

REQUEST FOR ACTION

To: Rachel Machi Wagoner
Director

From: Zoe Heller
Deputy Director, Division of Circular Economy

Request Date: November 9, 2023

Decision Subject: Consideration of MED-Project's Revised 2022 Annual Report for Covered Drugs

Action By: November 20, 2023

Summary of Request

MED-Project USA (MED-Project) submitted its revised 2022 annual report, titled, *MED-Project 2022 Annual Report, State of California, Covered Drugs (Revised 2022 Annual Report)* on August 21, 2023. This Request for Action presents staff's analysis regarding MED-Project's Revised 2022 Annual Report and MED-Project's covered drugs stewardship program.

Background

MED-Project is a stewardship organization that, as reported in its *Revised 2022 Annual Report*, represents more than 500 covered entities under its approved stewardship plan for covered drugs, titled, *A Product Stewardship Plan for Covered Drugs from Households (Plan)*. On December 9, 2021, the Department of Resources Recycling and Recovery (CalRecycle) conditionally approved MED-Project's *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 June 23, 2022, MED-Project's *Plan* was approved. MED-Project's *Revised 2022 Annual Report* covers the entire 2022 calendar year (January 1, 2022, through December 31, 2022).

PRC section 42033.2(a)(1) states that, on or before March 31, 2022, and each year thereafter, a program operator shall submit to CalRecycle a report that describes the stewardship program activities during the previous reporting period of one year. MED-Project submitted its 2022 Annual Report, titled, *MED-Project 2022 Annual Report, State of California, Covered Drugs (2022 Annual Report)* on March 31, 2023. CalRecycle determined the *2022 Annual Report* was complete and notified MED-Project on May 1, 2023, pursuant to PRC section 42033.2(d)(1) and 14 CCR section 18973.1(b). On June 21, 2023, CalRecycle conditionally approved MED-Project's *2022 Annual Report* in the Request for Action (RFA), titled, *Consideration of MED-Project's 2022 Annual Report for Covered Drugs (June 2023 RFA)*. On August 21, 2023, MED-Project submitted its *Revised 2022 Annual Report*, which is the subject of this Request for Action. CalRecycle has 90 days to approve, disapprove, or conditionally approve the *Revised 2022 Annual Report* pursuant to PRC section 42033.2(d)(2) and 14 CCR section 18973.1.

Staff Analysis

Staff evaluated MED-Project's *Revised 2022 Annual Report* to determine whether the requirements of statute, regulations, and MED-Project's *Plan* were met. The sections below present the requirements in the June 2023 Request for Action that CalRecycle required MED-Project to address, followed by a summary of staff's analysis of MED-Project's *Revised 2022 Annual Report* and MED-Project's covered drugs stewardship program.

Convenience Standards

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to PRC sections 42032.2(a)(1)(F), 42032.2(c) and 14 CCR section 18973.4(c)(3).

- a. Describe the circumstances that were beyond MED-Project'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).
- b. Describe the efforts that were undertaken to achieve compliance with the convenience standard for the counties that have been reported in Attachment C of the *2022 Annual Report* as not meeting the convenience standard requirement pursuant to 14 CCR section 18973.4(c)(3).
- c. For the 21 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, MED-Project'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).

Analysis: Requirements (a) and (c) Met, Requirement (b) Not Met

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. MED-Project reported supplementing 21 counties with mail-back distribution locations that did not have the minimum number of authorized collection sites established but it did not describe the circumstances beyond its control that prevented it from meeting the convenience standard outlined in PRC section 42032.2(a)(F)(i) in its *2022 Annual Report*. MED-Project's *Revised 2022 Annual Report* includes a description of the circumstances that were beyond its control that necessitated the use of supplemental mail-back distribution locations in the 21 counties where MED-Project did not establish the minimum number of authorized collection sites. The reasons MED-Project provides include: "(1) lack of interest in participation in the Program; (2) the appropriate party was not available to respond to MED-Project's outreach; (3) lack of response to MED-Project's outreach; (4) closure of the potential Authorized Collection Site during the Reporting Period; (5) the presence of an existing secure collection receptacle operated by another approved Program Operator; (6) not able to meet State Board and/or DEA

requirements, or (7) not open or accessible to public.” MED-Project met requirement (a).

