

STATE OF MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION

DRUG TAKE-BACK STEWARDSHIP PLAN

PROPOSAL

June 30, 2022

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SUBMITTED BY:



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Definitions

This Plan uses and incorporates definitions from LD 8 Chapter 94 and Sec 2. MRSA §1612 as well as other common terms used by Inmar and defined herein.

Authorized Collector means:

- (1) A person, company, corporation or other entity registered with the United States Department of Justice, Drug Enforcement Administration to collect controlled substances and non controlled substances for the purposes of safe disposal and destruction;
- (2) A law enforcement agency; or
- (3) A person, company, corporation or other entity authorized by the department to provide alternative collection methods for covered drugs that are household pharmaceutical waste and that are non controlled substances.

"Authorized collector" includes a mandatory pharmacy collector.

Authorized Employee means the designated contact person or persons at the Collection Location.

Board of Pharmacy means the Maine Board of Pharmacy.

Transporter means the common carrier used to transport Covered Drugs.

Collection Receptacle means a secure box, kiosk or other container:

- (1) Into which a person may deposit for disposal covered drugs that are household pharmaceutical waste and that is prominently labeled in a manner indicating that only such types of covered drugs may be deposited for disposal;
- (2) That meets applicable federal standards for the use described in subparagraph (1); and
- (3) That is located on the premises of an authorized collector participating in a stewardship program under this section

Collection Location means the location where an Authorized Collector operates a secure collection receptacle for collecting Covered Drugs.

Container means the cardboard box that both supports the Inner Liner inside the Collection Receptacle during drug collection and becomes the outer shipping package when the Inner Liner is full and/or removed from the Collection Receptacle.

Collection System is Inmar's term for collection methods including permanent Collection Receptacles at fixed locations and Mail-back Distribution Locations.

Collection Method means one of the two collection types (Collection Receptacle, Mail-back) authorized for collection and disposal of home-generated controlled substances by the DEA under 21 CFR Section 1317.

Convenience Standard means the goal of establishing a minimum of one Collection Location in each Service Center and one additional Collection Location for every ten thousand residents located within the Service Center.

Covered Drug means any substance recognized as a drug under 21 United States Code, Section 321(g)(1), as amended, and any regulations adopted pursuant to that provision, that is sold, offered for sale or dispensed in the State, whether directly or through a wholesaler, in any form, including, but not limited to, prescription and nonprescription drugs, drugs in medical devices and combination products, brand and generic drugs and drugs for veterinary use.

"Covered drug" does not include:

- (1) Vitamins or supplements;
- (2) Herbal-based remedies and homeopathic drugs, products or remedies;
- (3) Cosmetics, soap with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoo, sunscreen, toothpaste, lip balm, antiperspirant or other personal care products that are regulated as both cosmetics and nonprescription drugs under the Federal Food, Drug, and Cosmetic Act;
- (4) Pet pesticide products contained in pet collars, powders, shampoos, topical applications or other forms and prescription pet food;
- (5) Drugs that are biological products, as defined in 21 Code of Federal Regulations, Section 600.3(h), if the manufacturer provides a program to take back that drug;
- (6) Drugs for which a manufacturer provides a program to take back those drugs as part of a United States Department of Health and Human Services, Food and Drug Administration managed Risk Evaluation and Mitigation Strategy;
- (7) Emptied syringes or emptied medical devices or the component parts or accessories of those products or devices;
- (8) Drugs that are used solely in a clinical setting; and
- (9) Dialysate drugs required to perform home kidney dialysis

DEA means the U.S. Drug Enforcement Administration.

DEA Rule means the DEA Final Rule, "Disposal of Controlled Substances," 79 Fed. Reg. 53520 *et seq.* adopted on September 9, 2014 and codified at 21 CFR 1317.

Department means the Maine Department of Environmental Protection.

DOT means the U.S. Department of Transportation.

Drop-door means the door on the Collection Receptacle where Covered Drugs are deposited by residents.

Drug Take-back Stewardship Organization or "Stewardship Organization" means a corporation, nonprofit organization or other legal entity created by one or more manufacturers to implement a Stewardship Program.

Drug Take-back Stewardship Plan or "Plan" means a plan designed by a manufacturer or Stewardship Organization for the establishment of a Stewardship Program.

Drug Take-back Stewardship Program or "Stewardship Program" means a system implemented under this section for the collection, transportation and disposal of covered drugs that are household pharmaceutical waste.

