



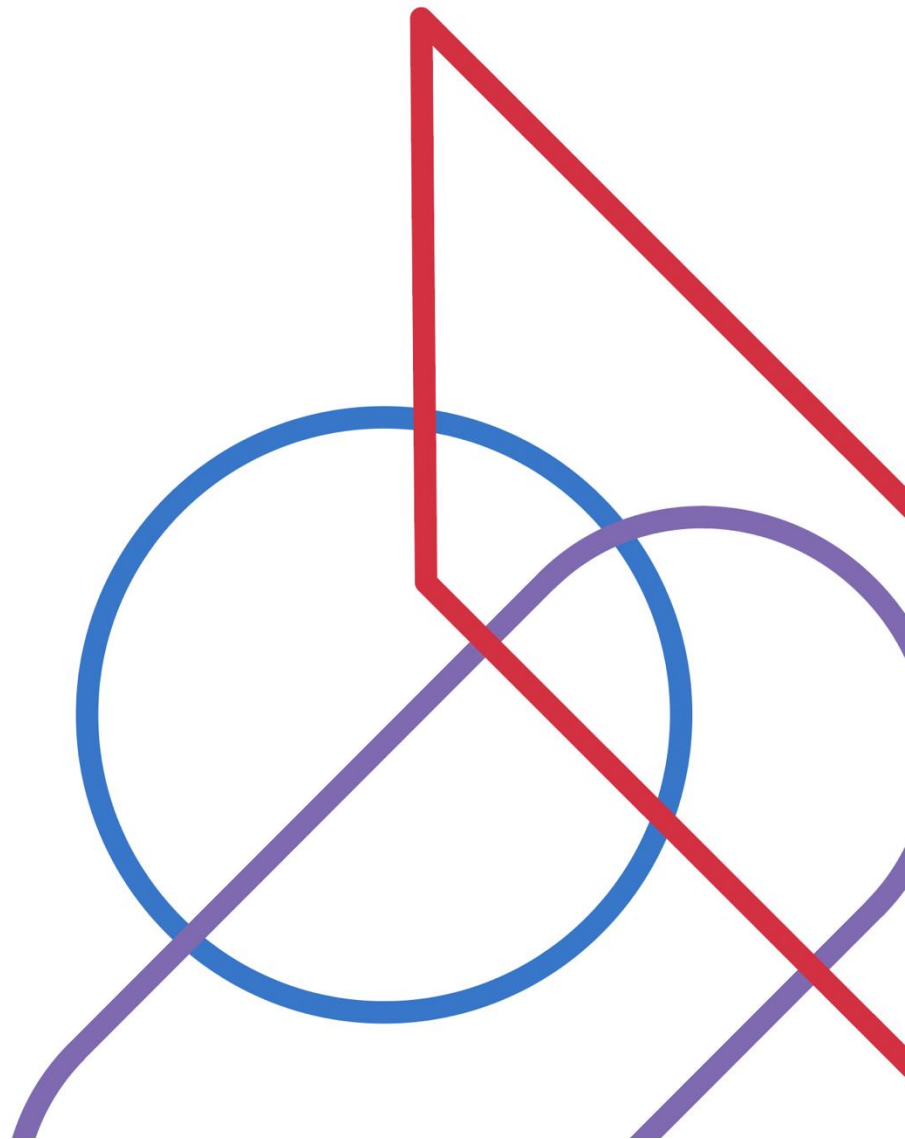
A Product Stewardship Plan for Household Pharmaceutical Waste

State of Maine

July 1, 2022

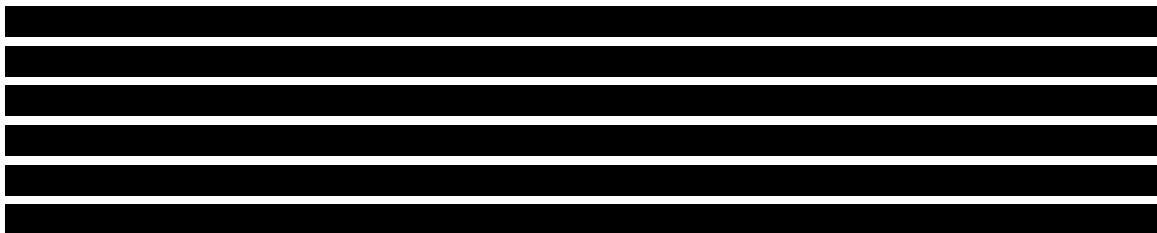
Prepared By: MED-Project ME, LLC

Submitted To: Maine Department of Environmental Protection



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I. Definitions

§1612. Drug take-back stewardship program Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

Capitalized terminology in the Plan has the meaning in these definitions. Capitalized terminology that is not defined in the Plan is defined in the legislation.

Carrier is the common carrier used to transport Household Pharmaceutical Waste.

Collection Location means a Pharmacy, LEA, or other Authorized Collector that has executed an agreement with MED-Project to be a Mail-Back Distribution Location or host a MED-Project Collection Receptacle for the collection of Household Pharmaceutical Waste from Residents under the Program.

DEA is the U.S. Drug Enforcement Administration.

DEA Rule is the DEA Final Rule, “Disposal of Controlled Substances,” 79 Fed. Reg. 53520 et seq., adopted on September 9, 2014.

Department is the Maine Department of Environmental Protection.

DOT is the U.S. Department of Transportation.

FDA is the U.S. Food and Drug Administration.

Help Desk is the call center, Website, and email-in database for Collection Locations and Authorized Collectors that can be reached at the toll-free number 1-833 MED-PROJECT or 1-833-633-7765, www.med-project.org, and/or by email at maine@med-project.org.

