

MED-Project 2021 Annual Report

State of California, Covered Drugs

March 31, 2022; Revised June 1, 2022

Prepared By: MED-Project USA

Submitted To: California Department of Resources Recycling and Recovery

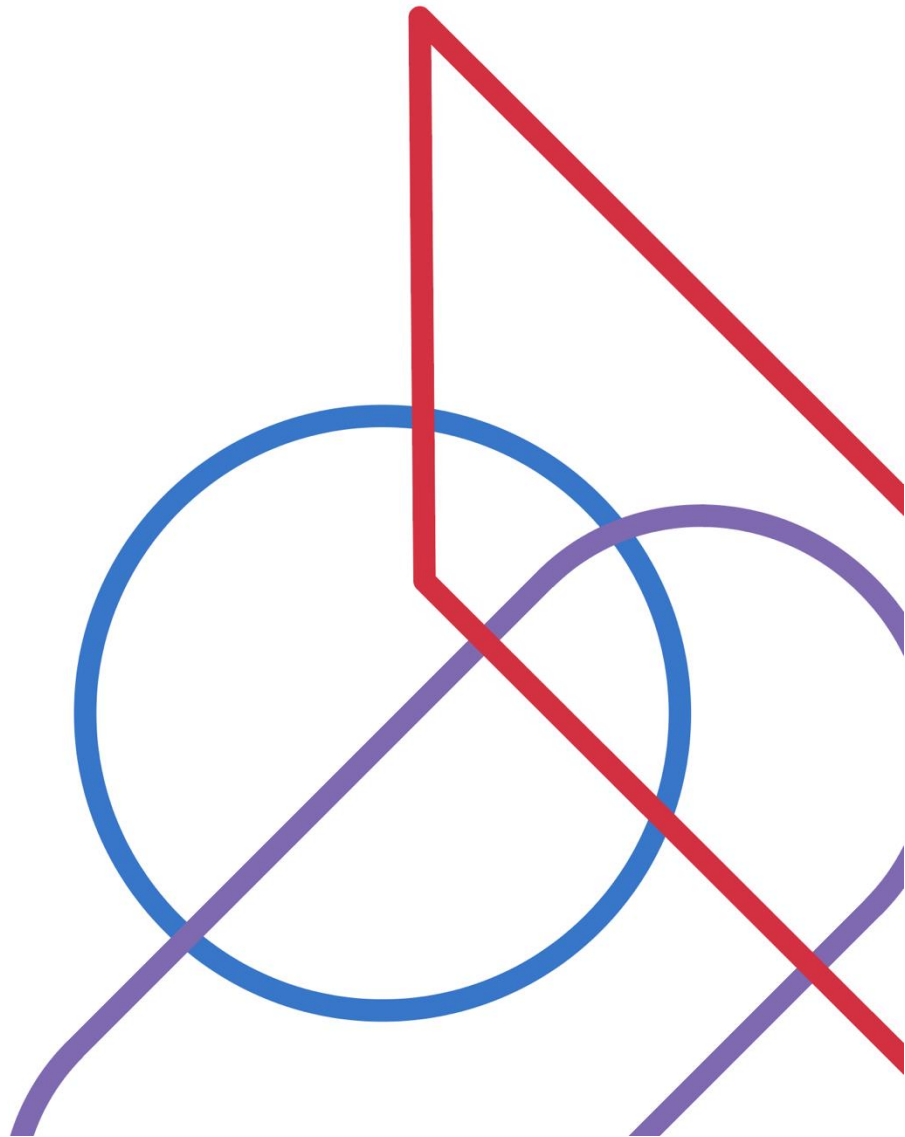


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I. Executive Summary

California Code of Regulations, Title 14, (“Regulation”) Section 18973.4(b): *“Executive Summary. A concise summary of the information contained in the report that includes, but is not limited to, the highlights, outcomes and challenges, achievement of the convenience standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code, education and outreach efforts, and ways in which challenges are being addressed.”*

MED-Project USA (“MED-Project”) operates a Product Stewardship Plan for Covered Drugs from Households in the State of California (“State”) under Chapter 2 (commencing with section 42030), Part 3, Division 30 of the California Public Resources Code. On December 9, 2021, the Director of the California Department of Resources Recycling and Recovery (“CalRecycle”), conditionally approved the MED-Project plan dated September 14, 2021 (the “Approved Plan”). MED-Project submitted a revised Product Stewardship Plan for Covered Drugs from Households, on March 9, 2022 (the “Revised Plan”).

