

Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

June 22, 2023

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

Sent via e-mail

**Dated**: June 22, 2023

# Re: CalRecycle's Completeness Determination of The Foundation's 2024 Annual Program Budget for Home-Generated Sharps Waste

Dear Chris Smith:

The Department of Resources Recycling and Recovery (CalRecycle) received The Drug Takeback Solution's Foundation's (The Foundation) 2024 annual program budget for home-generated sharps waste on May 31, 2023, titled, *Annual Program Budget for Home-Generated Sharps Waste Stewardship Program*, which included an independent financial audit of The Foundation's stewardship program titled, *Drug Takeback Solutions Foundation Financial Statements, Year Ended December 31, 2022.* Public Resources Code (PRC) section 42033.2(d)(1) and Title 14 of the California Code of Regulations (14 CCR) section 18973.1(b) require CalRecycle to determine if the annual program budget is complete and notify The Foundation of its determination within 30 days of receipt (i.e., by June 30, 2023).

Staff reviewed The Foundation's 2024 annual program budget for home-generated sharps waste for completeness pursuant to the requirements in PRC sections 42033.2(a)(2) and 42033.2(c) and 14 CCR sections 18973, 18973.1(b), and 18973.6 and found the annual program budget complete.

This completeness determination is separate from the compliance determination CalRecycle will now conduct pursuant to 14 CCR sections 18973.1(d) through (f). CalRecycle has 90 days from the date of the annual program budget submittal to review for compliance with all statutory and regulatory requirements and approve, conditionally approve, or disapprove the annual program budget (i.e., by August 29, 2023).

Questions regarding this letter may be directed to <a href="mailto:pharmasharps@calrecycle.ca.gov">pharmasharps@calrecycle.ca.gov</a>.

Regards,

Signed by: Rachel Machi Wagoner, Director

Cc: Jason Smyth, Supervisor, Pharmaceutical and Sharps Unit
Morgan Buchan, Environmental Scientist, Pharmaceutical and Sharps Unit

#### REQUEST FOR ACTION

To: Rachel Machi Wagoner

Director

From: Zoe Heller

Deputy Director, Division of Circular Economy

Request Date: August 15, 2023

**Decision Subject:** Consideration of The Drug Takeback Solutions Foundation's 2024

Annual Program Budget for Home-Generated Sharps Waste

Action By: August 29, 2023

#### **Summary of Request**

The Drug Takeback Solutions Foundation (The Foundation) submitted its 2024 annual program budget, titled, *Annual Program Budget for Home-Generated Sharps Waste Stewardship Program (2024 Annual Program Budget)*, which included an independent financial audit of The Foundation's stewardship program titled, *Drug Takeback Solutions Foundation Financial Statements*, *Year Ended December 31, 2022*, on May 31, 2023. This Request for Action presents a summary of staff's analysis regarding The Foundation's *2024 Annual Program Budget*.

#### **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). On December 20, 2022, The Foundation's *Plan* was approved. The Foundation's *2024 Annual Program Budget* includes anticipated costs for the upcoming calendar year of 2024 (January 1, 2024, through December 31, 2024).

PRC section 42033.2(a)(2) states that, on or before March 31, 2022, and each year thereafter, a program operator shall submit to CalRecycle a program budget for stewardship program implementation for the upcoming calendar year. The Foundation submitted its 2024 Annual Program Budget on March 31, 2023. CalRecycle determined The Foundation's annual program budget was incomplete and notified The Foundation on May 1, 2023, requiring The Foundation to revise and resubmit an annual program budget to CalRecycle within 30 days of the notice. On May 31, 2023, The Foundation submitted its 2024 Annual Program Budget that CalRecycle determined was complete and notified The Foundation on June 22, 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 2024 Annual Program Budget pursuant to PRC section 42033.2(d)(4) and 14 CCR section 18973.1.

### **Staff Analysis**

Staff evaluated The Foundation's 2024 Annual Program Budget to determine whether the requirements of PRC section 42033.2(c) and 14 CCR section 18973.6 were met. The section below presents a summary of staff's analysis of The Foundation's 2024 Annual Program Budget including one requirement where additional information from and/or additional actions by The Foundation may be necessary for CalRecycle to determine whether the requirements of PRC section 42033.2(c) and 14 CCR section 18973.6 were met.

