foundation will utilize its current relationships with Pharmacies and retail partners including online Pharmacies and Retail Pharmacies in California to inform them of the Program. A formal letter will be sent that describes the Program requirements.
- Phase 2 - The Foundation will conduct public outreach efforts to physical, online, and mail order Point of Sale Locations that are not currently included in the Program.

The Foundation's Service Provider utilizes available statewide prescription data to determine the number of prescriptions filled across the state, the number of patients that fulfill those prescriptions, and what percentage of those prescriptions filled are for Sharps. Using this data, the Service Provider can determine the rate of fulfillment at each Pharmacy across the state that the Service Provider supports on behalf of the Foundation and will provide Mail-Back Units at a rate consistent with the usage for each Pharmacy. If one Point of Sale Location fulfills prescriptions at a higher rate than another, the Foundation will provide that Point of Sale Location with more Mail-Back Units to distribute; the inverse also applies. Sales data for non-prescription Sharps being sold statewide is also used to ensure that a sufficient volume of Mail-Back Units is available to accommodate the volume of Sharps purchased over a selected time period.

Each shipment will contain a quantity of Mail-Back Units and instructions for Point of Sale Locations on how to offer Mail-Back Units at no cost to the Ultimate Users. Each Mail-Back Unit contains an insert/information sheet that provides the Program Operators' website and toll-free telephone number for Ultimate Users to direct any comments, questions, or concerns, and describes the appropriate use, proper storage, and repackaging for mailing the Sharps Waste Container.

b) Distribution of Sharps Waste Containers to Ultimate Users

14 CCR Section 18973.3(f)(2) How stewardship plan implementation will provide or initiate distribution of sharps waste containers and mail-back materials, which include mail-back packaging and information material, at no cost to ultimate users at the point of sale, to the extent allowable by law.

14 CCR Section 18973.3(f)(2)(A) Containers and mail-back materials shall be distributed in amounts sufficient to accommodate the volume of sharps purchased by the ultimate user over a selected time period.

Ultimate Users who purchase Sharps at a Point of Sale Location will be offered Mail-back Unit(s) to accommodate the amount of Sharps they are purchasing. The decision to accept or decline Mail-Back Unit(s) is at the Ultimate User's discretion. The Point of Sale

Location will initiate the distribution of the Mail-Back Unit(s) to the Ultimate User in the following ways:

- 1) Distributing the Mail-Back Unit(s) to the Ultimate User at the Point of Sale.
- 2) If the Ultimate User declines the Mail-Back Unit(s), they will be offered the opportunity to have the Mail-back Unit(s) shipped to them to arrive within five (5) days of the Point of Sale. The Point of Sale Location employee will be provided with instructions on how to request Mail-Back Unit(s) for Ultimate Users.
- 3) The Foundation will provide Point of Sale Locations with an ordering portal that will allow them to request Mail-Back Unit(s) directly from the Service Provider to be shipped to the Ultimate User. Once the Service Provider receives the request, the Sharps Waste Containers will be packaged according to the amount needed to adequately handle the amount of Sharps purchased. The Mail-Back Unit(s) will arrive to the Ultimate User within the required timeframe of five (5) business days from the Point of Sale.
- 4) Should Ultimate Users decline either option described above, Point of Sale Locations will provide Ultimate Users with an informational pamphlet describing additional options for requesting Mail-Back Unit(s) to be sent to them at a later date.

Educational materials that describe proper Sharps disposal will also include guidance on how Ultimate Users can order additional Mail-Back Unit(s) through the website or the toll-free telephone number.

Ultimate Users will be able to request up to three (3) Mail-Back Units at a time via the Program's website or toll-free telephone number. Ultimate Users will receive the Mail-Back Unit(s) no later than five (5) business days from date of request. Sharps Waste Containers and Mailers meet DEA Rule requirements under 21 CFR Section 1317.70(c).

