

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: August 1, 2022

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

Action By: August 16, 2022

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 (Revised Plan)* to the Department of Resources Recycling and Recovery (CalRecycle) on May 17, 2022, pursuant to the requirements in CalRecycle's February 2022 Request for Approval, titled, *Consideration of The Drug Takeback Solutions Foundation's Product Stewardship Plan for Covered Drugs*. This Request for Approval presents staff's analysis and compliance recommendation regarding The Foundation's *Revised Plan*.

Background

The Foundation is a stewardship organization that represents 25 covered entities under its *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 sections 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. The February 2022 Request for Approval required The Foundation to submit (1) a letter, within 30 days of February 16, 2022, committing to revise and resubmit its plan to meet the conditions specified in the "Staff Analysis" section of the February 2022 Request for Approval, and (2) a revised drugs plan, within 90 days of February 16, 2022, that included the additional information to meet the conditions specified in the "Staff Analysis" section of the February 2022 Request for Approval.

The Foundation submitted the required letter on March 15, 2022. On May 17, 2022, The Foundation submitted a *Revised Plan*, which is the subject of this Request for Approval.

Staff Analysis

Each condition in the February 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 *Revised Plan* submitted on May 17, 2022.

1. CalRecycle Condition 1

Requirements: 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), 42032.2(a)(1)(F)(ii), 42032.2(a)(1)(F)(iii), 42032.2(c), 42030(e)(1)(C), and 42036.2 and 14 CCR sections 18973.2(g)(1), 18973.2(g)(2), 18973.2(g)(2)(A), and 18973.2(g)(6)(E):

- a. Remove the phrases "make good faith efforts to" and "expects to be" in reference to the statutory minimum convenience requirement and the reasonable geographic spread requirement. The plan must state that The Foundation "shall" meet the requirements in PRC sections 42032.2(a)(1)(F)(i) through (iii).
- b. Describe how reasonable geographic spread is determined, including all the factors that will be used to calculate reasonable geographic spread and the number and locations of authorized collection sites. The Foundation must describe the 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. Mail-back distribution locations cannot be utilized in lieu of authorized collection sites to meet the requirements in PRC sections 42032.2(a)(1)(F)(i) and (ii), unless The Foundation provides evidence, as part of its revised plan, to satisfy the requirements in PRC section 42032.2(c).
- d. Clarify whether the plan's definition of "covered drug" does or does not include a combination product containing a drug in a medical device and how those products will be managed.
- e. Include the type of mailers distributed and the mailers distributed via request by website and toll-free phone number (not just Mailers distributed at Sites) when describing metrics that will be used to measure the number and type of preaddressed, prepaid mail-back materials distributed.
- f. Clarify that the program does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance.

Result: Conditions 1(d), (e), and (f) met. Conditions 1(a), (b), and (c) partially met. Additional information from and additional actions by The Foundation are necessary.

PRC sections 42032.2(a)(1)(F)(i) through (iii) require a stewardship plan for covered drugs to provide for a collection system, for authorized collection sites in each county in which the plan will be implemented, that (i) provides for a minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater, (ii) provides for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread, and (iii) provides for a

mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site.

The Foundation removed the phrases “make good faith efforts to” and “expects to” in reference to the statutory minimum convenience requirement and the reasonable geographic spread requirement in its *Revised Plan*. However, The Foundation’s definition of “Convenience Standard” only includes reference to PRC section 42032.2(a)(1)(F)(i) and omits PRC section 42032.2(a)(1)(F)(ii). Additionally, The Foundation’s *Revised Plan* does not describe how it will provide a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site pursuant to PRC section 42032.2(a)(1)(F)(iii). The Foundation’s *Revised Plan* partially met condition 1(a) as it did not affirmatively state that The Foundation will meet the requirements in PRC sections 42032.2(a)(1)(F)(i) through (iii).