#### **Annual Program Budget**

Requirements: A written program budget for stewardship program implementation for the upcoming calendar year pursuant to PRC sections 42033.2(a)(2) and 42033.2(c) and 14 CCR section 18973.6. Anticipated costs and the recommended funding level, including a reserve level amount, necessary to implement the stewardship program over a multiyear period in a prudent and responsible manner pursuant to PRC section 42033.2(c)(2) and 14 CCR section 18973.6(d). An independent financial audit of the stewardship program funded by the member covered entities participating in the stewardship program pursuant to PRC section 42033.2(c)(1).

Analysis: Requirements Met

#### Budget

The Foundation's 2024 Annual Program Budget includes a program budget for calendar year 2024, including cost categories and a description of each required cost category. A reserve level amount is provided, including a description justifying the amount indicated. The 2024 Annual Program Budget includes a multiyear program budget with a recommended funding level for calendar years 2022 through 2026.

#### Independent Financial Audit

The Foundation submitted an independent financial audit for the year ending December 31, 2022, with its 2024 Annual Program Budget that includes the independent auditor's report and financial statements. The Foundation asserted that the entirety of the independent financial audit contains information that is proprietary pursuant to 14 CCR section 18973(c).

The financial statements indicate that The Foundation began and ended calendar year 2022 with negative net assets. Page 4 of the independent financial audit includes expenses (\$2,175,823), which exceed revenue from annual participant fees (\$811,693), and contributions of cash and in-kind services from Inmar Rx (\$1,287,993).

The Foundation's 2024 Annual Program Budget appears to meet statutory and regulatory requirements. 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). A CalRecycle audit may include, but not be limited to, determining whether The Foundation is operating its stewardship program in a prudent and responsible manner, including an appropriate reserve level amount, consistent with PRC section 42034.

#### **Feedback from Interested Parties**

CalRecycle solicited public input on The Foundation's 2024 Annual Program Budget from June 2, 2023, through June 15, 2023, and did not receive any public comments.

<u>Action</u>
Pursuant to PRC section 42033.2(e) and 14 CCR section 18973.1, I hereby:  ☐ Approve The Foundation's 2024 Annual Program Budget.
$\square$ Conditionally approve The Foundation's 2024 Annual Program Budget.
☐ Disapprove The Foundation's 2024 Annual Program Budget.
☐ Disapprove The Foundation's <i>2024 Annual Program Budget</i> and refer The Foundation to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement.
Cianad by Doobol Moobi Waganar Director Detail August 16, 2022

**Signed by:** Rachel Machi Wagoner, Director **Dated:** August 16, 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. Annual Program Budget for Home-Generated Sharps Waste Stewardship *Program* (May 31, 2023)
  - https://www2.calrecycle.ca.gov/Docs/Web/123714
- 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

#### 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 homegenerated 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
  - o 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 homegenerated 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 mailback 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 mailback 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.

<u>Summary 1 of Requirements Not Met</u>: 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 choses 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**

<u>Requirements</u>: 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 homegenerated 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.

<u>Summary 2 of Requirements Not Met</u>: 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 homegenerated 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 homegenerated 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.

<u>Summary 3 of Requirement Not Met</u>: 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.

<u>Summary 4 of Requirement Not Met</u>: 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**

