

REQUEST FOR ACTION

To: Rachel Machi Wagoner
Director

From: Zoe Heller
Deputy Director, Division of Circular Economy

Request Date: June 20, 2023

Decision Subject: Consideration of The Drug Takeback Solutions Foundation's 2022 Annual Report for Home-Generated Sharps Waste

Action By: June 29, 2023

Summary of Request

The Drug Takeback Solutions Foundation (The Foundation) submitted its 2022 annual report, titled, *The Drug Takeback Solutions Foundation State of California Home-Generated Sharps Waste 2022 Annual Report (2022 Annual Report)* on March 31, 2023, as required by statute. This Request for Action presents a summary of staff's analysis regarding The Foundation's *2022 Annual Report* and The Foundation's home-generated sharps waste stewardship program.

Background

The Foundation is a stewardship organization that represents 15 covered entities under its approved stewardship plan for home-generated sharps waste, titled, *Stewardship Plan for Home-Generated Sharps Waste (Plan)*. On February 14, 2022, the Department of Resources Recycling and Recovery (CalRecycle) conditionally approved the *Plan* pursuant to Public Resources Code (PRC) section 42032(d)(1) and Title 14 of the California Code of Regulations (14 CCR) sections 18973.1(e) and (g). The Foundation's *2022 Annual Report* covers the period of time its *Plan* was conditionally approved through the end of the 2022 calendar year (February 14, 2022, through December 31, 2022).

PRC section 42033.2(a)(1) states that, on or before March 31, 2022, and each year thereafter, a program operator shall submit to CalRecycle a report that describes the stewardship program activities during the previous reporting period of one year. The Foundation submitted its *2022 Annual Report* on March 31, 2023. CalRecycle determined the *2022 Annual Report* was complete and notified The Foundation on May 1, 2023, pursuant to PRC section 42033.2(d)(1) and 14 CCR section 18973.1(b). CalRecycle has 90 days to approve, disapprove, or conditionally approve the *2022 Annual Report* pursuant to PRC section 42033.2(d)(2) and 14 CCR section 18973.1.

Staff Analysis

The Foundation states in its *2022 Annual Report* that it conducted the following program activities:

- Fully implemented its program within 270 days of CalRecycle approval of its *Plan*
- Distributed 3,823 sharps waste containers
- Established 127 point of sale sites participating in its program

- Conducted outreach that included approximately 1,000 calls and 17,000 letters to point of sale locations
- Researched organizations that work with homeless and underserved communities and household hazardous waste facilities to educate about disposal options
- Its primary focus was to:
 - Work with pharmacies and other point of sale locations to encourage their participation in The Foundation’s program
 - Educate point of sale locations and covered entities of their obligation to participate in the program
 - Expand the geographic spread of mail-back unit distribution locations

Additionally, The Foundation reported that it faced challenges in determining the specific locations where its covered entities’ covered products are sold.

Staff evaluated The Foundation’s *2022 Annual Report* to determine whether the requirements of statute, regulations, and The Foundation’s *Plan* were met. The sections below present a summary of staff’s analysis of The Foundation’s *2022 Annual Report* for those requirements where additional information from and/or additional actions by The Foundation may be necessary for CalRecycle to determine whether the requirements of statute, regulations, and The Foundation’s *Plan* were met.

Mail-Back Program

Requirements: Implement a mail-back program that provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale pursuant to PRC section 42032.2(d)(1)(F)(i) and 14 CCR section 18973.3(f)(2). Include 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 pursuant to 14 CCR section 18973.3(f)(6). Report the amount of sharps waste containers and mail-back materials distributed per county, through each of the following methods: provided at point of sale, initiated at point of sale, website requests, and toll-free telephone number requests, pursuant to 14 CCR section 18973.5(c)(2). Amount of home-generated sharps waste returned through the mail-back program, as required in the stewardship plan pursuant to 14 CCR section 18973.5(c)(3). The Pharmaceutical and Sharps Waste Stewardship Act does not apply to a sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018, pursuant to PRC section 42036.2(a). A program operator submitting an annual report shall provide to the department, upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of approval, pursuant to 14 CCR section 18973.1(a).

Analysis: Requirements Not Met

Pursuant to 14 CCR section 18972.1(a)(10), “provides or initiates distribution of a sharps waste container and mail-back materials” means one of the following: (A) To provide a sharps waste container and mail-back materials to the ultimate user, at the point of sale or prior, at no cost to the ultimate user; or, (B) To arrange, at the point

of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within five business days at no cost or inconvenience to the ultimate user; or, (C) Other methods of providing a sharps waste container and mail-back materials to the ultimate user at the point of sale or prior, at no cost to the ultimate user, if the method identified in subpart (A) above is not allowed by law and if the method identified in subpart (B) above is not allowed by law.

