

## REQUEST FOR ACTION

**To:** Zoe Heller  
Director

**From:** Clark Williams  
Branch Chief, Statewide Technical and Analytical Resources  
Branch

**Request Date:** June 25, 2024

**Decision Subject:** Consideration of MED-Project's 2023 Annual Report for Home-Generated Sharps Waste

**Action By:** June 27, 2024

---

### **Summary of Request**

MED-Project USA (MED-Project) submitted its 2023 annual report, titled, *MED-Project 2023 Annual Report; State of California, Home-Generated Sharps Waste (2023 Annual Report)* on March 29, 2024. This Request for Action presents a summary of staff's analysis regarding MED-Project's *2023 Annual Report* and MED-Project's home-generated sharps waste stewardship program.

### **Background**

Public Resources Code (PRC) section 42033.2(a)(1) states that, on or before March 31, 2022, and each year thereafter, a program operator shall submit to The Department of Resources Recycling and Recovery (CalRecycle) a report that describes the stewardship program activities during the previous reporting period of one year. MED-Project is a stewardship organization that, as reported in its *2023 Annual Report*, represents 89 covered entities under its approved stewardship plan for home-generated sharps waste, titled, *A Product Stewardship Plan for Home-Generated Sharps Waste (Plan)*. MED-Project's *2023 Annual Report* is required to cover the entire calendar year of 2023 (January 1, 2023, through December 31, 2023).

MED-Project submitted its *2023 Annual Report* on March 29, 2024. CalRecycle determined the *2023 Annual Report* was complete and notified MED-Project on April 29, 2024, pursuant to PRC section 42033.2(d)(1) and Title 14 of the California Code of Regulations (14 CCR) section 18973.1(b). CalRecycle has 90 days to approve, disapprove, or conditionally approve the *2023 Annual Report* pursuant to PRC section 42033.2(e)(1) and 14 CCR section 18973.1.

### **Staff Analysis**

MED-Project states in its *2023 Annual Report* that it conducted program activities including:

- Distributed 129,183 sharps waste containers and mail-back materials to ultimate users.
- Worked with "Point of Sale Sites," defined as "retail pharmacies, retail pharmacy chains, online retailers, and/or other retailers of sharps to ultimate users" in MED-

Project's *Plan* (point of sale sites), resulting in an additional 327 sites accepting the terms and conditions to participate in its program using the online ordering system, for a total of 4,253 point of sale sites initiating the distribution of sharps waste containers and mail-back materials.

- Executed an agreement with an additional 201 point of sale sites to provide sharps waste containers and mail-back materials, for a total of 358 point of sale sites providing sharps waste containers and mail-back materials at the point of sale.
- Conducted outreach to point of sale sites, covered entities, and distributors, over 14,500 times via multiple methods, including over 1,800 letters, over 9,700 emails, over 900 phone calls, and over 2,100 in-person site visits.
- Coordinated with the other approved program operator to develop a neutrally branded website and toll-free telephone number.
- Conducted a digital survey to solicit feedback on program awareness from ultimate users.
- Disposed of 29,950.2 pounds of home-generated sharps waste through the return of 20,111 sharps waste containers and mail-back materials by ultimate users.
- Received 351 reimbursement requests from 24 local agencies and reimbursed a total of \$484,327.25 for the collection of 306,019.2 pounds of home-generated sharps waste.

MED-Project reports a challenge that point of sale sites are not required to participate by providing or initiating the distribution of a sharps waste container and mail-back materials at the point of sale. MED-Project addressed this challenge by continuing varied strategies to secure point of sale site participation in its program. MED-Project also continued working with its covered entities and distributors by implementing a communications campaign that encouraged point of sale sites to participate in its program.

Staff evaluated MED-Project's *2023 Annual Report* to determine whether the requirements of statute, regulations, and MED-Project's *Plan* were met. Overall, MED-Project reports significant efforts undertaken during the reporting period to address the statutory, regulatory, and *Plan* requirements, as well as the requirement CalRecycle identified in the Request for Action, titled, *Consideration of MED-Project's Revised 2022 Annual Report for Home-Generated Sharps Waste*. The sections below present a summary of staff's analysis of MED-Project's *2023 Annual Report* and select components of its home-generated sharps waste stewardship program.

### **Mail-Back Program**

Requirements: Implement 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 14 CCR section 18973.3(f)(2). Include information on the mail-back program in the annual report pursuant to PRC section 42033.2(b)(5). Describe how ultimate users had an opportunity to dispose of their home-generated sharps waste as described in the approved stewardship plan pursuant to 14 CCR section 18973.5(c)(1). Include any other information the

department reasonably requires in the annual report, pursuant to PRC section 42033.2(b)(9). A program operator submitting an annual report shall provide to the department, upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of approval, pursuant to 14 CCR section 18973.1(a).

