

REQUEST FOR ACTION

To: Zoe Heller
Director

From: Clark Williams
Branch Chief, Statewide Technical and Analytical Resources
Branch

Request Date: June 25, 2024

Decision Subject: Consideration of The Drug Takeback Solutions Foundation's 2023 Annual Report for Home-Generated Sharps Waste

Action By: June 27, 2024

Summary of Request

The Drug Takeback Solutions Foundation (The Foundation) submitted its 2023 annual report, titled, *The Drug Takeback Solutions Foundation State of California Home-Generated Sharps Waste 2023 Annual Report (2023 Annual Report)* on March 29, 2024. This Request for Action presents a summary of staff's analysis regarding The Foundation's *2023 Annual Report* and The Foundation's home-generated sharps waste stewardship program.

Background

Public Resources Code (PRC) section 42033.2(a)(1) states that, on or before March 31, 2022, and each year thereafter, a program operator shall submit to The Department of Resources Recycling and Recovery (CalRecycle) a report that describes the stewardship program activities during the previous reporting period of one year. The Foundation is a stewardship organization that, as reported in its *2023 Annual Report*, represents 23 covered entities under its approved stewardship plan for home-generated sharps waste, titled, *Stewardship Plan for Home-Generated Sharps Waste (Plan)*. The Foundation's *2023 Annual Report* is required to cover the entire calendar year of 2023 (January 1, 2023, through December 31, 2023).

The Foundation submitted its *2023 Annual Report* on March 29, 2024. CalRecycle determined the *2023 Annual Report* was complete and notified The Foundation on April 29, 2024, pursuant to PRC section 42033.2(d)(1) and Title 14 of the California Code of Regulations (14 CCR) section 18973.1(b). CalRecycle has 90 days to approve, disapprove, or conditionally approve the *2023 Annual Report* pursuant to PRC section 42033.2(d)(2) and 14 CCR section 18973.1.

Staff Analysis

The Foundation states in its *2023 Annual Report* that it conducted program activities including:

- Continued to implement its approved *Plan*.
- Enrolled 203 "Point of Sale Locations," in its program, defined as "the Pharmacy, Retail Pharmacy, or other retailer including but not limited to an online retailer

that provides for the purchase or distribution of Sharps” in The Foundation’s *Plan* (point of sale locations).

- Distributed 32,088 sharps waste containers.
- Conducted outreach to point of sale locations that included telephone calls, emails, letters, and in-person visits.
- Conducted education and outreach to the public through programmatic advertising, influencer programs, direct mail campaigns, newspaper advertisements, targeted media, and digital out-of-home advertisements.
- Researched organizations that work with underserved and homeless communities and household hazardous waste facilities to educate about disposal options.
- Coordinated with the other program operator to initiate the jointly operated toll-free number and neutrally branded website.
- Completed surveys to measure public awareness and use of the program.
- Destroyed 3,180.97 pounds of home-generated sharps waste through the return of 2,196 sharps waste containers and mail-back materials by ultimate users.
- Reimbursed local agencies \$12,639 for the collection and destruction of 5,095 pounds of home-generated sharps waste.

The Foundation reported receiving feedback from point of sale locations who declined to participate in the program that, “they are not required to participate, do not have space to store Mail-Back Units, and have concerns regarding personnel constraints related to initiating the ordering of Mail-Back Units for Ultimate Users.”

Staff evaluated The Foundation’s *2023 Annual Report* to determine whether the requirements of statute, regulations, and The Foundation’s *Plan* were met. Overall, The Foundation reports improvements undertaken during the reporting period to address the statutory, regulatory, and *Plan* requirements, as well as the requirements CalRecycle identified in the Request for Action, titled, *Consideration of The Drug Takeback Solutions Foundation’s Revised 2022 Annual Report for Home-Generated Sharps Waste*. The sections below present a summary of staff’s analysis of The Foundation’s *2023 Annual Report* and select components of its home-generated sharps waste stewardship program, including components 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). Describe how ultimate users had an opportunity to dispose of their home-generated sharps waste as described in the approved stewardship plan, pursuant to 14 CCR section 18973.5(c)(1). Include a concise summary of the information contained in the report that includes, but is not limited to, the highlights, outcomes and challenges, education and outreach efforts, and ways in which challenges are being addressed, pursuant to 14 CCR section 18973.5(b). Include how the program operator complied with all elements in its stewardship plan pursuant to PRC section 42033.2(b)(8).

