

REQUEST FOR ACTION

To: Zoe Heller
Director

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

Request Date: June 25, 2024

Decision Subject: Consideration of The Drug Takeback Solutions Foundation's 2023 Annual Report for Covered Drugs

Action By: June 27, 2024

Summary of Request

The Drug Takeback Solutions Foundation (The Foundation) submitted its 2023 annual report, titled, *The Drug Takeback Solutions Foundation State of California Stewardship Plan for Covered Drugs 2023 Annual Report (2023 Annual Report)* on March 29, 2024. This Request for Action presents a summary of staff's analysis regarding The Foundation's *2023 Annual Report* and The Foundation's covered drugs stewardship program.

Background

The Foundation is a stewardship organization that, as reported in its *2023 Annual Report*, represents 87 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 *2023 Annual Report* covers the entire 2023 calendar year (January 1, 2023, through December 31, 2023).

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

Staff Analysis

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

- Enrolled 52 new authorized collection sites for a total of 457 authorized collection sites.
- Added 27 new mail-back distribution locations for a total of 622 mail-back distribution locations.
- Continued efforts to expand geographical spread and make progress towards the convenience standard.
- Collected a total of 69,000.44 pounds of covered drugs from authorized collection sites and 2,800.45 pounds of covered drugs through the return of 6,688 mail-back packages.
- Conducted education and outreach to the public including various methods of advertising and a survey of 1,000 ultimate users and 500 providers to measure public awareness.
- Coordinated with the other program operator on the development of a jointly operated website and toll-free number (completed outside of the reporting period).

The Foundation reported challenges it faced in meeting convenience standards, the primary challenge being its ability to establish additional authorized collection sites.

Staff evaluated The Foundation's *2023 Annual Report* to determine whether the requirements of statute, regulations, and The Foundation's *Plan* were met. While The Foundation reports certain improvements to address the statutory, regulatory, and *Plan* requirements, as well as the requirements CalRecycle identified in the Request for Action, titled, *Consideration of The Drug Takeback Solutions Foundation's Revised 2022 Annual Report for Covered Drugs*, the majority of The Foundation's collection system continues to utilize supplemental mail-back services rather than authorized collection sites, and it does not meet the convenience standard in most counties. The sections below present a summary of staff's analysis of The Foundation's *2023 Annual Report* and select components of its covered drugs program 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 Standard – Authorized Collection Sites

Requirements: Provide a description of how the convenience standards were met pursuant to PRC section 42032.2(a)(1)(F)(i) and (iii), and if convenience standards were not met, describe efforts made to achieve compliance 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

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. In its *2023 Annual Report*, The Foundation states it met the required number of authorized collection sites in six counties, similar to what it reported in 2022. Additionally, The Foundation states that it met the convenience standard in 22 counties by using either authorized collection sites and/or supplemental mail-back distribution locations to meet the minimum number of authorized collection sites. The Foundation reports a total of 622 active mail-back distribution locations in operation during the reporting period.

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, by means including establishing a mail-back program or other alternative form of collection and disposal. The Foundation describes circumstances beyond its control that prevented it from establishing the minimum number of authorized collection sites to include there being "a limited number of pharmacies" in 13 counties as well as, "safety and diversion concerns, space constraints, internal take-back programs, lack of interest or response, improper licensing, no public access, fear or preference against interactions with the California Board of Pharmacy, and not wanting to take on additional pharmacist responsibilities." The Foundation also describes challenges created by the closure of certain retail pharmacies in California and states that it is "contractually prohibited from approaching" three retail pharmacy chains "at a site-by-site level." The *2023 Annual Report* includes a description of the efforts The Foundation made to achieve the convenience standard which include, "conducting research via internet searches, using available internal sales tools, and leveraging current retail partners to identify potential pharmacies and law enforcement agency sites to serve as additional Authorized Collection Sites," in addition to evaluating alternative types of authorized collection sites such as "Long-Term Care Facilities." A list of potential authorized collection sites that The Foundation considered is provided in *Attachment A Potential Authorized Collectors Notified*.

Program operators may utilize mail-back distribution locations as a supplemental service pursuant to PRC section 42032.2(c), but mail-back service cannot be used exclusively in lieu of authorized collection sites to meet the convenience standard in PRC section 42032.2(a)(1)(F)(i), barring exceptional circumstances.

In counties where The Foundation established at least one authorized collection site in addition to mail-back distribution locations that, when combined, meet the necessary minimum number of authorized collection sites required, CalRecycle approves of The Foundation's use of supplemental mail-back service. Therefore, CalRecycle approves The Foundation's use of supplemental mail-back service in 19 counties (Butte, Contra Costa (incorporated), Fresno, Kern, Los Angeles, Madera, Mendocino, Monterey, Nevada, Orange, Placer, Riverside, Sacramento, San Bernardino, San Diego, San Joaquin, Shasta, Stanislaus, and Yolo) for the 2023 reporting period.