<ul> <li>□ Approve The Foundation's 2022 Annual Report.</li> <li>□ 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.</li> <li>□ 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</li> </ul>
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
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
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
through "Summary 4 of Requirement Not Met" in the "Staff Analysis" section above. □ Disapprove The Foundation's <i>2022 Annual Report</i> . Pursuant to 14 CCR section
☐ Disapprove The Foundation's 2022 Annual Report. Pursuant to 14 CCR section
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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. <u>The Drug Takeback Solutions Foundation State of California Home-Generated Sharps Waste 2022 Annual Report</u> (March 31, 2023) https://www2.calrecycle.ca.gov/Docs/Web/123372
  - a. <u>Attachment A Service Providers and Weights</u> https://www2.calrecycle.ca.gov/Docs/Web/123378
  - b. <u>Attachment B Participating Covered Entities and Covered Products</u> https://www2.calrecycle.ca.gov/Docs/Web/123384
- Stewardship Plan for Home-Generated Sharps Waste (October 15, 2022) https://www2.calrecycle.ca.gov/Docs/Web/122409
  - a. <u>Appendix A Program Budget</u> (October 15, 2022) https://www2.calrecycle.ca.gov/Docs/Web/122421
  - b. <u>Appendix B Participating Covered Entities</u> (October 15, 2022) https://www2.calrecycle.ca.gov/Docs/Web/122418
  - c. <u>Appendix C Service Providers</u> (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

#### 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 homegenerated 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).

<u>Analysis</u>: 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 homegenerated 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 homegenerated 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).

<u>Summary 1.1 of Requirement Not Met</u>: 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

<u>Requirement</u>: 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).

<u>Summary 2.1 of Requirement Not Met</u>: 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 homegenerated 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).

<u>Summary 3.1 of Requirement Not Met</u>: 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*.

<u>Action</u> Pursuant to PRC section 42033.2(e) and 14 CCR section 18973.1, I hereby: □ Approve The Foundation's <i>Revised 2022 Annual Report</i> .
□ Conditionally approve The Foundation's <i>Revised 2022 Annual Report</i> . 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 <i>Revised 2022 Annual Report</i> and:
oxtimes 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

☐ 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.

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).

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/).

- 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. <u>Attachment A Service Providers and Weights</u> (March 31, 2023) https://www2.calrecycle.ca.gov/Docs/Web/123378
  - b. Attachment B Participating Covered Entities and Covered Products (March 31, 2023)
     https://www2.calrecycle.ca.gov/Docs/Web/123384

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



Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

March 14, 2023

FedEx Tracking Number 7715 5453 1833

Chris Smith, RPh., President Drug Takeback Solutions Foundation 3929 West Point Blvd, Ste D Winston-Salem, NC 27103

Drug Takeback Solutions Foundation P.O. Box 997 Winston-Salem, NC 27102 Certified Mail 7022 0410 0001 9245 3565

Subject: Notice of Violation for Noncompliance with the California Pharmaceutical and Sharps Waste Stewardship Law Regarding the 2022 Annual Program Budget for Home-Generated Sharps

The Department of Resources Recycling and Recovery (CalRecycle) has authority for the California Pharmaceutical and Sharps Waste Stewardship Law (Public Resources Code (PRC) sections 42030 through 42036.4 and Title 14 California Code of Regulations (14 CCR) sections 18972.1 through 18975.2 or the "Law"). This Notice of Violation (NOV) serves as written notification, pursuant to 14 CCR, sections 18975.1(a) and 18975.2(b) that CalRecycle may commence an enforcement action against the Drug Takeback Solutions Foundation (Foundation) for noncompliance with the Law. CalRecycle may issue an accusation for penalties and/or revoke Foundation's stewardship plan for home-generated sharps waste.

Foundation has violated the requirements of the Law by submitting a non-compliant Annual Program Budget for Home-Generated Sharps, with a statutory deadline of March 31, 2022 for the first submission, (2022 Annual Sharps Budget) and failing to comply with requirements outlined in CalRecycle's October 18, 2022 Conditional Approval of the 2022 Annual Sharps Budget. CalRecycle's Conditional Approval of the 2022 Annual Sharps Budget required Foundation to correct deficiencies by December 17, 2022. Foundation failed to correct the deficiencies. On February 28, 2023, CalRecycle disapproved Foundation's 2022 Annual Sharps Budget, submitted on December 16, 2022, for failure to comply with:

- Web Content Accessibility Guidelines 2.0 for an Annual Budget (14 CCR section 18973(a)).

Consistent with PRC section 42033.2 Foundation must submit a compliant annual program budget for covered drugs within 60 days of the notice of disapproval (dated February 28, 2023) to CalRecycle. The program budget should be submitted to <a href="mailto:PharmaSharps@calrecycle.ca.gov">PharmaSharps@calrecycle.ca.gov</a>.

