

REQUEST FOR ACTION

To: Rachel Machi Wagoner
Director

From: Zoe Heller
Deputy Director, Division of Circular Economy

Request Date: June 20, 2023

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

Action By: June 29, 2023

Summary of Request

MED-Project USA (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, as required by statute. This Request for Action presents staff's analysis regarding MED-Project's *2022 Annual Report* and MED-Project's covered drugs stewardship program.

Background

MED-Project is a stewardship organization that, as reported in the *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 *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* 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). CalRecycle has 90 days to approve, disapprove, or conditionally approve the *2022 Annual Report* pursuant to PRC section 42033.2(d)(2) and 14 CCR section 18973.1.

Staff Analysis

MED-Project states in its *2022 Annual Report* that it conducted the following program activities:

- Fully implemented its program within 270 days of CalRecycle's approval of its *Plan*

- Installed 736 new authorized collection sites, resulting in a total of 1,017 active authorized collection sites and 115 active mail-back distribution locations
- Implemented an education and outreach program that includes a website, call center, initiatives targeted at ultimate users and to support authorized collectors, and distribution of printable materials and signage to participating sites
- Established a reasonable geographic spread of authorized collection sites so that more than 90 percent of ultimate users live within 15 miles of a MED-Project authorized collection site
- Collected a total of 277,037.9 pounds of covered drugs from authorized collection sites and 187.3 pounds of covered drugs through the return of 254 mail-back packages

MED-Project reported challenges meeting the convenience standards and identifying prospective authorized collection sites in rural low population counties.

Staff evaluated MED-Project's *2022 Annual Report* 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 *2022 Annual Report* 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.

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). 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 Partially Met

MED-Project's *2022 Annual Report* describes implementing its covered drugs stewardship program through activities that include establishing authorized collection sites (e.g., retail pharmacies, retail pharmacy chains, and law enforcement agencies), mail-back distribution locations in counties that did not have the minimum number of authorized collection sites or did not have a retail pharmacy operating as an authorized collection site. Additionally, MED-Project established a website and call center through which ultimate users can obtain information on collection options, including authorized collection site locations, and order free mail-back packages. MED-Project also operated a comprehensive education and outreach program that included digital media outreach campaigns.

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 MED-Project's *2022 Annual Report*, MED-Project has not met the required number of authorized collection sites in 21 counties. MED-Project states that the requirement is met when mail-back distribution locations that it established in those counties are combined with the number of authorized collection sites. Figure 1 in CalRecycle Appendix A shows a map of California with the number of additional authorized collection sites required in 21 counties for MED-Project 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. Additionally, 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, at this time it is unclear what responsibility program operators had regarding establishing a stewardship program in San Luis Obispo 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. MED-Project's *2022 Annual Report* does not describe the circumstances that were beyond MED-Project'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 21 counties. This information is necessary for CalRecycle to approve MED-Project's use of the mail-back distribution locations to meet this convenience standard.

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. MED-Project's approved *Plan* states that "MED-Project will locate Authorized Collection Sites so that greater than 90% of Ultimate Users live within a 15-mile drive of an Authorized Collection Site." However, based on the data provided in its *2022 Annual Report*, MED-Project did not achieve the geographic spread as outlined in the approved *Plan* in nine 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 nine counties where MED-Project 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.

Summary 1 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 MED-Project's *2022 Annual Report* as indicated in the "Action" section below.

- 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 authorization 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).

Authorized Collectors

Requirements: The annual report shall describe how the program operator complied with all elements in its stewardship plan during the previous reporting period of one year pursuant to PRC section 18973.4. Provide a list of potential authorized collectors that were notified of the opportunity to serve as an authorized collector pursuant to 14 CCR section 18973.4(c)(2)(A). Provide a list of potential authorized collectors that submitted a written offer to join the program and were rejected, and the reason(s) for each rejection pursuant to 14 CCR section 18973.4(c)(2)(E). Describe the process by which good faith negotiations with potential authorized collectors were conducted pursuant to 14 CCR section 18973.4(c)(2)(B).