This 2021 State of California Annual Report (“Report”) describes MED-Project’s activities in the State between December 9, 2021, and December 31, 2021 (the “Reporting Period”). The Approved Plan was in the beginning stages of implementation during this Reporting Period.

As such, MED-Project established Authorized Collection Sites during the reporting period in order to work toward the convenience standards outlined in 42032.2(a)(1)(F). By the end of the Reporting Period, 291 Authorized Collectors had agreed to participate in the Program and MED-Project had installed Secure Collection Receptacles at 291 Authorized Collection Sites.

Beginning with the Plan approval on December 9, 2021, MED-Project began implementation of the Program timeline discussed in Appendix F of the Approved Plan.

The following Sections of the Report address the specific reporting requirements in Regulation Section 18973.4 and/or Public Resources Code (“PRC”) Section 42033.2 and activities that occurred during the Reporting Period. Each section of the Report restates the corresponding Code or Regulation and provides the required information. Numbers in the Report have been rounded to the nearest tenth place. All Capitalized terminology not defined in this Executive Summary is derived from the Approved Plan.

II. Program Contact Information

Regulation Section 18973.4 (a): “Contact information pursuant to section 18973.2(a), including any changes or updates to this information.”

The primary contact person for MED-Project during the Reporting Period, was:

Jim Wilson
Lead Director, Legal and Compliance
MED-Project USA
1800 M Street, NW
Suite 400 South
Washington, DC 20036
Phone: 1 (833) 633-7765
Fax: 1 (866) 633-1812
california@med-project.org
www.med-projectusa.org

The M Street address is the mailing and physical address. The above contact information has not changed since submission of the Approved Plan.

III. Collection System

Regulation Section 18973.4(c)(1): Describe “[h]ow ultimate users had an opportunity to dispose of their covered drug(s) as described in the approved stewardship plan.”

A. Establishment of Authorized Collection Sites

Regulation Section 18973.4(c)(2): Describe “[e]fforts between the program operator and potential authorized collectors to establish authorized collection sites, including, but not limited to:

- (a) Pursuant to section 18973.2(d)(2), efforts to notify potential authorized collectors of the opportunity to serve as an authorized collector for the stewardship program in the counties in which the program operated, and the list of potential authorized collectors that were notified.
- (b) Pursuant to section 18973.2(d)(3), the process by which good faith negotiations with potential authorized collectors were conducted.

- (c) *Pursuant to section 18973.2(d)(4), efforts to work with retail pharmacies and retail pharmacy chains to fulfill the requirement in section 42032.2(b)(2) of the Public Resources Code, if applicable.*
- (d) *Pursuant to section 18973.2(d)(5), efforts to incorporate potential authorized collectors that submitted a written offer to join the stewardship program, and the list of potential authorized collectors that submitted written offers.*
- (e) *Pursuant to section 18973.2(d)(6), a list of potential authorized collectors that submitted a written offer to join the stewardship program and were rejected, and the reason(s) for each rejection.*
- (f) *Description of how the program operator complied with the requirement in section 18973.2(d)(7)."*

Prior to the Reporting Period, MED-Project began outreach to potential Authorized Collectors and notified them of the opportunity to serve as an Authorized Collector in the Program. MED-Project is providing the list of potential Authorized Collectors that were approached to participate in the Program as an accessible attachment to this Report. See Attachment A: List of Notified Potential Authorized Collectors. MED-Project sent notifications to 7,653 potential Authorized Collectors prior to the start of the Reporting Period, including to seven chain headquarters representing an additional 2,564 potential Authorized Collectors, for a total of 10,217 potential Authorized Collectors notified. MED-Project approached retail pharmacy chains and notified them of the opportunity to participate in the Program in a notification sent prior to the Reporting Period. MED-Project did not meet the requirement in section 42032.2(b)(2) during the Reporting Period. Retail Pharmacies accounted for 212 of the 291 Authorized Collectors that were active during the Reporting Period.

