



A Product Stewardship Plan for Covered Drugs from Households

State of California
March 9, 2022

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Section 1: Definitions

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

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

CalRecycle or Department: The State of California Department of Resources Recycling and Recovery and any successor agency.

Carrier: A common or contract carrier used to transport Covered Drugs.

DEA: The U.S. Drug Enforcement Administration.

DEA Rule: The DEA Final Rule, “Disposal of Controlled Substances,” 79 Fed. Reg. 53,520, codified at 21 C.F.R. § 1300, 1301, 1304, 1305, 1307 and 1317 and adopted on September 9, 2014.

DOT: The U.S. Department of Transportation.

Help Desk: Resources and support available to Authorized Collectors and Mail-Back Distribution Locations. The Help Desk is provided through the Website, a toll-free telephone number, or california@med-project.org.

Inhaler Mail-Back Packages: Pre-paid, pre-addressed Mail-Back Packages provided by Vendor for the collection and disposal of inhalers.

Injector Mail-Back Packages: Pre-paid, pre-addressed Mail-Back Packages provided by Vendor for the collection and disposal of Pre-filled Injector Products.

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

Mail-Back Distribution Location: a facility, such as a law enforcement agency, town hall, or library, that is open to the public and offers Mail-Back Packages to Ultimate Users.

Mail-Back Packages: Pre-paid, pre-addressed mail-back containers, envelopes, packages, or systems provided by Vendor for the collection and disposal of Covered Drugs.

Mail-Back Services: The provision of pre-paid, pre-addressed containers, envelopes, packages, or systems for the collection and disposal of Covered Drugs.

On-Demand Collection Service: A service method whereby Authorized Collector employees manage the removal and packaging of full Secure Collection Receptacle inner liners provided by Vendor for Carrier pick-up.

Pre-filled Injector Products: Pre-filled injector products with a retractable or otherwise securely covered needle from which Covered Drugs cannot be removed.

Program: The Stewardship Program established by this Plan.

Rapid Response: A response provided by Vendor to an incident or other event at an Authorized Collection Site requiring an urgent response. Rapid Response does not include emergencies that pose an immediate threat to the environment or health.

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

Secure Collection Receptacle: A kiosk supported by MED-Project for the collection of Covered Drugs at an Authorized Collection Site. Secure Collection Receptacles comply with all applicable laws, regulations, and other legal requirements.

Standard Mail-Back Packages: Pre-paid, pre-addressed mail-back envelopes provided by Vendor for the collection and disposal of Covered Drugs, except for inhalers or Pre-filled Injector Products.

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

Vendor: Any Vendor hired by MED-Project to provide goods or services under the Program.

Website: The website operated by MED-Project and located at www.med-project.org or www.medproject.org.

[PRC 42030, 14 CCR § 18972.1]

Section 2: Contact Information

Corporate Officer

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

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

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

[PRC 42032.2(a)(1)(A), 14 CCR § 18973.2(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), 42032.2(a)(1)(A), 14 CCR § 18973.2(b)]

Section 3: Covered Drugs Sold by Each Participating Covered Entity

[Appendix B](#) provides reference to an accessible Excel spreadsheet containing the list of each Covered Drug sold or offered for sale by each participating Covered Entity covered by the Plan.

[PRC 42032.2(a)(1)(A), 14 CCR § 18973.2(c)]

Section 4: Authorized Collectors

Participating Authorized Collectors

[Appendix C](#) provides reference to an accessible Excel spreadsheet containing the list of participating Authorized Collectors operating a Collection Site.

[PRC 42032.2(a)(1)(B), 14 CCR § 18973.2(d)(1)]

Notification

MED-Project began contacting potential Authorized Collectors in the State on January 15, 2021, through a direct mail campaign. [Appendix D](#) provides a template of the notification letter. Following the direct mail campaign, MED-Project contacted many of those potential Authorized Collectors at the headquarters and individual site level by phone, email, or through in-person site visits. [Appendix E](#) provides:

- A reference to an accessible Excel spreadsheet containing the list of potential Authorized Collectors that were notified of the opportunity to serve as an Authorized Collector.
- A reference to an accessible Excel spreadsheet containing the method by which each potential Authorized Collector was notified.

[Section 9: Education and Outreach to Authorized Collectors, Potential Authorized Collectors, Pharmacists, Providers, and Other Individuals](#) describes education and outreach to Authorized Collectors and potential Authorized Collectors in greater detail.

[PRC 42032.2(b)(1), 14 CCR § 18973.2(d)(2)]

Good Faith Negotiations

Regardless of whether MED-Project has achieved the minimum convenience standards in PRC 42032.2(a)(1), within 30 days of receiving an expression of interest from a potential Authorized Collector after Plan approval, MED-Project will begin good-faith negotiations by initiating a process that includes:

- Conducting an eligibility assessment.
- Providing a questionnaire to collect information required for an agreement if the potential Authorized Collector is eligible to participate in the Program.
- Providing a draft agreement based on information provided in the returned questionnaire.
- Providing a draft written offer to participate stating that the potential Authorized Collector has reviewed MED-Project’s draft agreement, identified no significant objections to the draft agreement, agreed to comply with all applicable laws, regulations, and other legal requirements and agreed to participate in the Program without compensation.
- Receiving a signed offer to participate from the potential Authorized Collector.

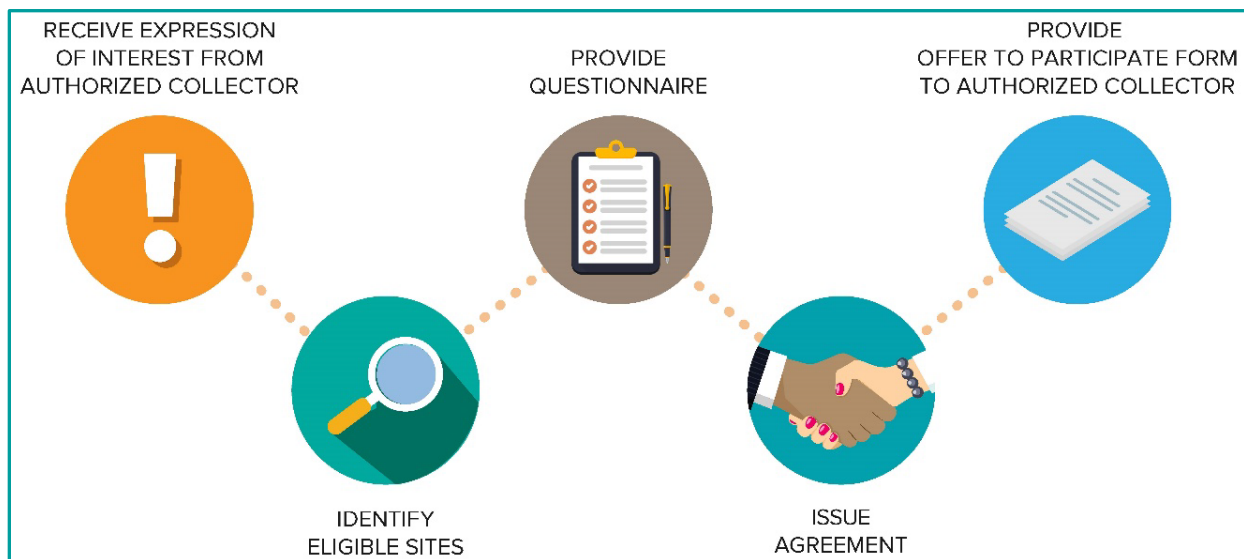


Figure 1: Good Faith Negotiations Process

If a potential Authorized Collector identifies objections to the MED-Project draft agreement, MED-Project will negotiate with that Authorized Collector to reach an agreement that will allow it to participate in the Program on terms consistent with the scope of the Law and Regulations. MED-Project will not exclude potential Authorized Collectors from Program participation when agreement terms cannot be reached, unless the potential Authorized Collector is unwilling to agree to terms regarding compliance with all applicable laws, regulations, other legal requirements, or any other MED-Project terms consistent with the scope of the approved Plan and SB212 (the “Statute”).

When conducting an eligibility assessment, MED-Project will evaluate criteria including but not limited to the following:

- DEA compliant Secure Collection Receptacle placement location.
- Clear and active State Board pharmacy license, as applicable.
- DEA registration status, as applicable.

While MED-Project will begin good-faith negotiations by initiating this process within 30 days as described above, it may take more than 30 days to complete the entire process. Any representative with authority to make commitments on behalf of a potential Authorized Collector can express interest in participating in the Program through email, US mail, fax, or the Help Desk. [Section 4: Incorporation of Potential Authorized Collectors](#) provides additional detail about how MED-Project will incorporate potential Authorized Collectors into the Program.

[PRC 42032.2(b)(1), 14 CCR § 18973.2(d)(3)]

Pharmacy Participation Requirements

MED-Project notifications to Retail Pharmacies notify the Retail Pharmacy of the requirement in PRC 42032.2(b)(2) to make a reasonable effort to serve as an Authorized Collector as part of a Stewardship Program.

PRC 42032.2(b)(2) requires a Retail Pharmacy Chain to have at least one location or 15 percent of its store locations, whichever is greater, serve as Authorized Collectors in a county where it has store locations and the minimum threshold described in PRC 42032.2(a)(1)(F)(i) is not met. As described in the Program implementation timeline provided in [Appendix F](#),

MED-Project will notify Retail Pharmacy Chains that have store locations in a county where MED-Project has not met the minimum threshold described in PRC 42032.2(a)(1)(F)(i). MED-Project will work with the Retail Pharmacy Chain to have at least one location or 15 percent of its store locations in such counties, whichever is greater, serve as Authorized Collectors before MED-Project fully implements operation of the Program.

[PRC 42032.2(b)(2), 14 CCR § 18973.2(d)(4)]

Incorporation of Potential Authorized Collectors

After Plan approval, MED-Project will enter into agreements with any potential Authorized Collector including it as an Authorized Collector in the Program within 90 days of receiving the signed written offer to participate as described in [Section 4: Good Faith Negotiations](#).

Once an agreement is executed, MED-Project will activate the potential Authorized Collector as an Authorized Collection Site by initiating a process that includes:

- A pre-installation visit and site orientation.
- Secure Collection Receptacle installation.
- Post-installation follow-up.
- Ongoing monitoring and support.

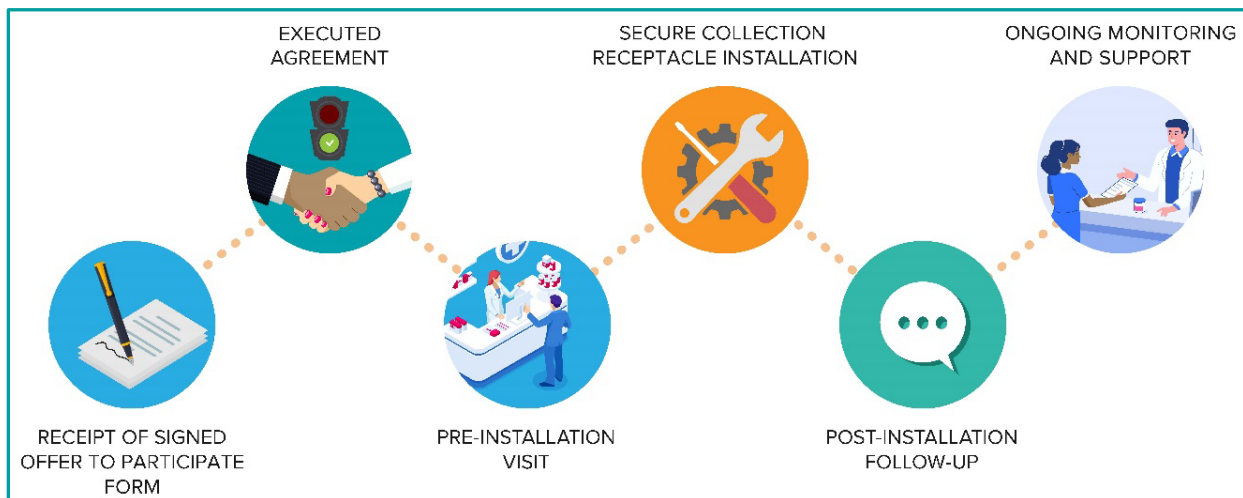


Figure 2: Process to Incorporate Potential Authorized Collectors

Secure Collection Receptacle installation is the responsibility of MED-Project once the Authorized Collector:

- Identifies a placement location that complies DEA Rule §§ 1317.75(d), 1317.35(a), and State Board requirements described in [Section 12: State Board](#).
- Requests assistance with the installation.

MED-Project pays costs associated with placement and maintenance of Secure Collection Receptacles.

During the Secure Collection Receptacle installation, MED-Project will provide the Authorized Collector Secure Collection Receptacle accessories, including:

- Signage, posters, and brochures.
- A binder containing guidance documents, logs, and forms.
- Graphite powder for the Secure Collection Receptacle locksets on the front door and drop-slot and an accompanying safety data sheet.
- An upper lock key and keychain with printed Help Desk phone number.
- A lower lock key and keychain with printed Help Desk phone number.
- Out-of-service temporary signage.

Examples of some of the Secure Collection Receptacle accessories are provided in [Appendix G](#).

[PRC 42032.2(b)(3), 14 CCR § 18973.2(d)(5)]

Reasons for Exclusion

As of Plan submission, MED-Project has not excluded any potential Authorized Collectors from the Program. MED-Project will exclude a potential Authorized Collector that is unable to comply with all applicable laws, regulations, other legal requirements, or any other MED-Project terms consistent with the scope of the approved Plan and the Statute.

[PRC 42032.2(a)(1)(B), 14 CCR § 18973.2(d)(6)]

Notification of Rejection

If a potential Authorized Collector is excluded from the Program, MED-Project will notify the potential Authorized Collector in writing of the reason for exclusion and any changes the potential Authorized Collector can make to join the Program.

[14 CCR § 18973.2(d)(7)]

Section 5: State Agency Determinations and Certifications

[Appendix H](#) provides the determinations received from the agencies.

[Appendix H](#) also includes the written certification by an authorized representative of MED-Project.

[PRC 42032(b)(1), 42032(b)(3), 42032(b)(4), 42032.2(a)(1)(C), 14 CCR §§ 18973.2(e)(1), 18973.2(e)(2)]

Section 6: Program Budgets and Funding

[14 CCR § 18973.6]

Initial Program Budget

[PRC 42033]

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

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

Kim Peterson
Director of Finance
MED-Project USA
1800 M Street, NW
Suite 400 South
Washington, DC 20036
Phone: 1 (833) 633-7765
Fax: 1 (866) 633-1812
california@med-project.org
www.med-projectusa.org

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

[14 CCR § 18973.6(a)]

Anticipated Costs to Implement the Program

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

actual performance may differ from what is projected in the Program budget. No guarantee is implied as to the accuracy of the Program budget.

The Program started on December 9, 2021. [Appendix I](#) provides MED-Project's initial Program budget for the period running from December 9, 2021, through December 31, 2025.

[PRC 42033(a), 14 CCR § 18973.6(b)]

Types of Activities Relative to Each Line-Item Cost Category

[14 CCR § 18973.6(e)]

Revenue

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

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

Costs

MED-Project provides budgeted Program costs as defined in 14 CCR § 18973.6 in [Appendix I](#). 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 the following activities:

- Purchase and replacement of Secure Collection Receptacles.
- Installation, sales tax, and shipping related to the purchase and replacement of Secure Collection Receptacles.

Collection and Disposal of Covered Drugs

This cost category covers the following activities:

- Collection, transportation, and disposal of Covered Drugs.
- Inspection and maintenance of Secure Collection Receptacles.
- Reimbursement of conversion or lease payments of Secure Collection Receptacles.
- Contracted and employed personnel costs associated with collection and disposal.
- Production, distribution, and postage of 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 & IT 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)-(d) requires that MED-Project maintain a reserve level and funding amount 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 substantially impact its revenue and expenses, such as accidents, disasters, or failures of MED-Project operational systems, collection and disposal Vendors, Authorized Collectors, etc. In addition, significant or sudden changes in market dynamics that affect collection and disposal

costs (e.g., transportation costs, cost of materials, participation of Authorized Collectors) 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:

- Capital costs.
- Collection, transportation, and disposal costs.
 - o Secure Collection Receptacle service costs.
 - o Mail-Back Package costs.
 - o Maintenance costs.
- Administrative costs.
- Education and outreach costs.
 - o Advertising and marketing costs.

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

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

[14 CCR §§ 18973.6(c), 18973.6(f)]

Annual Program Budget

MED-Project will submit a written budget for the Program annually to meet the requirements established in PRC 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. [Appendix A](#) provides reference to the list of the participating Covered Entities and includes manufacturers of branded and generic Prescription Drugs and Nonprescription Drugs.

MED-Project prepares the calendar year budget in advance of the calendar year. This budget is approved by the Board of Directors. After the budget has been finalized and approved, participating Covered Entities commit to participate and provide adequate funding for the Program in advance of the year. The initial five-year budget is detailed in [Appendix I](#). In addition, during the budget approval process, a reserve level is also approved, as described in [Section 6: Recommended Reserve](#). 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 [Appendix A](#), provide it with the funding to maintain reserves in a prudent and responsible manner.

[PRC 42032.2(a)(1)(D), 42033(b), 14 CCR §§ 18973.2(f), 18973.6(d)]

Section 7: Collection System

MED-Project will establish a safe and secure system for collecting Covered Drugs throughout the State through Authorized Collection Sites and Mail-Back Services. MED-Project will fully implement operation of the Program no later than 270 days after Plan approval by CalRecycle. [Appendix F](#) provides a timeline of Program activity that will occur between Plan approval and full implementation of the Program.

[PRC 42032(g), 42032.2(a)(1)(F), 14 CCR § 18973.1(m)]

Authorized Collection Sites

MED-Project will establish a minimum of five Authorized Collection Sites or one Authorized Collection Site per 50,000 Ultimate Users in every county in which the Program operates, whichever is greater. MED-Project will operate in every county in the State. To provide a reasonable geographic spread of Authorized Collection Sites, MED-Project will locate Authorized Collection Sites so that greater than 90% of Ultimate Users live within a 15-mile drive of an Authorized Collection Site.

To determine this reasonable geographic spread, MED-Project utilizes a combination of geographical mapping and information system tools and 2020 US Census block data to calculate the driving range for the percentage of Ultimate Users that live within 15 miles of an Authorized Collection Site. As part of this process, MED-Project uses industry standard geospatial analysis software to analyze population data at the census block level, and then calculate the percentage of residents that live within 15 miles or less of an Authorized Collection Site.

