

## REQUEST FOR APPROVAL

**To:** Rachel Machi Wagoner  
Director

**From:** Zoe Heller  
Deputy Director, Policy Development

**Request Date:** February 9, 2022

**Decision Subject:** Consideration of The Drug Takeback Solutions Foundation's  
Product Stewardship Plan for Home-Generated Sharps Waste

**Action By:** February 17, 2022

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### **Summary of Request**

The Drug Takeback Solutions Foundation (The Foundation) submitted its stewardship plan for home-generated sharps waste, which includes its initial program budget, titled, *Stewardship Plan for Home-Generated Sharps Waste: September 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 Sharps Waste: September 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 home-generated sharps waste are primarily mail-back programs where ultimate users are provided sharps waste containers and mail-back materials at the point of sale. 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 (CDPH), 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. 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, 18973.3, 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. Mail-back Program**

**Requirements:** A mail-back program that provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale pursuant to PRC section 42032.2(d)(1)(F)(i) and CCR section 18973.3(f)(2). Pursuant to CCR section 18972.1(a)(10), “provides or initiates distribution of a sharps waste container and mail-back materials” means one of the following: (A) To provide a sharps waste container and mail-back materials to the ultimate user, at the point of sale or prior, at no cost to the ultimate user; or, (B) To arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within five business days at no cost or inconvenience to the ultimate user; or, (C) Other methods of providing a sharps waste container and mail-back materials to the ultimate user at the point of sale or prior, at no cost to the ultimate user, if the method identified in subpart (A) above is not allowed by law and if the method identified in subpart (B) above is not allowed by law. Supplemental collection method(s) may be provided, in addition to, but not in lieu of, the mail-back program pursuant to CCR section 18973.3(f)(5). Distribute containers and mail-back materials in amounts sufficient to accommodate the volume of sharps purchased by the ultimate user over a selected time period pursuant to PRC section 42032.2(d)(1)(F)(i) and CCR section 18973.3(f)(2)(A). Provide ultimate users with necessary information on proper sharps waste disposal pursuant to PRC section 42032.2(d)(1)(F)(i)(I) and CCR section 18973.3(f)(2)(B).

**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 1.”

The Foundation Plan utilizes terminology inconsistently when describing mail-back materials and how the program proposes to provide or initiate distribution of sharps waste containers and mail-back materials at the point of sale. First, on page 10, the Plan states that as part of The Foundation’s efforts to inform “all Sharps Point of Sale entities” of the program requirements, it will conduct outreach to “Point of Sale entities that are not currently included in the Plan.” However, the Plan does not define “Point of Sale entities” or state which point of sale entities are “currently included in the Plan,” explain what it means to be “included in the Plan,” or how inclusion may occur. Next, on page 11 of the Plan, The Foundation proposes to initiate shipments of “sharps mail-back products” to each “Sharps Waste Container Distribution Location,” which is a term that is defined in the Plan as a location at which ultimate users can pick up a sharps waste container and mailer to use for the collection of home-generated sharps. In this context, it is unclear if “all Sharps Point of Sale entities” will be “Sharps Waste Container Distribution Locations,” or if only locations that are “included in the Plan” will provide or initiate distribution of sharps waste containers and mail-back materials at the point of sale. The Plan does not clearly indicate how The Foundation will provide or initiate the distribution of sharps waste containers and mail-back materials at the point of sale or prior, or at which locations this will occur. Additionally, although the Plan mentions outreach to online

“Point of Sale Entities,” it does not demonstrate how it will provide or initiate distribution of a sharps waste container and mail-back materials to an ultimate user who purchases covered products covered under the Plan from an online retailer.

