

# A Product Stewardship Plan for Home-Generated Sharps Waste

State of California August 22, 2022

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#### **Section 1: Definitions**

Capitalized terminology in the Plan has the meaning in these definitions. Capitalized terminology that is not defined in the Plan is defined in the Law or Regulations.

Call Center: The multi-lingual call center operated by MED-Project for Ultimate Users, which can be reached by callers at a toll-free telephone number.

CalRecycle: The State of California Department of Resources Recycling and Recovery and any successor agency. Also referred to as Department.

Carrier is a common or contract carrier used to transport Home-Generated Sharps Waste.

Department: The State of California Department of Resources Recycling and Recovery and any successor agency. Also referred to as CalRecycle.

DOT: The U.S. Department of Transportation.

Help Desk: Resources and support available to Retail pharmacies, Retail pharmacy chains, other retailers, online retailers, and Local Agencies. The Help Desk is provided through the Website, a toll-free telephone number, or emailing <a href="mailto:california@med-project.org">california@med-project.org</a>.

Law: Chapter 2 (commencing with section 42030), Part 3, Division 30 of the California Public Resources Code.

In-Scope Purchases: Defined, consistent with the applicable laws and regulations, as including purchases by an Ultimate User of any of the following: Sharps, Covered Drugs sold with or including a Sharp, and Covered Drugs sold for use with a Sharp; but excluding, consistent with California Public Resources Code Section 42030(u): components manufactured for use with external ambulatory insulin pump therapy systems or continuous glucose monitoring systems, including, but not limited to, insulin infusion sets, glucose sensors that are sterile goods indicated for single subcutaneous use, sterile drug delivery channels indicated for single subcutaneous use, and injection ports, and a "biological product," as defined in Section 262(i)(1) of Title 42 of the United States Code, including a "combination product," as defined in Section 3.2(e) of Title 21 of the Code of Federal Regulations.

Mail-Back Services: The provision of Sharps Mail-Back Packages for the collection and disposal of Sharps.

Point of Sale Sites: Retail pharmacies, Retail pharmacy chains, online retailers, and/or other retailers of Sharps to Ultimate Users.

Program: The Stewardship Program established by this Plan.

Regulations: California Code of Regulations Title 14, Division 7, Chapter 11, Article 4.

Sharps Mail-Back Packages: United States Food and Drug Administrationcleared sharps waste containers and pre-paid, pre-addressed mail-back materials provided by Vendor for the collection of Sharps.

State means the State of California, except where the Law does not apply to a Drug or a Sharp pursuant to PRC 42036.2(a).

Vendor is any vendor hired by MED-Project to provide goods or services under the Program.

Website is the website operated by MED-Project and located at <u>www.med-project.org</u> or <u>www.medproject.org</u>.

[PRC 42030, 14 CCR 18972.1]

#### **Section 2: Contact Information**

### **Corporate Officer**

The primary contact person for MED-Project USA ("MED-Project"), a Stewardship Organization managed by a board of directors representing the participating Covered Entities and organized as a non-profit organization exempt from income tax under § 501(c)(3) of the Internal Revenue Code, is:

Jim Wilson
Lead Director, Legal and Compliance
MED-Project USA
1800 M Street, NW
Suite 400 South
Washington, DC 20036
Phone: 1 (833) 633-7765
Fax: 1 (866) 633-1812
california@med-project.org
www.med-projectusa.org

The M Street address is both the mailing and physical address.

[PRC 42032.2(d)(1)(A)], 14 CCR 18973.3(a)]

#### **Covered Entities**

MED-Project submits this proposed Plan on behalf of participating Covered Entities. **Appendix A** provides reference to an accessible Excel spreadsheet containing the list of participating Covered Entities for which MED-Project is submitting this proposed plan.

[PRC 42031.4(b), 42032(a)(1), 14 CCR 18973.3(b)]

## **Section 3: Sharps Sold by Each Participating Covered Entity**

<u>Appendix B</u> provides reference to an accessible Excel spreadsheet containing the list of each Sharp (excluding those that are not Covered Products) sold or offered for sale by each participating Covered Entity covered by the Plan.

[PRC 42032.2(d)(1)(A), 14 CCR 18973.3(c)]

## **Section 4: State Agency Determinations and Certifications**

**Appendix C** provides the determinations received from the agencies.

Appendix C also includes the written certification by an authorized representative of MED-Project.

[PRC 42032(b)(1), 42032(b)(3), 42032(b)(4), 42032.2(d)(1)(B), 14 CCR 18973(e), 18973.3(d)]

## **Section 5: Program Budgets and Funding**

[14 CCR 18973.6, 18973.3(e)]

#### **Initial Program Budget**

[PRC 42033]

### Contact Information of the Person Responsible for Submitting and Overseeing the Program Budget

The primary contact person responsible for submitting and overseeing the Program budget on behalf of MED-Project USA is:

Kim Peterson Director of Finance MED-Project USA 1800 M Street, NW Suite 400 South Washington, DC 20036 Phone: 1 (833) 633-7765 Fax: 1 (866) 633-1812

california@med-project.org www.med-projectusa.org

The M Street address is both the mailing and physical address.

[14 CCR 18973.6(a)]

#### **Anticipated Costs to Implement the Program**

MED-Project's initial budget covers a five-year period of anticipated operations. In preparing this budget, MED-Project has allocated revenues and expenses in accordance with Generally Accepted Accounting Principles (GAAP). The Program budget is based on forecasts, projections, and other predictive statements that represented MED-Project's assumptions and expectations in light of the information that was available at the time the budget was submitted. MED-Project's Program budget is based on MED-Project's knowledge of performance, industry trends, and other factors, and involves risks, variables, and uncertainties. MED-Project's actual performance may differ from what is projected in the

Program budget. No guarantee is implied as to the accuracy of the Program budget.

The Program started on December 9, 2021. <u>Appendix D</u> provides MED-Project's initial Program budget for the period running from December 9, 2021, through December 31, 2025.

[PRC 42033(a), 14 CCR 18973.6(b)]

## Types of Activities Relative to Each Line-Item Cost Category

[14 CCR 18973.6(e)]

#### Revenue

MED-Project programs are funded by their participating Covered Entities. MED-Project, on behalf of the participating Covered Entities as referenced in **Appendix A**, will pay all administrative and operational costs associated with establishing and implementing the Program.

[PRC 42034, 42034.2(a)(2), 14 CCR 18974.1(a)]

#### Costs

MED-Project provides budgeted Program costs defined in 14 CCR 18973.6 in **Appendix D**. A description of each of the cost categories follows:

[PRC 42034.2(a)(1), 14 CCR 18973.6(b)(1) - 18973.6(b)(4)]

#### **Capital**

This cost category covers fixed, one-time, tangible purchases associated with the Program. No costs are anticipated for this category.

#### **Collection and Disposal of Sharps**

This cost category covers the following activities:

- Collection, transportation, and disposal of Home-Generated Sharps Waste.
- Contracted and employed personnel costs associated with collection and disposal.
- Acquisition, distribution, and postage of Sharps Mail-Back Packages.

#### **Administrative**

This cost category covers the following activities:

- Contracted and employed personnel overhead costs.
- Legal fees.
- Local and state business licensing fees.
- Local, state, and federal taxes.
- Property costs, including rentals.
- Insurance, utilities, phone, and internet.
- General equipment and supplies.
- Data and information technology services.
- External audit fee.
- CalRecycle administrative fee.

#### **Education and Outreach**

This cost category covers the following activities:

- Advertising.
- Marketing.
- Contracted and employed personnel costs associated with education and outreach.
- Website creation and maintenance.
- Operation of the Call Center.
- Survey methods.

#### **Recommended Reserve**

MED-Project financial records will be audited annually by an independent certified public accountant, as required by 14 CCR 18973.6(f) and PRC 42033.4(b).

14 CCR 18973.6(c) requires that MED-Project maintain a reserve level and funding amount that is sufficient to fund the Program's operations over a multiyear period in a fiscally prudent and responsible manner. The MED-Project Board of Directors established a reserve policy that directs MED-Project to have a prudent level of reserves. The MED-Project Board of Directors also instituted an investment policy to establish a clear understanding of MED-Project investment philosophy and investment objectives with respect to its reserves as outlined in its reserve policy

through deployment of an investment strategy for the long-term success of MED-Project in maintaining financial stability.

The reserves allow MED-Project to be prepared in case its operational expenses increase or planned revenues decrease outside of its approved annual budget because of factors beyond its control. The amount that MED-Project sets aside in this reserve is influenced by several factors.

First, MED-Project must be prepared for unforeseen circumstances that could have a substantial impact on its revenue and expenses, such as accidents, disasters, or failures of MED-Project operational systems, collection and disposal Vendors, etc. In addition, significant or sudden changes in market dynamics that affect collection and disposal costs (e.g., transportation costs, cost of materials) or other uncertainties could require MED-Project to use its financial reserves to continue funding the Program.

Next, MED-Project's network of collection and disposal Vendors rely on timely payment for services rendered. Therefore, to keep the Program functioning and its Vendors paid and operating, MED-Project has reserves to address the various financial risks it may encounter.

A reserve range and recommended reserve target is annually presented to the MED-Project Board of Directors for approval in conjunction with the normal budget cycle. The range and target are based on MED-Project's proposed operational and capital spending for the coming year along with an amount determined sufficient to address key drivers of potential significant budget variability including but not limited to:

- Collection, transportation, and disposal costs.
  - Sharps Mail-Back Packages costs.
- Administrative costs.
- Education and outreach costs.
  - Advertising and marketing costs.

These and other variables, including operating cash flow and investment performance of the reserve, are analyzed and evaluated for their potential impact. The level of reserve recommended in any given year is expected to approximate 25% of the annual Program budget based on the process and analysis set forth above.

For these reasons, MED-Project follows a reserve policy that will provide sufficient financial resources to permit a proper response to such exigencies promptly and properly. MED-Project will keep available cash and reserves to cover at least three months of the annual Program budget. For clarity, "cash" is cash on hand to fund the Program budget; it is separate from the reserves.

[14 CCR 18973.6(c), 18973.6(f)]

### **Annual Program Budget**

MED-Project will submit a written budget for the Program annually to meet the requirements established in 42033.2(a)(2), 42033.2(c), and 14 CCR 18973.6.

[PRC 42033.2(a)(2), 42033.2(c)]

### **Funding**

MED-Project programs are funded by their participating Covered Entities. Costs of the Program are apportioned only among the Covered Entities participating in the Program and not the full list of Covered Entities subject to the Law and Regulations. Costs are apportioned using a confidential cost allocation model approved by the Covered Entities participating in each program. Participating Covered Entities are invoiced and remit funds on an annual basis. <a href="#Appendix A">Appendix A</a> provides reference to the list of the participating Covered Entities funding the Program.

MED-Project prepares the calendar year budget in advance of the calendar year. This budget is approved by the MED-Project Board of Directors. After the budget has been finalized and approved, participating Covered Entities commit to participate and fund the Program in advance of the year. The initial five-year budget is detailed in <a href="Appendix D">Appendix D</a>. In addition, during the budget approval process, a reserve level is also approved, as described in <a href="Section 5">Section 5</a>: <a href="Recommended Reserve">Recommended Reserve</a>. If actual expenditures exceed the budget and reserves, there is a mechanism in place to raise additional funds from participating Covered Entities. MED-Project's many participating Covered Entities as referenced in <a href="Appendix A">Appendix A</a> provide it the funding to maintain reserves in a prudent and responsible manner.

[PRC 42032.2(a)(1)(D), 42033(b), 14 CCR 18973.3(e), 18973.6(d)]

## **Section 6: Mail-Back Program**

Within 270 days of Plan approval, MED-Project will establish a safe and secure Mail-Back Program for collecting Home-Generated Sharps Waste throughout the State through the distribution of Sharps Mail-Back Packages for the collection and disposal of Home-Generated Sharps Waste. The MED-Project Mail-Back Program will:

- Be provided at no cost to the Ultimate User.
- 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 and through the Website and Call Center. Ultimate Users may decline to have MED-Project provide or initiate the distribution of a Sharps Mail-Back Package at or prior to the Point of Sale of an In-Scope Purchase, including, without limitation, because they already have sufficient Sharps Mail-Back Packages or because another Program Operator provided or initiated the distribution of a Sharps Mail-Back Package for their In-Scope Purchase.
- Distribute Sharps Mail-Back Packages in amounts sufficient to accommodate the volume of In-Scope Purchases by an Ultimate User during a 12-month period. Each Ultimate User self-determines that number of containers they need during the above-referenced time period.
- Monitor for excessive requests that could indicate that Sharps Mail-Back Packages are being distributed in a way that is inconsistent with the Program.

All Sharps Mail-Back Packages will have inserts that provide:

- A description of the types of Home-Generated Sharps Waste that may go into the Sharps Mail-Back Package.
- Instructions for packaging and mailing a sharps disposal container.
- Information about proper sharps waste disposal.
- The Website web address and Call Center toll-free telephone number.

<u>Appendix E</u> provides sample mockups of the Sharps Mail-Back Package inserts.

[PRC 42032(g), 42032.2(d)(1)(F), 42032.2(d)(1)(F)(i)(I), 42032.2(d)(1)(F)(i)(II), 42032.2(d)(1)(F)(i)(III), 14 CCR 18973.1(m), 18973.3(f)]

### Handling, Transport, and Disposal

MED-Project will provide for a handling, transport, and disposal system that complies with applicable laws, regulations, and other legal requirements. MED-Project's Vendor for the collection and disposal of Home-Generated Sharps Waste will monitor the related tracking data and report to MED-Project.

Table 1 provides the Vendors the Program proposes to use. 1,2

Table 1: Vendors

Vendor	Mailing Address	Physical Address
PureWay Compliance, Inc.	16225 Park Ten Place, Suite 830, Houston, TX 77084	16225 Park Ten Place, Suite 830, Houston, TX 77084
Stericycle, Inc.	2355 Waukegan Road, Bannockburn, IL 60015	2355 Waukegan Road, Bannockburn, IL 60015

[PRC 42032.2(d)(1)(D), 42035.8, 14 CCR 18973.3(f)(1), 18973.3(f)(2), 18973.3(f)(4)]

<sup>&</sup>lt;sup>1</sup>The United States Postal Service approved PureWay Compliance, Inc. and Stericycle, Inc., to ship Sharps through the postal service. A complete listing of vendors that have completed the necessary requirements of Publication 52, Hazardous, Restricted and Perishable Mail section 346.322, permitting them to ship Sharps through the postal service may be requested by emailing ProductClassification@usps.gov.

<sup>&</sup>lt;sup>2</sup>The Vendors listed in Table 1 will arrange for Sharps Mail-Back Packages to be shipped from Ultimate Users to treatment and disposal facilities.

### **Distribution of Sharps Mail-Back Packages**

MED-Project 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, and through the Website and Call Center. As noted above, Ultimate Users may decline Sharps Mail-Back Packages at or prior to the Point of Sale of an In-Scope Purchase. The following sections provide a discussion of how MED-Project will provide Sharps Mail-Back Packages to Ultimate Users.

[14 CCR 18973.3(f)(2)]

## Including Potential Point of Sale Sites in the Program Identifying Potential Point of Sale Sites

MED-Project will identify Retail pharmacies and Retail pharmacy chains, online retailers, and/or other retailers of Sharps to Ultimate Users using publicly available information from the State Board and via communications
with Covered Entities and MED-Project launched and will continue to conduct
multiple messaging campaigns to participating Covered Entities  , regarding Point of Sale Site participation in the Program. MED-
Project provided communications to participating Covered Entities to issue to Point of Sale Sites asking them to contact
MED-Project about the Program. Covered Entities were provided a communication package to use to communicate to who would hen include information through emails to Point of Sale Sites. This outreach includes prepared materials to share through Sharps distribution channels.
Additionally, MED-Project will contract with a third-party vendor to identify online retailers that sell Sharps directly to consumers in California. MED-Project will select a hird-party vendor experienced in identifying online sellers who perform

legal sales of pharmaceutical products to consumers within the State.

MED-Project will send initial letters to the identified potential Point of Sale Sites notifying them of the requirement under the Law to Provide or Initiate Distribution of a Sharps Waste Container and Mail-Back Materials at the Point of Sale of In-Scope Purchases.

## Engaging Potential Point of Sale Sites to Initiate Distribution of Sharps Waste Containers and Mail-Back Materials at the Point of Sale

After the initial notification, MED-Project will include all potential Point of Sale Sites in the Program by registering them on its online ordering system to initiate the distribution of Sharps Mail-Back Packages and distribute information on how to properly dispose of Sharps. Upon accepting the terms and conditions to use the online ordering system, a non-online Point of Sale Site agrees to begin initiating the distribution of Sharps Mail-Back Packages and distributing information on how to properly dispose of Sharps at the non-online Point of Sale of In-Scope Purchases, in accordance with standard terms. Upon accepting the terms and conditions to use the online ordering system, the online Point of Sale Site agrees to issue information on how to properly dispose of Sharps to the Ultimate User and offers to initiate the distribution of a Sharps Mail-Back Package with every In-Scope Purchase at the Point of Sale.