In the *Revised Plan*, The Foundation includes a description for determining reasonable geographic spread by utilizing population estimates from the Department of Finance with Tableau, a data visualization tool, to map the authorized collection sites with population data to calculate the geographic spread and determine the number and location of collection receptacles needed per county and population. The geographic spread goal remains inconsistently described in The Foundation’s *Revised Plan*. The Foundation describes the geographic spread and reach goal as “90%” of ultimate users being within 15 miles of an “authorized collector” on page 13, “90%” of ultimate users being within 15 miles of either an “authorized collector or a mail-back distribution site” on page 23, but on page 20, the geographic spread goal is described as “all” (100%) ultimate users are located within 15 miles of an “authorized collection site.” It is unclear how the reach goal relates to the required geographic spread goal because The Foundation uses differing percentages and site terminology to describe goals in the *Revised Plan*. Therefore, condition 1(b) is partially met as The Foundation did not consistently describe its geographic spread goal throughout the *Revised Plan*.

The *Revised Plan* states The Foundation will meet the “Convenience Standards set forth in PRC 42032.2(a)(1)(F) using only Authorized Collection Sites” and will utilize mail-back distribution sites to increase access to disposal options for the homeless and underserved populations. However, The Foundation’s definition of “Convenience Standard” does not include reference to PRC section 42032.2(a)(1)(F)(ii), making it unclear if The Foundation intends to meet the convenience standard in subpart (i) alone, or both (i) and (ii). The Foundation’s *Revised Plan* partially met condition 1(c) as it did not 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.

The Foundation clarified its definition of “Covered Drug” to include “a drug in a medical device, or a combination product containing a drug and a medical device” and the *Revised Plan* describes how covered drugs will be managed. The Foundation’s *Revised Plan* met condition 1(d).

In the *Revised Plan*, The Foundation includes metrics for the types of mailers distributed by collection sites, distribution locations, website and toll-free number. The Foundation's *Revised Plan* met condition 1(e).

In the *Revised Plan*, The Foundation clarified that its program excludes local jurisdictions that currently operate a local stewardship program ordinance. The Foundation's *Revised Plan* met condition 1(f).

2. CalRecycle Condition 2

Requirements: CalRecycle required the *Revised Plan* to meet the following conditions pursuant to PRC sections 42032.2(a)(1)(D) and 42033(b) and 14 CCR sections 18973(d), 18973.2(f), and 18973.6(b) through (e):

- a. Include a narrative description of the types of activities that will be conducted under each of the line items in the budget. Include the departmental administrative fees in the initial program budget as either a separate line item or part of the administrative costs line item, pursuant to 14 CCR section 18973.6(b). Include a description of how costs are apportioned to and funds are remitted from participating covered entities.
- b. Clarify the reason for inclusion of a sharps container budget line item and describe the related activities in the plan or remove sharps containers from the budget.
- c. Include a justification for the proposed reserve level amount and commit to maintaining the reserve in a prudent and responsible manner.
- d. Correct all mathematical discrepancies and ensure an accurate initial five-year program budget is submitted.

Result: Conditions 2(b) and (d) met. Conditions 2(a) and (c) partially met. Additional information from and additional actions by The Foundation are necessary.

In the *Revised Plan*, The Foundation includes the departmental administrative fees as a separate line item and includes a description of how costs are apportioned to and funds remitted from participating covered entities, partially meeting condition 2(a). While The Foundation provided narrative descriptions for the costs categories provided in its *Revised Plan*, some required cost categories are missing. The *Revised Plan* does not specify if the Foundation will provide any grants, loans, sponsorships, reimbursements, or other incentives. These potential costs must be included as a line item in the budget, even if they are not applicable. Additionally, the *Revised Plan* does not include funding for an independent financial audit in the cost categories description. The *Revised Plan* partially met condition 2(a) as The Foundation did not include all required cost categories pursuant to 14 CCR section 18973.6(b).

