REQUEST FOR ACTION

То:	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 Home- Generated Sharps Waste	
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, Sharps (2022 Annual Report)* on March 31, 2023, as required by statute. This Request for Action presents a summary of staff's analysis regarding MED-Project's *2022 Annual Report* and MED-Project's home-generated sharps waste stewardship program.

Background

MED-Project is a stewardship organization that represents more than 50 covered entities under its approved stewardship plan for home-generated sharps waste, titled, *A Product Stewardship Plan for Home-Generated Sharps Waste (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 November 15, 2022, the *Plan* was approved. MED-Project's *2022 Annual Report* covers the entire calendar year of 2022 from 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*
- Established a statewide initiative to support point of sale site and retail pharmacy participation, including online and phone ordering systems

- Conducted outreach to point of sale sites over 46,000 times via multiple methods, including over 1,500 letters, over 10,000 postcards, over 20,000 emails, over 8,900 phone calls, and over 5,600 in-person site visits
- Established 3,988 point of sale sites that participate in MED-Project's online ordering system to initiate orders of "Sharps Mail-Back Packages" on behalf of ultimate users
- Initiated distribution of 8,536 "Sharps Mail-Back Packages" at the point of sale through the online ordering system and phone ordering system
- Distributed 4,487 "Sharps Mail-Back Packages" to point of sale sites
- Reimbursed local agencies \$17,555.01 for the collection of 12,644 pounds of home-generated sharps waste
- Launched the website and the call center, distributed printable materials and signage to participating sites, and initiated a statewide outreach campaign for ultimate users
- Disposed of 3,988 pounds of home-generated sharps waste from 1,958 sharps mail-back packages received from ultimate users

Additionally, MED-Project reported one challenge in creating a new statewide program: securing point of sale site participation when retailers are not required to participate by providing or initiating the distribution of a "Sharps Mail-Back Package" at the point of sale.

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.

Mail-Back Program

<u>Requirements</u>: A description of how ultimate users had an opportunity to dispose of their home-generated sharps waste as described in the approved stewardship plan pursuant to 14 CCR section 18973.5(c)(1). A mail-back program that provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale pursuant to PRC section 42032.2(d)(1)(F)(i) and 14 CCR section 18973.3(f)(2). 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: Requirements Partially Met

Pursuant to 14 CCR section 18972.1(a)(10), "provides or initiates distribution of a sharps waste container and mail-back materials" means one of the following: (A) To provide a sharps waste container and mail-back materials to the ultimate user, at the point of sale or prior, at no cost to the ultimate user; or, (B) To arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within five business days at no cost or inconvenience to

the ultimate user; or, (C) Other methods of providing a sharps waste container and mail-back materials to the ultimate user at the point of sale or prior, at no cost to the ultimate user, if the method identified in subpart (A) above is not allowed by law and if the method identified in subpart (B) above is not allowed by law.

MED-Project's 2022 Annual Report describes implementing its home-generated sharps waste stewardship program through activities including the establishment of point of sale sites (e.g., retail pharmacies, retail pharmacy chains, online retailers, and/or other retailers of sharps to ultimate users) that utilize its online and/or phone ordering system, non-online sites to distribute sharps mail-back packages, and a website and call center through which ultimate users can order free sharps mail-back packages. MED-Project also provided education and outreach to health care providers to educate ultimate users about how they can request free sharps mail-back packages prior to the point of sale.

According to MED-Project's 2022 Annual Report, 13,023 packages were distributed to or initiated at point of sale sites (see Table 1); 4,487 were "Sharps Mail-Back Packages" distributed to point of sale sites and 8,536 were "Sharps Mail-Back Packages" initiated at the point of sale through the ordering systems.

	Distributed
Supplied to Point of Sale Sites	4,487
Provided at Point of Sale	Unknown
Initiated at Point of Sale via Online Ordering System	7,065
Initiated at Point of Sale via Phone Ordering System	1,471
Total	13,023

Table 1. MED-Project "Sharps Mail-Back Package" Point of Sale	e Metrics
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Table 1 Description: Metrics of MED-Project "Sharps Mail-Back Packages" supplied to and initiated by point of sale sites.

Table 2. MED-Project "Sharps Mail-Back Package" Metrics

	Requested	Distributed
Website	7,037	7,000
Call Center	516	509
Total	7,553	7,509

Table 2 Description: Metrics of MED-Project "Sharps Mail-Back Packages" requested and distributed through the website and call center.

Page 8 of MED-Project's 2022 Annual Report states that, "Through Point of Sale Sites, there were over 2,200,000 times that Ultimate Users purchasing Sharps were provided information on Program usage at the Point of Sale." MED-Project does not explain in its 2022 Annual Report why the number of times that ultimate users who were "provided information on program usage at the point of sale" (2.2 million) is so much greater than the number of sharps waste containers and mail-back materials that were distributed to point of sale sites and initiated at the point of sale (13,023).

