



Department of
Resources Recycling and Recovery

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

Re: CalRecycle's Completeness Determination of The Foundation's 2022 Annual Report and 2024 Annual Program Budget for Covered Drugs

Dear Chris Smith:

The Department of Resources Recycling and Recovery (CalRecycle) received The Drug Takeback Solutions Foundation's (The Foundation) 2022 annual report and 2024 annual program budget for covered drugs on May 31, 2023, titled, *The Drug Takeback Solutions Foundation State of California Stewardship Plan for Covered Drugs 2022 Annual Report and Annual Program Budget for Covered Drugs*, respectively, the latter of 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 report and annual program budget are complete and notify The Foundation of its determinations within 30 days of receipt (i.e., by June 30, 2023).

Staff reviewed The Foundation's 2022 annual report and 2024 annual program budget for covered drugs for completeness pursuant to the requirements in PRC sections 42033.2(a) through (c) and 14 CCR sections 18973, 18973.1(b), 18973.4, and 18973.6 and found the annual report and annual program budget complete.

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

Questions regarding this letter may be directed to pharmasharps@calrecycle.ca.gov.

Regards,

Signed by: Rachel Machi Wagoner, Director

Dated: June 22, 2023

Cc: Jason Smyth, Supervisor, Pharmaceutical and Sharps Unit
Becky Haworth, 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 Covered Drugs

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 Covered Drugs (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 78 covered entities under its approved stewardship plan for covered drugs, titled, *Stewardship Plan for Covered Drugs (Plan)*. On February 16, 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.

Action

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

- Approve The Foundation's *2024 Annual Program Budget*.
- Conditionally approve The Foundation's *2024 Annual Program Budget*.
- Disapprove The Foundation's *2024 Annual Program Budget*.
- Disapprove The Foundation's *2024 Annual Program Budget* and refer The Foundation to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement.

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/) (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

1. [Annual Program Budget for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/123714) (May 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123714>
 - a. Attachment A – Independent Financial Audit (May 31, 2023)
2. [Stewardship Plan for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/122409) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122409>
 - a. [Appendix A – Program Budget](https://www2.calrecycle.ca.gov/Docs/Web/122424) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122424>
 - b. [Appendix B – Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122427) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122427>
 - c. [Appendix C – Participating Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/122430) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122430>
 - d. [Appendix D – Service Providers](https://www2.calrecycle.ca.gov/Docs/Web/122433) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122433>
 - e. [Appendix E – Drugs Sold or Offered for Sale in California by Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122436) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122436>
 - f. [Appendix F – Contacted Potential Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/122439) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122439>
 - g. [Appendix G – Participating Mail-Back Distribution Locations](https://www2.calrecycle.ca.gov/Docs/Web/122442) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122442>

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 2022 Annual Report for Covered Drugs

Action By: August 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 Stewardship Plan for Covered Drugs 2022 Annual Report (2022 Annual Report)* on May 31, 2023. This Request for Action presents a summary of staff's analysis regarding The Foundation's *2022 Annual Report* and The Foundation's covered drugs stewardship program.

Background

The Foundation is a stewardship organization that, as reported in the *2022 Annual Report*, represents 78 covered entities under its approved stewardship plan for covered drugs, titled, *Stewardship Plan for Covered Drugs (Plan)*. On February 16, 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 16, 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, which CalRecycle found incomplete on May 1, 2023, and required The Foundation to revise its 2022 annual report and resubmit to CalRecycle within 30 days. The Foundation resubmitted its *2022 Annual Report* on May 31, 2023. CalRecycle determined the *2022 Annual Report* 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 *2022 Annual Report* pursuant to PRC section 42033.2(d)(4) 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*
- Secured 409 authorized collection sites and 606 mail-back distribution locations
- Collected a total of 50,973.81 pounds of covered drugs from authorized collection sites and 806.99 pounds of covered drugs through the return of 1,713 mail-back packages
- Conducted outreach that included approximately 17,000 letters to potential authorized collectors
- Its primary focus was to:
 - Be fully operational by the required deadline
 - Educate potential authorized collectors of their obligation to participate in the program
 - Expand the geographic spread of collection receptacles

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.

Convenience Standards

Requirements: Provide a description of how the convenience standards were met pursuant to PRC section 42032.2(a)(1)(F), and if convenience standards were not met, describe efforts made to achieve compliance pursuant to 14 CCR section 18973.4(c)(3). Include necessary changes to calculations that account for changes in the number of authorized collection sites and most recent publicly available population calculations from the State of California Department of Finance pursuant to 14 CCR section 18973.4(c)(3). After a stewardship plan has been approved, a program operator may supplement services, if approved by the department, for a county in which it does not have the minimum number of authorized collection sites due to circumstances beyond the program operator's control pursuant to PRC section 42032.2(c).

