

## REQUEST FOR ACTION

**To:** Rachel Machi Wagoner  
Director

**From:** Zoe Heller  
Deputy Director, Materials Management and Local Assistance  
Division  
Acting Deputy Director, Policy Development and Analysis Office

**Request Date:** December 13, 2022

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

**Action By:** January 13, 2023

---

### **Summary of Request**

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

### **Background**

The Foundation is a stewardship organization that represents 10 covered entities under its *October 2022 Revised Plan*. On November 19, 2021, The Foundation submitted its *Stewardship Plan for Home-Generated Sharps Waste (Plan)* to CalRecycle pursuant to Public Resources Code (PRC) section 42032 and on December 16, 2021, an addendum, titled, *Addendum to Stewardship Plan for Sharps Waste* as part of the *Plan*. CalRecycle determined the *Plan* was complete and notified The Foundation on December 20, 2021, pursuant to PRC section 42032(c)(1) and Title 14, California Code of Regulations (14 CCR) section 18973.1(b).

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

On May 17, 2022, The Foundation submitted its *Stewardship Plan for Home-Generated Sharps Waste (May 2022 Revised Plan)*, to meet conditions specified in the "Staff Analysis" section of the February 2022 Request for Approval. On August 16, 2022, CalRecycle maintained the conditional approval of The Foundation's *May 2022 Revised*

*Plan* and provided The Foundation 60 days to submit a revised plan that addressed the remaining conditions specified in the August 2022 Request for Approval.

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

### **Staff Analysis**

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

### **CalRecycle Condition 1**

**Requirement:** CalRecycle required the *October 2022 Revised Plan* to meet the following condition 1(e) pursuant to PRC section 42032.2(d)(1)(F)(i) and 14 CCR section 18973.3(f)(2):

- e. The plan must explain how all ultimate users, including individuals without a permanent address, can receive sharps waste containers and mail-back materials through all approved options, including the option whereby ultimate users request sharps waste containers and mail-back materials through The Foundation's toll-free telephone number.

**Analysis:** Condition 1(e) met.

The Foundation's *October 2022 Revised Plan* includes sufficient description of how all ultimate users, including those without a permanent address, can receive sharps waste containers and mail-back materials at the point of sale. The *October 2022 Revised Plan* states that ultimate users without an address have the option to use United States Postal Service (USPS) General Delivery, and that information about this process will be provided to point of sale locations. The *October 2022 Revised Plan* includes options for ultimate users without an address to request sharps waste containers and mail-back materials through The Foundation's website and toll-free telephone number, which was not specified in The Foundation's *May 2022 Revised Plan*. Through The Foundation's website and telephone number, ultimate users can provide the address of a post office where sharps containers and mail-back materials are delivered in accordance with USPS policies. The *October 2022 Revised Plan* meets condition 1(e).

### **CalRecycle Condition 2**

**Requirements:** CalRecycle required the *October 2022 Revised Plan* to meet the following conditions pursuant to PRC sections 42032.2(d)(1)(C) and 42033(b), and 14 CCR sections 18973.3(e) and 18973.6(b) through (e):

- a. The budget must include all required cost categories, pursuant to 14 CCR section 18973.6(b), and a narrative description of the types of activities that will be conducted under each of the line items in the budget.
- b. Correct all mathematical discrepancies and ensure an accurate initial five-year program budget is submitted.
- c. The budget must include a justification for the proposed reserve level amount.

**Analysis:** Conditions 2(a), 2(b), and 2(c) met.

The Foundation's *May 2022 Revised Plan* did not include cost categories for capital costs, including, but not limited to, fixed, one-time, tangible purchases, and costs related to grants, loans, sponsorships, or other incentives as part of program implementation. The *October 2022 Revised Plan* includes all required cost categories and provides a narrative description of each cost category. The *October 2022 Revised Plan* meets condition 2(a).

The Foundation's *October 2022 Revised Plan* no longer includes a mathematical discrepancy between the total of the five-year departmental administrative fee amounts listed in "Appendix A" and the budget narrative of the *October 2022 Revised Plan*. The *October 2022 Revised Plan* meets condition 2(b).

The *October 2022 Revised Plan* sufficiently justifies The Foundation's reserve percentage, that "approximates 10 percent of additional Mail-Back Units," by asserting that it will be sufficient to cover impacts of unexpected cost variability including costs of collection, transportation, disposal, and other operational costs. The Foundation provides further justification in the *October 2022 Revised Plan* by noting that the reserve level would approximate about three months of education, operational, and administrative costs and provide sufficient cash for other unexpected costs. The *October 2022 Revised Plan* to meet condition 2(c).

### **CalRecycle Condition 3**

**Requirements:** CalRecycle required the *October 2022 Revised Plan* to meet the following conditions 3(a), 3(b), 3(c), and 3(e) pursuant to PRC sections 42031.6(a)(1) and 42031.6(a)(5) and 14 CCR sections 18973.3(i)(1) through (6):

- a. The plan must clarify that the education and outreach program is intended to promote ultimate user awareness and maximize ultimate user participation, and specify that signage will be provided to hospitals, pharmacies, and other locations, as necessary.
- b. The plan must describe how The Foundation's comprehensive education and outreach program will distribute materials in languages suited to local demographics.
- c. The plan must provide an accurate description of how the website will provide instructions for safe handling and proper disposal of home-generated sharps waste, not "substances."
- e. The plan must explain how the proposed annual education and outreach survey will evaluate the performance of the outreach and education program regarding ultimate user awareness, program usage, and accessibility. The plan must also describe the metrics that will be used to measure ultimate user awareness, program usage, and accessibility.