For any Point of Sale Sites, including those that have not accepted terms and conditions to use the online ordering system by September 5, 2022, MED-Project will also provide access to a phone ordering system for all Point of Sale Sites to begin initiating the distribution of Sharps Mail-Back Packages and provide information on how to properly dispose of Sharps at the Point of Sale of In-Scope Purchases, a system MED-Project is orienting Point of Sale Sites to through thousands of in-person visits. Use of the

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phone ordering system does not require a Point of Sale Site to accept terms and conditions of the MED-Project online ordering system.

## Engaging Potential non-online Point of Sale Sites to Provide Sharps Waste Containers and Mail-Back Materials at the Point of Sale

In addition to initiating the distribution of Sharps Mail-Back Packages, the Program also allows non-online Point of Sale Sites to provide Sharps Mail-Back Packages to Ultimate Users.

MED-Project will execute an agreement with any non-online Point of Sale Site that offers to participate in the Program and provide Sharps Mail-Back Packages for In-Scope Purchases, is able to comply with all applicable laws, regulations, and other legal requirements, and is willing to sign MED-Project's agreement.

Once a non-online Point of Sale Site has executed an agreement to provide Sharps Mail-Back Packages to Ultimate Users, MED-Project will offer the non-online Point of Sale Site Sharps Mail-Back Packages to provide with In-Scope Purchases at the Point of Sale.

Non-online Point of Sale Sites providing Sharps Mail-Back Packages at the Point of Sale of In-Scope Purchases will be able to order additional stock through the online ordering system.

#### **MED-Project Support for all Point of Sale Sites**

MED-Project will continue to support Point of Sale Sites via phone calls, inperson site visits, and other methods. As of the submission of this Plan,
MED-Project has completed over 2,000 in-person visits to non-online Point
of Sale Sites, targeting those non-online Point of Sale Sites that had not yet
activated the online ordering system, and sent over 20,000 emails,10,000
postcards, and 1,500 letters to Point of Sale Sites on how to activate the
online ordering system. MED-Project representatives also completed over
6,500 phone calls to Point of Sale Sites to educate them about the Program
and how to activate the online ordering system. MED-Project has also
featured an information booth at multiple retailer and pharmacy trade
shows to promote program awareness.

MED-Project will conduct outreach over 40,000 times via multiple methods, including over 1,500 letters, over 10,000 postcards, over 20,000 emails,

over 6,500 phone calls, and over 3,000 in-person site visits, by September 5, 2022. MED-Project is conducting these in-person site visits with non-online Point of Sale Sites to, among other things, assist them in using the online and phone ordering systems, and provide materials to promote the Program to Ultimate Users. By September 5, 2022, MED-Project will visit non-online Point of Sale Sites in-person that are not using the online ordering system in order to assist them in activating the online ordering system at their sites. After September 5, 2022, MED-Project will continue to perform in-person site visits through 2022, and into future years, for any new non-online Point of Sale Sites that have not yet accepted the terms and conditions of the online ordering system. **Section 10**: **Education and Outreach to Point of Sale Sites, Pharmacists, Providers, and Other Individuals** provides more detail about MED-Project's ongoing outreach to Point of Sale Sites.

MED-Project will supply information about proper Sharps waste disposal on the package insert with every Sharps Mail-Back Package. See <u>Appendix</u> <u>E</u>. MED-Project will also supply information about proper Sharps waste disposal for Point of Sale Sites to issue to an Ultimate User, including if an Ultimate User forgoes a Point of Sale Site's offer to provide or initiate the distribution of a Sharps Mail-Back Package to the Ultimate User.

MED-Project will also supply Point of Sale Sites with information about proper Sharps waste disposal through the Help Desk. MED-Project will supply Point of Sale Sites with educational materials to provide or initiate the distribution of a Sharps Mail-Back Package to the Ultimate User to accommodate the volume of sharps purchased by an Ultimate User over a 12-month period.

[PRC 42032.2(d)(1)(F)(i), 42032.2(d)(1)(F)(i)(I), 42032.2(d)(1)(F)(i)(II), 14 CCR 18973.3(f)(2)]

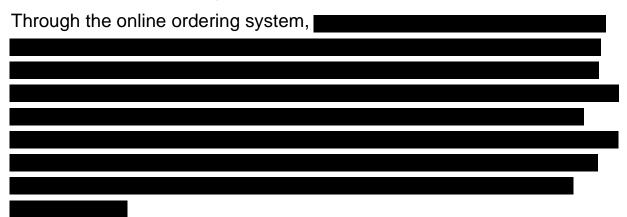
### Providing and Initiating the Distribution of Sharps Mail-Back Packages at the Point of Sale

A Point of Sale Site will offer to provide a Sharps Mail-Back Package or initiate distribution of a Sharps Mail-Back Package to Ultimate Users at the Point of Sale of In-Scope Purchases. If the Ultimate User wants a Sharps Mail-Back Package: (1) at non-online Point of Sale Sites that provide Sharps Mail-Back Packages, the Ultimate User will receive the Sharps

Mail-Back Package at the Point of Sale; (2) at Point of Sale Sites that initiate distribution of Sharps Mail-Back Packages, the Ultimate User will receive a Sharps Mail-Back Package at the Ultimate User's specified address within five business days of the In-Scope Purchase at a Point of Sale.

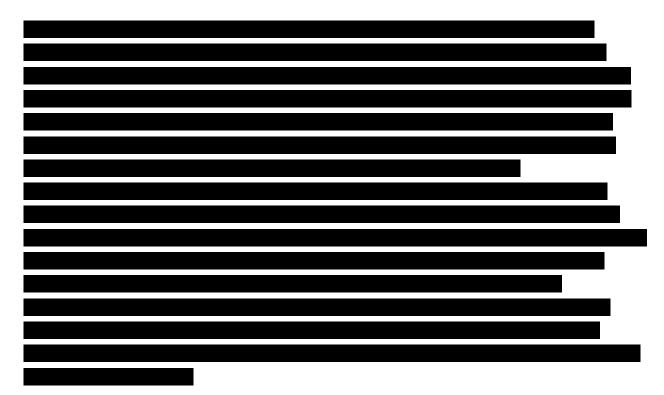
MED-Project's resources and support available through the online ordering system will allow a non-online Point of Sale Site to request that MED-Project send Sharps Mail-Back Packages to the non-online Point of Sale Site in bulk, with a default minimum order quantity of a case of 6 or 12 units. In this scenario, non-online Point of Sale Sites may log onto the MED-Project online ordering system to submit bulk orders by selecting the number of cases to be shipped. Once the bulk order is submitted, the selected number of cases of Sharps Mail-Back Packages will be shipped to the non-online Point of Sale Site. Once the bulk order arrives, the non-online Point of Sale Site has Sharps Mail-Back Packages at hand to provide to Ultimate Users. Upon receipt of the bulk order, the non-online Point of Sale Site directly provides Sharps Mail-Back Packages to Ultimate Users at the time of the In-Scope Purchase at a Point of Sale.

A Point of Sale Site will initiate distribution of a Sharps Mail-Back Package on behalf of an Ultimate User through MED-Project's online ordering system or phone ordering system.



A phone ordering system is also available to initiate distribution of a Sharps Mail-Back Package on behalf of an Ultimate User at the Point of Sale for an In-Scope Purchase, at all Point of Sale Sites and as an alternative to the online ordering system. When used by the Point of Sale Site, the phone ordering system connects the caller to a call center agent that will use the

online ordering system
When a Point of Sale Site initiates the distribution of a Sharps Mail-Back Package at the Point of Sale for an In-Scope Purchase, as described above, MED-Project or a Vendor receives an electronic notification. MED-Project or a Vendor will then ship a Sharps Mail-Back Package to the Ultimate User that arrives at the Ultimate User's specified address within five business days of the In-Scope Purchase at a Point of Sale.
MED-Project information about proper Sharps waste disposal provided with In-Scope Purchases at the Point of Sale will direct Ultimate Users to the Website and Call Center. For additional information about the Program that is provided to Ultimate Users, see <u>Section 10: Education and Outreach Program</u> .
The ability to request Sharps Mail-Back Packages through the Website and Call Center at any time will allow Ultimate Users to receive Sharps Mail-Back Packages to accommodate the volume of Sharps purchased prior to the Point of Sale of In-Scope Purchases. Section 10: Education and Outreach to Ultimate Users provides a description of how MED-Project will promote the availability of Sharps Mail-Back Packages through the Website and Call Center to Ultimate Users. Users will be able to self-assess the number of Sharps Mail-Back Packages required to accommodate the volume of Sharps purchased and request Sharps Mail-Back Packages, at any time, including prior to an In-Scope Purchase at a Point of Sale, through the Call Center and Website.



#### **Availability of Mail-Back Services to Ultimate Users**

Homeless individuals without a permanent address can use any of the services described above throughout the State. When a Point of Sale Site initiates distribution of a Sharps Mail-Back Package to a homeless individual without a permanent address, or when such an individual requests a Sharps Mail-Back Package through the Call Center or Website, MED-Project's systems will allow them to enter addresses of service providers such as shelters, churches, and to use USPS's General Delivery services to receive the Sharps Mail-Back Package in lieu of a permanent address. MED-Project supplied information about USPS General Delivery services to Point of Sale Sites through communications via email, letters, and on-site visits so that Point of Sale Sites can let their customers know about these services. MED-Project also supplies additional information to Point of Sale Sites and Ultimate Users on how to use USPS General Delivery services on the Website, and Call Center. MED-Project provides instructions to Point of Sale Sites on how to ship Sharps Mail-Back Packages to Ultimate Users without a permanent address on the online and phone ordering systems, and through the Help Desk as well. When using USPS General Delivery services, Point of Sales Sites and Ultimate Users are instructed to enter "General Delivery" as the street address, and

then enter the preferred city, state, and ZIP code. USPS General Delivery services allow individuals without a permanent address to receive mail at a USPS facility.

[PRC 42032.2(d)(1)(F)(i), 42032.2(d)(1)(F)(i)(III), 14 CCR 18973.3(f)(2)]

#### **Transportation of Sharps Mail-Back Packages**

Returned Sharps Mail-Back Packages will be transported via Carrier to an approved treatment facility and handled in compliance with all applicable laws, regulations, and other legal requirements. Each Sharps Mail-Back Package provided under the Program will have a unique identifier enabling tracking. Table 2 provides the transporters the Program may use.

Table 2: Transporters

Transporter	Mailing Address	Physical Address
Allied Waste Systems, Inc. DBA Republic Services <sup>4</sup>	14747 San Fernando Rd., Sylmar CA 91342	14747 San Fernando Rd., Sylmar CA 91342
HealthWise Services <sup>5</sup>	4800 E Lincoln Ave, Fowler, CA 93625	4800 E Lincoln Ave, Fowler, CA 93625
MedSharps, LLC	17340 Bell North Drive, Schertz, TX 78154	17340 Bell North Drive, Schertz, TX 78154
Stericycle, Inc.6	2355 Waukegan Road, Bannockburn, IL 60015	2355 Waukegan Road, Bannockburn, IL 60015
United States Postal Service <sup>7</sup>	475 L'Enfant Plaza, SW, Washington, DC 20260	475 L'Enfant Plaza, SW, Washington, DC 20260

<sup>&</sup>lt;sup>4</sup>Transport treated Sharps Mail-Back Packages to California landfills listed in Table 4.

<sup>&</sup>lt;sup>5</sup>lbid.

<sup>&</sup>lt;sup>6</sup>lbid.

<sup>&</sup>lt;sup>7</sup>The United States Postal Service will be used to transport untreated Sharps Mail-Back Packages from Ultimate Users to a treatment facility.

[PRC 42035.8, 14 CCR 18973.3(f)(1)]

## Treatment and Disposal of Sharps Mail-Back Packages

Upon arriving at a treatment facility, Sharps Mail-Back Packages will be scanned for receipt verification and weighed. Sharps will be sterilized by autoclaving and the autoclaved material will then be disposed of in a landfill as solid waste in compliance with all applicable laws, regulations, and other legal requirements.

Table 3 and Table 4 provide the treatment and disposal facilities the Program proposes to use.

Table 3: Treatment Facilities

Treatment Facility	Mailing Address	Physical Address
HealthWise Services8	4800 E Lincoln Ave, Fowler, CA 93625	4800 E Lincoln Ave, Fowler, CA 93625
MedSharps, LLC	17340 Bell N Dr., Schertz, TX 78154	17340 Bell N Dr., Schertz, TX 78154
Stericycle, Inc. Biohazardous Medical Waste Storage, Transfer, and Treatment Facility	245 W. Lodge Dr., Tempe, AZ 85283	245 W. Lodge Dr., Tempe, AZ 85283

<sup>&</sup>lt;sup>8</sup>The United States Postal Service will deliver Sharps Mail-Back Packages to, among other out of state facilities, HealthWise Services, Stericycle, Inc. Fresno, and Stericycle, Inc. Vernon, which are autoclave facilities located in the State, operating under California Department of Public Health permit numbers, TS/OST-89, TS/OST-22, and TS/OST-26 respectively. These facilities use steam sterilization (autoclave) in compliance with HSC § 117600 *et seq.* and 22 CCR 65600 *et seq.* HealthWise Services, Stericycle, Inc. Fresno, and Stericycle, Inc. Vernon do not receive any other type of Mail-Back Package under the Program. No other treatment facilities in the State will receive Sharps Mail-Back Packages.

Treatment Facility	Mailing Address	Physical Address
Stericycle, Inc. Fresno	4135 W Swift Ave, Fresno, CA 93722	4135 W Swift Ave, Fresno, CA 93722
Stericycle, Inc. Vernon	2775 E 26th St, Vernon, CA 90058	2775 E 26th St, Vernon, CA 90058

Table 4: Disposal Facilities

Disposal Facility	Mailing Address	Physical Address
American Avenue Disposal Site	18950 W. American Avenue, Kerman, CA 93630	18950 W. American Avenue, Kerman, CA 93630
Republic Services Apache Junction Landfill	4050 S. Tomahawk Road Apache Junction, AZ 85119	4050 S. Tomahawk Road Apache Junction, AZ 85119
Sunshine Canyon Landfill	Sunshine Canyon Rd, Sylmar, CA 91342	14747 San Fernando Rd., Sylmar, CA 91342
Tessman Road Landfill	7000 E IH 10, San Antonio, TX 78219	7000 E IH 10, San Antonio, TX 78219

[PRC 42035.8, 14 CCR 18973.3(f)(1)]

## **Section 7: Reimbursement to Local Agencies**

Upon request, MED-Project will reimburse Local Agencies for transportation and disposal costs related to Home-Generated Sharps Waste collected at local household hazardous waste facilities. MED-Project has a process to identify household hazardous waste facilities in California and will notify Local Agencies on an annual basis of the opportunity to receive reimbursement from MED-Project for the costs of transportation and disposal of Home-Generated Sharps Waste from household hazardous waste facilities.

A Local Agency may request reimbursement by registering with MED-Project. To register, the Local Agency will provide the facility name, point of contact, and the U.S. Department of the Treasury Internal Revenue Service Form W-9 for the facility receiving reimbursement. In accordance with the Law and Regulations, MED-Project will provide reimbursement to any facility operated by a Local Agency that is properly authorized to accept and manage household hazardous waste.

After registering, the Local Agency may submit a request for reimbursement through the Website that:

- Is limited to the actual costs of transportation and disposal incurred
   270 days or more after Plan approval.
- Includes an invoice for the costs to be reimbursed.
- Is submitted with a declaration under penalty of perjury that the Local Agency has not knowingly requested reimbursement for expenses prohibited by the Law, including for Sharps waste from a needle exchange program or medical waste generator.
- Requires the Local Agency to report on the total amount by weight of Home-Generated Sharps Waste disposed.

A Local Agency that has already registered with MED-Project will not be required to register again to submit additional requests for reimbursement.

MED-Project will respond to Local Agency requests within 14 days and issue payment within 45 days of receipt of the Local Agency's invoice. Reimbursements from MED-Project will be issued with a statement that the Local Agency attests under penalty of perjury that by settling the payment, they are eligible for reimbursement and all reimbursed expenses were

allowed under PRC 42032.2(d)(1)(F)(ii) and 14 CCR 18973.3(g). MED-Project will include the Local Agencies on its Website as collection sites where Ultimate Users may dispose of Home-Generated Sharps Waste.

MED-Project will request from the Local Agency any information under 14 CCR 18973.5(p) to be included in the annual report.

