

REQUEST FOR APPROVAL

To: Rachel Machi Wagoner
Director

From: Zoe Heller
Deputy Director, Policy Development

Request Date: February 4, 2022

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

Action By: February 17, 2022

Summary of Request

The Drug Takeback Solutions Foundation (The Foundation) submitted its stewardship plan for covered drugs, which includes its initial program budget, titled, *Stewardship Plan for Covered Drugs: October 21, 2021: Version 2 (November 15, 2021)* (Plan) to the Department of Resources Recycling and Recovery on November 19, 2021, pursuant to section 42032(a)(1) of the Public Resources Code. An addendum, titled, *Addendum to Stewardship Plan for Covered Drugs: October 21, 2021: Version 2 (November 15, 2021)* (see Attachment 1), was submitted on December 16, 2021, as part of the Plan. This Request for Approval presents staff's analysis and compliance recommendation regarding The Foundation's Plan.

Staff Analysis

Background

Senate Bill 212 (Jackson, Chapter 1001, Statutes of 2018) established the statewide Pharmaceutical and Sharps Waste Stewardship Act (Act), requiring the first statewide stewardship program for both covered drugs and home-generated sharps waste in the country. Stewardship programs for covered drugs are primarily required to be secure collection receptacle programs supplemented with mail-back programs. Under the Act, a program operator, which is either a covered entity or a stewardship organization established on behalf of a group of covered entities, must design and operate a statewide stewardship program for the proper collection and disposal of covered products at no cost to consumers. A covered entity can be a manufacturer, distributor, wholesaler, repackager, owner or licensee of a trademark or brand, or importer as defined in Public Resources Code (PRC) section 42030(f)(1), (see Attachment 2). Additional responsibilities of program operators include operating a comprehensive education and outreach program, submitting annual reports and annual budgets to the Department of Resources Recycling and Recovery (CalRecycle), and paying CalRecycle an administrative fee every three months that covers CalRecycle's, and any other state agency's, costs of implementation related to oversight and enforcement.

Because other state agencies have authority over the covered products or the handling, transport, and/or disposal of covered products, those state agencies, including, but not limited to the California State Board of Pharmacy and California Department of Public Health, are responsible for providing program operators compliance determinations with respect to the applicable laws and regulations they oversee prior to a program operator's submittal of its stewardship plan to CalRecycle. Additionally, annually on or before January 15, a covered entity, or a stewardship organization on behalf of a group of covered entities, must submit updated covered product lists to the California State Board of Pharmacy. For covered entities to be in compliance, a covered product sold or offered for sale in or into California must be subject to an approved stewardship plan within one year of the date of adoption of the implementing regulations (i.e., January 7, 2022). The covered entity can operate a stewardship program individually or be part of a stewardship organization with an approved stewardship plan. A program operator must fully implement the program described in that plan within 270 days of CalRecycle approval of its stewardship plan.

CalRecycle adopted regulations to approve, conditionally approve, or disapprove covered drugs and sharps stewardship plans, annual reports, and annual budgets, and provide oversight and enforcement of the Act. CalRecycle is also required to post a list of stewardship organizations and other entities that are in compliance with the Act and to coordinate with the California State Board of Pharmacy to obtain verified lists of covered products. Enforcement for non-compliance is addressed through administrative civil penalties, through revocation of an approved plan, and/or through other methods outlined in the implementing regulations.

PRC section 42032 requires that within six months of the adoption date of implementing regulations, a program operator shall submit to CalRecycle for approval a complete stewardship plan that meets the applicable requirements of PRC section 42030 *et seq.* and Title 14 of the California Code of Regulations (CCR) section 18972.1 *et seq.* (see Attachment 3), for the establishment and implementation of a stewardship program. CalRecycle's regulations became effective January 7, 2021. Therefore, stewardship plans were due to CalRecycle by July 7, 2021, unless the deadline was tolled by the California State Board of Pharmacy's review. CalRecycle has 90 days to review and approve, disapprove, or conditionally approve plans pursuant to PRC section 42032(d). CalRecycle's 90-day review period may be extended if CalRecycle needs to consult with another state agency.