Analysis: Requirements Not Met

The Foundation's *2022 Annual Report* describes implementing its covered drugs stewardship program through activities that include engaging with potential authorized collection sites (e.g., retail pharmacies, retail pharmacy chains, and law enforcement agencies) and establishing 409 authorized collection sites, making "progress toward the Convenience Standard."

PRC section 42030(a) defines an authorized collection site as a location where an authorized collector operates a secure collection receptacle for collecting covered products. PRC section 42032.2(a)(1)(F)(i) states that a program operator's collection system must provide for a minimum of five authorized collection sites or one authorized collection site per 50,000 people in each county in which the plan will be implemented, whichever is greater. Based on data contained in The Foundation's *2022 Annual Report*, The Foundation has not met the required number of authorized

collection sites in 44 counties. Figure 1 in CalRecycle Appendix A shows a map of California with the number of additional authorized collection sites required in 44 counties for The Foundation to meet the convenience standard in PRC section 42032.2(a)(1)(F)(i). CalRecycle acknowledges that there are no pharmacies available to serve as an authorized collection site in Alpine and Sierra counties to meet this requirement; however, law enforcement agencies and other entities can act as authorized collection sites.

Statute does not require a program operator to establish its statewide program in 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. Due to transitions that occurred with San Luis Obispo County's local stewardship program during the reporting period, it is currently unclear what responsibility program operators had regarding establishing a stewardship program in San Luis Obispo County.

The Foundation's approved *Plan* states that The Foundation "will review each yearly release from the Department of Finance to make adjustments as necessary to the Convenience Standard due to population changes" and "to determine the geographic spread of the population within each county." The Foundation's *2022 Annual Report* does not include information regarding reviewing and using the most recent publicly available population data from the State of California Department of Finance to calculate whether any changes to the required number of authorized collection sites were necessary, or whether it was used to determine geographic spread within each county.

PRC section 42032.2(c) states that, after a stewardship plan for covered drugs has been approved, the program operator may supplement service, *if approved by the department* (emphasis added), for a county in which it operates that does not have the minimum number of authorized collection sites *due to circumstances beyond the program operator's control* (emphasis added), by means including establishing a mail-back program. The Foundation's *2022 Annual Report* states that "analysis has been conducted to determine counties where full convenience may not be possible for both approved Program Operators based on the number of DEA approved potential Authorized Collection Sites available in some counties" and that "Mail-Back Service was used to supplement Collection Receptacles." However, the *2022 Annual Report* does not describe the circumstances that were beyond The Foundation's control that prevented it from meeting the convenience standard, outlined in PRC section 42032.2(a)(1)(F)(i), by establishing the required number of authorized collection sites in 44 counties. This information is necessary for CalRecycle to approve The Foundation's use of the mail-back distribution locations to supplement service.

Even if The Foundation's use of the mail-back distribution locations to supplement service was approved by the department, there are 23 counties where The Foundation did not establish enough combined authorized collection sites or mail-back distribution locations to meet the convenience standard. Additionally, in seven of those counties The Foundation did not establish any authorized collection sites or

mail-back distribution locations. Table 1 in CalRecycle Appendix A shows the number of authorized collection sites established, the number of authorized collection sites needed, and the number of mail-back distribution locations reported as established by The Foundation in each county.

PRC section 42032.2(a)(1)(F)(ii) requires a program operator to provide for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread. The Foundation's approved *Plan* states that The Foundation will "ensure that at least 90% of Ultimate Users live within a 15-mile drive of an Authorized Collection Site or a Mail-Back Distribution Site in counties where an authorized Retail Pharmacy is not available." Although The Foundation's *2022 Annual Report* does not include any information regarding reasonable geographic spread, based on the data provided, The Foundation did not achieve the geographic spread as outlined in the approved *Plan* in 25 counties. The geographic spread requirement must be met by using authorized collection sites alone and does not include mail-back distribution locations. Figure 2 in CalRecycle Appendix A shows a map of California with the 25 counties where The Foundation did not meet the geographic spread described in its approved *Plan* and the percentage of ultimate users within 15-miles of an authorized collection site.

See also "270 Day Full Program Implementation Deadline" section.