PRC section 42032.2(a)(1)(F)(iii) requires a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site. Based on a list of retail pharmacies obtained from the California Board of Pharmacy in 2023, there were no retail pharmacies available to serve as an authorized collection site in Alpine and Sierra Counties during the reporting period. The Foundation did not establish a mail-back program in either of these counties; therefore, PRC section 42032.2(a)(1)(F)(iii) was not met.

A mail-back program alone is permissible to meet the requirement of PRC section 42032.2(a)(1)(F)(i) when program operators demonstrate that there were exceptional circumstances beyond their control for not establishing authorized collection sites other than at a retail pharmacy. As discussed above, The Foundation neither met the minimum number of authorized collection sites nor supplemented with a mail-back program. Although The Foundation did establish two authorized collection sites in Alpine County, it did not establish any authorized collection sites in Sierra County, nor did it operate a mail-back program in either county; thus, PRC sections 42032.2(a)(1)(F)(i) and (iii) are unmet for these counties during the 2023 reporting period.

CalRecycle expects that The Foundation will continue to establish additional authorized collection sites in all 44 counties where the convenience standard is not met via authorized collection sites alone to minimize reliance on supplemental mail-back distribution locations as the program expands and report its efforts to establish authorized collection sites in subsequent annual reports pursuant to 14 CCR section 18973.4(c)(3).

Convenience Standard - Reasonable Geographic Spread

Requirement: Provide a description of how the convenience standard was met pursuant to PRC section 42032.2(a)(1)(F)(ii), and if the convenience standard was not met, describe efforts made to achieve compliance pursuant to 14 CCR section 18973.4(c)(3).

Analysis: Requirement Not Met

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 *2023 Annual Report* states its primary focus during the reporting period was, "to expand the geographical spread of Collection Receptacles," the *2023 Annual Report* does not include an analysis of reasonable geographic spread for any of the counties in which the *Plan* operates.

Transportation and Disposal

Requirements: 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). If applicable, provide a description and evaluation of the

process for selecting service providers in accordance with 14 CCR section 18973.4(k).

Analysis: Requirements Not Met

The Foundation's *2023 Annual Report* includes *Attachment C Service Providers (Attachment C)* which lists the name, mailing address, and physical address of its disposal facilities in addition to *Attachment D, Weights by Disposal Facility (Attachment D)*, which lists the weight of covered drugs disposed at four facilities. There are two "123 Compliant Logistics" disposal facilities in *Attachment C*, one is in Arizona and the other in Massachusetts. In *Attachment D*, "123 Compliant Logistics" is listed as disposing of 90.0 pounds of covered drugs, but it is unclear whether this was the Arizona or Massachusetts facility.

On January 19, 2024, The Foundation notified CalRecycle of a new disposal facility. Although the notification did not occur in 2023, The Foundation stated, "This information will also be included as part of The Foundation's Annual Report, to be submitted in March 2024." In the *2023 Annual Report*, submitted March 29, 2024, The Foundation did not state it had added or changed any service providers in 2023 and the new disposal facility mentioned in The Foundation's January 19, 2024, email, *Barron County Waste to Energy and Recycling Facility* located in Alma, Wisconsin, is not included in *Attachment C*.

Collection Metrics

Requirements: Report the amount of covered drugs collected pursuant to 14 CCR section 18973.4(c)(4)(B). Report the amount of mail-back materials distributed and returned pursuant to 14 CCR section 18973.4(c)(5)(C)-(D).

Analysis: Requirements Met

Attachment B 2023 Collection Information includes data from participating authorized collection sites that includes the weight of covered drugs collected and the number of receptacle liners picked up for transport and disposal. The Foundation reports collecting a total of 69,000.44 pounds of covered drugs through 2,131 liners during the reporting period.

The Foundation reports mail-back materials were available to ultimate users through its 622 mail-back distribution locations, "Program website," and "toll-free number." The three types of mail-back materials distributed include standard, inhaler, and "Combination Product Mail-Back Packages." The Foundation distributed 2,465 standard mail-back envelopes, 69 inhaler mail-back envelopes, and 431 "Combination Product Mail-Back Packages." The Foundation collected 2,800.45 pounds of covered drugs through the return of 6,688 standard mail-back envelopes and 61 "Combination Product Mail-Back Packages." The Foundation states, "There is a difference between total distributed and total Mail-Back Envelopes returned due to the fact that there were 606 operational Mail-Back Distribution Sites prior to the Reporting Period, resulting in a large number of Mailers being distributed prior to the Reporting Period, but returned during this Reporting Period."

