

REQUEST FOR ACTION

To: Rachel Machi Wagoner
Director

From: Zoe Heller
Deputy Director, Division of Circular Economy

Mark de Bie
Deputy Director, Waste Permitting, Compliance, and Mitigation
Division

Request Date: November 9, 2023

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

Action By: November 20, 2023

Summary of Request

The Drug Takeback Solutions Foundation (The Foundation) submitted its revised 2022 annual report, titled, *The Drug Takeback Solutions Foundation State of California Home-Generated Sharps Waste 2022 Annual Report (Revised 2022 Annual Report)* on August 21, 2023. This Request for Action presents a summary of staff's analysis regarding The Foundation's *Revised 2022 Annual Report* and The Foundation's home-generated sharps waste stewardship program.

Background

The Foundation is a stewardship organization that, as reported in its *Revised 2022 Annual Report*, 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 *Revised 2022 Annual Report* covers the entire 2022 calendar year (January 1, 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, titled, *The Drug Takeback Solutions Foundation State of California Home-Generated Sharps Waste 2022 Annual Report (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). On June 21, 2023, CalRecycle disapproved The Foundation's *2022 Annual Report* and referred The Foundation to CalRecycle's Waste Permitting, Compliance, and Mitigation Division (WPCMD) for potential enforcement in the Request for Action (RFA), titled, *Consideration of The Drug Takeback Solutions Foundation's 2022 Annual Report for Home-Generated Sharps*

Waste (June 2023 RFA). On August 11, 2023, in response to the referral, WPCMD issued The Foundation a Notice of Violation (NOV). The NOV provided written notice of noncompliance and that CalRecycle may commence an enforcement action against The Foundation for continued noncompliance with the Pharmaceutical and Sharps Waste Stewardship Law. The Foundation was required to revise and resubmit its 2022 annual report to CalRecycle within 60 days 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 of the *June 2023 RFA*. On August 21, 2023, The Foundation submitted its *Revised 2022 Annual Report*, which is the subject of this RFA. CalRecycle has 90 days to approve, disapprove, or conditionally approve the *Revised 2022 Annual Report* pursuant to PRC section 42033.2(d)(2) and 14 CCR section 18973.1.

Staff Analysis

Staff evaluated The Foundation’s *Revised 2022 Annual Report* to determine whether the requirements of statute, regulations, and The Foundation’s *Plan* were met, as directed in “Summary 1 of Requirements Not Met” through “Summary 4 of Requirement Not Met” in the “Staff Analysis” section of the *June 2023 RFA*. The sections below present a summary of staff’s analysis of The Foundation’s *Revised 2022 Annual Report* and The Foundation’s home-generated sharps waste stewardship program.

Additionally, this RFA provides a status of CalRecycle’s enforcement action.

June 2023 RFA Summary 1 of Requirements Not Met

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to PRC section 42032.2(d)(1)(F)(i) and 14 CCR sections 18973.3(f)(2), 18973.1(a), 18973.5(c)(2), 18973.5(c)(3), and 18973.3(f)(6).

- 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).

Analysis: Requirements (a) and (b) Met, Requirement (c) Not Met

The Foundation’s *2022 Annual Report* 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’s *Revised 2022 Annual Report* includes details about an ordering system that allows point of sale sites to order sharps waste containers and mail-back materials in bulk and on behalf of the ultimate user. Therefore, The Foundation met requirement (a).

The Foundation’s *2022 Annual Report* included a statement that covered entities were “required” to identify where their covered products are sold, which is misleading, as this is not a requirement pursuant to the statute or regulations. The Foundation provided clarification in its *Revised 2022 Annual Report* that covered entities were “encouraged” to identify where their covered products are sold. Therefore, The Foundation met requirement (b). However, it is unclear if The Foundation communicated to its covered entities in 2022 that covered entities are “required” or were “encouraged” to identify where their covered products are sold. CalRecycle expects that messaging between The Foundation and its covered entities is consistent with requirements from statute, regulations, and its approved plan. See the “Document Submittal” section below.