The Law allows for imposition of penalties of up to \$50,000 per day and/or revocation of Foundation's stewardship plan approval pursuant to PRC sections 42035.2 and 42035.4.

If you have questions, please contact Eric Yee at (916) 323-1934.

Sincerely,

Kim Sellards, PG, CFE Branch Chief Waste Evaluation and Enforcement Branch CalRecycle

#### ACKNOWLEDGEMENT OF RECEIPT AND REVIEW

March 14, 2023

SUBJECT: Notice of Violation for Noncompliance with the California Pharmaceutical and Sharps Waste Stewardship Law Regarding the 2022 Annual Program Budget for Home-Generated Sharps

### Sent by Email and Mail

Drug Takeback Solutions Foundation

Return this acknowledgement and the attached Notice of Violation to <a href="mailto:PharmaSharpsEnforcement@calrecycle.ca.gov">PharmaSharpsEnforcement@calrecycle.ca.gov</a> within 14 days of March 14, 2023.

I acknowledge receipt and review of the Notice and dating below.	e of Violation dated March 14, 2023 by signing		
Chris Smith, RPh., President	Date		



Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

August 11, 2023

FedEx Tracking Number 7730 3197 7250

Chris Smith, RPh., President Drug Takeback Solutions Foundation 3929 West Point Blvd, Ste D Winston-Salem, NC 27103

Drug Takeback Solutions Foundation P.O. Box 997 Winston-Salem, NC 27102 Certified Mail 7020 0090 0000 4008 1102

Subject: Notice of Violation for Noncompliance with the California Pharmaceutical and Sharps Waste Stewardship Law Regarding the 2022 Annual Report for Home-Generated Sharps Waste

The Department of Resources Recycling and Recovery (CalRecycle) has authority over the California Pharmaceutical and Sharps Waste Stewardship Law (Public Resources Code (PRC) sections 42030 through 42036.4 and Title 14 California Code of Regulations (14 CCR) sections 18972.1 through 18975.2 or the "Law"). This Notice of Violation (NOV) serves as written notification pursuant to 14 CCR sections 18975.1(a) and 18975.2(b) that CalRecycle may commence an enforcement action against the Drug Takeback Solutions Foundation (The Foundation) for noncompliance with the Law. CalRecycle may issue an accusation for penalties, revoke The Foundation's approval of the stewardship plan for home-generated sharps, and/or require additional reporting related to noncompliance with material requirements that were not met.

The Foundation has violated the requirements of the Law by submitting a non-compliant 2022 Annual Report for Home-Generated Sharps (2022 Sharps Annual Report), pursuant to PRC section 42033.2(b) and 14 CCR section 18973.5. On June 21, 2023, CalRecycle disapproved The Foundation's 2022 Sharps Annual Report, in a Request for Action dated June 21, 2023 (RFA), for failure to comply with the following requirements, as explained in detail on pages 2-9 in the RFA:

- 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)).
- Implementing a comprehensive education and outreach program (PRC section 42031.6 and 14 CCR section 18973.3(i)).
- 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)).

While PRC section 42033.2 requires The Foundation to submit a revised annual report for home-generated sharps waste and provide any supplemental information within 60 days of the notice of disapproval (dated June 21, 2023) to CalRecycle, it appears that it may not be possible for The Foundation to fix the deficiencies identified in the RFA since the annual report is a summary of the prior year's activities. Any annual reports should be submitted to <a href="mailto:PharmaSharps@calrecycle.ca.gov">PharmaSharps@calrecycle.ca.gov</a>.

The Law allows for imposition of penalties of up to \$50,000 per day, revocation of The Foundation's home-generated sharps waste stewardship plan approval, and/or requiring additional reporting relating to compliance with the material requirements that were not met pursuant to PRC sections 42035.2 and 42035.4.

If you have questions, please contact Eric Yee at (916) 323-1934.