Sharps Waste Containers are 1.4 quarts, approved by United States Postal Service (USPS) and Food and Drug Administration (FDA) 501(k) cleared. To ensure that Mail-Back Units are distributed to Ultimate Users in amounts sufficient to accommodate the volume of Sharps purchased over a selected time period, the Foundation will provide education to Point of Sale Locations. Employees of the Point of Sale Locations will be trained on how to provide the number of Mail-Back Units required to accommodate the Ultimate User based on the amount of Sharps being purchased..

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 Unit Distribution Locations to serve the Homeless community throughout the state. The Service Provider will provide the CDSS and CoC with educational materials that emphasize that all populations, including the Homeless, have access to no-cost safe Sharps disposal through the Stewardship Program.

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 Point of Sale Locations. Using this service, the Ultimate User can place a request either through the Program's website or toll-free telephone number and provide the address of their desired post office and the Mail-Back Unit is delivered to the post office of choice according to USPS policies.

c) Instructions

14 CCR Section 18973.3(f)(2)(B) For any sharps, the packaging, an insert or instructions, or separate information provided to the ultimate user shall include all necessary information on proper sharps waste disposal.

14 CCR Section 18973.3(f)(2)(C) All sharps waste containers shall include, on a label affixed to the container or packaging or on a separate insert included in the

container or packaging, the program operator's internet website and toll-free telephone number.

An insert is included in each Sharps Waste Container that has instructions for proper use, including how to utilize the Sharps Waste Container in a safe manner, and the Program Operator's toll-free telephone number and website information.

The insert has an image of a typical Sharp and reads:

- Accepted: Sharps products including pre-loaded products containing a Sharp (i.e., hypodermic needle, syringe, or lancet)
- Not Accepted: Unwanted medicines that are not pre-loaded products containing a Sharp, inhalers, herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, and illicit drugs.

d) Labeling and Packaging

14 CCR Section 18973.3(f)(2)(D) Prepaid postage shall be affixed to the container or mail-back packaging.

The Foundation will provide prepaid, pre-addressed Mail-Back Units to Ultimate Users, in-home hospice providers, and homeless shelters at no cost. As described above, Sharps Waste Containers include an insert that provides written instructions for the safe return of Home-Generated Sharps Waste. The Program Operators' toll-free telephone number and website is also listed on the insert.

2. Local Agency Requests

§ 18973.3(g)(1) Description of the process for coordinating with local agencies, or an agent on behalf of a local agency, for the removal of home-generated sharps waste from local household hazardous waste facilities, either by reimbursement for transportation and disposal costs or removal of the home-generated sharps waste.

§ 18973.3(g)(2) Requests by local agencies, or an agent on behalf of a local agency, shall include an invoice and shall be submitted to the program operator, as necessary. Such requests shall comply with the requirements in subsection (1)(F)(ii) of subdivision (d) of section 42032.2 of the Public Resources Code. Program operators shall respond to requests by local agencies within 14 days of receipt of the request and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies).

§ 18973.3(g)(2)(A) A program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of receipt of the local agency's invoice.

§ 18973.3(g)(2)(B) A program operator that provides for the removal of the home-generated sharps waste from the local household hazardous waste facilities shall do so as often as required according to section 117904 of the Health and Safety Code or by the local enforcement authority.

- a) The Service Provider, on behalf of the Foundation, will work to establish contacts at all household hazardous waste facilities in order to be compliant with this portion of the Regulation. If a household hazardous waste facility disposes of Home-Generated Sharps Waste, the Service Provider will work with that agency to determine the cost of transportation and disposal and will reimburse the facility within 45 days of receipt of the local agency's invoice.
- b) The Service Provider will provide Home-Generated Sharps Waste Containers at each Local Jurisdiction solid waste/recycling center, transfer station, and/or landfill across the state (prioritizing the sites with more traffic and convenience) in quantities of ten (10) at a time. In doing so, the Program will be able to provide a better solution for these locations to dispose of Home-Generated Sharps Waste that end up in a landfill. This collection method is supplemental and not in lieu of the Mail-Back Program nor local agencies' ability to request reimbursement as described in paragraph c) below.
- c) Requests from local agencies or an agent on their behalf must include an invoice and comply with the requirements in subsection (1)(F)(ii) of subdivision (d) of section 42032.2 of the Public Resources Code. The Foundation will ensure that the Service Provider provides a response within 14 days of receipt of the request and identifies the method to resolve the request by selecting either reimbursement or removal from the household hazardous waste facility. If resolved via reimbursement, payment is to be issued within 45 days of receipt of the local agency's invoice.
- d) The Service Provider will arrange for the removal of Home-Generated Sharps Waste collected from the local household hazardous waste facility as often as required according to CA HSC Section 117904 or by the local enforcement authority.
- e) In accordance with 14 CCR Section 18973.3(f)(8), the Foundation

