

A Product Stewardship Plan for Home-Generated Sharps Waste

State of California September 14, 2021

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

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, who have executed an agreement with MED-Project to participate in the Program.

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

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

Appendix B 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 is anticipated to start in Q4 2021. <u>Appendix D</u> provides MED-Project's initial Program budget for the period running from October 5, 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 <u>Appendix A</u>, 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 <u>Appendix D</u>. 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 a range of 25-75% 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 six months of the annual Program budget.

[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. <u>Appendix A</u> provides reference to the list of the participating Covered Entities funding the Program.

MED-Project prepares the fiscal 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 <u>Appendix D</u>. In addition, during the budget approval process, a reserve level is also approved, as described in **Section 5:** <u>Recommended Reserve</u>. 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 <u>Appendix A</u> 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 In-Scope Purchases and through the Website and Call Center.
- Provide Ultimate Users with instructions at the Point of Sale of In-Scope Purchases for ordering Sharps Mail-Back Packages.
- 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 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 using the Sharps Mail-Back Package.
- Information about proper sharps waste disposal, including information about household hazardous waste facilities that accept Home-Generated Sharps Waste.
- The Website web address and Call Center toll-free telephone number.

Appendix E 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	Address
PureWay Compliance, Inc.	16225 Park Ten Place, Suite 830, Houston, TX 77084
Stericycle, Inc.	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)]

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 In-Scope Purchases and through the Website and Call Center. 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)]

¹The 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.

²The Vendors listed in Table 1 will arrange for Sharps Mail-Back Packages to be shipped from Ultimate Users to treatment and disposal facilities.

Identifying and Notifying Potential Point of Sale Sites

MED-Project will identify Retail pharmacies and Retail pharmacy chains using publicly available information from the State Board. 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 third-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. MED-Project will send reminders to non-responders after Program approval, before and after full Program implementation, and annually thereafter.

Following the initial notification, MED-Project will conduct additional outreach via phone calls, on-site visits, and other methods. **Section 10:** <u>Education and Outreach to Potential and Existing Point of Sale</u> <u>Sites, Pharmacists, Providers, and Other Individuals</u> provides more detail about MED-Project's ongoing outreach to potential Point of Sale Sites.

Interested potential Point of Sale Sites will be able to register to participate in the Program. Once registered, MED-Project will provide Point of Sale Sites with the ability to initiate distribution of a Sharps Mail-Back Package at the Point of Sale and distribute information on how to properly dispose of Sharps to Ultimate Users. MED-Project will execute an agreement with any potential non-online Point of Sale Site that offers to participate in the Program and provide for 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 Point of Sale Site has executed an agreement to participate in the Program, MED-Project will offer them the following services:

 Sharps Mail-Back Packages to provide with In-Scope Purchases at the Point of Sale. An ordering system designed to initiate distribution of a Sharps Mail-Back Package at the Point of Sale of In-Scope Purchases.

MED-Project will offer the above-referenced services to non-online Point of Sale Sites. Online Point of Sale Sites will be given access to an ordering system designed to initiate distribution of a Sharps Mail-Back Package at the Point of Sale of In-Scope Purchases as well as instructions for ordering Sharps Mail-Back Packages to provide to Ultimate Users at the Point of Sale of In-Scope Purchases. See <u>Appendix E</u>.

MED-Project will provide information about proper Sharps waste disposal with each of the options offered.

Point of Sale Sites providing Sharps Mail-Back Packages or instructions for ordering Sharps Mail-Back Packages at the Point of Sale of In-Scope Purchases will be able to order additional stock through the Help Desk. MED-Project will provide Point of Sale Sites with training and educational materials to provide Sharps Mail-Back Packages to Ultimate Users to accommodate the volume of sharps purchased by an Ultimate User over a 12-month period.

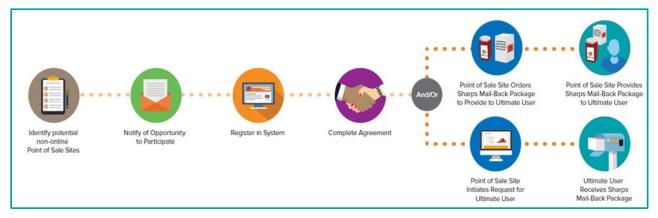


Figure 1: Identification of Potential Non-Online Point of Sale Sites and Point of Sale Site Flow



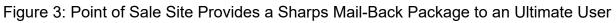
Figure 2: Identification of Potential Online Point of Sale Sites and Point of Sale Site Flow

[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)]

Ultimate User Requests for Sharps Mail-Back Packages

A Point of Sale Site will offer to provide a Sharps Mail-Back Package, initiate distribution of a Sharps Mail-Back Package, or provide instructions for ordering a Sharps Mail-Back Package to Ultimate Users at the Point of Sale of In-Scope Purchases. MED-Project's resources and support available through the Help Desk will allow a non-online Point of Sale Site to request Sharps Mail-Back Packages in bulk, with a default minimum order quantity of 12 units. In cases where the non-online Point of Sale Site provides Sharps Mail-Back Packages to Ultimate Users, fulfillment will be immediate.