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

Injector Mail-Back Packages are pre-paid, pre-addressed, United States Food and Drug Administration-cleared sharps container mail-back systems provided by Vendor for the collection of Pre-filled Injector Products.

Law Enforcement Agency or **LEA** is a federal, state, tribal, or local law enforcement office or agency.

Mail-Back Distribution Location means a Pharmacy, LEA, or other Authorized Collector that has executed an agreement with MED-Project to offer Mail-Back Packages to Residents to dispose of Household Pharmaceutical Waste.

Mail-Back Packages are pre-paid, pre-addressed Mail-Back Envelopes provided by Vendor for Household Pharmaceutical Waste that is not a Pre-filled Injector Product or an inhaler. Mail-Back Packages also include Injector Mail-Back Packages or Inhaler Mail-Back Packages provided by Vendor for the collection and disposal of Household Pharmaceutical Waste.

MED-Project Collection Receptacle means a Collection Receptacle provided by MED-Project or an existing Collection Receptacle that can be serviced by Vendor at no cost to the Collection Location.

Plan or Product Stewardship Plan is the product stewardship plan presented in this submittal by MED-Project.

Pre-filled Injector Products are pre-filled injector products with a retractable or otherwise securely covered needle where medicine cannot be removed from them or where they contain more than trace amounts of Household Pharmaceutical Waste.

Program or Product Stewardship Program or MED-Project Program is the MED-Project product stewardship program set forth in this Plan.

Resident means a person over the age of 18 residing in the State.

State means the State of Maine.

Vendor is any vendor retained by MED-Project to carry out its obligations under the Program.

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

II. Collection of All Covered Drugs

§1612.3.A. A certification that the stewardship program will accept all covered drugs that are household pharmaceutical waste regardless of who manufactured the covered drugs;

Appendix A provides a written certification that MED-Project will accept all Covered Drugs that are Household Pharmaceutical Waste regardless of who manufactured the Covered Drugs.

III. Contact Information

§1612.3.B. Contact information for the person submitting the plan to whom the department shall direct all related inquiries, a list of participating manufacturers and their brands, contact information for each participating manufacturer and a list of the covered drugs manufactured by any participating manufacturer that are branded or labeled for sale in the State by a retailer under the retailer's own brand or store label;

A. Program Contact Information

The contact person for MED-Project ME, LLC (“MED-Project”) who is submitting the Plan and to whom the Department shall direct all related inquiries is:

Jim Wilson
Lead Director, Legal and Compliance
MED-Project ME, LLC
1800 M Street, NW
Suite 400 South
Washington, DC 20036
Phone: 1 (833) 633-7765
maine@med-project.org

B. Participating Manufacturers

MED-Project submits this proposed Plan on behalf of participating Manufacturers. MED-Project submitted a separate spreadsheet file with the list of participating Manufacturers, their brands, and contact information for each participating Manufacturer.

C. Covered Drugs

MED-Project submitted a separate spreadsheet file with a list of Covered Drugs manufactured by the Manufacturers participating in the Plan that are branded or labeled for sale by a retailer under the retailer's own brand or store label.

IV. Collection of Household Pharmaceutical Waste

§1612.3.C. A description of how the stewardship program will make available free, convenient and ongoing collection opportunities for covered drugs that are household pharmaceutical waste to all persons seeking to dispose of such covered drugs and how the collection opportunities will be geographically distributed in a way to ensure access in rural and underserved areas, as determined based on geographic information systems modeling. The plan must include a list of authorized collectors and collection locations;

MED-Project will make available free, convenient, and ongoing collection opportunities for Covered Drugs that are Household Pharmaceutical Waste to Residents through the development of a network of Collection Locations that are geographically distributed to provide access in rural and underserved areas.

The list of Collection Locations participating in the Program as of June 24, 2022, was provided as a separate spreadsheet file.

A. Collection Opportunities in Rural and Underserved Areas

Based on GIS analysis of the number and geographic distribution of Mandatory Pharmacy Collectors operating in the State and obligated to participate in a Drug Take-Back Stewardship Program under 38 M.R.S.A. §1612.8.A, MED-Project expects that greater than 95% of residents will live within 15-miles of a Mandatory Pharmacy Collector participating in a program approved under 38 M.R.S.A. §1612.4. Under 38 M.R.S.A. §1612.8.A, a Mandatory Pharmacy Collector may participate in an approved Drug Take-Back Stewardship Program by making Mail-Back Envelopes available to consumers of Covered Drugs upon request, hosting a Collection Receptacle, or by providing another approved method of collection.

Figure 1 shows a map of Mandatory Pharmacy Collectors, including those that currently have agreements to participate as a MED-Project Collection Location, operating in the State, overlaid atop US Census population data.

