

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 MED-Project's 2023 Annual Report for Covered
Drugs

Action By: June 27, 2024

Summary of Request

MED-Project USA (MED-Project) submitted its 2023 annual report, titled, *MED-Project 2023 Annual Report, State of California, Covered Drugs (2023 Annual Report)* on March 29, 2024, as required by statute. This Request for Action presents staff's analysis regarding MED-Project's *2023 Annual Report* and MED-Project's covered drugs stewardship program.

Background

MED-Project is a stewardship organization that, as reported in the *2023 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 *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. MED-Project submitted its *2023 Annual Report* on March 29, 2024. CalRecycle determined the *2023 Annual Report* was complete and notified MED-Project 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

MED-Project states in its *2023 Annual Report* that it conducted program activities including:

- Installed collection receptacles at 34 new authorized collection sites, resulting in a total of 1,046 active authorized collection sites and 120 active mail-back distribution locations.
- Continued efforts to achieve 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 558,210.8 pounds of covered drugs from authorized collection sites and 1,110.4 pounds of covered drugs through the return of 1,457 mail-back packages.
- Maintained an education and outreach program that includes a website, call center, continued distribution of printable materials and signage to participating authorized collection sites, ran outreach campaigns targeted at ultimate users, and initiatives to support authorized collectors and encourage potential authorized collector participation.
- Coordinated with the other approved program operator to include the common mark (e.g., decal, emblem, or logo) on all program materials and to develop a neutrally branded website and toll-free telephone number.
- Conducted a digital survey to solicit feedback on program awareness from ultimate users.

MED-Project reported challenges meeting the convenience standards and identifying prospective authorized collection sites in counties with a population of less than 100,000.

Staff evaluated MED-Project's *2023 Annual Report* to determine whether the requirements of statute, regulations, and MED-Project's *Plan* were met. Overall, MED-Project reports significant efforts undertaken during the reporting period to address the statutory, regulatory, and *Plan* requirements, as well as the requirement CalRecycle identified in the Request for Action, titled, *Consideration of MED-Project's Revised 2022 Annual Report for Covered Drugs*. The sections below present a summary of staff's analysis of MED-Project's *2023 Annual Report*, 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.

Convenience Standard - Authorized Collection Sites

Requirements: Provide a description of how the convenience standards were met pursuant to PRC sections 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: Requirement 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. Based on data contained in MED-Project's *2023 Annual Report*, MED-Project did not establish the required number of authorized collection sites in 16 counties, a decrease from the 21 counties MED-Project reported in 2022. However, MED-Project states that it "met the convenience standard in PRC Section 42032.2(a)(1)(F)(i) and (iii) during the Reporting Period, with a combination of Authorized Collection Sites and Mail-Back Distribution Locations."

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 or other alternative form of collection and disposal. In its approved *Plan*, MED-Project commits to conduct digital media outreach promoting the availability of mail-back services and provide one mail-back distribution location in each county that does not have the minimum number of authorized collection sites due to circumstances beyond its control.

The circumstances MED-Project reports were beyond its control for establishing the minimum number of authorized collection sites in the 16 counties in 2023 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." The *2023 Annual Report* includes a description of the efforts MED-Project made to achieve compliance in the 16 counties that did not have the minimum number of authorized collection sites pursuant to statute and its approved *Plan*. Within these 16 counties, MED-Project identifies 102 potential authorized collection sites in *Attachment D: Sites in 16 Counties that were Contacted* and conducted outreach to these sites 161 times by in-person visits, pre-installation assessments, phone calls, and email check-ins. MED-Project issued notifications to retail pharmacy chains inviting participation as an authorized collection site. MED-Project also launched additional digital media outreach campaigns promoting the availability of mail-back services, pursuant to its approved *Plan*.

Program operators may utilize mail-back distribution locations as 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. MED-Project reports a total of 120 active mail-back distribution locations in operation during the reporting period. In the 16 counties where MED-Project did not establish the required number of authorized collection sites, at least one mail-back distribution

location was established for each authorized collection site necessary to meet the minimum number of authorized collection sites required, consistent with MED-Project's approved *Plan*. Based on the information provided in the *2023 Annual Report*, CalRecycle approves MED-Project's use of supplemental mail-back service in 16 counties (Alpine, Amador, Calaveras, Colusa, Del Norte, Glenn, Inyo, Lake, Lassen, Mariposa, Modoc, Mono, San Benito, Sierra, Tehama, and Trinity) 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. Therefore, and taking into account MED-Project's mail-back efforts described below, MED-Project met the requirements of PRC section 42032.2(a)(1)(F)(iii). 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. Although MED-Project did not establish any authorized collection sites in Alpine County, it did establish eight mail-back distribution locations and provided the exceptional circumstances beyond its control for why it was unable to secure an authorized collection site, therefore meeting PRC sections 42032.2(a)(1)(F)(i) and (iii) for the 2023 reporting period.