[PRC 42032.2(d)(1)(F)(ii)-42032.2(d)(1)(F)(ii)(IV), 14 CCR 18973.3(g)(1)-18973.3(g)(2)(B), 18973.3(k)]

## **Section 8: Ongoing Support**

MED-Project will manage a Help Desk to provide the following support functions:

- Answer questions and monitor comments from Point of Sale Sites and Local Agencies.
- Direct and respond to requests for support from Point of Sale Sites.
- Receive and fulfill requests from Points of Sale Sites for additional stock of Sharps Mail-Back Packages to provide for In-Scope Purchases.
- Receive and fulfill requests for signage from hospitals, Pharmacies, and other locations upon request.
- Receive and fulfill requests for printed educational and outreach materials for distribution to Ultimate Users from Point of Sale Sites, healthcare providers and other stakeholders who interact with Ultimate Users.
- Provide Point of Sale Sites access to instructional materials, including written instructions, downloadable forms, and/or video instruction guides.
- Provide Point of Sale Sites information about USPS General Delivery services.
- Accept Local Agency requests for reimbursement allowed under PRC 42032.2(d)(1)(F)(ii) and 14 CCR 18973.3(g).

The sections on <u>Section 6: Mail-Back Program</u> and <u>Section 10:</u>
<u>Education and Outreach Program</u> provide more information about Help Desk services.

## **Section 9: Repeal of Local Programs**

Pursuant to PRC 42032.2(e) and 42036.2, if a Local Jurisdiction repeals its local stewardship program ordinance, MED-Project will expand the Program into that Local Jurisdiction within 270 days of the effective date of the local stewardship program ordinance repeal. During this period, MED-Project will:

- Transition MED-Project program in the Local Jurisdiction into the Program services, as applicable.
- Assess implementation requirements to expand the Program into the Local Jurisdiction.
- Establish a schedule to expand the Program, including the education and outreach program, into the Local Jurisdiction.
- Provide CalRecycle with updated participating Covered Entity list, as applicable.

Within 270 days after the effective date of the local stewardship program ordinance repeal, MED-Project will provide services in the Local Jurisdiction consistent with those described in the Plan.

[PRC 42032.2(e), 14 CCR 18973.3(h)]

## **Section 10: Education and Outreach Program**

MED-Project will conduct a comprehensive education and outreach program to promote awareness and maximize Ultimate User participation in the Program. MED-Project's education and outreach program will:

- Promote the Program to Ultimate Users by providing signage for hospitals, Pharmacies, and other locations, as necessary.
- Provide educational and outreach materials for persons authorized to prescribe drugs, Pharmacies, pharmacists, Ultimate Users, and others, as necessary.
- Provide information on the Program, including disposal options, and receive requests for Sharps Mail-Back Packages from Ultimate Users through the Website and Call Center.
- Provide information about USPS General Delivery services to Ultimate Users through the Website and Call Center.
- Provide additional outreach materials as needed to promote the collection and proper management of Home-Generated Sharps Waste.
- Encourage Ultimate Users to separate products that are not covered products from Covered Products before disposing of them through the Program.

MED-Project will promote Program participation to the following target audiences:

- 1. Ultimate Users.
- 2. Point of Sale Sites, Pharmacists, Providers, and Other Individuals.

The education and outreach program will reach target audiences through a variety of media channels and formats to:

 Inform Ultimate Users where, why, and how to dispose of Home-Generated Sharps Waste safely.

 Encourage participation from a variety of private businesses and public agencies.

- Account for the diverse media consumption habits, behaviors, and motivating factors of Ultimate Users, businesses, and stakeholders across the state.
- Improve message retention.

Appendix F provides an initial media and outreach plan for the first two years of Program operation.

The MED-Project outreach and education program will not promote the disposal of Home-Generated Sharps Waste in a manner that is inconsistent with the services offered to Ultimate Users by the Program, including through messaging on its signage, educational and outreach materials, and Website.

[PRC 42031.6(a), 42031.6(a)(2), 42031.6(a)(4), 42031.6(a)(5), 42031.6(b), 42032.2(f), 14 CCR 18973.3(i)(6), 18973.3(i)(7)]

#### **Education and Outreach to Ultimate Users**

The following sections describe elements of MED-Project's education and outreach program to Ultimate Users.

#### **Ultimate User Audiences**

- Ultimate User.
- General Public.
- Consumers.
- Patients.

#### **Ultimate User Key Messages**

- Importance of safe handling and proper disposal.
- How to properly dispose.
- What services are available.
- How to access these services.
- How to use USPS General Delivery services.
- What items are covered/not covered in the Program.

#### **Ultimate User Outreach Methods**

- Website.
- Toll-free phone number.
- Educational communications.
- Public Service Announcements.
- Online advertising.
- Traditional and social media.
- Special events (community fairs, etc.).

#### **Educational and Outreach Materials**

MED-Project will provide educational and outreach materials to entities participating in the Program and, upon request or through the Help Desk, to persons authorized to prescribe drugs, Pharmacies, pharmacists, Ultimate Users, and others as necessary. Educational and outreach materials will:

- Be translated into English and Spanish when provided as a printed hard copy. MED-Project's printed materials will feature universally recognized translation icons that direct Ultimate Users to the Website to view or print translated documents. The tool MED-Project uses to provide translations is similar to the one the State uses to provide translations of its website. MED-Project's Website and/or Call Center will support translation into all of the languages specified per the most recent available California Secretary of State's voting materials language requirements, which accounts for local demographics consistent with section 7295 of the Government Code.
- Be provided in a printable online version with translations available through a third-party translation tool in languages suited to local demographics, consistent with section 7295 of the Government Code, which requires that any materials explaining services available to the public be translated into non-English languages spoken by a "substantial number of public." To satisfy this requirement, MED-Project will use a Google Translate based product to provide translations in over 100 languages, covering 95% of spoken languages at the county level.
- Instruct Ultimate Users to separate products that are not covered products from Covered Products before disposing of them through the Program.

<u>Appendix G</u> provides sample images of MED-Project educational and outreach materials.

[PRC 42031.6(a)(2), 14 CCR 18973.3(i)(1)]

## Signage for Hospitals, Pharmacies, and Other Locations

MED-Project will promote the Program to Ultimate Users by providing signage and materials free of charge for hospitals, Pharmacies, and other locations upon request or through the Help Desk. The signage and printed materials will:

- Be translated into English and Spanish when provided as a printed hard copy.
- Be provided in printable online version with translations available through a third-party translation tool in languages suited to local demographics, consistent with section 7295 of the Government Code, which requires that any materials explaining services available to the public be translated into non-English languages spoken by a "substantial number of public." To satisfy this requirement, MED-Project will use a Google Translate based product to provide translations in over 100 languages, covering 95% of spoken languages at the county level.
- Use plain language and explanatory graphics to promote the Program in a way that is readily understandable to Ultimate Users.

<u>Appendix H</u> provides sample images of MED-Project signage for hospitals, Pharmacies, and other locations.

[PRC 42031.6(a)(1), 14 CCR 18973.3(i)(2)]

#### **Website for Ultimate Users**

MED-Project will establish a Website that provides information intended to promote the use of the Program. The Website will be:

- Mobile responsive and accessible by common device and browser systems.
- Translated into languages suited to local demographics using a thirdparty translation tool, consistent with section 7295 of the Government Code, which requires that any materials explaining services available to the public be translated into non-English languages spoken by a

"substantial number of public." To satisfy this requirement, MED-Project will use a Google Translate based product to provide translations in over 100 languages, covering 95% of spoken languages at the county level.

- Maintained to ensure all information is up-to-date and accurate.
- Evaluated for conformance to WCAG 2.1 Level A & AA and updated as required to provide accessibility to disabled individuals in compliance with section 7405 of the Government Code and the Web Content Accessibility Guidelines 2.0.

#### Website content will provide:

- Instructions for safe handling and proper disposal of Home-Generated Sharps Waste, including instructions to separate products that are not covered products from Covered Products before depositing them into a Sharps Mail-Back Package.
- A calendar of community events.
- A web form to accept requests for Sharps Mail-Back Packages from Ultimate Users. The web form will allow Ultimate Users to select the type and quantity of Sharps Mail-Back Packages and enter their name and shipping address for fulfillment.
- Information about how to use USPS General Delivery services.
- User-friendly access to public service announcements used in MED-Project's media campaigns.
- Links to MED-Project's social media webpages.
- Direct links to the nearest household hazardous waste facilities:
  - o Household Hazardous Waste Facilities Sorted by City.
  - Home-Generated Sharps and Pharmaceutical Consolidation Points.

The Website will communicate information in multiple formats, including:

- Video.
- Audio.
- Text.
- Explanatory graphics.
- Printable materials.

<u>Appendix I</u> provides a sample mockup of the Website and its supporting pages. <u>Appendix J</u> provides a Program implementation timeline with details about the timing of the launch of the Website.

[PRC 42031.6(a)(3), 14 CCR 18973.3(i)(3)]

#### **Call Center**

MED-Project will establish a Call Center to serve as an option for Ultimate Users to request Sharps Mail-Back Packages and to obtain information about the Program. The Call Center will provide:

- An interactive voice response system in English and Spanish.
   Ultimate Users will be given the option, in English, to continue in their preferred language after being offered English or Spanish.
- Human representatives to receive requests for services and questions about the Program from Ultimate Users.
- Translators available to provide language options suited to local demographics.
- Teletype services for hearing- and speech-impaired Ultimate Users.
- Instructions for safe handling and proper disposal of Home-Generated Sharps Waste, including instructions to separate products that are not covered products from Covered Products before depositing them into a Sharps Mail-Back Package.
- A mechanism to accept requests for Sharps Mail-Back Packages from Ultimate Users and information about how to use USPS General Delivery services.
- Information on collection options for Home-Generated Sharps Waste, including a ZIP code-based map locator to help Ultimate Users find the nearest household hazardous waste facilities that accept Home-Generated Sharps Waste, including location address, phone number, and hours of operation.

<u>Appendix J</u> provides a Program implementation timeline with details about the timing of the launch of the Call Center. <u>Appendix K</u> provides the sample Call Center flow.

[14 CCR 18973.3(i)(4)]

#### **Public Service Announcements**

The public service announcements will include multiple video, audio, and static media variants highlighting safe handling and proper disposal of Home-Generated Sharps Waste. The messaging will target Ultimate Users aged 18 and over. The messaging will include information about the proper and safe disposal of Home-Generated Sharps Waste. Depending on local considerations, additional paid advertising channels may include:

- Direct mail.
- Out-of-home and/or outdoor media.
- Social media influencers and sponsorships.
- Digital media.
- Advertisement targeting.

[PRC 42031.6(a)(4)]

## **Digital and Online Media**

MED-Project will seek to participate in advertising for non-profit organizations such as Google Ad Grants or other similar programs. MED-Project will launch a statewide campaign specifically targeting individuals with inquiries related to the disposal of Home-Generated Sharps Waste, such as home health care lifestyle-related keywords.

[PRC 42031.6(a)(4)]

#### **Traditional and Social Media**

MED-Project will distribute press releases directly to major media outlets and local media. In addition, MED-Project will provide a template for press releases and emails to partners and local health officials to spread through their own networks, allowing for customized news and announcements with specific details about their jurisdiction, organization, agency, or business.

MED-Project will provide education and outreach by utilizing a variety of methods and communication channels throughout the year. The methods will target Ultimate Users aged 18 and over and will be scheduled to maximize awareness of the Program, while also taking into account the timing of relevant community events, such as Earth Day. This approach has shown to increase the scope and diversity of the audience reached while also improving message retention.

To provide geographic dispersal of advertising across the State, MED-Project will execute advertising campaigns in each of the State's Designated Market Areas (DMAs).

MED-Project will maintain a social media presence on major platforms featuring relevant information, Program news and developments, frequently asked questions, and video/audio content. Ultimate User inquiries on the platform will be directed to contact the Call Center or visit the Website for a response.

[PRC 42031.6(a)(4)]

### **Special Events**

MED-Project will arrange to participate in relevant and compatible community events, such as Earth Day, to inform Ultimate Users of the Program. MED-Project will also work with local community organizations on events where coordinated efforts are appropriate.

[PRC 42031.6(a)(4)]

#### **Ultimate User Feedback**

MED-Project will solicit feedback from Ultimate Users through two or more survey methods on channels that include:

- Website.
- Mobile applications.
- Digital media.
- Telephone.

MED-Project efforts to obtain Ultimate User feedback will be designed to determine:

- The percentage of Ultimate Users that are aware of the Program or exposed to the education and outreach program.
- The percentage of Ultimate Users that have used the Program.
- The percentage of Ultimate Users that believe the Program is accessible and easy to use.

MED-Project will use this feedback to improve Program effectiveness in the following areas:

- Messaging.
- Outreach to Ultimate Users through various communication channels or tools.
- Availability of Mail-Back Services for Ultimate Users through the Website and Call Center.

# **Education and Outreach to Point of Sale Sites, Pharmacists, Providers, and Other Individuals**

MED-Project will perform education and outreach to promote the Program to Point of Sale Sites. These businesses are the most closely involved entities to the Point of Sale of In-Scope Purchases, where information is provided and Sharps Mail-Back Packages must be either provided or distribution initiated to Ultimate Users who make In Scope Purchases. MED-Project will also connect with healthcare providers and other stakeholders who interact with Ultimate Users to provide medical recommendations and education about the opportunity to distribute printed materials about the Program. MED-Project will engage with Covered Entities that interface with Point of Sale Sites, to communicate information about participating in the Program.

#### **Outreach to Point of Sale Sites**

#### **Point of Sale Site Audiences**

- Retail pharmacies.
- Retail pharmacy chains.
- Other retailers.
- Online retailers.
- Healthcare providers and persons authorized to prescribe drugs (pharmacists, doctors, general practitioners, health/medical specialists, dentists, clinicians).
- Veterinarians.
- Hospitals.
- Local law enforcement.
- Local governmental agencies.

- State governmental agencies.
- Household hazardous waste facilities.
- Non-governmental organizations.
- Community organizations.

#### **Point of Sale Site Key Messages**

- What is the Program.
- What services are part of the Program.
- How to participate in the Program.
- How to comply.
- Where/how to obtain information on requirements.
- How to use the Help Desk, and online and phone ordering systems.
- How to use USPS General Delivery services.

#### **Point of Sale Site Methods**

- Website.
- Videos.
- Direct communication.
- Direct mail and outreach.
- Traditional and social media events.
- Printed materials.
- Industry associations or organization events.
- Presentations.
- In-person visits to Point of Sale Sites.

#### **Website for Point of Sale Sites**

MED-Project will establish a Website intended to educate Point of Sale Sites and other stakeholders about the Program. The Website content is tailored to share relevant details and information that will be useful for the target audience to learn more about the Program and how they can participate.

#### **Video Series**

MED-Project will produce a series of educational videos for Point of Sale Sites to simplify outreach and communications:

- Program Overview: An overview of the State's requirements regarding educating the public and offering mail-back materials.
- How to Participate: A detailed breakdown of what is involved in the Program and how to provide or initiate distribution of Sharps Mail-Back Packages, including the end-user experience and the responsibilities of the site.
- Getting Started: A step-by-step walkthrough of the onboarding process.
- Restocking Materials: A step-by-step walkthrough of how to maintain a supply of educational materials and/or Sharps Mail-Back Packages.

#### **Direct Communication**

MED-Project maintains an account management team that is fully dedicated to building and maintaining relationships with Point of Sale Sites, and other stakeholders, such as Covered Entities , both at a corporate and individual site level. This team also manages in-person and virtual meetings and presentations with decision-makers at Point of Sale Sites, and other stakeholders, such as Covered Entities , to promote the Program.

MED-Project will provide three levels of support to Point of Sale Sites:

- Account Management Team: Manages communications at a corporate or brand level.
- 2. Operations Support Staff: Serves as the direct points-of-contact for individual Point of Sale Sites at the local level. Operations support staff assist with outreach, onboarding, staff orientation and education, ongoing in-person site visits to new non-online Point of Sale Sites that are not activated on the online ordering system, and monitoring Sharps Mail-Back Package usage at Point of Sale Sites or replenishment to help Point of Sale Sites maintain a sufficient stock of Sharps Mail-Back Packages.
- 3. Help Desk: Features online and phone support along with full access to multimedia guidance materials. Point of Sale Sites can also order

additional Sharp Mail-Back Packages and/or printed materials for distribution to Ultimate Users at no cost to the Point of Sale Sites.

#### **Direct Mail and Outreach**

MED-Project will promote Program awareness through methods like:

- Direct mail of educational materials to a targeted list: MED-Project will distribute printed materials to create awareness and provide updates or communicate changes to participating businesses and individuals.
- Outreach via email and presentations to Point of Sale Sites, and other stakeholders, such as Covered Entities
   promoting the Program and information about participation for Point of Sale Sites.
- Press/Media Relations: MED-Project will distribute press releases, alerts, and guest-submitted articles to relevant industry publications in the State.
- Media Placement: MED-Project will secure advertising in industryspecific publications, periodicals, and newsletters.
- Printed Materials: MED-Project will provide the educational and outreach materials described in the section on **Section 10**:
   <u>Educational and Outreach Materials</u> for distribution to Ultimate Users.