The Foundation removed the sharps container budget line item from the budget in the *Revised Plan*, meeting condition 2(b).

In the *Revised Plan*, The Foundation proposes a reserve amount for the first five years to cover unexpected overages in operational costs and commits to maintain the reserve in a prudent and responsible manner, partially meeting condition 2(c). However, it is unclear if the reserve amount covers unexpected overages in only the

“operational” cost category of the budget or overages for all program costs. Appendix A of the *Revised Plan* includes a line item for reserve amounts for 2022 through 2026. Additionally, the proposed reserve amounts listed range from approximately six to ten percent of each year’s total budget amount. There is no justification as to why these proposed reserve amounts are appropriate. The Foundation partially met condition 2(c) as the *Revised Plan* did not include a justification for the proposed reserve level amounts.

The five-year program budget provided in Appendix A does not contain any mathematical errors and therefore The Foundation’s *Revised Plan* met condition 2(d).

3. CalRecycle Condition 3

Requirements: CalRecycle required the *Revised Plan* to meet the following conditions pursuant to PRC sections 42031.6(a)(1), 42031.6(a)(2), and 42031.6(a)(5) and 14 CCR sections 18973.2(j)(1) through (6):

- a. Clarify that the education and outreach program is intended to promote ultimate user awareness and maximize ultimate user participation. Specify that signage will be provided to hospitals, pharmacies, and other locations, as necessary.
- b. Explain the methodology The Foundation proposes to use to determine which languages are suited to various local demographics.
- c. Describe how the website’s digital content and navigability will be accessible to disabled individuals.
- d. Clarify that language options suited to local demographics will be available for live translation through the toll-free telephone number and how non-English language users will understand that live translation services are available in other languages. Explain how the toll-free telephone number will provide services for hearing-impaired and speech-impaired individuals. Specify that the toll-free telephone number will accommodate requests from homebound, homeless, and disabled ultimate users.
- e. Explain how the proposed biennial education and outreach survey will evaluate the annual 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. Include sufficient detail about the components of the comprehensive education and outreach program in the plan that is not dependent upon an additional CalRecycle review process.
- f. Describe how The Foundation’s comprehensive education and outreach program will encourage users to separate covered products from products that are not covered.

Result: Conditions 3(b), (c), and (f) met. Conditions 3(a), (d), and (e) partially met. Additional information from and additional actions by The Foundation are necessary.

The *Revised Plan* describes education and outreach methods The Foundation will use to promote ultimate user awareness and maximize ultimate user participation, including printed materials, traditional media, programmatic advertising, social

media, and targeted media. The Foundation states that “promotional materials” will be provided to hospitals and pharmacies but does not clarify that signage is part of the promotional materials that will be provided to hospitals, pharmacies, and other locations, as necessary. Therefore, the Foundation’s *Revised Plan* partially met condition 3(a) as The Foundation did not specify that signage will be provided to hospitals, pharmacies, and other locations, as necessary.

In the *Revised Plan*, The Foundation proposes to translate materials based on the languages available on the California Voter Registration website for the methodology to determine which languages are suited to various local demographics. The *Revised Plan* also states that whenever notice of availability of materials is given, either orally or in writing, it will be provided in English and any non-English language(s) that the materials have been translated into. The Foundation’s *Revised Plan* met condition 3(b).

The Foundation states in the *Revised Plan* that the website will be compliant with Web Content Accessibility Guidelines 2.0. The Foundation’s *Revised Plan* met condition 3(c).

In the *Revised Plan*, The Foundation clarifies that language options suited to local demographics will be available for live translation through the toll-free telephone number and explains how non-English language users will understand that live translation services are available in other languages. The *Revised Plan* also states that the toll-free telephone number will provide services for hearing-impaired and speech-impaired individuals. However, The Foundation did not specify that the toll-free telephone number will accommodate requests from homebound, homeless, and disabled ultimate users, therefore the *Revised Plan* partially met condition 3(d).

