

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 Covered Drugs from Households

Action By: June 24, 2022

Summary of Request

MED-Project USA (MED-Project) submitted a revised stewardship plan for covered drugs, which includes its initial program budget, titled, *A Product Stewardship Plan for Covered Drugs from Households (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 Covered Drugs from Households*. An addendum, titled, *Appendix C – Participating Authorized Collection Sites Addendum_20220309*, was submitted on March 21, 2022, as part of the *Revised Plan*. 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 200 covered entities. MED-Project submitted *A Product Stewardship Plan for Covered Drugs from Households (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 drugs 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 sections 42032.2(a)(1)(D) and 42033(b) and CCR sections 18973.2(f), 18973.6, 18973.6(c) and 18973.6(e):

- a. Include departmental administrative fees in the initial program budget as either a separate line item or part of the administrative costs line item, pursuant to CCR section 18973.6(b). Provide an amount for the departmental administrative fees.
- b. Clarify the description of "fiscal year" so that it is clear that MED-Project's fiscal year will not conflict with its obligation to submit annual calendar year budgets to CalRecycle that meet all statutory and regulatory requirements.
- c. Include a reserve level amount in the budget.
- d. Clarify the meaning of "cash and reserves," including how it relates to MED-Project's reserve range and reserve amount.

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

MED-Project includes departmental administrative fee estimates as separate line items in the five-year budget in its *Revised Plan*, which meets condition 1(a). CalRecycle notes that regardless of the estimated departmental administrative fee amount included in MED-Project's, or any program operator's, budget, program operators are responsible for paying the actual departmental administrative fee amount, pursuant to PRC section 42034.2.

MED-Project replaced "fiscal year" with "calendar year" in its *Revised Plan*, which meets condition 1(b). The *Revised Plan* specifies that the reserve is "expected to approximate 25% of the annual Program budget" and includes the reserve as a separate line item in the five-year budget, which meets conditions 1(c). Additionally, the *Revised Plan* clarifies that "cash" is cash on hand and is separate from the reserves, which meets condition 1(d).

2. CalRecycle Condition 2

Requirements: CalRecycle required the *Revised Plan* to meet the following conditions pursuant to CCR sections 18973.2(j)(1), (2), and (4):

- a. Explain how non-English and non-Spanish language users will understand that education and outreach materials are available in other languages suited to local demographics and how materials are distributed to these users.

- b. Explain how non-English and non-Spanish language users will understand that translators are available in the call center when an interactive voice response system is only provided in English and Spanish.
- c. Clarify that signage and labeling for secure collection receptacles will contain explanatory graphics for items not accepted in the secure collection receptacle.

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

MED-Project's *Revised Plan* specifies that printed materials will include "universally recognized translation icons" that will direct ultimate users to the website to view and print translated materials, which meets condition 2(a).

MED-Project's *Revised Plan* clarifies that the call center will include an option, in English, for ultimate users "to continue in their preferred language after being offered English or Spanish." Staff understand this approach to be consistent with current call center practices. MED-Project's *Revised Plan* meets condition 2(b).

MED-Project's *Revised Plan* includes explanatory graphics for items not accepted in its sample signage and labeling for collection receptacles, which meets condition 2(c).

3. CalRecycle Condition 3

Requirements: CalRecycle required the *Revised Plan* to meet the following conditions pursuant to PRC sections 42032.2(b)(1) and (3) and CCR sections 18973.2(d)(3) and (5):

- a. Describe good faith negotiations with potential authorized collectors that will continue to be conducted even after minimum convenience standards have been achieved.
- b. Clarify that potential authorized collectors will not be excluded from participating in the program when agreement terms cannot be reached. MED-Project's terms must be consistent with the scope of statute, which allows authorized collectors to be accepted into the program if they offer to participate, in writing and without compensation.

