

REQUEST FOR ACTION

To: Zoe Heller
Director

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

Request Date: June 21, 2024

Decision Subject: Consideration of The Drug Takeback Solutions Foundation's 2025 Annual Program Budget for Covered Drugs

Action By: July 1, 2024

Summary of Request

The Drug Takeback Solutions Foundation (The Foundation) submitted its 2025 annual program budget, titled, *Annual Program Budget for Covered Drugs (2025 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, 2023*, on April 1, 2024. This Request for Action presents a summary of staff's analysis regarding The Foundation's *2025 Annual Program Budget*.

Background

Public Resources Code (PRC) section 42033.2(a)(2) states that, on or before March 31, 2022, and each year thereafter, a program operator shall submit to the Department of Resources Recycling and Recovery (CalRecycle) a program budget for stewardship program implementation for the upcoming calendar year. The Foundation, a stewardship organization that represents 87 covered entities under its approved stewardship plan for covered drugs, submitted its *2025 Annual Program Budget* on April 1, 2024. The Foundation's *2025 Annual Program Budget* includes anticipated costs for the upcoming calendar year of 2025 (January 1, 2025, through December 31, 2025). The Foundation submitted an independent financial audit for the year ending December 31, 2023, with its 2025 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 confidential and proprietary pursuant to Title 14 of the California Code of Regulations (14 CCR) section 18973(c).

CalRecycle determined The Foundation's annual program budget 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, conditionally approve, or disapprove the *2025 Annual Program Budget* pursuant to PRC section 42033.2(d)(2) and 14 CCR section 18973.1.

Staff Analysis

Staff evaluated The Foundation's *2025 Annual Program Budget* 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 *2025 Annual*

Program Budget for requirements where additional information from and/or additional actions by The Foundation are necessary for CalRecycle to determine whether the requirements of statute, regulations, and The Foundation’s plan were met.

1. Requirement: 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: Requirement Not Met

In a cover letter submitted on March 29, 2024, The Foundation states that its independent financial auditor “conducted a comprehensive audit of the Foundation’s drugs and sharps stewardship programs nationwide for 2023” and

[REDACTED]

The Foundation must submit an independent financial audit for its program in California, not “nationwide.” A “nationwide” audit of The Foundation does not allow CalRecycle to accurately determine whether the requirements of statute, regulations, and The Foundation’s plan were met.

Additionally, PRC section 42033.2(c)(1) requires an independent financial audit *of the stewardship program* (emphasis added). Statute anticipates that these independent financial audits will pertain to the program for the respective covered product (covered drugs or home-generated sharps). Moreover, the information in this independent financial audit demonstrates the necessity of separate audits.

[REDACTED]

However, the participants (and thus the revenue) are different for each program. For these reasons, separate independent financial audits for each program are necessary, pursuant to PRC section 42033.2(c)(1), to determine whether the requirements of statute, regulations, and The Foundation’s plan were met.

Because The Foundation operates separate stewardship programs for covered drugs and home-generated sharps waste and submits separate budgets for its covered drugs and home-generated sharps waste programs, separate independent financial audits for its sharps and drugs programs will allow CalRecycle to

[REDACTED] and evaluate whether The

Foundation is operating each of its stewardship programs in a prudent and responsible manner consistent with PRC section 42034. This may include, but not be limited to, evaluating The Foundation’s reserve and funding levels and anticipated costs in its annual program budgets in addition to reported actual expenses, pursuant to PRC section 42033.2(c) and 14 CCR sections 18973.4(n) and 18973.6(b) through (d).

2. Requirements: 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 sections 18973.6(b) through (d). The program

operator shall maintain reserves in a prudent and responsible manner pursuant to 14 CCR section 18973.6(c).