The Foundation is a stewardship organization that represents nine covered entities under its proposed Plan (see Plan, page 46 for a list of covered entities). The Foundation also operates pharmaceutical stewardship programs in five local jurisdictions in California. Overall, staff found The Foundation's Plan substantially compliant with all material requirements in CCR sections 18973, 18973.2, and 18973.6, but additional information from and additional actions by The Foundation are necessary (see CCR section 18973.1(e)). The components of The Foundation's Plan which are

deficient, and the conditions The Foundation must meet for CalRecycle to approve its Plan, pursuant to CCR section 18973.1(g), are described below.

The Foundation Plan Areas of Identified Deficiencies

1. Collection System

Requirement: Describe a collection system that meets the requirements in PRC section 42032.2(a)(1)(F) for authorized collection sites in each county in which the plan will be implemented. Describe processes used to collect, track, and properly manage covered drugs from collection through final disposal pursuant to CCR section 18973.2(g)(1). Describe how convenience standards will be met for each county, including how reasonable geographic spread is determined, including all factors applied to develop the determination pursuant to PRC section 42032.2(a)(1)(F) and CCR section 18973.2(g)(2). This chapter does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018, pursuant to PRC section 42036.2(a).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet conditions outlined below under the section titled “CalRecycle Condition 1.”

The Foundation proposes to establish a system for collecting covered drugs in each county, except for counties that are excluded pursuant to PRC section 42036.2. Collection will occur through receptacles installed at authorized collection sites and via mail-back services. The Foundation’s Plan states that it will “make good faith efforts to” establish a minimum of five authorized collection sites in each county in which the program is implemented, or one per 50,000 people in the county, whichever is greater. Additionally, the Plan states that “The Foundation expects to be fully operational within 270 days of Plan approval.” Use of phrasing such as “make good faith efforts to” and “expects to be” does not commit The Foundation to achieving the minimum convenience requirements set in statute. If The Foundation does not meet the minimum convenience requirements it will be out of compliance with PRC section 42032.2(a)(1)(F).

The Foundation’s Plan description of how it will determine reasonable geographic spread and the factors that will be used to make the determination is incomplete and inconsistent. The Plan states that it will use Department of Finance’s population data to determine the geographic spread of the population within each county and the population center to determine the number and location of authorized collector sites needed to ensure that all ultimate users are located within 15 miles of an authorized collector site. The Plan utilizes the term “authorized collector site” which is not defined in statute. The Plan should use the terminology defined in statute (e.g., authorized collection site) or include definitions for new terms that are used in the Plan. Additionally, the geographic spread goal is not consistently described in the Plan. For example, on page 15 and page 22, the Plan states “geographic spread and reach for 90 percent of Ultimate Users would be within 15 miles of an Authorized

Collector.” On page 20, the Plan says, “all Ultimate Users are located within 15 miles of an Authorized Collector Site.” The incomplete and inconsistent descriptions contained in the Plan make it unclear as to what the goal is and will adversely impact CalRecycle’s ability to evaluate whether the geographic spread goal has been achieved. Moreover, on page 22, in the last bullet of the Plan implementation timeline, The Foundation proposes to achieve reasonable geographic spread by using both authorized collection sites and mail-back distribution sites. Additionally, the “Convenience Standard” definition references reasonable geographic spread but does not include the requirement in PRC section 42032.2(a)(1)(F)(ii). The Foundation cannot utilize mail-back distribution sites to meet the reasonable geographic spread requirement in PRC section 42032.2(a)(1)(F)(ii). The reasonable geographic spread applies solely to authorized collection sites.

The Foundation’s Plan proposes that kiosks will accept all unwanted covered drugs as defined in PRC section 42030. However, the definition of “covered drug” in PRC section 42030(e) includes “a drug in a medical device, or a combination product containing a drug and a medical device.” The Foundation does not adequately describe whether covered drugs in a combination product, such as a prefilled syringe or auto-injector, will be accepted in the kiosks or if the products must be managed separately. If a combination product must be managed separately, the Plan must describe how that product will be managed.