**Analysis:** Conditions 3(a), (b), (c), and (e) met.

The Foundation's *October 2022 Revised Plan* clarifies that education and outreach is intended to promote ultimate user awareness and maximize ultimate user participation. The *October 2022 Revised Plan* also specifies that signage will be distributed to hospitals, pharmacies, persons authorized to prescribe drugs, pharmacists, participants

of the program, and locations that distribute sharps waste containers and mail-back materials. The *October 2022 Revised Plan* meets condition 3(a).

The *October 2022 Revised Plan* describes how all printed materials will be distributed in languages suited to local demographics, consistent with section 7295 of the Government Code and all hard-copy educational material and signage in English and Spanish will include “a QR code coupled with a universally recognized translation icon” that directs ultimate users to a webpage where printable translated materials are available. The *October 2022 Revised Plan* meets condition 3(b).

The *October 2022 Revised Plan* specifies that The Foundation’s website will include education and outreach materials on safe handling, storage, and proper disposal of home-generated sharps waste. The Foundation’s *October 2022 Revised Plan* meets condition 3(c).

The Foundation’s *May 2022 Revised Plan* included reference to a biennial survey, making it unclear how annual performance will be evaluated. The *October 2022 Revised Plan* proposes an annual survey of covered entities, pharmacists, and healthcare professionals in California who interact with ultimate users to measure awareness and program usage. There is no reference to a “biennial” survey in the *October 2022 Revised Plan* and it is clear how annual performance will be evaluated through The Foundation’s survey. The *October 2022 Revised Plan* meets condition 3(e).

#### **CalRecycle Condition 4**

**Requirement:** CalRecycle required the *October 2022 Revised Plan* to meet the following condition pursuant to PRC section 42032.2(e) and 14 CCR section 18973.3(h):

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

**Analysis:** Condition 4(a) met.

The *October 2022 Revised Plan* includes sufficient description of how The Foundation will incorporate a local jurisdiction into its program within 270 days of the repeal of a sharps stewardship ordinance in a local jurisdiction. The *October 2022 Revised Plan* no longer includes language that assumes it is the jurisdiction’s responsibility to notify The Foundation of a repeal and includes a statement that The Foundation will consistently monitor local jurisdictions to remain aware of any program changes or repeals. The *October 2022 Revised Plan* meets condition 4(a).

#### **CalRecycle Condition 6**

**Requirements:** CalRecycle required the *October 2022 Revised Plan* to meet the following conditions pursuant to PRC section 42030(q) and 14 CCR sections 18973(d), 18973.3(a), and 18973.6(a):

- a. Use terminology defined in PRC and 14 CCR or define and consistently utilize terminology within the plan. The plan must clarify that The Foundation will provide reimbursement for costs associated with “transportation and disposal” of home-generated sharps waste.

- b. Ensure that all references, including statutory and regulatory citations, in the plan are correct.
- c. The Foundation must provide all required contact information to ensure that The Foundation and Inmar are fully identified as separate entities.

Analysis: Conditions 6(a), 6(b), and 6(c) met.

The Foundation's *May 2022 Revised Plan* contained multiple instances of inconsistent terminology and use of terminology that is not defined in PRC, 14 CCR, or the *May 2022 Revised Plan*. The *October 2022 Revised Plan* addresses these inconsistencies and undefined terms and provides a clear narrative of how The Foundation's program will function. The *October 2022 Revised Plan* meets condition 6(a).

The Foundation's *May 2022 Revised Plan* included incorrect references and statutory and regulatory citations. The *October 2022 Revised Plan* includes appropriate citations for a home-generated sharps waste stewardship plan (14 CCR section 18973.3) instead of a covered drugs stewardship plan (14 CCR section 18973.2). On page 4, the *October 2022 Revised Plan* still references "the Covered Entities listed in Appendix E," when there is no Appendix E. Staff note that the correct appendix appears to be "Appendix B – Participating Covered Entities." The *October 2022 Revised Plan* meets condition 6(b).

The *October 2022 Revised Plan* includes the required missing mailing and physical address(es) and website for the person(s) responsible for submitting and overseeing the stewardship plan and program budget on behalf of the program operator to ensure The Foundation and Inmar are separate entities. The *October 2022 Revised Plan* meets condition 6(c).

### **CalRecycle Condition 9**

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

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

Analysis: Condition 9(a) met.

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

### **Stakeholder Feedback**

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

## **Action**

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

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

**Signed by:** Rachel Machi Wagoner, Director

**Dated:** December 20, 2022

## **Attachments:**

Documents listed below are posted to CalRecycle's website. To request documents that are referenced in this report but are not listed below, please submit a Public Records Act request (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

1. [Stewardship Plan for Home-Generated Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/122409) (October 15, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122409>
  - a. [Appendix A – Program Budget](https://www2.calrecycle.ca.gov/Docs/Web/122421) (October 15, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122421>
  - b. [Appendix B – Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122418) (October 15, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122418>
  - c. [Appendix C – Service Providers](https://www2.calrecycle.ca.gov/Docs/Web/122415) (October 15, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122415>
  - d. [Appendix D – Sharps Sold or Offered for Sale in California by Participating Covered Entities](https://www2.calrecycle.ca.gov/Docs/Web/122412) (October 15, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122412>
2. [Consideration of The Drug Takeback Solutions Foundation's Revised Stewardship Plan for Home-Generated Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/122019) (August 16, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122019>
3. [Addendum to Stewardship Plan for Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/120195) (December 16, 2021)  
<https://www2.calrecycle.ca.gov/Docs/Web/120195>
4. [Consideration of The Drug Takeback Solutions Foundation's Product Stewardship Plan for Home-Generated Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/120858) (February 14, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/120858>