The *Revised Plan* appears to propose an annual survey and commits to reporting the survey results in the annual report. However, a biennial survey is also referenced in the *Revised Plan* as being conducted in subsequent years. The *Revised Plan* partially met condition 3(e) as it is not clear how the Foundation will assess annual performance of the education and outreach program in the years in which it does not conduct a survey. Although The Foundation proposes to design survey questions that will “evaluate the effectiveness of different messaging,” the *Revised Plan* does not include clear metrics that will be used to evaluate the performance of the education and outreach program, specifically the metrics that will be used to measure ultimate user awareness, program usage, and accessibility. Therefore, The Foundation partially met condition 3(e) as it did not clarify whether the survey is annual or biennial and describe the metrics that will be used to measure ultimate user awareness, program usage, and accessibility. Additionally, The Foundation’s *Revised Plan* states that it “will work with the Department to design any additional signage that meets the needs and requirements of the Program.” Although CalRecycle encourages consistent communication from program operators on program activities, The Foundation must independently design signage or labeling for its secure collection receptacles and coordinate with other approved program operators for consistency.

In the *Revised Plan*, The Foundation states that all education messaging will include guidance on separating covered products from not covered products before disposal via authorized collection sites or mail-back. The Foundation's *Revised Plan* met condition 3(f).

4. CalRecycle Condition 4

Requirements: CalRecycle required the *Revised Plan* to meet the following conditions pursuant to PRC section 42032.2(b)(3) and 14 CCR section 18973.2(d)(5):

- a. Describe how potential authorized collectors will be incorporated into the program within 90 days of receiving a written offer to participate without compensation, 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. The Foundation's terms must be consistent with the scope of statute, which allows authorized collectors to be accepted to participate in the program if they offer to participate, in writing and without compensation.

Result: Conditions 4(a) and (b) met.

In the *Revised Plan*, The Foundation clarifies that potential authorized collectors will be incorporated into the program within 90 days of written offer to participate. The Foundation's *Revised Plan* met condition 4(a).

In the *Revised Plan*, The Foundation states it will include all potential authorized collectors who negotiate in good faith with The Foundation but will reject any potential authorized collector that refuses to comply with US Drug Enforcement Administration and/or California Board of Pharmacy rules and regulations. The Foundation's *Revised Plan* met condition 4(b).

5. CalRecycle Condition 5

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

- a. Describe the processes, logistics, and timing of implementation that will be utilized by the stewardship program to expand into jurisdictions that repeal their local stewardship program ordinance.

Result: Condition 5(a) partially met.

In the *Revised Plan*, The Foundation describes the processes and logistics of implementation that will be utilized to expand the stewardship program into jurisdictions that repeal their local stewardship program ordinance, including identifying differences and updating and expanding the program as necessary. However, the *Revised Plan* states The Foundation will incorporate its program into a jurisdiction that has repealed their local ordinance "within 270 days of the effective date of their notification of repeal." It is the responsibility of The Foundation to incorporate its program into the jurisdiction within 270 days of the repeal effective date regardless of notification by the jurisdiction. The Foundation's *Revised Plan*

partially met condition 5(a) as it did not describe how it will expand its stewardship program into jurisdictions that repeal their local stewardship program ordinance within 270 days of the effective date of repeal.

6. CalRecycle Condition 6

Requirement: CalRecycle required the *Revised Plan* to meet the following condition pursuant to 14 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 and does not place responsibilities, outside of those that are mutually acceptable, on other program operators.

Result: Condition 6(a) met.

In the *Revised Plan*, The Foundation proposes 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 and does not place responsibilities on other program operators. The Foundation's *Revised Plan* met condition 6(a).