In its *Plan*, The Foundation stated its Mail-Back Program will:

- Provide Mail-Back Units at all Points of Sale where Covered Products are sold.
- 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.
- 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.

The Foundation's *Plan* states that its mail-back program will "provide Mail-Back Units at all Points of Sale where covered products are sold" **and** (emphasis added), if the ultimate user prefers, "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." However, The Foundation's *2022 Annual Report* states that point of sale sites in its program were provided the options of either "1) initiating the distribution of Sharps Waste Containers on behalf of Ultimate Users" **or** (emphasis added) "2) Ordering inventory to keep Sharps Waste Containers on-site and physically distribute them at the Point of Sale." Because The Foundation's *Plan* states that point of sale locations will be equipped to provide **and** (emphasis added) initiate, based on ultimate user preferences, and its *2022 Annual Report* states that point of sale locations were provided these options instead of the ultimate user, The Foundation failed to implement point of sale services to ultimate users as described in its *Plan*.

Additionally, The Foundation did not describe whether it provided the option for an ordering portal for all point of sale locations to order sharps waste containers on behalf of ultimate users according to its *Plan*. The Foundation must describe how it initiated the distribution of sharps waste containers on behalf of ultimate users at point of sale sites, which includes detail about The Foundation's ordering portal (see item (a) under Summary 1 of Requirements Not Met).

The Foundation's *2022 Annual Report* reported that, "31 Locations elected to initiate the order of Sharps Waste Containers on behalf of Ultimate Users" and "96 Point of Sale Locations elected to keep Sharps Waste Containers on-site to distribute to Ultimate Users at the Point of Sale." As defined in The Foundation's *Plan*, a "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.” The distribution of a “Sharps Waste Container” instead of a “Mail-Back Unit” (defined in The Foundation’s *Plan* as a combination of a “Sharps Waste Container” and “Mailer”), does not meet the statutory requirement of providing or initiating a sharps waste container and mail-back materials. The Foundation’s *2022 Annual Report* states that The Foundation “had difficulty identifying product placement” despite providing “outreach to Covered Entities informing them of the requirement to identify where their Covered Product is sold.” The Foundation reports 127 point of sale sites participating in its program and 15 counties where sharps waste containers and mail-back materials were distributed. Therefore, it is unclear if The Foundation is providing and initiating the distribution of a sharps waste container and mail-back materials for ultimate users at every point of sale when covered products under its program are sold pursuant to PRC section 42032.2(d)(1)(F)(i) and as described in its *Plan*. Separately, The Foundation’s statement that covered entities are “required” to identify where their covered products are sold is misleading, as this is not a requirement pursuant to the statute or regulations. Although The Foundation can collaborate with the covered entities participating in its program to obtain this information, it should not be conveyed as a statutory or regulatory requirement. Regardless, The Foundation is required to provide or initiate the distribution of sharps waste containers and mail-back materials for ultimate users at every point of sale when covered products under its program are sold. The Foundation must clarify what requirement it is referencing in the following statement: “The Foundation provided outreach to Covered Entities informing them of the requirement to identify where their Covered Product is sold,” on page 3 of the *2022 Annual Report* (see item (b) under Summary of Requirements Not Met).

Table 1. The Foundation Sharps Waste Container Distribution Metrics

	Distributed	“Received at Destruction”
Provided at Point of Sale	3,768	10
Initiated at Point of Sale	18	0
Website Requests	37	1
Toll Free Phone Number Requests	0	0
Total	3,823	11

Table 1 Description: The number of sharps waste containers distributed by method and the number of sharps waste containers received at destruction by method.

Pages 5 and 6 of The Foundation’s *2022 Annual Report* include tables that provide the amount of “Sharps Waste Containers” distributed by county, the amount distributed and returned, and the amount destroyed. One table states “Provided at [Point of Sale]” while another states “Distributed at [Point of Sale]” but the metric

(3,768) is the same. The amount of “Sharps Waste Containers” distributed by The Foundation to point of sale sites may be different than the amount of “Sharps Waste Containers” provided to ultimate users at the point of sale, pursuant to 14 CCR sections 18973.5(c)(2)(A) and 18973.3(f)(6). These tables utilize inconsistent terminology that makes it unclear if The Foundation is reporting the number of sharps waste containers and mail-back materials provided to ultimate users at the point of sale pursuant to 14 CCR section 18973.5(c)(2)(A).

