

REQUEST FOR APPROVAL

To: Rachel Machi Wagoner
Director

From: Zoe Heller
Deputy Director, Materials Management and Local Assistance
Division
Acting Deputy Director, Policy Development and Analysis Office

Request Date: November 7, 2022

Decision Subject: Consideration of MED-Project's Revised Stewardship Plan for Home-Generated Sharps Waste

Action By: November 21, 2022

Summary of Request

MED-Project USA (MED-Project) submitted a revised stewardship plan for home-generated sharps waste, which includes its initial program budget, titled, *A Product Stewardship Plan for Home-Generated Sharps Waste (August 2022 Revised Plan)* to the Department of Resources Recycling and Recovery (CalRecycle) on August 22, 2022, pursuant to the requirements in CalRecycle's June 2022 Request for Approval, titled, *Consideration of MED-Project's Revised Product Stewardship Plan for Home-Generated Sharps Waste*. This Request for Approval presents a summary of staff's analysis and compliance recommendation regarding MED-Project's *August 2022 Revised Plan*.

Background

MED-Project is a stewardship organization that represents more than 50 covered entities. MED-Project submitted *A Product Stewardship Plan for Home-Generated Sharps Waste (Plan)* to CalRecycle on September 14, 2021, pursuant to Public Resources Code (PRC) section 42032. CalRecycle determined the *Plan* was complete and notified MED-Project on October 11, 2021, pursuant to PRC section 42032(c)(1) and Title 14, California Code of Regulations (14 CCR) section 18973.1(b).

On December 9, 2021, CalRecycle conditionally approved MED-Project's *Plan* pursuant to PRC section 42032(d)(1) and 14 CCR sections 18973.1(e) and (g). CalRecycle provided MED-Project 90 days to submit a revised plan that addressed the conditions specified in the December 2021 Request for Approval.

On March 9, 2022, MED-Project submitted *A Product Stewardship Plan for Home-Generated Sharps Waste (March 2022 Revised Plan)* to meet conditions specified in the "Staff Analysis" section of the December 2021 Request for Approval. On June 23, 2022, CalRecycle maintained the conditional approval of MED-Project's *March 2022 Revised Plan* and provided MED-Project 60 days to submit a revised plan that addressed the remaining conditions specified in the June 2022 Request for Approval.

On August 22, 2022, MED-Project submitted its *August 2022 Revised Plan* which is the subject of this Request for Approval.

Staff Analysis

Each condition in the June 2022 Request for Approval that CalRecycle required MED-Project to address is listed below, followed by a summary of staff's analysis of MED-Project's *August 2022 Revised Plan*.

1. CalRecycle Condition 1

Requirements: CalRecycle required the *August 2022 Revised Plan* to meet the following conditions pursuant to PRC section 42032.2(d)(1)(F)(i) and 14 CCR sections 18972.1(a)(10) and 18973.3(f)(2)):

- a. Describe how the program will provide or initiate distribution of sharps waste containers and mail-back materials at all points of sale where any sharps covered under the plan are sold.
- b. Provide circumstances and justification whereby provision and arranging for arrival, pursuant to 14 CCR sections 18972.1(a)(10)(A) and (B), are illegal or remove any reference to 14 CCR section 18972.1(a)(10)(C).
- c. Ensure all ultimate users, including individuals without a permanent address, will be able to receive a sharps mail-back package through approved options in MED-Project's program at all points of sale where any sharps covered under the plan are sold.
- d. If justification for the use of the option pursuant to 14 CCR section 18972.1(a)(10)(C) is provided in the plan, MED-Project must ensure the option under 14 CCR section 18972.1(a)(10)(C) results in substantially the same level of convenience as the options under 14 CCR sections 18972.1(a)(10)(A) and (B).

Result: Conditions 1(a) through (d) met.

The *August 2022 Revised Plan* modifies the definition of "Point of Sale Site" to include "Retail pharmacies, Retail pharmacy chains, online retailers, and/or other retailers of Sharps to Ultimate Users." This definition no longer limits participation in the program and is consistent with MED-Project's assertion that it will "provide or initiate distribution of Sharps Mail-Back Packages to Ultimate Users at or prior to the Point of Sale of all In-Scope Purchases."

