

REQUEST FOR ACTION

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: December 13, 2022

Decision Subject: Consideration of The Drug Takeback Solutions Foundation's
Revised Stewardship Plan for Covered Drugs

Action By: January 13, 2023

Summary of Request

The Drug Takeback Solutions Foundation (The Foundation) submitted a revised stewardship plan for covered drugs, which includes its initial program budget, titled, *Stewardship Plan for Covered Drugs (October 2022 Revised Plan)* to the Department of Resources Recycling and Recovery (CalRecycle) on October 15, 2022, pursuant to the conditions in CalRecycle's August 2022 Request for Approval, titled, *Consideration of The Drug Takeback Solutions Foundation's Revised Stewardship Plan for Covered Drugs*. This Request for Action presents a summary of staff's analysis regarding The Foundation's *October 2022 Revised Plan*.

Background

The Foundation is a stewardship organization that represents 65 covered entities under its *October 2022 Revised Plan*. On November 19, 2021, The Foundation submitted its *Stewardship Plan for Covered Drugs (Plan)* to CalRecycle, pursuant to Public Resources Code (PRC) section 42032, and on December 16, 2021, an addendum, titled, *Addendum to Stewardship Plan for Covered Drugs* as part of the *Plan*. CalRecycle determined the *Plan* was complete and notified The Foundation on December 20, 2021, pursuant to PRC section 42032(c)(1) and Title 14, California Code of Regulations (14 CCR) section 18973.1(b).

On February 16, 2022, CalRecycle conditionally approved The Foundation's *Plan* pursuant to PRC section 42032(d)(1) and 14 CCR section 18973.1(e) and (g). CalRecycle provided The Foundation 90 days to submit a revised plan that addressed the conditions specified in the February 2022 Request for Approval.

On May 17, 2022, The Foundation submitted its *Stewardship Plan for Covered Drugs (May 2022 Revised Plan)*, to meet conditions specified in the "Staff Analysis" section of the February 2022 Request for Approval. On August 16, 2022, CalRecycle maintained the conditional approval of The Foundation's *May 2022 Revised Plan* and provided The Foundation 60 days to submit a revised plan that addressed the remaining conditions specified in the August 2022 Request for Approval.

On October 15, 2022, The Foundation submitted its *October 2022 Revised Plan*, which is the subject of this Request for Action.

Staff Analysis

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

CalRecycle Condition 1

Requirements: CalRecycle required the *October 2022 Revised Plan* to meet the following conditions pursuant to PRC sections 42032.2(a)(1)(F), 42032.2(a)(1)(F)(i), 42032.2(a)(1)(F)(ii), 42032.2(a)(1)(F)(iii), and 42032.2(c) and 14 CCR sections 18973.2(g)(2):

- a. The plan must state that The Foundation will meet the requirements in PRC sections 42032.2(a)(1)(F)(i) through (iii).
- b. The Foundation must describe the reasonable geographic spread goals consistently throughout the plan.
- c. Demonstrate that the requirements in PRC sections 42032.2(a)(1)(F)(i) and (ii) will be met by utilizing collection sites, not mail-back distribution locations.

Analysis: Conditions 1(a), (b), and (c) met.

The Foundation's *October 2022 Revised Plan* revises the definition of "Convenience Standard" to include the requirements of minimum number of authorized collection sites, reasonable geographic spread of authorized collection sites, and mail-back services covering counties where there is not an authorized retail pharmacy operating as an authorized collection site as described in PRC section 42032.2(a)(1)(F)(i)-(iii). The *October 2022 Revised Plan* includes language specifying how The Foundation will meet the requirements in PRC sections 42032.2(a)(1)(F)(i) through (iii) and provides descriptions of how convenience standards will be met in each county. The *October 2022 Revised Plan* meets condition 1(a).

The *October 2022 Revised Plan* consistently describes reasonable geographic spread goals of ensuring 90 percent of ultimate users live within a 15-mile drive of an authorized collection site to meet requirements outlined in PRC section 42032.2(a)(1)(F)(ii). Additionally, The Foundation describes a goal of ensuring 90 percent of ultimate users live within a 15-mile drive of a mail-back distribution site in counties where an authorized retail pharmacy is not available. The *October 2022 Revised Plan* meets condition 1(b).

The *October 2022 Revised Plan* clarifies that the convenience standard set forth in PRC Section 42032.2(a)(1)(F)(i-ii) will be met using authorized collection sites and that mail-back services will be provided for any counties where there is not an authorized retail pharmacy operating as an authorized collection site. The *October 2022 Revised Plan* meets condition 1(c).