7. CalRecycle Condition 7

Requirements: CalRecycle required the *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 clearly describe activities that will be conducted at all potential authorized collection sites, not just pharmacies.
- b. 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 statutory and regulatory citations in the plan are correct.
- d. Consistently identify The Foundation as the stewardship organization and program operator. Consistently identify Inmar as The Foundation's service provider and include its mailing and physical address(es) in Appendix D. Ensure that the plan demonstrates that The Foundation and Inmar are separate entities.

Result: Conditions 7(a) and (c) not met. Conditions 7(b) and (d) partially met. Additional information from and additional actions by The Foundation are necessary.

In the *Revised Plan*, The Foundation describes documentation and tracking activities by "authorized pharmacy employees" but does not clarify if the documentation and tracking activities will be conducted at all potential authorized collection sites, including authorized collection sites other than pharmacies, such as law enforcement agencies. The Foundation's *Revised Plan* did not meet condition 7(a) as it did not clearly describe activities that will be conducted at all potential authorized collection sites, not just pharmacies.

While some corrections were made, multiple inconsistencies in terminology, formatting issues, and grammatical errors remain in the *Revised Plan*. For example,

The Foundation defines “Collection Receptacle Collection Supply Bundle” which includes the acronym “CRKCSB” but within the *Revised Plan*, the term “Collection Receptacle Supply Bundle (CRSB)” is used. Similarly, The Foundation defines “Collection Receptacle Collection Kit” including the acronym “CRCK,” but The Foundation uses the undefined acronym “CRK” in the *Revised Plan*. Additionally, the *Revised Plan* utilizes terminology and acronyms that are not defined. While not an exhaustive list, the following are examples of terms and acronyms that are not defined in the *Revised Plan*: “CA ADC,” “ASTM,” “Starter Kit,” and “Local Jurisdiction.” The term “covered entity,” as defined in PRC section 42030(f), is used throughout the *Revised Plan*. However, when describing the education and outreach program, The Foundation proposes to ensure “California Covered Entities” understand where and how to return covered drugs. It is unclear if “California Covered Entities” has the same meaning as “covered entity.” Additionally, The Foundation’s *Revised Plan* uses the phrase “Program operational costs” in the budget section but is not defined or explained. It is unclear if the phrase is synonymous with “Program Budget,” also undefined, or how it relates to the required initial five-year program budget. Formatting and grammatical errors persist in the *Revised Plan* such as misnumbered pages and the duplicate use of Roman numeral XIV in the table of contents. The definition of “Convenience Standard” is inconsistent with the statutory requirement because, while it includes a narrative requirement for reasonable geographic spread, the citation to subpart (ii) is missing. The reasonable geographic spread requirement is housed in PRC section 42032.2(a)(1)(F)(ii). The Foundation’s *Revised Plan* partially met condition 7(b) as it did not use terminology defined in PRC and 14 CCR, define and consistently use terminology, or correct all grammatical and formatting errors in the *Revised Plan*.

The Foundation’s *Revised Plan* also includes incorrect references and regulatory citations. For example, the citation referenced in the certification statement on page 49 is incorrect. Additionally, the *Revised Plan* often refers to section numbers without referencing the name of the statute or the regulations or omitting the word “section” (see page 38, for example: the proper citation is “14 CCR section 18974,” not “18974”). The Foundation did not meet condition 7(c) as it did not ensure that statutory and regulatory citations used in the *Revised Plan* are correct.

In the *Revised Plan*, The Foundation clarifies that Inmar and The Foundation are separate entities and Inmar is identified as a service provider in the *Revised Plan* and listed in Appendix D. However, the *Revised Plan* is missing some required contact information pursuant to 14 CCR sections 18973.2(a), 18973.6(a), and 18973.2(b), which includes required 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. The missing contact information is necessary to ensure CalRecycle can contact The Foundation and its covered entities and to ensure Inmar and The Foundation are fully identified as separate entities to meet condition 7(d).