The Foundation proposes utilizing mail-back distribution locations for any county where an authorized collection site is unavailable in order to meet the convenience standard in PRC section 42032.2(a)(1)(F). Program operators may utilize mail-back distribution locations as a supplemental service pursuant to PRC section 42032.2(c), but mail-back service cannot be used in lieu of authorized collection sites to meet the convenience standard in PRC sections 42032.2(a)(1)(F)(i) and (ii). The Plan is unclear if the mail-back distribution locations are supplemental services or utilized to meet the requirement in PRC section 42032.2(a)(1)(F)(iii). Further, the Plan does not describe which counties do not have an authorized retail pharmacy operating as an authorized collection site, necessitating mail-back service, pursuant to PRC section 42032.2(a)(1)(F)(iii).

The Foundation proposes metrics for the mail-back materials in which the “quantity of Mailers by Site will be measured against the Mailers returned via the Mailer’s unique tracking number and distribution location identifier.” The Plan does not describe that metrics will be collected for each type of mailer (i.e., standard or inhaler) distributed or the mechanism of distribution for each type of mail-back materials distributed to ultimate users, such as requests by website and toll-free telephone number.

The Foundation’s Plan states on page 13 that “counties” that currently operate a local Stewardship Program ordinance are excluded from the program. This is inconsistent with the requirement in PRC section 42036.2(a) as a local jurisdiction may also be a city, city and county, a joint powers authority, or public service district.

CalRecycle Condition 1: Pursuant to CCR section 18973.1(g), The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- 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). (The requirements necessitating this condition appear in PRC section 42032.2(a)(1)(F) and CCR section 18973.2(g)(2)).
- 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. (The requirement necessitating this condition appears in CCR section 18973.2(g)(2)(A)).
- 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). (The requirements necessitating this condition appear in PRC sections 42032.2(a)(1)(F)(i) and (ii) and 42032.2(c), and CCR section 18973.2(g)(2)).
- 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. (The requirements necessitating this condition appear in PRC section 42030(e)(1)(C) and CCR section 18973.2(g)(1)).
- 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. (The requirement necessitating this condition appears in CCR section 18973.2(g)(6)(E)).
- 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. (The requirement necessitating this condition appears in PRC section 42036.2).

2. Program Budget and Funding

Requirements: Demonstrate adequate funding for all costs, including administrative and operational costs, pursuant to PRC section 42032.2(a)(1)(D). Include a description of the types of activities relative to line items outlined in CCR section 18973.6(b) pursuant to PRC section 42032.2(a)(1)(D) and CCR sections 18973.2(f) and 18973.6(e). Describe how costs are apportioned to and funds remitted from participating covered entities pursuant to CCR section 18973.6(d). Funding level must cover the stewardship plan’s budgeted costs to operate the stewardship

program over a multi-year period pursuant to PRC section 42033(b). Provide a recommended reserve amount and justification pursuant to CCR section 18973.6(c).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet the conditions outlined below under the section titled “CalRecycle Condition 2.”

The Plan includes an initial five-year budget that covers anticipated costs to implement the program from 2022 through 2026. The Foundation does not fully demonstrate adequate funding for all administrative costs for the first five calendar years of operation pursuant to CCR section 18973.2(f). The estimates for the departmental administrative fee are not included in The Foundation’s five-year budget despite CalRecycle providing the departmental administrative fee estimate to The Foundation in advance of its Plan submittal. Additionally, the Plan does not describe how costs are apportioned to and funds remitted from participating covered entities. The Foundation’s proposed five-year budget includes a line item for sharps containers, but The Foundation’s Plan does not describe how the sharps containers will be utilized to collect covered drugs.

The Plan does not include narrative descriptions of the types of activities relative to each line item cost category. To comply with the requirement in CCR section 18973.6(e), the budget must contain a narrative description that enables CalRecycle to understand what is contained in each cost category in order to determine if the program funds are managed in a prudent and responsible manner.

The Foundation proposes a reserve level amount of 15 percent of the total estimated budget for the first five years of program expenses. It is unclear how the reserve relates to annual operating expenses, and if the reserve will be recalculated if the initial five-year budget changes or after the fifth year of program expenses. There is no justification as to why 15 percent of the total estimated budget for the first five years of program expenses is an appropriate reserve level amount. Additionally, the Plan does not state that the reserve will be maintained in a prudent and responsible manner pursuant to CCR section 18973.6(c). Finally, the reserve level included in The Foundation’s budget is not (mathematically) 15 percent of the total estimated budget for the first five-years of program expenses.