<u>Summary 1 of Requirements Not Met</u>: 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. Clarify why the number of Ultimate Users purchasing Sharps that were provided information on Program usage at the Point of Sale (2.2 million) is greater than the number of sharps waste containers and mail-back materials that were distributed to point of sale sites and initiated at the point of sale (13,023) pursuant to 14 CCR section 18973.1(a). MED-Project is required to provide or initiate the distribution of a sharps waste container and mail-back materials at the point of sale pursuant to PRC section 42032.2(d)(F)(i) and 14 CCR section 18973.3(f)(2).

Education and Outreach

<u>Requirements</u>: Implement a comprehensive education and outreach program pursuant to PRC section 42031.6 and 14 CCR section 18973.3(i). A program operator shall not promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program pursuant to PRC section 42031.6(b) and 14 CCR section 18973.3(i)(7). Maintain an Internet Web site for purposes of providing information on the program, including disposal options, and to receive requests for sharps waste containers from ultimate users pursuant to PRC section 42032.2(d)(1)(E) and 14 CCR section 18973.3(i)(3).

Analysis: Requirements Partially Met

MED-Project conducted education and outreach using mechanisms described in its *Plan,* including social media, accessible website, digital media campaign, production and distribution of promotional materials, participation in in-person events to educate pharmacists, and a targeted digital campaign to provided education and outreach to health care providers so they could educate ultimate users about how to request free sharps mail-back packages prior to the point of sale. Additionally, MED-Project activated a call center for ultimate users and a help desk for point of sale sites, hospitals, pharmacies, and other locations, and launched outreach campaigns to participating covered entities and distributors regarding point of sale site participation in MED-Project's sharps program.

However, in addition to providing information regarding how to utilize the free sharps mail-back program, some pages on MED-Project's website appear to promote the disposal of sharps waste at local government household hazardous waste (HHW) facilities disproportionally over the mail-back services offered to ultimate users by its

stewardship program. The "California State – Sharps Disposal Program" website includes four graphics at the bottom of the page listing pages with more information with "Mail-Back Services" being listed after "Find a Location" to drop off a sharps waste container. The top of the page says, "Get Started" and upon clicking that link, the user is redirected to the "Find a Location" page, not the "Mail-Back Services" page. Additionally, the Frequently Asked Questions page regarding MED-Project's sharps program does not reference the mail-back program and instead directs the reader to utilize disposal at HHW facilities. MED-Project's *2022 Annual Report* states that there were 9,153 visits to the "Find a location" page that points the public to HHW facilities and 11,650 visits to the "Mail-Back Services" page. While HHW facilities can be included in MED-Project's education and outreach, MED-Project must promote its mail-back program as the primary method of sharps waste disposal for ultimate users.

Statute and regulations require that education and outreach materials, including the website, will promote the disposal of a covered product in a manner consistent with the services offered to ultimate users by the stewardship program pursuant to the requirements listed above.

Transportation and Disposal

<u>Requirements</u>: Describe the methods used to transport and dispose of consolidated home-generated sharps waste, including the mechanism(s) used to track the collection, transportation, and disposal of home-generated sharps waste. For each disposal facility provide the name of facility, the mailing and physical address, and the total weight of material disposed pursuant to 14 CCR sections 18973.5(d)(1) and (d)(3). 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: Requirements 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 methods that were used to transport and dispose of consolidated home-generated sharps waste, but instead states there is a "system" in place. Additionally, the 2022 Annual Report includes only a partial description of the mechanism(s) used to track the transportation and disposal of home-generated sharps waste, stating that "each Sharps Mail-Back Package...had a unique identifier enabling tracking." MED-Project notes that tracking is enabled by the unique identifier but does not describe how tracking occurs or how the unique identifier allows "Sharps Mail-Back Package[s]" to be tracked from collection through disposal. Annual reports must contain all necessary information to meet the requirements in PRC sections 42033.2(a)(1) and 42033.2(b) and 14 CCR section 18973.5.

In addition, MED-Project's *2022 Annual Report* lists MedSharps, LLC and Stericycle, Inc. Vernon as disposal facilities. However, MED-Project's *Plan lists* MedSharps,

LLC and Stericycle, Inc. Vernon as treatment facilities. An explanation was not provided for why these facilities are listed differently in MED-Project's *Plan* and its *2022 Annual Report*.

<u>Summary 3 of Requirements Not Met</u>: 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. Include a description in the annual report of the methods used to transport and dispose of home-generated sharps waste, including a description of the mechanism(s) to track the collection, transportation, and disposal of homegenerated sharps waste pursuant to 14 CCR section 18973.5(d)(1).
- b. Clarify the list of disposal facilities provided in the annual report pursuant to 14 CCR sections 18973.1(a) and 18973.5(d)(3).