#### **Traditional and Social Media**

MED-Project will distribute press releases directly to major media outlets and local media and will provide templates for press releases and emails to partners and local health officials to spread throughout their own networks, allowing for customized announcements that offer specific details about their jurisdiction, organization, agency, or business.

MED-Project will also use its social media platforms to supplement outreach activity and perform efforts to assist in the distribution of information that builds awareness.

## **Industry Associations and Events**

MED-Project will arrange to establish and maintain a presence at key industry events, conferences and/or tradeshows targeting point of sale site staff, pharmacists and/or healthcare providers. MED-Project participation

would include activities such as organizing a booth presence or advertising opportunities.

## **Section 11: Metrics**

The following sections provide the metrics MED-Project will use to measure Program performance.

[14 CCR 18973.3(f)(6), 18973.3(f)(8), 18973.3(i)(5)]

# **Sharps Mail-Back Packages Distributed and Home- Generated Sharps Waste Returned**

MED-Project will use the following metrics to measure participation in the Program and the number of Sharps Mail-Back Packages distributed by county and Home-Generated Sharps Waste returned:

- The number of Point of Sale Sites that have accepted the terms and conditions to participate in the Program using the online ordering system to initiate the distribution of Sharps Mail-Back Packages at the Point of Sale of In-Scope Purchases.
- The number of non-online Point of Sale Sites that have executed an agreement to participate in the Program and provide Sharps Mail-Back Packages for In-Scope Purchases at the Point of Sale.
- The number of Sharps Mail-Back Packages distributed to Point of Sale Sites to provide at the Point of Sale of In-Scope Purchases.
- The number of Sharps Mail-Back Packages initiated at the Point of Sale of In-Scope Purchases via the online ordering system.
- The number of Sharps Mail-Back Packages initiated at the Point of Sale of In-Scope Purchases via the phone ordering system.
- The number of Sharps Mail-Back Packages requested by Ultimate Users and distributed through the Website.
- The number of Sharps Mail-Back Packages requested by Ultimate Users and distributed through the Call Center.
- Amount by weight of Home-Generated Sharps Waste returned.

[14 CCR 18973.3(f)(6)]

# Home-Generated Sharps Waste Collected by Household Hazardous Waste Facilities

MED-Project will collect the following metrics to measure the amount of Home-Generated Sharps Waste collected by household hazardous waste facilities operated by Local Agencies that request reimbursement:

- Name and location of household hazardous waste facilities receiving reimbursement.
- Reimbursement total by facility.
- Total amount by weight of home-generated sharps waste disposed as reported to MED-Project.

[14 CCR 18973.3(f)(8)]

# Performance of the Comprehensive Education and Outreach Program

In addition to the metrics described in Section 11: Sharps Mail-Back
Packages Distributed and Home-Generated Sharps Waste Returned
and Section 11: Home-Generated Sharps Waste Collected by
Household Hazardous Waste Facilities, MED-Project will measure
results of the education and outreach program using the following metrics:

### **Education and Outreach Overall Program Awareness**

- Percent of respondents aware of the Program.
- Accessibility/ease of use.

### **Education and Outreach Program Participation**

- Engagement with the Website.
- Engagement with the Call Center.

#### **Education and Outreach Media-Related Statistical Data**

- Reach relative to population aged 18 and over.
- Per-campaign impressions.
- Number of media placements.
- Complete list of placements by date and time.
- Number of visits to the Website.
- Numbers of calls to the Call Center.

#### **Education and Outreach General Statistical Data**

 Amount of printable materials and signage distributed to Point of Sale Sites, hospitals, Pharmacies, and other locations.



[14 CCR 18973.3(i)(5)]

## **Section 12: Coordination Efforts**

MED-Project will comply with its obligations to coordinate with other Program Operators under Regulations § 18973.3(j). After CalRecycle's approval of another Program Operator, in an effort to coordinate with that Program Operator, MED-Project will: (1) contact the Program Operator with an offer to confer on coordination under the Regulations; (2) propose a schedule for such coordination; and (3) propose terms for coordination of the Stewardship Programs. The following sections describe the basic elements of the coordination terms MED-Project proposes. When applicable to its coordination efforts (or otherwise), MED-Project will comply with 14 CCR 18973.1(i).

[14 CCR 18973.3(j)]

### **Coordination: Education and Outreach**

Each Program Operator will meet the education and outreach requirements established by the Law and Regulations independently. MED-Project proposes that all Program Operators develop a common Stewardship Program decal, emblem, or logo that can be used on the Website and on educational and outreach materials, as appropriate to identify Stewardship Program services to the public and all program participants.

#### **Coordination: Website**

MED-Project proposes that all Program Operators will use a neutrally branded and unique Stewardship Program website that conforms to WCAG 2.1 Level A & AA to serve as a combined website directory webpage to distribute web traffic to all approved Stewardship Programs. The neutrally branded website directory webpage would provide:

- A mechanism for Ultimate Users to submit requests for sharps waste containers and mail-back materials. Requests would be divided and forwarded equally among approved Program Operators, as appropriate. This will supersede the corresponding webpage on the Website, described in **Section 10: Website for Ultimate Users**.
- A directory or listing of approved Stewardship Programs which would direct Ultimate Users to each Program Operator's website where their services will be available.

MED-Project would direct Ultimate Users who initially visit the Website to the neutrally branded website.

#### **Coordination: Call Center**

MED-Project proposes that all Program Operators would use a neutrally branded, toll-free telephone number to serve as a combined call center directory to distribute calls from Ultimate Users to all approved Stewardship Programs. Calls from Ultimate Users would be divided and forwarded equally among approved Program Operators' toll-free telephone numbers, as appropriate. For example, calls inquiring about sharps waste containers and mail-back materials would be routed equally among approved Program Operators. Calls inquiring about additional services would be routed equally among approved Program Operators providing the additional service(s) requested.

## **Section 13: Compliance with Applicable Laws**

The following sections provide an overview of how MED-Project's Program is designed to comply with all applicable laws, regulations, and other legal requirements.

[PRC 42032.2(d)(1)(D), 42035.8, 14 CCR 18973(f)(1)]

## **MED-Project Agreements**

MED-Project contracts and agreements with Vendor(s) involved in the collection and disposal of Home-Generated Sharps Waste collected under the Program and Point of Sale Sites require compliance with all applicable laws, regulations, and other legal requirements. Below is a summary of some of the elements of those agreements.

#### **Vendor Contracts**

MED-Project contracts for Vendors involved in the collection and disposal of Home-Generated Sharps Waste collected under the Program generally require that Vendor:

- Follow all applicable laws, regulations, and other legal requirements.
- Maintain all professional and governmental permits, licenses, consents, authorizations, and certifications required by applicable laws for the performance of Program services.
- Provide Program services in a timely, professional, and commercially diligent manner according to generally accepted industry and professional standards.
- Maintain complete and accurate documents of matters relating to the services to demonstrate compliance as required by applicable laws.
- Implement procedures and safeguards to prevent workplace hazards, including procedures and safeguards to prevent industry-specific workplace hazards.
- Immediately notify MED-Project of any action, suit, or proceeding before or by any court or governmental authority that could materially affect Vendor ability to provide Program services.
- Obtain written pre-approval before changing transporters or disposal facilities.

- Report safety, security, or other procedural deviations, including but not limited to as required by applicable laws, regulations, and other legal requirements.
- Maintain comprehensive information security programs and notify MED-Project in the event of a data breach.
- Maintain complete and accurate records, such as books, documents, and accounting procedures and practices. MED-Project may audit such records.
- Provide written reports related to Program services.

## **Point of Sale Site Agreements**

MED-Project agreements for Point of Sale Sites with physical locations that provide or initiate distribution of Sharps Mail-Back Packages to Ultimate Users at the Point of Sale of In-Scope Purchases generally require that the Point of Sale Site:

- Notify Ultimate Users at the Point of Sale of the opportunity to receive a Sharps Mail-Back Package with In-Scope Purchases.
- Provide or initiate distribution of a Sharps Mail-Back Package to Ultimate Users free of charge.
- Complete documentation under all applicable laws for providing or initiating distribution of Sharp Mail-Back Packages.
- Securely maintain documentation required under the Program and provide such documentation to MED-Project upon request.

## **United States Department of Transportation**

When transporting Home-Generated Sharps Waste in Sharps Mail-Back Packages, Vendor will comply with the DOT Hazardous Materials Regulations. Shipments of Home-Generated Sharps Waste in Sharps Mail-Back Packages will comply with applicable shipping papers, packaging, placarding, and other requirements as set forth by DOT Hazardous Materials Regulations.

Home-Generated Sharps Waste collected via Sharps Mail-Back Packages will be packaged and mailed in compliance with applicable United States Postal Service ("USPS") requirements.

## **California Department of Public Health**

When transporting and/or treating Sharps, MED-Project and its Vendors will comply with all applicable laws, including the California Health and Safety Code.

### **Section 14: Policies and Procedures**

The following sections provide a description of the policies and procedures maintained by MED-Project, Vendor, and any other relevant entities participating in the Program.

[14 CCR 18973.3(f)(1)]

## **Collection, Transportation, and Disposal**

MED-Project will enter into agreements with all relevant entities participating in the Program. Agreements with Vendors involved in the collection and disposal of Home-Generated Sharps Waste require that all persons handling or disposing of Home-Generated Sharps Waste comply with all applicable laws, regulations, and other legal requirements.

Agreements with Vendors will also require that they comply with all applicable laws, regulations, and other legal requirements. Sharps Mail-Back Packages provided under the Program will have a unique identifier enabling tracking. MED-Project's Vendors involved in the collection and disposal of Home-Generated Sharps Waste monitor the related tracking data and report to MED-Project.

[PRC 42032.2(d)(1)(D)]

#### **Record Maintenance**

MED-Project has policies and procedures in place to properly maintain its internal records, including the records required to meet its reporting obligations and to manage its Program. MED-Project's record maintenance system:

- Maintains records electronically on cloud-based business collaboration, document management, and customer relationship management platforms.
- Secures data through user and group level security policies.
- Is backed up on a predetermined schedule.

MED-Project's records include, but may not be limited to:

- Minutes, books, and records that clearly reflect the activities and transactions of the Program.
- Information about Sharps Mail-Back Package distribution (i.e., number of Mail-Back Packages distributed in the State).
- Information about receipt of returned Sharps Mail-Back Packages (i.e., amount by weight of Home-Generated Sharps Waste returned).
- Documentation of treatment of Home-Generated Sharps Waste (i.e., facility destination records).

MED-Project will maintain records as required by all applicable laws, including the Law and Regulations. MED-Project also requires that its Vendors maintain certain records as required under the Law and Regulations.

MED-Project minutes, books, and Program records will be audited annually by a certified public accountant, and the audit will be delivered to CalRecycle with the annual report and Program budget.

[PRC 42033.4(a)-42033.4(b)(2), 42035.6(b), 14 CCR 18973.3(f)(3), 18974(a), 18974(b), 18974(c)]

## **Discovery of Critical Instances of Noncompliance**

MED-Project policies and procedures require that if any critical instances of noncompliance with Plan policies and procedures are discovered, MED-Project will identify corrective actions and implement them to correct the noncompliance. MED-Project's corrective actions will depend on the incident, but examples could include training initiatives, monitoring, and implementing changes to policies or procedures.

[14 CCR 18973.3(f)(9)]

## Safety and Security Problem Management

MED-Project has an incident management system that requires evaluation of incidents for potential safety and security problems. MED-Project agreements require Vendors involved in the collection and disposal of Home-Generated Sharps Waste to report security problems. Whenever safety and security problems are identified, MED-Project or the Vendor undertake a root cause analysis to identify and implement corrective

actions, which, depending on the problem, could include training initiatives, monitoring, and implementing changes to policies and procedures. MED-Project will report safety and security problems as required. MED-Project will notify involved parties of incidents for potential safety and security problems, as applicable.

[PRC 42032.2(a)(1)(H), 14 CCR 18973.3(f)(5)(A)(iv)]

#### **Selection of Service Providers**

MED-Project maintains and follows policies and procedures for selecting service providers. Under these policies and procedures, MED-Project determines when to use a competitive bidding process, including issuing requests for proposals, to select service providers based on several risk factors, including:

- Annual contract value.
- Service provider field and competitive landscape.
- Existing cost and quality of service.
- Risk to fulfilling legal responsibilities.

When MED-Project issues requests for proposals, MED-Project follows a process that includes sending a request for proposals to a qualified service provider field and reviewing the proposals in a manner designed to meet anti-trust and competitive bidding process guidelines. MED-Project periodically reviews service provider agreements to determine if a competitive bidding cycle should be implemented to achieve competitive cost and quality in maintaining services.

[14 CCR 18973.3(I)]

# **Section 15: Reporting**

By March 31, 2022, and by each subsequent March 31<sup>st</sup>, MED-Project will submit an annual report to CalRecycle describing Program activities during the previous reporting period. The annual report will be submitted in accordance with the requirements under PRC 42033.2(b) and 14 CCR 18973.5.

[PRC 42033.2(a)(1), 42033.2(b)-42033.2(b)(9), 14 CCR 18973.5]

# **Section 16: Regulatory Mapping**

**Appendix L** provides a map of the components of the Plan to the requirements in the applicable sections of the Regulations.

**Appendix M** provides a description of how MED-Project satisfies the June 23, 2022, Request for Approval Conditions.

# **Appendix A**

# **Participating Covered Entities**

The full list of participating Covered Entities as of March 1, 2022 was provided in a separate, accessible Excel spreadsheet as an attachment with the Plan.

## **Appendix B**

# **Sharps Sold or Offered for Sale by Participating Covered Entities**

MED-Project provided the list of Sharps sold or offered for sale by each participating Covered Entity to the State Board on January 14, 2022, in a separate accessible Excel spreadsheet. The January 14, 2022, list will be submitted with this Plan as an accessible Excel spreadsheet.

# **Appendix C**

## **State Board Determination Letter**

Below is the Plan determination provided by the State Board on August 6, 2021.



California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

Phone: (916) 518-3100 Fax: (916) 574-8618

www.pharmacy.ca.gov



#### VIA REGULAR MAIL AND EMAIL

August 6, 2021

Jim Wilson Lead Director, Legal and Compliance MED-Project USA 1800 M Street, NW Suite 400 South Washington, D.C. 20036 jwilson@med-project.org

Dear Mr. Wilson:

Pursuant to Section 42032(b) of the Public Resources Code, this letter constitutes the Board of Pharmacy's (Board) response to the MED-Project plan for Sharps you submitted to the Board on May 12, 2021 entitled "MED-Project USA Stewardship Plan For Home-Generated Sharps Waste" (Plan). We believe that your Plan complies with pharmacy law of California.

Our review was based solely on California pharmacy law. In evaluating your Plan for compliance with pharmacy law, the Board relied upon the facts and details contained in the Plan. Please note that any different or additional facts in the design or operation of your Plan could result in a different conclusion.

Please note: For certain facilities or pharmacies overseen by other agencies or boards, there could be additional requirements for those types of facilities. As such, the Board's determination of compliance should not be interpreted as a determination of full compliance with all legal provisions.

Sincerely,

Lyle Matthews, Pharm.D., MAM Assistant Executive Officer California State Board of Pharmacy

Cc: Jason Smyth – CalRecycle

# **California Department of Public Health Determination**

Below is the Plan determination provided by the California Department of Public Health on September 10, 2021.

# California Department of Public Health Determination of Compliance Dated September 10, 2021



State of California—Health and Human Services Agency California Department of Public Health



September 10, 2021

Mr. Jim Wilson Lead Director, Legal and Compliance MED-Project USA 1800 M Street, NW, Suite 400 S Washington, DC 20036

# RE: Product Stewardship Plan for Covered Sharps from Households; DETERMINATION OF COMPLIANCE

Dear Mr. Wilson:

The Medical Waste Management Program of the California Department of Public Health (Department) has reviewed the MED-Project USA Stewardship Plan (Plan) to become an approved program operator through California's Pharmaceutical and Sharps Waste Stewardship Program (established by Senate Bill 212) to operate sharps take-back programs in cities and counties in California.

The Department determined that the redline Plan submitted on September 9, 2021 is compliant with the Medical Waste Management Act, California Health and Safety Code Section 117600 et seq.

If you have any questions or need further assistance regarding the Department's review, please feel free to contact me directly by phone at 916-210-8533 or via email at **Thomas.Horner@cdph.ca.gov**.

Sincerely,

Thomas Horner
Date: 2021.09.10
11:49:05-07'00'

Thomas Horner

Senior Environmental Scientist

Chief, Medical Waste Management Program

PHAB

Advantage

Selection of Health Dispersion

Advantage

Advant

#### **Certifications**

As required by 14 CCR § 18973(d), I hereby declare, under penalty of perjury, that the information provided in this document is true and correct, to the best of my knowledge.