will record and track the following information to maintain metrics from local agencies that request reimbursement:

- 1) Name and location of the local household hazardous waste facility requesting reimbursement
- 2) Frequency at which each facility requests reimbursement
- 3) Total amount reimbursed by facility
- 4) Total weight generated by Home-Generated Sharps Waste collected and disposed as requested by the Foundation

B. Transport

All Home-Generated Sharps Waste will be transported via the United States Postal Service (USPS) to the Program's licensed Service Provider.

C. Disposal

All collected Home-Generated Sharps Waste received by the Program's Service Provider will be transported by said Service Provider to an appropriately licensed 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 and disposal of Home-Generated Sharps Waste.

VII. Tracking

A. Tracking of Home-Generated Sharps Waste begins with Mail-Back Unit distribution and concludes with the destruction of the collected Home-Generated Sharps Waste at the destruction facility.

B. Upon receipt of a Sharps Waste Container from an Ultimate User, the Program's Service Provider will record and track the following data elements for each received Sharps Waste Container:

- Date received
- Serialized barcode label information
- USPS shipping tracking number
- Weight and date transported to disposal facility
- Disposal date
- Manifest number (if applicable).

All information recorded will be transferred to the Program Operator daily for tracking of each Sharps Waste Container returned.

VIII. Education and Outreach

14 CCR Section 18973.3(i) Education and Outreach. Description of a comprehensive education and outreach program

The Foundation is committed to education and outreach for all Program Participants impacted 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 Home-Generated Sharps Waste is widely understood by Ultimate Users, Point of Sale Locations, Mail-Back Unit Distribution Locations 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 distributed free of charge to persons authorized to prescribe drugs, hospitals, Pharmacies, pharmacists, Mail-Back Unit Distribution Locations, Ultimate Users, and others Program Participants. 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 themes:

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

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 Section 18973.3(i)(1) 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 Section 18973.2(i)(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 and outreach materials, including signage, will be developed and distributed to Point of Sale Locations participating in the Program, and upon request, to persons authorized to prescribe drugs, hospitals, Pharmacies, pharmacists, Ultimate Users and other locations as necessary.

Educational materials will accompany the distribution of Sharps Waste Containers and instruct Ultimate Users on proper Home-Generated Sharps Waste disposal and the importance of separating Covered Products from non-Covered Products. All materials are also available upon request through the toll-free telephone number.

All printed material, including signage for hospitals, pharmacies, and other locations as necessary will be distributed in languages suited to local demographics, consistent with section 7295 of the Government Code which requires translation into any non-English language spoken by a substantial number of the public. Translated languages are determined 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).

The Foundation will distribute all hard-copy educational material and signage in English and Spanish and will include on each copy a QR code coupled with a universally recognized translation icon and a list of the available languages in their native translation directing Ultimate Users to a webpage where printable versions of the materials are available in each offered translation. All materials are provided free of charge including those translated into additional languages.

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 Home-Generated Sharps Waste consistent with the services offered by the Program.

2. Traditional Media

General awareness media campaigns about the 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 Stewardship Program.

3. Programmatic Advertising

Programmatic advertising will leverage the Service Provider'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 Ultimate Users.

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 Ultimate Users 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 Section 18973.3(i)(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 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 Ultimate Users, 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 Google Translate languages
- Provide information on collection options for Home-Generated Sharps Waste
- Accept requests for Mail-Back Units from Ultimate Users including those who are Homeless, Homebound, or disabled
- Clearly indicate what Home-Generated Sharps Waste are and are not accepted and encourage separation of Covered Products from non-Covered Products. Graphics of Home-Generated Sharps Waste are provided for additional clarity.