MED-Project based this reasonable geographic spread on factors including: (1) access provided by stewardship programs for other types of products sold within the State; (2) the availability of Mail-Back Services to all Ultimate Users through the Website and Call Center; and (3) the availability of Authorized Collection Sites the Program provides pursuant to the Authorized Collector participation requirements established in PRC § 42032.2(a)(1)(F)(i) and 42032.2(b). MED-Project applies this same reasonable geographic spread to both urban and rural areas across the State because it anticipates that in urban areas, the reasonable geographic

spread will not only be met, but likely exceeded, due to MED-Project's compliance with the Authorized Collector participation requirements referenced above and the high number of available potential Authorized Collection Sites.

To further explain its rationale for why the same reasonable geographic spread applies to urban and rural areas, MED-Project provides the following analyses of its anticipated Authorized Collection Sites in Los Angeles County. These analyses are intended only to illustrate why, given the level of Authorized Collector participation anticipated under the Authorized Collector participation requirements referenced above, MED-Project is not proposing separate reasonable geographic spread standards for urban and rural areas. These analyses do not establish enforceable requirements separate from the reasonable geographic spread established above (which, for clarity, is: "MED-Project will locate Authorized Collection Sites so that greater than 90% of Ultimate Users live within a 15-mile drive of an Authorized Collection Site.").

- In Los Angeles County, analysis of Authorized Collection Sites where MED-Project has currently installed and active kiosks, as well as Authorized Collectors where MED-Project has currently scheduled kiosk installations, shows that greater than 90% of Ultimate Users will live within a 5-mile drive of an Authorized Collection Site.
- In Los Angeles County, in addition to driving distances, MED-Project also analyzed drive times for Authorized Collection Sites with currently installed and active MED-Project kiosks, as well as Authorized Collectors where MED-Project has currently scheduled kiosk installations. Utilizing these data, MED-Project's findings show that more than 95% of Ultimate Users in Los Angeles County (including Ultimate Users within a 5-minute drive and Ultimate Users within a 5-to-10-minute drive), will live within a 10-minute drive of an Authorized Collection Site.

These illustrative examples demonstrate that MED-Project's reasonable geographic spread of Authorized Collection Sites is appropriately applied in both urban and rural areas. To expand convenient access to the Program, MED-Project will offer Mail-Back Services to all Ultimate Users.

MED-Project will rely on the most recent publicly available population calculation from the State of California Department of Finance provided in its E-1 Population Estimates for Cities, Counties, and the State to determine the number of Authorized Collection Sites required in each county and determine the reasonable geographic spread of Authorized Collection Sites. Using these data, MED-Project will annually re-evaluate the number of Authorized Collection Sites required in each county and the reasonable geographic spread of Authorized Collection Sites. If additional Authorized Collection Sites are necessary to meet the number of required Authorized Collection Sites or reasonable geographic spread, MED-Project will secure the necessary participating Authorized Collection Sites within 270 days of this re-evaluation.

[PRC 42032.2(a)(1)(F)(i) - 42032.2(a)(1)(F)(iii), 14 CCR § 18973.2(g)(2) - 18973.2(g)(2)(B)]

Mail-Back Services

[PRC 42032.2(c)]

Mechanisms to Provide Ultimate Users with Mail-Back Services

MED-Project will provide three types of Mail-Back Packages: Standard Mail-Back Packages, Inhaler Mail-Back Packages, and Injector Mail-Back Packages. All Mail-Back Packages will be available for request by all Ultimate Users, including Ultimate Users who are Homeless, Homebound, or disabled, through the Website and Call Center.

Once received, requests for Mail-Back Packages will be processed through MED-Project's fulfillment system and Mail-Back Packages will be shipped to Ultimate Users.

All Mail-Back Packages will provide:

- Instructions for using the Mail-Back Package.
- A description of the types of Covered Drugs that may go into the Mail-Back Package.
- Mailing restrictions and a notice that only packages provided by Vendor will be accepted for destruction.
- Instructions for returning the Mail-Back Package.
- Information about other options for disposing of Covered Drugs through the Program.

[Appendix J](#) provides sample mockups of the Mail-Back Packages and inserts. Ultimate Users are instructed to remove items and medication that are not accepted before disposing of inhalers and injectors. More information on what is and is not accepted is available in [Section 9: Educational and Outreach Materials for Ultimate Users](#).

[PRC 42032.2(a)(1)(G)(i), 14 CCR §§ 18973.2(g)(6)(A), 18973.2(g)(6)(B)]

Supplemental Services

In counties that do not have the minimum number of Authorized Collection Sites due to circumstances beyond MED-Project's control, MED-Project will do both of the following:

- Conduct digital media outreach promoting the availability of Mail-Back Services.
- Provide one Mail-Back Distribution Location for each Authorized Collection Site necessary to meet the minimum number of Authorized Collection Sites.

In the event that a county does not have a Retail Pharmacy operating as an Authorized Collection Site, MED-Project will do both of the following:

- Conduct digital media outreach promoting the availability of Mail-Back Services.
- Provide at least one Mail-Back Distribution Location in the County.

Mail-Back Distribution Locations will be located in facilities, such as libraries, town halls, or law enforcement agencies, that are open to the public and will distribute Mail-Back Packages to Ultimate Users. MED-Project will supply Mail-Back Distribution Locations with Standard Mail-Back Packages, Inhaler Mail-Back Packages, and Injector Mail-Back Packages. Mail-Back Distribution Locations may request additional Mail-Back Packages through the Help Desk as needed to maintain inventory. MED-Project will monitor the frequency of these requests and remind Mail-Back Distribution Locations to request Mail-Back Packages to maintain inventory. MED-Project will fulfill Mail-Back Distribution Location requests for additional Mail-Back Packages.

[Appendix K](#) provides reference to an accessible Excel spreadsheet containing the list of potential Mail-Back Distribution Locations that were notified of the opportunity to serve in the Program.

[PRC 42032.2(c)(1), 14 CCR § 18973.2(g)(6)(C)]

Alternative Methods of Collection for Covered Drugs

Some Covered Drugs that are not Controlled Substances may not be commingled with other Covered Drugs. For such Covered Drugs, MED-Project will provide Mail-Back Services. Specifically, inhalers may not be commingled with other Covered Drugs in Standard Mail-Back Packages or Injector Mail-Back Packages. Pre-filled Injector Products may not be commingled with other Covered Drugs in Standard Mail-Back Packages, Inhaler Mail-Back Packages, or Secure Collection Receptacles. For these Covered Drugs, MED-Project will provide the Inhaler Mail-Back Packages and Injector Mail-Back Packages according to the process described in [Section 7: Mechanisms to Provide Ultimate Users with Mail-Back Services](#).

Homeless individuals without a permanent address can use any of the services described above throughout the State. When a homeless individual without a permanent address requests a Mail-Back Package through the Call Center or Website, MED-Project's systems will allow them to enter addresses of service providers such as shelters, churches, and to use USPS's General Delivery service to receive the Mail-Back Package in

lieu of a permanent address. The USPS General Delivery Service allows individuals without a permanent address to receive mail at a USPS facility.

[PRC 42032.2(a)(1)(G)(ii), 14 CCR § 18973.2(g)(6)(D)]

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. Each Mail-Back Package, inner liner, and shipping box provided under the Program will have a unique identifier enabling tracking. MED-Project's Vendors involved in the collection and disposal of Covered Drugs monitor the related tracking data and report to MED-Project.

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

Table 1: Vendors

Vendor	Mailing Address	Physical Address
Covanta Environmental Solutions, LLC	190 Shellyland Road, Manheim, PA 17545	190 Shellyland Road, Manheim, PA 17545
PureWay Compliance, Inc.	16225 Park Ten Place, Suite 830, Houston, TX 77084	16225 Park Ten Place, Suite 830, Houston, TX 77084
Stericycle, Inc.	2355 Waukegan Road, Bannockburn, IL 60015	2355 Waukegan Road, Bannockburn, IL 60015

[PRC 42032.2(a)(1)(E), 42032.2(a)(1)(G)(iii)(II), 42035.8, 14 CCR §§ 18973.2(g)(1), 18973.2(g)(3), 18973.2(g)(5)]

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.

Secure Collection Receptacle Service

MED-Project provides for the collection, transportation, and disposal of Covered Drugs at no cost to Authorized Collectors. Authorized Collector employees shall prepare the inner liner for shipment when it is full and at a time that is convenient allowing the Authorized Collector to avoid disruptions to operations or minimize storage time. When servicing a Secure Collection Receptacle, two Authorized Collector employees will:

- Check the Secure Collection Receptacle for any damage.
- Remove the inner liner and box from the Secure Collection Receptacle.
- Seal the inner liner at once following procedures meeting all DEA requirements.
- Replace the removed inner liner and box with a replenishment inner liner and box provided by Vendor.
- Match the unique identifier of the inner liner to the tracking number on the shipping label.
- Package the inner liner for transport.
- Prepare the packaged inner liner for shipment and perform applicable pre-transportation functions following the DOT Hazardous Materials Regulations (“HMR”) and Vendor shipping requirements.
- Schedule a pick-up from Carrier to be completed.

Authorized Collector employees will have access to instructional materials and other support in performing these functions through the Help Desk. See [Section 7: Ongoing Support](#). Under DEA regulations, Authorized Collector employees will document each phase of the process. See [Section 12: Applicable Laws – Secure Collection Receptacles](#).

If the package with the sealed inner liner is prepared before Carrier pick-up, the Authorized Collector will store the inner liner in compliance with all applicable laws, regulations, and other legal requirements until Carrier pick-up. MED-Project and the reverse distributor Vendor will monitor the inner liner management activity through Vendor and Carrier’s transportation tracking system. Authorized Collector staff will monitor the Secure Collection Receptacle and store inner liners in accordance with the DEA

requirements described in [Section 12: Applicable Laws – Secure Collection Receptacles](#).

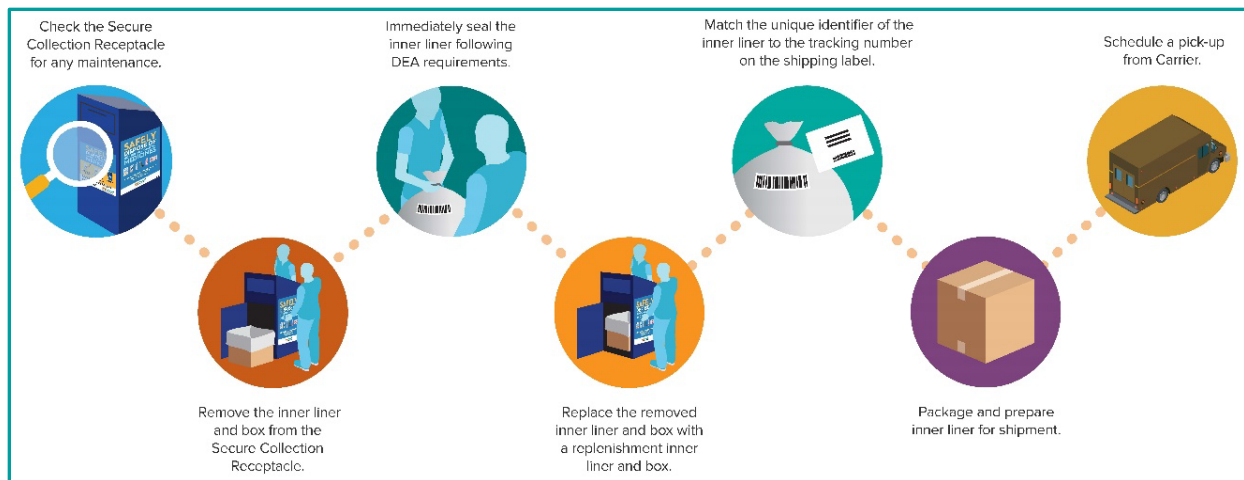


Figure 3: Secure Collection Receptacle Service Process

Authorized Collectors participating via the On-Demand Collection Service method will receive an initial supply of inner liners and boxes.

Replenishment inner liners and boxes will ship automatically, as needed, when packaged inner liners are picked up by Carrier. If an Authorized Collector participating via the On-Demand Collection Service method must lock Secure Collection Receptacle because it is full, it can order additional inner liners and boxes through the Help Desk. Once received, MED-Project will utilize a system designed to fulfill orders within two business days by placing an order with Vendor. MED-Project can work with an Authorized Collector to adjust the number of replenishment inner liners and boxes to prevent depletion of replenishment inner liners and boxes.

MED-Project will provide the Authorized Collector a Secure Collection Receptacle self-inspection questionnaire, and the Authorized Collector will inspect a Secure Collection Receptacle no less than quarterly to monitor for general wear and tear and clean the Secure Collection Receptacle as necessary to maintain proper function. Additionally, when servicing a Secure Collection Receptacle, Authorized Collector employees will inspect the Secure Collection Receptacle for any needed maintenance. The Authorized Collector employees will submit any maintenance requests through the Help Desk. MED-Project will assess maintenance requests and initiate a response within one business day. Most maintenance requests will be resolved within two business days. Minor maintenance issues will be

resolved within five business days. If necessary, a maintenance request may receive a Rapid Response.

MED-Project will provide for an inspection of the Secure Collection Receptacle annually. During the inspection, MED-Project will clean the Secure Collection Receptacle as necessary to maintain proper function, monitor the Secure Collection Receptacle for general wear and tear, and verify the status of the Authorized Collector's DEA registration and license with the State Board.

[PRC 42032.2(a)(1)(G)(iii)(I), 14 CCR § 18973.2(g)(7)]

Transportation and Receipt of Covered Drugs

Upon Carrier pick-up, packaged inner liners from Authorized Collection Sites will be tracked by the Carrier's tracking system until they are scanned for receipt at an approved reverse distributor facility. After receipt by the reverse distributor, the packaged inner liner may be stored in accordance with all applicable laws, regulations, and other legal requirements. If applicable, the reverse distributor will transfer the packaged inner liner to an approved transporter for transport to an approved disposal facility.

Returned Mail-Back Packages will be transported by Carrier to an approved facility and handled in compliance with all applicable laws, regulations, and other legal requirements. Each Mail-Back Package will have a unique identifier for tracking. Any management of filled Standard Mail-Back Packages will comply with the applicable security requirements of DEA Rule § 1317.

Table 2 provides the transporters the Program proposes to use.²

²The United States Postal Service will be used to transport Mail-Back Packages, including Injector Mail-Back Packages, from Ultimate Users to a reverse distributor or treatment facility.

Table 2: Transporters

Transporter	Mailing Address	Physical Address
Covanta Environmental Solutions Carriers II, LLC	2515 S Holt Rd, Indianapolis, IN 46241	2515 S Holt Rd, Indianapolis, IN 46241
Covanta Environmental Solutions dba Chesapeake Waste Solutions, LLC	5300 N 33rd St. Milwaukee, WI 53209	5300 N 33rd St. Milwaukee, WI 53209
Doncin Transport, Inc.	3478 Sunnyside Rd., Manheim, PA 17545	3478 Sunnyside Rd., Manheim, PA 17545
EMS Dispatch, Inc.	316 W Mount Vernon St, Lansdale, PA 19446	316 W Mount Vernon St, Lansdale, PA 19446
HealthWise Services ³	4800 E Lincoln Ave, Fowler, CA 93625	4800 E Lincoln Ave, Fowler, CA 93625
Heritage Transport	1626 Research Way, Indianapolis, IN 46231	1626 Research Way, Indianapolis, IN 46231
MedSharps, LLC	17340 Bell North Drive, Schertz, TX 78154	17340 Bell North Drive, Schertz, TX 78154
Omada Worldwide Expedite, Inc.	853 S. Columbia Road, Suite 175, Plainfield, IN 46168	853 S. Columbia Road, Suite 175, Plainfield, IN 46168
Online Transport Inc.	6311 W Stoner Dr, Greenfield, IN 46140	6311 W Stoner Dr, Greenfield, IN 46140
Ross Transportation Services, Inc.	36790 Giles Road, Grafton, OH 44044	36790 Giles Road, Grafton, OH 44044
Sodrel Logistics, LLC	1 Sodrel Dr., Clarksville, IN 47129	1 Sodrel Dr., Clarksville, IN 47129

³HealthWise will be used to transport treated Sharps Mail-Back Packages to a California landfill listed in Table 5.

Transporter	Mailing Address	Physical Address
Stericycle, Inc.	2355 Waukegan Road, Bannockburn, IL 60015	2355 Waukegan Road, Bannockburn, IL 60015
Tri-State Motor Transit Co.	8141 E. 7th St., Joplin, MO, 64801	8141 E. 7th St., Joplin, MO, 64801
United Parcel Service, Inc.	55 Glenlake Parkway NE, Atlanta, GA 30328	55 Glenlake Parkway NE, Atlanta, GA 30328
United States Postal Service	475 L'Enfant Plaza, SW, Washington, DC 20260	475 L'Enfant Plaza, SW, Washington, DC 20260
Waste Recovery Solutions, LLC	343 King St., Myerstown, PA 17067	343 King St., Myerstown, PA 17067

Table 3 provides the reverse distributor facilities the Program proposes to use.

Table 3: Reverse Distributors

Reverse Distributor Facility	Mailing Address	Physical Address
Covanta Environmental Solutions, LLC	2515 S Holt Rd, STE 200, Indianapolis, IN 46241	2515 S Holt Rd, STE 200, Indianapolis, IN 46241
Covanta Manheim, Pennsylvania Facility	190 Shellyland Road, Manheim, PA 17545	190 Shellyland Road, Manheim, PA 17545
Sedgwick dba SRCL Expert Solutions, LLC	2670 Executive Drive, Suite A, Indianapolis, IN 46241	2670 Executive Drive, Suite A, Indianapolis, IN 46241
Stericycle, Inc. Warren, Ohio	1901 Pine Avenue, SE, Warren, OH 44483	1901 Pine Avenue, SE, Warren, OH 44483

Disposal of Covered Drugs

Upon receipt from Carrier or an approved transporter at an approved reverse distributor facility, packaged inner liners will be recorded for receipt verification, weighed, and destroyed or treated at an approved treatment facility. Upon arriving at an approved facility, Mail-Back Packages will be

recorded for receipt verification, weighed, and then destroyed or treated at an approved treatment facility.