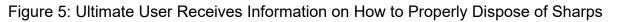
A Point of Sale Site will initiate distribution of a Sharps Mail-Back Package through MED-Project's ordering system and will be designed to be fulfilled within five business days.



Figure 4: Point of Sale Site Initiates Distribution of a Sharps Mail-Back Package to an Ultimate User

MED-Project's fulfillment system is designed to receive and process requests for Sharps Mail-Back Packages, from Ultimate Users, or Point of Sale Sites made on behalf of Ultimate Users for In-Scope Purchases, to arrive within five business days of the In-Scope Purchase at a Point of Sale Site. For Ultimate Users that may have been provided a Sharps Mail-Back Package prior to the Point of Sale of In-Scope Purchases, and may not select to receive a Sharps Mail-Back Package, or elect to not have one initiated at the Point of Sale of In-Scope Purchases, MED-Project will offer a Point of Sale Site materials to provide Ultimate Users that provide instructions for ordering a Sharps Mail-Back Package and information about proper Sharps waste disposal.





Instructions for ordering a Sharps Mail-Back Package and other MED-Project education and outreach provided with In-Scope Purchases at Point of Sale Sites will direct Ultimate Users to the Website and Call Center. See <u>Section 10: Education and Outreach Program</u> for a description of the MED-Project education and outreach program. After receiving a request from an Ultimate User through the Website or Call Center, MED-Project will process requests from Ultimate Users for Sharps Mail-Back Packages through a fulfillment system. MED-Project's fulfillment system is designed to fulfill requests from Ultimate Users for Sharps Mail-Back Packages within five business days of the request.

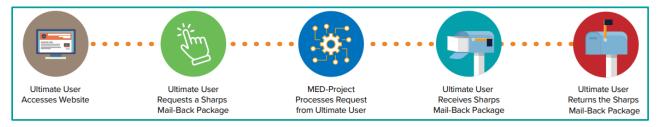


Figure 6: Ultimate User Requests a Sharps Mail-Back Package via the Website



Figure 7: Ultimate User Requests a Sharps Mail-Back Package via the Call Center

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. See 14 CCR 18972.1(a)(10)(C). **Section 10:** <u>Education and Outreach to Ultimate Users</u> 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.

[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	Address
HealthWise Services ³	4800 E Lincoln Ave, Fowler, CA 93625
MedSharps, LLC	17340 Bell North Drive, Schertz, TX 78154

³Transport treated Sharps Mail-Back Packages to California landfills listed in Table 4.

Transporter	Address
Allied Waste Systems, Inc. DBA Republic Services⁴	14747 San Fernando Rd., Sylmar CA 91342
Stericycle, Inc.⁵	2355 Waukegan Road, Bannockburn, IL 60015
TriHaz Solutions, LLC	900 Conception Ave, Huntsville, AL 35801
United States Postal Service ⁶	475 L'Enfant Plaza, SW, Washington, DC 20260

[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

⁴lbid.

⁵lbid.

⁶The United States Postal Service will be used to transport untreated Sharps Mail-Back Packages from Ultimate Users to a treatment facility.

Treatment Facility	Address
HealthWise Services ⁷	4800 E Lincoln Ave, Fowler, CA 93625
MedSharps, LLC	17340 Bell N Dr., Schertz, TX 78154
Stericycle, Inc. Biohazardous Medical Waste Storage, Transfer, and Treatment Facility	245 W. Lodge Dr., Tempe, AZ 85283
Stericycle, Inc. Fresno	4135 W Swift Ave, Fresno, CA 93722
Stericycle, Inc. Vernon	2775 E 26th St, Vernon, CA 90058
TriHaz Solutions, LLC	900 Conception Ave, Huntsville, AL 35801

Table 4: Disposal Facilities

Disposal Facility	Address
American Avenue Disposal Site	18950 W. American Avenue, Kerman, CA 93630
North Montgomery Regional Landfill	115 Division Street, Montgomery, AL 36104

⁷The 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.

Disposal Facility	Address
Republic Services Apache Junction Landfill	4050 S. Tomahawk Road Apache Junction, AZ 85119
Sunshine Canyon Landfill	Sunshine Canyon Rd, Sylmar, CA 91342
Tessman Road Landfill	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. MED-Project will verify that the household hazardous waste facility is listed on the <u>California</u> <u>Department of Public Health</u> and <u>California Department of Toxic</u> <u>Substances Control</u> websites.