Additionally, as required by 14 CCR § 18973.3(d)(2), I hereby certify that, at the time of submission to the Department, the stewardship plan, including all aspects of the plan related to the handling, transportation, and disposal of Home-Generated Sharps Waste is in compliance with all applicable local, state, and federal laws and regulations.

Jim Wilson

Lead Director, Legal and Compliance

MED-Project USA

1800 M Street, NW

Suite 400 South

Washington, DC 20036

Phone: 1 (833) 633-7765 Fax: 1 (866) 633-1812

<u>california@med-project.org</u> www.med-projectusa.org

The M Street address is both the mailing and physical address.

## **Appendix D**

## **Five-Year Initial Program Budget**

#### **Total Revenue**

- 2021: \$389,838

- 2022: \$4,928,150

- 2023: \$9,911,628

- 2024: \$8,568,094

- 2025: \$8,217,522

## **Total Program Costs**

- 2021: \$389,838

- 2022: \$4,928,150

- 2023: \$9,911,628

- 2024: \$8,568,094

- 2025: \$8,217,522

## Capital Costs (Including, but Not Limited to, Fixed, One-Time, Tangible Purchases)

- 2021: \$0

- 2022: \$0

- 2023: \$0

- 2024: \$0

- 2025: \$0

# **Costs of Collection, Transportation, and Disposal of Covered Products**

- 2021: \$104,990

- 2022: \$2,449,736

- 2023: \$5,504,894

- 2024: \$5,486,205

- 2025: \$5,411,389

#### **Administrative Costs**

- 2021: \$237,838

- 2022: \$1,988,481

- 2023: \$2,023,815

- 2024: \$1,829,423

- 2025: \$1,580,027

## **Departmental Administrative Fee Costs**

See note.<sup>1</sup>

- 2021: \$-

- 2022: \$-

- 2023: \$1,571,430

- 2024: \$455,667

- 2025: \$457,583

#### **Education and Outreach Costs**

- 2021: \$47,009

- 2022: \$489,933

- 2023: \$811,489

- 2024: \$796,798

- 2025: \$768,522

# Grant, Loan, Sponsorships, or Other Incentive Costs (As Part of Program Implementation)

- 2021: \$0

- 2022: \$0

- 2023: \$0

- 2024: \$0

- 2025: \$0

<sup>&</sup>lt;sup>1</sup>The Law provides that Program Operators must pay the first administrative fee "[o]n or before the end of the 2022-23 fiscal year." PRC § 42034.2(a)(1). This budget accordingly provides for the payment in 2023 of administrative fees accrued prior to 2023. The estimated Departmental Administrative Fee is based on a CalRecycle document provided to MED-Project on January 20, 2022.

## Reserve

- 2021: \$97,460

- 2022: \$1,232,038

- 2023: \$2,477,907

- 2024: \$2,142,023

- 2025: \$2,054,381

# **Appendix E**

# **Sample Sharps Mail-Back Package**



Figure 1: Biohazard Container and Sharps and Injector Mail-Back Package Shipping Label/Box

## Sample Sharps Mail-Back Package Insert

MAIL-BACK PACKAGE IS FOR SHARPS



**NOTE:** The following are not accepted in Sharps Mail-Back Packages: Controlled substances (such as opioids), unwanted medicine separate from sharps, batteries, illicit or illegal drugs, and biologics (such as insulin).

Please separate and remove any items that are not accepted before disposing.



#### **DISPOSAL OF HOUSEHOLD MEDICINE:**

**1** SHARPS USAGE

If there are specific instructions on the label, package or package insert, please follow those instructions.

2 SAFE DISPOSAL INFORMATION

Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps.

Never place sharps in a trash, recycling, or green waste container. Never flush sharps down the drain or toilet.

**3** MAIL-BACK SERVICES

Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of www.med-project.org.

For more information about the MED-Project program, please visit www.med-project.org or call 1-844-MED-PROJECT 1-844-633-7765 (TTY: 711)



Figure 2: Mail-Back Package Insert for Sharps Disposal

Figure 2 Description: Mail-Back Package is for Sharps

Note: The following are not accepted in Sharps Mail-Back Packages:

- Controlled substances (such as opioids)
- Unwanted medicine separate from sharps
- Batteries
- Illicit or illegal drugs
- Biologics (such as insulin)

Please separate and remove any items that are not accepted before disposing.

Disposal of Household Sharps

- 1. Sharps Usage: If there are specific instructions on the label, package or package insert, please follow those instructions.
- 2. Safe Disposal Information: Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps. Never place sharps in a trash, recycling, or green waste container. Never flush sharps down the drain or toilet.
- 3. Mail-Back Services: Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of <a href="https://www.med-project.org">www.med-project.org</a>.

For more information about the MED-Project program, please visit <a href="https://www.med-project.org">www.med-project.org</a> or call 1-844-MED-Project / 1-844-633-7765 (TTY: 711).

# **Appendix F**

## **Initial Media and Outreach Plan**

Media and Promotion: Year 1 (30 Days – 180 Days)

Not applicable.

Media and Promotion: Year 1 (210 Days - 270 Days)

Launch social media activity.

# Media and Promotion: Year 1 (240 Days)

Finalize public service announcements and outreach strategy for upcoming year.

## Media and Promotion: Year 1 (300 – 360 Days)

- Public service announcement launch in California.
- Continue social media activity.

# Media and Promotion: Year 1 (300 Days)

Launch grant-based online advertising campaign.

## Media and Promotion: Year 1 (330 Days – 360 Days)

Ongoing grant-based online advertising campaign.

# Media and Promotion: Year 2 (30 – 360 Days)

- Public service announcements available via online access.
- Ongoing grant-based online advertising campaign.
- Continue social media activity.

Local promotion for confirmed events if needed.

# Outreach Materials and Collateral: Year 1 (30 - 210 Days)

- Develop signage and outreach materials for production and distribution.
- Develop Point of Sale Site participation information and factsheets.
- Launch outreach campaigns to participating Covered Entities
   , regarding Point of Sale Site participation in the Program.

# Outreach Materials and Collateral: Year 1 (210 Days – 270 Days)

- Finalize signage and outreach materials for production and distribution.
- Finalize Point of Sale Site participation information and factsheets.
- Provide educational signage/posters to Point of Sale Sites, as necessary.
- Provide educational signage and materials to Point of Sale Sites upon request and via the Help Desk.
- Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
- Continue outreach campaigns to participating Covered Entities
   , regarding Point of Sale Site participation in the Program.

# **Outreach Materials and Collateral: Year 1 (270 Days)**

Release educational video series for Point of Sale Sites.

# Outreach Materials and Collateral: Year 1 (300 Days – 360 Days)

- Provide educational signage/posters to Point of Sale Sites, as necessary.
- Provide educational and outreach materials and/or Sharps Mail-Back Packages to Point of Sale Sites upon request via Website and Help Desk.
- Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
- Provide access to educational and outreach materials for Ultimate Users on Website.

# **Outreach Materials and Collateral: Year 2 (30 Days)**

- Revise customer outreach materials if needed.
- Revise educational/information if needed.
- Revise Program factsheets if needed.

# Outreach Materials and Collateral: Year 2 (30 Days – 90 Days)

- Provide educational signage/posters to Point of Sale Sites as necessary.
- Provide educational and outreach materials and/or Sharps Mail-Back Packages to Point of Sale Sites upon request via Website and Help Desk.
- Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
- Provide access to educational and outreach materials for Ultimate Users on Website.

# Outreach Materials and Collateral: Year 2 (120 Days)

- Revise customer outreach materials if needed.
- Revise educational/information if needed.
- Revise Program factsheets if needed.

# Outreach Materials and Collateral: Year 2 (120 Days – 180 Days)

- Provide educational signage/posters to Point of Sale Sites, as necessary.
- Provide educational and outreach materials and/or Sharps Mail-Back Packages to Point of Sale Sites upon request via Website and Help Desk.
- Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
- Provide access to educational and outreach materials for Ultimate Users on Website.

# **Outreach Materials and Collateral: Year 2 (210 Days)**

- Revise customer outreach materials if needed.
- Revise educational/information if needed.
- Revise Program factsheets if needed.

# Outreach Materials and Collateral: Year 2 (210 Days – 270 Days)

- Provide educational signage/posters to Point of Sale Sites, as necessary.
- Provide educational and outreach materials and/or Sharps Mail-Back Packages to Point of Sale Sites upon request via Website and Help Desk.
- Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
- Provide access to educational and outreach materials for Ultimate Users on Website.

# Outreach Materials and Collateral: Year 2 (300 Days)

- Revise customer outreach materials if needed.
- Revise educational/information if needed.
- Revise Program factsheets if needed.

# Outreach Materials and Collateral: Year 2 (300 Days – 360 Days)

- Provide educational signage/posters to Point of Sale Sites, as necessary.
- Provide educational and outreach materials and/or Sharps Mail-Back Packages to Point of Sale Sites upon request via Website and Help Desk.
- Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
- Provide access to educational and outreach materials for Ultimate Users on Website.

# Communications and Website: Year 1 (30 Days – 60 Days) Not applicable.

## **Communications and Website: Year 1 (90 Days)**

- Launch Website with informational pages that are in compliance with accessibility requirements and language options.
- Activate Call Center access for Ultimate Users.
- Activate Help Desk for Point of Sale Sites and stakeholders.

# Communications and Website: Year 1 (120 Days – 180 Days)

- Update Website information as needed.
- Implement Vendor processes to fulfill requests for Sharps Mail-Back Packages.

### **Communications and Website: Year 1**

Press release announcing annual report highlights.

# Communications and Website: Year 1 (210 Days – 270 Days)

- Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
- Provide access to educational and outreach materials for Ultimate Users on Website.
- Provide information about USPS General Delivery services through the Website and Call Center.
- Update Website information as needed.
- Maintain all Mail-Back Services through the Website and Call Center.
- Launch ability for Points of Sale Sites to provide or initiate distribution of Sharps Mail-Back Packages to Ultimate Users.
- Launch Mail-Back Services including provision of Sharps Mail-Back
   Packages through the Website and Call Center for all Ultimate Users.

# **Communications and Website: Year 1 (300 Days)**

Press release campaign announcing program launch.

# Communications and Website: Year 1 (300 Days – 360 Days)

Update Website information as needed.

# Communications and Website: Year 2 (30 Days – 180 Days)

- Update Website information as needed.
- Program updates issued.

### Communications and Website: Year 2

Press release announcing annual report highlights.

# Communications and Website: Year 2 (210 Days – 360 Days)

- Update Website information as needed.
- Program updates issued.

# Point of Sale Site Activity: Year 1 (30 Days – 90 Days)

- Identify potential Point of Sale Sites.
- Onsite visit/presentations or phone contacts as needed.

# Point of Sale Site Activity: Year 1 (90 Days – 180 Days)

- Notify potential Point of Sale sites about the Program.
- Continue follow-up with Point of Sale Sites.
- Onsite visits/presentations or phone contact as needed.

# Point of Sale Site Activity: Year 1 (210 Days - 270 Days)

- Continue follow-up with Point of Sale Sites.
- In-person site visits/presentations or phone contact as needed.
- Notify Point of Sale Sites about USPS General Delivery services.
- Notify Point of Sale Sites about the phone ordering system.
- Remind Point of Sale Sites about how to use the online ordering system.

 Provide information about USPS General Delivery services through the Help Desk and the online and phone ordering systems.

## Point of Sale Site Activity: Year 1 (300 Days – 360 Days)

- Continue follow-up with Point of Sale Sites.
- Onsite visits/presentations or phone contact as needed.

Point of Sale Site Activity: Year 2 (30 Days – 180 Days)

Onsite visits/presentations or phone contact as needed.

Point of Sale Site Activity: Year 2 (210 Days – 270 Days)

Onsite visits/presentations or phone contact as needed.

Point of Sale Site Activity: Year 2 (300 Days – 360 Days)

Onsite visits/presentations or phone contact as needed.

**Events: Year 1 (30 Days – 180 Days)** 

Not applicable.

**Events: Year 1 (210 Days – 270 Days)** 

Establish event options for the balance of first year of operations.

**Events: Year 1 (300 Days – 330 Days)** 

Not applicable.

**Events: Year 1 (360 Days)** 

Not applicable.

Events: Year 2 (30 Days – 90 Days)

Any events will be as outlined in the established event schedule.

**Events: Year 2** 

Earth Day (April).

**Events: Year 2 (120 Days – 360 Days)** 

Any events will be as outlined in the established event schedule.

**Events: Year 2 (360 Days)** 

Establish event options for the upcoming year.

# **Appendix G**

ENGLISH

# **Sample Educational and Outreach Materials**



# SAFELY DISPOSE OF SHARPS



Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may cause injury.



Figure 3: Safe Disposal of Sharps Brochure Containing Contact Information and Accepted and Not Accepted Medications (Front)

USA.BR.02.101102.SCA.01.01.01.01.00

Figure 3 Description: What should you do with your sharps?

For more information about the MED-Project Program, visit <a href="www.med-project.org">www.med-project.org</a> or call 1-844-MED-Project / 1-844-633-7765 (TTY: 711)

Sharps Disposal – Accepted:

Sharps such as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications contained in U.S. Food and Drug Administration cleared sharps containers.

Please separate and remove any items that are not accepted before disposing.

Sharps Disposal – Not Accepted:

Controlled substances (such as opioids), unwanted medicine separate from sharps, batteries, illicit or illegal drugs, and biologics (such as insulin)

Safely Dispose of Sharps

- Sharps Usage
- Safe Disposal Information
- Mail-Back Services

Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may cause injury.

MED-Project™

Medication Education & Disposal

www.med-project.org

SB212 Program

# DISPOSAL OF

# **DISPOSAL OF** HOUSEHOLD SHARPS HOUSEHOLD SHARPS



If there are specific instructions on the label, package or package insert, please follow those instructions.



SAFE DISPOSAL INFORMATION

> Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps. Never place sharps in a trash, recycling, or green waste container. Never flush sharps down the drain or toilet.



**MAIL-BACK SERVICES** 

Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of www.med-project.org.



Sharps can be dangerous to people and pets if not disposed of safely. Sharps can cause injuries and/or spread infections that cause serious health conditions. These infections may include: Hepatitis B (HBV), Hepatitis C (HCV), and Human

Immunodeficiency Virus (HIV).

Safe sharps disposal is important whether you are at home, at work, at school, traveling, or in other public places such as hotels, parks, and restaurants. Pet owners who use needles to give medicine to their pets should follow the same sharps disposal quidelines used for humans.

#### SHARPS DISPOSAL CONTAINERS

All sharps disposal containers should be made of heavy-duty plastic; able to close with a tight-fitting, puncture resistant lid without sharps being able to come out; upright and stable during use; leakresistant; and properly labeled as "sharps waste" or with the biohazard symbol and the word "BIOHAZARD".



Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps. Sharps disposal containers should be kept out of reach of children and pets.

DO NOT REUSE SHARPS DISPOSAL CONTAINERS

Figure 4: Safe Disposal of Sharps Brochure Containing Sharps Usage and Disposal Information, and Mail-Back Services (Back)

### **Image Description**

### Figure 4: Disposal of Household Sharps

- 1. Sharps Usage: If there are specific instructions on the label, package or package insert, please follow those instructions.
- 2. Safe Disposal Information: Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps. Never place sharps in a trash, recycling, or green waste container. Never flush sharps down the drain or toilet.
- 3. Mail-Back Services: Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of <a href="www.med-project.org">www.med-project.org</a>.

### Disposal of Household Sharps

Sharps can be dangerous to people and pets if not disposed of safely. Sharps can cause injuries and/or spread infections that cause serious health conditions. These infections may include: Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV).

Safe sharps disposal is important whether you are at home, at work, at school, traveling, or in other public places, such as hotels, parks, and restaurants. Pet owners who use needles to give medicine to their pets should follow the same sharps disposal guidelines used for humans.

## **Sharps Disposal Containers**

All sharps disposal containers should be made of heavy-duty plastic; able to close with a tight-fitting, puncture resistant lid without sharps being able to come out; upright and stable during use; leak-resistant; and properly labeled as "sharps waste" or with the biohazard symbol and the word "Biohazard".

Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps. Sharps disposal containers should be kept out of reach of children and pets.

Do Not Reuse Sharps Disposal Containers

# **Sample Point of Sale Information**





## DISPOSAL OF HOUSEHOLD SHARPS



Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps.

#### **ACCEPTED FOR SHARPS DISPOSAL**



**ACCEPTED:** Sharps such as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications, contained in U.S. Food and Drug Administration-cleared sharps containers.

Please separate and remove any items that are not accepted before disposing.



**NOT ACCEPTED:** Controlled substances (such as opioids), unwanted medicine separate from sharps, batteries, illicit or illegal drugs, and biologics (such as insulin).



#### MAIL-BACK SERVICES

Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of www.med-project.org.