Include any other information the department reasonably requires, pursuant to 42033.2(b)(9). 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

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 *2023 Annual Report* describes how ultimate users and point of sale locations were able to request sharps waste containers and mail-back materials through The Foundation's website and toll-free number until the jointly operated, neutrally branded website and toll-free number became operational on October 26, 2023. See the "Education and Outreach" section for an analysis of The Foundation's website.

In addition to the list above, The Foundation's *Plan* includes details about how point of sale locations will initiate the distribution of the "Mail-Back Units" to ultimate users by "distributing the Mail-Back Unit(s) to the Ultimate User at the Point of Sale" and "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 *2023 Annual Report* states 203 point of sale locations were able to provide sharps waste containers and mail-back materials to ultimate users but does not include a number for how many point of sale locations were able to initiate the distribution of sharps waste containers and mail-back materials to ultimate users. Because The Foundation did not report the number of point of sale locations initiating the distribution of sharps waste containers and mail-back materials at the point of sale, it is unclear where providing and initiating are occurring. Specifically, it is unclear whether The Foundation is providing and initiating the distribution of a sharps waste container and mail-back materials according to ultimate user preferences, at every point of sale when products covered under its plan are sold, pursuant to PRC section 42032.2(d)(1)(F)(i) and as described in its *Plan*.

Additionally, the *2023 Annual Report* describes how point of sale locations use "an ordering mechanism via the neutrally branded website, [www.sharpstakebackcalifor\[n\]ja.org](http://www.sharpstakebackcalifor[n]ja.org), whereby Point of Sale locations order Mail-

Back Units on behalf of Ultimate Users that are shipped to arrive within 5 business days.” However, the *Plan* describes how “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.” From the context of The Foundation’s *Plan*, it is clear that “Service Provider” means the Foundation’s Service Provider. According to The Foundation’s *Plan*, the portal provided to the point of sale location can only lead to service from The Foundation’s Service Providers. Therefore, to satisfy its *Plan* obligations, The Foundation can only provide point of sale locations with its portal and not the portal of another program operator. Regarding the neutrally branded website (“www.sharpstakebackcalifornia.org”), The Foundation describes how “The Foundation and the other Program Operator will each distribute 50[percent] of the Mailers via a rotating button that directs Ultimate Users to each Program Operator every other time.” Providing point of sale locations with a link to the neutrally branded website instead of “an ordering portal that will allow them to request Mail-Back Unit(s) directly from the Service Provider” is not consistent with The Foundation’s *Plan*, which contemplates providing point of sale locations with The Foundation’s portal exclusively.

The Foundation did not fulfill its obligation to initiate the 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), in instances where a point of sale location was redirected to “the other Program Operator” (MED-Project). Redirection to MED-Project led to the provision of services that did not use The Foundation’s Service Providers without any certainty that the unique commitments made by The Foundation in its *Plan* would be carried out (e.g., the opportunity to order “Mail-Back Units in quantities of three per form submission” from The Foundation, as described in the *2023 Annual Report*). Furthermore, it is unclear how The Foundation obtained an accurate count of how many sharps waste containers and mail-back materials were initiated at the point of sale when its point of sale locations were directed to MED-Project. See the “Metrics” section below for further analysis of The Foundation’s reported metrics.

Metrics

Requirements: Report the amount of sharps waste containers and mail-back materials distributed per county, through website requests and toll-free telephone number requests, pursuant to 14 CCR section 18973.5(c)(2)(C) and (D). Report the amount of home-generated sharps waste returned through the mail-back program pursuant to 14 CCR section 18973.5(c)(3). For each local agency that has requested removal or reimbursement, pursuant to the requirements in subsection (1)(F)(ii) of subdivision (d) of section 42032.2 of the PRC, provide details including, but not limited to: facility location, reimbursement payment amount, as applicable, and the amount of home-generated sharps waste collected, as required in the stewardship plan pursuant to 14 CCR section 18973.3(f)(8), pursuant to 14 CCR section 18973.5(p)(2).