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 receiving reimbursement on its Website as collection sites where Ultimate Users may dispose of Home-Generated Sharps Waste.



Figure 8: Local Agency Reimbursement for Home-Generated Sharps Waste Disposal

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 potential and existing Point of Sale Sites and Local Agencies.
- Receive expressions of interest in the Program from potential Point of Sale Sites.
- 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 and instructions for proper Sharps waste disposal 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.
- 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 on the 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.

After the end of the 270-day period, 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 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. Potential and existing 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.

Outreach 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.
- 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.
- 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.

Appendix G 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.

Appendix H 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:

- Direct links to the nearest household hazardous waste facilities:
 - Household Hazardous Waste Facilities Sorted by City.
 - Home-Generated Sharps and Pharmaceutical Consolidation Points.

- 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.
- User-friendly access to public service announcements used in MED-Project's media campaigns.
- Links to MED-Project's social media webpages.

The Website will communicate information in multiple formats, including:

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

Appendix I provides a sample mockup of the Website and its supporting pages. See <u>Section 13: Compliance with Applicable Laws</u> for a description of how MED-Project proposes to provide a neutrally branded website if CalRecycle approves more than one Stewardship Program. Appendix J 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.
- 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.
- Information on collection options for Home-Generated Sharps Waste, including a ZIP code-based map locator provided on a publicly available, third-party platform to help Ultimate Users find the nearest household hazardous waste facilities, that have received reimbursements from MED-Project, 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 Potential and Existing Point of Sale Sites, Pharmacists, Providers, and Other Individuals

MED-Project will perform education and outreach to encourage participation from potential 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.

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.
- If participating, how to comply.
- Where/how to obtain information on requirements.

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.

Website for Point of Sale Sites

MED-Project will establish a Website intended to educate potential and existing Point of Sale Sites and other stakeholders about the Program and the opportunity to participate. 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 potential and existing 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 joining the Program 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 potential and existing Point of Sale Sites, both at a corporate and individual site level. This team also manages in-person and virtual meetings and presentations with decision-makers at potential Point of Sale Sites to encourage participation in the Program.

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

- 1. 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, 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 encourage participation of relevant businesses and individuals and provide updates or communicate changes to participating businesses and individuals.
- 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.

Disclaimer

The written and verbal materials distributed under the education and outreach program will include a disclaimer similar to: "This material has been supplied for the purpose of compliance with law and does not necessarily reflect the views of MED-Project or the companies participating in the MED-Project Product Stewardship Plan."

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 the number of Sharps Mail-Back Packages distributed by county and Home-Generated Sharps Waste returned:

- 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.
- 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: <u>Sharps Mail-Back</u> <u>Packages Distributed and Home-Generated Sharps Waste Returned</u> and Section 11: <u>Home-Generated Sharps Waste Collected by</u> <u>Household Hazardous Waste Facilities</u> 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

- Number of participating Point of Sale Sites.
- 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

If more than one Stewardship Program is approved, MED-Project will coordinate with other Program Operators to avoid confusion to the public and all program participants related to the services provided by all Stewardship Programs. The following sections describe the basic elements of coordination MED-Project proposes to take upon approval of another Stewardship Program.

[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. Program Operators will develop a common Stewardship Program decal, emblem, or logo, as approved by CalRecycle, 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 31st, 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 A

Participating Covered Entities

The full list of participating Covered Entities as of June 30, 2021 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 in a separate accessible Excel spreadsheet attachment with the Plan. The information was provided by participating Covered Entities between January 6, 2021, and June 30, 2021.

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 Business, Consumer Services and Housing Agency Department of Consumer Affairs Gavin Newsom, Governor



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,

Digitally signed by Thomas Horner Date: 2021.09.10 11:49:05 -07:00

Thomas Horner Senior Environmental Scientist Chief, Medical Waste Management Program

> Medical Waste Management Program, MS 7405, IMS K-2 • P.O. Box 997377 Sacramento, CA 95899-7377 • (916) 449-5671 www.cdph.ca.gov/medicalwaste



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 collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.

Julson

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: \$545,304
- 2022: \$5,785,031
- 2023: \$9,358,683
- 2024: \$11,685,215
- 2025: \$13,325,812

Total Program Costs

- 2021: \$545,304
- 2022: \$5,785,031
- 2023: \$9,358,683
- 2024: \$11,685,215
- 2025: \$13,325,812

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: \$114,082
- 2022: \$2,567,900
- 2023: \$5,032,745
- 2024: \$7,226,973
- 2025: \$9,077,936

Administrative Costs

- 2021: \$413,300
- 2022: \$2,333,597

- 2023: \$2,370,684
- 2024: \$2,446,236
- 2025: \$2,310,089

Departmental Administrative Fee Costs

- See note.¹
- 2021: \$-
- 2022: \$-
- 2023: \$-
- 2024: \$-
- 2025: \$-

Education and Outreach Costs

- 2021: \$17,922
- 2022: \$883,535
- 2023: \$1,955,255
- 2024: \$2,012,007
- 2025: \$1,937,787

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

- 2021: \$0
- 2022: \$0
- 2023: \$0
- 2024: \$0
- 2025: \$0

¹MED-Project understands that CalRecycle is establishing the departmental administrative fee. MED-Project will include the administrative fee in the budget once the fee has been established.