MED-Project established 291 Authorized Collection Sites in the State prior to the end of the Reporting Period. Prior to the end of the Reporting Period, MED-Project entered into agreements with 1,579 Authorized Collectors. Ultimate Users had the opportunity to dispose of Covered Drugs at 291 of the 1,579 Authorized Collectors during the Reporting Period.

MED-Project conducted good faith negotiations with potential Authorized Collectors during the Reporting Period. MED-Project received expressions of interest in Program participation from 880 potential Authorized Collectors prior to the end of the Reporting Period. MED-Project began good faith negotiations with each of these potential Authorized Collectors within 30 days of receiving their expression of interest. MED-Project conducted those good faith negotiations following the process described in Approved Plan Section 4. There were no written offers to join the stewardship program from Authorized Collectors received during the Reporting Period.

MED-Project did not exclude any potential Authorized Collectors from the Program during the Reporting Period. Accordingly, MED-Project did not have reason to notify potential Authorized Collectors of the reason for exclusion.

B. Convenience Standard

Regulation Section 18973.4 (c)(3): *“How the convenience standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code were met. Include necessary changes to calculations that account for changes in the number of authorized collection sites and most recent publicly available population calculations from the State of California Department of Finance. If the convenience standards were not met, describe efforts made to achieve compliance.”*

Although the Approved Plan was only conditionally approved a few weeks before the end of the Reporting Period, by the end of the Reporting Period MED-Project provided a reasonable geographic spread of Authorized Collection Sites so that more than 90% of Ultimate Users live within a 15-mile drive of an Authorized Collection Site. Figure 1 gives a visual representation of how MED-Project provided a reasonable geographic spread of the Authorized Collection Sites by the end of the Reporting Period.

Given the date of the Approved Plan’s conditional approval, MED-Project did not meet the convenience standards in Code Section 42032.2(a)(1)(F)(i) or (iii) during the Reporting Period and continues to progress toward meeting those convenience standards within 270 days of Approved Plan conditional approval.

STATE OF CALIFORNIA

2021 Covered Drugs Annual Report

Legend

- Active Authorized Collector Sites (291)

Reference Features

- Interstate
- US Highway
- County Boundary
- Unpopulated State and/or Federal Lands