Analysis: Requirements Met

According to The Foundation’s *2023 Annual Report*, 20,749 sharps waste containers and mail-back materials were provided to point of sale locations or initiated at point of sale (see Table 1); 20,472 were “Mail-Back Units” provided to point of sale locations to distribute to ultimate users and 277 were “Mail-Back Units” initiated at point of sale. Additionally, a total of 11,339 “Mail-Back Units” were distributed via the website and call center (see Table 1). A total of 2,196 “Mail-Back Units” were returned through The Foundation’s program, equating to 3,180.97 pounds of home-generated sharps waste. The Foundation also provided a total of \$12,639.00 in reimbursements to local agencies with a corresponding weight of 5,095 pounds of home-generated sharps waste destroyed (see Table 2).

Table 1. The Foundation “Mail-Back Unit” Metrics

Method of Distribution	Number of Mail-Back Units
Provided to point of sale locations	20,472
Provided at point of sale	Not Reported
Initiated at point of sale	277
Website	10,817
Call Center	522
Total	32,088

Table 1 Description: The Foundation’s metrics for sharps waste containers and mail-back materials provided to point of sale locations and initiated at point of sale and distributed to ultimate users through website and call center requests.

Table 2. The Foundation Local Agency Reimbursement Metrics

Metric	Amount
Local Agency Reimbursement Requests	15
Local Agencies Reimbursed	3
Total Reimbursed to Local Agencies	\$12,639.00
Home-generated sharps waste collected (in pounds)	5,095

Table 2 Description: The Foundation’s metrics regarding reimbursement requests from local agencies and home-generated sharps waste collected.

Requirements: Report the amount of sharps waste containers and mail-back materials distributed per county, provided at point of sale and initiated at point of sale, pursuant to 14 CCR section 18973.5(c)(2)(A) and (B). 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

As shown in Table 1 above, The Foundation did not report metrics regarding the amount of sharps waste containers and mail-back materials provided to ultimate users at the point of sale in its *2023 Annual Report*.

As described in the “Mail-Back Program” section above, it is unclear how The Foundation obtained an accurate count of how many sharps waste containers and mail-back materials were initiated at the point of sale in instances when its point of sale locations were directed to MED-Project.

Education and Outreach

Requirements: Describe and evaluate the comprehensive education and outreach activities pursuant to 14 CCR section 18973.3(i), including, but not limited to, numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.3(i)(5). Discuss what the metrics, described in 14 CCR section 18973.5(i)(2), reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility, pursuant to 14 CCR section 18973.5(i)(2) and (3). The annual report shall be complete and correct pursuant to 14 CCR section 18973(d). 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). 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).

Analysis: Requirements Not Met

The *2023 Annual Report* describes how The Foundation provided education and outreach materials to point of sale locations participating in its program, persons authorized to prescribe drugs, hospitals, pharmacies, pharmacists, and ultimate users. The Foundation utilized internet advertisements, influencer marketing on social media, direct mail campaigns, newspaper advertisements, audio advertisements, and digital billboard advertisements. Across all methods of advertising, The Foundation reports receiving a total of 6,740,974 impressions. Additionally, The Foundation describes analyzing its marketing data to “identify the location of low volume Mail-Back Unit requests” and using the results to identify and target outreach efforts to rural and historically underserved areas.

Page 29 of the *Plan* states that The Foundation will “conduct an annual survey of Covered Entities, pharmacists, and healthcare professionals in the state of California who interact with Ultimate Users” and provide the following data points from its survey:

- 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.