CalRecycle Condition 2: Pursuant to CCR section 18973.1(g), The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- 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 CCR section 18973.6(b). Include a description of how costs are apportioned to and funds are remitted from participating covered entities (The requirements

necessitating these conditions appear in PRC sections 42032.2(a)(1)(D) and 42033(b), and CCR sections 18973.2(f) and 18973.6(b), (d), and (e)).

- 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. (The requirements necessitating this condition appear in PRC sections 42032.2(a)(1)(D) and 42033(b), and CCR sections 18973.2(f), 18973.6(b) and 18973.6(e)).
- c. Include a justification for the proposed reserve level amount and commit to maintaining the reserve in a prudent and responsible manner. (The requirements necessitating this condition appear in CCR sections 18973.6(c) and 18973.6(e)).
- d. Correct all mathematical discrepancies and ensure an accurate initial five-year program budget is submitted. (The requirements necessitating this condition appear in PRC sections 42032.2(a)(1)(D) and 42033(b) and CCR section 18973(d)).

3. Education and Outreach

Requirements: Describe a comprehensive education and outreach program that includes activities to promote program awareness and maximize ultimate user participation, including, but not limited to, provision of educational and outreach materials. Education and outreach materials include signage for hospitals and pharmacies and be distributed in languages suited to local demographics, pursuant to PRC section 42031.6(a) and CCR section 18973.2(j). Describe signage or labeling for secure collection receptacles that is designed with explanatory graphics which are readily understandable by all ultimate users pursuant to CCR sections 18973.2(j)(1) and (2). Establish a website that is accessible to disabled individuals and a toll-free telephone number that provides services for hearing-impaired and speech-impaired individuals to provide information to promote the stewardship program pursuant to PRC section 42031.6(a)(3) and CCR sections 18973.2(j)(3) and (4). Describe metrics to evaluate performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility pursuant to CCR section 18973.2(j)(5). Encourage ultimate users to separate products that are not covered products from covered products pursuant to PRC section 42031.6(a)(5) and CCR section 18973.2(j)(6).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet the conditions outlined below under the section titled “CalRecycle Condition 3.”

The Plan describes how The Foundation will utilize social media and influencers to create content and inspire program participation among ultimate users. However, this section of the Plan also describes that the tactics are used to ensure the “covered entities receiving the content are the ones most inclined to act.” It is not clear if social media outreach is targeting ultimate users or covered entities, as defined in PRC section 42030(f).

The Plan states that the signage on the drug collection kiosk will include products that are covered and not covered under the Plan, however, this information should not be limited to kiosk signage. The Plan does not demonstrate how aspects of the education and outreach program (e.g., website and printed materials) will encourage users to separate covered products from products that are not covered pursuant to PRC section 42031.6(a)(5) and CCR section 18973.2(j)(6). The Plan suggests that sharps and syringes are the only prohibited products, however, there are other products that are not a covered drug pursuant to PRC section 42030(e)(2).

The Foundation's 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.

The Foundation proposes to translate materials "into any non-English language spoken by a substantial number of the public served by the agency, pursuant to section 7295 of the Government code." Although The Foundation proposes that kiosk signage will include the top languages spoken in each county based on census data, the Plan does not provide a description of how local demographics will be analyzed to determine what languages are spoken by a substantial number of the public and, therefore, are the languages that other education and outreach materials will be translated into. The Plan states that educational materials will be developed for pharmacists and health care practitioners but does not specify that these materials will include signage for hospitals and pharmacies.