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

- a. Clarify whether Department of Finance's most recent publicly available population data was used to calculate whether any changes to the required number of authorized collection sites was necessary, or whether it was used to determine geographic spread within each county pursuant to 14 CCR section 18973.4(c)(3).
- b. Describe the circumstances that were beyond The Foundation's control that necessitated the use of supplemental mail-back distribution locations in counties that did not have the minimum number of authorized collection sites pursuant to PRC section 42032.2(c).
- c. Describe the efforts that were undertaken to achieve compliance with the convenience standard, including reasonable geographic spread, for the counties that have been reported in Attachment B of the *2022 Annual Report* as not meeting the convenience standard requirement pursuant to 14 CCR section 18973.4(c)(3).
- d. For the 44 counties that do not meet the convenience standards pursuant to PRC section 42032.2(a)(1)(F)(i), provide a list of the potential authorized collection sites that were considered, The Foundation's efforts to secure those locations, and the reasons those locations were not feasible as an authorized collection site pursuant to 14 CCR section 18973.4(c)(3).

Education and Outreach

Requirements: Implement a comprehensive education and outreach program pursuant to PRC section 42031.6 and 14 CCR section 18973.2(j). 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 18973.2(j)(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 that provides information on the program, including instructions for safe handling and proper disposal of covered drugs and information on collection options, and to receive requests for mail-back materials from ultimate users pursuant to PRC section 42032.2(a)(1)(G)(i) and 14 CCR section 18973.2(j)(3). The annual report shall be complete and correct pursuant to 14 CCR section 18973(d). A program operator submitting an annual report shall provide to the department, upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of approval, pursuant to 14 CCR section 18973.1(a).

Analysis: Requirements Not Met

The Foundation's *2022 Annual Report* describes providing educational materials to participating authorized collection sites and mail-back distribution locations. The Foundation reports that it posted twice on social media.

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*:

- Appears to promote "local take-back events" as a disposal option for covered drugs (PDF pages 17 to 18). The take-back events The Foundation appears to be promoting are hosted by the DEA. The Foundation did not report hosting any collection events and The Foundation's *Plan* did not identify any proposed alternative forms of collection pursuant to 14 CCR section 18973.2(g)(6). 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 Inmar Intelligence or the Producers participating in the Inmar Intelligence (Source: U.S. Food and Drug Administration) Product Stewardship Plan" (PDF pages 17 to 18). This statement makes it unclear whether The Foundation or Inmar Intelligence is implementing and operating The Foundation's *Plan*. Inmar Intelligence does not have a CalRecycle approved stewardship plan and is not an approved program operator. 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.

The Foundation’s *2022 Annual Report* does not include any examples of signage on collection receptacles.

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 covered drugs stewardship program by November 13, 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 covered drugs stewardship program, including disposal options, or request mail-back materials.

Per the *Plan*, this website is required to, among other things, provide information on collection options for covered drugs, accept requests from ultimate users for mail-back materials, and include a list of authorized collection sites that includes all collection receptacles in the state, operated by all program operators. As of June 2023, The Foundation’s website did not operate as it is described in its *Plan* and as required in the statute and regulations. “Takebackfoundation.org” includes limited information about The Foundation’s covered drugs stewardship program and does not provide a mechanism to accept requests for mail-back materials. This website links out to a different website (“safemedicinedrop.com”), which appears to be operated by Inmar Intelligence. The Foundation’s *Plan* states that the website will “display a list of Authorized Collection Site physical addresses, telephone numbers, and hours of operation. The list will be inclusive of all Collection Receptacles located in the state, including those operated by other Program Operators.” However, the list of the “safemedicinedrop.com” website only includes The Foundation’s authorized collection locations, not all approved program operators. 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 18973.2(k). Describe how ultimate users had an opportunity to dispose of their covered drug(s) as described in the approved stewardship plan pursuant to 14 CCR section 18973.4(c)(1).

Analysis: Requirements Not Met

The Foundation had 270 days from February 16, 2022, the date of conditional approval of its stewardship plan for covered drugs, 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.

Based on data contained in The Foundation's *2022 Annual Report*, The Foundation has not met the required number of authorized collection sites in 44 counties. Even if The Foundation's use of the mail-back distribution locations to supplement service were approved by the department, there are 23 counties where The Foundation did not establish enough combined authorized collection sites or mail-back distribution locations to meet the convenience standard. Additionally, in seven of those counties The Foundation did not establish any authorized collection sites or mail-back distribution locations. The Foundation did not fully implement the collection system pursuant to PRC section 42032.2(a)(1)(F) and as described in its approved *Plan*.

The Foundation's *Plan* describes that it will offer mail-back services through distribution locations, as well as accept requests through its website and toll-free telephone number. The *2022 Annual Report* states that the ordering mechanism for the website and toll-free telephone number "were made available to Ultimate Users during the Reporting Period." However, when providing metrics for mail-back services, the toll-free telephone number is not listed as a mechanism of distribution and the associated amounts of mail-back materials distributed and returned are not included. It is unclear if the toll-free telephone number is not listed because those services were not available to ultimate users, or if it is because no mail-back materials were distributed through this mechanism.