CalRecycle Condition 2

Requirements: CalRecycle required the *October 2022 Revised Plan* to meet the following conditions 2(a) and 2(c) pursuant to PRC sections 42032.2(a)(1)(D) and 42033(b) and 14 CCR sections 18973.2(f), and 18973.6(b) through (e):

- a. The budget must include all required cost categories, pursuant to 14 CCR section 18973.6(b), and a narrative description of the types of activities that will be conducted under each of the line items in the budget.
- c. The budget must include a justification for the proposed reserve level amounts.

Analysis: Conditions 2(a) and (c) met.

The Foundation's *October 2022 Revised Plan* includes all required cost categories, including costs related to grants, loans, sponsorships, or other incentives. The *October 2022 Revised Plan* also includes a description of funding for an independent financial audit in its budget. The *October 2022 Revised Plan* meets condition 2(a).

The Foundation has determined a reserve level that "approximates 10 percent of additional Collection Receptacle needs" is sufficient to cover estimated impacts of unexpected cost variability including costs of collection, transportation, disposal, and other program costs for the program year. The reserve level would approximate three months of education, operational, and administrative costs and provide sufficient cash to respond to unplanned needs, unexpected events, and losses of income or large unbudgeted expenses throughout the program year. The Foundation provided sufficient reserve level justification in the *October 2022 Revised Plan* to meet condition 2(c).

Staff note that "Appendix A - Program Budget" of the *October 2022 Revised Plan* contains mathematical errors for the cost category "Total Operational Expenses." The Total Operational Expenses for fiscal years 2023 to 2026 do not accurately total the subcategories. CalRecycle will review The Foundation's March 31, 2023, annual program budget for accuracy of all cost category totals and compliance with all other statutory and regulatory requirements.

CalRecycle Condition 3

Requirements: CalRecycle required the *October 2022 Revised Plan* to meet the following conditions 3(a), 3(d), and 3(e) pursuant to PRC sections 42031.6(a)(1) and 42031.6(a)(2) and 14 CCR sections 18973.2(j)(2), 18973.2(j)(4), and 18973.2(j)(5):

- a. The plan must specify that signage will be provided to hospitals, pharmacies, and other locations, as necessary.
- d. The plan must specify that the toll-free telephone number will accommodate requests from homebound, homeless, and disabled ultimate users.
- e. The plan must explain how the proposed annual education and outreach survey will evaluate the performance of the outreach and education program regarding ultimate user awareness, program usage, and accessibility. Describe the metrics that will be used to measure ultimate user awareness, program usage, and accessibility.

Analysis: Conditions 3(a), (d), and (e) met.

The Foundation's *October 2022 Revised Plan* clarifies that promotional materials, including signage, will be provided free of charge to hospital, pharmacies, and other locations, as necessary. The *October 2022 Revised Plan* meets condition 3(a).

The *October 2022 Revised Plan* specifies that the call center will accommodate requests from homeless, homebound, and disabled ultimate users. The *October 2022 Revised Plan* meets condition 3(d).

The *October 2022 Revised Plan* states that The Foundation will conduct an annual survey of ultimate users, pharmacists, and healthcare professionals with questions designed to assess the effectiveness and awareness of the program. The *October 2022 Revised Plan* includes clear metrics that will be used to evaluate the performance of the education and outreach program, including using the percentage of survey respondents to measure ultimate user awareness, program usage, and accessibility. Additionally, the *October 2022 Revised Plan* no longer includes reference to a biennial survey which eliminates confusion about how annual performance will be evaluated through The Foundation's survey. The *October 2022 Revised Plan* removed language regarding CalRecycle's involvement to design signage or labeling for secure collection receptacles. The *October 2022 Revised Plan* meets condition 3(e).

CalRecycle Condition 5

Requirement: CalRecycle required the *October 2022 Revised Plan* to meet the following condition pursuant to PRC section 42032.2(e) and 14 CCR section 18973.2(i):

- a. The plan must describe how The Foundation will expand its stewardship program into jurisdictions that repeal their local stewardship program ordinance within 270 days of the effective date of repeal.

Analysis: Condition 5(a) met.

The *October 2022 Revised Plan* includes sufficient description of how it will expand into jurisdictions within 270 days of the effective date of the repeal of a local jurisdiction ordinance. Additionally, the *October 2022 Revised Plan* no longer includes language that assumes it is the jurisdiction's responsibility to notify The Foundation of a repeal and includes a statement that The Foundation will consistently monitor local jurisdictions to remain aware of any program changes or repeals. The *October 2022 Revised Plan* meets condition 5(a).