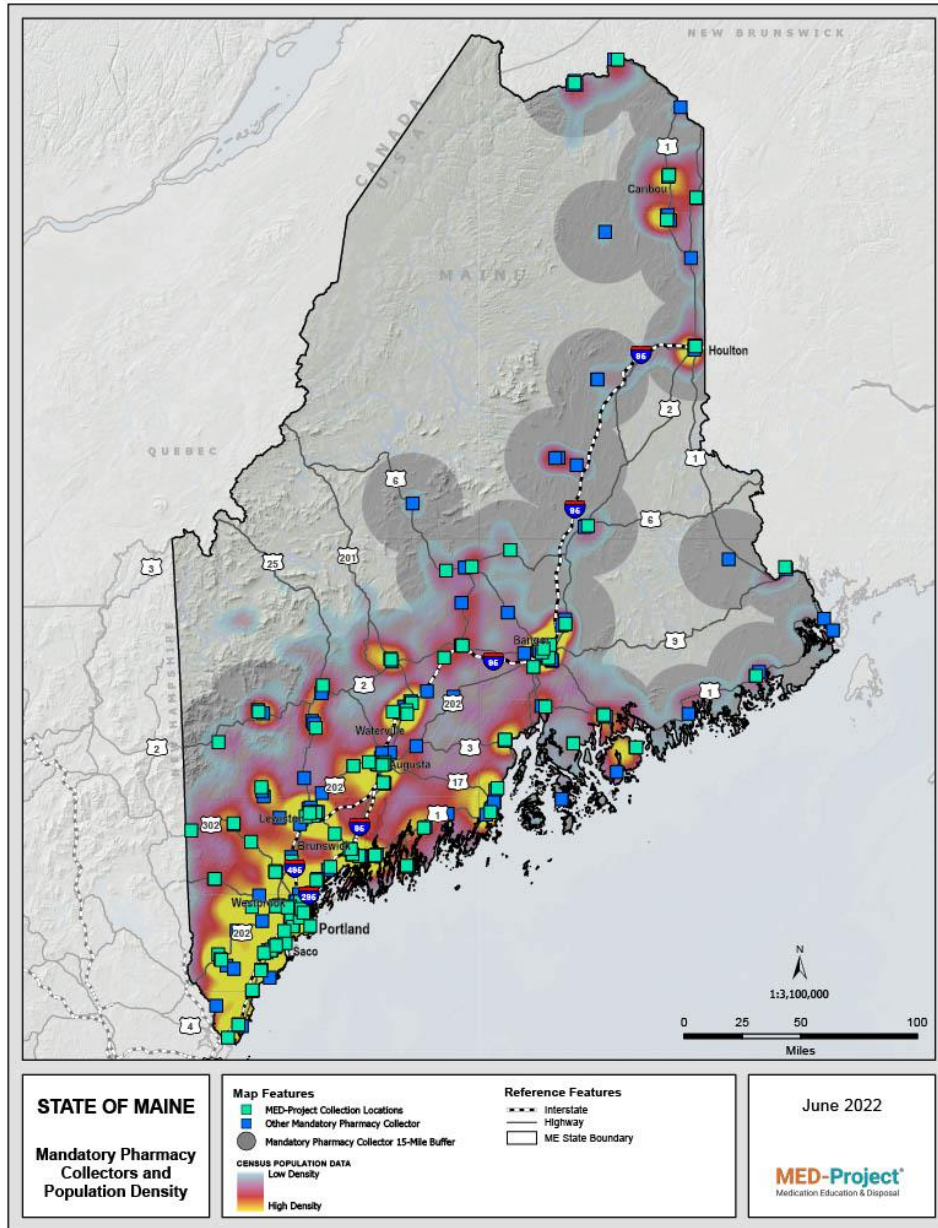


Figure 1: Potential Collection Locations

V. Collection Methods

§1612.3.D. A description of the collection methods to be used to ensure that only covered drugs that are household pharmaceutical waste will be collected by authorized collectors under the stewardship program and a description of how separation of those covered drugs from packaging by consumers will be encouraged to reduce transportation and disposal costs. The plan must ensure that collection methods used under the program include mail-back envelopes and collection receptacles and do not include home disposal methods involving packets, bottles or other containers that a person may use to render nonretrievable or destroy a covered drug that is household pharmaceutical waste by means of a chemical process;

The following sections describe how MED-Project will collect Household Pharmaceutical Waste at Collection Locations.

A. Mandatory Pharmacy Collectors

§1612.8.A. A mandatory pharmacy collector shall participate in a stewardship program and shall provide for the safe collection of covered drugs that are household pharmaceutical waste under that program through the use of:"

§1612.8.A(1) Mail-back envelopes made available to consumers of covered drugs upon request;"

§1612.8.A(2) Collection receptacles; or"

§1612.8.A(3) Any other method of collection that complies with applicable United States Department of Justice, Drug Enforcement Administration regulations under 21 Code of Federal Regulations, Part 1300, 1301, 1304, 1305, 1307 or 1317 and that has been approved by the department as a method of collection for use in the stewardship program, except that the department may not approve for use in any stewardship program under this section a method of home disposal involving packets, bottles or other containers that a person may use to render nonretrievable or destroy a covered drug that is household pharmaceutical waste by means of a chemical process."

A mandatory pharmacy collector that is a pharmacy not located in the State that provides covered drugs to residents in the State by mail shall provide for the safe collection of covered drugs that are household pharmaceutical waste through the use of mail-back envelopes and shall ensure that consumers in the State purchasing covered drugs from the pharmacy are provided with information regarding the availability of such envelopes upon request and instructions regarding how the customer can request an envelope

MED-Project will provide Mandatory Pharmacy Collectors the opportunity to participate in the Program as a Collection Location. Mandatory Pharmacy Collectors will be able to participate as a Mail-Back Distribution Location or host a MED-Project Collection Receptacle for the collection of Household Pharmaceutical Waste from Residents. To participate in the Program, a Mandatory Pharmacy Collector must comply with all

applicable laws, regulations, other legal requirements, and any other MED-Project terms consistent with the scope of the approved Plan.

If multiple Drug Take-Back Stewardship Programs are approved by the Department, 38 M.R.S.A. recognizes that such approval will have impacts on the multiple programs. Accordingly, MED-Project will accept fair and reasonable numbers of Mandatory Pharmacy Collectors into the MED-Project Program.