Table 4 provides the treatment facilities the Program proposes to use.⁴

Table 4: Treatment Facilities

Treatment Facility	Mailing Address	Physical Address
Clean Harbors Aragonite, LLC (Incinerator)	11600 North Aptus Rd., Grantsville, UT 84029	11600 North Aptus Rd., Grantsville, UT 84029
Curtis Bay Energy, LP (Incinerator)	3200 Hawkins Point Road, Baltimore, MD 21226	3200 Hawkins Point Road, Baltimore, MD 21226
HealthWise Services (Autoclave)	4800 E Lincoln Ave, Fowler, CA 93625	4800 E Lincoln Ave, Fowler, CA 93625
Heritage Thermal Services – Ohio (Incinerator)	1250 Saint George Street, East Liverpool, OH 43920	1250 Saint George Street, East Liverpool, OH 43920
Indianapolis Resource Recovery Facility in Indiana, operating as Covanta Indianapolis, Inc. (Incinerator)	2320 S Harding St., Indianapolis, IN 46221	2320 S Harding St., Indianapolis, IN 46221
Lancaster County Waste to Energy Facility (Incinerator)	1299 Harrisburg Pike, P.O. Box 4425, Lancaster, PA 17604	1911 River Road, Bainbridge, PA 17502
MedSharps, LLC (Autoclave)	17340 Bell N Dr., Schertz, TX 78154	17340 Bell N Dr., Schertz, TX 78154
Ross Incineration Services, Inc. (Incinerator)	36790 Giles Road, Grafton, OH 44044	36790 Giles Road, Grafton, OH 44044

⁴The United States Postal Service will deliver Injector Mail-Back Packages to, among other out of state facilities, HealthWise Services, an autoclave facility located in the State operating under California Department of Public Health permit number TS/OST-89. HealthWise uses steam sterilization (autoclave) in compliance with HSC § 117600 et seq. and 22 CCR 65600 et seq. As an autoclave facility, HealthWise Services does not receive any other type of Mail-Back Package under the Program. No other treatment facilities in the State will receive Injector Mail-Back Packages.

Treatment Facility	Mailing Address	Physical Address
Stericycle, Inc., Warren, Ohio Facility (Incinerator)	1901 Pine Avenue, SE, Warren, OH 44483	1901 Pine Avenue, SE, Warren, OH 44483
Veolia – Port Arthur (Incinerator)	7665 Highway 73, Beaumont, TX 77705	7665 Highway 73, Beaumont, TX 77705

Table 5 provides the disposal facilities the Program proposes to use to dispose of treated Injector Mail-Back Packages.

Table 5: Disposal Facilities

Disposal Facility	Mailing Address	Physical Address
American Avenue Disposal Site	18950 W. American Avenue, Kerman, CA 93630	18950 W. American Avenue, Kerman, CA 93630
Tessman Road Landfill	7000 E IH 10, San Antonio, TX 78219	7000 E IH 10, San Antonio, TX 78219

Ongoing Support

MED-Project will manage a Help Desk for Authorized Collectors and potential Authorized Collectors to provide the following support functions:

- Answer questions and monitor comments from Authorized Collectors and potential Authorized Collectors.
- Receive expressions of interest in the Program from potential Authorized Collectors.
- Direct and respond to requests for maintenance or a Rapid Response from Authorized Collectors.
- Receive and fulfill requests for additional inner liners and boxes or rush services from Authorized Collectors.
- Receive and fulfill requests for education and outreach material from Authorized Collectors.
- Provide Authorized Collectors access to instructional materials, including written instructions, downloadable forms, and/or video instruction guides.

Rapid Response

An unplanned event may necessitate service at an Authorized Collection Site. A major event, such as a flood, earthquake, or fire, may jeopardize the security characteristics of the Secure Collection Receptacle as well as the structural integrity of the Authorized Collection Site. Such events may require the involvement of law enforcement, fire, or other emergency service personnel. Authorized Collector employees will be directed to call 911 in situations posing an immediate threat to the environment or health. Once the area is safe for access, Vendor will dispatch rapid responders to secure the Secure Collection Receptacle and remove its contents. Vendor maintains a network of rapid responders that can be contacted in the case of an incident or other event requiring a Rapid Response and is able to respond within three hours in most cases when notified of a requested Rapid Response. Rapid responders will bring all necessary equipment to manage the specific needs of the Authorized Collection Site requiring a Rapid Response.

Section 8: 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 authorized collection sites participating in the MED-Project program in the Local Jurisdiction into the Program.
- Identify any gaps between the local stewardship program ordinance's convenience standard and convenience standard described in PRC 42032.2(a)(1)(F).
- Establish a schedule to expand the Program, including the education and outreach program, into the Local Jurisdiction.
- Provide CalRecycle with updated participating Covered Entity and Authorized Collection Site lists as applicable.

Within 270 days after the effective date of the local stewardship program ordinance repeal, MED-Project will maintain a network of Authorized Collection Sites that meets the convenience standard described in PRC 42032.2(a)(1)(F).

[PRC 42032.2(e), 14 CCR § 18973.2(i)]

Section 9: 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 Mail-Back Packages from Ultimate Users through the Website and Call Center.
- Provide additional outreach materials as needed to promote the collection and disposal of Covered Drugs.
- 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 Authorized Collectors.
3. Pharmacies, pharmacists, and others who can educate Ultimate Users about the Program.

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 Covered Drugs safely.
- Encourage participation from a variety of private businesses and public agencies.
- Account for the diverse media consumption habits, behaviors, and motivating factors of residents, businesses, and stakeholders across the state.
- Improve message retention.

[Appendix L](#) 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 Covered Drugs 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)(5), 42031.6(b), 42032.2(f), 14 CCR §§ 18973.2(j)(6), 18973.2(j)(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

- Residents.
- General Public.
- Consumers.
- Patients.

Ultimate User Key Messages

- Take as prescribed.
- Store securely.
- Safely dispose.
- What services are available.
- How to access these services.
- What items are covered/not covered in the Program.

Ultimate User Methods

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

Educational and Outreach Materials for Ultimate Users

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

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

[Appendix M](#) provides sample images of MED-Project education and outreach materials, including a list of “Accepted” and “Not Accepted” items that can be disposed of in Secure Collection Receptacles.

[PRC 42031.6(a)(2), 14 CCR § 18973.2(J)(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. This signage and printed 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.
- Use plain language and explanatory graphics to promote the Program in a way that is readily understandable to Ultimate Users.

Secure Collection Receptacle signage will be designed with explanatory images that are readily understandable by all Ultimate Users and instruct Ultimate Users to separate products that are not covered products from Covered Products before disposing of them through the Program.

[Appendix N](#) provides sample images of MED-Project signage for hospitals, Pharmacies, and other locations.

[Appendix O](#) provides a sample mockup of the Secure Collection Receptacle and receptacle signage.

[PRC 42031.6(a)(1), 14 CCR § 18973.2(J)(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 third-party 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:

- Information on collection options for Covered Drugs.
- Instructions to separate products that are not covered products from Covered Products before disposing of them through the Program.
- A list of Authorized Collection Sites, including a ZIP code-based map locator provided on a publicly available, third-party platform to help Ultimate Users find the nearest disposal locations, including physical addresses, contact telephone numbers, and days and hours of operation.
- A calendar of community events.
- A web form to accept requests for Mail-Back Packages from Ultimate Users, including those who are Homeless, Homebound, or disabled. The web form will allow Ultimate Users to select the type and quantity of Mail-Back Package and enter their name and shipping address for fulfillment.
- Information to promote the Program, including instructions for safe handling and proper disposal of Covered Drugs.
- 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 P](#) provides a sample mockup of the Website and its supporting pages. See [Section 11: Coordination Efforts](#) for a description of how MED-Project proposes to provide a neutrally branded website if CalRecycle approves more than one Stewardship Program. [Appendix F](#) provides a

Program implementation timeline with details about the timing of the launch of the Website.

[PRC 42031.6(a)(3), 42032.2(a)(1)(G)(i), 14 CCR § 18973.2(J)(3)]

Call Center

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

- An interactive voice response system in English and Spanish. Ultimate Users will be given the option, in English, to continue in their preferred language after being offered English or Spanish.
- Human representatives to receive requests for services and questions about the Program from Ultimate Users.
- Translators available to provide language options suited to local demographics.
- Teletype services for hearing- and speech-impaired individuals.
- Information on disposal options.
- A list of Authorized Collection Sites, including physical addresses, contact telephone numbers, and days and hours of operation.
- Provide instructions to separate products that are not covered products from Covered Products before disposing of them through the Program.
- A schedule of community events.
- A mechanism to accept requests for Mail-Back Packages from Ultimate Users who are Homeless, Homebound, or disabled.
- Information to promote the Program, including instructions for safe handling and proper disposal of Covered Drugs.

[Appendix F](#) provides a Program implementation timeline with details about the timing of the launch of the Call Center. [Appendix Q](#) provides the sample Call Center flow.

[PRC 42032.2(a)(1)(G)(i), 14 CCR § 18973.2(J)(4)]

Public Service Announcements

The Public service announcement campaign will include multiple video, audio, and static media variants highlighting different disposal options. The messaging will target residents over the age of 18. The message will include the proper and safe disposal of Covered Drugs. 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 advertisement grants for non-profit organization, 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 Covered Drugs, 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 residents over the age of 18 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 residents over the age of 18 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:

- Outreach to Ultimate Users through various communication channels or tools.
- Convenient resources for Ultimate Users to find Covered Drug disposal options in their area.
- Information about Program collection services.

Education and Outreach to Authorized Collectors, Potential Authorized Collectors, Pharmacists, Providers, and Other Individuals

MED-Project will perform education and outreach to support Authorized Collectors and encourage participation from potential Authorized Collectors. MED-Project will also connect with providers and other stakeholders who interact with Ultimate Users to provide medical recommendations, education, or who prescribe Covered Drugs, about the opportunity to distribute printed materials about the Program.

Outreach to Authorized Collectors, Potential Authorized Collectors, Pharmacists, Providers, and Other Individuals

Authorized Collector Audiences

- Healthcare providers and persons authorized to prescribe drugs (Pharmacists, doctors, general practitioners, health/medical specialists, dentists, clinicians).
- Veterinarians.
- Pharmacies / retailers / points-of-sale.
- Hospitals.
- Local law enforcement agencies.
- Local governmental agencies.
- State governmental agencies.
- Solid waste facilities.
- Non-governmental organizations.
- Community organizations.

Authorized Collector Key Messages

- What is the Program.
- What services are part of the Program.
- How to participate.
- If participating, how to comply.
- Where/how to obtain information on requirements.

Authorized Collector Methods

- Website.
- Videos.
- Direct communication.
- Direct mail and outreach.
- Traditional and social media events.
- Printed materials.
- Presentation.

Website for Authorized Collectors, Potential Authorized Collectors, Pharmacists, Providers, and Other Individuals

MED-Project will establish a Website intended to educate Authorized Collectors 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 Authorized Collectors and potential Authorized Collectors to simplify outreach and communications:

- Program Overview: An overview of the requirements regarding educating the public and Program participation.
- How to Participate: A detailed breakdown of what is involved in participating as an Authorized Collection Site, including the Ultimate User experience and the responsibilities of the site.
- Getting Started: A step-by-step walkthrough of the onboarding process.
- Ongoing Support: Information on how to get support and continuing Program Services.

Direct Communication

MED-Project maintains an account management team for building and maintaining relationships with Authorized Collectors and potential Authorized Collectors, both at a corporate and individual level. This team also manages in-person and virtual meetings and presentations with decision-makers at potential Authorized Collectors to encourage Program participation.

MED-Project will provide three levels of support to Authorized Collectors and potential Authorized Collectors:

1. Account Management Team: Manages communications at a corporate or brand level.
2. Operations Support Staff: Serve as the direct points-of-contact for individual sites at the local level. Operations support staff assist with outreach, onboarding, staff orientation and education, and monitoring service schedule or replenishment inner liner and box usage to help Authorized Collectors maintain a sufficient stock of boxes and inner liners.
3. Help Desk: Features online and phone support along with full access to multimedia guidance materials.

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 potential Authorized Collectors and provide updates or communicate changes to participating Authorized Collectors.
- Press/Media Relations: MED-Project will distribute press releases, alerts, and guest-submitted articles to relevant publications in the State.
- Printed Materials: MED-Project will provide the educational and outreach materials described in [Section 9: Educational and Outreach Materials for Ultimate Users](#) for distribution to Ultimate Users.

Traditional and Social Media

MED-Project will distribute press releases directly to major media outlets and local media and provide templates for press releases and emails to partners and local health officials to spread throughout their own networks, allowing for customized news and announcements with 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.

Section 10: Metrics

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

Covered Drugs Collected from Ultimate Users

MED-Project will collect the following information for each Authorized Collection Site:

- Weight of Covered Drugs collected under the Program.
- Number of instances that collected Covered Drugs were picked up for disposal.
- Number of Secure Collection Receptacle inner liners picked up for disposal.
- Number of instances and corresponding amount of time Secure Collection Receptacles were not available to the public during the Authorized Collection Site's business hours.

[14 CCR § 18973.2(g)(4)]

Mail-Back Packages Distributed

MED-Project will collect the following information for Mail-Back Services:

- The number of each type of Mail-Back Package distributed.
- The number of each type of Mail-Back Package disposed.

[14 CCR § 18973.2(g)(6)(E)]

Performance of the Comprehensive Education and Outreach Program

In addition to the metrics in [Section 10: Covered Drugs Collected from Ultimate Users](#) and [Section 10: Mail-Back Packages Distributed](#), MED-Project will measure results of the education and outreach program using the following metrics.

[14 CCR § 18973.2(J)(5)]

Overall Program Awareness

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

Program Participation

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

Media

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

In-Store Outreach

- Number of participating locations.
- Amount of printable materials and signage distributed to participating locations.

Section 11: Coordination Efforts

MED-Project will comply with its obligations to coordinate with the other Program Operator(s) under Regulation § 18973.2(k). After CalRecycle's approval of another Program Operator, in an effort to coordinate with that Program Operator, MED-Project will: (1) contact the Program Operator with an offer to confer on coordination under the Regulations; (2) propose a schedule for such coordination; and (3) propose terms for coordination of the Stewardship Programs. Because MED-Project currently operates stewardship programs for covered drugs in 13 Local Jurisdictions covering approximately 1 in 5 California residents, many Ultimate Users are already familiar with MED-Project's brand. The following sections describe the basic elements of the coordination terms MED-Project proposes. When applicable to its coordination efforts (or otherwise), MED-Project will comply with 14 CCR 18973.1(i).

[14 CCR § 18973.2(k)]

Education and Outreach

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

Secure Collection Receptacles

To avoid confusion to the public and all Program participants, MED-Project will provide the Stewardship Program decal, emblem, or logo on Secure Collection Receptacles along with Program signage. Secure Collection Receptacles will not need to be exactly the same and may differ in color, shape, or size.

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 page to distribute web traffic to all approved Stewardship Programs. The neutrally branded website directory page would provide:

- A map displaying all Program Operators' Authorized Collection Sites and locations providing pre-addressed, pre-paid mailing envelopes to Ultimate Users, if applicable.
- A directory or listing of approved Stewardship Programs which would direct Ultimate Users to each Program Operator's website where services, such as collection events, educational and outreach materials, and mail-back materials for Ultimate Users, including those who are Homeless, Homebound, or disabled, will be available.

Each Program Operator would be expected to provide the mail-back services, educational and outreach materials, and other additional services included in the Program Operator's approved plan.

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

Call Center – Outreach and Education

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 between each approved Program Operator's toll-free telephone number, as appropriate. For example, calls inquiring about Mail-Back Services would be routed equally among approved Program Operators. Calls inquiring about additional services would be routed equally to approved Program Operators providing the additional service(s) requested.

Section 12: Compliance with Applicable Laws

The following sections provide an overview of applicable laws, regulations, and other legal requirements with which the Program is designed to comply. Each entity under the Plan is independently responsible for its compliance obligations.

[PRC 42032.2(a)(1)(E), 42032.2(a)(1)(G)(iii)(II), 42035.8, 14 CCR §§ 18973.2(g)(1), 18973.2(g)(6)(C)]

MED-Project Agreements

MED-Project contracts and agreements with Vendor(s) and Authorized Collectors require compliance with all applicable laws, regulations, and other legal requirements. Below is a summary of some of the elements these agreements generally include to demonstrate how MED-Project maintains the required policies and procedures.

Vendor Contracts

MED-Project contracts for Vendors involved in the collection and disposal of Covered Drugs 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.
- Provide confirmation that employee trainings are complete.
- Comply with industry-standard safety and security procedures.
- 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.
- Use commercially reasonable measures to prevent theft or diversion of Covered Drugs.
- Report safety, security, or other procedural deviations.
- 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.

Authorized Collector Agreements

Agreements with Authorized Collectors generally require that the Authorized Collector:

- Comply with all applicable laws regarding the collection, handling, processing, and disposal of Covered Drugs.
- Possess all required authorizations to enter into an agreement for Program services.
- Identify a responsible manager and provide qualified staff.
- Have qualified staff present for unlocking and locking the Secure Collection Receptacle.
- Complete documentation under all applicable laws for Secure Collection Receptacle delivery, installation, or removal and for Covered Drug collection, storage, transportation, or disposal.
- Maintain any documentation required under the Program and provide such documentation to MED-Project upon request.
- Make the Secure Collection Receptacle available to the public during business hours unless there is a safety, security, service, maintenance, or other condition requiring the Authorized Collector to lock the Secure Collection Receptacle.
- Promptly notify MED-Project of any service or maintenance concerns.
- Collect and store Covered Drugs and cause the transportation and disposal of Covered Drugs.
- Establish and implement procedures limiting access to Secure Collection Receptacle keys to qualified staff.
- Lock the Secure Collection Receptacle and cooperate with MED-Project for Secure Collection Receptacle removal upon termination of the agreement.
- Report any theft, unexplained loss, or diversion of Covered Drugs, safety or security problem, or environmental incident.

DEA Controlled Substances Act and Implementing Regulations

Collection of Controlled Substances is generally limited to Schedule II, III, IV, or V Controlled Substances that are lawfully possessed by an Ultimate User. See DEA Rule §§ 1317.75(b); 1317.70(b). Schedule I Controlled Substances, Controlled Substances that are not lawfully possessed, and other illicit or dangerous substances will not be collected. Because these provisions of the DEA Rule limit collection of Controlled Substances to those lawfully possessed by an Ultimate User or certain other persons, pharmacies are prohibited from disposing of their own inventory or stock through the Program. See *id.*; see also § 1317.05.

The DEA Rule provides that law enforcement agencies can accept Controlled Substances for disposal, however, the DEA Rule also provides that retail pharmacies, reverse distributors, hospitals/clinics with on-site pharmacies, narcotic treatment programs, and certain other entities, can modify their registration with the DEA to “collectors” and become authorized at their discretion on a voluntary basis to accept Controlled Substances.

