

REQUEST FOR APPROVAL

To: Rachel Machi Wagoner
Director

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

Request Date: June 6, 2022

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

Action By: June 24, 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 (Revised Plan)* to the Department of Resources Recycling and Recovery (CalRecycle) on March 9, 2022, pursuant to the requirements in CalRecycle's December 2021 Request for Approval, titled, *Consideration of MED-Project's Product Stewardship Plan for Home-Generated Sharps Waste*. This Request for Approval presents staff's analysis and compliance recommendation regarding MED-Project's *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 (CCR) section 18973.1(b).

On December 9, 2021, CalRecycle conditionally approved MED-Project's *Plan* pursuant to PRC section 42032(d)(1) and 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. The December 2021 Request for Approval required MED-Project to submit (1) a letter, within 30 days of December 9, 2021, committing to revise and resubmit its plan to meet the conditions specified in the "Staff Analysis" section of the December 2021 Request for Approval, and (2) a revised sharps plan, within 90 days from December 9, 2021, that included the additional information to meet the conditions specified in the "Staff Analysis" section of the December 2021 Request for Approval.

MED-Project submitted the required letter on January 7, 2022. On March 9, 2022, MED-Project submitted a *Revised Plan*, which is the subject of this Request for Approval. CalRecycle consulted with other state agencies during its review, pursuant to PRC section 42032(d)(2) and CCR section 18973.1(c), and has timely completed its review.

Staff Analysis

Each condition in the December 2021 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 *Revised Plan* submitted on March 9, 2022.

1. CalRecycle Condition 1

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

- a. Describe how the program will (1) 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, and (2) 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 to the ultimate user within five business days of the point of sale (not just fulfill an order within five business days).
- b. Provide circumstances and justification whereby provision and arranging for arrival, pursuant to CCR sections 18972.1(a)(10)(A) and (B), are illegal or remove the option under CCR section 18972.1(a)(10)(C), described in the *Plan*, which provides instructions to the ultimate user at the point of sale for the ultimate user to arrange for arrival of sharps waste containers and mail-back materials.
- c. Explain how all ultimate users, including homeless individuals without a permanent address, can receive sharps mail-back packages through all approved options, including the option whereby ultimate users are instructed to order a mail-back package through MED-Project's website or call center.
- d. If justification for the use of the option pursuant to CCR section 18972.1(a)(10)(C), described in the *Plan*, is provided per CalRecycle Condition 1b, MED-Project must (1) explain how all ultimate users, including homeless individuals without a permanent address, can receive sharps mail-back packages through this option whereby ultimate users are instructed to order a mail-back package through MED-Project's website or call center, and (2) ensure the option under CCR section 18972.1(a)(10)(C) results in substantially the same level of convenience as the options under CCR sections 18972.1(a)(10)(A) and (B).
- e. Provide all necessary information regarding proper sharps disposal to ultimate users, including but not limited to, a description of "biologics," items that are and are not accepted in mail-back packages, and instructions for repackaging and mailing a sharps container.

Result: Conditions 1(a) through (d), above, partially met; additional information from and additional actions by MED-Project are necessary. Condition 1(e) met.

The *Revised Plan* modified the definition of “Point of Sale Site,” limiting participation to locations that are licensed with the Board of Pharmacy (BOP) and are registered on MED-Project’s ordering system. This definition is not consistent with statute because not all sites that sell covered sharps are required to be licensed with BOP (e.g., sites that sell lancets) and not all sites where covered sharps are sold may choose to register with MED-Project’s ordering system. Ultimately, MED-Project only partially met condition 1(a). The refusal of a point of sale site to register with MED-Project’s online ordering system does not relieve MED-Project, as a program operator, of its obligation to provide or initiate the distribution of sharps waste containers and mail-back materials at or prior to the point of sale for products covered under its plan.

Assuming the *Revised Plan* refers to the option under CCR section 18972.1(a)(10)(A) when using the term “provide” and CCR section 18972.1(a)(10)(B) when using the term “initiate distribution,” MED-Project’s *Revised Plan* lacks sufficient description of how the ordering system will initiate distribution of sharps waste containers and mail-back materials. The actions that occur at the point of sale, such as how the site will initiate the request, how a site will know which products require providing or initiating, and who at the site will be performing the steps for initiation of a sharps mail-back package, are not described.

MED-Project’s *Revised Plan* includes language that sharps mail-back packages will arrive “at the Ultimate User’s specified address within five business days of the In-Scope Purchase at a Point of Sale Site.” While MED-Project specifies that sharps mail-back packages will arrive within five business days as required, the issue persists regarding the definition of “Point of Sale Site” as described above. Therefore, MED-Project did not meet condition 1(a), which required MED-Project to describe how its program will provide or initiate distribution of sharps waste containers and mail-back materials at all points of sale where any sharps covered under its *Revised Plan* are sold and which required MED-Project to describe how its program will arrange for sharps waste containers and mail-back materials to arrive within five business days of the point of sale or prior rather than five business days from a request.