Sincerely,

Kim Sellards, PG, CFE Branch Chief Waste Evaluation and Enforcement Branch CalRecycle



Yana Garcia Secretary for Environmental Protection Rachel Machi Wagoner CalRecycle Director

November 6, 2023

FedEx Tracking Number 7860 0618 7420

Chris Smith, RPh., President Drug Takeback Solutions Foundation 3929 West Point Blvd, Ste D Winston-Salem, NC 27103

Drug Takeback Solutions Foundation P.O. Box 997 Winston-Salem, NC 27102 Certified Mail 7020 0090 0000 4008 2383

Subject: Notice of Violation of Public Resources Code (PRC) section 42034.2(a) for Non-Payment of Pharmaceutical and Sharps Waste Stewardship Program Departmental Administrative Fee for Home-Generated Sharps Waste for October 2021 through March 2023

Invoice#: 0000001518736 Balance Due: \$543,730.50

This Notice of Violation (NOV) serves as written notification that The Drug Takeback Solutions Foundation (The Foundation) has violated the requirements of the Pharmaceutical and Sharps Waste Stewardship Law by failing to pay the Department of Resources Recycling and Recovery's (CalRecycle) departmental administrative fee on time, pursuant to Public Resources Code (PRC) section 42034.2(a). Prior to this NOV, CalRecycle has provided the original invoice dated May 31, 2023 and the three notices of nonpayment: a first, second, and Final Notice as required by Government Code section 16580-16586.

As of November 6, 2023, CalRecycle has not received payment on the amount listed above. Please find enclosed a copy of the previously sent final invoice detailing CalRecycle's full cost of administering and enforcing the California Pharmaceutical and Sharps Waste Stewardship Act for The Foundation's home-generated sharps waste stewardship program from October 1, 2021 through March 31, 2023.

To avoid enforcement actions related to The Foundation's nonpayment of CalRecycle's departmental administrative fee, submit payment via check, money order, cashier's check, credit card (<a href="www.CalRecycle.ca.gov/PayOnline">www.CalRecycle.ca.gov/PayOnline</a>) or ACH payment (see below instructions) upon receipt of this letter. Payment must be received within 15 days of the date of this Notice of Violation letter.

The attached invoice package includes the total expenditures during the invoice period and a general description of activities performed. To the extent this invoice does not cover all of the

state's costs, as outlined in PRC section 42034.2, these costs will be invoiced at a later date. CalRecycle will notify The Foundation in the event the actual costs are adjusted.

#### Payment information:

Bank Name: Bank of America Sacramento Main

2000 Clayton Road Bldg. D, 5th Floor

Concord, CA 94520

Account: Resources Recycling and Recovery Account

Account #: 14999-26673

Routing #: 121000358 (ACH is preferred method of payment)

Reference: CalRecycle Account Number, Account Name or Invoice.

Address: 1001 | Street 19th Floor MS-19A, Sacramento, CA 95812-2815

Failure to remit full payment of the administrative fees by **November 22, 2023** will result in initiation of collections procedures and enforcement actions by CalRecycle, which may include issuance of administrative penalties, revocation of The Foundation's approved homegenerated sharps waste stewardship plan, and any other enforcement actions the statute allows (PRC sections 42035.2(a) and 42035.4). Failure to pay CalRecycle's departmental administrative fees on time are not the only instances of noncompliance that CalRecycle may take into consideration to support its enforcement actions.

Questions specific to the payment process may be directed to <a href="mailto:Collections@calrecycle.ca.gov">Collections@calrecycle.ca.gov</a> or (916) 341-6305. Questions related to this NOV may be directed to Eric Yee at <a href="mailto:PharmaSharpsEnforcement@calrecycle.ca.gov">PharmaSharpsEnforcement@calrecycle.ca.gov</a> or (916) 323-1934.

Sincerely,

Mark de Bie Date: 2023.11.06
13:52:38 - 08'00'

Mark de Bie, Deputy Director Waste Permitting, Compliance and Mitigation Division Department of Resources Recycling and Recovery

Enclosures: Invoice

#### **INVOICE**



Invoice Number: Invoice Date: Due Date: Customer ID: 0000001518736 05/31/2023 06/30/2023 0000000680

Resources Recycling & Recovery

The Drug Takeback Solutions Foundation Sharps Attn: Chris Smith P.O. Box 997 Winston-Salem NC 27102

Billing The Drug Takeback Solutions Foundation for sharps program costs incurred by CalRecycle to administer and enforce the Pharmaceutical and Sharps Waste Stewardship law from October 2021 through March 2023.