Analysis: Requirements Met

In its *Plan*, MED-Project states that its mail-back program will:

- Provide or initiate distribution of Sharps Mail-Back Packages to Ultimate Users at or prior to the Point of Sale of all In-Scope Purchases [consistent with the definition of covered products pursuant to PRC section 42030(g)], and through the Website and Call Center.

MED-Project operated an online and phone ordering system, a website, and a call center to initiate the distribution of sharps waste containers and mail-back materials to ultimate users, consistent with its *Plan*. MED-Project added 327 point of sale sites in its online ordering system to initiate the distribution of sharps waste containers and mail-back materials to ultimate users. In addition, MED-Project engaged with vendors to provide sharps waste containers and mail-back materials at the point of sale to ultimate users and executed an agreement with an additional 201 point of sale sites to provide sharps waste containers and mail-back materials to ultimate users. MED-Project reported 4,253 sites that initiate the distribution of sharps waste containers and mail-back materials to ultimate users and 358 sites that provide sharps waste containers and mail-back materials to ultimate users.

**Metrics**

Requirements: Report the amount of sharps waste containers and mail-back materials distributed per county, through each of the following methods: provided at point of sale, initiated at point of sale, website requests, and toll-free telephone number requests pursuant to 14 CCR section 18973.5(c)(2). Report the amount of home-generated sharps waste returned through the mail-back program pursuant to 14 CCR section 18973.5(c)(3). For each local agency that has requested removal or reimbursement, pursuant to the requirements in subsection (1)(F)(ii) of subdivision (d) of section 42032.2 of the Public Resources Code, provide details including, but not limited to: facility location, reimbursement payment amount, as applicable, and the amount of home-generated sharps waste collected, as required in the stewardship plan pursuant to section 18973.3(f)(8), pursuant to 14 CCR section 18973.5(p)(2).

Analysis: Requirements Met

MED-Project's *2023 Annual Report* includes the required metrics related to distribution of sharps waste containers and mail-back materials and the collection and disposal of sharps waste. MED-Project reports the amount of sharps waste containers and mail-back materials provided to ultimate users at point of sale sites after conducting a digital survey to point of sale sites to verify the metric. MED-Project reports distributing a total of 129,183 sharps waste containers and mail-back

materials to ultimate users: 42,211 were provided at the point of sale, 47,106 were initiated at the point of sale, 35,409 were distributed through the website, and 4,457 were distributed through the call center (see Table 1). A total of 20,111 sharps waste containers were returned through MED-Project's program, equating to the disposal of 29,950.2 pounds of home-generated sharps waste. In addition, MED-Project reports that it received 351 reimbursement requests from 24 local agencies and reimbursed \$484,327.25 for the collection of 306,019.2 pounds of home-generated sharps waste (see Table 2).

**Table 1. Sharps Waste Container and Mail-back Material Distribution Metrics**

<b>Method of Distribution</b>	<b>Number of Containers and Mail-back Materials</b>
<b>Provided at point of sale</b>	42,211
<b>Initiated at point of sale</b>	47,106
<b>Website</b>	35,409
<b>Call Center</b>	4,457
<b>Total</b>	129,183

Table 1 Description: MED-Project's metrics regarding the amount of sharps waste containers and mail-back materials provided and initiated by point of sale sites to ultimate users, and the amount distributed through website and call center requests.

**Table 2. Local Agency Reimbursements and Weight Collected**

<b>Metric</b>	<b>Amount</b>
<b>Local Agency Reimbursement Requests</b>	351
<b>Local Agencies Reimbursed</b>	24
<b>Total Reimbursed to Local Agencies</b>	\$484,327.25
<b>Home-generated sharps waste collected (in pounds)</b>	306,019.2

Table 2 Description: MED-Project's metrics regarding reimbursement requests from local agencies and home-generated sharps waste collected.

**Education and Outreach**

Requirements: Implement a comprehensive education and outreach program pursuant to PRC section 42031.6 and 14 CCR section 18973.3(i). Describe and evaluate the comprehensive education and outreach activities pursuant to 14 CCR section 18973.3(i). Discuss what the metrics, described in 14 CCR section 18973.5(i)(2), reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility, pursuant to 14 CCR sections 18973.5(i)(2) and (3).