MED-Project's *March 2022 Revised Plan* lacked sufficient description of how the ordering system will initiate distribution of sharps waste containers and mail-back materials. MED-Project's *August 2022 Revised Plan* describes how the online ordering system will function at the point of sale. MED-Project also added a phone ordering system for initiating distribution of sharps waste containers and mail-back materials at or prior to the point of sale. This option will allow point of sale locations to "initiate" without needing to register with MED-Project's online ordering system. MED-Project's *August 2022 Revised Plan* describes how, and states that, MED-Project will provide or initiate distribution of sharps waste containers and mail-back materials at or prior to the point of sale. The *August 2022 Revised Plan* specifies that, in general, the term "provide" refers to the option under 14 CCR section 18972.1(a)(10)(A) and the term "initiate" refers to the option under 14 CCR section

18972.1(a)(10)(B). MED-Project also states that as part of its education and outreach program, and as a supplement to providing or initiating at all points of sale, it will provide information at the point of sale on how an ultimate user can request a sharps waste container and mail-back materials on the website and via the call center at their discretion, including prior to the point of sale. CalRecycle notes that it is the program operator's responsibility to provide or initiate distribution of sharps waste containers and mail-back materials at the point of sale or prior, and allowing ultimate users to acquire a container prior to the point of sale does not relieve MED-Project of this requirement. MED-Project's *August 2022 Revised Plan* meets condition 1(a).

MED-Project's *March 2022 Revised Plan* cited "CCR section 18972.1(a)(10)(C)" following a description of how ultimate users can request sharps mail-back packages via the website or call center. MED-Project removed the citation in response to conditions 1(b) and 1(d) which required MED-Project to provide circumstances and justification whereby provision and arranging for arrival, pursuant to 14 CCR sections 18972.1(a)(10)(A) and (B), are illegal or remove any reference to 14 CCR section 18972.1(a)(10)(C). MED-Project's *August 2022 Revised Plan* meets conditions 1(b) and 1(d).

MED-Project's *August 2022 Revised Plan* provides options for homeless individuals to receive sharps mail-back packages via the call center and website and provides options "such as shelters, churches, and to use USPS's General Delivery Service...in lieu of a permanent address." The *August 2022 Revised Plan* describes that point of sale locations and the website and call center will have additional information on how to use USPS General Delivery and that employees of point of sale location and ultimate users will be instructed to enter "General Delivery" as the street address when placing an order for a sharps container and mail-back materials. MED-Project's *August 2022 Revised Plan* meets condition 1(c).

Stakeholder Feedback

CalRecycle solicited public input on MED-Project's *August 2022 Revised Plan* from August 22, 2022, through September 6, 2022, and received comment letters from the Pharmaceutical Product Stewardship Work Group and UltiMed, Inc. CalRecycle considered all comment letters received when reviewing MED-Project's *August 2022 Revised Plan* for compliance.

Summary of Staff Analysis

CalRecycle staff analyzed MED-Project's *August 2022 Revised Plan* and determined it meets all conditions from CalRecycle's June 2022 Request for Approval without the need to consider or evaluate MED-Project's claims within "Appendix M."

Action

Based on the analysis within this Request for Approval, I hereby approve MED-Project's *August 2022 Revised Plan*.

Signed by: Rachel Machi Wagoner, Director

Dated: November 15, 2022

Attachments:

Documents listed below are posted to CalRecycle's website.

1. [*A Product Stewardship Plan for Home-Generated Sharps Waste*](https://www2.calrecycle.ca.gov/Docs/Web/119592) (September 14, 2021)
<https://www2.calrecycle.ca.gov/Docs/Web/119592>
 - a. [*Appendix A – Participating Covered Entities*](https://www2.calrecycle.ca.gov/Docs/Web/119595) (September 14, 2021)
<https://www2.calrecycle.ca.gov/Docs/Web/119595>
 - b. [*Appendix B – Covered Products*](https://www2.calrecycle.ca.gov/Docs/Web/119598) (September 14, 2021)
<https://www2.calrecycle.ca.gov/Docs/Web/119598>
2. [*Consideration of MED-Project's Product Stewardship Plan for Home-Generated Sharps Waste*](https://www2.calrecycle.ca.gov/Docs/Web/120129) (December 9, 2021)
<https://www2.calrecycle.ca.gov/Docs/Web/120129>
3. [*A Product Stewardship Plan for Home-Generated Sharps Waste*](https://www2.calrecycle.ca.gov/Docs/Web/120942) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120942>
 - a. [*Appendix A - Participating Covered Entities*](https://www2.calrecycle.ca.gov/Docs/Web/120924) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120924>
 - b. [*Appendix B - Covered Products*](https://www2.calrecycle.ca.gov/Docs/Web/120930) (March 9, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120930>
4. [*Consideration of MED-Project's Revised Product Stewardship Plan for Home-Generated Sharps Waste*](https://www2.calrecycle.ca.gov/Docs/Web/121686) (June 23, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/121686>
5. [*A Product Stewardship Plan for Home-Generated Sharps Waste*](https://www2.calrecycle.ca.gov/Docs/Web/122100) (August 22, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122100>
 - a. [*Appendix A – Participating Covered Entities*](https://www2.calrecycle.ca.gov/Docs/Web/122106) (August 22, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122106>
 - b. [*Appendix B – Covered Products*](https://www2.calrecycle.ca.gov/Docs/Web/122109) (August 22, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122109>