Service Period: 10/01/2021 - 03/31/2023

<u>Line</u> 1	<u>Description</u> Material Management & Local	<u>Quantity</u> 3,433.46	<u>Rate</u> 78.65	<u>Amount</u> 270,026.00
2	Compliance & Enforcement	3,759.35	67.65	254,337.05
3	Legal	205.46	91.04	18,704.38
4	Information Technology	7.80	46.64	363.81
5	Audits	3.34	89.73	299.26

Amount Due (USD):

\$ 543,730.50

#### **INVOICE**



 Invoice Number:
 0000001518736

 Invoice Date:
 05/31/2023

 Due Date:
 06/30/2023

 Customer ID:
 0000000680

Resources Recycling & Recovery

For billing questions, please contact us at (916)-341-6305 Contains confidential information and unauthorized use or disclosure is prohibited by State law.

\_\_\_\_\_

Please detach this portion of the bill and return it with your payment.

Customer Name: The Drug Takeback Solutions
Customer ID: 0000000680
Invoice ID: 0000001518736
Due Date: 06/30/2023
Fiscal Year: 2021-2022

Amount Due: \$543,730.50 Amount Paid:

Remit Payment To:

Resources Recycling & Recovery 1001 I Street P.O. Box 2711 MS-19A Sacramento CA 95812-2711



Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

June 30, 2023

The Drug Takeback Solution Foundation – Sharps Program Attn: Chris Smith P.O Box 997 Winston-Salem, NC 27102

### **First Notice**

Re: Pharmaceutical and Sharps Waste Stewardship Administrative Fee October

2021 through March 2023 Invoice#: 0000001518736 Balance Due: \$543.730.50

Dear The Drug Takeback Solution Foundation,

Please find the enclosed invoice detailing CalRecycle's full cost of administering and enforcing the California Pharmaceutical and Sharps Waste Stewardship Act for The Drug Takeback Solution Foundation's home-generated sharps waste stewardship program from October 1, 2019, through March 31, 2023.

This invoice package includes the total expenditures during the invoice period and a general description of activities performed. To the extent this bill does not cover all of the state's costs, as outlined in Public Resources Code section 42034.2, these costs will be billed at a later date. CalRecycle will notify The Drug Takeback Solution Foundation in the event CalRecycle's actual costs are adjusted.

Questions specific to the payment process may be directed at <a href="mailto:collections@calrecycle.ca.gov">Collections@calrecycle.ca.gov</a> or (916) 341-6305. Questions related to programmatic activities may be directed to Jason Smyth at <a href="mailto:Pharmasharps@calrecycle.ca.gov">Pharmasharps@calrecycle.ca.gov</a> or (916) 341-6676.

Please submit payment via check, money order, cashier's check, credit card (<a href="www.CalRecycle.ca.gov/PayOnline">www.CalRecycle.ca.gov/PayOnline</a>) or ACH payment (see below instructions) upon receipt of this letter. Payment must be received within 30 days of the date of this letter to avoid collection actions.

Bank Name: Bank of America Sacramento Main

2000 Clayton Road Bldg. D, 5th Floor

Concord, CA 94520

**Account:** Resources Recycling and Recovery Account

**Account #:** 14999-26673

**Routing #:** 121000358 (ACH is preferred method of payment)

Reference: CalRecycle Account Number, Account Name or Invoice.

Address: 1001 I Street 19th Floor MS-19A, Sacramento, CA 95812-2815

Sincerely,

Nam Duong Accounting Officer (Specialist) Fiscal Services Branch

Enclosures: Invoice



Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

July 31, 2023

The Drug Takeback Solution Foundation – Sharps Program Attn: Chris Smith P.O Box 997 Winston-Salem, NC 27102

### **Second Notice**

Re: Pharmaceutical and Sharps Waste Stewardship Administrative Fee October

2021 through March 2023 Invoice#: 0000001518736 Balance Due: \$543.730.50

Dear The Drug Takeback Solution Foundation,

Please find the enclosed invoice detailing CalRecycle's full cost of administering and enforcing the California Pharmaceutical and Sharps Waste Stewardship Act for The Drug Takeback Solution Foundation's home-generated sharps waste stewardship program from October 1, 2019, through March 31, 2023.