The Foundation proposes to establish a website that will be "mobile-optimized" and will publicize collection options and educate all affected parties. However, the Plan does not describe if the website will meet the requirement for digital content and navigability that is accessible to disabled individuals and maintained to ensure all information is up to date and accurate, as required. The Foundation proposes a toll-free call center that interested parties can call to learn more about the stewardship program and drugs disposal best practices. Although the description mentions that "the call center is operated with live operators and will be staffed with a third-party service to assist with live translation in the required languages," the description does not state how services to hearing-impaired and speech-impaired individuals will be accommodated. The Foundation proposes to offer live translation services for the toll-free telephone number in the "required languages." However, it is unclear if live translation will be offered for the same 12 languages that the website will be translated into or a different suite of languages and how the caller would find out they can access telephone support in another language. Furthermore, the Plan does not specify that the toll-free call center will accommodate requests for mail-back materials from ultimate users who are homebound, homeless, or disabled.

The Plan describes a biennial survey of ultimate users, pharmacists, and healthcare professionals to measure public awareness of the program. The Foundation proposes to design survey questions that will "evaluate the effectiveness of different

messaging for raising awareness of the Program and for increasing knowledge of or changing attitudes towards risks posed by improper storage or disposal of Covered Drugs.” However, the Plan does not include clear metrics that will be used to evaluate the performance of the education and outreach program or demonstrate how a biennial survey will generate metrics and numerical results that can be reported annually. Additionally, The Foundation proposes to submit survey responses related to the biennial education and outreach program survey for CalRecycle’s review. Although CalRecycle encourages consistent communication from program operators on program activities, The Foundation’s Plan shall not be contingent on CalRecycle reviewing and approving the biennial survey or its results. Program components, including how The Foundation will conduct its comprehensive education and outreach program, must be included in the Plan, and results from the evaluation of the performance of the comprehensive education and outreach program from the previous reporting year must be included in the annual report, as opposed to a separate submission to CalRecycle.

CalRecycle Condition 3: Pursuant to CCR section 18973.1(g), The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- 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. (The requirements necessitating these conditions appear in PRC sections 42031.6(a)(1), 42031.6(a)(2), and CCR sections 18973.2(j)(1) and (2)).
- b. Explain the methodology The Foundation proposes to use to determine which languages are suited to various local demographics. (The requirement necessitating this condition appear in CCR section 18973.2(j)(2)).
- c. Describe how the website’s digital content and navigability will be accessible to disabled individuals. (The requirement necessitating this condition appears in CCR section 18973.2(j)(3)).
- 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. (The requirement necessitating these conditions appears in CCR section 18973.2(j)(4)).
- 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. (The requirement necessitating these conditions appears in CCR section 18973.2(j)(5)).

- f. Describe how The Foundation's comprehensive education and outreach program will encourage users to separate covered products from products that are not covered. (The requirements necessitating this condition appear in PRC section 42031.6(a)(5) and CCR section 18973.2(j)(6)).

4. Authorized Collectors

Requirements: Provide a description of the process to incorporate potential authorized collectors that submit a written offer to join the stewardship program pursuant to PRC sections 42032.2(a)(1)(B) and 42032.2(b)(3) and CCR section 18973.2(d)(5). As applicable, provide a description of the reasons for excluding potential authorized collectors, including those who request joining the program, pursuant to CCR section 18973.2(d)(6).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet the conditions outlined below under the section titled "CalRecycle Condition 4."

Program operators are required to incorporate potential authorized collectors, who offer to participate in the stewardship program without compensation, within 90 days of receiving the written offer to participate. The Foundation proposes a process to add authorized collectors to the program that is consistent with this requirement. However, the proposed process includes a timeline that appears to be inconsistent with this requirement. For example, page 15 describes activities to bring an authorized collector into the program within 90 days of receiving the written offer according to a timeline that extends up to 270 days from receipt of a written offer.

The Foundation states that its policy is not to exclude any potential authorized collector from participating in the program. However, the Plan states that a potential authorized collector would be excluded if the potential authorized collector refuses to sign a contract agreement and/or comply with the DEA and/or BOP rules. PRC section 42032.2(b)(3) requires inclusion of any potential authorized collectors that offer to participate in writing and without compensation. Potential authorized collectors that request in writing and without compensation to join the stewardship program and negotiate in good faith with The Foundation regarding the terms of agreement must not be excluded.

CalRecycle Condition 4: Pursuant to CCR section 18973.1(g) The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- 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. (The requirements necessitating this condition appear in PRC section 42032.2(b)(3) and CCR section 18973.2(d)(5)).