On page 12 of the Plan, The Foundation proposes that every ultimate user will have access to a sharps waste container and “Mailer” at the point of sale *or* (emphasis added) will be able to request to have those materials shipped to them at no cost. Ultimate users will also receive information on how to request additional materials online or via the toll-free telephone number. CCR section 18972.1(a)(10)(C) states that other methods of providing containers and mail-back materials are only allowed if both providing at the point of sale and arranging for arrival within five business days of the point of sale are illegal. The Plan does not demonstrate how providing and arranging for arrival of containers and mail-back materials are illegal and therefore permissible to use other methods of providing containers and mail-back materials, such as requiring the ultimate user to request them. The Foundation’s Plan does not demonstrate how the program operator will arrange for a sharps waste container and mail-back materials to be sent to the ultimate user if it is not provided at the point of sale, and instead places the responsibility on the ultimate user to request materials, which conflicts with the requirement. Additionally, The Foundation proposes to inform medical providers and pharmacists on how to request sharps waste containers and mail-back materials for ultimate users who cannot request them. It is the program operator’s responsibility to provide or initiate distribution of sharps waste containers and mail-back materials at all points of sale, not to simply provide others an option to request the materials. The Plan does not guarantee that medical providers or pharmacists will request sharps waste containers and mail-back materials on behalf of ultimate users. The Plan does not state that ultimate users who do not receive a sharps waste container and mail back materials at the point of sale will be sent and receive the materials within five business days of the sale.

The Foundation proposes that Inmar will use statewide prescription data to provide sharps waste containers and mailers to pharmacies at a rate consistent with the number of sharps prescriptions filled at each pharmacy. The Foundation also plans to allow ultimate users to request up to three sharps mail-back units at a time through the program’s website and phone number. Although the Plan describes how it will distribute sharps waste containers and mail-back materials to pharmacies in amounts sufficient to accommodate the volume of sharps prescriptions filled at each pharmacy, it does not describe how these materials will be provided to ultimate users at the point of sale in amounts sufficient to accommodate the volume of sharps purchased by the ultimate user over a selected time period.

The Plan states that the insert included with a sharps waste container will read “Accepted: Pre-loaded products containing a Sharp (i.e., hypodermic needle, syringe, or lancet) and auto-injectors.” The term “pre-loaded products” is not defined and is unclear if this refers to sharps that come with a medicine already contained within the sharps product (i.e., a combination product). Additionally, “sharps” is

included in the list of items not accepted in the container, therefore the scope of covered products that will be managed under the proposed program is unclear. This will lead to confusion for the ultimate user regarding how to properly dispose of sharps waste. Additionally, the last sentence included on the insert references “Injector Mail-Back Packages” which is not defined or used elsewhere in the Plan.

The Plan notes that The Foundation will work with the California Department of Social Services (CDSS) and Continuum of Care (CoC) to identify locations that can distribute sharps waste containers to homeless populations. However, The Foundation does not commit to providing or initiating distribution for homeless individuals regardless of CDSS's and/or CoC's involvement, such as how individuals without an address may request to have a sharps waste container and mail-back materials sent to them.

As part of its proposal to address local agency requests, the Plan states that Inmar will provide sharps waste containers, ten at a time, to solid waste/recycling centers, transfers stations, and landfills across the state. The purpose of providing sharps waste containers to these locations is not clear. However, if The Foundation is proposing to distribute sharps waste containers to ultimate users at these locations, this activity cannot be in lieu of the mail-back program pursuant to PRC section 42032.2(d)(1)(F) and CCR section 18973.3(f)(5). Additionally, the Plan, in multiple places, omits the requirement that mail-back materials must be provided with sharps-waste containers (for example, Plan pages 14, 19, and 20).

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. Clarify and demonstrate how the Plan complies with the requirement to (1) provide sharps waste containers and mail-back materials at all points of sale where any covered products covered under the Plan are sold, and/or (2) arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive to the ultimate user within five business days of the point of sale. Ensure that the revised plan states that mail-back materials will be provided with sharps waste containers. (The requirements necessitating these conditions appear in PRC section 42032.2(d)(1)(F)(i) and CCR sections 18972.1(a)(10) and 18973.3(f)(2)).
- b. Provide circumstances and justification whereby providing and arranging for arrival, pursuant to CCR sections 18972.1(a)(10)(A) and (B), are illegal. Alternatively, remove the option under CCR section 18972.1(a)(10)(C), described in the Plan, which requires the ultimate user to request sharps waste containers and mail-back materials. (The requirements necessitating this condition appear in PRC section 42032.2(d)(1)(F)(i) and CCR sections 18973.3(f)(2) and 18972.1(a)(10)).
- c. Explain how sharps waste containers and mail-back materials will be distributed to ultimate users in amounts sufficient to accommodate the volume of sharps purchased over a selected time period. (The requirements

necessitating this condition appear in PRC section 42032(d)(1)(F)(i) and CCR section 18973.3(f)(2)(A)).