The DEA Rule:

- Provides for the collection of Controlled Substances at Authorized Collection Sites at law enforcement agencies, and registered retail pharmacies, hospitals or clinics with on-site pharmacies, narcotic treatment programs, and certain other entities.
- Provides for the use of Mail-Back Programs to collect Controlled Substances.
- Establishes detailed collection, recordkeeping, security, and other measures for all approved collection methods.
- Provides that all collected pharmaceutical products be destroyed so that the products are rendered non-retrievable.

Controlled Substances collected pursuant to the Program may be commingled with non-Controlled Substances at Authorized Collection Sites and in Standard Mail-Back Packages per the DEA Rule. See §§ 1317.75(b); 1317.70(b).

DEA Registration Modification

Pursuant to DEA Rule. § 1301.51(b), pharmacies and narcotic treatment programs may modify their registrations to become Authorized Collectors by submitting a request to the DEA or online at www.DEAdiversion.usdoj.gov. This request must contain:

- The registrant’s name, address, and registration number (as printed on the registration certificate).
- The collection methods the registrant intends to conduct.
- A signature in accordance with § 1301.13(j).

MED-Project will consult with participating pharmacies and narcotic treatment programs, as requested, regarding how to modify DEA registrations to become Authorized Collectors.

Applicable Laws – Secure Collection Receptacles

Secure Collection Receptacles must be securely placed and maintained inside an Authorized Collector’s registered location or a law enforcement agency’s physical location in accordance with DEA Rule §§ 1317.75(d) and 1317.35(a). At pharmacies, Secure Collection Receptacles must be placed in the immediate proximity of a designated area where Controlled Substances are stored and at which an employee is present (e.g., can be seen from the counter), pursuant to DEA Rule § 1317.75(d)(2). At a hospital or clinic with an on-site Pharmacy, Secure Collection Receptacles must be placed in an area regularly monitored by employees but not near areas of the facility where urgent or emergency care is provided. DEA Rule § 1317.75(d)(2)(i).

Pursuant to DEA Rule §§ 1317.75(e) and (f), Secure Collection Receptacles at pharmacies, hospitals and clinics with on-site pharmacies, narcotic treatment programs, and long-term care facilities will:

- Be securely fastened to a permanent structure.
- Be securely locked, substantially constructed containers with a permanent outer container and removable inner liner.
- Include a small opening in the outer container that allows contents to be added to the inner liner but does not allow removal of the inner liner's contents.
- Prominently display a sign indicating that only Schedule II-V controlled and non-Controlled Substances are acceptable to be placed in the Secure Collection Receptacle.
- Except at a narcotic treatment program, have the small opening in the outer container locked or made inaccessible to the public when an Authorized Collection Site employee is not present, or when the Secure Collection Receptacle is not being monitored by long-term care facility employees. DEA Rule § 1317.75(f).

The proposed design of the Pharmacy Secure Collection Receptacle satisfies these requirements through heavy gauge steel; multiple locking mechanisms, including:

- A locking mechanism on the drop-slot.
- A tamper-resistant drop-slot.
- Commercial hinges.

The locking mechanism on the drop-slot will prevent Secure Collection Receptacle overflow once the Authorized Collection Site locks the container upon reaching its maximum level. MED-Project Pharmacy Secure Collection Receptacles will come with signage required under the DEA Rule.⁵

Under DEA Rule § 1317.60(a), Collection Receptacle inner liners will:

- Be waterproof, tamper-evident, and tear-resistant.
- Be removable and sealable immediately upon removal without emptying or touching Secure Collection Receptacle contents.
- Make the contents of the inner liner not viewable from the outside when sealed.
- Clearly indicate the size of the inner liner.
- Bear a permanent, unique identifier for tracking purposes.

While the DEA Rule does not require law enforcement agency Secure Collection Receptacles to meet these same requirements, MED-Project will offer these Secure Collection Receptacles and inner liners to law enforcement agencies.

Section 1317.75(g) provides that Pharmacy Secure Collection Receptacle inner liner installation or removal shall be performed “by or under the supervision of at least two employees of the authorized collector.” Section 1317.60 limits inner liner access to employees of the collector and requires two employees to seal the inner liner upon its removal from the permanent outer container.

The Pharmacy Secure Collection Receptacle sealed inner liner must not be opened, x-rayed, analyzed, or otherwise penetrated. DEA Rule § 1317.60(c). Section 1317.75(c) prohibits the counting, sorting, inventorying,

⁵Specifically, as required under § 1317.75(e)(4), all Secure Collection Receptacles will prominently display a sign stating that: “Only Schedule II-V controlled and non-controlled substances that are lawfully possessed by the ultimate user are acceptable to be placed in the kiosk. Schedule I controlled substances, illicit or dangerous substances, and any controlled substances not lawfully possessed by the ultimate user may not be placed in the kiosk.”

or individual handling of any substances deposited into a Pharmacy Secure Collection Receptacle.

Authorized Collectors participating in the Program shall keep all records required under the DEA Rule, including those required under DEA Rule §§ 1304 and 1317.35. At Authorized Collection Sites that are law enforcement agencies, Vendor and the law enforcement agency shall keep any records of removal, storage, or destruction of the collected Covered Drugs in a manner consistent with the law enforcement agency's recordkeeping requirements for illicit Controlled Substances evidence per DEA Rule § 1317.35.

The law enforcement agency shall store Covered Drugs in a manner to prevent the diversion of Controlled Substances consistent with its standard procedures for storing illicit Controlled Substances. Collected Covered Drugs shall be transferred to the disposal facility in a manner to prevent the diversion of Covered Drugs and consistent with the law enforcement agency's standard procedures for transferring illicit Controlled Substances.

Applicable Laws – Mail-Back Services

Per DEA Rule § 1317.70(c), Standard Mail-Back Packages will be:⁶

- Nondescript with no markings or information potentially indicating that they contain Covered Drugs, including Controlled Substances.
- Water and spill-proof, tamper-evident, tear-resistant, and sealable.
- Pre-addressed with and delivered to Vendor's registered address.
- Provided with a unique identifier enabling tracking.

When using Mail-Back Services, Ultimate Users and persons lawfully entitled to dispose of an Ultimate User decedent's property will not be required to provide any personally identifiable information. See DEA Rule § 1317.70(d).

Per DEA Rule § 1317.70(e), Vendor will only accept Standard Mail-Back Packages provided by Vendor or packages lawfully forwarded under DEA requirements. Within three business days of receipt, Vendor will notify the DEA if it receives Standard Mail-Back Packages likely containing

⁶Note that Inhaler Mail-Back Packages are not used to collect Controlled Substances.

Controlled Substances that Vendor did not make available or did not agree to receive per DEA requirements.

Per DEA Rule § 1317.70(f), when Standard Mail-Back Packages are received, only Vendor employees will handle the Standard Mail-Back Packages; Standard Mail-Back Packages will not be opened, x-rayed, analyzed, or otherwise penetrated upon receipt by Vendor.

If Vendor needs to store filled Standard Mail-Back Packages, they will follow all applicable security requirements of DEA Rule § 1317, including securely storing Covered Drugs consistent with the requirements for Schedule II Controlled Substances.

All Covered Drugs will be destroyed in compliance with DEA requirements. Vendor will keep all records required under the DEA Rule, including those identified in § 1304.22(f).

United States Department of Transportation

Covered Drugs collected at an Authorized Collection Site will be prepared for transport and transported in compliance with the applicable requirements under the DOT Hazardous Materials Regulations. Covered Drugs collected at an Authorized Collection Site will be packaged and shipped in accordance with DOT Special Permit 20255 or 20390. Covered Drugs collected via Mail-Back Packages will be packaged and mailed in compliance with applicable United States Postal Service (“USPS”) requirements. For example, Inhaler Mail-Back Packages will be mailed in “strong outer packaging” with the appropriate markings, as required under USPS Publication 52 for shipping mailable gases like inhalers. See USPS Publication 52, section 342.22.

Covered Drugs collected via Mail-Back Packages will be packaged and mailed in compliance with applicable United States Postal Service USPS requirements. For example, Inhaler Mail-Back Packages will be mailed in “strong outer packaging” with the appropriate markings, as required under USPS Publication 52 for shipping mailable gases like inhalers. See USPS Publication 52, section 342.22.

State Board

The State Board's Regulations, at Article 9.1 of Division 17 of Title 16 of the California Code of Regulations, establish requirements applicable to pharmacies, hospitals/clinics with on-site pharmacies, distributors, and reverse distributors conducting certain drug take-back services. Among other things, the State Board Regulations provide:

- That California-licensed pharmacies and hospitals/clinics with on-site pharmacies must comply with regulations of the DEA and State Board and be in good standing with, and notify, the State Board to host a Secure Collection Receptacle. See 16 CCR §§ 1776, 1776.1(i).
- That pharmacies must “know and adhere” to all applicable “federal, state, and local requirements governing the collection and destruction of dangerous drugs” when operating a Secure Collection Receptacle. See 16 CCR § 1776.1(b).
- Secure Collection Receptacle placement and monitoring requirements. See 16 CCR §§ 1776.3(b)-(d).
- Secure Collection Receptacle inner liner, container, and signage requirements. See 16 CCR §§ 1776.3(f), (h), (m).
- Inner liner handling, storage, and destruction requirements. See, e.g., 16 CCR §§ 1776.3(h)-(j), 1776.5(a)-(c).
- Pharmacy and reverse distributor recordkeeping requirements. See 16 CCR §§ 1776.5(e)-(f), 1776.6.
- Pharmacy drug Mail-Back Program requirements. See 16 CCR § 1776.2.

Each entity described within the Plan, including Vendor and Authorized Collectors, is individually responsible for complying with its respective obligations under the State Board Regulations. These entities must comply with these requirements independently, and MED-Project cannot step into their shoes for compliance purposes or function as a stand-in regulator overseeing this compliance. As described in [Section 4: Good Faith Negotiations](#) and [Section 7: Secure Collection Receptacle Service](#), MED-Project will verify an Authorized Collector's DEA registration and

license with the State Board during good faith negotiations and annual physical Secure Collection Receptacle inspections.

Section 13: Policies and Procedures

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

Collection, Transportation, and Disposal

MED-Project will enter into agreements with all relevant entities participating in the Program before establishing Authorized Collection Sites. Agreements with Authorized Collectors and Vendors involved in the collection and disposal of Covered Drugs generally require that all persons handling or disposing of Covered Drugs comply with all applicable laws, regulations, and other legal requirements. These policies shall be followed by persons handling Covered Drugs collected under the Program.

Agreements with Authorized Collectors and Vendors will also generally require that they comply with all applicable laws, regulations, and other legal requirements. MED-Project will provide Authorized Collectors with training materials to assist with their compliance efforts. [Appendix G](#) provides samples of some of the materials that will be provided. The Help Desk described in [Section 7: Ongoing Support](#) also will be available should Authorized Collectors require assistance.

Each Mail-Back Package, inner liner, and shipping box provided under the Program will have a unique identifier enabling tracking. MED-Project's Vendors involved in the collection and disposal of Covered Drugs monitor the related tracking data and report to MED-Project.

[PRC 42032.2(a)(1)(H)]

Record Maintenance

MED-Project has systems 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.
- Mail-Back Package distribution.
- Receipt of returned Mail-Back Packages.
- Documentation of final disposal of Covered Drugs.

MED-Project will maintain records as required by all applicable laws, including the Law and Regulation. MED-Project also requires that its Vendors and Authorized Collectors maintain certain records, including those required under the DEA Rule, State Board, and the Law and Regulation. Vendors and Authorized Collectors are required to meet the record retention requirements of all applicable laws, including the Law and Regulation.

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

[PRC 42032.2(a)(1)(H), 42033.4(a) - 42033.4(b)(2), 42035.6(b), 14 CCR §§ 18973.2(h), 18974(a) - 18974(c)]

Discovery of Critical Instances of Noncompliance

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.

[PRC 42032.2(a)(1)(H), 14 CCR § 18973.2(g)(8)]

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 Covered Drugs 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 provide reporting as required in the Annual Report. Additionally, MED-Project will notify involved parties, including Authorized Collectors and/or reverse distributors, of incidents of potential safety and security problems, as applicable. In addition, MED-Project will remind the aforementioned entities of their reporting obligations as registered entities under DEA and the State Board, where applicable.

[PRC 42032.2(a)(1)(H), 14 CCR § 18973.2(g)(10)]

Selection of Service Providers

MED-Project's policies and procedures require a competitive bidding process for selecting 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.

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 antitrust 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 § 18973.2(m)]

Section 14: Reporting

By January 15, 2022 and again each following January 15, MED-Project will provide to the State Board a list of Covered Drugs and a list and description of any drugs that are not Covered Drugs that are sold or offered for sale by each participating Covered Entity.

By March 31, 2022, and by each subsequent March 31, MED-Project will submit an annual report to CalRecycle describing the Program activities during the previous reporting period. The annual report will describe how the Program complied with all elements in the Plan and will comply with all reporting requirements under the Law and Regulations.

Because of diversion concerns associated with identifying amounts of Covered Drugs collected at individual Authorized Collection Sites, MED-Project will provide the total weight of drugs collected at each Authorized Collection Site on a list that uses a unique site ID for each Authorized Collection Site. MED-Project will provide CalRecycle with a confidential site identification list that can be used to match each unique site ID to an Authorized Collection Site participating in the Program.

[PRC 42031(a)(2), 42033.2(a)(1), 42033.2(b), 14 CCR § 18973.4]

Section 15: Data Sources

Appendix R identifies certain third-party data used in the Plan.

Section 16: Regulatory Mapping

[Appendix S](#) 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 March 1, 2022, was provided in a separate, accessible Excel spreadsheet as an attachment with the Plan.

Appendix B

Covered Drugs Sold or Offered for Sale by Participating Covered Entities

MED-Project provided the list of Covered Drugs sold or offered for sale by each participating Covered Entity to the State Board on January 14, 2022, in a separate, accessible Excel Spreadsheet.

The January 14, 2022 list will be submitted with this Plan as an accessible Excel Spreadsheet.

Appendix C

Participating Authorized Collection Sites

MED-Project provided the list of Participating Authorized Collection Sites in a separate, accessible Excel spreadsheet as an attachment with the Plan.

Appendix D

Sample Potential Authorized Collector Notification Letter



MED-Project USA

4096 Piedmont Avenue | Unit 174 | Oakland, CA 94611
Phone: (833) 633-7765 | Fax: (866) 633-1812
california@med-project.org

April 1, 2021

<<SITE_NAME>>

<<CITY>>, <<STATE>> <<ZIP_CODE>>

Re: Opportunity to Participate in MED-Project Stewardship Program
Pursuant to Recently Enacted California Legislation

Dear <<SITE_NAME>>:

MED-Project USA (“MED-Project”) is a non-profit product stewardship program operator that provides household unwanted medicine return services and related education in regions that mandate drug take-back services for residents. MED-Project currently operates in thirteen jurisdictions across California, as well as the states of Washington and Massachusetts. As you may know, the state of California passed Senate Bill No. 212 in 2018, establishing a comprehensive statewide take-back system for unwanted medicine from households. Upon a successful plan submission and approval, MED-Project anticipates providing free take-back services for all California residents.

MED-Project is writing to notify you of the opportunity, available to you free of charge, for <<SITE_NAME>> to participate in the MED-Project product stewardship program in California by hosting a secure collection receptacle. If you choose to participate in the program, MED-Project will cover the cost of a secure collection receptacle installation, signage and other educational materials, and the transportation and disposal of collected unwanted medicine. If you currently host a collection receptacle, you also have the option of joining the MED-Project Program. MED-Project

will support you every step of the way, including a 24/7 help desk, online support, media programs, and in-person consultations.

One of our goals is to assist eligible sites interested in participating as host sites with learning more about MED-Project's program. If you are interested in learning more, please fill out the Participation Assessment Form included in this letter. You may return the filled-out form via any of the following methods:

- Email: california@med-project.org.
- Help Desk: (833) 633-7765.
- Fax: (866) 633-1812.
- Mail: MED-Project USA, 4096 Piedmont Avenue, Unit 174, Oakland, CA 94611.

For more information, please visit <https://med-projectusa.org>. Thank you for your interest in MED-Project's product stewardship program in California.

Sample Participation Assessment Form

Participation Assessment Form

Please fill out requested Site information below.

California Senate Bill No. 212 in the State of California

For more information on California Senate Bill No. 212, please visit:

[California Legislative Information Website – Senate Bill 212.](#)

MED-Project USA

MED-Project USA (“MED-Project”) is the stewardship organization that is submitting an unwanted medication disposal plan in compliance with California Senate Bill No. 212. For more information regarding MED-Project, please visit <https://med-projectusa.org>.

Requested Site Information

Site Name: .

Site Street Address: .

Site City, State, ZIP Code: .

Point of Contact First Name: .

Point of Contact Last Name:

Point of Contact Phone Number:

Point of Contact Last Name:

Point of Contact Email Address:

Company Hours of Operation:

Company Website URL:

1. Are you familiar with the recent California legislation regarding the safe disposal of unwanted medicine from households?

Yes:

No:

Somewhat:

2. Are you interested in participating in the MED-Project product stewardship plan by hosting a secure collection receptacle for the collection of unwanted medicine from residents?

Yes:

No:

Maybe:

3. Do you currently have a collection receptacle for unwanted medicine at your site?

Yes:

No:

If you answered Yes, who oversees or manages your Site's current collection receptacle?

4. If you work in a pharmacy, does the pharmacy have a Drug Enforcement Administration (DEA) Number?

Yes:

No:

5. Are you interested in receiving additional information about participating in this program?

Yes: (If Yes, please fill out Point-of-Contact fields above).

No:

6. Type of Site:

Hospital: Law Enforcement Agency: Retail Pharmacy:

Additional Comments:

Appendix E

Potential Authorized Collectors MED-Project Notified of the Opportunity to Participate in the Program

MED-Project provided the list of potential Authorized Collectors that were notified of the opportunity to participate in the Program in a separate, accessible Excel Spreadsheet as an attachment with the Plan.

Appendix F

Program Implementation Timeline

Collection Methods: Days 1–90

- Establish approximately 200 Authorized Collection Sites in counties that have potential Authorized Collectors.
- Include potential Authorized Collectors in the Program within 90 days of receipt of a written offer to participate.

Collection Methods: Days 91–180

- Establish an additional 300 Authorized Collection Sites in counties that have potential Authorized Collectors.
- Notify Retail Pharmacy Chains of the requirement to have at least one location or 15 percent of its store locations serve as Authorized Collectors in a county where the minimum threshold described in PRC 42032.2(a)(1)(F)(i) is not met.