The Foundation’s *Revised 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 (See Table 1 below). The Foundation described that it used the methodology from its *Plan* to determine these metrics. The Foundation’s *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.” Because The Foundation did not provide metrics for the amount of sharps waste containers and mail-back materials provided at the point of sale, The Foundation did not meet requirement (c). CalRecycle expects that The Foundation will collect metrics for sharps waste containers and mail-back materials provided at the point of sale to ultimate users per county and report the metrics in subsequent annual reports, pursuant to 14 CCR section 18973.5(c)(2).

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

	Distributed	Received at Destruction
Provided to Point of Sale	3,672	10
Provided at Point of Sale	Unknown	10
Initiated at Point of Sale	15	0
Website Requests	36	1
Toll Free Phone Number Requests	0	0
Total	3,723	11

Table 1 Description: The number of “Mail-Back Units” distributed by method and the number of “Mail-Back Units” received at destruction by method.

June 2023 RFA Summary 2 of Requirements Not Met

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR sections 18973.5(d)(1) and 18973.5(d)(3)(C):

- 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).

Analysis: Requirements (a) and (b) Met

The *2022 Annual Report* lacked a description of The Foundation's tracking methods for home-generated sharps waste. The *2022 Revised Annual Report* includes a description of how The Foundation tracks sharps waste containers and mail-back materials from the initial request by an ultimate user through destruction. The Foundation's *2022 Revised Annual Report* states that its service provider records and tracks several items for each "Mail-Back Unit," including the date received, serialized barcode label information, USPS shipping tracking number, weight and date transported to disposal facility, disposal date, and manifest number (if applicable). Therefore, The Foundation met requirement (a).

The *Revised 2022 Annual Report* includes *Attachment A: Service Providers and Weights* that includes the required information for total weights of material disposed for each disposal facility. Therefore, The Foundation met requirement (b).

June 2023 RFA Summary 3 of Requirement Not Met

Requirement: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR section 18973.5(j)(2).

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

Analysis: Requirement (a) Not 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 *Revised 2022 Annual Report*. The list of covered entities and covered products in its *Revised 2022 Annual Report* appears to be the same document that was initially included in its *2022 Annual Report*. Therefore, The Foundation did not meet requirement (a).

Summary 1.1 of Requirement 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 *Revised 2022 Annual Report* and require resubmittal, 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).

June 2023 RFA Summary 4 of Requirement Not Met

Requirement: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR section 18973(d):

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

Analysis: Requirement (a) Not Met

The Foundation's *Revised 2022 Annual Report* includes a reporting period for the entire 2022 calendar year (January 1, 2022, through December 31, 2022). The reporting period is consistent with statute and regulations.

Page 5 of The Foundation's *2022 Annual Report* included a table titled "Sharps Distributed by County" that listed the amount of "Sharps Waste Containers distributed by county." The Foundation's *Revised 2022 Annual Report* includes a similar table titled "Mail-Back Units Distributed by County," making it clear that the metrics reflect sharps waste containers and mail-back materials, not sharps. Throughout its *Revised 2022 Annual Report*, The Foundation clarified 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").

The Foundation's *Revised 2022 Annual Report* clarifies that the date CalRecycle conditionally approved its sharps stewardship plan is February 14, 2022. Other sections of the *Revised 2022 Annual Report* reference 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. However, page 2 of the *Revised 2022 Annual Report* states that the "Plan became fully operational on November 11, 2023," making it unclear when The Foundation's program was fully implemented. Additionally, 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. Therefore, The Foundation did not meet requirement (a).

Summary 2.1 of Requirement 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 *Revised 2022 Annual Report* and require resubmittal, 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).

Additional Requirements Not Met

In addition to the above analysis and evaluation of the "Summary 1 of Requirements Not Met" through "Summary 4 of Requirement Not Met" in the "Staff Analysis" section of the *June 2023 RFA*, staff identified new instances of requirements not met that were not present in The Foundation's *2022 Annual Report*.

Requirements: The annual report is required to be in compliance with section 7405 of the Government Code, and the Web Content Accessibility Guidelines 2.0 published in 2008 by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level AA success criteria to allow for posting on the department's website pursuant to 14 CCR section 18973(a).