Appendix E

Sample Sharps Mail-Back Package



Figure 9: Biohazard Container and Sharps and Injector Mail-Back Package Shipping Label/Box

Sample Sharps Mail-Back Package Insert

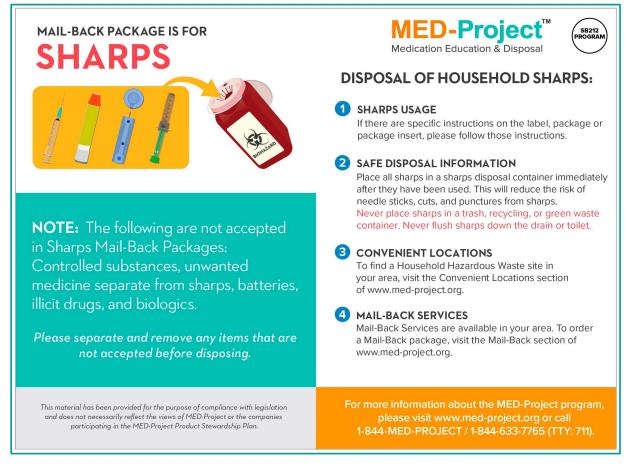


Figure 10: Mail-Back Package Insert for Sharps Disposal

Figure Description

Figure 10 Description: Mail-Back Package is for Sharps

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

- Controlled substances
- Unwanted medicine separate from sharps
- Batteries
- Illicit drugs
- Biologics

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.
- Convenient Locations: To find a Household Hazardous Waste site in your area, visit the Convenient Locations section of <u>www.med-</u> project.org.
- Mail-Back Services: Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of <u>www.med-</u> <u>project.org</u>.

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the companies participating in the MED-Project Product Stewardship Plan.

For more information about the MED-Project program, please visit <u>www.med-project.org</u> 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 – 60 Days)

- Develop signage and outreach materials for production and distribution.
- Develop potential Point of Sale Site participation information and factsheets.

Outreach Materials and Collateral: Year 1 (90 Days)

- Finalize signage and outreach materials for production and distribution.
- Finalize potential Point of Sale Site participation information and factsheets.

Outreach Materials and Collateral: Year 1 (120 Days – 180 Days)

Provide educational signage/posters to Point of Sale Sites as sites are activated.

Outreach Materials and Collateral: Year 1 (180 Days)

Provide educational and outreach materials to potential household hazardous waste facilities operated by Local Agencies.

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

- Provide educational signage/posters to Point of Sale Sites as sites are activated.
- Provide educational signage and materials to Point of Sale Sites upon request and via the Help Desk.
- Provide educational and outreach signage for Local Agencies, hospitals, Pharmacies, and other locations upon request and via the Help Desk.

Outreach Materials and Collateral: Year 1 (270 Days)

Release educational video series for potential and existing Point of Sale Sites.

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

- Provide educational signage/posters to Point of Sale Sites as sites are activated.
- 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 Local Agencies, 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 sites are activated.
- 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 Local Agencies, 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 sites are activated.
- 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 Local Agencies, 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 sites are activated.
- 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 Local Agencies, 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 sites are activated.
- 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 Local Agencies, 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 interested potential 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.
- 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 (210 Days)

Press release announcing annual report highlights.¹

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

- 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.

¹Timing based on plan approval in October 2021.

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 (210 Days)

Press release announcing annual report highlights.²

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

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

- Send reminders to non-responders before full Program implementation.
- Continue follow-up with potential Point of Sale Sites.
- Onsite visits/presentations or phone contact as needed.

²Timing based on plan approval in October 2021.

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

- Continue follow-up with potential Point of Sale Sites.
- Send reminders to non-responders after Program implementation.
- Onsite visits/presentations or phone contact as needed.

Collection Site Activity: Year 2 (30 Days – 180 Days)

Onsite visits/presentations or phone contact as needed.

Collection Site Activity: Year 2 (210 Days – 270 Days)

- Onsite visits/presentations or phone contact as needed.
- Initial annual reminders to non-responders.