The Foundation’s *2022 Annual Report* states that 11 sharps mail-back containers were received for destruction; 10 of which were distributed at the point of sale and one that was received from a website request. However, when describing the metrics The Foundation would use 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, its *Plan* states the “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.” Using the methodology provided in its *Plan*, staff would expect the number of sharps waste containers received for destruction to match the number of sharps waste containers that were distributed by each method. For example, 10 were received for destruction from distribution at the point of sale, therefore 10 were distributed at the point of sale, and one was received for destruction that was distributed from website requests, therefore one was distributed from website requests. Because The Foundation reported different numbers received for destruction than were distributed by method, The Foundation must describe the methodology it used to determine and report the number of sharps waste containers distributed and returned pursuant to 14 CCR section 18973.3(f)(6). The Foundation must provide metrics and a description of the methodology, consistent with The Foundation’s approved *Plan*, that The Foundation used to determine the amount of sharps waste containers and mail-back materials that were distributed to ultimate users and returned per county (see item (c) under Summary of Requirements Not Met).

Additionally, PRC section 42036.2(a) states that the statewide program does not apply to a sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018. Alameda County has a sharps ordinance that took effect prior to April 18, 2018, but is included in The Foundation’s metrics for the number of “Sharps Waste Containers distributed by county.” The Foundation must only report on its statewide home-generated sharps waste stewardship program implemented in accordance with CalRecycle’s approval of its *Plan*. Jurisdictions with local stewardship program ordinances that took effect before April 18, 2018, are not to be included.

See also “270 Day Full Program Implementation Deadline” section.

Summary 1 of Requirements Not Met: The following serves as written notice of the requirements that must be met should the Director choose to conditionally approve or disapprove The Foundation’s *2022 Annual Report* as indicated in the “Action” section below.

- a. Describe how The Foundation initiated the distribution of sharps waste containers on behalf of ultimate users at point of sale sites, which includes detail about The Foundation's ordering portal, pursuant to PRC section 42032.2(d)(1)(F)(i) and 14 CCR section 18973.3(f)(2).
- b. Clarify what requirement The Foundation is referencing in the following statement: "The Foundation provided outreach to Covered Entities informing them of the requirement to identify where their Covered Product is sold," on page 3 of the *2022 Annual Report*, pursuant to 14 CCR section 18973.1(a).
- c. Provide metrics and a description of the methodology, consistent with the approved *Plan*, The Foundation used to determine the amount of sharps waste containers and mail-back materials that were distributed to ultimate users and returned per county pursuant to 14 CCR sections 18973.5(c)(2), 18973.5(c)(3), and 18973.3(f)(6).

Education and Outreach

Requirements: Implement a comprehensive education and outreach program pursuant to PRC section 42031.6 and 14 CCR section 18973.3(i). A program operator shall not promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program pursuant to PRC section 42031.6(b) and 14 CCR section 18973.3(i)(7). A program operator shall fully implement operation of an approved stewardship program no later than 270 days after approval by the department of the stewardship plan that establishes the stewardship program, pursuant to PRC section 42032(g) and 14 CCR section 18973.1(m). Maintain an Internet Web site for purposes of providing information on the program, including disposal options, and to receive requests for sharps waste containers from ultimate users pursuant to PRC section 42032.2(d)(1)(E) and 14 CCR section 18973.3(i)(3). The annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirements Not Met

The Foundation's *2022 Annual Report* contains examples of its education and outreach materials. Additionally, The Foundation states "In accordance with PRC Section 42031.6(b), The Foundation ensured that all education and outreach material was consistent with services offered to Ultimate Users during the Reporting Period." However, staff's analysis of the education and outreach materials found that The Foundation's *2022 Annual Report*:

- Includes information that misrepresents the law by stating that CalRecycle is mandating the distribution of sharps waste containers at point of sale locations and that retailers or point of sale sites are required to offer, provide, or initiate distribution of sharps waste containers and mail-back materials at the point of sale (Figure 1, page 15 and Figure 2, page 16). The Foundation, as a program operator and through the implementation of its home-generated sharps waste stewardship program, is required to provide or initiate distribution of sharps waste containers and mail-back materials at the point of sale, to the extent allowable by law pursuant to PRC section 42032.2(d)(1)(F)(i) and 14 CCR section 18973.3(f)(2).