1. Mail-Back Distribution Locations

Once a Collection Location has executed an agreement to become a Mail-Back Distribution Location, MED-Project will provide three types of Mail-Back Packages:

- Mail-Back Envelopes for Household Pharmaceutical Waste that are not Pre-filled Injector Products or inhalers.
- Inhaler Mail-Back Packages for inhalers.
- Injector Mail-Back Packages for Pre-filled Injector Products.

Mail-Back Packages will include:

- Instructions for using the Mail-Back Package.
- A description of the types of Household Pharmaceutical Waste that may be returned.
- Mailing restrictions and a notice that only packages provided by Vendor will be accepted for destruction.
- Instructions to direct Residents to recycle remaining packaging if transferring Household Pharmaceutical Waste to a sealed bag.
- Instructions to discourage Residents from improper disposal methods, such as flushing Household Pharmaceutical Waste or placing it in the garbage.
- Instructions for returning the Mail-Back Package.
- Information about other options for disposing of Household Pharmaceutical Waste through the Program.

Pre-filled Injector Products cannot be commingled with other Household Pharmaceutical Waste in Mail-Back Packages or Inhaler Mail-Back Packages and will be collected in Injector Mail-Back Packages. Inhalers will be collected in Inhaler Mail-Back Packages.

Mail-Back Distribution Locations will be offered signage indicating that the site offers Mail-Back Packages and written materials with more information about Program offerings. MED-Project will provide Mail-Back Packages as requested by the Mail-Back Distribution Locations. MED-Project's Help Desk will allow Mail-Back Distribution Locations to request Mail-Back Packages as needed to maintain stock.

2. MED-Project Collection Receptacles

Upon executing an agreement to host a MED-Project Collection Receptacle, MED-Project will provide Collection Locations a MED-Project Collection Receptacle, Program

signage, brochures, and other printed materials that will direct Residents on how to dispose of Household Pharmaceutical Waste. MED-Project Collection Receptacle signage will direct Residents to:

- Dispose of Covered Drugs that are Household Pharmaceutical Waste only.
- Recycle remaining packaging if transferring Household Pharmaceutical Waste to a sealed bag.
- Not use improper disposal methods for Household Pharmaceutical Waste, such as flushing or placing it in the garbage.

All MED-Project Collection Receptacles must be securely placed and maintained inside a Collection Location's registered location. MED-Project Collection Receptacles, as well as inner liners and containers, must meet federal and state law specifications.

Pre-filled Injector Products cannot be commingled with other Household Pharmaceutical Waste in MED-Project Collection Receptacles and will be collected in Injector Mail-Back Packages.

B. Nonresident Mandatory Pharmacy Collectors

MED-Project will offer instruction sheets regarding how a Resident can request a Mail-Back Envelope to any Mandatory Pharmacy Collector not located within the State that provides Covered Drugs to Residents by mail. To receive and distribute instruction sheets from MED-Project, a pharmacy must execute an agreement with MED-Project to provide an instruction sheet and meet certain requirements, including making the instruction sheets available to all consumers and in accordance with the terms of the Plan.

Each instruction sheet will include the web address of MED-Project's Website, which provides consumers information on drug take-back and safe drug disposal methods and allows consumers to order a prepaid Mail-Back Package.

C. Notification of Authorized Collectors That Are Not Mandatory Pharmacy Collectors

1612.8.B. An operator shall notify all authorized collectors that are not mandatory pharmacy collectors of the opportunity to serve on a voluntary basis as a collection location under the stewardship program and shall ensure that any such authorized collector that requests to participate in the program is added to the program within 90 days of the operator's receipt of the request. A participating authorized collector that is not a mandatory pharmacy collector may use any of the collection methods described under paragraph A.

MED-Project will notify Authorized Collectors that are not Mandatory Pharmacy Collectors in the State of the opportunity to serve as a Collection Location.

MED-Project will include any Authorized Collector that is not a Mandatory Pharmacy Collector in the Program within 90 days of MED-Project receiving the Authorized Collector's request to participate. To participate in the Program, an Authorized Collector that is not a Mandatory Pharmacy Collector must comply with all applicable laws, regulations, other legal requirements, or any other MED-Project terms consistent with the scope of the approved Plan.

D. MED-Project Collection Receptacle Service

§1612.8.C. The operator shall ensure that all collection receptacles located at a collection location under the stewardship program are emptied and serviced as often as necessary to avoid the receptacles reaching storage capacity and to ensure proper operation.

At Collection Locations that host a MED-Project Collection Receptacle, employees shall prepare MED-Project Collection Receptacle inner liners for shipment. This enables Collection Locations to control the timing for servicing the MED-Project Collection Receptacle when it is full. Collection Location employees, following instructions provided by Vendor, will:

- Check the MED-Project Collection Receptacle for any damage.
- Remove the inner liner and box from the MED-Project 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 by Carrier.

Under DEA regulations, Collection Location employees will document each phase of the process.

If the package with the sealed inner liner is prepared before Carrier pick-up, the Collection Location 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 systems. Collection Location staff will monitor the MED-Project Collection Receptacle and store inner liners in accordance with DEA requirements.