Collection Methods: Days 181–270

- Establish an additional 300 Authorized Collection Sites in counties that have potential Authorized Collectors to provide an Authorized Collection Site within a 15-mile drive of 90% of Ultimate Users.
- Work with the Retail Pharmacy Chains to meet the participation requirements in PRC 42032.2(a)(1)(F)(i).
- Provide one Mail-Back Distribution Location for each Authorized Collection Site necessary to meet the minimum number of Authorized Collection Sites.
- Provide a Mail-Back Distribution Location in a County if that County does not have a Retail Pharmacy operating as an Authorized Collection Site.

Mailer Services: Days 1–90

Implement Vendor processes to fulfill requests for Mail-Back Services.

Mailer Services: Days 91–180

Launch Mail-Back Services through the Website and Call Center for all Ultimate Users.

Mailer Services: Days 181–270

Maintain all Mail-Back Services through the Website and Call Center.

Education and Outreach: Days 1–90

- Launch accessible Website that provides:
 - Translations using a third-party translation tool.
 - Convenient Locations map.
 - Other informational pages.
- Activate the Call Center for Ultimate Users and the Help Desk for Authorized Collectors and potential Authorized Collectors.

Education and Outreach: Days 91–180

- Launch social media activity.

Education and Outreach: Days 181–270

- Provide educational and outreach materials available to pharmacies, pharmacists, Ultimate Users, and others upon request and via the Help Desk.
- Release educational video series for Authorized Collectors and potential Authorized Collectors.
- Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
- Provide educational signage and posters to Authorized Collection Sites.
- Finalize PSA for release. Continue social media activity.

Appendix G

Sample Inner Liner Step Log

0. PRE-STEP: HOLDING (Empty Inner Liner Held at Collection Site)

0. PRE-STEP: HOLDING (Empty Inner Liner Held at Collection Site)

Address where Inner Liner Held:

Inner Liner Unique Identifier:

Inner Liner Size (gallons):

Date Inner Liner Received:

1st Employee Witness Name:

Signature: _____

2nd Employee Witness Name:

Signature: _____

Collector DEA Registration Number (If Applicable):

1. INSTALLATION (Place Inner Liner into Shipping Container inside of Secure Collection Receptacle)

Date Inner Liner Installed in Secure Collection Receptacle:

1st Employee Witness Name:

Signature: _____

2nd Employee Witness Name:

Signature: _____

2. REMOVAL (Removal and Sealing of Inner Liner)

Date Inner Liner Removed from Secure Collection Receptacle and Sealed:

Address where Inner Liner Removed Same as Address in Section 0?

Yes No

Inner Liner Unique Identifier and Size Same as in Section 0?

Yes No

Collector Registration Number Same as in Section 0 (if applicable)?

Yes No

If you checked No for any of the questions above, please explain:

1st Employee Witness Name:

Signature: _____

2nd Employee Witness Name:

Signature: _____

3. STORAGE (Inner Liner Placed in Storage)

Date Inner Liner Placed in Storage:

Inner Liner UPS Tracking Number:

Address where Inner Liner Stored Same as Address in Section 0?

Yes No

1st Employee Witness Name:

Signature: _____

2nd Employee Witness Name:

Signature: _____

4. DESTRUCTION (Inner Liner Shipped for Destruction)

Date Inner Liner Shipped for Destruction:

Method of Shipment: United Parcel Service (UPS) Carrier Transport

Preserve any paperwork related to shipment.

Inner Liner UPS Tracking Number Same as in Section 3?

Yes No

If you checked No for any of these questions, please explain:

1st Employee Witness Name:

Signature: _____

2nd Employee Witness Name:

Signature: _____

Sample Setup and Closing of a Box and Inner Liner

User Instructions

Setup

1. Gently pull the bottom of the box apart ~6–8” in the middle, exposing (2x) 6” strips of double-stick foam adhesive on the bottom flaps of the box.
2. Peel off white adhesive backing on two bottom flaps.
3. Continue pulling the bottom of the box apart, when mechanically advantageous, push in the furthest two vertical edges of the box to make the bottom rectangular.
4. With the box upright, press the bottom of the box flat in a ‘+’ shaped pattern to engage the double stick adhesive.
5. Install the liner bag over the edges of the box.
6. Insert the absorbent pouch [If in plastic bag, remove from bag and place inside the liner bag].



Closing

1. Unfold the bag from the carton. Carefully squeeze out any air by draping over the edge of the box, then close the zipper closure.
2. Remove adhesive backing from side of liner bag.
3. Carefully fold over the zipper edge twice so that the 'back side' of the bag is stuck to the front side of the bag by the adhesive. This removes strain from the zipper closure, ensuring it does not come apart and provides evidence of tampering after closure.
4. Close the two 'half-flaps' on the sides of the box.
5. Close the full flap with one tab insert.
6. Remove (3x) white adhesive backings on the sides of the box.
7. Close the top of the box, first pushing the single flap on the front down on the exposed adhesive, subsequently press the side flaps down on the adhesive.



The box is now ready for shipment!

Questions?

Contact MED-Project.

(833) MED-Project (833-633-7765)

www.med-project.org

Sample MED-Project On-Demand Collection Service System

Welcome to the MED-Project On-Demand Collection Service system!

Simple On-Demand Collection Service Process:

Your site will receive a 3-Pack of Box/Liner Systems from our vendor containing three boxes and three inner liners. All boxes come with a UPS return shipping label already on each box for convenient returns.

1. Placing in the Secure Collection Receptacle: When you receive your Box/Liner Systems, place an inner liner and its corresponding box in the Secure Collection Receptacle. Once the inner liner is full, remove the inner liner and box and replace them with a new inner liner and box.
2. Shipping: Seal the inner liner in its box and ship via UPS.
3. Receiving new Box/Liner Systems: Once you are down to two inner liners and two boxes on hand, another 3-Pack of Box/Liners containing three boxes and three inner liners will be mailed to you.

Convenient Replenishment Process:

1. Allows you to have two inner liners and boxes on hand at your site at all times.
2. Triggers the shipment of replenishment Box/Liner Systems once you are down to two inner liners and two boxes on hand.

Note: After your first shipment of a 3-Pack of Box/Liner Systems, your next 3-Pack of Box/Liner Systems will auto-ship to you and begin your site's regular replenishment cycle.



Our Box/Liner Systems are clearly marked and include Setup and Closing instructions.

MED-Project provides this information as guidance for host sites. The host site is responsible for ensuring compliance with all applicable laws regarding the collection, handling, storage, and disposal of Unwanted Medicine.

Servicing Your MED-Project Secure Collection Receptacle

Two Employee Witnesses (Important)

You must have two Authorized Collector Employees present for witnessing the entire Inner Liner Step Log (Step Log) process. Note: Law Enforcement Agency procedures may vary.

Steps 1 through 4: Locking and Unlocking the Secure Collection Receptacle and Documentation

1. Retrieve the Secure Collection Receptacle keys from the designated location at your convenience or when the Secure Collection Receptacle is full.
2. Record the date and sign-out time in the Secure Collection Receptacle Keys Log.
3. Lock the Secure Collection Receptacle hopper.
4. Unlock the Secure Collection Receptacle front door.

Secure Collection Receptacle Inspection (Important)

Before moving the box, inspect the inside of the Secure Collection Receptacle and the areas surrounding the inner liner and box for any leakage, overflow, punctures, damages, or spillage.

Inner Liner and Box Integrity (Important)

The inner liner is opaque to prevent visual recognition of the contents. If any issues are discovered regarding the Secure Collection Receptacle or integrity of the inner liner and box, the Authorized Collector Employees should immediately lock the Secure Collection Receptacle and hopper and call the MED-Project Help Desk at 833-633-7765 or 833-MED-PROJECT (24 hours/7 days a week).

Steps 5 through 6: Removing and Sealing Inner Liner and Box

5. Remove the inner liner and box (shipping container) from the Secure Collection Receptacle after satisfactory inspection. Do not sort, inventory, or handle the contents inside of the inner liner.
6. Seal the inner liner immediately and prepare the box for transport.

Inner Liner Unique Identifier and Shipping Tracking Number (Important)

The sealed inner liner must not be opened, X-rayed, analyzed, or otherwise penetrated. The Authorized Collector Employees must date, sign, and document the unique identifier on the inner liner and tracking number on the shipping label in the Step Log after removing the inner liner and box from the Secure Collection Receptacle. To do this, match the inner liner's unique identifier to the unique identifier in the Step Log and record the required information.

Steps 7 through 13: Documenting, Storing, Pickup

7. Prepare a new box and match the unique inner liner identifier to the tracking number on the box shipping label.
8. Place the new, empty inner liner and box in the Secure Collection Receptacle.
9. Lock the Secure Collection Receptacle front door and unlock the hopper.
10. Document the date and sign-in time for the Secure Collection Receptacle keys in the Secure Collection Receptacle Keys Log.
11. Document installing a new inner liner and box in the Secure Collection Receptacle in a new Step Log.
12. Securely store the box containing the sealed inner liner in compliance with all laws, regulations, and other legal requirements until it is picked up by UPS. Document the storage in the Step Log.
13. When the packaged inner liner is ready for pickup, contact UPS for pickup. If you have a regular UPS pickup scheduled, simply transfer the packaged inner liner to UPS when they come on their regular schedule. Sites may also request a UPS pickup by calling UPS at (888) 742-5877.

UPS Pickup (Important)

Once UPS arrives to pick up the sealed inner liner in the box, the Authorized Collector Employees must witness the transfer of the sealed inner liner and box to UPS, including witnessing the scanning of the UPS label by the UPS driver prior to leaving the Authorized Collector site, and then document this transfer in the Step Log.

Appendix H

State Board Determination Letters

Below are the Plan determinations provided by the State Board on September 7, 2021, and July 6, 2021.

State Board Determination of Compliance Dated September 7, 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

September 7, 2021

Jim Wilson
Lead Director, Legal and Compliance
MED-Project USA

Suite 400 South
Washington, D.C. 20036
jwilson@med-project.org

Dear Mr. Wilson,

Thank you for the submittal of the revised MED-Project Covered Drugs Stewardship Plan sent on Aug. 6, 2021 (Revised Plan). We understand the Revised Plan is in response to feedback from both the CA Board of Pharmacy and the California Department of Public Health.

The Board of Pharmacy has completed our review of your Revised Plan. At this time, we believe your Revised Plan complies with pharmacy law in California. In evaluating your Revised Plan for compliance with pharmacy law, the Board relied upon the facts and details contained in the Revised Plan. Please note that any different or additional facts in the design or operation of your Plan could result in a different conclusion. Further, the Board's determination of compliance should not be interpreted as a determination of full compliance with all California law.

The Board does not intend to review any future revisions unless it relates directly to an area of California pharmacy law and its regulations. Such subsequent reviews will be performed under the provisions of Section 42032(d)(2) of the Public Resources Code.

Sincerely,

Lyle Matthews, Pharm.D., MAM
Inspector
California State Board of Pharmacy

Cc: Jason Smyth - CalRecycle

State Board Determination of Noncompliance Dated July 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

July 6, 2021

Jim Wilson
Lead Director, Legal and Compliance
MED-Project USA

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 covered drugs you submitted to the Board on April 9, 2021 entitled "A Product Stewardship Plan for Covered Drugs from Households" (Plan). Your other stewardship plan submitted to the Board covering sharps will be analyzed in a separate letter within 90 days of the date you submitted the sharps stewardship plan.

There are several areas that we find your Plan to be non-compliant with pharmacy law and other areas that are not described with sufficient detail to make a determination whether the Plan complies with pharmacy law.

Areas of Non-Compliance:

- I. **Authorized Participating Pharmacies.** Pharmacy law requires that pharmacies participating in drug take back programs must be registered with the DEA as a collector (16 CCR section 1776.1(h)), and pharmacies cannot participate in any drug take back program if either the pharmacy or the pharmacist-in-charge is on probation with

the Board (16 CCR section 1776.1(l)). The Board could find no mention of what entity is responsible for screening to ensure that only eligible pharmacies under California law with the requisite DEA registration are eligible to participate in your Plan. This should be clarified and specified in the Plan.

II. **Signage on Kiosks.** The draft signage on your kiosks as specified in Appendix L of your Plan does not appear to include all the information required by 16 CCR section 1776.1. The kiosks and signage submitted have the following issues:

- Under this regulation, the name and phone number of the responsible pharmacy participating in the program must be listed. We note that Appendix L contains information about MED-Project's name and telephone number but not the required information for the pharmacy. We note that Appendix N which contains a picture of the kiosks seems to have a space for the pharmacy name in a very small font, but it could be missed by consumers. This is in contrast with the prominence of MED-Project's name and telephone number.
- The draft signage in Appendix L and Appendix N does not give clear guidance on what may and may not be deposited into the kiosks. For example, although the Board's regulations do not expressly prohibit inhalers, the Board understands that other regulations or recyclers guidance generally prohibit depositing inhalers and your Plan also states that inhalers are handled via mail back. The signage also has a picture with needles crossed out but does not otherwise state that medical sharps and needles cannot be placed in the receptacles and does not define other medical sharps that may not be deposited into the kiosks. Your kiosks must give clear guidance of what may be deposited into the kiosks, including Schedule II-IV controlled substances. Also, your kiosk must identify what may not be deposited, including the items specified in section 1776.1(e) and (g).
- When drafting your signage for the kiosks, it is the Board's view that the information required by its regulations should be

presented with at least equal prominence as information not required, including but not limited, to information about MED-Project, to facilitate proper usage of the kiosks.

III. Operation of the Kiosks. 16 CCR section 1776.3 governs aspects of the placement and operation of kiosks in licensed pharmacies. Section 1776.3(i) requires that liners may only be removed from a locked receptacle by or under the supervision of two employees of the pharmacy. Throughout your Plan, different methods to prepare the inner liner for shipment are described. Some such descriptions violate pharmacy law. For example, the Plan indicates that MED-Project service technicians could be involved in, or supervising employees of the collection site, in preparing the inner liner for shipment. The general statements in your Plan raise confusion over the roles of the collection site employees and MED-Project service technicians. Please note that under California pharmacy law, a service technician can only remove the liner if supervised by two employees of the pharmacy. If two pharmacy employees are doing tasks related to the removal of the inner liner it should not be done at the direction of a vendor or service technician but rather in conformity with California law.

Section 1776.3(j) requires that removed liners must be stored in a secured, locked location in the pharmacy for no longer than 14 days. Your Plan does not explicitly state this requirement

IV. Mail-Back Provisions. Mail-back packages need to be available at the collection sites. See 16 CCR section 1776.2(a). There does not seem to be any reference to pharmacies having mail-back containers at the pharmacy. The only reference in your Plan for a consumer to obtain mail-back containers is for the consumer to call MED-Project to request a mail-back package. The Board has concerns that only providing mail-back containers via a request from consumers could harm consumers with no address, lack of technology and/or would involve some entity gathering personal information from consumers that might be used in other ways, including to market products and services to those consumers. For these reasons, mail-back

containers for covered drugs must be available at the collection sites or the pharmacies in which kiosks are located.

V. Compliance with California Pharmacy and DEA Laws Regarding Drug Take-Back Programs

California pharmacy law requires notification to the Board and/or DEA in certain circumstances, including but not limited to, when a collector ceases to maintain a kiosk. Also, California pharmacy law and DEA regulations impose recordkeeping requirements in connection with drug take-back programs. Your Plan does not specify whether the collection site or MED-Project is responsible for these notifications and/or recordkeeping requirements. Pharmacies participating as collection sites in stewardship plans are still required to comply with the Board's and DEA's rules, including required notifications and recordkeeping, regarding drug take-back programs. We believe that your Plan should clearly notify participating pharmacies of this fact.

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.

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



TOMÁS J. ARAGÓN, M.D., Dr.P.H.
Director and State Public Health Officer

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



GAVIN NEWSOM
Governor

September 10, 2021

Mr. Jim Wilson

MED-Project USA
1800 M Street, NW, Suite 400 S
Washington, DC 20036

RE: Product Stewardship Plan for Covered Drugs 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 pharmaceutical take-back programs in cities and counties in California.

The Department determined that the redline Plan submitted on September 2, 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 and determination, 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
11:33:45 -07'00'

Thomas Horner
Senior Environmental Scientist

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 § 18973.2(e)(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.



Jim Wilson
Lead Director, Legal and Compliance

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.

Appendix I

Five-Year Initial Program Budget

Total Revenue

- 2021: \$1,421,947
- 2022: \$6,287,511
- 2023: \$8,091,074
- 2024: \$6,244,437
- 2025: \$5,850,355

Total Program Costs

- 2021: \$1,421,947
- 2022: \$6,287,511
- 2023: \$8,091,074
- 2024: \$6,244,437
- 2025: \$5,850,355

Capital Costs

(Including, but not limited to, fixed, one-time, tangible purchases.)

- 2021: \$685,554
- 2022: \$225,675
- 2023: \$0
- 2024: \$0
- 2025: \$0

Collection, Transportation, and Disposal of Covered Product Costs

- 2021: \$333,964
- 2022: \$2,772,113
- 2023: \$2,832,033
- 2024: \$2,874,637
- 2025: \$2,873,287

Administrative Costs

- 2021: \$286,079
- 2022: \$2,599,819
- 2023: \$2,031,240
- 2024: \$1,822,197
- 2025: \$1,429,516

Departmental Administrative Fee Costs¹

- 2021: \$-
- 2022: \$-
- 2023: \$2,357,145
- 2024: \$683,500
- 2025: \$686,375

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

Education and Outreach Costs

- 2021: \$116,350
- 2022: \$689,904
- 2023: \$870,655
- 2024: \$864,102
- 2025: \$861,177

Grant, Loan, Sponsorship, or Other Program Implementation Incentive Costs

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

Reserve

- 2021: \$355,487
- 2022: \$1,571,878
- 2023: \$2,022,768
- 2024: \$1,561,109
- 2025: \$1,462,589

Appendix J

Sample Standard Mail-Back Package Mockup



Figure 4: Sample Standard Mail-Back Package Envelope

Sample Inhaler Mail-Back Package Mockup



Figure 5: Sample Inhaler Mail-Back Package Envelope


Sample Injector Mail-Back Package Mockup




Figure 6: Sample Injector Container and Mail-Back Package Box

Sample Mail-Back Package Inserts

**MAIL-BACK PACKAGE IS FOR
MEDICINE**



MED-Project™
Medication Education & Disposal



DISPOSAL OF HOUSEHOLD MEDICINE:

- 1 MEDICINE USAGE**
If there are specific instructions on the label, package or package insert, please follow those instructions.
- 2 SAFE STORAGE INFORMATION**
Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it. Do not place medicine in the trash or recycling, and never flush down the toilet.
- 3 CONVENIENT LOCATIONS**
To find kiosk sites in your area, visit the Convenient Locations section of www.med-project.org.
- 4 MAIL SERVICES FOR DISPOSAL**
For more information about mail disposal options, visit the Mail Services for Disposal section of www.med-project.org.