Separately, a pharmacy that sells covered products under its own brand name or a pharmacy that otherwise fits under the definition of covered entity is required to join a stewardship organization or develop and submit a stewardship plan to become a program operator. In the case of covered sharps, the requirement to provide or initiate the distribution of sharps waste containers and mail-back materials at the point of sale pursuant to PRC section 42032.2(d)(1)(F)(i) may apply to a pharmacy if the pharmacy is a covered entity and chooses to become a program operator. Therefore, because PRC section 42032.2(d)(1)(F)(i) applies to retailers only under certain circumstances, it is not accurate to make definitive statements that retailers and point of sale sites are required to provide or initiate the distribution of sharps waste containers and mail-back materials at the point of sale. Program operators are required to provide or initiate the distribution of sharps waste containers at the point of sale.

- Appears to promote “local take-back events” as a disposal option for home-generated sharps waste (Figure 3, pages 17 to 18). The Foundation did not report it hosted any collection events and The Foundation’s *Plan* did not identify any supplemental collection methods pursuant to 14 CCR section 18973.3(f)(5). Therefore, it appears The Foundation is promoting the disposal of covered products inconsistent with the services offered to ultimate users by the stewardship program.
- Includes the disclaimer, “This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of The Drug Takeback Solutions Foundation” (Figure 3, pages 17 to 18). Education and outreach materials must provide information about the program that is consistent with statute and regulations and with the services offered to ultimate users by the stewardship program. The Foundation does not describe what “views” it intends to communicate nor why the disclaimer is necessary.

Education and outreach materials must be consistent with requirements in statute, regulations, and The Foundation’s *Plan*. CalRecycle expects that education and outreach materials will not include statements that misrepresent the legal requirements and will promote the disposal of a covered product in a manner consistent with the services offered to ultimate users by the stewardship program pursuant to the requirements listed above.

Additionally, The Foundation states in its *Plan* that it will develop a website as part of implementation of its stewardship program with the URL “takebackfoundation.org.” The Foundation was required to fully implement its home-generated sharps waste stewardship program by November 11, 2022, pursuant to PRC section 42032(g) and 14 CCR section 18973.1(m). However, its internet website “takebackfoundation.org” was not available to the public until December 2022. Ultimate users were unable to utilize The Foundation’s internet website during this time to receive information on The Foundation’s home-generated sharps waste stewardship program, including disposal options, or request sharps waste containers.

Per the *Plan*, this website is required to, among other things, provide information on collection options for home-generated sharps waste, accept requests from ultimate users for sharps waste containers and mail-back materials, and clearly indicate what covered products are and are not accepted. As of April 2023, “Takebackfoundation.org” does not contain any information about The Foundation’s home-generated sharps waste stewardship program or provide a mechanism to accept requests for sharps waste containers and mail-back materials. This website links out to a different website (“safemedicinedrop.com”), which appears to be operated by Inmar Intelligence. The “safemedicinedrop.com” website appears focused on medication disposal, with the homepage having no reference to sharps and prompting the user to enter their zip code if they have unwanted medicine at home. The Foundation’s website did not operate as it is described in its *Plan* and as required in the statute and regulations.

270 Day Full Program Implementation Deadline

Requirements: A program operator shall fully implement operation of an approved stewardship program no later than 270 days after approval by the department of the stewardship plan that establishes the stewardship program pursuant to PRC section 42032(g) and 14 CCR section 18973.1(m). Coordinate with other program operators to avoid confusion to the public and all program participants pursuant to 14 CCR section 18973.3(j).

Analysis: Requirements Not Met

As described in the “Mail-Back Program” section above, The Foundation’s *Plan* states that point of sale locations will be equipped to provide **and** (emphasis added) initiate, based on ultimate user preferences, whereas its *2022 Annual Report* describes The Foundation providing options to point of sale locations to do either, and point of sale locations choosing to do one or the other. The Foundation failed to implement point of sale services as described in its *Plan* by the 270-day full program implementation deadline. Additionally, CalRecycle is concerned that limited number of point of sale locations, 127 point of sale locations in 15 counties, may indicate that providing or initiating is not occurring at every point of sale of covered sharps subject to The Foundation’s stewardship program.