However, The Foundation's *2023 Annual Report* includes survey results of 500 healthcare providers. It is unclear if covered entities and pharmacists were included in the survey, as described in The Foundation's *Plan*. The Foundation's survey of healthcare providers revealed the following: 67 percent of healthcare providers stated they were aware of the program for ultimate users, 61 percent stated they were exposed to the program, and 75 percent stated that the program is convenient. The Foundation did not include the method of contact for the survey, the percentage of respondents that have used the program, and which collection method was used. The results of the survey also state that "73[percent] stated that they would be likely to ask their patients to utilize a drop-off box to discard their unwanted needles or sharps." It is unclear what The Foundation means when referencing a "drop-off box" since its statewide program for home-generated sharps waste is a mail-back program.

The Foundation also indicates that it conducted a survey of 1,000 residents "using the same questions as those surveys sent to providers," but did not include the results in its *2023 Annual Report* or explain how the question regarding asking *patients* (emphasis added) to utilize a "drop-off box" applies to residents.

The *2023 Annual Report* includes sample education and outreach materials that include the neutrally branded website ("sharpstakebackcalifornia.org") that went live on October 26, 2023, and screenshots from an "Inmar Intelligence" webpage. Page 31 includes a picture of a webpage listed as "The Foundation's individual website homepage," that appears to prompt the user to enter their zip code in response to the question "Unwanted medication at home?" The Foundation's *Plan* states that its website will "provide information on collection options for Home-Generated Sharps Waste." It is unclear how the question pertaining to "unwanted medication" applies to ultimate users seeking disposal options for home-generated sharps waste and how an ultimate user would navigate to the "ordering page" that is pictured on page 31 of the *2023 Annual Report*. Therefore, the *2023 Annual Report* does not indicate that The Foundation operated a website as described in its *Plan* and as required in the statute and regulations.

Service Providers

Requirements: Provide a description and evaluation of the process for selecting service providers, if applicable, pursuant to 14 CCR section 18973.5(*l*). An annual report shall be complete and correct pursuant to 14 CCR section 18973(*d*).

Analysis: Requirements Not Met

On page 13, The Foundation states that it "has not added or changed any service providers for the Reporting Period." However, page 6 states that "The Foundation was notified by their Service Provider that one additional disposal facility, Covanta - Hayward / Biologic Environmental Services & Waste Solutions, was used to treat waste during the Reporting Period." This disposal facility is listed as "Destruction"

under “Service Provider” in *Attachment A: Service Providers and Disposal Facilities*. Therefore, it is unclear whether The Foundation added or changed any service providers in 2023. Additionally, The Foundation did not include a description and evaluation of its process for selecting the additional service provider used. Throughout the *2023 Annual Report*, The Foundation refers to “Service Provider,” as defined in its *Plan*, and “service provider,” which creates confusion about which service provider The Foundation is referencing. See the “Document Submittals” section for further analysis of this terminology.

Reimbursement and Removal Requests

Requirement: Describe 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 pursuant to 14 CCR section 18973.3(g)(1). Describe any grants, loans, sponsorships, reimbursements, or other incentives provided, as applicable, pursuant to 14 CCR section 18973.5(m). An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirements Not Met

The Foundation is required to, upon request, provide reimbursement for transportation and disposal costs of home-generated sharps waste, or removal of home-generated sharps waste to local agencies pursuant to 14 CCR section 18973.3(g)(1) and its *Plan*. The Foundation’s *2023 Annual Report* mentions providing reimbursement for “destruction” costs and does not specify if it includes “transportation and disposal” costs. Therefore, it is unclear if The Foundation provided local agencies reimbursement for costs associated with transportation and disposal, as required. Page 19 of The Foundation’s *Plan* describes “selecting either reimbursement or removal from the household hazardous waste facility” in response to a local agency request. However, the *2023 Annual Report* does not describe if removal was provided or if it is still an option being considered by The Foundation, as described in its *Plan*.

On page 13 of the *2023 Annual Report*, The Foundation states that “There were no grants, loans, sponsorships, reimbursements, or other incentives provided during the Reporting Period,” but describes receiving 15 requests from local agencies and providing a total of \$12,639.00 in reimbursements on pages 15 and 16.