8. CalRecycle Condition 8

Requirement: CalRecycle required the *Revised Plan* to meet the following condition pursuant to 14 CCR section 18973.2(c):

- a. Address the discrepancy between the covered drug list provided in the Plan and the covered drug lists submitted to Board of Pharmacy on or about January 2021. Include a complete and accurate list of covered drugs sold or offered for sale by each covered entity participating in the plan.

Result: Condition 8(a) met.

In the *Revised Plan*, The Foundation submitted a list of updated covered drugs sold or offered for sale by each covered entity participating in the plan, meeting condition 8(a).

9. CalRecycle Condition 9

Requirement: CalRecycle required the *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.

Result: Condition 9(a) not met. Additional information from and additional actions by The Foundation are necessary.

The *Revised Plan* contains over 30 accessibility errors. Most of the errors result from the PDF document not being correctly and completely tagged, which may prevent a vision impaired reader from obtaining needed information. A tagged PDF contains tags, which create invisible formatting for assistive technologies such as screen readers to read the information aloud in a logical order. Other errors relate to alternative text (which provides a description of non-text information that can be read by a screen reader) in the determination letters and incorrect heading structure. The Foundation did not meet condition 9(a) as it did not ensure the *Revised Plan* is compliant with section 7405 of the Government Code and with the Web Content Accessibility Guidelines 2.0.

Stakeholder Feedback

CalRecycle solicited public input on The Foundation's *Revised Plan* from May 18, 2022, through June 1, 2022, and did not receive any public comments.

Summary of Staff Analysis

CalRecycle staff analyzed The Foundation's *Revised Plan* to determine whether it met all the conditions from CalRecycle's February 2022, Request for Approval. Additional information is still required from The Foundation regarding conditions 1(a), 1(b), 1(c), 2(a), 2(c), 3(a), 3(d), 3(e), 5(a), 7(a), 7(b), 7(c), 7(d), and 9(a), discussed in the "Staff Analysis" section above, for CalRecycle to determine if The Foundation's plan shall be approved pursuant to 14 CCR section 18973.1(d).

Condition 1(a): The plan must state that The Foundation will meet the requirements in PRC sections 42032.2(a)(1)(F)(i) through (iii).

Condition 1(b): The Foundation must describe the geographic spread goals consistently throughout the plan.

Condition 1(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.

Condition 2(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.

Condition 2(c): The budget must include a justification for the proposed reserve level amounts.

Condition 3(a): The plan must specify that signage will be provided to hospitals, pharmacies, and other locations, as necessary.

Condition 3(d): The plan must specify that the toll-free telephone number will accommodate requests from homebound, homeless, and disabled ultimate users in the plan.

Condition 3(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.

Condition 5(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.

Condition 7(a): The plan must describe activities that will be conducted at all potential authorized collection sites, not just pharmacies.

Condition 7(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.

Condition 7(c): Ensure that all references, including statutory and regulatory citations, in the plan are correct.

Condition 7(d): The Foundation must provide all required contact information to ensure that The Foundation and Inmar are fully identified as separate entities.

Condition 9(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.

Options

1. Find The Foundation did not meet the conditions, as specified in CalRecycle's February 2022, Request for Approval. The Foundation's proposed stewardship plan for covered drugs remains "conditionally approved." Require The

- Foundation 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 The Foundation did not meet the conditions for approval and (1) disapprove The Foundation’s proposed stewardship plan for covered drugs, and (2) refer The Foundation 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 The Foundation did not meet all conditions, as specified in CalRecycle’s February 2022, Request for Approval. The Foundation’s proposed stewardship plan for covered drugs remains “conditionally approved.” The Foundation must revise and resubmit to resolve the issues identified in the “Staff Analysis” section above within 60 days of signature of this Request for Approval. The Foundation 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 (i.e., by November 13, 2022). Failure to comply with all conditions and resubmit the plan within 60 days may result in disapproval of The Foundation’s proposed stewardship plan for covered drugs.

Dated: August 16, 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. [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
2. [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