Within the *2022 Annual Report*, The Foundation states that “due to the operational date of November 11, 2022, The Foundation was unable to coordinate with existing Program Operators during the Reporting Period.” The Foundation had 270 days from February 14, 2022, the date of conditional approval of its stewardship plan for home-generated sharps waste, to its 270-day full program implementation deadline on November 11, 2022, to coordinate with other program operators to avoid confusion to the public and all program participants, but failed to do so. The Foundation reported in the *2022 Annual Report* that the terms of coordination were agreed to on March 3, 2023.

The Foundation’s *Plan* includes an “Estimated Total Program Operating Budget” of \$3,407,000.00 for “FY 2022” but reports actual expenses of \$988,553.68 during the 2022 reporting period. It is unclear why The Foundation spent \$2.4 million less than

the amount budgeted in 2022. This may be a result of The Foundation not meeting several statutory, regulatory, and approved *Plan* requirements, therefore not incurring expenses associated with full implementation of the program.

Transportation and Disposal

Requirements: Describe the methods used to transport and dispose of consolidated home-generated sharps waste, including mechanism(s) used to track the collection, transportation, and disposal of home-generated sharps waste. For each disposal facility provide the name of facility, the mailing and physical address, and the total weight of material disposed pursuant to 14 CCR section 18973.5(d).

Analysis: Requirements Partially Met

The Foundation's *2022 Annual Report* states that it has a "serialization system in place that allows for the tracking of Sharps Waste Containers Mailers from initial shipment through destruction," and then refers to its *Plan* for additional information about its methods used to track the collection, transportation, and disposal of home-generated sharps waste. The *2022 Annual Report* lacks a description of those methods. Annual reports must contain all necessary information to meet the requirements pursuant to PRC sections 42033.2(a)(1) and 42033.2(b) and 14 CCR section 18973.5.

Attachment A: Service Providers and Weights includes a list of "Transporters and Disposal Facilities." The Foundation is required to provide the total weight of material disposed at each disposal facility, but weights are given for all service providers listed on *Attachment A: Service Providers and Weights*. The Foundation does not distinguish between service providers used for the transportation of home-generated sharps waste and those that are disposal facilities. It is unclear if corresponding weights of material disposed are zero due to the service provider not being a disposal facility, or if no material was disposed.

Summary 2 of Requirements Not Met: The following serves as written notice of the requirements that must be met should the Director choose to conditionally approve or disapprove The Foundation's *2022 Annual Report* as indicated in the "Action" section below.

- a. Include a description in the annual report about the methods used to transport and dispose of home-generated sharps waste, including a description of the mechanism(s) to track the collection, transportation, and disposal of home-generated sharps waste pursuant to 14 CCR section 18973.5(d)(1).
- b. Include the total weight of material disposed for each disposal facility, distinguishing between service providers used for the transportation of home-generated sharps waste and those that are disposal facilities pursuant to 14 CCR section 18973.5(d)(3)(C).

Mailing and Physical Addresses

Requirement: Provide a list of participating covered entities covered by the stewardship plan and their contact information, including, but not limited to, mailing and physical address pursuant to PRC section 42033.2(b)(1) and 14 CCR section 18973.5(j)(2).

Analysis: Requirement Partially Met

The Foundation provides one address for each covered entity, with the exception of specifying mailing and physical addresses for Global Diabetic Distributors, Inc., in its *2022 Annual Report*.

Summary 3 of Requirement Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove The Foundation's *2022 Annual Report* as indicated in the "Action" section below.

- a. Include all mailing and physical addresses associated with each covered entity pursuant to 14 CCR section 18973.5(j)(2).

Document Submittals

Requirement: Submit a written report describing the stewardship program activities during the previous reporting period of one year pursuant to PRC section 42033.2(a)(1) and 14 CCR section 18973.5. An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirement Partially Met

The Foundation was required to submit a written report describing its stewardship program for home-generated sharps waste activities during the previous reporting period of one year (i.e., January 1, 2022, through December 31, 2022). However, The Foundation's *2022 Annual Report* states that its "reporting period" is from February 16, 2022, through December 31, 2022. The Foundation must utilize correct terminology from statute and regulations when referring to its reporting period, even if its annual report only includes activities from the date of conditional approval through the end of the year in 2022.

There are several other instances where The Foundation utilizes incorrect and inconsistent terminology and dates throughout its *2022 Annual Report*. For example, The Foundation's *2022 Annual Report* states that February 16, 2022, is the conditional approval date of its stewardship plan for home-generated sharps waste. February 14, 2022, is the actual date that CalRecycle conditionally approved The Foundation's stewardship plan for home-generated sharps waste. The Foundation also states that its "operational dates" begin on November 13, 2022. Page 11 of the *2022 Annual Report* mentions the date November 11, 2022, which reflects the accurate date of the 270-day full program implementation deadline for The Foundation's home-generated sharps waste stewardship program. The Foundation describes activities that occurred "prior to the program initiation date," but does not define "program initiation" or specify what date this refers to.