Result: Conditions 3(a) and (b) met

MED-Project's *Revised Plan* specifies that good faith negotiations will occur with potential authorized collectors within 30 days of receiving interest to participate regardless of whether MED-Project has achieved the minimum convenience standards, which meets condition 3(a).

MED-Project's *Revised Plan* specifies that a potential authorized collector will not be excluded from participating in the program unless the potential authorized collector is unable to comply with all applicable laws, regulations, other legal requirements, or other MED-Project terms consistent with the scope of the approved plan and statute, which meets condition 3(b). MED-Project must comply with PRC section

42032.2(b)(3) and CCR section 18973.2(d)(5) by including any potential authorized collector who offers to participate in writing and without compensation into its stewardship program as an authorized collector, including those potential authorized collectors who submit their written offer without using MED-Project's draft written offer. All provisions of statute and regulations will be enforced.

4. CalRecycle Condition 4

Requirement: CalRecycle required the *Revised Plan* to meet the following conditions pursuant to PRC sections 42032.2(a)(1)(F), 42032.2(a)(1)(F)(i) and (iii), 42032.2(c), 42032.2(a)(1)(G)(i) and CCR sections 18973.2(g)(2), 18973.2 (g)(2)(A) and (B), 18973.2(g)(6), and 18973.2(g)(6)(A) and (B):

- a. Remove the phrasing "seek to" and "strive to" in reference to statutory minimum convenience requirements and geographic spread goal. The stewardship plan must state that MED-Project "shall" meet the reasonable geographic spread convenience goal, as defined by MED-Project. Clarify that authorized collection sites will be reevaluated annually to determine the number of authorized collection sites needed in each county to meet the convenience standards.
- b. Describe how reasonable geographic spread is determined, including all the factors applied to develop the determination.
- c. Per PRC section 42032.2(c), propose distribution locations that provide prepaid, preaddressed mail-back envelopes or an alternate form of collection and disposal in counties that do not have the minimum number of Authorized Collection Sites.
- d. Clarify how ultimate users without permanent addresses or access to a phone or internet can receive mail-back materials through the website or call center.
- e. Provide mail-back services or an alternative form of collection and disposal system in counties where there is not an authorized retail pharmacy operating an authorized collection site, per PRC sections 42032.2(a)(1)(F)(iii) and 42032.2(c).

Result: Conditions 4(a) through (e) met

Regarding condition 4(a), MED-Project removes phrasing in its *Revised Plan* that did not commit to meeting the statutory minimum convenience requirements and geographic spread goal, and uses language that commits MED-Project to meeting the statutory requirements. Additionally, MED-Project's *Revised Plan* clarifies that it will annually re-evaluate population estimates for cities, counties, and the state published by the State of California Department of Finance to determine the number of authorized collection sites required in each county. MED-Project's *Revised Plan* meets condition 4(a).

MED-Project's *Revised Plan* describes a process whereby MED-Project will utilize a combination of geographical mapping and information system tools and 2020 US

Census block data to calculate the driving range for the percentage of ultimate users that live within 15 miles of an authorized collection site. MED-Project proposes to apply the same reasonable geographic spread determination to both urban and rural areas, which meets condition 4(b).

If the minimum number of authorized collection sites are not operating in a county due to circumstances beyond MED-Project's control, MED-Project's *Revised Plan* proposes to provide one mail-back distribution location for each authorized collection site necessary to meet the minimum number of authorized collection sites in addition to conducting digital media outreach. MED-Project will provide at least one mail-back distribution location in a county that does not have a retail pharmacy operating as an authorized collection site. MED-Project's *Revised Plan* meets conditions 4(c) and (e).

Regarding condition 4(d), MED-Project's *Revised Plan* proposes to accommodate ultimate users without a permanent address by allowing addresses of service providers such as shelters, churches, and USPS's General Delivery service to receive mail-back packages in lieu of a permanent address. Additionally, proposed mail-back distribution locations will be located in facilities open to the public, such as libraries, town halls, or law enforcement agencies. MED-Project's *Revised Plan* meets condition 4(d).