N

1 : 5,395,000

0 25 50 100 Miles

Reporting Period
December 9 - December 31, 2021

MED-Project™
Medication Educator & Disposal

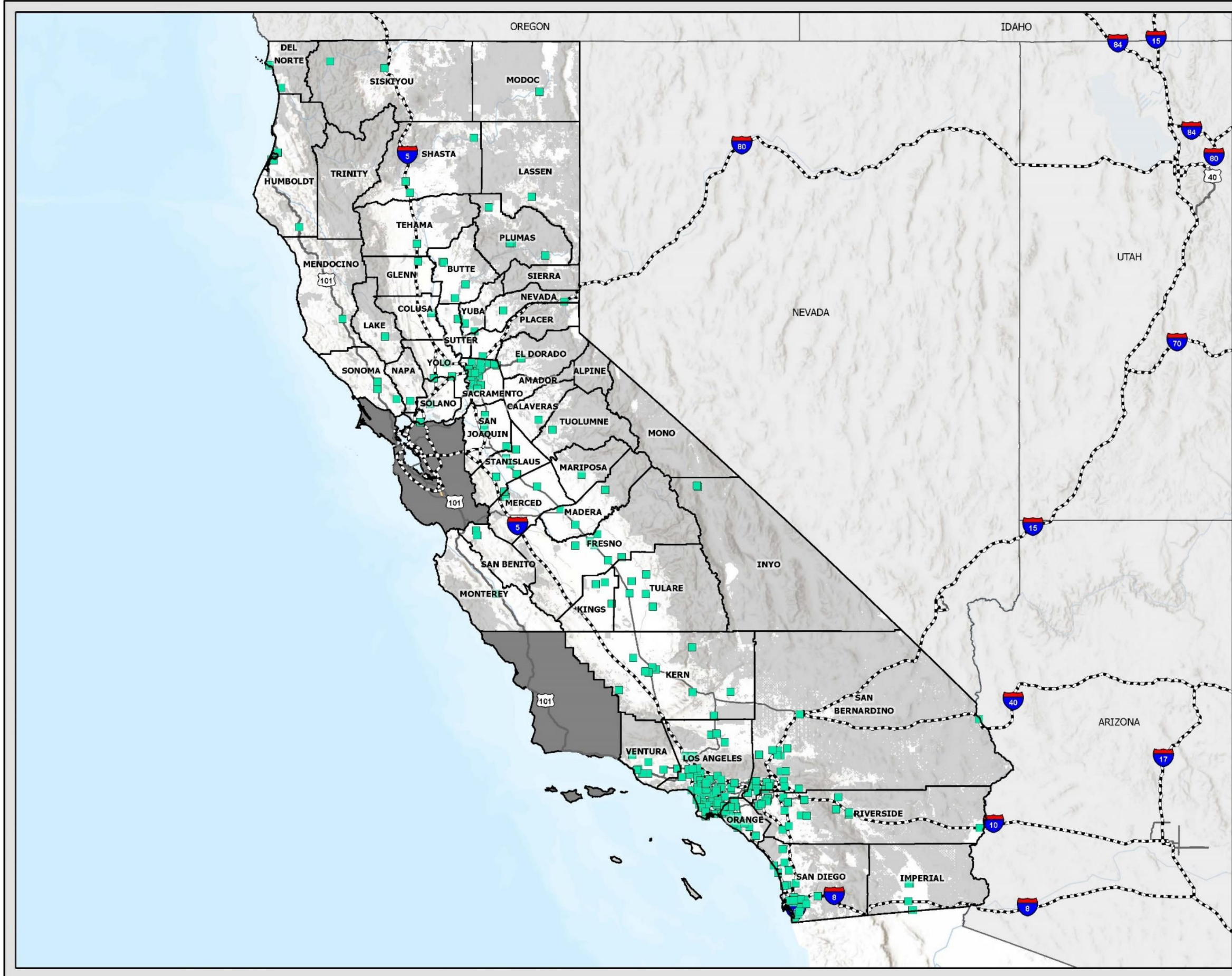


Figure 1: Map of Authorized Collectors Activated by the End of the Reporting Period

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C. Participating Authorized Collectors

Code Section 42033.2(b)(4): “For a stewardship plan for covered drugs, the name and location of authorized collection sites at which covered drugs were collected.”

Regulation Section 18973.4(c)(4): “For each participating authorized collection site, include the following:

- (a) Name and physical address;
- (b) Amount of covered drugs collected, as required in the stewardship plan pursuant to section 18973.2(g)(4);
- (c) Number of instances that collected covered drugs were picked up for disposal;
- (d) Number of receptacle liners picked up for disposal;
- (e) Number of instances and corresponding amount of time the secure collection receptacle was not available to the public during business hours. For each instance, provide a description of why the secure collection receptacle was not available.”

MED-Project established 291 Authorized Collection Sites by the end of the Reporting Period. See Appendix A, for collection data for all Authorized Collectors with collection data by the end of the Reporting Period. All sites not listed in Appendix A did not collect Covered Drugs during the Reporting Period.

D. Mail-Back Services

Regulation Section 18973.4(c)(5): “For each type of mail-back service utilized, include the following, as applicable:

- (a) List of distribution locations;
- (b) Mechanism(s) of distribution;
- (c) Amount of mail-back materials distributed, as required in the stewardship plan pursuant to section 18973.2(g)(6)(E);
- (d) Amount of mail-back material returned, as required in the stewardship plan pursuant to section 18973.2(g)(6)(E)”

Given the date of the Approved Plan's conditional approval, MED-Project did not distribute or collect Mail-Back Packages during the Reporting Period. Distribution and collection of Mail-Back Packages will begin in 2022.