Metrics

Requirements: For each participating authorized collection site, include the amount of covered drugs collected, number of instances that collected covered drugs were picked up for disposal, and the number of receptacle liners picked up for disposal pursuant to 14 CCR section 18973.4(c)(4) and PRC section 42033.2(b)(3). For each type of mail-back service utilized, include the mechanism(s) of distribution, amount of mail-back materials distributed, and amount of mail-back materials returned pursuant to 14 CCR section 18973.4(c)(5). Describe how ultimate users had an opportunity to dispose of their covered drug(s) as described in the approved stewardship plan pursuant to 14 CCR section 18973.4(c)(1). 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 Partially Met

Attachment B 2022 Collection Information of The Foundation's *2022 Annual Report* reports the amount of covered drugs collected by weight and the number of liners and instances that that covered drugs were picked up for disposal at 371 authorized collection sites. However, The Foundation reports having 409 participating authorized collection sites. It is not clear why The Foundation did not report the required metrics for the remaining 38 participating authorized collection sites. The amount of covered drugs collected by weight and the number of liners and instances

that that covered drugs were picked up for disposal at *each* (emphasis added) authorized collection site is required, even if the numbers are zero.

The Foundation’s *Plan* describes that it will offer mail-back services through distribution locations as well as accept requests through its website and toll-free telephone number. The *2022 Annual Report* states that the ordering mechanism for the website and toll-free telephone number “were made available to Ultimate Users during the Reporting Period.” However, when providing metrics for mail-back services, the toll-free telephone number is not listed as a mechanism of distribution and the associated amounts of mail-back materials distributed and returned are not included. See Table 1, below. It is unclear if the toll-free telephone number is not listed because those services were not available to ultimate users, or if it is because no mail-back materials were distributed through this mechanism.

Table 1. The Foundation “Mailers by Type of Request” Metrics

	Total # Distributed	Total # Returned	Total Weight (lbs)
Mail-Back Distribution Sites	3,040	1,713	806.99
Website	3	0	0
Total	3,043	1,713	806.99

Table 1 Description: Metrics of The Foundation “Mailers by Type of Request” distributed and returned through mail-back distribution sites and the website, including “total weight.”

When describing the metrics The Foundation would use to measure the amount of mail-back materials distributed and metrics that will be used to measure the amount of materials returned, its *Plan* states the “Quantity of Mailers distributed is measured against the quantity of Mailers returned via the Mailer’s unique tracking number and distribution location identifier.” Using the methodology provided in its *Plan*, staff would expect the quantity of mailers returned to match the quantity of mailers that were distributed by each method. For example, 1,713 were returned from distribution at mail-back distribution sites, therefore 1,713 were distributed at mail-back distribution sites, and zero were returned that were distributed from website requests, therefore zero were distributed from website requests. Because The Foundation reported different numbers returned than were distributed by method, The Foundation must describe the methodology it used to determine and report the number of mail-back materials distributed and returned pursuant to 14 CCR section 18973.2.(g)(6)(E). 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 mail-back materials that were distributed and returned.

Summary 2 of Requirements Not Met: The following serves as written notice of the requirements that must be met should the Director choose to conditionally approve

or disapprove The Foundation's *2022 Annual Report* as indicated in the "Action" section below.

- a. Include the amount of covered drugs collected, number of instances that collected covered drugs were picked up for disposal, and the number of receptacle liners picked up for disposal for each participating authorized collection site, pursuant to 14 CCR section 18973.4(c)(4) and PRC section 42033.2(b)(3).
- b. Clarify any discrepancies between reported metrics and the number of participating authorized collection sites pursuant to 14 CCR section 18973.1(a).
- c. Include the amount of mail-back materials distributed through the toll-free telephone number and amount of mail-back materials returned (that were distributed through the toll-free telephone number, or clarify why mail-back material metrics for the toll-free telephone number were not reported pursuant to 14 CCR section 18973.4(c)(5).
- d. Provide metrics and a description of the methodology, consistent with the approved *Plan*, The Foundation used to determine the amount of mail-back materials that were distributed and returned pursuant to 14 CCR sections 18973.4(c)(5)(C), 18973.4(c)(5)(D), and 18973.2(g)(6)(E).

Collection, Transportation and Disposal

Requirements: Describe the methods used to transport and dispose of covered drugs, including mechanism(s) used to track the collection, transportation, and disposal of covered drugs. For each disposal facility provide the name of facility, the mailing and physical address, and the total weight of covered drugs disposed pursuant to 14 CCR section 18973.4(d). Provide a description of whether policies and procedures for collecting, transporting, and disposing of covered drugs, as established in the stewardship plan, were followed during the reporting period pursuant to 14 CCR section 18973.4(e)(1).