Collection 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 (120 Days)

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

Sample Educational and Outreach Materials

WHAT SHOULD SAFELY **YOU DO WITH DISPOSE OF** YOUR SHARPS **SHARPS?** For more information about the MED-Project UNWANTED Program, visit www.med-project.org CONVENIENT MAIL-BACK SERVICES SAFE DISPOSAL INFORMATION LOCATIONS or call 1-844-MED-PROJECT 1-844-633-7765 (TTY: 711) SHARPS DISPOSAL Safely disposing of home-generated used sharps is important. Sharps that are not disposed of safely may ACCEPTED: cause injury. Sharps such as hypodermic needles, pen needles, not accepted before disposing. **MED-Project**[™] NOT ACCEPTED: Medication Education & Disposal www.med-project.org SB212

Figure 11: Safe Disposal of Sharps Brochure Containing Contact Information and Accepted and Not Accepted Medications (Front)

Figure 11 Description: What should you do with your sharps?

For more information about the MED-Project Program, visit <u>www.med-</u> project.org 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, unwanted medicine separate from sharps, batteries, illicit drugs, and biologics

Safely Dispose of Sharps

- Sharps Usage
- Safe Disposal Information
- Convenient Locations
- 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

SAFE DISPOSAL INFORMATION

those instructions.

SHARPS USAGE

on the label, package or

If there are specific instructions

package insert, please follow

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.

CONVENIENT LOCATIONS

To find a Household Hazardous Waste site in your area, visit the Convenient Locations section of www.med-project.org.



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.



DISPOSAL OF HOUSEHOLD SHARPS 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; 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

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the companies participating in the MED-Project Product Stewardship Plan.

Figure 12: Safe Disposal of Sharps Brochure Containing Sharps Usage and Disposal Information, Convenient Locations, and Mail-Back Services(Back)

Image Description

Figure 12: 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.
- Convenient Locations: To find a Household Hazardous Waste site in your area, visit the Convenient Locations section of <u>www.med-</u> project.org.
- Mail-Back Services: Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of <u>www.medproject.org</u>.

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

MED-Project[™]

Medication Education & Disposal



DISPOSAL OF HOUSEHOLD SHARPS

HIGHALARD

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, unwanted medicine separate from sharps, batteries, illicit drugs, and biologics.



CONVENIENT LOCATIONS

To find a Household Hazardous Waste site in your area, visit the Convenient Locations section of www.med-project.org.



2 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)

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the companies participating in the MED-Project Product Stewardship Plan.

Figure 13: Sample Disposal of Household Sharps Information for Point of Sale Sites

Figure 13 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, unwanted medicine separate from sharps, batteries, illicit drugs, and biologics.

- Convenient Locations: To find a Household Hazardous Waste site in your area, visit the Convenient Locations section of <u>www.med-</u> project.org.
- Mail-Back Services: Mail-Back Services are available in your area. To order a Mail-Back package, visit the Mail-Back section of <u>www.medproject.org</u>.

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

Appendix H

Sample Signage for Hospitals, Pharmacies, and Other Locations

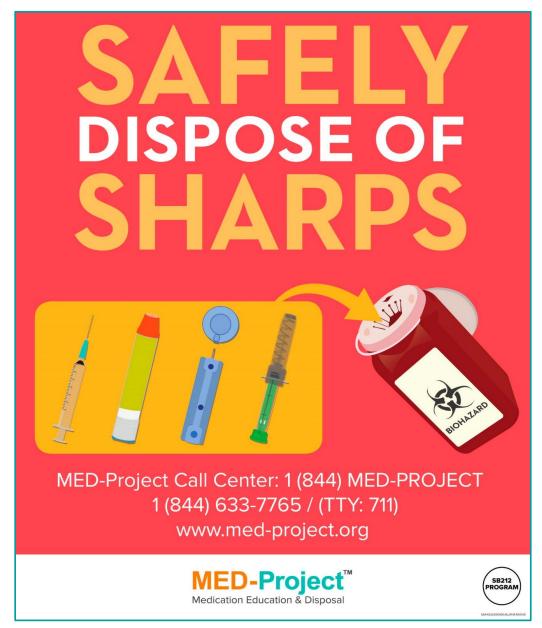


Figure 14: Sharps Disposal Signage Placed in Hospitals, Pharmacies, and Other Locations

Appendix I

Sample Webpage Mockups



Figure 15: Sample California State MED-Project Sharps Program Website Home Page

Figure 15 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
- MEDfaq
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Convenient Locations
- Mail-Back Services
- Privacy Policy

Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn

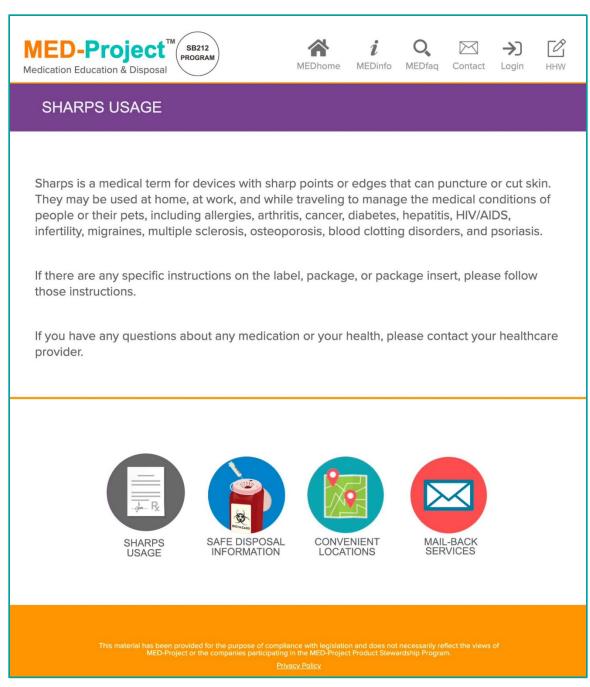


Figure 16: Sample California State Sharps Program Website Sharps Usage Page Containing Sharps Information

Figure 16 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.

Linked California State MED-Project Website Pages

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- HHW
- Safe Disposal Information
- Convenient Locations
- Mail-Back Services
- Privacy Policy

Linked Social Media Sites

- Facebook

- Twitter
- LinkedIn

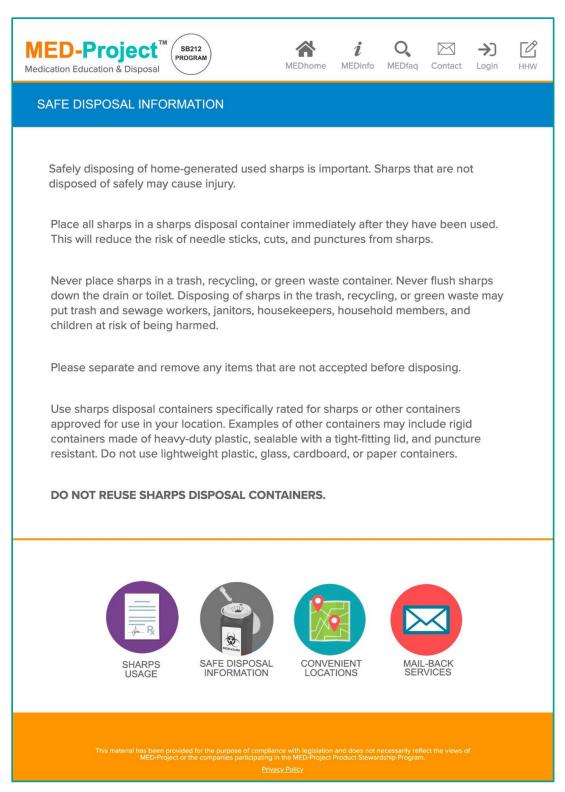


Figure 17: Sample California State Sharps Program Website Safe Disposal Information Page

Figure 17 Description: MED-Project[™] Medication Education & Disposal – SB212 Program – California State Sharps Program – Safe Disposal 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.

Linked California State MED-Project Website Pages

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- HHW
- Sharps Usage
- Convenient Locations

- Mail-Back Services
- Privacy Policy

Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn

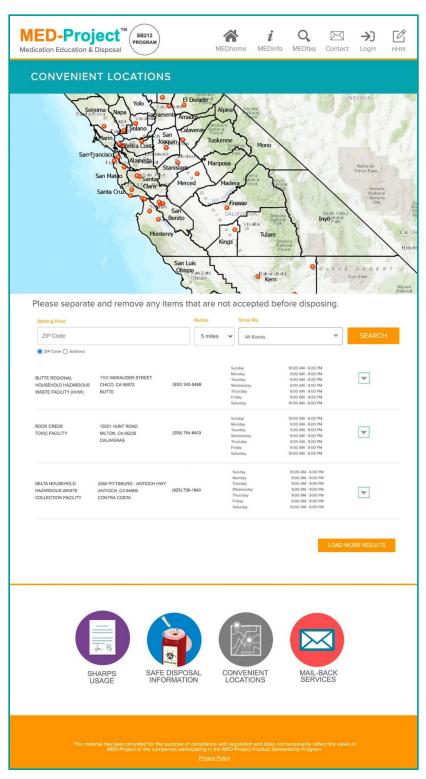


Figure 18: Sample California State Sharps Program Website Convenient Locations Page

Figure 18 Description: MED-Project[™] Medication Education & Disposal – SB212 Program – California State Sharps Program – Convenient Locations Website Page

Note: There is a sample map containing Secure Collection Receptacle locations located in Sacramento, California. 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: Convenient Locations are returned after filling out map form fields.