Analysis: Requirements Not Met

The Foundation's *2025 Annual Program Budget* includes the following recommended funding levels: \$2,572,756 for 2024, \$1,373,465 for 2025, and \$1,404,984 for 2026. For the upcoming calendar year of 2025, The Foundation's total recommended funding level includes capital costs, operational costs, education and outreach costs, administrative costs, and the departmental administrative fee. Additionally, The Foundation specifies a reserve level of \$175,935 for 2025 "in order to accommodate unplanned needs, and provide cushion against unexpected events, losses of income or large unbudgeted expenses." If The Foundation continues to establish reserve level amounts that approximate a "10[percent] increase in the costs associated with operating Collection Receptacles..." [REDACTED] it is unclear how The Foundation will meet the requirement to operate in a prudent and responsible manner. Because the independent financial audit does not include The Foundation's reserve level amount, CalRecycle cannot evaluate whether The Foundation is maintaining its reserves and operating in a prudent and responsible manner.

3. Requirement: Each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products pursuant to PRC section 42034.

Analysis: Requirement Not Met

The independent financial audit does not contain sufficient information to establish that PRC section 42034 has been met. [REDACTED]

[REDACTED]

[REDACTED] Pursuant to PRC section 42034, covered entities are required to pay all costs associated with establishing and implementing the stewardship program. To date, all of The Foundation's annual program budgets have stated it has "long-term commitments from the Covered Entities who will cover all costs associated with the Program." However, the independent financial audit states that [REDACTED]

[REDACTED]

4. Requirement: Pursuant to 14 CCR section 18973.6(f)(3), the independent financial audit shall include, but not be limited to, an opinion on the stewardship organization's compliance with the aspects of PRC section 42034 and the regulations (14 CCR, Division 7, Chapter 11, Article 4).

Analysis: Requirement Not Met

The independent auditor's report states the opinion that, "the financial statements ... present fairly, in all material respects, the financial position of Drug Takeback Solutions Foundation as of December 31, 2023, and the results of its operations and its cash flows for the year then ended in accordance with accounting principles generally accepted in the United States of America." The independent financial audit does not contain an opinion on the stewardship organization's compliance with the aspects of PRC section 42034 and the regulations, pursuant to 14 CCR section 18973.6(f)(3).

5. Requirements: A stewardship plan, initial program budget, annual report, annual budget, or any document associated with the foregoing that is submitted to the department shall meet all the requirements outlined in subsections (a) through (e) of 14 CCR section 18973. Documents are required to be in compliance with section 7405 of the Government Code, and the Web Content Accessibility Guidelines 2.0 published in 2008 by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level AA success criteria to allow for posting on the department's website pursuant to 14 CCR section 18973(a).

Analysis: Requirements Not Met

The Foundation's independent financial audit document contains multiple accessibility errors.

CalRecycle may conduct its own audits 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 sections 42033.2(c)(1) and 42034 and 14 CCR sections 18973.6(c) and (d).

Feedback from Interested Parties

CalRecycle solicited public input on The Foundation's *2025 Annual Program Budget* 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 *2025 Annual Program Budget*.

Action

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

- Approve The Foundation's *2025 Annual Program Budget*.
- Conditionally approve The Foundation's *2025 Annual Program Budget*. 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 2025 Annual Program Budget. Direct staff to identify how the 2025 Annual Program Budget 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 2025 Annual Program Budget on the bases of the information reported by The Foundation and the information and analysis contained in this Request for Action. The Foundation failed to demonstrate it is operating its program in a prudent and responsible manner. As discussed in the analysis above, the information submitted by The Foundation is insufficient to show it satisfied key budget requirements, and it is unclear how The Foundation will meet its program's financial needs [REDACTED]

In addition, The Foundation is provided notice that it must submit an independent financial audit that includes an opinion of the covered drugs stewardship program's compliance with PRC section 42034 and regulations pursuant to 14 CCR section 18973.6(f)(3) with all subsequent annual program budgets and must submit an independent financial audit that is limited in scope to its covered drugs stewardship program with all subsequent annual program budgets.

Signed by:

Zoe Heller
Director

Dated: July 1, 2024

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/PublicNotices/Documents/15685) (April 1, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15685>