- 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. (The requirements necessitating this condition appear in PRC section 42032.2(b)(3) and CCR section 18973.2(d)(5)).

5. Ordinance Repeals

Requirements: Describe processes, logistics, and timing of implementation that will be utilized to expand the stewardship program into jurisdictions that repeal their local stewardship program ordinance, including how the stewardship program will meet the convenience standards pursuant to PRC section 42032.2(e) and CCR section 18973.2(i).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet the condition outlined below under the section titled "CalRecycle Condition 5."

The Plan states that in the event of local stewardship program ordinance repeal, "The Foundation would work with the jurisdiction to include them in the statewide program, set up Kiosk sites in accordance with the Convenience Standard laid out in the Plan," and transition existing kiosks within 90 days of the repeal of the ordinance. The Plan does not describe the processes, logistics, and timing of all implementation activities that will be necessary to expand the program into a jurisdiction that repeals its local stewardship ordinance. For example, the Plan does not describe how the education and outreach program will be expanded into a jurisdiction that repeals its ordinance. In addition to transitioning existing kiosks, new kiosk sites may be necessary to ensure the convenience standard is met. The processes, logistics, and timing for these new kiosks sites is not described.

CalRecycle Condition 5: Pursuant to CCR section 18973.1(g), The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- 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. (The requirements necessitating this condition appear in PRC section 42032.2(e) and CCR section 18973.2(i)).

6. Coordination Efforts

Requirement: Describe coordination efforts with other program operators to avoid confusion to the public and all program participants pursuant to CCR section 18973.2(k).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet the condition outlined below under the section titled “CalRecycle Condition 6.”

The Foundation proposes coordination efforts with approved program operators that includes fair funding of a common stewardship program website, toll-free telephone number, and program logo to prevent ultimate user confusion. However, The Foundation’s proposal states that the website name and program logo will be approved by CalRecycle, which places coordination responsibilities on CalRecycle in order for The Foundation to meet this requirement. The Plan uses language such as “The Operators will...” to describe coordination efforts. The Foundation cannot compel other Program Operators to conduct activities in its Plan and goes beyond describing how The Foundation intends to coordinate. The Foundation must work with other program operators to mutually agree to specific coordination efforts.

Additionally, the Plan states that The Foundation will coordinate with other program operators to ensure that “ultimate users” do not encounter confusion. However, the Plan needs to describe coordination to avoid confusion to all program participants such as pharmacists, pharmacies, and others, not just ultimate users.

CalRecycle Condition 6: Pursuant to CCR section 18973.1(g), The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- 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. (The requirement necessitating this condition appears in CCR section 18973.2(k)).

7. Document Submittals

Requirement: A stewardship plan shall be complete and correct pursuant to CCR section 18973(d).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet the condition outlined below under the section titled “CalRecycle Condition 7.”

Throughout the Plan, The Foundation utilizes terminology inconsistently and introduces new terms without a definition and/or context. The Plan includes terms such as “traditional media outlet,” “influencer,” “Program oversight and operation teams,” and “Program” without providing a definition. Defined terms such as “Kiosk Collection Kit” (KCK), and “Authorized Collection Site,” are not utilized consistently. For example, page 19 includes the term “Authorized Collector Site” to refer to an “Authorized Collection Site” and the Plan uses two acronyms for the term “Kiosk Collection Kit.” The definition on page 9 uses “KCK” as the acronym, but pages 20 and 21 use “KSK” to refer to the Kiosk Collection Kits. The Plan uses the word “residents” and “covered entities” to presumably describe an ultimate user (see e.g.,

pages 27 and 28). There are multiple inconsistencies in the Definitions Section, (Section II). For example, the definition of “Distributor” is inconsistent with the statutory definition. The foregoing lists examples and is not an exhaustive list of all inconsistent terminology in the Plan.