This invoice package includes the total expenditures during the invoice period and a general description of activities performed. To the extent this bill does not cover all of the state's costs, as outlined in Public Resources Code section 42034.2, these costs will be billed at a later date. CalRecycle will notify The Drug Takeback Solution Foundation in the event CalRecycle's actual costs are adjusted.

Questions specific to the payment process may be directed at <a href="mailto:collections@calrecycle.ca.gov">Collections@calrecycle.ca.gov</a> or (916) 341-6305. Questions related to programmatic activities may be directed to Jason Smyth at <a href="mailto:Pharmasharps@calrecycle.ca.gov">Pharmasharps@calrecycle.ca.gov</a> or (916) 341-6676.

Please submit payment via check, money order, cashier's check, credit card (<a href="www.CalRecycle.ca.gov/PayOnline">www.CalRecycle.ca.gov/PayOnline</a>) or ACH payment (see below instructions) upon receipt of this letter. Payment must be received within 30 days of the date of this letter to avoid collection actions.

Bank Name: Bank of America Sacramento Main

2000 Clayton Road Bldg. D, 5th Floor

Concord, CA 94520

**Account:** Resources Recycling and Recovery Account

**Account #:** 14999-26673

**Routing #:** 121000358 (ACH is preferred method of payment)

Reference: CalRecycle Account Number, Account Name or Invoice.

Address: 1001 I Street 19th Floor MS-19A, Sacramento, CA 95812-2815

Sincerely,

Nam Duong Accounting Officer (Specialist) Fiscal Services Branch

Enclosures:

Invoice



Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

August 31, 2023

The Drug Takeback Solution Foundation – Sharps Program Attn: Chris Smith P.O Box 997 Winston-Salem, NC 27102

## **Final Notice**

Re: Pharmaceutical and Sharps Waste Stewardship Administrative Fee October

2021through March 2023 Invoice#: 0000001518736 Balance Due: \$543.730.50

Dear The Drug Takeback Solution Foundation,

As of August 31, 2023, we still have not received payment on the amount(s) listed above. Please find the enclosed invoice detailing CalRecycle's full cost of administering and enforcing the California Pharmaceutical and Sharps Waste Stewardship Act for The Drug Takeback Solution Foundation's covered drugs stewardship program from October 1, 2021, through March 31, 2023.

Please submit payment via check, money order, cashier's check, credit card (<a href="www.CalRecycle.ca.gov/PayOnline">www.CalRecycle.ca.gov/PayOnline</a>) or ACH payment (see below instructions) upon receipt of this letter. Payment must be received within 30 days of the date of this letter to avoid collection actions.

This invoice package includes the total expenditures during the invoice period and a general description of activities performed. To the extent this bill does not cover all of the state's costs, as outlined in Public Resources Code section 42034.2, these costs will be billed at a later date. CalRecycle will notify The Drug Takeback Solution Foundation in the event CalRecycle's actual costs are adjusted.

Questions specific to the payment process may be directed at <a href="mailto:collections@calrecycle.ca.gov">Collections@calrecycle.ca.gov</a> or (916) 341-6305. Questions related to programmatic activities may be directed to Jason Smyth at <a href="mailto:Pharmasharps@calrecycle.ca.gov">Pharmasharps@calrecycle.ca.gov</a> or (916) 341-6676.

**Bank Name:** Bank of America Sacramento Main

2000 Clayton Road Bldg. D, 5th Floor

Concord, CA 94520

**Account:** Resources Recycling and Recovery Account

**Account #:** 14999-26673

**Routing #:** 121000358 (ACH is preferred method of payment)

Reference: CalRecycle Account Number, Account Name or Invoice.

Address: 1001 I Street 19th Floor MS-19A, Sacramento, CA 95812-2815

Sincerely,

Nam Duong Accounting Officer (Specialist) Fiscal Services Branch

Enclosures: Invoice