MED-Project’s *Revised Plan* incorrectly cites “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. The requirements to provide a mechanism to accept requests for sharps waste containers and mail-back materials via the website and telephone number are pursuant to CCR sections 18973.3(i)(3)(A) and (4), respectively. Therefore, as written, it is unclear whether MED-Project’s *Revised Plan* proposes to provide or initiate distribution of sharps waste containers and mail-back materials pursuant to CCR section 18973.1(a)(10)(C). Staff are unable to conclude whether MED-Project met conditions 1(b) and 1(d). MED-Project must either provide circumstances and justification whereby provision and arranging for arrival, pursuant to CCR sections 18972.1(a)(10)(A) and (B), are illegal or remove the option under CCR section 18972.1(a)(10)(C). If justification for the use of the option pursuant to CCR section 18972.1(a)(10)(C) is provided in MED-Project’s plan, MED-Project must also provide additional information required in condition 1(d).

Regarding condition 1(c), MED-Project's *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." However, MED-Project's *Revised Plan* does not describe how individuals who utilize USPS's General Delivery Service will be communicated with at the point of sale or via the website and call center to ensure they understand how to obtain a sharps container and mail-back materials. Condition 1(c), for homeless individuals to receive sharps mail-back packages, was partially met by MED-Project in the *Revised Plan*. Additionally, MED-Project must meet condition 1(a) to ensure all ultimate users, including homeless individuals, will be able to receive or be provided a sharps mail-back package through MED-Project's program at all points of sale where any sharps covered under the plan are sold.

MED-Project's *Revised Plan* includes sufficient information on proper sharps disposal to meet condition 1(e) by including a description of "biologics." Additionally, the *Revised Plan* lists items that are and are not accepted in sharps mail-back containers and provides instructions for packaging and mailing a sharps mail-back container.

2. CalRecycle Conditions 2 through 8

Requirements: CalRecycle required the *Revised Plan* to meet the conditions specified in the "Staff Analysis" section of the December 2021 Request for Approval.

Result: Conditions 2(a) through 8(a) met

MED-Project's *Revised Plan* includes additional information, clarifications, and descriptions to meet conditions 2(a) through 8(a) related to the "Program Budget and Funding," "Education and Outreach," "Local Agency Requests," "Ordinance Repeals," "Coordination Efforts," "Handling, Transport, and Disposal System," and "Compliance Certifications" sections of the December 2021 Request for Approval. The revisions provided needed clarity regarding the scope of MED-Project's home-generated sharps waste stewardship program and how MED-Project intends to operate its program.

Stakeholder Feedback

CalRecycle solicited public input on MED-Project's *Revised Plan* from March 10, 2022, through March 23, 2022, and received three stakeholder comment letters. CalRecycle considered all comment letters received when reviewing MED-Project's *Revised Plan* for compliance. One of the three comment letters was from the Pharmaceutical Product Stewardship Work Group which articulated support for MED-Project's *Revised Plan*. The remaining two letters were submitted by UltiMed, Inc., which articulated questions and concerns about the point of sale site provision and budget in MED-Project's *Revised Plan*.

Summary of Staff Analysis

CalRecycle staff analyzed MED-Project's *Revised Plan* to determine whether it met all the conditions from CalRecycle's December 2021 Request for Approval. Additional information is still required from MED-Project regarding conditions 1(a) through (d)

discussed in the “Staff Analysis” section above for CalRecycle to determine if MED-Project’s plan shall be approved pursuant to CCR section 18973.1(d).

Condition 1(a): The plan must 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.

Conditions 1(b): The plan must either provide circumstances and justification whereby provision and arranging for arrival, pursuant to CCR sections 18972.1(a)(10)(A) and (B), are illegal or remove any reference to CCR section 18972.1(a)(10)(C).

Condition 1(c): The plan must ensure all ultimate users, including homeless individuals referenced in condition 1(c), 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.

Condition 1(d): If justification for the use of the option pursuant to CCR section 18972.1(a)(10)(C) is provided in MED-Project’s plan, MED-Project must also provide additional information required in condition 1(d).

Options

1. Find MED-Project did not meet the conditions, as specified in CalRecycle’s December 2021 Request for Approval. MED-Project’s proposed stewardship plan for home-generated sharps waste remains “conditionally approved.” Require MED-Project to revise and resubmit to resolve the issues identified in the “Staff Analysis” section above within 60 days of signature of this Request for Approval.
2. Find MED-Project did not meet the conditions for approval and (1) disapprove MED-Project’s proposed stewardship plan for home-generated sharps waste, and (2) refer the covered entities participating in MED-Project’s *Revised Plan* to the Waste Permitting, Compliance and Mitigation Division for potential enforcement pursuant to Title 14, California Code of Regulations section 18973.1(h).

Action

Based on the analysis contained within this Request for Approval, I hereby find MED-Project did not meet all conditions, as specified in CalRecycle’s December 2021 Request for Approval. MED-Project’s proposed stewardship plan for home-generated sharps waste remains “conditionally approved.” MED-Project must revise and resubmit its plan to resolve the issues identified in the “Staff Analysis” section above within 60 days of signature of this Request for Approval. MED-Project must fully implement its plan, revised to comply with the conditions outlined in the “Summary of Staff Analysis,” within 270 days from the date of conditional approval on December 9, 2021. Failure to comply with all conditions and resubmit the plan within 60 days may result in disapproval of MED-Project’s proposed stewardship plan for home-generated sharps waste.

Dated: June 23, 2022

Signed by: Rachel Machi Wagoner, Director

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/) (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

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)
<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>