CalRecycle expects that MED-Project will continue to establish additional authorized collection sites in the 16 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

Requirements: 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. MED-Project's approved *Plan* states that "MED-Project will locate Authorized Collection Sites so that greater than 90 percent of Ultimate Users live within a 15-mile drive of an Authorized Collection Site." Based on the data provided in its *2023 Annual Report*, MED-Project did not achieve its geographic spread goal as outlined in its approved *Plan* in nine counties. MED-Project includes a description of the efforts it made to achieve compliance in the nine counties where it did not achieve its geographic spread goal in its *2023 Annual Report*. Within the

nine counties, MED-Project identifies 72 potential authorized collectors in *Attachment E: List of Potential Authorized Collectors Considered in Nine Counties* and it conducted outreach to these site 146 times by in-person visits, pre-installation assessments, phone calls, and email check-ins. MED-Project issued notifications to retail pharmacy chains inviting participation as an authorized collection site. MED-Project also launched additional digital media outreach campaigns promoting the availability of mail-back services in these areas. MED-Project reports that “the potential Authorized Collectors listed in Attachment E were not feasible as an Authorized Collection Site” for the same reasons noted above with regards to the minimum number of authorized collection sites.

In addition to reporting its reasonable geographic spread pursuant to its approved *Plan*, MED-Project describes an approach to calculate reasonable geographic spread that uses a stratified geographic spread based on county populations from highly populated counties to less populated counties. MED-Project reports using US 2020 Census Block population data and the most recent publicly available population calculations from the State of California Department of Finance provided in the E-1 Population Estimates for Counties as the basis for its updated stratified geographic spread goal. Additionally, MED-Project is measuring the distance in miles driven versus the direct distance between two points. MED-Project describes the stratified geographic spread goal it used to achieve compliance as follows:

“For more highly populated counties with a population of greater than or equal to 200,000 residents per county, MED-Project provided a reasonable geographic spread of Authorized Collection Sites so that more than 90 percent of Ultimate Users in these counties live within a 15-mile drive of an Authorized Collection Site.

In counties with a population of greater than or equal to 100,000 residents and less than 200,000 residents per county, MED-Project provided a reasonable geographic spread of Authorized Collection Sites so that more than 90 percent of Ultimate Users live within a 30-mile drive of an Authorized Collection Site.

In counties with a population of greater than or equal to 50,000 residents and less than 100,000 residents per county, MED-Project provided a reasonable geographic spread of Authorized Collection Sites so that more than 90 percent of Ultimate Users live within a 45-mile drive of an Authorized Collection Site.

In counties with a population of greater than or equal to 5,000 residents and less than 50,000 residents per county, MED-Project provided a reasonable geographic spread of Authorized Collection Sites so that more than 75 percent of Ultimate Users live within a 45-mile drive of an Authorized Collection Site.”

MED-Project states that it met the updated geographic spread goal stratified by county population that it describes in the *2023 Annual Report*. However, if MED-Project wishes for compliance with PRC section 42032.2(a)(1)(F)(ii) to be evaluated using this new reasonable geographic spread goal, this is considered a significant change to its *Plan* and requires CalRecycle approval prior to implementation, pursuant to PRC section 42032(e).

Should MED-Project elect to update the geographic spread goal in its approved *Plan*, MED-Project will need to submit the “significant change” to CalRecycle for approval, pursuant to PRC section 42032(e) and 14 CCR section 18793.1(i), and include all factors applied to develop the determination in accordance with 14 CCR section 18973.2(g)(2)(A). If approved, CalRecycle would then determine whether MED-Project achieved the new reasonable geographic spread of authorized collection sites at a county level pursuant to its approved *Plan* in subsequent annual reports in accordance with PRC section 42032.2(a)(1)(F)(ii) and its *Plan*.

CalRecycle notes that retail pharmacy chains’ participation in the covered drugs stewardship program, pursuant to PRC section 42032.2(b)(2), supports MED-Project’s attainment of a convenience standard as well as reasonable geographic spread.

Collection and Disposal 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

MED-Project compiled covered drugs collection data from participating authorized collection sites that includes the weight collected, number of instances that covered drugs were picked up for transport to disposal, and the number of receptacle liners picked up for transport to disposal in *Attachment F: Authorized Collector Collection Data*. MED-Project reports collecting a total of 558,210.8 pounds of covered drugs through 13,179 pickups at 1,003 authorized collection sites during the reporting period.