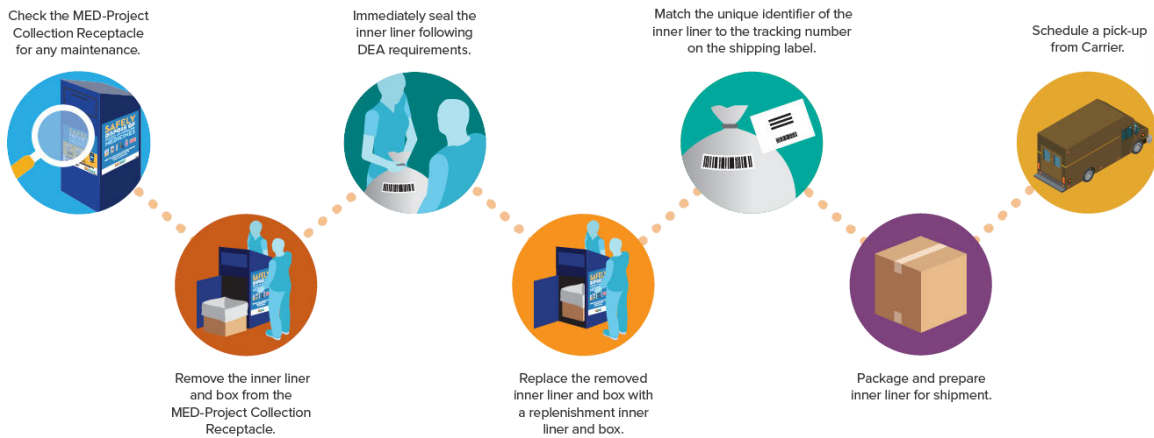


Figure 2: MED-Project Collection Receptacle Service Process

Collection Locations will receive an initial supply of inner liners and boxes, and replenishment inner liners and boxes will ship automatically, as needed, when packaged inner liners are picked up by Carrier. MED-Project will provide a system to fulfill orders for additional inner liners and boxes. Collection Locations will be able to specify a replenishment schedule, including the number of replenishment inner liners and boxes, to prevent inner liner and box depletion.

E. Information on Safe Drug Disposal Options

§1612.8.D. A mandatory pharmacy collector participating in a stewardship program shall provide information on covered drug collection and safe drug disposal options to a consumer upon dispensing a covered drug, including the availability of mail-back envelopes upon request. An authorized collector that is located in the State that is providing for the collection of covered drugs that are household pharmaceutical waste through the use of mail-back envelopes shall ensure that information regarding the availability of such envelopes upon request is prominently posted, displayed or otherwise provided to consumers purchasing covered drugs.

See section X.D.2 for information about written materials provided to all Collection Locations.

F. Collection Mechanisms, Program Information, and other Program Services

§1612.8.E. As part of a stewardship program, all collection mechanisms, program information and other program services must be provided by the operator free of charge to authorized collectors, including, but not limited to, the installation, maintenance and emptying of collection receptacles; the provision of mail-back envelopes, educational materials, brochures and signage; and drug-disposal-specific surveillance.

MED-Project pays all costs associated with placement and maintenance of MED-Project Collection Receptacles and the provision of Mail-Back Packages and education and

outreach materials, such as brochures and signage. There is no fee to Authorized Collectors or consumers for MED-Project Program's services.

MED-Project provides a Help Desk for Collection Locations to provide the following support functions:

- Direct and respond to requests for maintenance from Collection Locations.
- Receive and fulfill requests for additional inner liners and boxes or additional services from Collection Locations hosting a MED-Project Collection Receptacle.
- Receive and fulfill requests for additional Mail-Back Packages from Mail-Back Distribution Locations.
- Receive and fulfill requests for signage from Collection Locations.
- Receive and fulfill requests for written materials from Collection Locations and other interested parties upon request.
- Provide Authorized Collectors access to instructional materials, including written instructions, downloadable forms, and/or video instruction guides.

G. Collection Location Services

§1612.8.F. Collection of covered drugs that are household pharmaceutical waste at collection locations under a stewardship program must be made available to consumers free of charge. An operator and an authorized collector may not charge a point-of-sale fee to consumers, a fee that could be passed on to consumers or any other fee relating to the collection and disposal of covered drugs that are household pharmaceutical waste.

There is no fee to Authorized Collectors or consumers for MED-Project Program's services.

H. Separation of Household Pharmaceutical Waste from Packaging

MED-Project education and outreach materials instruct Residents to return Household Pharmaceutical Waste in its original container or a sealed bag. These materials encourage Residents who transfer their Household Pharmaceutical Waste to a sealed bag to recycle all remaining packaging.

VI. Joint Website

§1612.3.E. A certification that, upon implementation of the plan, the operator, jointly with the operators of other approved plans if any, will develop and administer a publicly accessible website that includes:

- 1. A list of authorized collectors, collection locations and the collection methods available at each collection location available under each stewardship program, updated as necessary;*
- 2. General information regarding the purpose and scope of the stewardship program or programs and the opportunities available to consumers under the program or programs for the safe disposal of covered drugs that are household pharmaceutical waste; and*
- 3. A statement that the stewardship program or programs are designed for the collection of covered drugs that are household pharmaceutical waste only;*

Appendix B provides a written certification that, upon implementation of the Plan, MED-Project, jointly with the operators of other approved Drug Take-Back Stewardship Plans, if any, will develop and administer a publicly accessible website that includes:

- A list of Authorized Collectors, collection locations, and the collection methods available at each collection location available under each Stewardship Program, updated as necessary.
- General information regarding the purpose and scope of the Stewardship Program or programs and the opportunities available to consumers under the program or programs for the safe disposal of Covered Drugs that are Household Pharmaceutical Waste.
- A statement that the Stewardship Program or programs are designed for the collection of Covered Drugs that are Household Pharmaceutical Waste only.