- Include educational and outreach materials on safe handling, storage and proper disposal of Home-Generated Sharps Waste.
- Feature links to social media pages for more useful content.

C. Toll-Free Telephone Number

14 CCR Section 18973.3(i)(4) Establishment of a toll-free telephone number to serve as an option for ultimate users to request sharps waste containers and mail-back materials, and to obtain information about the program, including, but not limited to what is outlined in section 18973.3(i)(3)(A)-(E). 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 telephone number that Ultimate Users can call to learn more about the Stewardship Program and safe Home-Generated Sharps Waste disposal practices. Ultimate Users will be able to request information about Sharps Waste Containers, or request that a Mail-Back Unit 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). 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 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 Homebound, Homeless, and disabled Ultimate Users. All operators are trained to assist and answer any and all questions related to the Stewardship Program. Ultimate Users without an address can request Mail-Back Units via the toll-free telephone number by providing the address of their desired post office according to the USPS General Delivery policy.

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

D. Education

14 CCR Section 18973.3(i)(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 a home-generated sharps consolidation point or mail-back program.

14 CCR Section 18973.3(i)(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 Home-Generated Sharps Waste is widely understood by Ultimate Users, hospitals, Pharmacies, and other locations.
2. All education key messages will include, but not be limited to, the following:
 - Encourage Ultimate Users to separate Covered Products from not-Covered Products.
 - Discourage the disposal of Home-Generated Sharps Waste in the garbage or sewer system.
 - Promote the disposal of Home-Generated Sharps Waste in a manner consistent with the services offered by the Stewardship Program.
3. The Foundation will coordinate to ensure that Ultimate Users clearly understand the logistics, safety, and educational components of the Stewardship Program.

IX. Coordination Efforts

14 CCR Section 18973.3(j) 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 home-generated sharps waste are in operation concurrently or new stewardship programs begin operating.

Should there be multiple approved Program Operators, the Foundation will work together with other approved Program Operators to avoid confusion to the public and all Program Participants pursuant to CCR section 18973.3(j).

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 in the general public and all Program Participants and take action to address
- Jointly agree to a state-wide Program logo that will be readily recognizable for use on educational materials, the website and other materials seen by the Ultimate User and any other Program Participants.

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 Home-Generated Sharps Waste disposal, statistics regarding the dangers of Home-Generated Sharps Waste in the waste stream, drug abuse statistics, and other Program advocacy. The Foundation is also willing to coordinate on means of Sharps Waste Container distribution and any other pertinent information related to the success of the Program. This coordination will be conducted with a fair and equitable division of resources. Additionally, the Foundation is willing to coordinate with other Program Operators to ensure consistent messaging among the types of educational outreach.

X. Metrics

14 CCR Section 18973.3(f)(6) Metrics that will be used to measure the amount of sharps waste containers and mail-back materials distributed and metrics that will be used to measure the amount of home-generated sharps waste returned.

A. Sharps Waste Containers

1. The Service Provider will utilize Sharps Waste Containers that are serialized and unique for the purpose of tracking. Each serial number listed on the prepaid shipping label will be unique to that individual Sharps Waste Container. The Service Provider will be able to determine, in mass quantity, where each Container was shipped based on the unique serial number assigned to each individual Container and each case pack that is shipped. Once the Container is entered into the USPS supply chain network, the

Service Provider will be able to track the serial number on the Container through destruction. The record of destruction will be passed to the Service Provider via a SFTP file transfer, and that information will be cataloged on a secure server.