For more information about the MED-Project program: Visit www.MED-Project.org or call 1 (844) MED-PROJECT (633-7765)



Figure 5: Sample Disposal of Household Sharps Information for Point of Sale Sites

Figure 5 Description: Sample Disposal of Household Sharps

Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps.

Accepted for Sharps Disposal

### Accepted:

Sharps such as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications, contained in U.S. Food and Drug Administration-cleared sharps containers.

Note: Please separate and remove any items that are not accepted before disposing.

#### Not Accepted:

Controlled substances (such as opioids), unwanted medicine separate from sharps, batteries, illicit or illegal drugs, and biologics (such as insulin).

Mail-Back Services: Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of www.med-project.org.

For more information about the MED-Project program: Visit <u>www.MED-Project.org</u> or call 1 (844) MED-Project (633-7765)

# **Appendix H**

Sample Signage for Hospitals, Pharmacies, and Other Locations

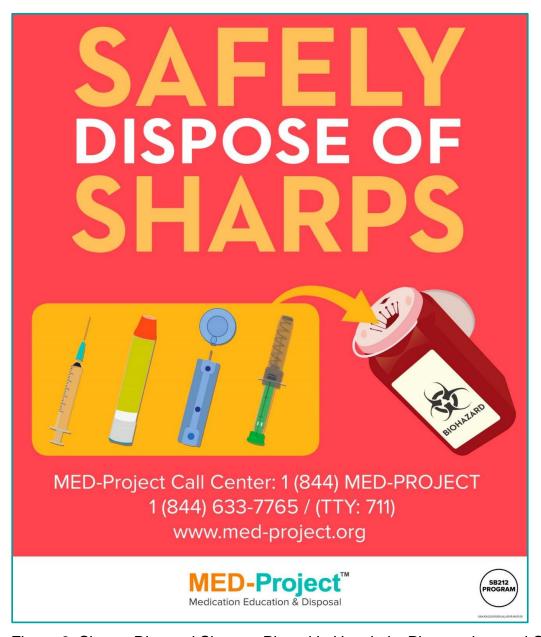


Figure 6: Sharps Disposal Signage Placed in Hospitals, Pharmacies, and Other Locations

# **Appendix I**

# **Sample Webpage Mockups**















#### CALIFORNIA STATE SHARPS PROGRAM

Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may cause injury.

















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Figure 7: Sample California State MED-Project Sharps Program Website Home Page

Figure 7 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Sharps Program – Home/Landing Website Page

Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may cause injury.

Linked California State MED-Project Website Pages

- MEDhome
- MEDinfo
- MEDfag
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Mail-Back Services
- Household Hazardous Waste Sites
- Privacy Policy
- Accessibility Statement

### Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn















#### SHARPS USAGE

Sharps is a medical term for devices with sharp points or edges that can puncture or cut skin. They may be used at home, at work, and while traveling to manage the medical conditions of people or their pets, including allergies, arthritis, cancer, diabetes, hepatitis, HIV/AIDS, infertility, migraines, multiple sclerosis, osteoporosis, blood clotting disorders, and psoriasis.

If there are any specific instructions on the label, package, or package insert, please follow those instructions.

If you have any questions about any medication or your health, please contact your healthcare provider.









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Figure 8: Sample California State Sharps Program Website Sharps Usage Page Containing Sharps Information

Figure 8 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Sharps Program – Sharps Usage Website Page

Sharps is a medical term for devices with sharp points or edges that can puncture or cut skin. They may be used at home, at work, and while traveling to manage the medical conditions of people or their pets, including allergies, arthritis, cancer, diabetes, hepatitis, HIV/AIDS, infertility, migraines, multiple sclerosis, osteoporosis, blood clotting disorders, and psoriasis.

If there are any specific instructions on the label, package, or package insert, please follow those instructions.

If you have any questions about any medication or your health, please contact your healthcare provider.

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Mail-Back Services
- Household Hazardous Waste Sites
- Privacy Policy
- Accessibility Statement















#### SAFE DISPOSAL INFORMATION

Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may cause injury.

Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps.

Never place sharps in a trash, recycling, or green waste container. Never flush sharps down the drain or toilet. Disposing of sharps in the trash, recycling, or green waste may put trash and sewage workers, janitors, housekeepers, household members, and children at risk of being harmed.

Please separate and remove any items that are not accepted before disposing.

Use sharps disposal containers specifically rated for sharps or other containers approved for use in your location. Examples of other containers may include rigid containers made of heavy-duty plastic, sealable with a tight-fitting lid, and puncture resistant. Do not use lightweight plastic, glass, cardboard, or paper containers.

DO NOT REUSE SHARPS DISPOSAL CONTAINERS.









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Figure 9: Sample California State Sharps Program Website Safe Disposal Information Page

Figure 9 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Sharps Program – distribute Information Website Page

Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may cause injury.

Place all sharps in a sharps disposal container immediately after they have been used. This will reduce the risk of needle sticks, cuts, and punctures from sharps.

Never place sharps in a trash, recycling, or green waste container. Never flush sharps down the drain or toilet. Disposing of sharps in the trash, recycling, or green waste may put trash and sewage workers, janitors, housekeepers, household members, and children at risk of being harmed.

Please separate and remove any items that are not accepted before disposing.

Use sharps disposal containers specifically rated for sharps or other containers approved for use in your location. Examples of other containers may include rigid containers made of heavy-duty plastic, sealable with a tight-fitting lid, and puncture resistant. Do not use lightweight plastic, glass, cardboard, or paper containers.

Do not reuse Sharps Disposal Containers.

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Mail-Back Services
- Household Hazardous Waste Sites
- Privacy Policy

- Accessibility Statement

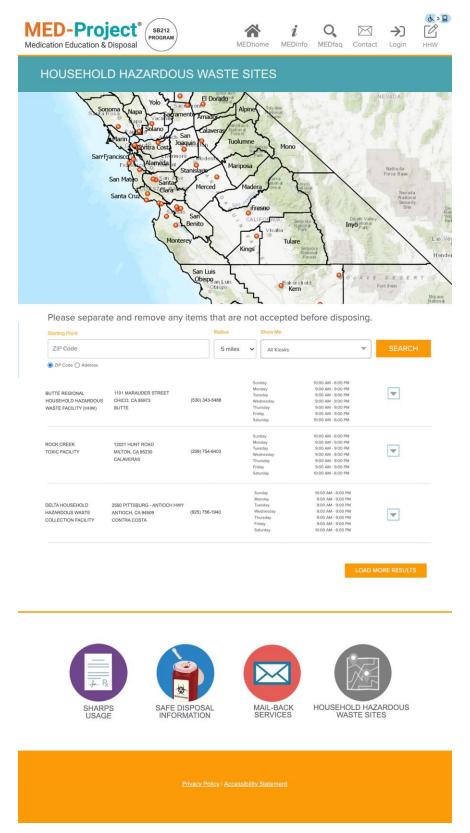


Figure 10: Sample California State Sharps Program Website Household Hazardous Waste Sites Page

Figure 10 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Sharps Program – Household Hazardous Waste Sites Page

Note: There is a sample map containing Household Hazardous Waste Sites. Items in this map populate based on information filled out in the form search fields.

Please separate and remove any items that are not accepted before disposing.

Map Form Fields and Sample Entries

- Starting Point (ZIP code): 95973
- Radius Drop-Down Menu (Miles): 5 miles
- Show Me Drop-Down Menu (Options): All Kiosks
- Search Button

Note: Household Hazardous Waste Sites are returned after filling out map form fields.

Sample Household Hazardous Waste Site:

- Site Name: Butte Regional Household Hazardous Waste Facility (HHW)
- Address: 1101 Marauder Street, Chico, CA 95973, Butte
- Phone Number: (530) 343-5488
- Hours of Operation:
  - Sunday 10:00 a.m. 6:00 p.m.
  - o Monday 9:00 a.m. − 9:00 p.m.
  - o Tuesday 9:00 a.m. − 9:00 p.m.
  - o Wednesday 9:00 a.m. − 9:00 p.m.
  - Thursday 9:00 a.m. 9:00 p.m.
  - Friday 9:00 a.m. 9:00 p.m.
  - Saturday 10:00 a.m. 6:00 p.m.
- Load More Results Button

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Mail-Back Services
- Household Hazardous Waste Sites
- Privacy Policy
- Accessibility Statement

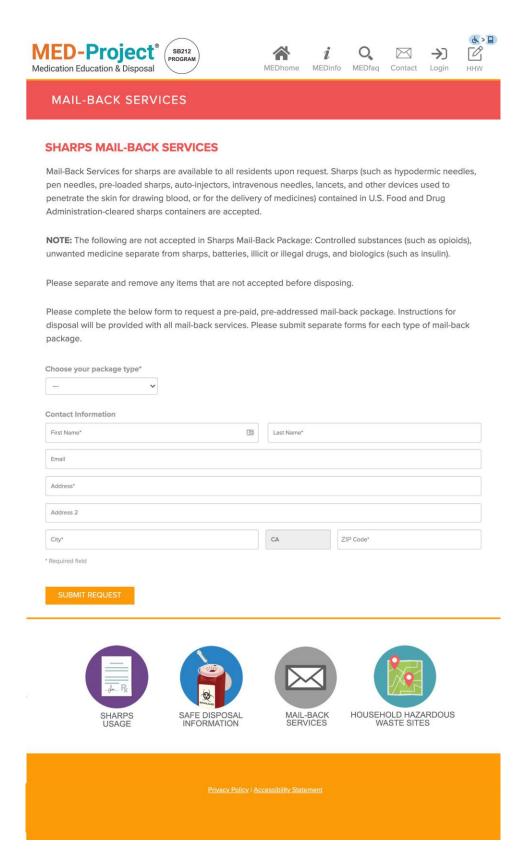


Figure 11: Sample California State Sharps Program Website Sharps Mail-Back Services Page

Figure 11 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Sharps Program – Sharps Mail-Back Services Website Page

Mail-Back Services

Sharps Mail-Back Services

Mail-Back Services for sharps are available, free of charge, to all residents upon request. Sharps such as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medication are accepted.

Note: The following are not accepted in Sharps Mail-Back Packages: Controlled substances (such as opioids), unwanted medicine separate from sharps, batteries, illicit or illegal drugs, and biologics (such as insulin).

Please separate and remove any items that are not accepted before disposing.

Please complete the below form to request a pre-paid, pre-addressed mail-back package. Instructions for disposal will be provided with all mail-back services. Please submit separate forms for each type of mail-back package.

Mail-Back Services Form Fields

Note: \*Required field

- Choose your package type\* Drop-Down Menu
- Contact Information
  - First Name\*
  - Last Name\*
  - o Email
  - Address\*
  - o Address 2
  - City
  - State
  - ZIP Code\*
- Submit Request Button

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Mail-Back Services
- Household Hazardous Waste Sites
- Privacy Policy
- Accessibility Statement

















#### **MEDinfo**

Medicine helps treat diseases, manages chronic conditions, and improves health and well-being for millions of Americans. It is important that patients use their sharps as directed by their health care provider and as indicated on the label or packaging.

Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may cause injury.

For additional information on the program, MED-Project has developed an educational toolkit which includes the materials below

Brochure – Sharps Program
English

Frequently Asked Questions English

Radio Public Service Announcement (PSA) – Sharps Program

**English** 

Video Public Service Announcement (PSA) - Sharps Program

English

Login to your account to order brochures.

If you would like any of these materials emailed to you, contact <code>california@med-project.org</code>.

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Figure 12: Sample California State Sharps Program Website MEDinfo Page

Figure 12 Text: MED-Project™ Medication Education & Disposal – SB212 Program – California State Sharps Program – MEDinfo Website Page MEDinfo

Medicine helps treat diseases, manages chronic conditions, and improves health and well-being for millions of Americans. It is important that patients use their sharps as directed by their health care provider and as indicated on the label or packaging.

Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may cause injury.

For additional information on the program, MED-Project has developed an education toolkit which includes the materials below

- Brochure Sharps Program (English)
- Frequently Asked Questions (English)
- Radio Public Service Announcement (PSA) Sharps Program (English)
- Video Public Service Announcement (PSA) Sharps Program (English)

If you would like to order brochures, click here (hyperlink to ordering).

If you would like any of these materials emailed to you, contact california@med-project.org.

- MEDhome
- MEDfaq
- Contact
- Login
- HHW
- Privacy Policy
- Accessibility Statement

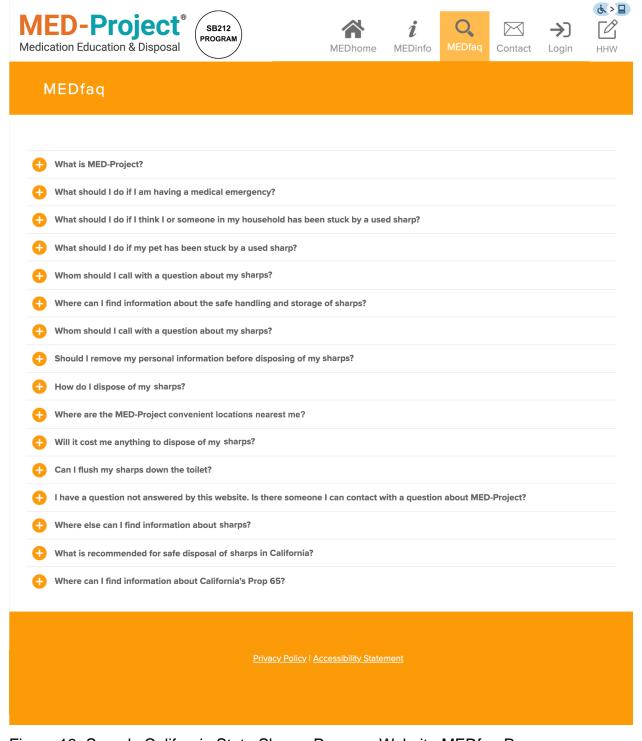


Figure 13: Sample California State Sharps Program Website MEDfaq Page

Figure 13 Text: MED-Project™ Medication Education & Disposal – SB212 Program – California State Sharps Program – MEDfaq Website Page MEDfaq

- What is MED-Project?
- What should I do if I am having a medical emergency?
- What should I do if I think I or someone in my household has been stuck by a used sharp?
- What should I do if my pet has been stuck by a used sharp?
- Whom should I call with a question about my sharps?
- Where can I find information about the safe handling and storage of sharps?
- Should I remove my personal information before disposing of my sharps?
- How do I dispose of my sharps?
- Where are the MED-Project convenient locations nearest me?
- Will it cost me anything to dispose of my sharps?
- Can I flush my sharps down the toilet?
- I have a question not answered by this website. Is there someone I can contact with a question about MED-Project?
- Where else can I find information about sharps?
- What is recommended for safe disposal of sharps in California?
- Where can I find information about California's Prop 65?

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- HHW
- Privacy Policy
- Accessibility Statement















#### CONTACT

If you are experiencing a medical emergency, please dial 911. If you are experiencing a non-emergency but suspect that you or another individual has ingested something poisonous, please call Poison Control at 1 (800) 222-1222.

If you have questions about your medication, please call your health care provider.

#### Local Agencies/Point of Sale Sites

Login to your account to order brochures.

If you have any questions, comments, or concerns, login to your account.

For answers to some frequently asked questions, visit the MED-Project FAQ page.

#### Residents

If you are a resident of California and have questions about MED-Project, please contact:

1 (844) MED-PROJECT or 1 (844) 633-7765 or (TTY: 711)

If you would like to leave feedback about the MED-Project Program, answer our community feedback questionnaire.

#### Local Agencies and Points of Sale

If you are a household hazardous waste facility operrated by a Local Agency or a point of sale site interested in participating in the MED-Project Program, please contact us at:

Click here: Login or Register for an Account

Call us by Phone: 1 (833) MED-PROJECT or

1 (833) 633-7765

Fax us: 1 (866) 633-1812

Email us: Email Inquiries for Sharps Disposal:

california@med-project.org

Address: Dr. Victoria Travis, PharmD, MS, MBA

National Program Director

MED-Project USA

4096 Piedmont Ave, Unit 174

Oakland, CA 94611

#### **Covered Entities**

If you are a covered entity interested in participating in the MED-Project Stewardship Plan, please contact:

Phone: 1 (202) 495-3131

Email: compliance@med-project.org

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Figure 14: Sample California State Sharps Program Website Contact Page

Figure 14 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Sharps Program – Contact Website Page

#### Contact

If you are experiencing a medical emergency, please dial 911. If you are experiencing a non-emergency but suspect that you or another individual has ingested something poisonous, please call Poison Control at 1 (800) 222-1222.

If you have questions about your medication, please call your health care provider.

Local Agencies/Point of Sale Sites

If you would like to order brochures, click here (hyperlinked to ordering).

If you have any questions, comments, or concerns, please click here (hyperlinked to questions, comments, concerns).

For answer to some frequently asked questions about MED-Project, click here (hyperlinked to frequently asked questions about MED-Project).