VII. Secure Handling of Household Pharmaceutical Waste

§1612.3.F. Information on how covered drugs that are household pharmaceutical waste will be safely and securely tracked, handled and transported from collection through final disposition and policies to ensure security and compliance with all applicable federal and state laws, rules and regulations including, but not limited to, 21 Code of Federal Regulations, Section 1317.90 and 40 Code of Federal Regulations, Sections 239 to 282;

MED-Project provides for Program compliance with all applicable laws, regulations, and other legal requirements by:

1. Requiring compliance for participating entities.
2. Supporting such compliance as needed.
3. Monitoring Program operations.

Because MED-Project does not collect or dispose of Household Pharmaceutical Waste itself, laws and regulations addressing the collection and disposal of Household Pharmaceutical Waste apply to Vendors and Collection Locations. Nevertheless, to provide for MED-Project's compliance with applicable requirements, MED-Project has policies and procedures for maintaining its internal records. More detail on MED-Project's compliance program follows below. In brief:

- MED-Project supports participating entity compliance, including by providing guidance to Collection Locations to self-assess their records and MED-Project Collection Receptacles and by providing ongoing support through the Help Desk.
- MED-Project agreements require all entities participating in the Program, including Vendors and Collection Locations to follow all applicable laws, regulations, and other legal requirements, including, but not limited to, the laws and regulations listed in Table 1.

Table 1: Regulatory Compliance Requirements

Laws and Regulations	Citation	Regulatory Level
Controlled Substances Act and DEA Implementing Regulations	21 U.S.C. § 801, <i>et seq.</i> ; 21 C.F.R. Parts 1300, 1301, 1304, 1305, 1307, and 1317	Federal
United States Department of Transportation Hazardous Materials Regulations	49 C.F.R. Parts 171, <i>et seq.</i>	Federal

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 Household Pharmaceutical Waste monitor the related tracking data and report to MED-Project.

MED-Project conducts periodic reviews of Vendors involved in the collection and disposal of Household Pharmaceutical Waste to address trends and service levels. MED-Project will monitor compliance of Vendors involved in the collection and disposal of Household Pharmaceutical Waste through reporting and audits performed by MED-Project or third parties. For Vendors, these activities will include:

- Review and inspection of weekly and monthly reporting from Vendors involved in collection and disposal of Household Pharmaceutical Waste from MED-Project Collection Receptacles.
- MED-Project assessment of reported data, including reconciling reported data with invoices and verifying services provided by Vendors involved in collection and disposal each month.
- MED-Project review and assessment of independent third-party, in-person, and comprehensive disposal facility reviews to assess critical environmental, operational, and financial information relating to disposal facilities.
- In-person audits of Vendors involved in the collection and disposal of Household Pharmaceutical Waste, when determined necessary or appropriate, for example, if the Vendor has reported safety, security, or other procedural deviations which require follow-up.

For Authorized Collectors hosting a MED-Project Collection Receptacle, these activities will include:

- Providing training materials to Collection Location staff to regularly self-assess their records and MED-Project Collection Receptacle.
- Periodic inspections by MED-Project of each MED-Project Collection Receptacle, including a review of the required documentation and record-keeping.

These activities are designed to evaluate current logistics practices associated with services provided to confirm they are sufficient to meet the Collection Locations' needs and to enhance secure pick-up and transportation of Household Pharmaceutical Waste from MED-Project Collection Receptacles to reverse distributor receiving sites.

MED-Project agreements require that Collection Locations and Vendors involved in the collection and disposal of Household Pharmaceutical Waste maintain policies and procedures covering safety, security, and compliance with all applicable laws, regulations, and other legal requirements. These policies and procedures shall be followed by persons handling Household Pharmaceutical Waste collected under the Program.

A. Transportation and Receipt of Household Pharmaceutical Waste

Upon Carrier pick-up following the MED-Project Collection Receptacle service described in section V.D, packaged inner liners from Collection Locations will be tracked by the Carrier and Vendor tracking systems until they are scanned for receipt at a

reverse distributor facility. After receipt by the reverse distributor, the packaged inner liner will 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 a permitted disposal facility meeting federal requirements.

Returned Mail-Back Packages will be transported by Carrier to a permitted facility meeting all federal requirements and handled in compliance with all applicable laws, regulations, and other legal requirements. Any management of returned Mail-Back Envelopes for Household Pharmaceutical Waste that are not injectors or inhalers will comply with all applicable laws, regulations, and other legal requirements.

B. Disposal of Household Pharmaceutical Waste

Upon receipt at a reverse distributor facility, all Household Pharmaceutical Waste collected under the Program except Injector Mail-Back Packages will be recorded for receipt verification, weighed, and destroyed at a permitted disposal facility meeting federal requirements.

Upon arriving at a treatment facility, Injector Mail-Back Packages will be recorded for receipt verification, weighed, treated, and then disposed of at a disposal facility.

VIII. Monitoring to Prevent Tampering

§1612.3.G. A description of how the collection system will be designed and monitored to prevent tampering;

MED-Project will provide for a handling, transport, and disposal system that complies with applicable laws, regulations, and other legal requirements. Systems are in place that are designed to monitor for and prevent tampering. Additionally, the MED-Project Collection Receptacle is designed using heavy gauge steel and multiple locking mechanisms, including:

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

MED-Project Collection Receptacle inner liners are waterproof, tamper-evident, and tear-resistant.

Mail-Back Envelopes for Household Pharmaceutical Waste that are not for Pre-filled Injector Products or inhalers are sealable, water and spill-proof, tamper-evident, and tear-resistant.