2. When an Ultimate User requests a Sharps Waste Container to be shipped to their location via the ordering mechanism on the website, the Service Provider will initiate a shipment, provide tracking at the point of order, and monitor the shipment directly to the Ultimate User's requested location. Once the Sharps Waste Container is shipped, a notification will be provided that the Sharps Waste Container has been filled and shipped back. The documentation regarding fulfillment will be contained within the Service Provider's document repository systems, as well as the documentation for destruction.
3. Quantity of Sharps Waste Containers by Distribution Location will be measured against quantity of Sharps Waste Containers returned via the Sharps Waste Container's unique serial number and Distribution Location identifier. The Service Provider will use Sharps Waste Container return metrics to adjust the number of Sharps Waste Containers distributed to meet the distribution needs of each location.
4. Weight measure data will be captured by the Program's Service Provider for all Sharps Waste Containers returned through the Program's mail-back process for use in metric reporting.

B. Education and Outreach

14 CCR Section 18973.3(i)(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 Covered Entities, pharmacists, and healthcare professionals in the state of California who interact with Ultimate Users. The goal of the survey is to measure public awareness and use of the Stewardship Program.

The survey will measure how the above groups assess the convenience and accessibility of the methods for collecting Home-Generated Sharps Waste, and assess knowledge and attitudes regarding the risks, such as potential injury and spread of disease from improperly storing and improperly discarding or abandoning Home-Generated Sharps Waste. The Foundation will design survey questions to evaluate the effectiveness of different messaging for raising

awareness of the Stewardship Program and for increasing knowledge of or changing attitudes towards risks posed by improper storage or disposal of Home-Generated Sharps Waste. 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

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 Mail-Back Unit Distribution Locations, 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.

XI. Records

14 CCR Section 18973.3(f)(3) Collection, Transportation, and Disposal System Records. Description of how and where the records generated during the collection, transportation, and disposal of collected home-generated sharps waste will be maintained. These records shall include, but are not limited to: collection manifests, mailer distributions, receipts of returned home-generated sharps waste return mailings, and final disposal of home-generated sharps waste, as applicable.

A. Storage

The Foundation will maintain records pertaining to Mailer distributions, receipts of returned Sharps Waste Containers and final disposal of Home-Generated Sharps Waste. Original copies of all necessary records will be retained by Service Providers as applicable. The Foundation is responsible for retaining copies of these records. A document repository will be used to manage these records. There will be a role-based security system in place to ensure access is limited. Records will also include items related to incident reporting, waste files, weights, serial numbers, collection services, process reviews, and audits and inspections of Service Providers.

B. Retention

Pursuant to 14 CCR Sections 18974 (a), (b), and (c), records generated throughout Plan 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.

XII. Plan Compliance

14 CCR Section 18973.3(f)(9) Corrective actions will be taken if a program operator discovers critical instances of noncompliance with stewardship plan policies and procedures.

A. Monitoring

The Program Operator will conduct the following monitoring activities:

- Formalized reviews/audits of required tracking/reporting documentation.
- Random/unscheduled on-site visits.
- Scheduled on-site audits of participant locations for compliance with the Controlled Substances Act, 21 USC Sections 801-971 and 21 CFR Section 1317; United States Department of Transportation Hazardous Materials Regulation, 49 CFR parts 100-185; State Board, the Medical Waste Management Act, CHSC Sections 117600-118360 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, process/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 Program participants via a series of video recorded sessions or live sessions.

XIII. Audits

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

- Review of documentation used by Service Providers
- 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 Home-Generated Sharps Waste.

The audit will be conducted by an independent third-party auditor. A copy of completed audits will be provided to the Department within 30 days of audit completion.

XIV. Repeal of a Local Stewardship Program Ordinance

14 CCR Section 18973.3(h) 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.

Should any Local Jurisdiction (e.g., city or county) repeal their local Sharps stewardship ordinance, the Foundation would work with the Local Jurisdiction to incorporate the statewide Program into its jurisdiction within 270 days of the effective date of 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 its ordinance include:

1. Identifying any differences in the programs such as reporting, education and outreach programs.
2. Develop a project schedule that details the following:
 - a. Updating existing Program Participants with new Program requirements as necessary
 - b. Expanding education and outreach into the Local Jurisdiction.
 - c. Notification and/or necessary reporting to the Department.

XV. Product Verification

14 CCR Section 18974.3(a) through 14 CCR Section 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 Product to log on to the Department's website to determine and verify that the Covered Entity providing the Covered Product follows the law. Any discovery of non-compliance will be reported to the Department within 30 days of discovery.