Sample Convenient Location:

- 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.
 - Monday 9:00 a.m. 9:00 p.m.
 - Tuesday 9:00 a.m. 9:00 p.m.
 - 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

Linked California State MED-Project Website Pages

- MEDhome
- MEDinfo
- MEDfaq

- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Mail-Back Services
- Privacy Policy

Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn

MED-Project TM (SB212) Medication Education & Disposal		MEDhome 1	<i>i</i> MEDinfo	Q MEDfaq	Contact	→) Login	ННШ		
MAIL-BACK SERVICES									
SHARPS MAIL-BACK SERVICES Mail-Back Services for sharps are availab Sharps such as hypodermic needles, pen devices that are used to penetrate the sk	need	dles, intrave	enous	needles,	lancets, a	and othe	er		
NOTE: The following are not accepted in substances, unwanted medicine separate				-		biologic	:S.		
Please separate and remove any items the Please complete the below form to reque Instructions for disposal will be provided forms for each type of mail-back package Choose your package type*	est a p with a	ore-paid, pr	e-addr	essed m	ail-back p	-			
Email									
Address 2									
City*		CA ZIP Code*							
* Required field SUBMIT REQUEST									
SHARPS USAGE SAFE DISPOS INFORMATIO		CONVENII	ENT	MAIL	-BACK VICES				
This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the companies participating in the MED-Project Product Stewardship Program. <u>Privacy Policy</u>									

Figure 19: Sample California State Sharps Program Website Sharps Mail-Back Services Page

Figure 19 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, unwanted medicine separate from sharps, batteries, illicit drugs, and biologics.

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

Please complete the below form to request a pre-paid, pre-addressed mailback 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
 - o City
 - o State
 - ZIP Code*
- Submit Request Button

Linked California State MED-Project Website Pages

- MEDhome

- MEDinfo
- MEDfaq
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Convenient Locations
- Privacy Policy

Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn

MED-Pro Medication Education	-	SB212 PROGRAM	MEDhome	<i>i</i> MEDinfo	Q MEDfaq	Contact	→) Login	HHW
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 English Frequently Asked G English Radio Public Servic English Video Public Servic English	Questions		-					
If you would like to order brochures, click here. If you would like any of these materials emailed to you, contact california@med-project.org.								
This ma	aterial has been pr MED-Proje	rovided for the purpose oct or the companies pa	e of compliance with legi articipating in the MED-P <u>Privacy Policy</u>	slation and does roject Product S	s not necessa Stewardship Pi	rily reflect the v ogram.	iews of	

Figure 20: Sample California State Sharps Program Website MEDinfo Page

Figure 20 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 **<u>california@med-project.org</u>**.

Linked California State MED-Project Website Pages

- MEDhome
- MEDfaq
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Convenient Locations

- Privacy Policy

Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn

MED-Project TM Medication Education & Disposal	MEDhome	i MEDinfo	Q MEDfaq	Contact	→) Login	HHW			
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?									
Where can I find information about the safe handling and storage of sharps?									
Whom should I call with a question about my 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 medication or sharps down the toilet?	Can I flush my medication or sharps down the toilet?								
I have a question not answered by this website. Is there someo	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?									
This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the companies participating in the MED-Project Product Stewardship Program. MED-Project or the companies participating in the MED-Project Product Stewardship Program. <u>Privacy Policy</u>									

Figure 21: Sample California State Sharps Program Website MEDfaq Page

Figure 21 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?

Linked California State MED-Project Website Pages

- MEDhome
- MEDinfo
- Contact
- Login
- HHW
- Sharps Usage
- Safe Disposal Information

- Convenient Locations
- Privacy Policy

Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn







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HHW

CONTACT

If you are experiencing a medical emergency, please dial 911. If For answers to some frequently asked questions about MED-Project, click here. 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. Residents If you are a resident of California and have questions about If you have questions about your medication, please call your MED-Project, please contact: health care provider. 1 (844) MED-PROJECT or 1 (844) 633-7765 or (TTY: 711) Local Agencies/Point of Sale Sites If you would like to order brochures, click here. If you would like to leave feedback about the MED-Project Program, please click here. If you have any questions, comments, or concerns, please click here. 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 1 (866) 633-1812 Fax us: 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

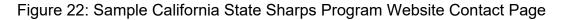


Figure 22 Description: MED-Project[™] Medication Education & Disposal – SB212 Program – California State Sharps Program – Contact Website Page

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-</u> 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

Linked California State MED-Project Website Pages

- MEDhome
- MEDinfo
- MEDfaq
- Login
- HHW
- Sharps Usage
- Safe Disposal Information
- Convenient Locations
- Privacy Policy

Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn

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</u> to Local Agencies.