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

The following items are not accepted in Medicine Mail-Back Envelopes: herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, sharps, illicit or illegal drugs, pet pesticide products, animal medicines, biologics (such as insulin), and inhalers.

If transferring medication to a sealed bag, please be sure to recycle remaining packaging.

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

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




Figure 7: Sample Mail-Back Package for Medicine Insert

Figure Description

Figure 7 Description: Mail-Back Package is for Medicine

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

Note: The following items are not accepted in Medicine Mail-Back Envelopes:

- Herbal remedies
- Vitamins
- Supplements
- Cosmetics
- Other personal care products
- Medical devices
- Batteries
- Mercury-containing thermometers
- Sharps
- Illicit or illegal drugs
- Pet pesticide products
- Animal medicines
- Biologics (such as insulin)
- Inhalers

If transferring medication to a sealed bag, please be sure to recycle remaining packaging.

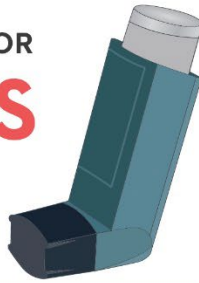
To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Disposal of Household Medicine

- **Medicine Usage:** If there are specific instructions on the label, package or package insert, please follow those instructions.
- **Safe Storage Information:** Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it. Do not place medicine in the trash or recycling, and never flush down the toilet.
- **Convenient Locations:** To find kiosk sites in your area, visit the Convenient Locations section of www.med-project.org.
- **Mail Services for Disposal:** For more information about mail disposal options, visit the Mail Services for Disposal section of www.med-project.org.

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

MAIL-BACK PACKAGE IS FOR
INHALERS



MED-ProjectTM
Medication Education & Disposal



DISPOSAL OF HOUSEHOLD MEDICINE:

1 MEDICINE USAGE

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

2 SAFE STORAGE INFORMATION

Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it. Do not place medicine in the trash or recycling, and never flush down the toilet.

3 CONVENIENT LOCATIONS

To find kiosk sites in your area, visit the Convenient Locations section of www.med-project.org.

4 MAIL SERVICES FOR DISPOSAL

For more information about mail disposal options, visit the Mail Services for Disposal section of www.med-project.org.

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

Only place undamaged inhalers in their original containers in the Inhaler Mail-Back Package. Inhaler Mail-Back Packages can only be used for inhalers and cannot accept other types of items.

If transferring medication to a sealed bag, please be sure to recycle remaining packaging.

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

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



Figure 8: Sample Mail-Back Package Insert for Inhalers

Figure Description

Figure 8 Description: Mail-Back Package is for Inhalers

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

Note: Only place undamaged inhalers in their original containers in the Inhaler Mail-Back Package. Inhaler Mail-Back Packages can only be used for inhalers and cannot accept other types of items.

If transferring medication to a sealed bag, please be sure to recycle remaining packaging.

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Disposal of Household Medicine

1. **Medicine Usage:** If there are specific instructions on the label, package or package insert, please follow those instructions.
2. **Safe Storage Information:** Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it. Do not place medicine in the trash or recycling, and never flush down the toilet.
3. **Convenient Locations:** To find kiosk sites in your area, visit the Convenient Locations section of www.med-project.org.
4. **Mail Services for Disposal:** For more information about mail disposal options, visit the Mail Services for Disposal section of www.med-project.org.

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

MAIL-BACK PACKAGE IS FOR INJECTORS



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

NOTE: Injector Mail-Back Packages can only be used for pre-filled injector products and cannot be used for inhalers, biologics (such as insulin), or other types of unwanted medicine or items.

MED-Project™
Medication Education & Disposal



DISPOSAL OF HOUSEHOLD MEDICINE:

- 1 MEDICINE USAGE**
If there are specific instructions on the label, package or package insert, please follow those instructions.
- 2 SAFE STORAGE INFORMATION**
Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it. Do not place medicine in the trash or recycling, and never flush down the toilet.
- 3 MAIL SERVICES FOR DISPOSAL**
For more information about mail disposal options, visit the Mail Services for Disposal section of www.med-project.org.

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



Figure 9: Sample Mail-Back Package Insert for Injectors

Figure Description

Figure 9 Description: Mail-Back Package is for Injectors

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

Note: Injector Mail-Back Packages can only be used for pre-filled injector products and cannot be used for inhalers, biologics, or other types of unwanted medicine or items.

Disposal of Household Medicine

1. Medicine Usage: If there are specific instructions on the label, package or package insert, please follow those instructions.
2. Safe Storage Information: Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it. Do not place medicine in the trash or recycling, and never flush down the toilet.
3. Mail Services for Disposal: For more information about mail disposal options, visit the Mail Services for Disposal section of www.med-project.org.

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

Appendix K

Potential Mail-Back Distribution Locations MED-Project Notified of the Opportunity to Participate in the Program

MED-Project provided the list of potential Mail-Back Distribution Locations that were notified of the opportunity to participate in the Program in a separate, accessible Excel Spreadsheet as an attachment with the Plan.

Appendix L

Initial Media and Outreach Plan

- Media and Promotion: Year One (30 – 150 Days)
 - Not applicable.
- Media and Promotion: Year One (180 Days)
 - Launch social media activity.
- Media and Promotion: Year One (210 Days)
 - Continue social media activity.
- Media and Promotion: Year One (240 Days)
 - Continue social media activity.
 - Finalize PSA and outreach strategy for upcoming year.
- Media and Promotion: Year One (270 Days)
 - Continue social media activity.
 - Finalize PSA concept and online video.
- Media and Promotion: Year One (300 Days)
 - Continue social media activity.
 - Launch PSA.
 - Launch grant-based online advertising campaign.
 - Conduct additional digital media outreach promoting the availability of Mail-Back Services in counties that do not have the minimum number of Authorized Collection Sites or do not have a Retail Pharmacy operating as an Authorized Collection Site.

- Media and Promotion: Year One (330 Days – 360 Days)
 - o Continue social media activity.
 - o Continue running PSA.
 - o Continue grant-based online advertising campaign.
 - o Continue conducting additional digital media outreach promoting the availability of Mail-Back Services in counties that do not have the minimum number of Authorized Collection Sites or do not have a Retail Pharmacy operating as an Authorized Collection Site.

- Media and Promotion: Year Two (30 Days)
 - o Continue social media activity.
 - o Continue to broadcast PSAs and make accessible through Website.
 - o Continue grant-based online advertising campaign.
 - o Conduct local promotion for confirmed events if/when needed.
 - o Continue conducting additional digital media outreach promoting the availability of Mail-Back Services in counties that do not have the minimum number of Authorized Collection Sites or do not have a Retail Pharmacy operating as an Authorized Collection Site.

- Media and Promotion: Year Two (60 Days – 360 Days)
 - o Continue social media activity.
 - o Continue to broadcast PSAs and make accessible through Website.
 - o Continue grant-based online advertising campaign.
 - o Continue conducting local promotion for confirmed events if/when needed.
 - o Continue conducting additional digital media outreach promoting the availability of Mail-Back Services in counties that do not have the minimum number of Authorized Collection Sites or do not have a Retail Pharmacy operating as an Authorized Collection Site.
- Outreach Materials and Collateral: Year One (30 Days)
 - o Not applicable.
- Outreach Materials and Collateral: Year One (90 Days – 180 Days)
 - o Finalize signage and outreach materials for production and distribution.
 - o Finalize Authorized Collector participation information and Program factsheets.

- Outreach Materials and Collateral: Year One (180 Days – 270 Days)
 - o Provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Provide access to Ultimate Users for downloading educational and outreach materials through the Website.
- Outreach Materials and Collateral: Year One (270 Days)
 - o Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.
 - o Release educational video series for Authorized Collectors and potential Authorized Collectors.
- Outreach Materials and Collateral: Year One (300 Days – 360 Days)
 - o Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.

- Outreach Materials and Collateral: Year Two (30 Days)
 - o Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.
 - o Revise Ultimate User outreach materials if needed.
 - o Revise educational information for Authorized Collectors, hospitals, Pharmacies, and other locations if needed.
 - o Revise Program factsheets if needed.
- Outreach Materials and Collateral: Year Two (60 Days – 90 Days)
 - o Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.

- Outreach Materials and Collateral: Year Two (120 Days)
 - o Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.
 - o Revise Ultimate User outreach materials if needed.
 - o Revise educational information for Authorized Collectors, hospitals, Pharmacies, and other locations if needed.
 - o Revise Program factsheets if needed.
- Outreach Materials and Collateral: Year Two (150 Days – 180 Days)
 - o Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.

- Outreach Materials and Collateral: Year Two (210 Days)
 - o Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.
 - o Revise Ultimate User outreach materials if needed.
 - o Revise educational information for Authorized Collectors, hospitals, Pharmacies, and other locations if needed.
 - o Revise Program factsheets if needed.
- Outreach Materials and Collateral: Year Two (240 Days – 270 Days)
 - o Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - o Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - o Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - o Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.

- Outreach Materials and Collateral: Year Two (300 Days)
 - Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.
 - Revise Ultimate User outreach materials if needed.
 - Revise educational information for Authorized Collectors, hospitals, Pharmacies, and other locations if needed.
 - Revise Program factsheets if needed.
- Outreach Materials and Collateral: Year Two (330 Days – 360 Days)
 - Continue to provide educational signage and posters to Authorized Collectors as sites are activated.
 - Continue to provide educational and outreach materials to Authorized Collectors upon request via the Help Desk.
 - Continue to provide educational and outreach signage for hospitals, Pharmacies, and other locations upon request and via the Help Desk.
 - Continue to provide access to Ultimate Users for downloading educational and outreach materials through the Website.
- Communications and Website: Year One (30 Days – 60 Days)
 - Not applicable.
- Communications and Website: Year One (90 Days)
 - Launch Website with informational pages, including convenient locations, that comply with accessibility requirements and language options.
 - Activate Call Center access for Ultimate Users.

- Communications and Website: Year One (120 Days – 150 Days)
 - o Update Website information as needed.
- Communications and Website: Year One (180 Days)
 - o Launch full Website for Authorized Collectors to access service options.
 - o Provide access to Mail-Back Services through the Website and Call Center.
- Communications and Website: Year One
 - o Disseminate press release announcing annual report highlights.
- Communications and Website: Year One (210 Days)
 - o Update Website information as needed.
 - o Maintain all Mail-Back Services through the Website and Call Center.
- Communications and Website: Year One (240 Days – 270 Days)
 - o Continue to update Website information as needed.
 - o Continue to maintain all Mail-Back Services through the Website and Call Center.
- Communications and Website: Year One
 - o Conduct a press release campaign announcing Program launch.
- Communications and Website: Year One (300 Days)
 - o Continue to update Website information as needed.
- Communications and Website: Year One (330 Days – 360 Days)
 - o Continue to update Website information as needed.
- Communications and Website: Year Two (30 Days – 180 Days)
 - o Continue to update Website information as needed.
 - o Issue any Program updates.

- Communications and Website: Year Two
 - Disseminate press release announcing annual report highlights.
- Communications and Website: Year Two (210 Days)
 - Continue to update Website information as needed.
 - Issue any Program updates.
- Communications and Website: Year Two (240 Days – 360 Days)
 - Continue to update Website information as needed.
 - Issue any Program updates.
- Collection Site Activity: Year One (30 Days – 90 Days)
 - Continue to conduct follow-ups and negotiations with potential Authorized Collectors.
 - Conduct on-site visits, phone contacts (as needed), and presentations.
- Collection Site Activity: Year One (120 Days – 240 Days)
 - Continue to conduct follow-ups and negotiations with potential Authorized Collectors.
 - Continue to conduct on-site visits, phone contacts (as needed), and presentations.
 - Notify Retail Pharmacy Chains of the requirement to have at least one location or 15 percent of its store locations serve as Authorized Collectors in a county where the minimum threshold described in PRC 42032.2(a)(1)(F)(i) is not met.
- Collection Site Activity: Year One (270 Days)
 - Notify Authorized Collectors and other stakeholders of the availability of free educational and outreach materials.
 - Continue to conduct on-site visits, phone contacts (as needed), and presentations.
 - Work with Retail Pharmacy Chains to meet the participation requirements detailed in PRC 42032.2(a)(1)(F)(i).

- Collection Site Activity: Year One (300 Days – 360 Days)
 - o Continue to conduct on-site visits, phone contacts (as needed), and presentations.
- Collection Site Activity: Year Two (30 Days – 360 Days)
 - o Continue to conduct on-site visits, phone contacts (as needed), and presentations.
- Events: Year One (30 Days – 240 Days)
 - o Not applicable.
- Events: Year One (270 Days)
 - o Establish event schedule for the first year of operations.
- Events: Year One (300 Days – 360 Days)
 - o Refer to the established event schedule for details on any scheduled events.
- Events: Year Two (30 Days – 90 Days)
 - o Refer to the established event schedule for details on any scheduled events.
- Events: Year Two
 - o Earth Day (April).
- Events: Year Two (150 Days – 330 Days)
 - o Refer to the established event schedule for details on any scheduled events.
- Events: Year Two (360 Days)
 - o Refer to the established event schedule for details on any scheduled events.
 - o Establish event options for the upcoming year.

Appendix M

Sample Education and Outreach Materials

What items can I dispose of at a kiosk?

UNWANTED MEDICINE DISPOSAL



ACCEPTED:

Medication in any dosage form, except for those identified as Not Accepted below, in their original container or sealed bag.

If transferring medicine to a sealed bag, please be sure to recycle remaining packaging.

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



NOT ACCEPTED:

Herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, sharps, illicit or illegal drugs, pet pesticide products, animal medicines, biologics (such as insulin).

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



ENGLISH

USA_BR.01.101102.SCA.01.01.01.00

SAFELY DISPOSE OF EXPIRED OR UNWANTED MEDICINE



MEDICINE USAGE



SAFE STORAGE INFORMATION



CONVENIENT LOCATIONS



MAILSERVICES FOR DISPOSAL



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Medication Education & Disposal

www.med-project.org



Figure 10: Safely Dispose of Expired or Unwanted Medicine Brochure (Front)

Figure Description

Figure 10 Description: Safely Dispose of Expired or Unwanted Medicine

What items can I dispose of at a kiosk?

Unwanted Medicine Disposal

Accepted:

Medication in any dosage form, except for those identified as Not Accepted below, in their original container or a sealed bag.

Note: If transferring medicine to a sealed bag, please be sure to recycle remaining packaging.

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

Not Accepted:

- Herbal remedies
- Vitamins
- Supplements
- Cosmetics
- Other personal care products
- Medical devices
- Batteries
- Mercury-containing thermometers
- Sharps
- Illicit or illegal drugs
- Pet pesticide products
- Animal medicines
- Biologics (such as insulin)

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

- Medicine Usage
- Safe Storage Information
- Convenient Locations
- Mail Services for Disposal

MED-Project™ Medication Education & Disposal

www.med-project.org

SB212 Program

WHAT SHOULD YOU DO WITH YOUR EXPIRED OR UNWANTED MEDICINE?

There are a number of ways to dispose of expired or unwanted medicine.

Medicine helps treat diseases, manages chronic conditions, and improves health and well-being for millions of Americans. It is important that patients take their medicine as prescribed by their health care provider, and as indicated on the label or packaging. It is also important to be sure to store medicine securely to prevent accidental ingestion or misuse by others, especially children.

If you have expired or unwanted medicine, proper disposal is easy.



To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

DISPOSAL OF HOUSEHOLD MEDICINE

1 MEDICINE USAGE

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



2 SAFE STORAGE INFORMATION

Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it. Do not place medicine in the trash or recycling, and never flush down the toilet.



3 CONVENIENT LOCATIONS

To find kiosk sites in your area, visit the Convenient Locations section of www.med-project.org.



4 MAIL SERVICES FOR DISPOSAL

For more information about mail disposal options, visit the Mail Services for Disposal section of www.med-project.org.



Figure 11: Safely Dispose of Expired or Unwanted Medicine Brochure (Back)

Figure Description

Figure 11 Description: Disposal of Household Medicine

What should you do with your expired or unwanted medicine?

There are a number of ways to dispose of expired or unwanted medicine.

Medicine helps treat diseases, manages chronic conditions, and improves health and well-being for millions of Americans. It is important that patients take their medicine as prescribed by their health care provider, and as indicated on the label or packaging. It is also important to be sure to store medicine securely to prevent accidental ingestion or misuse by others, especially children.

If you have expired or unwanted medicine, proper disposal is easy.

Note: To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Disposal of Household Medicine

1. **Medicine Usage:** If there are specific instructions on the label, package or package insert, please follow those instructions.
2. **Safe Storage Information:** Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it. Do not place medicine in the trash or recycling, and never flush down the toilet.
3. **Convenient Locations:** To find kiosk sites in your area, visit the Convenient Locations section of www.med-project.org.
4. **Mail Services for Disposal:** For more information about mail disposal options, visit the Mail Services for Disposal section of www.med-project.org.

Sample Authorized Collection Site In-Store Display



The image shows a sample in-store display for medication disposal. The background is a solid blue color. At the top, the word "SAFELY" is written in large, bold, yellow capital letters. Below it, "DISPOSE OF" is in white, "EXPIRED OR UNWANTED" is in light blue, "MEDICINE" is in light blue, and "HERE" is in large, bold, black capital letters. Below the text, there are six icons representing various types of medication: a clear plastic bag with yellow and purple pills, a white pill bottle with yellow and purple pills, a white spray bottle, a green inhaler, a pink liquid bottle, and a blister pack with red pills. Below the icons, the text reads: "MED-Project Call Center: 1 (844) MED-PROJECT", "1 (844) 633-7765 / (TTY: 711)", and "www.med-project.org". At the bottom of the display, there is a white banner. On the left side of the banner, the "MED-Project" logo is displayed in orange and teal, with "TM" to the right. Below the logo, the text "Medication Education & Disposal" is written in black. On the right side of the banner, there is a circular logo with the text "SB212 PROGRAM" inside.

SAFELY
DISPOSE OF
EXPIRED OR UNWANTED
MEDICINE
HERE

MED-Project Call Center: 1 (844) MED-PROJECT
1 (844) 633-7765 / (TTY: 711)
www.med-project.org

MED-ProjectTM
Medication Education & Disposal

SB212
PROGRAM

Figure 12: Safely Dispose of Expired or Unwanted Medicine Here Sample In-Store Signage

Appendix N

Sample Signage for Hospitals, Pharmacies, and Other Locations

The signage features a blue background with the text "SAFELY DISPOSE OF EXPIRED OR UNWANTED MEDICINE" in large, bold letters. Below the text are icons of various medications: a pill jar, a pill bottle, a tube of ointment, an inhaler, a pink bottle, and a blister pack. At the bottom, contact information for MED-Project is provided, including a call center number and website. The MED-Project logo and "SB212 PROGRAM" logo are also present.