Analysis: Requirements Partially Met

MED-Project's *2022 Annual Report* referenced the list of potential authorized collectors that were notified of the opportunity to participate in the program that MED-Project submitted in 2021 and did not include a list of potential authorized collectors that were notified during the 2022 calendar reporting period. Additionally, on page 7 of its *2022 Annual Report*, MED-Project refers to its approved *Plan* for a description of the process by which good faith negotiations with potential authorized collectors are conducted. 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(c)(2)(A). 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.

The *2022 Annual Report* states that MED-Project "excluded" two potential authorized collectors from the program as they were not able to meet Federal Drug Enforcement Administration requirements. However, MED-Project did not identify the two potential authorized collectors that were rejected as required by 14 CCR section 18973.4(c)(2)(E).

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 MED-Project's *2022 Annual Report* as indicated in the "Action" section below.

- 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).

Collection, Transportation, and Disposal

Requirement: Describe the methods used for transportation and disposal of covered drugs, including mechanism(s) used to track the collection, transportation, and disposal of covered drugs. For each disposal facility, include the name of the facility, the mailing and physical address, and the total weight of covered drugs disposed pursuant to 14 CCR 18973.4(d).

Analysis: Requirement Partially Met

MED-Project's *2022 Annual Report* states that "MED-Project operates a handling, transport, and disposal system that complies with applicable laws, regulations, and other legal requirements." The *2022 Annual Report* does not describe the mechanisms that were used to transport and dispose of covered drugs, only that there is a "system" in place. Additionally, the *2022 Annual Report* includes a partial description of the mechanism(s) used to track the collection, transportation, and disposal of covered drugs, only stating that "each Mail-Back Package, inner liner, and shipping box...had a unique identifier enabling tracking." MED-Project notes that tracking is enabled by the unique identifier but does not describe whether tracking is occurring or how the unique identifier allows "each Mail-Back Package, inner liner, and shipping box" to be tracked from collection through disposal. 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(d)(1).

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

- 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).

Actual Expenses from Reporting Period

Requirements: Provide a list of all actual expenses incurred during the previous reporting period of one year pursuant to 14 CCR section 18973.4(n) that

summarizes expenses in accordance with the budget categories specified in 14 CCR section 18973.6(b). 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: Requirement Partially Met

MED-Project's *2022 Annual Report* lists 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. MED-Project must clarify the departmental administrative fee costs listed in the *2022 Annual Report*.

Summary 4 of Requirement Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove MED-Project's *2022 Annual Report* as indicated in the "Action" section below.

- 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).

Education and Outreach

Requirements: Include a description and evaluation of the comprehensive education and outreach activities pursuant to 14 CCR section 18973.4(i). An annual report shall be complete and correct pursuant to 14 CCR section 18973(d).

Analysis: Requirements Partially Met

MED-Project refers to its approved *Plan* to supplement the information or descriptions provided in the *2022 Annual Report*. On page 20, the *2022 Annual Report* refers to the *Plan* for the information provided on the website. 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.

Additionally, MED-Project's *2022 Annual Report* includes data for 2023 with regards to *Daily Impressions for Digital Media (Attachment F)*. The *2022 Annual Report* must include information from the 2022 calendar year reporting period.

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 MED-Project's *2022 Annual Report* as indicated in the "Action" section below.

- 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).

Feedback from Interested Parties

CalRecycle solicited public input on MED-Project's *2022 Annual Report* from April 4, 2023, through April 18, 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 *2022 Annual Report*.
- Conditionally approve MED-Project's *2022 Annual Report*. Pursuant to 14 CCR section 18973.1(j), MED-Project must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date of 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 MED-Project's *2022 Annual Report*. Pursuant to 14 CCR section 18973.1(k), MED-Project must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date of 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 MED-Project's *2022 Annual Report* and refer MED-Project to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement. Pursuant to 14 CCR section 18973.1(k), MED-Project must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date of this Request for Action notice is issued that includes the additional information specified in "Summary 1 of Requirements Not Met" through "Summary 5 of Requirement Not Met" in the "Staff Analysis" section above.