Additionally, page 5 of The Foundation's *2022 Annual Report* has a table titled "Sharps Distributed by County" that lists the amount of "Sharps Waste Containers distributed by county." The Foundation's description of the table and the title of the table are inconsistent, making it unclear if the table includes metrics for sharps or sharps waste containers. On page 3 of its *2022 Annual Report*, The Foundation refers to the distribution of "Sharps Waste Containers," which, as defined in its *Plan*,

does not include a prepaid, pre-addressed label for shipping the sharps waste container filled with home-generated sharps waste (defined as “Mailer” in its *Plan*). Also, on page 3 of its *2022 Annual Report*, The Foundation states that ultimate users were able to receive and order “Mail-Back Units” (defined in The Foundation’s *Plan* as a combination of a “Sharps Waste Container” and “Mailer”). Due to The Foundation’s inconsistent use of terminology in its *2022 Annual Report*, it is unclear if ultimate users are receiving “Mail-Back Units” or if ultimate users are only receiving “Sharps Waste Containers.” Page 7 of the *2022 Annual Report* describes The Foundation’s process for “tracking of Sharps Waste Containers Mailers,” but “Sharps Waste Containers Mailers” is not a defined term.

In addition to the statements that misrepresent the legal requirements made by The Foundation mentioned in the “Education and Outreach” section of this Request for Action, The Foundation refers to an “obligation” for point of sale sites and covered entities to participate in The Foundation’s program on page 2 of its *2022 Annual Report*. This statement made by The Foundation does not refer to requirements pursuant to the statute or regulations.

Summary 4 of Requirement Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove The Foundation’s *2022 Annual Report* as indicated in the “Action” section below.

- a. Utilize correct and consistent terminology and dates within the annual report pursuant to 14 CCR section 18973(d).

Feedback from Interested Parties

CalRecycle solicited public input on The Foundation’s *2022 Annual Report* from April 4, 2023, through April 18, 2023, and did not receive any public comments.

Action

Pursuant to PRC section 42033.2(e) and 14 CCR section 18973.1, I hereby:

- Approve The Foundation’s *2022 Annual Report*.
- Conditionally approve The Foundation’s *2022 Annual Report*. Pursuant to 14 CCR section 18973.1(j), The Foundation must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date this Request for Action notice is issued that includes the additional information specified in “Summary 1 of Requirements Not Met” through “Summary 4 of Requirement Not Met” in the “Staff Analysis” section above.
- Disapprove The Foundation’s *2022 Annual Report*. Pursuant to 14 CCR section 18973.1(k), The Foundation must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date this Request for Action notice is issued that includes the additional information specified in “Summary 1 of Requirements Not Met” through “Summary 4 of Requirement Not Met” in the “Staff Analysis” section above.
- Disapprove The Foundation’s *2022 Annual Report* and refer The Foundation to CalRecycle’s Waste Permitting, Compliance, and Mitigation Division for potential enforcement. Pursuant to 14 CCR section 18973.1(k), The Foundation must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date this Request for Action notice is issued that includes the additional information specified in “Summary

1 of Requirements Not Met” through “Summary 4 of Requirement Not Met” in the “Staff Analysis” section above.

Signed by: Rachel Machi Wagoner, Director

Dated: June 21, 2023

Attachments:

Documents listed below are posted to CalRecycle’s website.

1. [*The Drug Takeback Solutions Foundation State of California Home-Generated Sharps Waste 2022 Annual Report*](#) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123372>
 - a. [Attachment A – Service Providers and Weights](#)
<https://www2.calrecycle.ca.gov/Docs/Web/123378>
 - b. [Attachment B – Participating Covered Entities and Covered Products](#)
<https://www2.calrecycle.ca.gov/Docs/Web/123384>
2. [*Stewardship Plan for Home-Generated Sharps Waste*](#) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122409>
 - a. [Appendix A – Program Budget](#) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122421>
 - b. [Appendix B – Participating Covered Entities](#) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122418>
 - c. [Appendix C – Service Providers](#) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122415>
 - d. [Appendix D – Sharps Sold or Offered for Sale in California by Participating Covered Entities](#) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122412>