SAFELY
DISPOSE OF
EXPIRED OR UNWANTED
MEDICINE

MED-Project Call Center: 1 (844) MED-PROJECT
1 (844) 633-7765 / (TTY: 711)
www.med-project.org

MED-Project™
Medication Education & Disposal

SB212
PROGRAM

Figure 13: Safely Dispose of Expired or Unwanted Medicine Sample Signage for Hospitals, Pharmacies, and Other Locations

Appendix O

Sample Secure Collection Receptacle and Receptacle Signage Mockups



Figure 14: Sample Secure Collection Receptacle with Signage

 **ACCEPTED:** Medication in any dosage form, except for those identified as Not Accepted below, in their original container or sealed bag.



 **NOT ACCEPTED:** Herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, sharps, illicit or illegal drugs, pet pesticide products, animal medicines, biologics (such as insulin).



Please separate and remove any medication listed as not accepted before disposing.

Figure 15: Secure Collection Receptacle Sample Signage

Figure Description

Figure 15 Description: Accepted and Not Accepted Medicine

Accepted: Medication in any dosage form, except for those identified as Not Accepted below, in their original container or sealed bag.

Not Accepted:

- Herbal remedies
- Vitamins
- Supplements
- Cosmetics
- Other personal care products
- Medical devices
- Batteries
- Mercury-containing thermometers
- Sharps
- Illicit or illegal drugs
- Pet pesticide products
- Animal medicines
- Biologics (such as insulin)

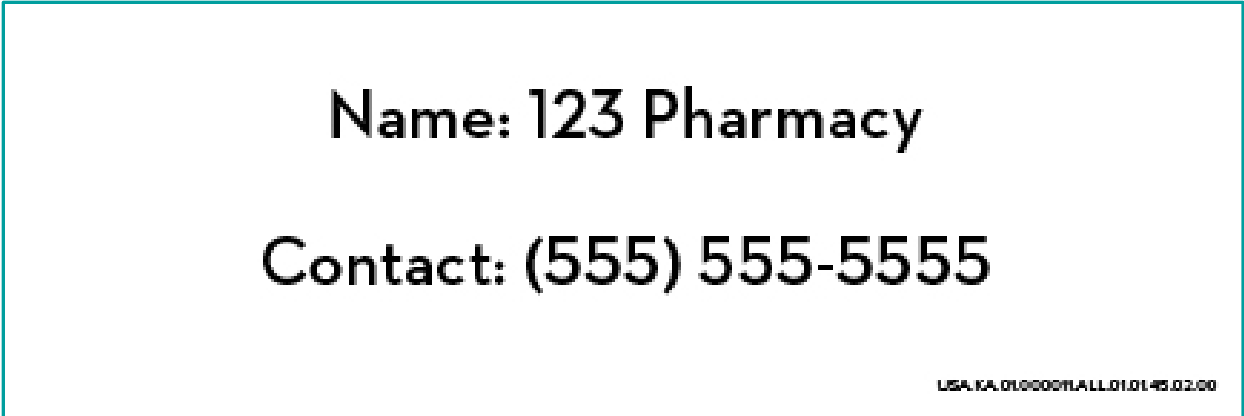


Figure 16: Secure Collection Receptacle Sample Signage

SAFELY DISPOSE OF EXPIRED OR UNWANTED MEDICINE



- 1** Cross out or remove personal identifying information from the medicine packaging.



- 2** Leave the product in its original container or place solid medicine in a sealed plastic bag.

If transferring medication to a sealed bag, please be sure to recycle remaining packaging.



- 3** Put medicine in the kiosk.

Only schedule II-V controlled and non-controlled substances that are lawfully possessed by the ultimate user are acceptable to be placed in the kiosk. Schedule I controlled substances, illicit or dangerous substances, and any controlled substances not lawfully possessed by the ultimate user may not be placed in the kiosk.

⚠️ PROP 65 WARNING: Entering this area, or coming into contact with items or materials in this kiosk, can expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.p65Warnings.ca.gov.

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

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Medication Education & Disposal

USA#1 01-0000003 2CAL06.C2 4/01/00

Figure 17: Secure Collection Receptacle Sample Safely Dispose of Expired or Unwanted Medicine Signage

Figure Description

Figure 17 Description: Safely Dispose of Expired or Unwanted Medicine

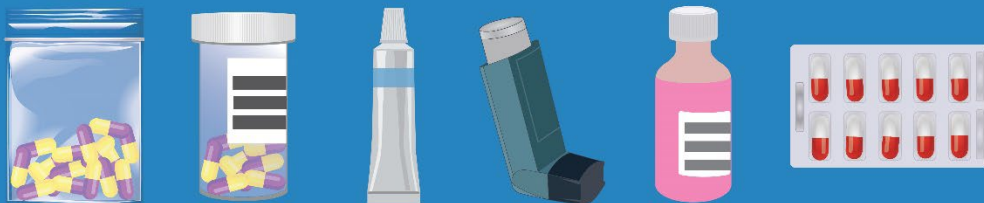
1. Cross out or remove personal identifying information from the medicine packaging.
2. Leave the product in its original container or place solid medicine in a sealed plastic bag. If transferring medication to a sealed bag please be sure to recycle remaining packaging.
3. Put medicine in the kiosk.

Note: Only schedule II-V controlled and non-controlled substances that are lawfully possessed by the ultimate user are acceptable to be placed in the kiosk. Schedule I controlled substances, illicit or dangerous substances, and any controlled substances not lawfully possessed by the ultimate user may not be placed in the kiosk.

Prop 65 Warning: Entering this area, or coming into contact with items or materials in this Secure Collection Receptacle, can expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.p65Warnings.ca.gov.

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

SAFELY DISPOSE OF EXPIRED OR UNWANTED MEDICINE



MED-Project Call Center: 1 (844) MED-PROJECT
1 (844) 633-7765 / (TTY: 711)
www.med-project.org

MED-Project[™]
Medication Education & Disposal

Figure 18: Secure Collection Receptacle Sample Safely Dispose of Expired or Unwanted Medicine Signage

Appendix P

Sample Webpage Mockups

CALIFORNIA STATE UNWANTED MEDICINE PROGRAM

Medicine helps treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It is important that patients take their medicine as prescribed by their health care provider. However, if you have expired or unwanted **medicine**, proper disposal is important and easy.



MEDICINE
USAGE



SAFE STORAGE
INFORMATION



CONVENIENT
LOCATIONS



MAIL SERVICES
FOR DISPOSAL



Figure 19: Sample California State MED-Project Unwanted Medicine Program Website Home/Landing Page

Figure Description

Figure 19 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Unwanted Medicine Program – Home/Landing Website Page

California State Unwanted Medicine Program

Medicine helps treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It is important that patients take their medicine as prescribed by their health care provider. However, if you have expired or unwanted medicine, proper disposal is important and easy.

Linked California State MED-Project Unwanted Medicine Program Website Pages

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- Medicine Usage
- Safe Storage Information
- Convenient Locations
- Mail Services for Disposal
- Privacy Policy
- Accessibility Statement

Linked Social Media Sites

- Facebook
- Twitter
- LinkedIn

SAFE STORAGE INFORMATION

It is important that patients take their medicine as prescribed by their health care provider and as indicated on the label or packaging. It is also important to be sure to store medicine securely to prevent accidental ingestion or misuse by others, especially children. If you have expired or unwanted medicine, proper storage and disposal are easy.

Follow these instructions on secure storage of unwanted or expired medicine.

USE AS DIRECTED

Use medicine as directed. Never give away or share it. If you have any questions, ask your healthcare providers.

STORE SAFELY

Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it.

DISPOSE OF IT IMMEDIATELY

Count medicine to know how many are left and if there are any missing. Dispose expired, unwanted, or unused medicine immediately and properly.

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

Do not place medicine in the trash or recycling and never flush any medication down the sink or toilet.

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

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.



MEDICINE
USAGE



SAFE STORAGE
INFORMATION



CONVENIENT
LOCATIONS



MAIL SERVICES
FOR DISPOSAL

Figure 20: Sample California State Unwanted Medicine Program Website Safe Storage Information Page

Figure Description

Figure 20 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Unwanted Medicine Program – Safe Storage Information Website Page

Safe Storage Information

It is important that patients take their medicine as prescribed by their health care provider and as indicated on the label or packaging. It is also important to be sure to store medicine securely to prevent accidental ingestion or misuse by others, especially children. If you have expired or unwanted medicine, proper storage and disposal are easy.

Follow these instructions on secure storage of unwanted or expired medicine.

- Use as Directed: Use medicine as directed. Never give away or share it. If you have any questions, ask your healthcare providers.
- Store Safely: Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medicine in a secure location safely away from people or pets that might come in contact with it.
- Dispose of It Immediately: Count medicine to know how many are left and if there are any missing. Dispose expired unwanted, or unused medicine immediately and properly.

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

Do not place medicine in the trash or recycling and never flush any medication down the sink or toilet.

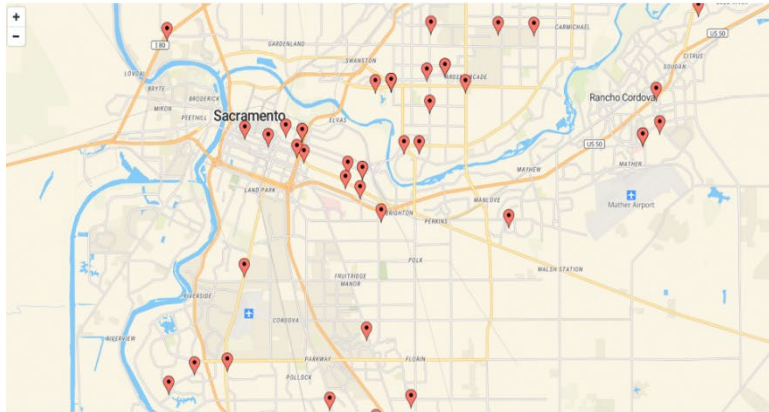
Never place sharps in the trash or recycling, and never flush them down the toilet. Disposing of sharps in the trash or recycling may put trash and sewage workers, janitors, housekeepers, household members, and children at risk of being harmed.

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Linked California State MED-Project Unwanted Medicine Program Website Pages

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- Medicine Usage
- Convenient Locations
- Mail Services for Disposal
- Privacy Policy
- Accessibility Statement

CONVENIENT LOCATIONS



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

Starting Point:
 Radius:
 Show Me:

ZIP Code Address

RITE AID	5400 SUNRISE BOULEVARD CITRUS HEIGHTS, CA 95610 SACRAMENTO	(916) 961-2064	Sunday Monday Tuesday Wednesday Thursday Friday Saturday	10:00 AM - 6:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 10:00 AM - 6:00 PM	<input type="button" value="v"/>
RITE AID	6681 AUBURN BOULEVARD CITRUS HEIGHTS, CA 95621 SACRAMENTO	(916) 726-1415	Sunday Monday Tuesday Wednesday Thursday Friday Saturday	10:00 AM - 6:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 10:00 AM - 6:00 PM	<input type="button" value="v"/>
RITE AID	6639 WATT AVENUE NORTH HIGHLANDS, CA 95660 SACRAMENTO	(916) 726-1415	Sunday Monday Tuesday Wednesday Thursday Friday Saturday	10:00 AM - 6:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 9:00 AM - 9:00 PM 10:00 AM - 6:00 PM	<input type="button" value="v"/>



MEDICINE USAGE



SAFE STORAGE INFORMATION



CONVENIENT LOCATIONS



MAIL SERVICES FOR DISPOSAL

[Privacy Policy](#) | [Accessibility Statement](#)

Figure 21: Sample California State Unwanted Medicine Program Website Convenient Locations Page

Figure Description

Figure 21 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Unwanted Medicine Program – Convenient Locations Website Page

Convenient Locations

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
- Radio buttons (located under Starting Point field) for Starting Point search options of: ZIP Code or Address
- 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 and clicking the Search button.

Sample Convenient Location:

- Site Name: Rite Aid
- Address: 5409 Sunrise Boulevard, Citrus Heights, CA 95610, Sacramento
- Phone Number: (916) 961-2064
- Hours of Operation:
 - o Sunday 10:00 a.m. – 6:00 p.m.
 - o Monday 9:00 a.m. – 9:00 p.m.
 - o Tuesday 9:00 a.m. – 9:00 p.m.
 - o Wednesday 9:00 a.m. – 9:00 p.m.
 - o Thursday 9:00 a.m. – 9:00 p.m.
 - o Friday 9:00 a.m. – 9:00 p.m.
 - o Saturday 10:00 a.m. – 6:00 p.m.
- Load More Results Button

Linked California State MED-Project Unwanted Medicine Program Website Pages

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- Medicine Usage
- Safe Storage Information
- Mail Services for Disposal
- Privacy Policy
- Accessibility Statement

MAIL SERVICES FOR DISPOSAL

MEDICINE MAIL-BACK SERVICES

Mail-Back Services for expired or unwanted medicines are available, free of charge, to all residents upon request. Medications in any dosage form, except for those identified as not accepted below, in their original container or sealed bag are accepted.

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

NOTE: The following items are not accepted in Medicine Mail-Back Envelopes: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, sharps, illicit or illegal drugs, pet pesticide products, animal medicines, biologics (such as insulin), and inhalers.

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

INHALER MAIL-BACK SERVICES

Mail-Back Services for inhalers are available, free of charge, to all residents upon request.

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

NOTE: Only place undamaged inhalers in their original containers in the Inhaler Mail-Back Package. Inhaler Mail-Back Packages can only be used for inhalers and cannot accept other types of items.

INJECTOR MAIL-BACK SERVICES

Mail-Back Services for pre-filled injector products are available to all residents upon request.

NOTE: Injector Mail-Back Packages can only be used for pre-filled injector products and cannot be used for inhalers, biologics (such as insulin), or other types of unwanted medicine or items.

Please complete the form below to request free mail services for disposal options. Instructions for disposal will be provided with each service option. Please submit separate forms for each type of service requested.

Select mail services for disposal option *

Contact Information

<input type="text" value="First Name*"/>	<input type="text" value="Last Name*"/>
<input type="text" value="Email"/>	
<input type="text" value="Address*"/>	
<input type="text" value="Address 2"/>	
<input type="text" value="City*"/>	<input type="text" value="CA"/>
<input type="text" value="Zip Code*"/>	

* Required field

SUBMIT REQUEST



MEDICINE
USAGE



SAFE STORAGE
INFORMATION



CONVENIENT
LOCATIONS



MAIL SERVICES
FOR DISPOSAL

Figure 22: Sample California State Unwanted Medicine Program Website Mail Services for Disposal Page

[Figure Description](#)

Figure 22 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Unwanted Medicine Program – Mail Services for Disposal Website Page

Medicine Mail-Back Services

Mail-Back Services for expired or unwanted medicine are available, free of charge, to all residents upon request.

Medication in any dosage form, except for those identified as not accepted below, in their original container or sealed bag are accepted.

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Note: The following items are not accepted in Medicine Mail-Back Envelopes:

- Herbal remedies
- Vitamins
- Supplements
- Cosmetics
- Other personal care products
- Medical devices
- Batteries
- Mercury-containing thermometers
- Sharps
- Illicit or illegal drugs
- Pet pesticide products
- Animal medicines
- Biologics (such as insulin)
- Inhalers

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

Inhaler Mail-Back Services

Mail-Back Services for inhalers are available, free of charge, to all residents upon request.

To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Note: Only place undamaged inhalers in their original containers in the Inhaler Mail-Back Package. Inhaler Mail-Back Packages can only be used for inhalers and cannot accept other types of items.

Injector Mail-Back Services

Mail-Back Services for pre-filled injector products are available to all residents upon request.

Note: Injector Mail-Back Packages can only be used for pre-filled injector products and cannot be used for inhalers, biologics, or other types of unwanted medicine or items.

Please complete the form below to request free mail services for disposal options. Instructions for disposal will be provided with each service option. Please submit separate forms for each type of service requested.

Mail-Back Services for Disposal Form Field

Note: * denotes required fields.

- Select mail services for disposal option drop-down menu*

Contact Information Form Fields

- First Name*
- Last Name*
- Email
- Address*
- Address 2
- City*
- State*
- Zip Code*
- Submit Request button

Linked California State MED-Project Unwanted Medicine Program Website Pages

- MEDhome
- MEDinfo
- MEDfaq
- Contact
- Login
- Medicine Usage
- Safe Storage Information
- Convenient Locations
- Privacy Policy
- Accessibility Statement

MEDInfo

Medicine helps treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It is important that patients take their medicine as prescribed by their health care provider and as indicated on the label or packaging. It is also important to be sure to store medicine securely to prevent accidental ingestion or misuse by others, especially children.

For more information on safe storage, visit [Safe Storage Information](#).

There are a number of ways to dispose of expired or unwanted medicine. To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Do not place medicine in the trash or recycling, and never flush any medication down the sink or toilet.

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

Brochure – Medicine Program

[English](#)

Frequently Asked Questions

[English](#)

Radio Public Service Announcement (PSA) – Medicine Program

[English](#)

Video Public Service Announcement (PSA) – Medicine Program

[English](#)

Login to your account to [order brochures](#).

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

Figure 23: Sample California State Unwanted Medicine Program Website MEDInfo Page

[Figure Description](#)

Figure 23 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Unwanted Medicine Program – MEDinfo Website Page

Medicine helps treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It is important that patients take their medicine as prescribed by their health care provider and as indicated on the label or packaging. It is also important to be sure to store medicine securely to prevent accidental ingestion or misuse by others, especially children.

For more information on safe storage, please click here (hyperlink to Safe Storage Information Website page).

There are a number of ways to dispose of expired or unwanted medicine. To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Do not place medicine in the trash or recycling, and never flush any medication down the sink or toilet.

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

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

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

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

Linked California State MED-Project Unwanted Medicine Program Website Pages

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

MEDfaq

- + What is MED-Project?
- + What should I do if I am having a medical emergency?
- + What should I do if I think I have ingested something poisonous?
- + What should I do if my pet has ingested medication?
- + Whom should I call with a question about my medication?
- + Where can I find information about the safe storage of medication?
- + Should I remove my personal information before disposing of my unwanted medicine?
- + How do I dispose of my expired or unwanted medicine?
- + Where are the MED-Project locations nearest me?
- + Will it cost me anything to dispose of my expired or unwanted medicine?
- + Can I flush my medication down the toilet?
- + I am unable to go to a kiosk. How can I dispose of my expired or unwanted medicine?
- + 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 the safe disposal of expired or unwanted medicine?
- + What is recommended for safe disposal of expired or unwanted medicine in California?
- + Where can I find information about California's Prop 65?