- d. Ensure that all inserts and instructions provided with the sharps waste containers are consistent with the scope of covered products that will be managed under this program. Explain how “Injector Mail-Back Packages” may be utilized as part of the program. (The requirements necessitating these conditions appear in PRC sections 42030(e), 42030(g), 42030(l), 42030(u), and 42032(d)(1)(F)(i)(I) and CCR section 18973.3(f)(2)(B)).
- e. Explain how all ultimate users, including homeless individuals without a permanent address, can receive sharps waste containers and mail-back materials through all approved options, including the option whereby ultimate users are instructed to order sharps waste containers and mail-back materials through The Foundation’s website or toll-free telephone number. (The requirements necessitating this condition appear in PRC section 42032.2(d)(1)(F)(i) and CCR sections 18972.1(a)(10) and 18973.3(f)(2)).
- f. Ensure that the stewardship program established by this Plan will be a mail-back program and that any supplemental collection methods are provided in addition to, but not in lieu of, the mail-back program. (The requirements necessitating this condition appear in PRC section 42032.2(d)(1)(F) and CCR section 18973.3(f)(5)).

## **2. Program Budget and Funding**

**Requirements:** Demonstrate adequate funding for all costs including administrative and operational costs, pursuant to PRC section 42032.2(d)(1)(C). 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(d)(1)(C) and CCR sections 18973.3(e) 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 program budget that covers anticipated costs to implement the program from 2022 through 2026. The budget details capital expenses and education and outreach costs. However, the budget only includes a limited description of activities related to operational costs and does not describe the types of activities related to administrative costs. 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 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 participating covered entities.

The initial five-year budget for the education and outreach program contains mathematical errors that make it unclear what is being proposed. For example, the “Year 1 Total Education and Outreach Costs” included in the budget is \$405,000. However, the “Year 1” amounts for each line item listed under “Education and Outreach” sum to \$115,000, not \$405,000. There are similar costs discrepancies in the education and outreach category for each year of the five year budget.

The Foundation proposes a reserve level amount of 15 percent of the total estimated budget for the first five years of program expenses, which is \$3,179,321, per the initial program budget provided in the Plan. 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).

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(d)(1)(C) and 42033(b), and CCR sections 18973.3(e) and 18973.6(b), (d), and (e)).
- b. 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(d)(1)(C) and 42033(b)).
- 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 (e)).

### **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 must include signage for hospitals and pharmacies and be distributed in languages suited to local demographics, pursuant

to PRC section 42031.6 and CCR sections 18973.3(i)(1) and (2). 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 18973.3(i)(6). 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 42032.2(d)(1)(E) and CCR sections 18973.3(i)(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 18973.3(i)(5).

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 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.” However, The Foundation 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 materials will be translated into. Additionally, 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. Although the Plan describes that the insert provided with the sharps container will include what is and is not accepted in the sharps waste container, 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.

The Foundation proposes to establish a website that will be “mobile-optimized” and use “enhanced search engine optimization to ensure easy location and access.” However, the Plan lacks specificity on whether the website’s digital content and navigability will be accessible to disabled individuals and maintained to ensure all information is up to date and accurate, as required. 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. The Plan does not state that the toll-free telephone number will include services for hearing- and speech-impaired individuals.

The Plan, on page 19, does not provide an accurate description that meets the requirement in CCR section 18973.3(i)(3)(B). The Plan states that the website will “clearly indicate what substances are and are not accepted.” Sharps are not substances, even though they may contain substances.