The Foundation utilizes the same definition for “Authorized Collection Site” and “Authorized Collector” as PRC section 42030 which can include persons or entities other than pharmacies. Page 13 of the Plan describes methods to identify potential authorized collectors that include pharmacies, hospitals/clinics with onsite pharmacies and qualified law enforcement agencies. However, the Plan describes certain activities that will be conducted by only “authorized pharmacy employees.” For example, on page 18 the Plan describes documentation and tracking activities that will be conducted by “authorized pharmacy employees.” The Plan needs to clearly describe activities that will be conducted at all potential authorized collection sites, not just pharmacies.

Further, the Plan contains formatting and grammatical errors such as duplicate use of Roman numeral XIV in the table of contents that must be corrected.

The Foundation describes a process for auditing its service providers on page 38. The Plan states that “copies of the audit will be provided to the Department within 30 days of their completion in accordance with 18974.2.” The latter section of CCR section 18974.2 applies to audits of covered entities and authorized collectors, not service providers to a stewardship organization. The reference to CCR section 18974.2 is incorrect.

The Foundation, as the entity submitting this Plan, is considered the program operator pursuant to PRC section 42030(q), and states that it is responsible for the services described in the Plan (page 6). However, throughout the Plan, The Foundation and Inmar Rx Solutions (Inmar) are identified as being responsible for fulfilling certain program operator requirements. The Plan provides contradictory information regarding the entity that will implement certain requirements. For example, on pages 6-7 the Plan states that The Foundation has contracted with Inmar to provide education and outreach services, but page 30 of the Plan states that The Foundation will operate a toll-free call center. If Inmar is a service provider for The Foundation, its roles in implementing the applicable laws must be clearly stated in the Plan, without any contradictions, and its mailing and physical address(es) must be included in the Plan pursuant to CCR section 18973.2(g)(5). Moreover, as stated in the Plan, Inmar shall operate as a service provider, although it is not clear in all aspects of the Plan if Inmar and The Foundation are separate entities, as these terms appear to be used interchangeably.

CalRecycle Condition 7: Pursuant to CCR section 18973.1(g), The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- a. The Plan must clearly describe activities that will be conducted at all potential authorized collection sites, not just pharmacies. (The requirements necessitating this condition appear in PRC sections 42032.2(a)(1)(G)(iii)(II) and 42032.2(a)(1)(H), and CCR section 18973.2(g)(1)).
- b. Use terminology defined in PRC and CCR or define and consistently utilize terminology within the Plan. Correct formatting and grammatical errors contained in the Plan. (The requirement necessitating these conditions appears in CCR section 18973(d)).
- c. Ensure that statutory and regulatory citations in the Plan are correct. (The requirement necessitating this condition appears in CCR section 18973(d)).
- 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. (The requirements necessitating these conditions appear in PRC section 42030(q) and CCR section 18973(d)).

8. Covered Drugs List

Requirements: Include a list of covered drugs sold or offered for sale by each participating covered entity covered by the stewardship plan pursuant to PRC sections 42031(a)(1), 42032.2(a)(1)(A) and CCR section 18973.2(c).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet the condition outlined below under the section titled "CalRecycle Condition 8."

The Plan includes a list of covered products from nine covered entities. However, the list of covered products included in the Plan differs from the list of covered products submitted to Board of Pharmacy pursuant to PRC section 42031(a)(1). The Plan does not provide an explanation for the difference between the list contained in the Plan and the list submitted to the Board of Pharmacy.

CalRecycle Condition 8: Pursuant to CCR section 18973.1(g), The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- 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. (The requirement necessitating these conditions appears in CCR section 18973.2(c)).

9. Accessibility

Requirements: The document is required to comply with section 7405 of the Government Code, and the Web Content Accessibility Guidelines 2.0 published in

2008 by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level AA success criteria, pursuant to CCR section 18973(a).

Result: Additional information from and additional actions by The Foundation are necessary. The Foundation must meet the condition outlined below under the section titled “CalRecycle Condition 9.”

The Plan contains numerous accessibility errors, most of which are errors related to the tables included in the appendices of the Plan.

CalRecycle Condition 9: Pursuant to CCR section 18973.1(g), The Foundation must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

- 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. (The requirement necessitating this condition appears in CCR section 18973(a)).