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

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

The Foundation's *Revised 2022 Annual Report* contains multiple accessibility errors.

The Foundation included certification statements signed by Chris Smith in its *2022 Annual Report* and *Revised 2022 Annual Report* that declare the information provided in each document is "true and correct." However, there are several instances where CalRecycle identified unmet requirements and The Foundation adjusted the narrative and information in its *Revised 2022 Annual Report* from what was initially provided in its *2022 Annual Report*. The two annual report submissions contradict one another and make it impossible for all statements in both annual reports to be true and correct. Thus, The Foundation's annual reports were not correct, and The Foundation failed to meet the requirement in 14 CCR section 18973(d). Moreover, The Foundation has falsely certified, in at least one of the annual reports, that all information provided in each annual report was true and correct, per 14 CCR section 18973(e). Examples include the following:

- As referenced in the "*June 2023 RFA Summary 1 of Requirements Not Met*" section above, The Foundation adjusted the narrative of what it communicated to its covered entities, so one of the annual reports is not "true and correct."
- Within the *2022 Annual Report*, The Foundation stated that "due to the operational date of November 11, 2022, The Foundation was unable to coordinate with existing Program Operators during the Reporting Period." However, The Foundation's *Revised 2022 Annual Report* provides a new reason for why it was unable to coordinate by stating "The other Program Operator chose to delay the collaboration until the Foundation received full approval from CalRecycle." It is unclear if this information is "true and correct" based on CalRecycle's understanding of coordination between program operators. Regardless, 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's *2022 Annual Report* contained a frequently asked questions page for "Point of Sale Locations" (Figure 1, page 15 and Figure 2, page 16) that misrepresented 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. The Foundation omitted the frequently asked questions sheet in its *Revised 2022 Annual Report*, so one of the annual reports is not "true and correct" and it is unclear whether The Foundation distributed this information to point of sale sites in 2022.
- The Foundation's *2022 Annual Report* included a statement that misrepresented legal requirements by referring to an "obligation" for point of sale sites and covered entities to participate in The Foundation's program. The Foundation removed reference to "obligation" in its *Revised 2022 Annual Report* and instead states "The Foundation worked with Pharmacies and other Point of Sale Locations, encouraging them to participate in the program and providing educational materials on program requirements." One of the annual reports is not "true and correct" and it is unclear if The Foundation communicated to point of sale sites and covered entities in 2022 that they are obligated to participate in The Foundation's program.
- The Foundation's *2022 Annual Report* also included example education and outreach materials (Figure 3, pages 17 to 18) that appeared to promote "local take-back events" as a disposal option for home-generated sharps waste. 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 promoted the disposal of covered products inconsistent with the services offered to ultimate users by the stewardship program. The Foundation edited its educational brochure (Figure 1, pages 16 to 17) to remove reference to "local take-back events" in its *Revised 2022 Annual Report*. One of the annual reports is not "true and correct." It is unclear which version of the educational brochure was utilized and if "local take-back events" were advertised to ultimate users in 2022.
- Education and outreach materials in the *2022 Annual Report* (Figure 3, pages 17 to 18) included 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." CalRecycle noted in the *June 2023 RFA* that 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 and that The Foundation does not describe what "views" it intends to communicate nor why the disclaimer is necessary. This disclaimer was removed from the example education and outreach materials in The Foundation's *Revised 2022 Annual Report* submission (Figure 3, pages 16 to 17). One of the annual reports is not "true and correct," and it is unclear if the

disclaimer was included in The Foundation's 2022 education and outreach materials.

As noted in the *June 2023 RFA*, CalRecycle expects that messaging between The Foundation and point of sale sites is consistent with requirements from statute, regulations, and its approved plan. The Foundation is required to implement its approved *Plan*, which states it will provide and initiate distribution of sharps waste containers and mail-back materials at the point of sale. Additionally, education and outreach materials must be consistent with requirements in statute, regulations, and The Foundation's *Plan*.