Actual Expenses for Departmental Administrative Fees

Requirement: Provide a list of all actual expenses incurred during the previous reporting period of one year pursuant to 14 CCR section 18973.5(q) that summarizes expenses in accordance with the budget categories specified in 14 CCR section 18973.6(b). 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

The Foundation lists \$0 in departmental administrative fees under its actual expenses in 2023. However, according to CalRecycle's records, The Foundation paid a total of \$551,352.56 for invoices regarding departmental administrative fees in 2023.

Document Submittals

Requirement: An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirement Not Met

There are several instances where The Foundation utilizes inconsistent terminology and statements throughout its *2023 Annual Report*. As described in the "Reimbursement and Removal Requests" section above, on page 13 of the *2023 Annual Report*, The Foundation states that "There were no grants, loans, sponsorships, reimbursements, or other incentives provided during the Reporting Period," but describes receiving 15 requests from local agencies and providing a total of \$12,639.00 in reimbursements on pages 15 and 16. Additionally, as described in the "Service Providers" section above, The Foundation utilizes inconsistent terminology regarding "Service Provider," as defined in its *Plan*, and "service provider" throughout its *2023 Annual Report*.

CalRecycle Compliance and Inspection Activities

As part of the Pharmaceutical and Sharps Waste Stewardship Act, CalRecycle provides statewide compliance and enforcement oversight for regulated entities including, but not limited to pharmaceutical manufacturers, distributors, importers, pharmaceutical retail locations, and the stewardship organizations.

In 2023, CalRecycle staff conducted 179 inspections at sharps retailers to evaluate retailer compliance with the Pharmaceutical and Sharps Waste Stewardship Act. Sharps retailers are required to monitor CalRecycle's website and notify CalRecycle of any products not listed on the website. Of the 179 retailers inspected, 137 (77 percent) were noncompliant at the time of the inspection. However, within 60 days, all violations were corrected.

Feedback from Interested Parties

CalRecycle solicited public input on The Foundation's *2023 Annual Report* from April 3, 2024, through April 16, 2024, and received comment letters from Anne Vogel-Marr, Executive Director of the Pharmaceutical Product Stewardship Work Group, and Dr. Victoria Travis, National Program Director of MED-Project USA. CalRecycle considered these comments when reviewing The Foundation's *2023 Annual Report*.

Action

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

- Approve The Foundation's *2023 Annual Report*.
- Conditionally approve The Foundation's *2023 Annual Report*. Direct staff to identify the conditions to be met for approval and provide written notice to The Foundation within 30 days of signature of this Request for Action, pursuant to 14 CCR section 18973.1(j).

Disapprove The Foundation's 2023 Annual Report. Direct staff to identify how the 2023 Annual Report does not comply and provide written notice to The Foundation within 30 days of signature of this Request for Action, pursuant to 14 CCR section 18973.1(k).

I disapprove The Foundation's 2023 Annual Report on the bases of the information reported by The Foundation and information and analysis contained in this Request for Action. The Foundation's 2023 Annual Report is not substantially compliant because it does not demonstrate that their stewardship program provides adequate access to safe disposal of home-generated sharps waste to the ultimate user. In addition to omissions and inconsistencies articulated in the analysis, The Foundation's 2023 Annual Report fails to demonstrate it is operating its program to provide and initiate the distribution of sharps waste containers and mail-back materials at the point of sale pursuant to statute and its approved Plan.

Signed by:

Zoe Heller
Director

Dated: June 27, 2024

Attachments:

Documents listed below are posted to CalRecycle's website.

1. [The Drug Takeback Solutions Foundation State of California Home-Generated Sharps Waste 2023 Annual Report](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15694>
 - a. [Attachment A – Service Providers and Weights](#)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15695>
 - b. [Attachment B – Participating Covered Entities and Covered Products](#)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15696>
 - c. [Attachment C – Mail-Back Unit Distribution by County](#)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15697>
 - d. [Attachment D – State Agency Determinations](#)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15698>
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>
3. [Consideration of The Drug Takeback Solutions Foundation's Revised 2022 Annual Report for Home-Generated Sharps Waste](#) (November 17, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/126243>