Signed by: Rachel Machi Wagoner, Director

Dated: June 21, 2023

Attachments:

Documents listed below are posted to CalRecycle's website. To request the *2022 Annual Report* and its associated attachments, please submit a Public Records Act request (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

1. [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](#) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123351>
 - f. [Attachment F Daily Impressions for Digital Media](#) (March 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123357>

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	Alpine	1,200	0	N/A**	0	N/A**	7
2	Butte	201,608	37	5	8	0	0
3	Contra Costa (incorporated)	979,614	134	20	54	0	1
4	El Dorado	190,465	33	5	5	0	1
5	Fresno	1,011,273	150	21	29	0	0
6	Humboldt	135,168	28	5	13	0	0
7	Imperial	179,329	28	5	8	0	0
8	Kern	909,813	145	19	36	0	0
9	Kings	152,023	19	5	6	0	0
10	Los Angeles	9,861,224	1853	198	258	0	0
11	Madera	157,396	19	5	7	0	1
12	Mendocino	89,999	16	5	5	0	1
13	Merced	284,338	33	6	10	0	0
14	Monterey	433,716	51	9	12	0	0
15	Orange	3,162,245	673	64	87	0	0
16	Placer	409,025	69	9	13	0	0
17	Plumas	18,942	4	5	5	0	1
18	Riverside	2,435,525	376	49	72	0	0
19	Sacramento	1,576,618	227	32	50	0	4
20	San Bernardino	2,187,665	308	44	61	0	0
21	San Diego	3,287,306	491	66	99	0	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	San Joaquin	784,298	86	16	17	0	0
23	Shasta	180,531	37	5	7	0	1
24	Sierra	3,229	0	N/A**	2	N/A**	4
25	Solano	447,241	49	9	13	0	0
26	Sonoma	482,404	71	10	14	0	1
27	Stanislaus	549,466	73	11	20	0	0
28	Sutter	99,145	20	5	6	0	2
29	Tulare	475,014	66	10	20	0	1
30	Ventura	833,652	163	17	27	0	0
31	Yolo	221,165	31	5	6	0	0
32	Colusa	21,807	3	5	2	3	4
33	Del Norte	27,218	6	5	4	1	2
34	Glenn	28,750	5	5	3	2	4
35	Inyo	18,978	4	5	4	1	3
36	Lassen	30,274	4	5	2	3	4
36	Mariposa	17,045	2	5	1	4	10
38	Modoc	8,690	2	5	2	3	5
39	Mono	13,379	2	5	1	4	8
40	San Benito	65,479	6	5	3	2	3
41	Trinity	16,023	2	5	1	4	5
42	Amador	40,297	6	5	1	4	5
43	Calaveras	45,049	7	5	2	3	13

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
44	Lake	67,407	10	5	1	4	5
45	Napa	136,179	18	5	4	1	3
46	Nevada	101,242	14	5	3	2	2
47	Siskiyou	43,830	7	5	3	2	4
48	Tehama	65,052	9	5	3	2	3
49	Tuolumne	55,291	11	5	3	2	3
50	Yuba	82,275	12	5	4	1	4
	Totals		5420	760	1017	48	115

*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, so MED-Project is providing a mail-back program. (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 C Participating Authorized Collectors* that MED-Project 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 E Mail-Back Distribution Locations* that MED-Project provided with its *2022 Annual Report*. The green rows (1 through 31) show the counties where MED-Project established the required numbers or more of authorized collection sites. The yellow rows (32 through 41) show the counties where MED-Project established at least half or more of the registered pharmacies available as authorized collection sites. The red rows (42 through 50) show the counties where MED-Project 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.