A. Tracking Information Provided by Vendors

MED-Project requires its Vendors involved with collection and disposal services to track and analyze certain metrics and data related to the collection and disposal of Household Pharmaceutical Waste collected under the Program and to report that information to MED-Project at regular periods and upon request. Through these policies, MED-Project and Vendors involved in the collection and disposal of Household Pharmaceutical Waste safely and securely track Household Pharmaceutical Waste collected under the Program through final disposal and destruction.

Additionally, MED-Project's agreements with its Vendors involved with collection and disposal services require that the Vendors maintain complete and accurate records, such as books, documents, and accounting procedures and practices. The agreements also allow MED-Project to audit such records.

B. Safety and Security

MED-Project has an incident management system that requires evaluation of incidents for potential safety and security issues. MED-Project agreements require Vendors involved in the collection and disposal of Household Pharmaceutical Waste to report safety or security issues. Agreements with Collection Locations also require reporting of any safety or security issues. Whenever a potential safety or security issue is reported, MED-Project and/or Vendor undertake a root cause analysis to identify and implement corrective and preventative actions to resolve the issue. MED-Project's incident management system tracks the corrective and preventative actions to completion.

MED-Project will communicate with Collection Locations to remind them of any obligations they may have to report to the DEA regarding any safety or security issues.

IX. Measurement of Household Pharmaceutical Waste

§1612.3.H. A description of how the stewardship program will measure the amount of collected and disposed of covered drugs that are household pharmaceutical waste;

Upon receipt from a Carrier or a transporter at a reverse distributor or treatment facility, Mail-Back Packages and packaged inner liners will be recorded for receipt verification and weighed prior to destruction or treatment.

X. Education and Outreach

§1612.3.I. A description of the education and outreach materials that will be used by the stewardship program to encourage consumer awareness and participation and to meet the performance goals established pursuant to paragraph J, including, but not limited to, a publicly accessible website with the information described in paragraph E and printed materials, including brochures and signage, containing similar information for use by authorized collectors and at collection locations. The plan must ensure that the program provides education and outreach materials to authorized collectors for distribution to consumers in accordance with subsection 8, paragraph E;

MED-Project will conduct an education and outreach program to encourage consumer awareness of and participation in the Program. MED-Project’s education and outreach program will provide signage and other educational and outreach materials to Collection Locations and provide information on the Program, including on collection and disposal options.

A. Objectives

The MED-Project education and outreach program will be designed to reach Residents through a variety of media channels and formats to:

- Inform Residents how to dispose of Household Pharmaceutical Waste under the Program.
- Account for the diverse media consumption habits, behaviors, and motivating factors of Residents across the State.
- Promote awareness of proper disposal methods for Household Pharmaceutical Waste.

B. Elements of the MED-Project Education and Outreach Program

The education and outreach program will include multiple and varied elements designed to reach Residents and provide consistent access to timely and relevant information.

[REDACTED]

C. Media Strategy

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D. Tactics and Channels

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XI. Performance Goals

§1612.3.J. A description of the performance goals to be established under the stewardship program to measure the success of the program and a description of how the program will be designed to achieve or exceed those goals. Performance goals must include, but are not limited to, the implementation of education and outreach efforts designed to:

- 1. Ensure awareness of the program by 60% of residents of the State after one year of stewardship program implementation, by 70% of residents of the State after 2 years of implementation and by 75% of residents of the State after 4 years of implementation; and*
- 2. Discourage the use of improper disposal methods for covered drugs that are household pharmaceutical waste, such as flushing the drugs or placing them in the garbage;*

MED-Project establishes these performance goals to measure the success of the implementation of the education and outreach efforts designed to ensure awareness of the program as required by 38 M.R.S.A. §1612.3.J(1)) and discourage the use of improper disposal methods for Covered Drugs that are Household Pharmaceutical Waste. MED-Project's primary performance goal will be to achieve a minimum of 50% reach among Residents at a 2+ frequency. These goals will be revisited and revised based on the outcome of the awareness assessments and the needs of the campaign.

Metrics used to measure the performance goals will include:

Program Participation:

- Engagement with the Website.
- Total pounds collected.
- Number of page views to the list of Collection Locations on the Website.

Media:

- Reach relative to Residents.
- Per-campaign impressions.
- Per-campaign frequency.
- Number of media placements.
- Complete list of placements by date and day.
- Number of visits to the Website.

In-Store Outreach:

- Number of Collection Locations.
- Number of printable materials and signage distributed to Collection Locations.

A. Education and Outreach Assessment

§1612.9. Education and outreach assessment. During the 2nd and 3rd years of implementation of a stewardship program, and every 2 years after that 3rd year, the operator of the program shall fund an independent 3rd-party assessment of the effectiveness of the program's education and outreach efforts, including, but not limited to, progress achieving the consumer awareness goal described in subsection 3, paragraph J, subparagraph (1) and efforts under the program to discourage the use of improper disposal methods for covered drugs that are household pharmaceutical waste, as described in subsection 3, paragraph J, subparagraph (2). The methods and scope of the assessment under this subsection must be developed with input from the department. The operator shall implement changes as necessary to the stewardship program's education and outreach efforts if demonstrated by the results of the assessment.

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

XII. Survey

§1612.3.K. A description of how the manufacturer or stewardship organization will fund a representative survey of residents of the State by an independent 3rd party prior to implementation of the stewardship program to assess baseline public awareness regarding proper disposal methods for unwanted drugs; and

MED-Project will fund a representative survey of Residents by an independent third-party prior to the implementation of the Program to assess baseline public awareness of proper disposal methods for Household Pharmaceutical Waste. Costs of funding the survey will be allocated as described in section XIII. MED-Project will include the results of the survey in the first annual report.