MED-Project’s *Revised 2022 Annual Report* provides a description of the efforts conducted to meet the convenience standard in the 21 counties in which it did not establish the minimum number of authorized collection sites. MED-Project conducted outreach 247 times to 117 potential authorized collectors through in-person visits, pre-installation assessments, phone calls, and email check-ins. MED-Project also contacted pharmacy chains and invited participation to serve as an authorized collector in the 21 counties. CalRecycle expects MED-Project to demonstrate, in subsequent annual reports, progress in establishing additional authorized collection sites in these 21 counties and a corresponding reduction in the need to use supplemental mail-back distribution locations. MED-Project did not achieve the geographic spread goal of 90% of ultimate users living within 15-miles of an authorized collection site in nine counties as described in the *June 2023 RFA*. The staff calculated geographic spread average for those nine counties is 71%. This requirement must be met on a county basis pursuant to PRC section 42032.2(a)(1)(F). The geographic spread requirement must be met by using authorized collection sites alone and does not include mail-back distribution locations. Therefore, requirement (b) is not met. CalRecycle expects that MED-Project will continue to establish authorized collection sites in the nine counties to achieve the geographic spread requirement on a per county basis and report its efforts to establish authorized collection sites in subsequent annual reports, pursuant to 14 CCR section 18973.4(c)(3).

MED-Project submitted Attachment D, a list of the potential authorized collection sites that were considered in the 21 counties where MED-Project did not establish the minimum number of authorized collection sites with its *Revised 2022 Annual Report*. MED-Project met requirement (c).

Authorized Collectors

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR section 18973.4(c)(2).

- a. Provide a list of potential authorized collectors that were notified of the opportunity to participate in the program. Clarify which of these notifications occurred during calendar year 2022 pursuant to 14 CCR section 18973.4(c)(2)(A).
- b. Provide a list of potential authorized collectors that were rejected from participating in the program and the reason for rejection pursuant to 14 CCR section 18973.4(c)(2)(E).
- c. Include descriptions of the good faith negotiations that occurred with potential authorized collectors in the annual report pursuant to 14 CCR section 18973.4(c)(2)(B).

Analysis: Requirements (a), (b), and (c) Met

In the *2022 Annual Report*, MED-Project referenced the list of potential authorized collectors that were notified of the opportunity to participate in the program that was submitted in 2021, but it did not include a list of potential authorized collectors that

were notified during the 2022 reporting period. MED-Project submitted Attachment A, a list of the potential authorized collectors that were contacted about participation as an authorized collector in the counties where its program operated during the reporting period with the *Revised 2022 Annual Report*. MED-Project met requirement (a).

In the *2022 Annual Report*, MED-Project stated that it “excluded” two potential authorized collectors from the program but did not identify or provide a list of the excluded potential authorized collectors. MED-Project submitted Attachment C with its *Revised 2022 Annual Report* that lists the potential authorized collectors excluded from participation in its program. MED-Project met requirement (b).

In the *2022 Annual Report*, MED-Project referred to its approved Plan for a description of the process by which good faith negotiations with potential authorized collectors are conducted instead of providing enough of a description for the reader to understand what is being described as a standalone document. Good faith negotiations described in the *Revised 2022 Annual Report* include conducting an eligibility assessment, collecting information, providing a draft agreement, providing a draft written offer to participate, and receiving a signed offer to participate from the potential authorized collector. MED-Project met requirement (c).

Collection, Transportation, and Disposal

Requirement: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR section 18973.4(d).

- a. Include additional description in the annual report of the methods used to transport and dispose of covered drugs, including a description of the mechanism(s) to track the collection, transportation, and disposal covered drugs, pursuant to 14 CCR section 18973.4(d)(1).

Analysis: Requirement (a) Met

In the *2022 Annual Report*, MED-Project did not provide enough description of the mechanism(s) used to track, transport, and dispose of covered drugs for CalRecycle to determine if this requirement was met. In the *Revised 2022 Annual Report*, MED-Project includes additional information in its description of its process used for tracking, transporting, and disposing of covered drugs. MED-Project described the tracking that occurs upon carrier pick-up through transport to an approved disposal facility. MED-Project met requirement (a).

Actual Expenses from Reporting Period

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR sections 18973.4(n), and 18973.1(a).

- a. Clarify why \$701,750 in departmental administrative fee costs are listed as an actual expense incurred pursuant to 14 CCR sections 18973.1(a) and 18973.4(n).

Analysis: Requirement (a) Met

In the *2022 Annual Report*, MED-Project listed departmental administrative fee costs of \$701,750 as an actual expense incurred, although CalRecycle did not issue MED-

Project an invoice during the 2022 reporting period. In its *Revised 2022 Annual Report*, MED-Project clarifies that the departmental administrative fees are included as an estimate due to its accrual accounting method. MED-Project states that the departmental administrative fees included in its *Revised 2022 Annual Report* are based on a fee estimate provided by CalRecycle. Staff verified that MED-Project's estimate of \$701,750 in departmental administrative fees is reasonable based on CalRecycle's fee estimate. Therefore, MED-Project met requirement (a).