#### Residents

If you are a resident of California and have questions about MED-Project, please contact:

1 (844) MED-Project or 1 (844) 633-7765 or (TTY:711)

If you would like to leave feedback about the MED-Project Program, please click here (hyperlinked to feedback).

Local Agencies and Points of Sale

If you are a household hazardous waste facility operated by a Local Agency or a point of sale site interested in participating in the MED-Project Program, please contact us at:

- Click here: Login or Register for an Account
- Call us by Phone: 1 (833) MED-Project or 1 (833) 633-7765
- Fax us: 1 (866) 633-1812
- Email us: Email inquiries for Sharps Disposal: <u>california@med-project.org</u>

 Address: Dr. Victoria Travis, PharmD, MS, MBA, National Program Director, MED-Project USA, 4096 Piedmont Ave, Unit 174, Oakland, CA 94611

#### **Covered Entities**

If you are a covered entity interested in participating in the MED-Project Stewardship Plan, please contact:

Phone: 1 (202) 495-3131

Email: <a href="mailto:compliance@med-project.org">compliance@med-project.org</a>

- MEDhome
- MEDinfo
- MEDfaq
- Login
- HHW
- Privacy Policy
- Accessibility Statement

# **Appendix J**

# **Program Implementation Timeline from Plan Approval Date**

# Household Hazardous Waste Facilities Operated by Local Agencies (Days 1–90)

Identify household hazardous waste facilities operated by Local Agencies that may have the opportunity for reimbursement allowed under PRC 42032.2(d)(1)(F)(ii) and 14 CCR 18973.3(g).

# Household Hazardous Waste Facilities Operated by Local Agencies (Days 91–180)

Notify household hazardous waste facilities operated by Local Agencies of the opportunity for reimbursement allowed under PRC 42032.2(d)(1)(F)(ii) and 14 CCR 18973.3(g).

# Household Hazardous Waste Facilities Operated by Local Agencies (Days 181–270)

Implement process to reimburse household hazardous waste facility expenses allowed under PRC 42032.2(d)(1)(F)(ii) and 14 CCR 18973.3(g). MED-Project will reimburse costs incurred 270 days or more after Plan approval following the process described in <u>Section 7: Reimbursement to Local Agencies</u>.

# Mail-Back Services (Days 1-90)

- Identify potential Point of Sale Sites.
- Identify Retail pharmacies and Retail pharmacy chains using publicly available information from the State Board.
- Identify non-pharmacy potential Point of Sale Sites and online retailers that sell Sharps directly to consumers in the State.

## Mail-Back Services (Days 91-180)

- Notify all identified potential Point of Sale Sites about the Program.
- Conduct additional outreach via phone calls, on-site visits, and other methods.

- Implement Vendor processes to fulfill requests for Sharps Mail-Back Packages.
- Register potential Point of Sale Sites on the online ordering system to participate in the Program.

#### Mail-Back Services (Days 181–270)

- Launch Mail-Back Services including provision of Sharps Mail-Back
   Packages through the Website and Call Center for all Ultimate Users.
- Launch the online ordering system for Point of Sale Sites to initiate distribution of Sharps Mail-Back Packages to Ultimate Users for In-Scope Purchases at Point of Sale Sites.
- Launch the phone ordering system for Point of Sale Sites to initiate distribution of Sharps Mail-Back Packages to Ultimate Users for In-Scope Purchases at Point of Sale Sites.
- Make information available about USPS General Delivery Services through the online and phone ordering systems, Help Desk, Website, and Call Center.
- Work with Retail pharmacy chains that have varied and often proprietary customer engagement and check-out systems.

### **Education and Outreach (Days 1–90)**

- Launch accessible Website that provides:
  - o Translations using a third-party translation tool.
  - o Other informational pages.
- Activate the Call Center for Ultimate Users.
- Activate the Help Desk for Point of Sale Sites, hospitals, Pharmacies, other locations, pharmacists, providers and other individuals.
- Launch outreach campaigns to participating Covered Entities
   , regarding Point of Sale Site participation in the Program.

#### **Education and Outreach (Days 91–180)**

- Make educational and outreach materials available to Ultimate Users, Point of Sale Sites, hospitals, Pharmacies, other locations, pharmacists, providers, and other individuals upon request and via the Help Desk.
- Continue outreach campaigns to participating Covered Entities
   , regarding Point of Sale Site participation in the Program.

#### **Education and Outreach (Days 181–270)**

- Release educational video series for Point of Sale Sites.
- Provide educational signage and materials to Point of Sale Sites, upon request, and via the Help Desk.
- Continue outreach campaigns to participating Covered Entities
   , regarding Point of Sale Site participation in the Program.
- Launch social media activity.
- Release educational video series for Point of Sale Sites.
- Finalize public service announcement for release.

## **Appendix K**

## **Sample Call Center Flow**

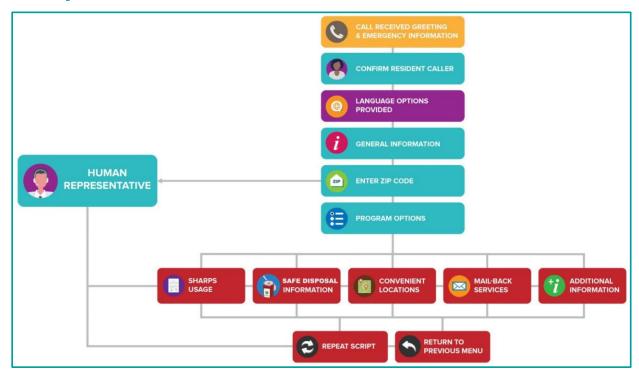


Figure 15: Sample Call Center Flow

#### **Figure Description**

Figure 15 Description: Sample Call Center Flow

- 1. Call received at the Call Center; Greeting and Emergency Information heard.
- 2. Caller confirms they are a resident.
- 3. Language options are provided.
- 4. General Information provided.
- 5. Resident enters ZIP code to either access menu options or speak with a Human Representative.
- 6. Menu options:
  - Note: Fields marked with \* require speaking with a Human Representative.
  - Sharps Usage
  - Safe Disposal Information
  - Mail-Back Services\*
  - Household Hazardous Waste Sites\*
  - Additional Information
- 7. Option to repeat script.
- 8. Option to return to previous menu.

## **Appendix L**

### **Regulatory Map**

#### Citations to 14 CCR

#### 18973(a)

- Regulatory Requirement: The Plan shall comply with section 7405 of the Government Code and the Web Content Accessibility Guidelines 2.0.
- Plan Section(s): Entire Plan.

#### 18973(b)

- Regulatory Requirement: The Plan shall be submitted electronically.
- Plan Section(s):N/A.

#### 18973(c)

- Regulatory Requirement: Cover letter explaining the justification of claims of confidentiality.
- Plan Section(s): N/A.

#### 18973(d)

- Regulatory Requirement: Completeness and correctness of the Plan.
- Plan Section(s):
  - o Appendix L.

#### 18973(e)

- Regulatory Requirement: Certification.
- Plan Section(s):
  - Section 4: State Agency Determinations and Certifications.
  - o Appendix C.

#### 18973.1(a) - (I)

- Regulatory Requirement: Stewardship Plan approvals.
- Plan Section(s): N/A.

#### 18973.1(m)

- Regulatory Requirement: Implementation of an approved plan.
- Plan Section(s):
  - o Section 6: Mail-Back Program.
  - o Appendix J.

#### 18973.3(a)

- Regulatory Requirement: Contact information of the corporate officer.
- Plan Section(s):
  - Section 2: <u>Corporate Officer</u>.

#### 18973.3(b)

- Regulatory Requirement: Contact information for each participating Covered Entity.
- Plan Section(s):
  - Section 2: Covered Entities.
  - o Appendix A.

#### 18973.3(c)

- Regulatory Requirement: List of Sharps sold by each participating Covered Entity.
- Plan Section(s):
  - Section 3: Sharps Sold by Each Participating Covered Entity.
  - o Appendix A.

#### 18973.3(d)(1)

- Regulatory Requirement: State Agency Determinations.
- Plan Section(s):
  - o Section 4: State Agency Determinations and Certifications.
  - o Appendix C.

#### 18973.3(d)(2)

- Regulatory Requirement: Compliance Certifications.
- Plan Section(s):
  - Section 4: State Agency Determinations and Certifications.
  - o Appendix C.

#### 18973.3(e)

- Regulatory Requirement: Initial Program budget and Program funding.
- Plan Section(s):
  - Section 5: Program Budgets and Funding.
  - Appendix D.

#### 18973.3(f)(1)

- Regulatory Requirement: Processes and policies that will safely and securely collect Home-Generated Sharps Waste.
- Plan Section(s):
  - Section 6: <u>Handling, Transport, and Disposal</u>.
  - o Section 14: Policies and Procedures.

#### 18973.3(f)(2)

- Regulatory Requirement: Mail-Back Packages for Home-Generated Sharps Waste.
- Plan Section(s):
  - o Section 6: Mail-Back Program.

#### 18973.3(f)(2)(A)

- Regulatory Requirement: Distribution of Sharps Mail-Back Packages.
- Plan Section(s):
  - Section 6: Mail-Back Program.

#### 18973.3(f)(2)(B)

- Regulatory Requirement: Instructions in Sharps Mail-Back Packages regarding proper Sharps disposal.
- Plan Section(s):
  - Section 6: Mail-Back Program.

#### 18973.3(f)(2)(C)

- Regulatory Requirement: Labeling on Sharps Waste Containers.
- Plan Section(s):
  - Section 6: Mail-Back Program.

#### 18973.3(f)(2)(D)

- Regulatory Requirement: Prepaid postage affixed on Sharps Mail-Back Packages.
- Plan Section(s):
  - o Section 6: Mail-Back Program.

#### 18973.3(f)(3)

- Regulatory Requirement: Collection, transportation, and disposal system records.
- Plan Section(s):
  - o Section 14: Policies and Procedures.

#### 18973.3(f)(4)

- Regulatory Requirement: Service providers used to transport, process, or dispose of Home-Generated Sharps Waste.
- Plan Section(s):
  - o Section 6: <u>Handling, Transport, and Disposal</u>.

#### 18973.3(f)(5)

- Regulatory Requirement: Supplemental Services and Safety and Security Incidents.
- Plan Section(s): N/A.

#### 18973.3(f)(6)

- Regulatory Requirement: Metrics to measure amount of Sharps Mail-Back Packages distributed and Home-Generated Sharps Waste collected.
- Plan Section(s):
  - o Section 11: Metrics.

#### 18973.3(f)(7)

- Regulatory Requirement: Metrics to measure amount of Home-Generated Sharps Waste collected through supplemental collection methods.
- Plan Section(s): N/A.

#### 18973.3(f)(8)

- Regulatory Requirement: Metrics to measure amount of Home-Generated Sharps Waste collected by household hazardous waste facilities.
- Plan Section(s):
  - Section 11: <u>Home-Generated Sharps Waste Collected by Household Hazardous Waste Facilities</u>.

#### 18973.3(f)(9)

- Regulatory Requirement: Critical instances of noncompliance.
- Plan Section(s):
  - Section 14: <u>Discovery of Critical Instances of</u> <u>Noncompliance</u>.

#### 18973.3(g)(1)

- Regulatory Requirement: Process for coordinating with Local Agencies for Home-Generated Sharps Waste removal or reimbursement.
- Plan Section(s):
  - Section 7: Reimbursement to Local Agencies.

#### 18973.3(g)(2)

- Regulatory Requirement: Fulfilling Local Agency requests.
- Plan Section(s):
  - o Section 7: Reimbursement to Local Agencies.

#### 18973.3(g)(2)(A)

- Regulatory Requirement: Issuing payment within 45 days.
- Plan Section(s):
  - o Section 7: Reimbursement to Local Agencies.

#### 18973.3(g)(2)(B)

- Regulatory Requirement: Removal of Home-Generated Sharps Waste.
- Plan Section(s): N/A.

#### 18973.3(h)

- Regulatory Requirement: Ordinance repeals.
- Plan Section(s):
  - o Section 9: Repeal of Local Programs.

#### 18973.3(i)(1)

- Regulatory Requirement: Activities to promote awareness.
- Plan Section(s):
  - Section 10: Educational and Outreach Materials.
  - o Appendix G.

#### 18973.3(i)(2)

- Regulatory Requirement: Materials distributed in languages suited to local demographics.
- Plan Section(s):
  - Section 10: <u>Signage for Hospitals, Pharmacies, and Other Locations</u>.
  - o Appendix H.

#### 18973.3(i)(3)

- Regulatory Requirement: Website.
- Plan Section(s):
  - Section 10: <u>Website for Ultimate Users</u>.
  - o Appendix I.

#### 18973.3(i)(4)

- Regulatory Requirement: Toll-free telephone number.
- Plan Section(s):
  - Section 10: Website for Ultimate Users.
  - o Appendix I.

#### 18973.3(i)(5)

- Regulatory Requirement: Education and outreach program performance metrics.
- Plan Section(s):
  - Section 11: <u>Performance of the Comprehensive</u>
     Education and Outreach Program.

#### 18973.3(i)(6)

- Regulatory Requirement: Encouraging Ultimate Users to separate products that are not Covered Products from Covered Products.
- Plan Section(s):
  - Section 10: Education and Outreach Program.

#### 18973.3(i)(7)

- Regulatory Requirement: Disposal promotions inconsistent with the Program.
- Plan Section(s):
  - Section 10: Education and Outreach Program.

#### 18973.3(j)

- Regulatory Requirement: Coordination Efforts.
- Plan Section(s):
  - o Section 13: Compliance with Applicable Laws.

#### 18973.3(k)

- Regulatory Requirement: Process for providing grants.
- Plan Section(s): N/A.

#### 18973.3(I)

- Regulatory Requirement: Process for selecting service providers.
- Plan Section(s):
  - Section 14: <u>Selection of Service Providers</u>.

#### 18973.5

- Regulatory Requirement: Submission of an annual report to
   CalRecycle on or before March 31, 2022, and each year thereafter.
- Plan Section(s):
  - o Section 15: Reporting.

#### 18973.6

- Regulatory Requirement: Submission of an initial five-year budget and an annual budget.
- Plan Section(s):
  - Section 5: Program Budgets and Funding.
  - o Appendix D.

#### 18973.6(a)

- Regulatory Requirement: Contact information of the corporate officer.
- Plan Section(s):
  - Section 5: <u>Contact Information of the Person Responsible</u> for Submitting and Overseeing the Program Budget.

#### 18973.6(b)

- Regulatory Requirement: Anticipated costs to implement the Program.
- Plan Section(s):
  - o Section 5: Initial Program Budget.
  - Appendix D.

#### 18973.6(c)

- Regulatory Requirement: Recommended reserve level amount and description justifying the reserve level amount indicated.
- Plan Section(s):
  - o Section 5: Recommended Reserve.

#### 18973.6(d)

- Regulatory Requirement: Recommended funding level to cover budgeted costs and operate the Program over a multi-year period.
- Plan Section(s):
  - Section 5: <u>Funding</u>.
  - o Appendix D.

#### 18973.6(e)

- Regulatory Requirement: Description of the types of activities relative to each line-item cost category.
- Plan Section(s):
  - Section 5: <u>Types of Activities Relative to Each Line-Item</u>
     Cost Category.

#### 18973.6(f)

- Regulatory Requirement: Member Covered Entities shall fund an annual audit.
- Plan Section(s):
  - Section 5: <u>Recommended Reserve</u>.

#### 18974(a)

- Regulatory Requirement: Maintain records to support compliance with the Regulations and the Law.
- Plan Section(s):
  - Section 14: Record Maintenance.

#### 18974(b)

- Regulatory Requirement: Maintain and provide access to records for a minimum of three years after submission of a document which relies upon those records.
- Plan Section(s):
  - o Section 14: Record Maintenance.

#### 18974(c)

- Regulatory Requirement: Covered Product records.
- Plan Section(s): N/A.

#### 18974.1(a)

- Regulatory Requirement: Pay all administrative and operational costs associated with the Program.
- Plan Section(s):
  - Section 5: Revenue.

#### 18974.2

- Regulatory Requirement: Provide a copy of audits of participating Covered Entities to CalRecycle within 30 days.
- Plan Section(s): N/A.