The Plan describes a biennial survey of “Covered Entities, pharmacists, and healthcare professionals.” The Foundation proposes this survey will assess public awareness by measuring the percentage of covered entities, pharmacists, and healthcare professionals that are aware of the program and how these groups assess the accessibility of the program. Program accessibility might entail ensuring the toll-free call center provides services for hearing-impaired and speech-impaired individuals and ensuring the internet website’s digital content and navigability is accessible to disabled individuals. It is not clear how surveying covered entities will evaluate the performance of the outreach and education program related to making ultimate users aware of the program, program usage, and program accessibility pursuant to CCR section 18973.3(i)(5). Although The Foundation proposes to design survey questions that will “evaluate the effectiveness of different messaging,” 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 a project plan 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 section 42031.6(a)(1) and CCR sections 18973.3(i)(1) and (2)).
- b. Explain the methodology The Foundation proposes to use to determine which languages are suited to various local demographics. Describe how The Foundation’s comprehensive education and outreach program will promote participation in the stewardship program, encourage users to separate covered products from products that are not covered, and distribute materials

- in languages suited to local demographics. (The requirements necessitating these conditions appear in PRC 42031.6(a)(5) and CCR section 18973.3(i)(2) and 18973.3(i)(6)).
- c. Describe how the website's digital content and navigability will be accessible to disabled individuals. Provide an accurate description of how the website will provide instructions for safe handling and proper disposal of home-generated sharps waste, not "substances." (The requirement necessitating this condition appears in CCR section 18973.3(i)(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. (The requirements necessitating these conditions appear in PRC section 42032.2(d)(1)(E) and CCR section 18973.3(i)(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 18973.3(i)(5)).

#### **4. 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 pursuant to PRC section 42032.2(e) and CCR section 18973.3(h).

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 4."

The Plan states that if a local stewardship program ordinance is repealed, The Foundation will work with the jurisdiction to include them in the statewide program within 90 days of the date of the ordinance repeal. Although timing is included, the Plan does not describe the processes or logistics of implementation that will be necessary for the stewardship program to expand into jurisdictions that repeal their ordinance. For example, the Plan does not describe how the education and outreach program will be expanded into a jurisdiction that repeals its ordinance.

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 condition:

- a. Describe the processes and logistics of implementation that will be utilized to expand the stewardship program into jurisdictions that repeal their local stewardship program ordinance. (The requirements necessitating this condition appear in PRC section 42032.2(e) and CCR section 18973.3(h)).

## 5. Coordination Efforts

Requirement: Describe coordination efforts with other program operators to avoid confusion to the public and all program participants pursuant to CCR section 18973.3(j).

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 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 Program 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 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. 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 18973.3(j)).

## 6. 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 conditions outlined below under the section titled “CalRecycle Condition 6.”

As described in the Mail-back Program section of this Request for Approval (see heading “1”), The Foundation’s Plan utilizes terminology such as “Point of Sale entities ... not currently included in the Plan,” “Sharps Point of Sale entities,” and “Sharps Waste Container Distribution Location,” and it is unclear whether these terms are synonymous or if each term has a different meaning. The Plan does not consistently utilize terminology such as “sharps mail-back products,” “Mailer,” and “Mail-back Unit.” The definition of the term “Mail-back Unit” includes an undefined term - “Covered Home-Generated Sharps Waste.” The Plan generally defines “Stewardship Plan” or “Plan” as any stewardship plan. However, the word “Plan” is used throughout to refer specifically to The Foundation’s Plan. The Plan’s definition of “Sharps Waste Container” includes reference to “21 CFR Section 1317,” which lists requirements for collection of controlled substances, including collection receptacles. This makes it unclear if the “secure repositories” referenced in the definition are FDA approved sharps disposal containers or a larger sharps collection receptacle (i.e., a sharps consolidation point). The “Sharps Waste Container” definition also says “insert section,” suggesting there may be missing information.

The Foundation uses the term “Ultimate User” as defined in PRC section 42030(z) but later introduces an undefined term, “State Ultimate User,” when discussing requests for “Sharps Mail-back Units” via telephone and website. The terms, “patient” and “shopper” are also used on page 17, possibly to refer to an ultimate user. The term “covered entity,” as defined in PRC section 42030(f), is used throughout the Plan. However, when describing the education and outreach program, The Foundation proposes to ensure “California Covered Entities” understand where and how to return home-generated sharps waste. It is unclear if “California Covered Entities” has the same meaning as “covered entity.” The education and outreach section of the Plan uses phrases and terminology such as “traditional media,” “behaviorally targeted display,” and “social influencer marketing programs” that are not defined or explained.