The total weight of covered drugs collected through The Foundation’s covered drugs stewardship program are presented in Table 1, below. CalRecycle notes that the total amount collected differs from the reported amount (71,801.40 pounds) of covered drugs disposed during the reporting period in *Attachment D Weights by Disposal Facility*.

Table 1. Covered Drugs Collected in 2023

	Weight (pounds)
Authorized Collection Sites (457)	69,000.44
Mail-Back Envelopes (via website, toll-free number, and 622 mail-back distribution locations)	2,800.45
Total	71,800.89

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 provide electronic examples of promotional marketing materials and shall describe and evaluate its education and outreach numerical metrics including but not limited to ultimate user awareness, program usage, and accessibility pursuant to 14 CCR sections 18973.2(j)(5) and 18973.4(i). A program operator shall provide a discussion of what its numerical metrics reveal about the performance of its outreach and education program including but not limited to ultimate user awareness, program usage, and accessibility pursuant to 14 CCR section 18973.4(i)(3). 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). An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirements Not Met

The Foundation reports that it provided educational materials to authorized collection sites and mail-back distribution locations with the intent of educating authorized collectors and ultimate users about the program. Efforts included programmatic advertising, influencer programs, direct mail campaigns, newspaper advertisements, targeted media, a targeted audio campaign, and digital out-of-home advertisements. In its *2023 Annual Report*, The Foundation describes the metrics that were used “to evaluate performance of the education and outreach program including Ultimate User awareness, Program usage, and accessibility.” For newspaper advertisements, The Foundation states that the advertisements it ran in three newspapers “garnered a total of 2,024,148 impressions, meaning that 2,024,148 readers were served the advertisement.” However, the table titled, “Table 1- Outreach Activities Overview,”

states there were 135,957 impressions with a frequency of “nine” and in another table titled, “Table 2 – Newspaper Outreach,” it states there were 4,048,296 impressions among three newspapers and 18 insertions. It is unclear why these metrics differ. The Foundation reports the direct mail campaign was the most successful outreach effort, increasing the number of “Mailers” requested monthly.

The Foundation conducted a survey of 1,000 ultimate users and 500 “providers” but does not define “providers” making it unclear whether the survey was provided to “pharmacists, and healthcare professionals in the State of California who interact with Ultimate Users” as stated in its *Plan*. Additional terminology related to the how the survey was conducted is not defined or explained in the *2023 Annual Report* including, “survey application publishers,” “survey platform partners,” and “partner applications.” The Foundation states that residents and “providers” were asked the same survey questions and for “providers,” “68 percent stated they have used the Program (45 percent using a Collection Receptacle and 23 percent using Mailers).” The Foundation does not describe what it means for a provider to “use the Program.” Although The Foundation provides the results from the survey it conducted, it does not discuss what these results reveal about the performance of the education and outreach program pursuant to 14 CCR section 18973.4(i)(3). For example, the survey results indicate that 16 percent of ultimate users have used a collection receptacle and 5 percent have used “Mailers,” however The Foundation does not discuss what these results reveal about program usage. Additionally, in its *Plan*, The Foundation states that results from the survey will be used to improve the program such as by “adjusting the number or location of Authorized Collection Sites, providing additional services in Historically Underserved Communities, improving outreach to and education for Ultimate Users, including Historically Underserved Communities, and/or identifying other methods for improving service and outreach,” however, there is no discussion regarding how the survey results, which indicate potentially low program usage, will be used to improve the program as described in its *Plan*.

Actual Expenses for Departmental Administrative Fees

Requirements: Provide a list of all actual expenses incurred during the reporting period and summarize the expenses for each budget category in accordance with 14 CCR sections 18973.6(b) and 18973.4(n). 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). An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirements Not Met

The Foundation lists \$2,316,503.36 in departmental administrative fees under its actual expenses in 2023. However, according to CalRecycle’s records, The Foundation paid a total of \$381,375.45 for invoices regarding departmental administrative fees in 2023.

Authorized Collectors

Requirements: Provide a list of authorized collectors and their contact information which shall include the name of the authorized collector, mailing and physical address, contact name, title, and email address pursuant to 14 CCR section 18973.4(j)(3). An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirements Not Met

In The Foundation's list of authorized collectors, it is unclear if the addresses listed are mailing addresses, physical addresses, or both. Additionally, there are six locations that are not consistently included in the attachment, as well as a location that appears to be located outside of the statewide program and not in Kern County, as described.