E. Alternate Forms of Collection and Disposal

Regulation Section 18973.4(c)(6): *“For each alternative form of collection and disposal, include the following, as applicable:*

- (a) Method(s) of collection;*
- (b) Name and address of location(s);*
- (c) Number of collections;*
- (d) Amount of materials distributed, as required in the stewardship plan pursuant to section 18973.2(g)(6)(E);*
- (e) Amount of material collected, as required in the stewardship plan pursuant to section 18973.2(g)(6)(E)”*

MED-Project did not use alternative forms of collection or disposal during the Reporting Period.

IV. Transportation and Disposal System

Regulation Section 18973.4(d): *“Transportation and Disposal System. Description of the methods used for transportation and disposal of covered drugs, including the following:*

- (1) Mechanism(s) for tracking the collection, transportation, and disposal of covered drugs*
- (2) Name and mailing address of each service provider used to transport or process covered drugs*
- (3) For each disposal facility, include the following:*
 - (a) Name of disposal facility*
 - (b) Mailing and physical address*
 - (c) Weight of covered drugs disposed*

MED-Project operates a handling, transport, and disposal system that complies with applicable laws, regulations, and other legal requirements. Each Mail-Back Package,

inner liner, and shipping box provided under the Program during the Reporting Period had a unique identifier enabling tracking.

MED-Project used the following facilities for transporting or processing Covered Drugs during the Reporting Period:

- Covanta Environmental Solutions Carriers II, LLC; 2515 S Holt Road, Indianapolis, IN 46241
- Covanta Environmental Solutions, LLC; 2515 S Holt Road, Indianapolis, IN 46241
- United Parcel Service, Inc.; 55 Glenlake Parkway NE, Atlanta, GA 30328

MED-Project disposed of Covered Drugs at two disposal facilities during the Reporting Period:

1. Indianapolis Resource Recovery Facility in Indiana, operating as Covanta Indianapolis, Inc.
 - Mailing Address: 2320 S Harding Street, Indianapolis, IN 46221
 - Physical Address: 2320 S Harding Street, Indianapolis, IN 46221
 - Pounds of Covered Drugs Disposed: 723.6
2. Stericycle, Inc. Warren, Ohio
 - Mailing Address: 1901 Pine Avenue, SE, Warren, OH 44483
 - Physical Address: 1901 Pine Avenue, SE, Warren, OH 44483
 - Pounds of Covered Drugs Disposed: 6,574.7

V. Policies and Procedures

Code Section 42033.2(b)(6): *“Whether policies and procedures for collecting, transporting, and disposing of covered products, as established in the stewardship plan, were followed during the reporting period and a description of each instance of noncompliance, if any occurred.”*

Regulation Section 18973.4(e): *“Policies and Procedures. Pursuant to subdivision (b)(6) of section 42033.2 of the Public Resources Code, provide the following:*

- (1) *Description of whether policies and procedures for collecting, transporting, and disposing of covered drugs, as established in the stewardship plan, were followed during the reporting period*
- (2) *Description of each instance of noncompliance from stewardship plan policies and procedures, if any occurred*

- (3) *Corrective actions taken, or that will be taken, if the program operator discovered critical instances of noncompliance with stewardship plan policies and procedures”*

Regulation Section 18973.4(f): *“Description of updates, that have been made or will be made, to the processes and policies followed to safely and securely collect, track, and properly manage covered drugs from collection through final disposal.*

Policies and procedures for collecting, transporting, and disposal of covered drugs, as established in the Approved Plan, were followed during the Reporting Period. During the Reporting Period, MED-Project did not make or initiate updates to the Approved Plan processes and policies followed to safely and securely collect, track, and properly manage Covered Drugs from collection through final disposal.

VI. Repeal of Local Ordinances

Regulation Section 18973.4(g): *“Ordinance Repeal. Pursuant to subdivision (e) of section 42032.2 of the Public Resources Code, description of processes, logistics, and timing of implementation that will be necessary for the stewardship program to expand into jurisdictions not previously included in the stewardship plan, in the event of the repeal of a local stewardship program ordinance. The description shall include an explanation of how the stewardship program will meet the convenience standards, pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code.”*

Effective November 15, 2021, San Luis Obispo County withdrew from the San Luis Obispo County Integrated Waste Management Authority, which administered a local stewardship program ordinance. Pursuant to PRC 42032.2(e) and 42036.2, MED-Project is expanding the Program into the unincorporated areas of San Luis Obispo County.