The Foundation’s Plan also includes incorrect regulatory citations. For example, the regulatory citations for “Coordination Efforts” (page 20) and “Plan Compliance” (page 23) are incorrect. The definition of the term “the Regulation” (page 6) includes an incorrect citation to the applicable regulatory article (Division 8 instead of 7). The Foundation describes a process for auditing its service providers on pages 23-24. The Plan states that “the audit will be conducted pursuant to section 42034.4 of the [PRC].” Section 42034.4 of PRC applies to audits of covered entities or authorized collectors (for covered drugs), not service providers to a stewardship organization.

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 4). However, throughout the Plan, either The Foundation or 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 (e.g., page 4 states that The Foundation has contracted with Inmar to provide education and

outreach services, but page 19 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 18973.3(f)(4). Moreover, as stated in the Plan, Inmar shall operate as a service provider for The Foundation, 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 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 conditions:

- a. Use terminology defined in PRC and CCR or define and consistently utilize terminology within the Plan. (The requirement necessitating this condition appears in CCR section 18973(d)).
- b. Ensure that statutory and regulatory citations in the Plan are correct. (The requirement necessitating this condition appears in CCR section 18973(d)).
- c. 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)).

## **7. Records**

Requirement: A program operator shall keep records that clearly reflect the activities of the stewardship program pursuant to PRC section 42033.4(a) and CCR section 18974. Describe how and where the records generated during the collection, transportation, and disposal of home-generated sharps waste will be maintained, including all required records, pursuant to CCR section 18973.3(f)(3).

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 7."

The Foundation proposes that it will utilize a document repository to manage records. The Plan states that the Inmar team will manage record keeping, but that "The Foundation will maintain records for collection services, process reviews, and audits and inspections of Service Providers." It is not clear if Inmar or The Foundation will be maintaining records. The Foundation also proposes that "records will include items related to incident reporting, waste files, weights, serial numbers, etc." It is unclear if mailer distributions, receipts of returned home-generated sharps waste return mailings, and final disposal of home-generated sharps waste records will be maintained pursuant to CCR section 18973.3(f)(3).

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 conditions:

- a. Clarify who is responsible for maintaining records. Ensure that records pertaining to mailer distributions, receipts of returned home-generated sharps waste return mailings, and final disposal of home-generated sharps waste will be maintained. (The requirement necessitating these conditions appears in CCR section 18973.3(f)(3)).

## **8. Covered Entities**

Requirements: Include contact information for each covered entity participating in the stewardship plan pursuant to CCR section 18973.3(b). Include a list of sharps sold or offered for sale by each participating covered entity covered by the stewardship plan pursuant to CCR section 18973.3(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 8.”

The Plan includes a list and contact information for nine participating covered entities. However, the list of sharps sold or offered for sale by covered entities participating in the Plan only lists sharps sold by three of the nine covered entities. There is no explanation of why there is not a list of sharps sold or offered for sale for some of the covered entities participating in the Plan.

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 conditions:

- a. Provide the list of sharps sold or offered for sale by each covered entity participating in the plan. Explain any instances when the Plan does not include a list of sharps sold or offered for sale by a covered entity participating in the Plan. (The requirements necessitating these conditions appear in CCR section 18973.3(b) through (c)).

## **9. Accessibility**

Requirement: 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 over 100 accessibility errors. Most of the errors result from the PDF document not being 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 November 16, 2021 letter from CDPH and the table headers in Appendices A, B, C, and D.

**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 four stakeholder comment letters. CalRecycle considered all comment letters when reviewing The Foundation's Plan for compliance. The four letters were submitted by UltiMed, Inc., National Stewardship Action Council, Pharmaceutical Product Stewardship Working Group, and MED-Project USA. Each letter articulates questions and concerns about The Foundation's Plan that generally align with CalRecycle's findings regarding the mail-back program, education and outreach, ordinance repeals, and 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 its 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 Takeback Solutions Foundation's Product Stewardship Plan for Home-Generated Sharps Waste*. 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 14, 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 Sharps Waste: September 21, 2021: Version 2 \(November 15, 2021\)](#) (submitted December 16, 2021)  
<https://www2.calrecycle.ca.gov/Docs/Web/120195>
2. [Pharmaceutical and Sharps Waste Stewardship Act](#) (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=](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](#) (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)