Collection System

Requirements: Describe the efforts made between the program operator and potential authorized collectors to establish authorized collection sites including a list of potential authorized collectors that were notified in the counties in which the program operated pursuant to 14 CCR section 18973.4(c)(2)(A). An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirements Not Met

On page 4 of the *2023 Annual Report*, The Foundation states that it notified "9,655 Potential Authorized Collectors" of the opportunity to serve as an authorized collector but on page 6 states that the "list encompasses both potential Authorized Collectors and Mail-Back Distribution Sites." In the list of potential authorized collectors notified titled, *Attachment A Potential Authorized Collectors Notified, (Attachment A)*, The Foundation includes potential mail-back distribution locations, making it difficult to distinguish between which of the contacts listed are potential authorized collectors as opposed to mail-back distribution locations. Additionally, several of the contacts listed did not specify a county, which prevents CalRecycle from evaluating whether The Foundation's efforts were satisfactory in the counties in which the program operated pursuant to 14 CCR section 18973.4(c)(2)(A).

Document Submittals

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

Analysis: Requirement Not Met

The Foundation indicated that it had 451 authorized collection sites and 622 mail-back distribution locations for a total of 1,071 sites. However, the total number of sites is 1,073.

On pages 2 and 8 of the *2023 Annual Report*, The Foundation states it enrolled 52 new authorized collections sites. However, in the table provided on page 7, titled, *New Disposal Options Secured by County During the Reporting Period*, The Foundation reports 44 new authorized collection sites. It is unclear how many new authorized collection sites were added during the reporting period.

The Foundation also refers to “Appendix 1 Figure 7” for an example of a cross-device display advertisement although only one Appendix, titled *Appendix A*, was included in its *2023 Annual Report*. It is unclear whether The Foundation intended to include an “Appendix 1.”

As discussed in the “Education and Outreach” section above, The Foundation uses undefined terminology such as, “providers,” “survey application publishers,” “survey platform partners,” and “partner applications.”

CalRecycle Compliance and Inspection Activities

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

In 2023, CalRecycle staff conducted 188 inspections at pharmaceutical retailers and law enforcement kiosks to evaluate compliance with the Pharmaceutical and Sharps Waste Stewardship Act. The requirements for retailers include monitoring CalRecycle’s website and notifying CalRecycle of any products not listed on the website. For those that have a collection kiosk, they are required to maintain records. Of the 188 locations inspected, 141 (75 percent) were noncompliant at the time of the inspection. However, within 60 days, all violations were corrected.

Feedback from Interested Parties

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

Action

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

- Approve The Foundation’s *2023 Annual Report*.
- Conditionally approve The Foundation’s *2023 Annual Report*. Direct staff to identify the conditions to be met for approval and provide written notice to The Foundation within 30 days of signature of this Request for Action, pursuant to 14 CCR section 18973.1(j).
- Disapprove The Foundation’s *2023 Annual Report*. Direct staff to identify how the *2023 Annual Report* does not comply and provide written notice to The Foundation within 30 days of signature of this Request for Action, pursuant to 14 CCR section 18973.1(k).

I disapprove The Foundation’s 2023 Annual Report on the bases of the information reported by The Foundation and the information and analysis contained in this Request for Action. The Foundation’s 2023 Annual Report is not substantially compliant because it does not demonstrate that their stewardship program provides adequate access to safe disposal of covered drugs to the ultimate user. In addition to omissions and inconsistencies articulated in the

analysis, The Foundation's 2023 Annual Report demonstrates it disproportionately relied on supplemental mail-back opportunities for ultimate users rather than achieve the statutory convenience standard by establishing the required number of authorized collection sites across the state.

Signed by:

Zoe Heller
Director

Dated: June 27, 2024

Attachments:

The documents listed below are posted to CalRecycle's website. To request documents that are referenced in this report but are not listed below, please submit a Public Records Act request:

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

1. [The Drug Takeback Solutions Foundation State of California Stewardship Plan for Covered Drugs 2023 Annual Report](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15684>
 - a. [Attachment A – Potential Authorized Collectors Notified](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15686>
 - b. [Attachment B – 2023 Collection Information](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15687>
 - c. [Attachment C – Service Providers](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15688>
 - d. [Attachment D – Weights by Disposal Facility](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15689>
 - e. [Attachment E – Covered Entities and Product List](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15690>
 - f. [Attachment F – State Agency Determinations](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15691>
2. [Stewardship Plan for Covered Drugs](#) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122409>
 - a. [Appendix A – Program Budget](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122424>
 - b. [Appendix B – Participating Covered Entities](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122427>
 - c. [Appendix C – Participating Authorized Collectors](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122430>
 - d. [Appendix D – Service Providers](#)
<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>
 - f. [Appendix F – Contacted Potential Authorized Collectors](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122439>

- g. [Appendix G – Participating Mail-Back Distribution Locations](https://www2.calrecycle.ca.gov/Docs/Web/122442)
<https://www2.calrecycle.ca.gov/Docs/Web/122442>
- 3. [Consideration of The Drug Takeback Solutions Foundation’s Revised 2022 Annual Report for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/125826) (January 8, 2024)
<https://www2.calrecycle.ca.gov/Docs/Web/125826>