Stakeholder Feedback

CalRecycle solicited public input on The Foundation’s Plan from November 22, 2021, through December 8, 2021, and received two stakeholder comment letters. CalRecycle considered both letters when reviewing The Foundation’s Plan for compliance. The Pharmaceutical Product Stewardship Work Group and MED-Project USA submitted letters that expressed concerns regarding The Foundation’s Plan. The concerns expressed in the stakeholder letters generally align with CalRecycle’s findings regarding insufficient detail about how The Foundation’s Plan will comply with specific program requirements and the lack of budget clarity.

California Environmental Quality Act

Staff recommend that CalRecycle file a Notice of Exemption for the Plan with the State Clearinghouse as provided under the California Environmental Quality Act.

Summary of Staff Analysis

CalRecycle staff reviewed The Foundation’s Plan to determine whether all statutory and regulatory requirements were met and found the Plan to be substantially compliant. Several components of The Foundation’s Plan require additional information from and additional actions by The Foundation for CalRecycle to determine if the Plan is compliant.

Options

1. Conditionally approve The Foundation’s Plan, contingent upon The Foundation providing the following to CalRecycle:
 - a. A letter, within 30 days of signature on this Request for Approval, committing to revise and resubmit its Plan, to meet the conditions specified in the Staff Analysis section of this Request for Approval.

- b. A revised plan, within 90 days of signature on this Request for Approval, that includes the additional information to meet the conditions specified in the Staff Analysis section of this Request for Approval. The revised plan shall incorporate the information provided in the addendum, submitted December 16, 2021.
2. Disapprove The Foundation's Plan. The Foundation shall resubmit its revised plan within 60 days of signature on this Request for Approval and CalRecycle will review the revised Plan within 90 days of resubmittal.

Action

Based on The Foundation's Plan and analysis within this Request for Approval, I hereby conditionally approve The Foundation's Plan, contingent upon The Foundation (1) providing a letter, within 30 days of signature on this Request for Approval, committing to revise and resubmit its Plan to meet the conditions specified in the Staff Analysis section of this Request for Approval, and (2) revising and resubmitting its Plan within 90 days as described in the Recommendation and Staff Analysis sections above. Failure to comply with all the conditions and resubmit within 90 days may result in disapproval of The Foundation's Plan. This Request for Approval shall serve as the written notice of the conditions that CalRecycle must identify pursuant to the first sentence in CCR section 18973.1(g). CalRecycle's conditional approval constitutes an approval for purposes of PRC section 42032(g). The Foundation must fully implement the Plan, revised to comply with the conditions outlined in the Staff Analysis, within 270 days from signature of this Request for Approval, titled, *Consideration of The Drug Take Back Solutions Foundation's Product Stewardship Plan for Covered Drugs*. Additionally, I hereby direct staff to file a Notice of Exemption with the State Clearinghouse for the Plan as provided under the California Environmental Quality Act.

Dated: February 16, 2022

Signed by: Rachel Machi Wagoner, Director

Attachments:

Documents listed below are posted to CalRecycle's website. CalRecycle is unable to post documents that are non-ADA accessible and therefore is not able to post The Foundation's Plan. To request documents that are referenced in this Request for Approval but are not listed below, please submit a Public Records Act request (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

-
1. [Addendum to Stewardship Plan for Covered Drugs: October 21, 2021: Version 2 \(November 15, 2021\) \(submitted December 16, 2021\)](https://www2.calrecycle.ca.gov/Docs/Web/120192)
<https://www2.calrecycle.ca.gov/Docs/Web/120192>

2. [Pharmaceutical and Sharps Waste Stewardship Act](https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PRC&division=30.&title=&part=3.&chapter=2.&article=) (Public Resources Code sections 42030 *et seq*)
https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PRC&division=30.&title=&part=3.&chapter=2.&article=
3. [Pharmaceutical and Sharps Waste Stewardship Program Regulations](https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I3A11525A8CDD4A6E87920BBB389851C4&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1) (California Code of Regulations sections 18972.1 *et seq*)
[https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I3A11525A8CDD4A6E87920BBB389851C4&originationContext=documenttoc&transitionType=Default&contextData=\(sc.Default\)&bhcp=1](https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I3A11525A8CDD4A6E87920BBB389851C4&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1)