

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 MED-Project's 2025 Annual Program Budget for Covered Drugs

Action By: June 27, 2024

Summary of Request

MED-Project USA (MED-Project) submitted its 2025 annual program budget, titled, *MED-Project 2025 Annual Program Budget; State of California, Covered Drugs (2025 Annual Program Budget)*, including an independent financial audit, titled, *MED-Project CA, LLC; Financial Statements, Year Ended December 31, 2023*, on March 29, 2024. This Request for Action presents a summary of staff's analysis regarding MED-Project'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. MED-Project, a stewardship organization that represents more than 500 covered entities under its approved stewardship plan for covered drugs, submitted its *2025 Annual Program Budget* on March 29, 2024. MED-Project's *2025 Annual Program Budget* includes anticipated costs for the upcoming calendar year of 2025 (January 1, 2025, through December 31, 2025).

CalRecycle determined the *2025 Annual Program Budget* was complete and notified MED-Project on April 29, 2024, pursuant to PRC section 42033.2(d)(1) and Title 14 of the California Code of Regulations (14 CCR) section 18973.1(b). CalRecycle has 90 days to approve, disapprove, or conditionally approve the *2025 Annual Program Budget* pursuant to PRC section 42033.2(d)(2) and 14 CCR section 18973.1.

Staff Analysis

Staff evaluated MED-Project's *2025 Annual Program Budget* to determine whether the requirements of statute, regulations, and MED-Project's plan were met. The sections below present a summary of staff's analysis of MED-Project's *2025 Annual Program Budget*, including for those requirements where additional information from and/or additional actions by MED-Project may be necessary for CalRecycle to determine whether the requirements of statute, regulations, and MED-Project's plan 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(b) through (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) and 14 CCR section 18973.6(f).

Analysis: Requirements Met

MED-Project's *2025 Annual Program Budget* includes the following recommended funding levels: \$8,807,549 for 2024, \$8,977,598 for 2025, and \$9,270,274 for 2026. For the upcoming calendar year of 2025, MED-Project's total recommended funding level includes capital costs, costs of collection, transportation and disposal of covered products, administrative costs, education and outreach costs, and the departmental administrative fee. MED-Project specifies a reserve level of \$2,244,400 for 2025 which approximates 25 percent of its program budget. MED-Project's *2025 Annual Program Budget* includes an independent financial audit for the year ending December 31, 2023.

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. See Notice below.

MED-Project 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. MED-Project asserted that the independent financial audit contains financial information that is trade secret, confidential, and proprietary pursuant to 14 CCR section 18973(c).

The independent auditor's report states the opinion that, "the financial statements ... present fairly, in all material respects, the financial position of MED-Project CA, as of December 31, 2023, and the changes in its net assets 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 appear to 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).

Notice: To meet this requirement moving forward, MED-Project must submit an independent financial audit that includes an opinion of the covered drugs stewardship program's compliance with PRC section 42034 and the regulations pursuant to 14 CCR section 18973.6(f)(3) with all subsequent annual program budgets.

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. See Notice below.

MED-Project submitted an independent financial audit that covers both its pharmaceutical and home-generated sharps waste stewardship programs.

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 the independent financial audits provided this year demonstrates the need to identify the financial elements of components specific to a pharmaceutical or sharps program with that particular program and not with a combination of multiple programs. For these reasons, separate independent financial audits per program are necessary, pursuant to PRC section 42033.2(c)(1), to determine whether the requirements of statute, regulations, and MED-Project's plan were met. Because MED-Project 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 are necessary for CalRecycle to evaluate whether MED-Project 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 MED-Project'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 18973.5(q) and 18973.6(b) through (d).

Notice: To meet this requirement moving forward, MED-Project must submit an independent financial audit that is limited in scope to its covered drugs stewardship program with all subsequent annual program budgets.

CalRecycle may conduct its own audit of MED-Project, 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 MED-Project is operating its stewardship program in a prudent and responsible manner consistent with PRC section 42034.

Feedback from Interested Parties

CalRecycle solicited public input on MED-Project'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. CalRecycle considered these comments when reviewing MED-Project's *2025 Annual Program Budget*.

Action

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

- Approve MED-Project's *2025 Annual Program Budget*.
- Conditionally approve MED-Project's *2025 Annual Program Budget*. Direct staff to identify the conditions to be met for approval and provide written notice to MED-Project within 30 days of signature of this Request for Action, pursuant to 14 CCR section 18973.1(j).
- Disapprove MED-Project's *2025 Annual Program Budget*. Direct staff to identify how the *2025 Annual Program Budget* does not comply and provide written notice to MED-Project within 30 days of signature of this Request for Action, pursuant to 14 CCR section 18973.1(k).

I approve MED-Project's 2025 Annual Program Budget on the bases of the information reported by MED-Project and the information and analysis contained in this Request for Action. MED-Project's 2025 Annual Program Budget demonstrates it is operating its program in a prudent and responsible manner. Nevertheless, MED-Project 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

Date: June 27, 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/>).

1. [MED-Project 2025 Annual Program Budget; State of California, Covered Drugs](#)
(March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15676>
 - a. [MED-Project CA, LLC; Financial Statements, Year Ended December 31, 2023](#) (March 29, 2024)
<https://www2.calrecycle.ca.gov/Docs/Web/127986>