Figure 24: Sample California State Unwanted Medicine Program Website MEDfaq Page

Figure Description

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Figure 24 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Unwanted Medicine 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 have ingested something poisonous?
- What should I do if my pet has ingested medication?
- Whom should I call with a question about my medication?
- Where can I find information about the safe storage of medication?
- Should I remove my personal information before disposing of my unwanted medicine?
- How do I dispose of my expired or unwanted medicine?
- Where are the MED-Project locations nearest me?
- Will it cost me anything to dispose of my expired or unwanted medicine?
- Can I flush my medication down the toilet?
- I am unable to go to a kiosk. How can I dispose of my expired or unwanted medicine?
- 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 the safe disposal of expired or unwanted medicine?
- What is recommended for safe disposal of expired or unwanted medicine in California?
- Where can I find information about California's Prop 65?

Linked California State MED-Project Unwanted Medicine Program Website Pages

- [MEDhome](#)
- [MEDinfo](#)
- [MEDfaq](#)
- [Contact](#)
- [Login](#)
- [Privacy Policy](#)
- [Accessibility Statement](#)

This page is intentionally left blank.

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.

Convenient Locations/Host Sites - Request Materials

Login to your account to [order brochures](#).

If you have any questions, comments, or concerns, [login to your account](#).

For answers to some frequently asked questions, visit the MED-Project [FAQ](#) page.

Residents

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

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

If you would like to leave feedback about the MED-Project Program, answer our [community feedback questionnaire](#).

Convenient Locations

If you are a current kiosk drop-off site, or a retail pharmacy, hospital/clinic with an onsite pharmacy or a law enforcement agency interested in hosting a kiosk, please contact us:

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 Medicine 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 25: Sample California State Unwanted Medicine Program Website Contact Page

[Figure Description](#)

Figure 25 Description: MED-Project™ Medication Education & Disposal – SB212 Program – California State Unwanted Medicine 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.

Convenient Locations/Host Sites – Request Materials

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

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

For answers 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).

Convenient Locations

If you are a current kiosk drop-off site, or a retail pharmacy, hospital/clinic with an onsite pharmacy or a law enforcement agency interested in hosting a kiosk, please contact us:

- Click here: Login or Register for an Account (hyperlinked to login or registering 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 Medicine 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

Linked California State MED-Project Website Pages

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

Appendix Q

Sample Call Center Flow

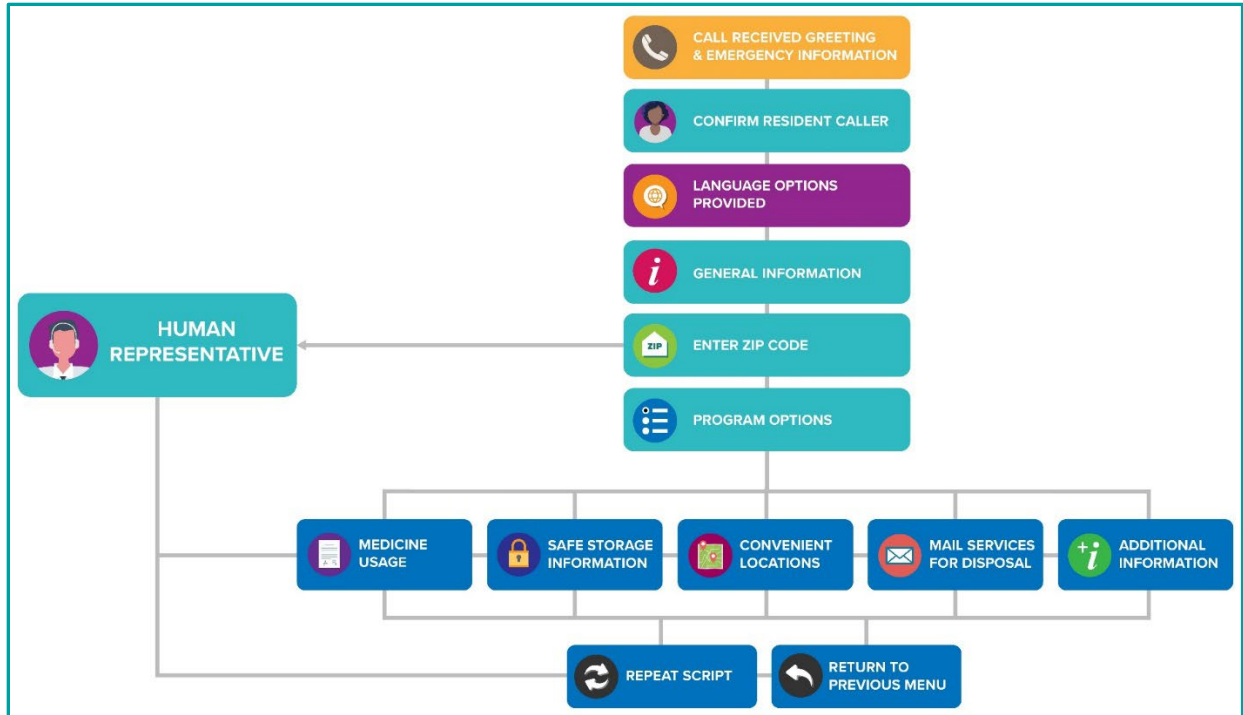


Figure 26: Sample IVR Call Center Script Flow

Figure Description

Figure 26 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:
 - Medicine Usage
 - Safe Disposal Information
 - Convenient Locations
 - Mail-Back Services
 - Additional Information
7. Option to repeat script.
8. Option to return to previous menu.

Appendix R

Third-Party Data Sources

CalRecycle

- Data Identified: Departmental Administrative Fee Costs
- Plan Section:
 - [Appendix I](#)

Department of Consumer Affairs

- URL: https://www.dca.ca.gov/consumers/public_info/index.shtml.
- Data Identified: Pharmacies, Distributors.
- Plan Section:
 - [Appendix E.](#)

Department of Health Care Services

- URL: <https://www.dhcs.ca.gov/individuals/Documents/NTP-Provider-Directory.pdf>.
- Data Identified: Narcotic Treatment Programs.
- Plan Section:
 - [Appendix E.](#)

Dun & Bradstreet

- URL: <https://www.dnb.com/>.
- Data Identified: Covered Entities.
- Plan Section:
 - [Appendix E.](#)

Food and Drug Administration

- URL: <https://www.fda.gov/>.
- Data Identified: Covered Entities.

- Plan Section:
 - [Appendix E.](#)

Law Enforcement Agencies

- URL: N/A.
- Data Identified: Participating Authorized Collection Sites.
- Plan Section:
 - [Appendix C.](#)

Commission on Peace Officer Standards and Training and the Tribal Law and Policy Institute

- URLs:
 - <https://post.ca.gov/le-agencies>.
 - <https://www.tribal-institute.org/lists/enforcement.htm>.
- Data Identified: Law Enforcement Agencies.
- Plan Section:
 - [Appendix E.](#)

Pharmaceutical Product Stewardship Work Group

- URL: N/A.
- Data Identified: Participating Covered Entities, Covered Drug Lists.
- Plan Sections:
 - [Appendix A.](#)
 - [Appendix B.](#)

Pharmacies

- URL: N/A.
- Data Identified: Participating Authorized Collection Sites.
- Plan Section:
 - [Appendix C.](#)

Western University of Health Sciences

- PDF URL: <https://www.westernu.edu/media/research/pdfs/Controlled-Subs-Reverse-Distributors.pdf>.
- Data Identified: Reverse Distributors.
- Plan Section:
 - [Appendix E](#).

Appendix S

Regulatory Map

Citations to 14 CCR

18973(a)

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

18973(b)

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

18973(c)

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

18973(d)

- Regulatory Requirement: Completeness and correctness of the Plan.
- Plan Section(s):
 - [Appendix S](#).

18973(e)

- Regulatory Requirement: Certification.
- Plan Section(s):
 - [Section 5: State Agency Determinations and Certifications.](#)
 - [Appendix H.](#)

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 7: Collection System.](#)

18973.2(a)

- Regulatory Requirement: Contact information of the corporate officer.
- Plan Section(s):
 - [Section 2: Corporate Officer.](#)

18973.2(b)

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

18973.2(c)

- Regulatory Requirement: List of each Covered Drug sold by each participating Covered Entity.
- Plan Section(s):
 - [Section 3: Covered Drugs Sold by Each Participating Covered Entity.](#)
 - [Appendix B.](#)

18973.2(d)(1)

- Regulatory Requirement: Contact information for each participating Authorized Collector.
- Plan Section(s):
 - [Section 4: Participating Authorized Collectors.](#)
 - [Appendix C.](#)

18973.2(d)(2)

- Regulatory Requirement: Potential Authorized Collectors that were notified of the opportunity to serve as an Authorized Collector.
- Plan Section(s):
 - [Section 4: Notification.](#)
 - [Appendix D.](#)
 - [Appendix E.](#)

18973.2(d)(3)

- Regulatory Requirement: Good faith negotiations.
- Plan Section(s):
 - [Section 4: Good Faith Negotiations.](#)

18973.2(d)(4)

- Regulatory Requirement: Efforts to work with Retail Pharmacies and Retail Pharmacy Chains to fulfill participation requirements.
- Plan Section(s):
 - o [Section 4: Pharmacy Participation Requirements.](#)

18973.2(d)(5)

- Regulatory Requirement: Process to incorporate potential Authorized Collectors that submit a written offer to participate.
- Plan Section(s):
 - o [Section 4: Incorporation of Potential Authorized Collectors.](#)

18973.2(d)(6)

- Regulatory Requirement: Reasons for excluding any potential Authorized Collectors.
- Plan Section(s):
 - o [Section 4: Reasons for Exclusion.](#)

18973.2(d)(7)

- Regulatory Requirement: Notifying any potential Authorized Collectors of the reasons they were rejected.
- Plan Section(s):
 - o [Section 4: Notification of Rejection.](#)

18973.2(e)(1)

- Regulatory Requirement: State Agency Determinations.
- Plan Section(s):
 - o [Section 5: State Agency Determinations and Certifications.](#)

18973.2(e)(2)

- Regulatory Requirement: Compliance Certifications.
- Plan Section(s):
 - o [Section 5: State Agency Determinations and Certifications.](#)
 - o [Appendix H.](#)

18973.2(f)

- Regulatory Requirement: Initial Program budget and Program funding.
- Plan Section(s):
 - o [Section 6: Program Budgets and Funding.](#)
 - o [Appendix I.](#)

18973.2(g)(1)

- Regulatory Requirement: Safely and securely collect, track, and properly manage Covered Drugs.
- Plan Section(s):
 - o [Section 7: Handling, Transport, and Disposal](#) et seq.
 - o [Section 13: Collection, Transportation, and Disposal.](#)

18973.2(g)(2)

- Regulatory Requirement: How convenience standards are met.
- Plan Section(s):
 - o [Section 7: Authorized Collection Sites.](#)

18973.2(g)(2)(A)

- Regulatory Requirement: Reasonable geographic spread.
- Plan Section(s):
 - o [Section 7: Authorized Collection Sites.](#)

18973.2(g)(2)(B)

- Regulatory Requirement: Reevaluation of convenience standards.
- Plan Section(s):
 - [Section 7: Authorized Collection Sites.](#)

18973.2(g)(3)

- Regulatory Requirement: Tracking mechanisms for collection, transportation, and disposal.
- Plan Section(s):
 - [Section 7: Handling, Transport, and Disposal.](#)
 - [Section 13: Collection, Transportation, and Disposal.](#)

18973.2(g)(4)

- Regulatory Requirement: Metrics to measure Covered Drugs collected.
- Plan Section(s):
 - [Section 10: Covered Drugs Collected from Ultimate Users.](#)

18973.2(g)(5)

- Regulatory Requirement: Service providers used to transport, process, or dispose of Covered Drugs.
- Plan Section(s):
 - [Section 7: Handling, Transport, and Disposal.](#)

18973.2(g)(6)(A)

- Regulatory Requirement: Description of mechanisms to provide mail-back materials or an alternative form of collection and disposal system.
- Plan Section(s):
 - [Section 7: Mechanisms to Provide Ultimate Users with Mail-Back Services.](#)

18973.2(g)(6)(B)

- Regulatory Requirement: Mail-Back Services or an alternative form of collection and disposal for Ultimate Users who are Homeless, Homebound, or disabled.
- Plan Section(s):
 - [Section 7: Mechanisms to Provide Ultimate Users with Mail-Back Services.](#)

18973.2(g)(6)(C)

- Regulatory Requirement: Supplemental Services.
- Plan Section(s):
 - [Section 7: Mechanisms to Provide Ultimate Users with Mail-Back Services.](#)
 - [Section 7: Supplemental Services.](#)
 - [Section 12: Compliance with Applicable Laws.](#)

18973.2(g)(6)(D)

- Regulatory Requirement: Alternative methods of collection for Covered Drugs that cannot be commingled with other Covered Drugs.
- Plan Section(s):
 - [Section 7: Alternative Methods of Collection for Covered Drugs.](#)

18973.2(g)(6)(E)

- Regulatory Requirement: Metrics to measure Mail-Back Packages distributed and returned.
- Plan Section(s):
 - [Section 10: Mail-Back Packages Distributed.](#)

18973.2(g)(7)

- Regulatory Requirement: Authorized Collection Site service schedule.
- Plan Section(s):
 - o [Section 7: Secure Collection Receptacle Service.](#)

18973.2(g)(8)

- Regulatory Requirement: Critical instances of noncompliance.
- Plan Section(s):
 - o [Section 13: Discovery of Critical Instances of Noncompliance.](#)

18973.2(g)(9)

- Regulatory Requirement: Authorized Collection Site funding.
- Plan Section(s):
 - o N/A.

18973.2(g)(10)

- Regulatory Requirement: Safety and security incident standard operating procedures.
- Plan Section(s):
 - o [Section 13: Safety and Security Problem Management.](#)

18973.2(h)

- Regulatory Requirement: Collection, transportation, and disposal system records.
- Plan Section(s):
 - o [Section 13: Record Maintenance.](#)

18973.2(i)

- Regulatory Requirement: Ordinance repeals.
- Plan Section(s):
 - o [Section 8: Repeal of Local Programs.](#)

18973.2(j)(1)

- Regulatory Requirement: Activities to promote awareness.
- Plan Section(s):
 - [Section 9: Educational and Outreach Materials for Ultimate Users.](#)
 - [Appendix M.](#)

18973.2(j)(2)

- Regulatory Requirement: Materials distributed in languages suited to local demographics.
- Plan Section(s):
 - [Section 9: Signage for Hospitals, Pharmacies, and Other Locations.](#)
 - [Appendix M.](#)
 - [Appendix N.](#)

18973.2(j)(3)

- Regulatory Requirement: Website.
- Plan Section(s):
 - [Section 9: Website for Ultimate Users.](#)
 - [Appendix P.](#)

18973.2(j)(4)

- Regulatory Requirement: Toll-free telephone number.
- Plan Section(s):
 - [Section 9: Call Center.](#)

18973.2(j)(5)

- Regulatory Requirement: Education and outreach program performance metrics.
- Plan Section(s):
 - o [Section 10: Performance of the Comprehensive Education and Outreach Program.](#)

18973.2(j)(6)

- Regulatory Requirement: Encouraging Ultimate Users to separate products that are not Covered Products from Covered Products.
- Plan Section(s):
 - o [Section 9: Education and Outreach Program.](#)

18973.2(j)(7)

- Regulatory Requirement: Disposal promotions inconsistent with the Program.
- Plan Section(s):
 - o [Section 9: Education and Outreach Program.](#)

18973.2(k)

- Regulatory Requirement: Coordination Efforts.
- Plan Section(s):
 - o [Section 11: Coordination Efforts.](#)

18973.2(l)

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

18973.2(m)

- Regulatory Requirement: Process for selecting service providers.
- Plan Section(s):
 - o [Section 13: Selection of Service Providers.](#)

18973.4

- Regulatory Requirement: Submission of an annual report to CalRecycle on or before March 31, 2022, and each year thereafter.
- Plan Section(s):
 - o [Section 14: Reporting.](#)

18973.6

- Regulatory Requirement: Submission of an initial five-year budget and an annual budget.
- Plan Section(s):
 - o [Section 6: Program Budgets and Funding.](#)

18973.6(a)

- Regulatory Requirement: Contact information of the corporate officer.
- Plan Section(s):
 - o [Section 6: Contact Information of the Person Responsible for Submitting and Overseeing the Program Budget.](#)

18973.6(b)

- Regulatory Requirement: Anticipated costs to implement the Program.
- Plan Section(s):
 - o [Section 6: Contact Information of the Person Responsible for Submitting and Overseeing the Program Budget.](#)
 - o [Section 6: Anticipated Costs to Implement the Program.](#)
 - o [Appendix I.](#)

18973.6(c)

- Regulatory Requirement: Recommended reserve level amount and description justifying the reserve level amount indicated.
- Plan Section(s):
 - [Section 6: Recommended Reserve.](#)

18973.6(d)

- Regulatory Requirement: Recommended funding level to cover budgeted costs and operate the Program over a multi-year period.
- Plan Section(s):
 - [Section 6: Funding.](#)
 - [Appendix I.](#)

18973.6(e)

- Regulatory Requirement: Description of the types of activities relative to each line-item cost category.
- Plan Section(s):
 - [Section 6: Types of Activities Relative to Each Line-Item Cost Category.](#)

18973.6(f)

- Regulatory Requirement: Member Covered Entities shall fund an annual audit.
- Plan Section(s):
 - [Section 6: Recommended Reserve.](#)

18974(a)

- Regulatory Requirement: Maintain records to support compliance with the Regulations and the Law.
- Plan Section(s):
 - [Section 13: Record Maintenance.](#)

18974(b)

- Regulatory Requirement: Maintain and provide access to records for a minimum of three years after submission of a document which relies upon those records.
- Plan Section(s):
 - [Section 13: Record Maintenance.](#)

18974(c)

- Regulatory Requirement: Covered Product records.
- Plan Section(s):
 - [Section 13: Record Maintenance.](#)

18974.1(a)

- Regulatory Requirement: Pay all administrative and operational costs associated with the Program.
- Plan Section(s):
 - [Section 6: Revenue.](#)

18974.2

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

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