MED-Project reports distributing mail-back packages through its website and call center. MED-Project also reports distributing mail-back packages at 120 mail-back distribution locations during the reporting period. The three types of mail-back packages distributed include standard, inhaler, and injector. MED-Project distributed 3,395 standard mail-back packages, 440 inhaler mail-back packages, and 1,653 injector mail-back packages. MED-Project collected and disposed 1,110.4 pounds of covered drugs through the return of a total 1,457 mail-back packages: 990 standard, 155 inhaler, and 312 injector mail-back packages.

The total weight of covered drugs collected and disposed through MED-Project’s covered drugs stewardship program are presented in Table 1, below.

Table 1. Covered Drugs Collected and Disposed in 2023

	Weight (pounds)
Authorized Collection Sites (1,003)	558,210.8
Mail-Back Packages (via website, call center, and 120 mail-back distribution locations)	1,110.4

Total	559,321.2
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Education and Outreach

Requirements: Implement a comprehensive education and outreach program pursuant to PRC section 42031.6 and 14 CCR section 18973.2(j). Describe and evaluate the comprehensive education and outreach activities pursuant to 14 CCR section 18973.2(i). Discuss what the metrics, described in 14 CCR section 18973.4(i)(3), reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility, pursuant to 14 CCR sections 18973.4(i)(2) and (3).

Analysis: Requirements Met

MED-Project reports continuing its ongoing education and outreach, including posting social media content, operating a website, completing digital media campaigns, and distributing promotional materials such as brochures and posters. Additionally, MED-Project conducted an awareness survey from October 10, 2023, to October 25, 2023, to gauge ultimate users' awareness and use of the covered drugs stewardship program. Out of the 1,000 survey respondents, 71 percent are aware of the disposal options through collection receptacles at authorized collection sites and mail-back services, 58 percent found the disposal options available and accessible, and 67 percent found the disposal options easy to use. MED-Project reports that it measured 5,270,281 impressions from its digital display media campaign and 3,338,337 impressions from its social media campaign. In addition, MED-Project's website was visited 51,302 times, and the call center received 1,257 calls. MED-Project uses the number of visits to the website and calls received through its call center as data points that can reflect the potential usage of the program. MED-Project's website is accessible per the Americans with Disabilities Act and has translations available and the call center has English and Spanish representatives. MED-Project reports the results of these metrics are used to measure the program's performance and that the results indicate that education and outreach efforts demonstrate a high level of success in raising awareness about disposal options in California. Therefore, it appears MED-Project has implemented a comprehensive education and outreach program, and CalRecycle expects awareness to continue to increase as the program develops.

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 MED-Project'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. CalRecycle considered these comments when reviewing MED-Project's *2023 Annual Report*.

Action

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

- Approve MED-Project's *2023 Annual Report*.
- Conditionally approve MED-Project's *2023 Annual Report*. 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 *2023 Annual Report*. Direct staff to identify how the *2023 Annual Report* 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 2023 Annual Report on the bases of the information reported by MED-Project and the information and analysis contained in this Request for Action because it demonstrates the stewardship program provides adequate access to safe disposal of covered drugs. While the geographic spread requirement was not met, MED-Project's 2023 Annual Report included a robust description of the efforts made to achieve compliance pursuant to 14 CCR section 18973.4(c)(3). MED-Project's 2023 Annual Report demonstrates substantial progress toward establishing the required number of authorized collection sites across the state and provision of supplemental mail-back opportunities for ultimate users in counties where it was unable to establish the required number of authorized collection sites. Under the circumstances, this progress results in adequate availability of access for the safe disposal of covered drugs.

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 2023 Annual Report](https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15663>
 - a. [Attachment A List of Potential Authorized Collectors Contacted](#) (March 29, 2024)

- <https://www2.calrecycle.ca.gov/PublicNotices/Documents/15664>
- b. [Attachment B List of Potential Authorized Collectors Submitting Written Offer to Participate](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15665) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15665>
- c. [Attachment C List of Sites Excluded from Participation](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15666) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15666>
- d. [Attachment D Sites in 16 Counties that were Contacted](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15667) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15667>
- e. [Attachment E List of Potential Authorized Collectors Considered in Nine Counties](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15668) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15668>
- f. [Attachment F Authorized Collector Collection Data](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15669) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15669>
- g. [Attachment G Participating Authorized Collectors](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15670) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15670>
- h. [Attachment H Instances Secure Collection Receptacles Were Not Available to the Public](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15671) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15671>
- i. [Attachment I Mail-Back Distribution Locations](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15672) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15672>
- j. [Attachment J Daily Impressions for Digital Media](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15673) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15673>
- k. [Attachment K List of Covered Products](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15674) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15674>
- l. [Attachment L List of Covered Entities](https://www2.calrecycle.ca.gov/PublicNotices/Documents/15675) (March 29, 2024)
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15675>
2. [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>
3. [Consideration of MED-Project’s Revised 2022 Annual Report for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/126234) (November 17, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/126234>