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 Containers and Inner Liners, as well as 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 covered drugs. The *2022 Annual Report* lacks a description of those methods. While referring to its approved *Plan* helps the reader understand where to go for additional information, there should be enough of a description in the annual report for the reader to understand what is being described in the annual report as a standalone document. 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 18973.4.

Attachment D Weights by Disposal Facility includes the weights disposed at each disposal facility. These weights sum to 21,788.25 pounds. *Attachment B 2022 Collection Information* includes the weight collected from each authorized collection

site, which sums to 50,973.81 pounds. The Foundation does not explain the discrepancy between these numbers.

The Foundation's Plan states that it will conduct monitoring activities, including "formalized reviews/audits of required tracking/reporting documentation, random/unscheduled on-site visits, and scheduled on-site audits of Authorized Collection Sites." The *2022 Annual Report* states that "policies and procedures for collecting, transporting, and disposing of covered drugs as established in the Stewardship Plan were followed correctly. There were no instances of noncompliance." However, it did not provide information about the monitoring activities that were described in its *Plan*. An annual report must describe how the program operator complied with all elements in its stewardship plan during the previous reporting period of one year. As the *2022 Annual Report* is written, it is unclear if The Foundation conducted these monitoring activities.

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

- a. Include a description in the annual report about the methods used to transport and dispose of covered drugs, including a description of the mechanism(s) to track the collection, transportation, and disposal of covered drugs pursuant to 14 CCR section 18973.4(d)(1).
- b. Explain the discrepancy between the weight of material disposed at each disposal facility and the weight collected from each authorized collection site pursuant to 14 CCR section 18973.4(d)(3)(C).
- c. Provide a description of whether policies and procedures, including monitoring activities, as established in the *Plan*, were followed during the reporting period pursuant to 14 CCR section 18973.4(e)(1).

Mailing and Physical Addresses

Requirements: 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 18973.4(j)(1). Provide a list of authorized collectors and their contact information, including, but not limited to, mailing and physical address pursuant to PRC section 42033.2(b)(4) and 14 CCR section 18973.4(j)(3). For each disposal facility, include its mailing and physical address pursuant to 14 CCR section 18973.4(d)(3).

Analysis: Requirements Partially Met

Staff's analysis of The Foundation's *2022 Annual Report* found that:

- *Attachment E Covered Entities and Product List* provides a mailing address for each covered entity, when both a mailing and physical address are required.
- *Attachment B 2022 Collection Information* provides one address for each authorized collector. It is unclear if these are the mailing and/or physical address when both are required.

- *Attachment D Weights by Disposal Facility* includes one address under the “Company Name” header. It is unclear if these are the mailing and/or physical address when both are required.

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

- a. Include all mailing and physical addresses associated with each covered entity pursuant to 14 CCR section 18973.4(j)(1).
- b. Include all mailing and physical addresses associated with each authorized collector pursuant to 14 CCR section 18973.4(j)(3).
- c. Include all mailing and physical addresses associated with each disposal facility pursuant to 14 CCR section 18973.4(d)(3).

Document Submittals

Requirements: 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 18973.4. A concise summary of the information contained in the report that includes, but is not limited to, the highlights, outcomes and challenges, achievement of the convenience standards, education and outreach efforts, and ways in which challenges are being addressed, pursuant to 14 CCR section 18973.4(b). An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirements Partially Met

The Foundation’s *2022 Annual Report* includes an executive summary that explains the highlights and outcomes of the information contained in the report. However, the executive summary does not include a summary of the challenges, ways in which challenges are being addressed, or education and outreach efforts, as required.

The Foundation was required to submit a written report describing its stewardship program for covered drugs 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 additional instances throughout its *2022 Annual Report* where The Foundation utilizes incorrect and inconsistent terminology and formatting. For example, page numbering errors where the page numbers one and two occur twice, and when discussing the process for conducting good faith negotiations with potential authorized collectors, The Foundation states that it “proceeds with an agreement to establish the Pharmacy as an Authorized Collector.” A pharmacy is not the only type of location that may serve as an authorized collector. The annual report

must clearly describe the activities that occurred at all potential authorized collection sites, not just pharmacies.

Summary 5 of Requirements Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove The Foundation's *2022 Annual Report* as indicated in the "Action" section below.

- a. Utilize correct and consistent terminology, dates, and formatting within the annual report pursuant to 14 CCR section 18973(d).
- b. Include a concise summary of the information included in the report, including challenges, ways in which challenges are being addressed, and education and outreach efforts pursuant to 14 CCR section 18973.4(b).

Feedback from Interested Parties

CalRecycle solicited public input on The Foundation's *2022 Annual Report* from June 2, 2023, through June 15, 2023, and did not receive any public comments.