Education and Outreach

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR sections 18973.4(i) and 18973(d).

- a. Include additional descriptions of the education and outreach activities and provide correct dates for statewide impressions in the annual report pursuant to 14 CCR sections 18973.4(i) and 18973(d).

Analysis: Requirements (a) Met

In the *2022 Annual Report*, MED-Project referred to its approved *Plan* to supplement the description regarding the information that is provided on its website. In the *Revised 2022 Annual Report*, MED-Project provides a detailed list of the information provided on its website such as information on collection options, a list of authorized collection sites, including a zip code-based map locator, and a form to accept requests for mail-back packages.

Additionally, MED-Project corrected the typographical date errors in *Attachment I, Daily Impressions for Digital Media*, submitted with its *Revised 2022 Annual Report*. MED-Project met requirement (a).

Feedback from Interested Parties

CalRecycle solicited public input on MED-Project's *Revised 2022 Annual Report* from August 23, 2023, through September 6, 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 MED-Project's *Revised 2022 Annual Report*.
- Conditionally approve MED-Project's *Revised 2022 Annual Report*.
- Disapprove MED-Project's *Revised 2022 Annual Report*.
- Disapprove MED-Project's *Revised 2022 Annual Report* and refer MED-Project to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement.

Signed by: Rachel Machi Wagoner, Director **Dated:** November 17, 2023

Attachments:

Documents listed below are posted to CalRecycle's website.

1. [MED-Project 2022 Annual Report, State of California, Covered Drugs](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125259>
 - a. [Attachment A List of Potential Authorized Collectors Contacted](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125226>
 - b. [Attachment B List of Potential Authorized Collectors Submitting Written Offer to Participate](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125229>
 - c. [Attachment C List of Sites Excluded from Participation](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125232>
 - d. [Attachment D List of Sites in 21 Counties that were Contacted](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125235>
 - e. [Attachment E Authorized Collector Collection Data](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125238>
 - f. [Attachment F Participating Authorized Collectors](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125241>
 - g. [Attachment G Instances Secure Receptacles Were Not Available to the Public](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125244>
 - h. [Attachment H Mail-Back Distribution Locations](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125247>
 - i. [Attachment I Daily Impressions for Digital Media](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125250>
 - j. [Attachment J List of Covered Products](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125253>
 - k. [Attachment K List of Covered Drugs Covered Entities](#) (August 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125256>
2. [Consideration of MED-Project's 2022 Annual Report for Covered Drugs](#) (June 21, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123882>
3. [MED-Project 2022 Annual Report](#) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123324>
 - a. [Attachment A List of Potential Authorized Collectors Submitting Written Offer to Participate](#) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123327>
 - b. [Attachment B Authorized Collector Collection Data](#) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123333>
 - c. [Attachment C Participating Authorized Collectors](#) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123339>
 - d. [Attachment D Instances Secure Receptacles Were Not Available to the Public](#) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123345>

- e. [Attachment E Mail-Back Distribution Locations](https://www2.calrecycle.ca.gov/Docs/Web/123351) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123351>
 - f. [Attachment F Daily Impressions for Digital Media](https://www2.calrecycle.ca.gov/Docs/Web/123357) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123357>
 - g. [Attachment G List of Covered Products](https://www2.calrecycle.ca.gov/Docs/Web/123360) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123360>
 - h. [Attachment H List of Covered Drugs Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/123363) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123363>
4. [A Product Stewardship Plan for Covered Drugs from Households](https://www2.calrecycle.ca.gov/Docs/Web/120945) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120945>
- a. [Appendix A - Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/120921) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120921>
 - b. [Appendix B - Covered Products](https://www2.calrecycle.ca.gov/Docs/Web/120927) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120927>
 - c. [Appendix C - Participating Authorized Collection Sites](https://www2.calrecycle.ca.gov/Docs/Web/120933) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120933>
 - d. [Appendix C – Participating Authorized Collection Sites Addendum](https://www2.calrecycle.ca.gov/Docs/Web/121092) (March 21, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/121092>
 - e. [Appendix E - Potential Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/120936) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120936>
 - f. [Appendix K – Potential Mail-Back Distribution Locations](https://www2.calrecycle.ca.gov/Docs/Web/120939) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120939>