XVI. Service Provider Selection Process

14 CCR Section 18973.3(l) Process for selecting service providers, including a description of any competitive procedures 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 process. 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.

XVII. Annual Report

14 CCR Section 18973.5 Annual Report for Home-Generated Sharps Waste.

The Foundation will submit its annual report for Home-Generated Sharps Waste 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 18973.5 of the Regulation.

XVIII. Administrative and Operational Costs

14 CCR Section 18974.1(a) 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.

The Foundation has secured commitments to enter long-term contracts with Covered Entities for participating in the Stewardship Program. 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 Covered Entity participating in the Program including costs for collecting, transporting, and disposing of Home-Generated Sharps Waste.

XIX. State Agency Determinations

14 CCR Section 18973.3(d)(1) Agency determinations pursuant to 42032.2(d)(1)(B) of the Public Resources Code. If a determination of noncompliance was initially issued, the stewardship plan shall include both the initial determination of noncompliance and the superseding determination of compliance. If any state agency failed to respond to a request for review within 90 days of receipt of the stewardship plan, the program operator shall include documentation of this request along with a written certification, signed by an authorized representative of the program operator, that at the time of submission to the department, the stewardship plan is consistent with all laws and regulations relevant to that agency's authority, and the applicable agency failed to respond within 90 days of receipt of the stewardship plan.

(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the handling, transportation, and disposal of home-generated sharps waste is in compliance with all applicable local, state, and federal laws and regulations.

Provided below are the Foundation's Home Generated Sharps Waste Stewardship Plan determinations:

- State Board of Pharmacy Determining Compliance Review - September 30, 2021
- State Board of Pharmacy Determination of Compliance - November 18, 2021
- Department of Public Health Determining Compliance Review - October 5, 2021
- Department of Public Health Determination of Compliance - November 16, 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. 30, 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 sharps you submitted to the Board on July 9th, 2021 entitled "Stewardship Plan for Home-Generated Sharps Waste July 8, 2021" (Plan).

Pursuant to our telephone conversation on September 28th in which we discussed certain issues with the Plan, you stated that you intended to submit a revised Plan to the Board to address the issues brought up by the Board and other agencies. 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 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 question, please feel free to contact me.

Sincerely,

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

Cc: Jason Smyth – CalRecycle



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 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 sharps you submitted to the Board on November 15, 2021 entitled "STEWARDSHIP PLAN FOR HOME-GENERATED SHARPS WASTE SEPTEMBER 21, 2021 Version 2 (November 15, 2021)"(Plan) that has the name, "CA_STATE_SHARPS_PLAN_CALRECYCLE 11-15-21" 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



TOMÁS J. ARAGÓN, M.D., Dr.P.H.
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM
Governor

October 5, 2021

Ms. Kristin Alstad
Senior Manager, Regulatory Compliance
Inmar
635 Vine Street
Winston Salem, NC 27101

RE: Product Stewardship Plan for Covered Sharps from Households, July 9, 2021; DETERMINING COMPLIANCE REVIEW

Dear Ms. Alstad:

The California Department of Public Health, Medical Waste Management Program (Department) has reviewed the Take Back Foundation/Inmar Safe Drug Disposal Stewardship Plan for Home-Generated Sharps Waste Sharps (Plan), submitted on July 9, 2021, to become an approved program operator through California's Pharmaceutical and Sharps Waste Stewardship Program (established by Senate Bill 212) to operate sharps takeback programs in cities and counties in California.

The Department requires additional information and documentation to determine the Plan's compliance with the Medical Waste Management Act, California Health and Safety Code Section 117600 *et seq.* (MWMA). Please refer to the following comments and questions of the Plan:

1. **Submitting Revised Application:** Please submit a revised redline application and ensure that *all* attachments are attached with the revised application.
2. **General Comments:**
 - a. The Plan appears to be a drug stewardship plan for products that have sharps in their method of delivery. However, drug and sharps terminology have been used interchangeably, making the plan difficult to follow and unclear as a result. Please revise the Plan to clearly describe and distinguish between drugs and sharps.
 - b. Please provide the USPS approval(s) for the mail-back package(s) and a copy of the instructions for what may and may not be disposed of into the mail-back packages or sharps containers.