## **Appendix M**

## The Plan Satisfies CalRecycle Conditions of Approval

#### **Introduction and Background**

1. MED-Project's August 2022 Stewardship Plan for Home-Generated Sharps Waste should be approved.

MED-Project is pleased to offer this August 2022 Stewardship Plan for Home-Generated Sharps Waste (the "Plan"). Working with CalRecycle, MED-Project revised the Plan to address CalRecycle's June 23, 2022 Request for Approval of the MED-Project March 9, 2022 Stewardship Plan for Home-Generated Sharps Waste ("June 2022 RFA") conditions of approval ("Condition(s)"). This Appendix explains how the Plan satisfies each Condition not identified as "met" in the June 2022 RFA. As described below:

- The Plan satisfies June 2022 RFA Condition 1(a). MED-Project is committed to providing or initiating¹ the distribution of sharps waste containers and mail-back materials at all Points of Sale where any Sharps covered under the Plan² are sold and has satisfied Condition 1(a) by revising the Plan to describe its comprehensive efforts to do so.
- The Plan satisfies June 2022 RFA Condition 1(b). In the event CalRecycle disagrees that the Plan satisfies Condition 1(a), MED-Project also demonstrates how the Plan satisfies 14 CCR § 18972.1(a)(10)(C) and June 2022 RFA Condition 1(b) [and 1(d)] to give CalRecycle every opportunity to fully approve the Plan. In brief, because MED-Project is not allowed by law to compel Point of Sale

<sup>&</sup>lt;sup>1</sup> With regard to sharps waste containers and mail-back materials, MED-Project generally refers to 14 CCR § 18972.1(a)(10)(A) when using the term "provide" and § 18972.1(a)(10)(B) when using the term "initiate."

<sup>&</sup>lt;sup>2</sup> Consistent with the Law and Regulations, the Plan does not limit Mail-Back Services to participating Covered Entities' Sharps. It provides Mail-Back Services for Sharps from both participating and non-participating Covered Entities. *See, e.g.*, Plan Section 1.

Sites to accept its Mail-Back Services, the Plan describes how MED-Project provides or initiates the distribution of sharps waste containers and mail-back materials at the Point of Sale to the extent allowable by law.

- The Plan satisfies June 2022 RFA Condition 1(c). MED-Project revised the Plan to explain how all Ultimate Users, including homeless individuals without a permanent address, can receive Sharps Mail-Back Packages through all approved options under the Plan.
- The Plan satisfies June 2022 RFA Condition 1(d). The Plan explains how MED-Project will provide convenient Mail-Back Services to all Ultimate Users, including homeless individuals without a permanent address.

Satisfying CalRecycle's June 2022 RFA Conditions, the Plan should be approved.

## 2. The Law and Regulations authorize CalRecycle to approve the Plan.

The Law requires a Stewardship Program to "provide[] or initiate[] the distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law." Cal. Pub. Res. Code 42032.2(d)(1)(F)(i); see also 14 CCR § 18973.3(f)(2) (requiring the Plan to describe how it will meet this requirement). The Regulations define "provides or initiates distribution of a sharps waste container and mail-back materials" to include:

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 [providing or initiating at the point of sale or prior] is not allowed by law. These methods must be approved by the department in a stewardship plan and result in substantially the same level of convenience to the ultimate user as [providing or initiating at the point of sale or prior].

14 CCR § 18972.1(a)(10)(C). CalRecycle based June 2022 RFA Conditions 1(a) - 1(d) on these requirements. Below MED-Project

describes how the Plan satisfies these legal standards and June 2022 RFA Conditions 1(a) - 1(d).

#### **Discussion**

1. The Plan satisfies June 2022 RFA Condition 1(a) by providing or initiating the distribution of sharps waste containers and mail-back materials at the Point of Sale.

Condition 1(a) requires MED-Project to: "[d]escribe how the program will (1) provide or initiate distribution of sharps waste containers and mail-back materials at all points of sale where any sharps covered under the plan are sold, and (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 (not just fulfill an order within five business days)." MED-Project has made comprehensive efforts in revising the Plan since receiving the June 2022 RFA Conditions and implementing new and existing strategies and tactics to provide or initiate the distribution of sharps waste containers and mail-back materials at all Points of Sale where any Sharps covered under the Plan are sold. These efforts include:

- Launching an easy-to-use online ordering system by September 5, 2022, that allows any Point of Sale Site with internet access to provide or initiate the distribution of Sharps Mail-Back Packages.
   Point of Sale Sites agree to terms and conditions when they use the online ordering system. See Plan Section 6.
- Launching an easy-to-use phone ordering system by September 5, 2022, that allows any Point of Sale Site to initiate the distribution of Sharps Mail-Back Packages at a Point of Sale and does not require the Point of Sale Site to sign an agreement with MED-Project. A Point of Sale Site will not be required to accept terms and conditions to use the phone ordering system. See Plan Section 6.

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<sup>&</sup>lt;sup>3</sup> The June 2022 RFA stated that "MED-Project specifies that sharps mail-back packages will arrive within five business days as required . . . ." See also Plan Section 6.



Extensive and sustained MED-Project outreach that encourages Point of Sale Sites to provide or initiate distribution of Sharps Mail-Back Packages at Points of Sale. As of the submission of this Plan, MED-Project has completed over 2,000 in-person visits to non-online Point of Sale Sites, targeting those non-online Point of Sale Sites that had not yet activated the online ordering system, and sent over 20,000 emails,10,000 postcards, and 1,500 letters to Point of Sale Sites on how to activate the online ordering system. MED-Project representatives also completed over 6,500 phone calls to Point of Sale Sites to educate them about the Program and how to activate the online ordering system. MED-Project has also featured an information booth at multiple retailer and pharmacy trade shows to promote program awareness. See Plan Section 6.

MED-Project will conduct outreach over 40,000 times via multiple methods, including over 20,000 emails, 10,000 postcards, 1,500 letters, 6,500 phone calls, and 3,000 in-person site visits, by September 5, 2022. MED-Project is conducting these in-person site visits with non-online Point of Sale Sites to, among other things, assist them in using the online and phone ordering systems, and provide materials to promote the Program to Ultimate Users. By September 5, 2022, MED-Project will visit non-online Point of Sale Sites in-person that are not using the online ordering system, in order to assist them in activating the online ordering system at their sites. After September 5, 2022, MED-Project will continue to perform inperson site visits through 2022, and into future years for new non-online Point of Sale Sites, that are not yet activated on the online ordering system. See Plan Sections 6 and 10.

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_	Providing communications to Covered Entities. MED-Project launched multiple messaging campaigns to participating Covered Entities regarding Point of Sale Site participation in the Program. Covered Entities were provided a communication package to use to communicate to who would then include information through emails to Point of Sale Sites. This outreach includes prepared materials to share through Sharps distribution channels. See Plan Sections 6 and 10.
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- Including all potential Point of Sale Sites in the Program by registering them on its online ordering system, and providing information on how to use the online ordering system, to initiate the distribution of Sharps Mail-Back Packages and to distribute information on how to properly dispose of Sharps. See Plan Sections 6 and 10.
- Revising the Point of Sale Site definition to make clear that all Retail pharmacies, Retail pharmacy chains, online retailers, and/or other retailers of Sharps to Ultimate Users are Point of Sale Sites, regardless of whether they are Board of Pharmacy licensed or activated on MED-Project's online ordering system. See Plan Section 1.

In response to the RFA Conditions, MED-Project has revised the Plan implementation timeline and media/outreach plans as necessary to commit itself further to the efforts described above. See Plan Appendix F and Appendix J.

Not only are these efforts described in the Plan; they are succeeding.
For any Point of Sale Sites, including those that have not accepted the terms and conditions of the online ordering system by September 5, 2022, MED-Project provides the phone ordering system to initiate the distribution of sharps waste containers and mail-back materials at the Point of Sale – a system MED-Project is orienting Point of Sale Sites

to through thousands of in-person visits.	See Plan Section 6. While these
Point of Sale Site offerings are designed	and being implemented to serve
all Point of Sale Sites,	
	See Plan Sections 6
and 10.	

The Plan clearly describes these comprehensive efforts to provide or initiate the distribution of sharps waste containers at the Point of Sale, to the extent allowable by law, providing the description that Condition 1(a) requires and meeting the requirements of the Law and Regulations.<sup>5</sup>

- 2. The Plan satisfies the Regulations and June 2022 RFA Condition 1(b).
  - a. MED-Project and its participating Covered Entities cannot compel Point of Sale Sites to accept MED-Project's Mail-Back Services.

If CalRecycle concludes the Plan does not satisfy Condition 1(a), CalRecycle should approve the Plan because it provides or initiates the distribution of sharps waste containers and mail-back materials to the extent allowable by law and complies with June 2022 RFA Condition 1(b) [and 1(d), discussed below]. June 2022 RFA Condition 1(b) requires MED-Project to: "[p]rovide circumstances and justification whereby provision and arranging for arrival, pursuant to CCR sections 18972.1(a)(10)(A) and (B), are illegal or remove the option under CCR section 18972.1(a)(10)(C), described in the *Plan*, which provides instructions to the ultimate user at the point of sale for the ultimate user to arrange for arrival of sharps waste containers and mail-back materials."

After receiving the June 2022 RFA from CalRecycle, MED-Project again discussed with its participating Covered Entities the possibility of compelling Point of Sale Sites to accept MED-Project's Mail-Back Services,

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<sup>&</sup>lt;sup>5</sup> These descriptions include the actions that occur at the Point of Sale when providing or initiating the distribution of sharps waste containers and mail-back materials, as required by the June 2022 RFA. See Plan Section 6.

perhaps through conditions on retailer sales or by limiting retailer purchases from distributors to products that include sharps waste containers and mail-back materials. These discussions once again confirmed that MED-Project's participating Covered Entities do not have such broad control over the retailer industry and cannot compel Point of Sale Sites to accept MED-Project's Mail-Back Services.

The Sharps distribution channels are international in scope and tremendously complex, involving manufacturers, distributors, wholesalers, group purchasing organizations, retailers, pharmacy benefit managers, third-party payers, and health insurers. *E.g.*, Drug Channels Institute, <a href="https://drugchannelsinstitute.com/wp-content/uploads/2012/11/Drug-Channels-2022-Chapters.jpg">https://drugchannelsinstitute.com/wp-content/uploads/2012/11/Drug-Channels-2022-Chapters.jpg</a> (last visited Aug. 12, 2022). Because of this complexity, MED-Project's participating Covered Entities do not have the leverage or relationships to compel Point of Sale Sites to allow MED-Project to provide its Mail-Back Services at their Points of Sale.

# b. MED-Project and its participating Covered Entities are not allowed by law to compel Point of Sale Sites to accept MED-Project's Mail-Back Services.

While MED-Project is making all-out efforts to provide or initiate the distribution of sharps waste containers and mail-back materials at all required Points of Sale, neither its Covered Entities' distribution chains, the Law, the Regulations, nor other law allow it to compel Point of Sale Sites to accept its Mail-Back Services. For instance, there is no authority that allows MED-Project (or its participating Covered Entities) to compel Point of Sale Sites into its Program or to encourage Point of Sale Sites through enforcement referrals to provide or initiate the distribution of sharps waste containers and mail-back materials at Points of Sale.

Lacking the authority to compel Point of Sale Sites to accept its Mail-Back Services, there is nothing MED-Project can do to mandate that Point of Sale Sites provide or initiate the distribution of sharps waste containers and mail-back materials under the Plan. Given these circumstances, compelling

Point of Sale Sites to accept MED-Project's Mail-Back Services is illegal or not allowed by law.<sup>6</sup>

c. MED-Project satisfies the Regulations and June 2022 RFA Condition 1(b) by describing how it will provide Mail-Back Services at the Point of Sale to the extent allowable by law.

Because it is not allowed by law to compel Point of Sale Sites to accept its Mail-Back Services, MED-Project provides or initiates the distribution of sharps waste containers and mail-back materials to the extent allowable by law under 14 CCR § 18972.1(a)(10)(C), Cal. Pub. Res. Code 42032.2(d)(1)(F)(i), and 14 CCR § 18973.3(f)(2) through its many efforts to provide Point of Sale services as described above in this Appendix and throughout the Plan. For the reasons described above, compelling Point of Sale Sites to allow MED-Project to provide or initiate the distribution of sharps waste containers and mail-back materials for the products covered by the Plan would require activities that are not allowed by law or otherwise outside MED-Project's, and its participating Covered Entities', authority. Through the collective efforts outlined above, the Plan describes how MED-Project provides or initiates the distribution of sharps waste containers and mail-back materials at the Point of Sale to the extent allowable by law in accordance with 14 CCR § 18972.1(a)(10)(C) and June 2022 RFA Condition 1(b), as well as Cal. Pub. Res. Code 42032.2(d)(1)(F)(i) and 14 CCR § 18973.3(f)(2).

#### 3. The Plan satisfies June 2022 RFA Condition 1(c).

June 2022 RFA Condition 1(c) requires that MED-Project "[e]xplain how all ultimate users, including homeless individuals without a permanent address, can receive sharps mail-back packages through all approved options, including the option whereby ultimate users are instructed to order a mail-back package through MED-Project's website or call center." MED-Project has provided Point of Sale Sites information describing how to serve homeless individuals without a permanent address through the online and phone ordering systems, as well as the Help Desk. See Plan Sections

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<sup>&</sup>lt;sup>6</sup> MED-Project interprets the term "illegal" in June 2022 RFA Condition 1(b) consistent with the controlling regulatory language of "not allowed by law." See 14 CCR § 18972.1(a)(10)(C).

6 and 10. This information will allow Point of Sale Sites to let their customers know about these services. MED-Project also provides additional information to Point of Sale Sites and Ultimate Users on how to use USPS General Delivery services on the Website and Call Center. See Plan Sections 6 and 10. Because of MED-Project's Plan revisions in response to this and the other June 2022 RFA Conditions, the Plan demonstrates that MED-Project is committed to allowing all Ultimate Users, including homeless individuals without a permanent address, to obtain Mail-Back Services through all approved options at all Point of Sale Sites where any Sharps covered under the Plan are sold.

#### 4. The Plan satisfies June 2022 RFA Condition 1(d).

June 2022 RFA Condition 1(d) provides that "[i]f justification for the use of the option pursuant to CCR section 18972.1(a)(10)(C), described in the Plan, is provided per CalRecycle Condition 1b, MED-Project must (1) explain how all ultimate users, including homeless individuals without a permanent address, can receive sharps mail-back packages through this option whereby ultimate users are instructed to order a mail-back package through MED-Project's website or call center, and (2) ensure the option under CCR section 18972.1(a)(10)(C) results in substantially the same level of convenience as the options under CCR sections 18972.1(a)(10)(A) and (B)." This Condition includes two subparts requiring MED-Project to, respectively: (1) describe how all Ultimate Users, including homeless individuals without a permanent address, can receive Sharps Mail-Back Packages through the Website or Call Center; and (2) ensure the option under 14 CCR § 18972.1(a)(10)(C) "results in substantially the same level of convenience as the options under CCR sections 18972.1(a)(10)(A) and (B)." MED-Project satisfies both subparts of June 2022 RFA Condition 1(d) for the reasons described below.

## a. MED-Project explains how the Website and Call Center will serve all Ultimate Users.

June 2022 RFA Condition 1(d) subpart (1) focuses on how all Ultimate Users, including homeless individuals without a permanent address, can receive Sharps Mail-Back Packages through the Website or Call Center. MED-Project has communicated with Point of Sale Sites and revised the Website, the Call Center, the Help Desk, and the online and phone

ordering systems, to make clear how homeless individuals without a permanent address can receive Sharps Mail-Back Packages. See Plan Sections 6 and 10. MED-Project emphasizes, however, that the Plan will provide Sharps Mail-Back Services to Ultimate Users, including homeless individuals without a permanent address, through the many efforts described in this Appendix. These efforts include, but are in no way limited to, Website and Call Center-based services. See Plan Section 6.

#### b. The Plan provides convenient Mail-Back Services.

As stated above, MED-Project believes the Plan satisfies June 2022 RFA Condition (1)(a). MED-Project is committed to providing or initiating the distribution of sharps waste containers and mail-back materials at all Points of Sale where any Sharps covered under the Plan are sold and has revised the Plan accordingly by describing, and committing to, the many services outlined above. Because MED-Project believes its methods for providing and initiating the distribution of sharps waste containers and mail-back materials described in this Appendix and the Plan satisfy June 2022 RFA Condition (1)(a), MED-Project necessarily also believes they provide "substantially the same level of convenience" as any other methods for providing or initiating the distribution of sharps waste containers and mail-back materials.

#### Conclusion

CalRecycle should conclude that the Plan satisfies the June 2022 RFA Conditions. The Plan meets Condition 1(a) by describing MED-Project's comprehensive efforts to provide or initiate the distribution of sharps waste containers and mail-back materials at all required Points of Sale to achieve the broadest reach possible. If, notwithstanding the Plan's description of MED-Project's comprehensive efforts to provide the required Point of Sale services, CalRecycle concludes MED-Project does not meet June 2022 RFA Condition 1(a), CalRecycle should alternatively approve the Plan under June 2022 RFA Condition 1(b) [and 1(d)] because the Plan describes how MED-Project will provide its Mail-Back Services to the extent allowable by law. The Plan meets Condition 1(c) by describing how all Ultimate Users, including homeless individuals without a permanent address, will receive Mail-Back Services at the Point of Sale. Finally, it

meets Condition 1(d) by providing convenient Mail-Back Services to all Ultimate Users.

Satisfying the June 2022 RFA Conditions, the Plan should be approved. MED-Project looks forward to continuing to implement its Plan for Ultimate Users across the State.

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