5. CalRecycle Condition 5

Requirement: CalRecycle required the *Revised Plan* to meet the following condition pursuant to PRC sections 42032.2(e) and 42036.2(a) and CCR section 18973.2(i):

- a. Remove all statements that indicate expansion into a local jurisdiction will occur after (as opposed to within) 270 days from the date a jurisdiction repeals its local stewardship program ordinance.

Result: Condition 5(a) met

MED-Project's *Revised Plan* proposes that expansion into a local jurisdiction will occur within 270 days from the date a jurisdiction repeals its local stewardship program ordinance. MED-Project's *Revised Plan* meets condition 5(a).

6. CalRecycle Condition 6

Requirement: CalRecycle required the *Revised Plan* to meet the following condition pursuant to CCR section 18973.2(k):

- a. Propose a process to coordinate with approved program operators to avoid confusion to the public and all program participants that is not dependent upon a CalRecycle approval process.

Result: Condition 6(a) met

MED-Project's description of its coordination efforts in its *Revised Plan* does not place responsibilities on CalRecycle or impose requirements on other program operators. MED-Project's *Revised Plan* meets condition 6(a).

7. CalRecycle Condition 7

Requirement: CalRecycle required the *Revised Plan* to meet the following condition pursuant to CCR section 18973.2(g)(5)(B):

- a. Include all mailing and physical addresses associated with each vendor.

Result: Condition 7(a) met

MED-Project's *Revised Plan* includes all mailing and physical addresses associated with each vendor. MED-Project's *Revised Plan* meets condition 7(a).

8. CalRecycle Condition 8

Requirement: CalRecycle required the *Revised Plan* to meet the following condition pursuant to PRC section 42032.2(a)(1)(A) and CCR section 18973.2(b):

- a. Include all required information in the covered entities list.

Result: Condition 8(a) met

MED-Project's *Revised Plan* includes the address and contact information associated with each covered entities listed. MED-Project's *Revised Plan* meets condition 8(a).

Stakeholder Feedback

CalRecycle solicited public input on MED-Project's *Revised Plan* from March 10, 2022, through March 23, 2022, and received one stakeholder comment letter from the Pharmaceutical Product Stewardship Work Group in support of MED-Project's *Revised Plan*.

Summary of Staff Analysis

CalRecycle staff analyzed MED-Project's *Revised Plan* and determined it meets all conditions from CalRecycle's December 2021 Request for Approval.

Action

Based on the analysis contained within this Request for Approval, I hereby approve MED-Project's *Revised Plan*. MED-Project must fully implement its *Revised Plan* within 270 days from the date of conditional approval on December 9, 2021.

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 Covered Drugs from Households](https://www2.calrecycle.ca.gov/Docs/Web/119601) (September 14, 2021)

<https://www2.calrecycle.ca.gov/Docs/Web/119601>

- a. [Appendix A - Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/119604) (September 14, 2021)
https://www2.calrecycle.ca.gov/Docs/Web/119604
 - b. [Appendix B - Covered Products](https://www2.calrecycle.ca.gov/Docs/Web/119607) (September 14, 2021)
https://www2.calrecycle.ca.gov/Docs/Web/119607
 - c. [Appendix C - Participating Authorized Collection Sites](https://www2.calrecycle.ca.gov/Docs/Web/119610) (September 14, 2021)
https://www2.calrecycle.ca.gov/Docs/Web/119610
 - d. [Appendix E - Potential Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/119613) (September 14, 2021)
https://www2.calrecycle.ca.gov/Docs/Web/119613
2. [Consideration of MED-Project's Product Stewardship Plan for Covered Drugs from Households](https://www2.calrecycle.ca.gov/Docs/Web/120132)
https://www2.calrecycle.ca.gov/Docs/Web/120132
 3. [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