Analysis: Requirements Met

MED-Project's Annual Report describes the various measures it uses to evaluate ultimate user awareness, program usage, and accessibility of its home-generated sharps waste stewardship program. MED-Project reports continuing its ongoing

education and outreach, including posting social media content, operating a website, completing digital media campaigns, and distributing promotional materials such as brochures and posters. MED-Project also described its activities such as media campaigns, press releases, educational videos, and attendance at local household hazardous waste collection events, designed to provide information about its program. Additionally, MED-Project conducted an awareness survey to gauge ultimate users' awareness and use of its home-generated sharps waste stewardship program. Out of the 300 survey respondents, MED-Project reports that 84 percent were aware of the home-generated sharps waste disposal options, 55 percent found the sharps disposal programs available and accessible, and 64 percent found the sharps disposal program easy to use. In addition, MED-Project's website was visited 152,095 times, and the call center received 4,164 calls. MED-Project's website is accessible per the Americans with Disabilities Act. Additionally, MED-Project provides information in multiple languages as its website provides translations and its call center services are offered in English or Spanish. MED-Project found that its survey results, combined with the engagement with its services, demonstrate the success of its education and outreach program. The information contained in the annual report indicates that MED-Project has implemented a comprehensive education and outreach program.

### **CalRecycle Compliance and Inspection Activities**

As part of the Pharmaceutical and Sharps Waste Stewardship Act, CalRecycle provides statewide compliance and enforcement oversight for regulated entities including, but not limited to pharmaceutical manufacturers, distributors, importers, pharmaceutical retail locations, and the stewardship organizations.

In 2023, CalRecycle staff conducted 179 inspections at sharps retailers to evaluate retailer compliance with the Pharmaceutical and Sharps Waste Stewardship Act. Sharps retailers are required to monitor CalRecycle's website and notify CalRecycle of any products not listed on the website. Of the 179 retailers inspected, 137 (77 percent) were noncompliant at the time of the inspection. However, within 60 days, all violations were corrected.

### **Feedback from Interested Parties**

CalRecycle solicited public input on MED-Project's *2023 Annual Report* from April 3, 2024, through April 16, 2024, and received comment letters from Anne Vogel-Marr, Executive Director of the Pharmaceutical Product Stewardship Work Group, and Dr. Victoria Travis, National Program Director of MED-Project. CalRecycle considered these comments when reviewing MED-Project's *2023 Annual Report*.

### **Action**

Pursuant to PRC section 42033.2(e) and 14 CCR section 18973.1, I hereby:

- Approve MED-Project's *2023 Annual Report*.
- Conditionally approve MED-Project's *2023 Annual Report*. Direct staff to identify the conditions to be met for approval and provide written notice to MED-Project within 30 days of signature of this Request for Action, pursuant to 14 CCR section 18973.1(j).
- Disapprove MED-Project's *2023 Annual Report*. Direct staff to identify how the *2023 Annual Report* does not comply and provide written notice to MED-Project within 30 days of signature of this Request for Action, pursuant to 14 CCR section 18973.1(k).

*I approve MED-Project's 2023 Annual Report on the bases of the information reported by MED-Project and the information and analysis contained in this Request for Action because it demonstrates the stewardship program provides adequate access to safe disposal of home-generated sharps waste.*

**Signed by:**

Zoe Heller  
Director

**Dated:** June 27, 2024

**Attachments:**

Documents listed below are posted to CalRecycle's website.

1. [\*MED-Project 2023 Annual Report; State of California, Home-Generated Sharps Waste\*](#) (March 29, 2024)  
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15677>
  - a. [\*Attachment A – Requests and Distribution by County\*](#) (March 29, 2024)  
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15678>
  - b. [\*Attachment B – Daily Impressions for Digital Media\*](#) (March 29, 2024)  
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15679>
  - c. [\*Attachment C – List of Sharps Covered Entities\*](#) (March 29, 2024)  
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15680>
  - d. [\*Attachment D – List of Sharps Covered Products\*](#) (March 29, 2024)  
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15681>
  - e. [\*Attachment E – Local Agency Reimbursements\*](#) (March 29, 2024)  
<https://www2.calrecycle.ca.gov/PublicNotices/Documents/15682>
2. [\*A Product Stewardship Plan for Home-Generated Sharps Waste\*](#) (August 22, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122100>
  - a. [\*Appendix A – Participating Covered Entities\*](#) (August 22, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122106>
  - b. [\*Appendix B – Covered Products\*](#) (August 22, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122109>
3. [\*Consideration of MED-Project's Revised 2022 Annual Report for Home-Generated Sharps Waste\*](#) (November 20, 2023)  
<https://www2.calrecycle.ca.gov/Docs/Web/126237>