Metrics

<u>Requirements</u>: Report the amount of sharps waste containers and mail-back materials distributed per county, through each of the following methods: provided at point of sale, initiated at point of sale, website requests, and toll-free telephone number requests pursuant to 14 CCR section 18973.5(c)(2). On or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit to the department: a written report describing the stewardship program activities during the previous reporting period of one year pursuant to PRC section 42033.2(a)(1). 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: Requirements Partially Met

Pursuant to 14 CCR section 18972.1(a)(10), "provides or initiates distribution of a sharps waste container and mail-back materials" means one of the following: (A) To provide a sharps waste container and mail-back materials to the ultimate user, at the point of sale or prior, at no cost to the ultimate user; or, (B) To arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within five business days at no cost or inconvenience to the ultimate user; or, (C) Other methods of providing a sharps waste container and mail-back materials to the ultimate user and arrive is the ultimate user at the point of sale or prior, at no cost to the ultimate user at the point of sale or prior, at no cost to the ultimate user, if the method identified in subpart (A) above is not allowed by law and if the method identified in subpart (B) above is not allowed by law.

MED-Project's 2022 Annual Report includes the amount of sharps waste containers and mail-back materials distributed to point of sale sites rather than the amount of sharps waste containers and mail-back materials that were provided to ultimate users at the point of sale. The amount of "Mail-Back Packages" distributed by MED-Project to point of sale sites may be different than the amount of "Mail-Back Packages" provided to ultimate users at the point of sale. Additionally, MED-Project's 2022 Annual Report states that "the metrics presented in this Annual Report only represent a few months during the Reporting Period as the Program began to gain momentum." MED-Project does not specify which metrics it is referring to, or why it was not able to collect metrics for the entire reporting period of one year. Annual reports must describe all stewardship program activities during the previous reporting period of one year pursuant to PRC section 42033.2(a)(1).

<u>Summary 4 of Requirements Not Met</u>: 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 description of the amount of sharps waste containers and mail-back materials that were provided at point of sale to ultimate users per county pursuant to 14 CCR section 18973.5(c)(2).
- b. Clarify which metrics MED-Project is referring to in the following statement: "the metrics presented in this Annual Report only represent a few months during the Reporting Period as the Program began to gain momentum" pursuant to 14 CCR section 18973.1(a).
- c. Clarify why MED-Project was unable to collect metrics that describe stewardship program activities for the entire reporting period of 2022 pursuant to PRC section 42033.2(a)(1).

Actual Expenses from Reporting Period

<u>Requirements</u>: Provide a list of all actual expenses incurred during the previous reporting period of one year pursuant to 14 CCR section 18973.5(q) 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 \$467,833 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.

<u>Summary 5 of Requirement Not Met</u>: 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.

Clarify why \$467,833 in departmental administrative fee costs are listed as an actual expense incurred pursuant to 14 CCR sections 18973.1(a) and 18973.5(q).

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.

<u>Action</u>

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 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.
 □ 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 this Request for Action is issued that includes the additional information specified in "Summary 1 of Requirements Not Met" to CalRecycle within 60 days of the date this Request for Action 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 additional information specified in "Summary 1 of Requirements Not Met" through "Summary 5 of Requirement 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 this Request for Action is noticed 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.

- 1. <u>MED-Project 2022 Annual Report, State of California, Sharps</u> (March 31, 2023) https://www2.calrecycle.ca.gov/Docs/Web/123369
 - a. <u>Attachment A Requests and Distribution by County</u> (March 31, 2023) https://www2.calrecycle.ca.gov/Docs/Web/123375
 - b. <u>Attachment B Daily Impressions for Digital Media</u> (March 31, 2023) https://www2.calrecycle.ca.gov/Docs/Web/123381
 - c. <u>Attachment C List of Sharps Covered Entities</u> (March 31, 2023) https://www2.calrecycle.ca.gov/Docs/Web/123387
 - d. <u>Attachment D List of Sharps Covered Products</u> (March 31, 2023) https://www2.calrecycle.ca.gov/Docs/Web/123390
 - e. <u>Attachment E Local Agency Reimbursements</u> (March 31, 2023) https://www2.calrecycle.ca.gov/Docs/Web/123393
- 2. <u>A Product Stewardship Plan for Home-Generated Sharps Waste</u> (August 22, 2022)

https://www2.calrecycle.ca.gov/Docs/Web/122100

- a. <u>Appendix A Participating Covered Entities</u> (August 22, 2022) https://www2.calrecycle.ca.gov/Docs/Web/122106
- b. <u>Appendix B Covered Products</u> (August 22, 2022)

https://www2.calrecycle.ca.gov/Docs/Web/122109