Action

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

- Approve The Foundation's *2022 Annual Report*.
- Conditionally approve The Foundation's *2022 Annual Report* Pursuant to 14 CCR section 18973.1(j), The Foundation must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date this Request for Action notice is issued that includes the additional information specified in "Summary 1 of Requirements Not Met" through "Summary 5 of Requirements Not Met" in the "Staff Analysis" section above.
- Disapprove The Foundation's *2022 Annual Report*. Pursuant to 14 CCR section 18973.1(k), The Foundation must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date this Request for Action notice is issued that includes the additional information specified in "Summary 1 of Requirements Not Met" through "Summary 5 of Requirements 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 5 of Requirements Not Met" in the "Staff Analysis" section above.

Signed by: Rachel Machi Wagoner, Director

Dated: August 16, 2023

Attachments:

Documents listed below are posted to CalRecycle's website.

1. [The Drug Takeback Solutions Foundation State of California Covered Drugs 2022 Annual Report](https://www2.calrecycle.ca.gov/Docs/Web/123732) (May 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123732>

- a. [Attachment A – Potential Authorized Collectors Notified](https://www2.calrecycle.ca.gov/Docs/Web/123717)
<https://www2.calrecycle.ca.gov/Docs/Web/123717>
- b. [Attachment B – 2022 Collector Information](https://www2.calrecycle.ca.gov/Docs/Web/123720)
<https://www2.calrecycle.ca.gov/Docs/Web/123720>
- c. [Attachment C – Service Providers](https://www2.calrecycle.ca.gov/Docs/Web/123723)
<https://www2.calrecycle.ca.gov/Docs/Web/123723>
- d. [Attachment D – Weights by Disposal Facility](https://www2.calrecycle.ca.gov/Docs/Web/123726)
<https://www2.calrecycle.ca.gov/Docs/Web/123726>
- e. [Attachment E – Covered Entities and Product List](https://www2.calrecycle.ca.gov/Docs/Web/123729)
<https://www2.calrecycle.ca.gov/Docs/Web/123729>
- 2. [Stewardship Plan for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/122409) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122409>
 - a. [Appendix A – Program Budget](https://www2.calrecycle.ca.gov/Docs/Web/122424) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122424>
 - b. [Appendix B – Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122427) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122427>
 - c. [Appendix C – Participating Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/122430) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122430>
 - d. [Appendix D – Service Providers](https://www2.calrecycle.ca.gov/Docs/Web/122433) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122433>
 - e. [Appendix E – Drugs Sold or Offered for Sale in California by Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122436) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122436>
 - f. [Appendix F – Contacted Potential Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/122439) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122439>
 - g. [Appendix G – Participating Mail-Back Distribution Locations](https://www2.calrecycle.ca.gov/Docs/Web/122442) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122442>

Figure 2 Geographic Spread of Authorized Collection Sites by County



Figure 2 Description: This map of California identifies the 25 counties that The Foundation did not achieve reasonable geographic spread in 2022 (colored in blue), with the number being the percentage of ultimate users within 15-miles of an authorized collection site. Yellow colored counties identify those counties where the reasonable geographic spread is greater than 90 percent of ultimate users within 15-miles of an authorized collection site. Grey colored counties identify those counties that, according to CalRecycle’s knowledge at the time of this Request for Action, have a local stewardship program ordinance pursuant to PRC section 42036.2. Due to transitions that occurred with San Luis Obispo County’s local stewardship program during the reporting period, at this time it is unclear what responsibility program operators had regarding establishing a stewardship program in San Luis Obispo County.

Table 1 Numerical Analysis of Authorized Collection Sites by County

Row	County	Total Population 1/1/2022	Number of Board of Pharmacy registered pharmacies*	Required number of authorized collection sites	Number of authorized collection sites established	Number of additional authorized collection sites needed	Number of mail-back distribution locations established
1	El Dorado	190,465	33	5	6	0	10
2	Imperial	179,329	28	5	5	0	1
3	Siskiyou	43,830	7	5	5	0	8
4	Solano	447,241	49	8	8	0	11
5	Sonoma	482,404	71	9	12	0	17
6	Ventura	833,652	163	16	19	0	9
7	Contra Costa (incorporated)	979,614	134	19	13	6	39
8	Kern	909,813	145	18	16	2	12
9	Los Angeles	9,861,224	1853	197	106	91	125
10	Monterey	433,716	51	8	4	4	15
11	Mendocino	89,999	16	5	3	2	8
12	Orange	3,162,245	673	63	50	13	50
13	Riverside	2,435,525	376	48	34	14	38
14	San Bernardino	2,187,665	308	43	22	21	30
15	San Diego	3,287,306	491	65	56	9	21
16	Alpine	1,200	0	N/A**	2	N/A**	0
17	Amador	40,297	6	5	1	4	2
18	Butte	201,608	37	5	1	4	10
19	Calaveras	45,049	7	5	0	5	1
20	Colusa	21,807	3	5	0	5	0
21	Del Norte	27,218	6	5	1	4	0