Because the Program had not yet been approved as of November 15, 2021, MED-Project is implementing the Approved Plan across the State, including in the unincorporated areas of San Luis Obispo County, in accordance with the timeline in Approved Plan Appendix F, including with regard to providing a network of Authorized Collection Sites that meets the convenience standard described in PRC 42032.2(a)(1)(F).

VII. Safety and Security Incidents

Code Section 42033.2(b)(7): *“Whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security.”*

Regulation Section 18973.4(h): *“Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken or will be taken to address the issue and improve safety and security. In addition, the following specific information about any incident(s) shall be made available to the department upon request, and shall include, but not be limited to:*

- (1) *Location and date*
- (2) *Description of specific incident*
- (3) *Cause(s) of specific incident*
- (4) *Parties involved*
- (5) *Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident”*

No safety or security problems occurred during collection, transportation, or disposal of collected Covered Drugs during the Reporting Period.

VIII. Education and Outreach

Regulation Section 18973.4(i): *“Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to section 18973.2(j), including, but not limited to, the following:*

- (1) *Electronic examples of promotional marketing materials*
- (2) *Numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.2(j)(5)*
- (3) *A discussion of what the metrics, described above in section 18973.4(i)(2), reveal about the performance of the comprehensive*

education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility

- (4) *Description of how the requirement of section 42031.6(b) of the Public Resources Code was met.”*

MED-Project did not begin education and outreach efforts during the Reporting Period. Per Appendix K of the Approved Plan, MED-Project will begin initial media and outreach activities 180 days after conditional approval on December 9, 2021, with the launch of a social media campaign.

IX. Participating Covered Entities and Their Covered Products

Code Section 42033.2(b)(1): *“A list of covered entities participating in the stewardship organization.”*

Code Section 42033.2(b)(2): *“The updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031 of covered products that each covered entity subject to the stewardship plan sells or offers for sale.*

Regulation Section 18973.4(j): *“Covered Entities, Covered Products, and Authorized Collectors. List of the following:*

- (1) *Participating covered entities covered by the stewardship plan and their contact information including, but not limited to, the following:*
 - (a) *Name of covered entity*
 - (b) *Mailing and physical address*
 - (c) *Contact name and title*
 - (d) *Email address*
- (2) *A copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (2) of subdivision (a) of section 42031 of the Public Resources Code.*
- (3) *Authorized collectors and their contact information including, but not limited to:*
 - (a) *Name of authorized collector*

(b) *Mailing and physical address*

(c) *Contact name and title*

(d) *Email address”*

The list of Covered Entities participating in the Program during the Reporting Period is provided in an accessible Excel spreadsheet attached in the submission of this Report. See Attachment B: List of Covered Entities.

The list of Covered Products sold or offered by sale by each participating Covered Entity is provided in an accessible Excel spreadsheet attached in the submission of this Report. This list was previously submitted to the Board of Pharmacy by January 15, 2022. See Attachment C: List of Covered Products.

A list of Authorized Collectors that were participating in the Program prior to the end of the Reporting Period is provided in an accessible Excel spreadsheet attached in the submission of this Report. See Attachment D: List of Participating Authorized Collectors.

X. Selection of Service Providers

Regulation Section 18973.4(k): “Description and evaluation of the process for selecting service providers, if applicable.”

MED-Project did not select any service providers during the Reporting Period.

XI. Incentives Provided

Regulation Section 18973.4(l): “Description of any grants, loans, sponsorships, reimbursements, or other incentives provided, as applicable.”

There were not grants, loans, sponsorships, reimbursement, or other incentives provided during the Reporting Period.

XII. Staffing Changes

Regulation Section 18973.4(m): “Description of changes in staffing of the stewardship program.”

MED-Project identifies two staff contacts in the Approved Plan. There were no changes to those staff during the Reporting Period.