Medical Waste Management Program, MS 7405, IMS K-2 • P.O. Box 997377
Sacramento, CA 95899-7377 • (916) 449-5671
www.cdph.ca.gov/medicalwaste



- c. Does the Plan offer mail-back packages and individual sharps waste containers (non-mail-back packages)?
- d. The plan indicated the use of Kiosks; however, the type of waste was not specified. Are the kiosks for home-generated pharmaceutical waste or home-generated sharps waste (i.e. sharps containers)? If the kiosks are intended for home-generated sharps waste containers, please provide the following information: who will collect, transport, and treat the collected containers; how the containers will be treated, and where the treated containers would be disposed of.

Once the above requested information is received, the Department will continue its review of the Plan. When sending in the requested information, please provide a complete Plan, including all attachments, with any required revisions. Receiving the requested information does not preclude the Department from requesting additional information in the future. Once the Department has determined the Plan is compliant with the MWMA, a determination of compliance letter can be issued.

If you have any questions or need further assistance regarding the Department's review, please feel free to contact me directly by phone at 916-210-8533 or via email at Thomas.Horner@cdph.ca.gov.

Sincerely,

FOR

Thomas Homer
Senior Environmental Scientist
Chief, Medical Waste Management Program

cc: Sheetal Singh, PhD
Environmental Program Manager I
Chief, Emergency, Restoration, and Waste Management Section

Jennifer Li
Environmental Scientist
Medical Waste Management Program



TOMÁS J. ARAGÓN, M.D., Dr.P.H.
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM
Governor

November 16, 2021

Ms. Kristin Alstad
Sr. Manager, Regulatory Compliance
Inmar Intelligence
635 Vine Street
Winston-Salem, NC 27101

**RE: Product Stewardship Plan for Covered Sharps from Households;
DETERMINATION OF COMPLIANCE**

Dear Ms. Alstad:

The California Department of Public Health, Medical Waste Management Program (Department) has reviewed The Drug Takeback Solutions Foundation's (in care of Inmar Intelligence) Sharps Stewardship Plan (Plan) to become an approved program operator through California's Pharmaceutical and Sharps Waste Stewardship Program (established by Senate Bill 212) to operate sharps takeback programs in cities and counties in California.

The Department determined that the "Stewardship Plan For Home-Generated Sharps Waste (Version 2)" submitted on November 15, 2021 is compliant with the Medical Waste Management Act, California Health and Safety Code Section 117600 *et seq.* (MWMA). In evaluating the Plan for compliance with the MWMA, the Department relied upon the facts and detail contained in the Plan. Please note that any different or additional facts in the design or operation of the Plan could result in a different conclusion.

If you have any questions or need further assistance regarding the Department's review, please feel free to contact me directly by phone at 916-210-8533 or via email at Thomas.Homer@cdph.ca.gov.

Sincerely,

Thomas Homer
Senior Environmental Scientist
Chief, Medical Waste Management Program

Medical Waste Management Program, MS 7405, IMS K-2 • P.O. Box 997377
Sacramento, CA 95899-7377 • (916) 449-5671
www.cdph.ca.gov/medicalwaste



Ms. Kristin Aistad
November 16, 2021
Page 2

cc: Sheetal Singh, PhD
Environmental Program Manager I
Chief, Emergency, Restoration, and Waste Management Section

Jennifer Li
Environmental Scientist
Medical Waste Management Program

XX. 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 18973.3(d)(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 handling, transportation, and disposal of Home-Generated Sharps Waste is in compliance with all applicable local, state, and federal laws and regulations.

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

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

XXI. Appendix A – Program Budget

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

XXII. Appendix B – Participating Covered Entities

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

XXIII. Appendix C – Service Providers

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

XXIV. Appendix D – Sharps Sold/Offered for Sale in California by Participating Covered Entities

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