Row	County	Total Population 1/1/2022	Number of Board of Pharmacy registered pharmacies*	Required number of authorized collection sites	Number of authorized collection sites established	Number of additional authorized collection sites needed	Number of mail-back distribution locations established
22	Fresno	1,011,273	150	20	8	12	25
23	Glenn	28,750	5	5	0	5	0
24	Humboldt	135,168	28	5	2	3	2
25	Inyo	18,978	4	5	1	4	1
26	Kings	152,023	19	5	1	4	3
27	Lake	67,407	10	5	2	3	1
28	Lassen	30,274	4	5	0	5	0
29	Madera	157,396	19	5	1	4	6
30	Mariposa	17,045	2	5	0	5	0
31	Merced	284,338	33	5	0	5	6
32	Modoc	8,690	2	5	2	3	0
33	Mono	13,379	2	5	1	4	0
34	Napa	136,179	18	5	2	3	2
35	Nevada	101,242	14	5	0	5	4
36	Placer	409,025	69	8	3	5	16
37	Plumas	18,942	4	5	0	5	0
38	Sacramento	1,576,618	227	31	12	19	41
39	San Benito	65,479	6	5	0	5	18
40	San Joaquin	784,298	86	15	5	10	18
41	Shasta	180,531	37	5	2	3	8
42	Sierra	3,229	0	N/A**	0	N/A**	0
43	Stanislaus	549,466	73	10	2	8	20
44	Sutter	99,145	20	5	0	5	3

Row	County	Total Population 1/1/2022	Number of Board of Pharmacy registered pharmacies*	Required number of authorized collection sites	Number of authorized collection sites established	Number of additional authorized collection sites needed	Number of mail-back distribution locations established
45	Tehama	65,052	9	5	0	5	4
46	Trinity	16,023	2	5	0	5	0
47	Tulare	475,014	66	9	0	9	10
48	Tuolumne	55,291	11	5	1	4	2
49	Yolo	221,165	31	5	0	5	7
50	Yuba	82,275	12	5	0	5	2
	Totals		5420	742	409	342	606

*Board of Pharmacy registered pharmacies are not inclusive of all potential authorized collection sites available to serve as an authorized collection site (e.g., law enforcement agency).

**No authorized retail pharmacies operating in Alpine and Sierra counties. (PRC section 42032.2(a)(1)(F)(iii))

Table 1 Description: County population totals are obtained from the most recently released Population Estimates for Cities, Counties, and the State from Department of Finance Demographic Research Unit. The number of registered pharmacies is derived from the Board of Pharmacy. The required number of authorized collection sites is based on PRC section 42032.2(a)(1)(F)(i) that requires program operators to provide a minimum of five authorized collection sites or one authorized collection site per 50,000 people in each county. The number of authorized collection sites established are derived from *Attachment B 2022 Collection Information* that The Foundation provided with its *2022 Annual Report*. The number of additional authorized collection sites needed was calculated by subtracting the number of authorized collection sites established from the number of authorized collection sites required. The number of mail-back distribution locations established are derived from *Attachment B 2022 Collection Information* that The Foundation provided with its *2022 Annual Report*. The green rows (1 through 6) show the counties where The Foundation established the required numbers or more of authorized collection sites. The yellow rows (7 through 15) show the counties where The Foundation established at least half or more of the registered pharmacies available as authorized collection sites. The red rows (16 through 50) show the counties where The Foundation established fewer than half of the registered pharmacies available as authorized collection sites. Due to transitions that occurred with San Luis Obispo County's local stewardship program during the

reporting period, at this time it is unclear what responsibility program operators had regarding establishing a stewardship program in San Luis Obispo County.



Department of
Resources Recycling and Recovery

Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

March 14, 2023

FedEx Tracking Number
7715 4908 6712

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 3558

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

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 covered drugs.

Foundation has violated the requirements of the Law by submitting a non-compliant Annual Program Budget for Covered Drugs, with a statutory deadline of March 31, 2022 for the first submission, (2022 Annual Drugs Budget) and failing to comply with requirements outlined in CalRecycle's October 18, 2022 Conditional Approval of the 2022 Annual Drugs Budget. CalRecycle's Conditional Approval 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 Drugs 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)).
- Completeness and correctness requirements for an Annual Budget, specifically for mathematical summation errors in the "Total Operational Expenses" category (14 CCR section 18973(d)).