CalRecycle Condition 7

Requirements: CalRecycle required the *October 2022 Revised Plan* to meet the following conditions pursuant to PRC sections 42032.2(a)(1)(G)(iii)(II) and 42032.2(a)(1)(H) and 14 CCR sections 18973(d) and 18973.2(g)(1):

- a. The plan must describe activities that will be conducted at all potential authorized collection sites, not just pharmacies.
- b. The plan must use terminology defined in PRC and 14 CCR or define and consistently utilize terminology within the plan. Correct formatting and grammatical errors contained in the plan.
- c. Ensure that all references, including statutory and regulatory citations, in the plan are correct.

- d. The Foundation must provide all required contact information to ensure that The Foundation and Inmar are fully identified as separate entities.

Analysis: Conditions 7(a), (b), (c), and (d) met

The Foundation's *October 2022 Revised Plan* replaces the term "authorized pharmacy employee" with "Authorized collection site employee" when describing the documentation and tracking activities conducted thus eliminating the restriction that only pharmacies participate as authorized collection sites. The *October 2022 Revised Plan* meets condition 7(a).

The Foundation's *May 2022 Revised Plan* contained multiple instances of inconsistent terminology and use of terms not defined in PRC, 14 CCR, or the *May 2022 Revised Plan*. The *October 2022 Revised Plan* addresses these inconsistencies and undefined terms and provides a clear narrative of how The Foundation's program will function. The *October 2022 Revised Plan* meets condition 7(b).

The Foundation's *May 2022 Revised Plan* included incorrect references and statutory and regulatory citations. The *October 2022 Revised Plan* contains correct references and citations, including the correct regulatory citation in the certification statement on page 51. The *October 2022 Revised Plan* meets condition 7(c).

The *October 2022 Revised Plan* includes the required missing mailing and physical address(es) and website for the person(s) responsible for submitting and overseeing the stewardship plan and budget on behalf of the program operator and the contact name and title of each covered entity participating in the stewardship plan to ensure CalRecycle can contact The Foundation and its covered entities and to ensure Inmar and The Foundation are fully identified as separate entities. The *October 2022 Revised Plan* meets condition 7(d).

CalRecycle Condition 9

Requirement: CalRecycle required the *October 2022 Revised Plan* to meet the following condition pursuant to 14 CCR section 18973(a):

- a. Correct accessibility errors in the plan to make it compliant with section 7405 of the Government Code and with the Web Content Accessibility Guidelines 2.0.

Analysis: Condition 9(a) met.

The Foundation's *October 2022 Revised Plan* corrects accessibility errors to make it compliant with section 7405 of the Government Code and with the Web Content Accessibility Guidelines 2.0. The *October 2022 Revised Plan* meets condition 9(a).

Stakeholder Feedback

CalRecycle solicited public input on The Foundation's *October 2022 Revised Plan* from October 17, 2022, through October 31, 2022, and did not receive any public comments.

Action

Pursuant to PRC section 42032(d)(1) and 14 CCR section 18973.1:

- Approve The Foundation's *October 2022 Revised Plan*
- Maintain conditional approval of The Foundation's *October 2022 Revised Plan*
- Disapprove The Foundation's *October 2022 Revised Plan*

Signed by: Rachel Machi Wagoner, Director

Dated: December 20, 2022

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/>).

1. [Stewardship Plan for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/122445) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122445>
 - a. [Appendix A – Program Budget](https://www2.calrecycle.ca.gov/Docs/Web/122424) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122424>
 - b. [Appendix B – Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122427) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122427>
 - c. [Appendix C – Participating Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/122430) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122430>
 - d. [Appendix D – Service Providers](https://www2.calrecycle.ca.gov/Docs/Web/122433) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122433>
 - e. [Appendix E – Drugs Sold or Offered for Sale in California by Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122436) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122436>
 - f. [Appendix F – Contacted Potential Authorized Collectors](https://www2.calrecycle.ca.gov/Docs/Web/122439) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122439>
 - g. [Appendix G - Participating Mail-Back Distribution Locations Providers](https://www2.calrecycle.ca.gov/Docs/Web/122442) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122442>
2. [Consideration of The Drug Takeback Solutions Foundation's Revised Stewardship Plan for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/122016) (August 16, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122016>
3. [Addendum to Stewardship Plan for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/120192) (December 16, 2021)
<https://www2.calrecycle.ca.gov/Docs/Web/120192>
4. [Consideration of The Drug Takeback Solutions Foundation's Product Stewardship Plan for Covered Drugs](https://www2.calrecycle.ca.gov/Docs/Web/120855) (February 16, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/120855>