XIII. Program Expenses

Regulation Section 18973.4(n): “A list of all actual expenses incurred during the previous reporting period. Expenses shall be summarized in accordance with the budget categories specified in section 18973.6(b).”

Annual Expenses

The following are the actual expenses incurred during the Reporting Period:

- Capital costs: ██████████
- Costs of collection, transportation and disposal of covered products: \$297,782
- Administrative costs: \$257,373
- Education and outreach costs: \$116,089 (\$100,000 paid to the media services provider for advertisement campaign development)
- Costs related to grants, loans, sponsorships, or other incentives as part of program implementation: \$0

XIV. Coordination

Regulation Section 18973.4(o): “Coordination Efforts. Description of how the program operator coordinated with other program operators to avoid confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.”

MED-Project did not conduct any coordination efforts in the Reporting Period.

XV. Plan Compliance

Code Section 42033.2(b)(8): “How the program operator complied with all elements in its stewardship plan.”

Regulation Section 18973.4(p): “State Agency Determinations pursuant to section 42032.2(a)(1)(C) of the Public Resources Code. Submit all agency determination(s) of compliance, noncompliance, and superseding determinations of compliance, if any, for the reporting period.”

MED-Project complied with all elements in the Approved Plan during the Reporting Period. There were no state agency determinations for the Approved Plan pursuant to Code section 42032.2(a)(1)(C) during the Reporting Period.

Appendix A

Authorized Collector Collection Data

Account Identifier	Number of Pickups	Number of Receptacle Liners Picked Up	Covered Drug Weight Collected	Number of Times the Collection Receptacle was Unavailable (During Business Hours)
140638	1	1	22.1	0
162125	1	1	30	0
148241	1	1	30.5	0
162115	1	1	32	0
151417	1	1	32.8	0
150908	1	1	34.7	0
140473	1	1	36.4	0
152078	1	1	39.4	0
147975	1	1	39.4	0
151802	2	2	39.7	0
152161	1	1	39.8	0
150640	1	1	40.3	0
150982	1	1	47.8	0
151502	1	1	49.2	0
162110	1	2	53.5	0
161463	1	1	53.8	0
152487	1	1	54.7	0
148470	1	1	65.5	0
162124	1	4	71.2	0
162133	1	2	72.1	0
161923	1	3	74.5	0
162117	1	2	75.8	0
161930	1	3	78.3	0
161928	1	2	85.6	0
162128	1	2	94.3	0
162112	1	3	96.7	0
161126	1	1	97.5	0
161934	1	3	99.2	0
162132	1	3	99.3	0
161936	1	2	99.7	0
162123	1	2	103.5	0
162129	1	2	104.3	0
161922	1	5	107.9	0
162113	1	4	127	0
161933	1	4	128.4	0
162130	1	3	130.8	0

Account Identifier	Number of Pickups	Number of Receptacle Liners Picked Up	Covered Drug Weight Collected	Number of Times the Collection Receptacle was Unavailable (During Business Hours)
161939	1	4	132.2	0
161924	1	4	135.4	0
161941	1	4	135.7	0
162127	1	3	137.8	0
161925	1	3	139.1	0
162116	1	3	139.5	0
161927	1	3	140.1	0
162118	1	4	141	0
162131	1	4	153.5	0
162119	1	4	159.2	0
162126	1	7	161.7	0
161935	1	5	165.6	0
161938	1	4	178.3	0
162121	1	4	208.9	0
161929	1	4	220	0
162120	1	5	230.9	0
161937	1	1	259	0
162114	1	5	259.9	0
161932	1	6	266.6	0
161926	1	7	278.7	0
162122	1	7	283	0
162111	1	9	310.6	0
161931	1	10	320.3	0
161921	1	8	384.4	0
161942	1	3	1031.1	0

Table 1: Authorized Collector Collection Data

Appendix B

Certifications

As Required by 14 CCR § 18793.2 (e), I hereby declare under penalty of perjury, that at the time of submission to the Department, the information provided in this document is true and correct, to the best of my knowledge.



Jim Wilson
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