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 PharmaSharps@calrecycle.ca.gov.

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 Covered Drugs

Sent by Email and Mail

Return this acknowledgement and the attached Notice of Violation to PharmaSharpsEnforcement@calrecycle.ca.gov within 14 days of March 14, 2023.

I acknowledge receipt and review of the Notice of Violation dated March 14, 2023 by signing and dating below.

Chris Smith, RPh., President
Drug Takeback Solutions Foundation

Date



Department of
Resources Recycling and Recovery

Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

August 24, 2023

FedEx Tracking Number
7731 6390 3197

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 1485

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

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 covered drugs, 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 Covered Drugs (2022 Drugs Annual Report), pursuant to PRC section 42033.2(b) and 14 CCR section 18973.5. On August 16, 2023, CalRecycle disapproved The Foundation's 2022 Drugs Annual Report, in a Request for Action dated August 16, 2023 (RFA), for failure to comply with the following requirements, as explained in detail on pages 2-7 in the RFA:

- Providing a collection system that complies with the convenience standards for authorized collection sites in each county in which the plan is implemented (PRC section 42032.2(a)(1)(F) and 14 CCR sections 18973.2(g)(2) and 18973.4(c)(3)).
- Implementing a comprehensive education and outreach program (PRC section 42031.6 and 14 CCR section 18973.2(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 covered drugs and provide any supplemental information within 60 days of the notice of disapproval (dated August 16, 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 PharmaSharps@calrecycle.ca.gov.

The Law allows for imposition of penalties of up to \$50,000 per day, revocation of The Foundation's covered drugs 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

November 6, 2023

FedEx Tracking Number
7740 0800 8492

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 2376

**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 Covered Drugs for October 2021 through
March 2023**

Invoice#: 0000001518735

Balance Due: \$377,506.66

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 covered drugs 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 (www.CalRecycle.ca.gov/PayOnline) 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 I 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 covered drugs 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 Collections@calrecycle.ca.gov or (916) 341-6305. Questions related to this NOV may be directed to Eric Yee at PharmaSharpsEnforcement@calrecycle.ca.gov or (916) 323-1934.

Sincerely,

Mark de Bie
Digitally signed by Mark
de Bie
Date: 2023.11.06
13:52:10 -08'00'

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

Enclosures:
Invoice

INVOICE



Invoice Number: 0000001518735
Invoice Date: 05/31/2023
Due Date: 06/30/2023
Customer ID: 0000000676

Resources Recycling & Recovery

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

Billing The Drug Takeback Solutions Foundation for drugs 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>	<u>Description</u>	<u>Quantity</u>	<u>Rate</u>	<u>Amount</u>
1	Material Management & Local	2,666.09	78.42	209,079.20
2	Compliance & Enforcement	2,429.79	62.94	152,936.24
3	Legal	166.32	89.22	14,839.05
4	Information Technology	10.82	39.47	427.07
5	Audits	2.60	86.58	225.10

Amount Due (USD): \$ 377,506.66

INVOICE



Invoice Number: 0000001518735
Invoice Date: 05/31/2023
Due Date: 06/30/2023
Customer ID: 0000000676

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: 0000000676
Invoice ID: 0000001518735
Due Date: 06/30/2023
Fiscal Year: 2021-2022

Amount Due: \$ 377,506.66
Amount Paid: _____

Remit Payment To:

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

000000067600000015187350037750666



Department of
Resources Recycling and Recovery

Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

June 30, 2023

The Drug Takeback Solution Foundation – Drugs 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#: 0000001518735

Balance Due: \$377,506.66

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 covered drugs stewardship program from October 1, 2021, 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 Collections@calrecycle.ca.gov or (916) 341-6305. Questions related to programmatic activities may be directed to Jason Smyth at Pharmasharps@calrecycle.ca.gov or (916) 341-6676.

Please submit payment via check, money order, cashier's check, credit card (www.CalRecycle.ca.gov/PayOnline) 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



July 31, 2023

The Drug Takeback Solution Foundation – Drugs 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#: 0000001518735

Balance Due: \$377,506.66

Dear The Drug Takeback Solution Foundation,

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Sincerely,

Nam Duong
Accounting Officer (Specialist)
Fiscal Services Branch

Enclosures:
Invoice



Department of
Resources Recycling and Recovery

Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

August 31, 2023

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

Final Notice

Re: Pharmaceutical and Sharps Waste Stewardship Administrative Fee October 2021 through March 2023

Invoice#: 0000001518735

Balance Due: \$377,506.66

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 (www.CalRecycle.ca.gov/PayOnline) 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.**

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

Sincerely,

Nam Duong
Accounting Officer (Specialist)
Fiscal Services Branch

Enclosures:
Invoice