XIII. Program Funding

§1612.3.L. Information on how the stewardship program will be financed in accordance with subsection 5.

§1612.5 Costs. A manufacturer, individually or jointly with one or more manufacturers, shall pay all costs associated with the implementation, administration and operation of the manufacturer's stewardship program, including, but not limited to:

§1612.5.A. Costs of installing, managing and servicing collection receptacles at and collecting covered drugs that are household pharmaceutical waste from participating authorized collectors, transporting such covered drugs for disposal, disposing of such covered drugs and providing mail-back envelopes;

§1612.5.B. Costs related to the development of, with input from authorized collectors and the department, a readily recognizable, consistent design for collection receptacles, as well as clear, standardized instructions for consumers regarding the use of collection receptacles;

§1612.5.C. Costs incurred by the department in accordance with subsection 11 in the review of submitted plans and plan amendments, the review of annual reports and the administration and enforcement of this section; and

§1612.5.D. Costs associated with the stewardship program assessments required under this section.

When 2 or more manufacturers participate in a stewardship program, or if multiple stewardship programs exist, the costs of implementing, administering and operating the program or programs must be fairly and reasonably allocated between each participating manufacturer so that the share of the costs that is allocated to each manufacturer is reasonably related to the revenue-based market share of covered drugs that the manufacturer sells in the State.

MED-Project will pay all costs associated with the implementation, administration, and operation of the Program.

[REDACTED]

XIV. Annual Reporting

§1612.10. Annual stewardship program reporting. Within 90 days after the first full year of implementation of a stewardship program, and annually thereafter, the operator of the program shall submit to the department a report describing the activities of the program during the prior calendar year, which must include, at a minimum:

Within 90 days after the first full calendar year of implementation, MED-Project will submit an annual report to the Department describing the activities of the Program during the prior calendar year. Any additional partial Program year preceding the prior calendar year will be included in that annual report. In subsequent years, an annual report will be submitted for a calendar year within 90 days after the end of that calendar year. The annual report will include at a minimum:

- A list of Manufacturers participating in the Program, including contact information.
- The amount by weight of material collected in the prior calendar year, including the amount by weight from each collection method used, both in total and by county.
- Details regarding the Program’s collection system, including:
 - A list of Authorized Collectors and associated Collection Locations with addresses.
 - A list of locations where Mail-Back Packages were provided under the Program.
 - A list of Collection Locations where MED-Project Collection Receptacles were made available under the Program.
 - Dates and locations of collection events held under the Program.
 - A list of the transporters and disposal facilities used under the Program for the transportation and disposal of collected Covered Drugs that are Household Pharmaceutical Waste.
- Information regarding any safety or security issues encountered in the collection, transportation, or disposal of Covered Drugs that are Household Pharmaceutical Waste under the Program during the prior calendar year and, if such issues occurred, a description of completed or anticipated changes to Program policies, procedures, or tracking mechanisms to address those issues.
- A description of the public education, outreach, and evaluation activities implemented in accordance with the approved Plan, including the results of the education and outreach assessments, when applicable.
- A description of how packaging collected under the Program was recycled, to the extent feasible.
- A description of the methods used under the Program to collect, transport, and dispose of Covered Drugs that are Household Pharmaceutical Waste, including:
 - Information regarding efforts by MED-Project to ensure that only Covered Drugs that are Household Pharmaceutical Waste were collected.

- How the methods are consistent with the federal hazardous waste regulations identified in 38 M.R.S.A. §1612.3.F.
- A summary of the Program's achievement of its performance goals as set forth in the approved Plan and, if any performance goals were not achieved, the efforts that will be made to achieve those goals the following calendar year.
- An analysis of the convenience of the collection system under the Program for people living in various regions of the State as determined based on geographic information systems modeling.
- The total cost of implementing, administering, and operating the Program in the prior calendar year, including an accounting of the Program's expenditures in the prior calendar year as verified through an independent third-party audit.
- Any recommendations for changes to the Program to improve the convenience of the collection system, to increase consumer awareness and education, or to better evaluate Program performance.
- An analysis of the revenue-based market share of Covered Drugs sold by participating Manufacturers in the State and any other information required by the Department for determining appropriate cost allocation in accordance with 38 M.R.S.A. §1612.5.

Appendix A

Certification that the Stewardship Plan Will Accept All Household Pharmaceutical Waste

Pursuant to 38 M.R.S.A. §1612.3.A, I certify that the Program will accept all Covered Drugs that are Household Pharmaceutical Waste, regardless of who manufactured the Covered Drugs.



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Appendix B

Certification that the Stewardship Plan Will Develop and Administer a Website with the Operators of Other Approved Drug Take-Back Stewardship Plans

Pursuant to 38 M.R.S.A. §1612.3.E, I certify that that, upon implementation of the Plan, MED-Project, jointly with the operators of other approved Drug Take-Back Stewardship Plans, if any, will develop and administer a publicly accessible website that includes:

- A list of Authorized Collectors, collection locations, and the collection methods available at each collection location available under each Stewardship Program, updated as necessary.
- General information regarding the purpose and scope of the Stewardship Program or programs and the opportunities available to consumers under the program or programs for the safe disposal of Covered Drugs that are Household Pharmaceutical Waste.
- A statement that the Stewardship Program or programs are designed for the collection of Covered Drugs that are Household Pharmaceutical Waste only.



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