CalRecycle may conduct its own audit of The Foundation, including a review of the independent certified public accountant audit for compliance with statute and regulations and consistency with the program operator's stewardship plan, annual report, and annual program budget pursuant to PRC section 42033.4(b)(3).

Summary 3.1 of Requirement 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 *Revised 2022 Annual Report* and require resubmittal, as indicated in the "Action" section below.

- a. Correct accessibility errors in the *Revised 2022 Annual Report* to make it compliant with section 7405 of the Government Code and with the Web Content Accessibility Guidelines 2.0, pursuant to 14 CCR section 18973(a).

Status of CalRecycle Enforcement Action

The *Revised 2022 Annual Report* did not provide information or supporting documentation to correct the violations outlined in CalRecycle's August 11, 2023, NOV by the required date of August 21, 2023. The NOV was issued to The Foundation for violating the requirements of the Pharmaceutical and Sharps Waste Stewardship Law for submitting a non-compliant *2022 Annual Report*, pursuant to PRC section 42033.2(b) and 14 CCR section 18973.5. The NOV identified violations resulting from failure to comply with the following requirements:

1. Implementing a mail-back program that provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale (PRC section 42032.2(d)(1)(F)(i) and 14 CCR section 18973.3(f)(2)). See first full paragraph on page 3 of the *June 2023 RFA* for further description of the unmet requirement.
2. Implementing a comprehensive education and outreach program (PRC section 42031.6 and 14 CCR section 18973.3(i)). See Analysis on pages 6-8 of the *June 2023 RFA* for further discussion of the unmet requirements.
3. Fully implementing operation of an approved stewardship program no later than 270 days after approval by CalRecycle of the stewardship plan that establishes the stewardship program (PRC section 42032(g) and 14 CCR section 18973.1(m)). See Analysis on pages 8-9 of the *June 2023 RFA* for further discussion of the unmet requirements.

CalRecycle staff are assessing next steps to address the compliance issues.

Feedback from Interested Parties

CalRecycle solicited public input on The Foundation's *Revised 2022 Annual Report* from August 23, 2023, through September 6, 2023, and received a comment letter from MED-Project USA. CalRecycle considered this comment letter when reviewing The Foundation's *Revised 2022 Annual Report*.

Action

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

- Approve The Foundation's *Revised 2022 Annual Report*.
- Conditionally approve The Foundation's *Revised 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 1.1 of Requirement Not Met" through "Summary 3.1 of Requirement Not Met" in the "Staff Analysis" section above.
- Disapprove The Foundation's *Revised 2022 Annual Report* and:
 - Refer The Foundation to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement.
 - Require The Foundation to 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 1.1 of Requirement Not Met" through "Summary 3.1 of Requirement Not Met" in the "Staff Analysis" section above, pursuant to 14 CCR section 18973.1(k).
 - Do not require The Foundation to revise and resubmit a 2022 annual report because (1) The Foundation has not demonstrated consistent forward progress toward meeting annual reporting requirements and (2) The Foundation was referred to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement on June 21, 2023.

Signed by: Rachel Machi Wagoner, Director

Dated: November 17, 2023

Attachments:

Documents listed below are posted to CalRecycle's website. To request documents that are referenced in this report but are not listed below, please submit a Public Records Act request (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

1. [The Drug Takeback Solutions Foundation State of California Home-Generated Sharps Waste 2022 Annual Report](https://www2.calrecycle.ca.gov/Docs/Web/123372) (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) (March 31, 2023)
<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) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123384>

2. [Stewardship Plan for Home-Generated Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/122409) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122409>
 - a. [Appendix A – Program Budget](https://www2.calrecycle.ca.gov/Docs/Web/122421) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122421>
 - b. [Appendix B – Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122418) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122418>
 - c. [Appendix C – Service Providers](https://www2.calrecycle.ca.gov/Docs/Web/122415) (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](https://www2.calrecycle.ca.gov/Docs/Web/122412) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122412>
3. [Consideration of The Drug Takeback Solutions Foundation’s 2022 Annual Report for Home-Generated Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/123894) (June 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123894>