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 potential Point of Sale Sites of the opportunity to participate in 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.
- Initiate registration process for interested potential Point of Sale Sites to be able to register on the Website 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 ability for Points of Sale Sites to provide or initiate distribution of Sharps Mail-Back Packages to Ultimate Users for In-Scope Purchases at Point of Sale Sites, or prior, at no cost to the Ultimate User, or arrange, at the Point of Sale Site, or prior, for a Sharps Mail-Back Package to be sent to the Ultimate User and arrive within five business days of the request, at no cost or inconvenience to the Ultimate User.

Education and Outreach (Days 1-90)

- Launch accessible Website that provides:
 - Translations using a third-party translation tool.
 - Other informational pages.
- Activate the Call Center for Ultimate Users.
- Activate the Help Desk for potential and existing Point of Sale Sites, Local Agencies, hospitals, Pharmacies, other locations, pharmacists, providers and other individuals.

Education and Outreach (Days 91–180)

- Provide educational and outreach materials to potential household hazardous waste facilities operated by Local Agencies.
- Make educational and outreach materials available to Ultimate Users, potential household hazardous waste facilities operated by Local Agencies, potential and existing Point of Sale Sites, hospitals, Pharmacies, other locations, pharmacists, providers, and other individuals upon request and via the Help Desk.

Education and Outreach (Days 181–270)

- Release educational video series for Authorized Collectors and potential Authorized Collectors.
- Provide educational signage and materials to Point of Sale Sites upon request and via the Help Desk.
- Launch social media activity.
- Release educational video series for potential and existing Point of Sale Sites.
- Finalize public service announcement for release.

Appendix K

Sample Call Center Flow

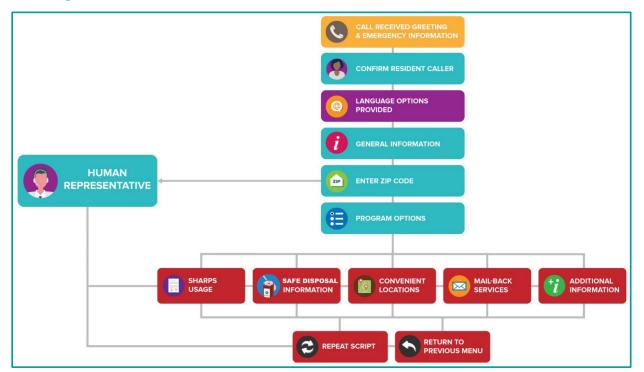


Figure 23: Sample Call Center Flow

Figure Description

Figure 23 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
 - Convenient Locations*
 - Mail-Back Services*
 - 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):
 - \circ 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):
 - Appendix L.

18973(e)

- Regulatory Requirement: Certification.
- Plan Section(s):
 - <u>Section 4: State Agency Determinations and</u> <u>Certifications</u>.
 - Appendix C.

18973.1(a) - (l)

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

18973.1(m)

- Regulatory Requirement: Implementation of an approved plan.
- Plan Section(s):
 - Section 6: Mail-Back Program.
 - 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: <u>Covered Entities</u>.
 - <u>Appendix A</u>.

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.
 - <u>Appendix A</u>.

18973.3(d)(1)

- Regulatory Requirement: State Agency Determinations.
- Plan Section(s):
 - <u>Section 4: State Agency Determinations and</u> <u>Certifications</u>.
 - Appendix C.

18973.3(d)(2)

- Regulatory Requirement: Compliance Certifications.
- Plan Section(s):
 - <u>Section 4: State Agency Determinations and</u> <u>Certifications</u>.
 - Appendix C.

18973.3(e)

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

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>.
 - Section 14: Policies and Procedures.

18973.3(f)(2)

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

18973.3(f)(3)

- Regulatory Requirement: Collection, transportation, and disposal system records.
- Plan Section(s):
 - 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):
 - 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):
 - 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</u> <u>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):
 - Section 7: Reimbursement to Local Agencies.

18973.3(g)(2)(A)

- Regulatory Requirement: Issuing payment within 45 days.
- Plan Section(s):
 - 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):
 - 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.
 - 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</u> <u>Locations</u>.
 - Appendix H.

18973.3(i)(3)

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

18973.3(i)(4)

- Regulatory Requirement: Toll-free telephone number.
- Plan Section(s):
 - Section 10: <u>Website for Ultimate Users</u>.
 - 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> <u>Education and Outreach Program</u>.

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):
 - 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):

• 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.
 - 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):
 - Section 5: Initial Program Budget.
 - <u>Appendix D</u>.

18973.6(c)

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

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>.
 - <u>Appendix D</u>.

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> <u>Cost Category</u>.

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: <u>Record Maintenance</u>.

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):
 - Section 14: <u>Record Maintenance</u>.

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: <u>Revenue</u>.

18974.2

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

• N/A.

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