Household Pharmaceutical Waste means useless, unwanted, expired or discarded drugs generated by a household.

Inhaler Mail-back Envelope (Envelope) means a pre-paid, pre-addressed envelope for the collection and disposal of inhalers.

Inmar's Plan (Plan) means the Product Stewardship Plan presented in this submission.

Inner Liner means the liner placed inside the Container that meets the requirements of 21 CFR Section 1317.60.

Liner Kit is a set of three (3) pre-labeled and pre-paid cardboard box Containers, liquid barriers, and Inner Liners that meet the requirements of 21 CFR § 1317.60.

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

Mail-back Distribution Location means a facility, such as a town hall or library, that offers pre-paid, pre-addressed Mailers to residents.

Mail-back Program means a method of collecting Covered Drugs from residents by using pre-paid, pre-addressed mailing envelopes.

Mail-back Starter Kit means 20 Standard Mail-back Envelopes and 5 Inhaler Mail-back Envelopes with a visual reorder trigger, including instructions to Mail-back Distribution Locations on how to reorder additional Mail-back Starter Kits.

Mailer is a generic term that refers to all pre-paid, pre-addressed Standard Mail-back Envelopes, Inhaler Mail-back Envelopes and Pre-filled Injector Mail-back Packages.

Mail-back Envelope means a prepaid, pre addressed mailing envelope, as authorized by federal law and regulation, that is provided by or through a company or organization licensed or otherwise authorized to dispose of Covered Drugs that are Household Pharmaceutical Waste received in such mailing envelopes

and that is made available through a Stewardship Program to persons seeking to dispose of Covered Drugs that are Household Pharmaceutical Waste.

Mandatory Pharmacy Collector means a pharmacy licensed by the Maine Board of Pharmacy pursuant to Title 32, section 13751.

Manufacturer means: (1) A person that has legal ownership of the brand of a covered drug sold in or into the State; or (2) If the person to which subparagraph (1) applies has no physical presence in the United States, a person that imports a covered drug that is branded by the person to which subparagraph (1) applies.

"Manufacturer" does not include a wholesaler that sells or offers for sale in the State at wholesale a covered drug if the covered drug is manufactured by a manufacturer that is a participant in a stewardship program.

"Manufacturer" does not include a retailer that sells or offers for sale in the State at retail a covered drug under the retailer's brand or store label if the covered drug is manufactured by a manufacturer that is a participant in a stewardship program.

Operator (Program Operator) means a Manufacturer or a Stewardship Organization that implements and operates a Stewardship Program.

Packaged Container means the full Inner Liner used in the Collection Receptacle after it is removed, secured within the Container, prepared, and sealed for transportation to a DEA Reverse Distributor.

Pre-filled Injector means an unused or partially used pre-filled injector product with a retractable or otherwise securely covered needle. This does not include emptied injector products.

Pre-filled Injector Mail-back Package means a pre-paid, pre-addressed, FDA-cleared sharps container and outer shipment package for the collection and disposal of Pre-filled Injector products.

Program Toll-free Phone Number means the single toll-free telephone number for residents to contact the Program Operator to ask questions, obtain Mailers or to locate a Collection Location.

Program Website means the single website for residents to obtain Mail-back Envelopes and Packages or to locate a Collection Location that is established pursuant to Sec 2. MRSA §1612.3(E).

Regional Service Centers (Service Centers) means service center community as defined by 30-A M.R.S.A. §4301, sub-§14-A that is identified pursuant to 105c220 of the State Planning Office.

Service Provider is any vendor retained by Inmar to provide materials or carry out its obligations under Inmar's Plan.

Standard Mail-back Envelope (Envelope) means a pre-paid and pre-addressed mailing envelope for the collection and disposal of all Covered Drugs except for those dispensed in an Inhaler or Pre-filled Injector.

A. Certification

Pursuant to section 2.38 MRSA §1612.3(A), Inmar’s certifies that the Stewardship Program will accept all Covered Drugs that are Household Pharmaceutical Waste regardless of who manufactured the Covered Drugs.

B. Contact Information

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336.770.1992

C. Collection Convenience

Inmar Rx Solutions, Inc. a wholly owned subsidiary of Inmar, Inc. (“Inmar”), submits this proposed Drug Take-back Plan on behalf of the Manufacturers represented in Appendix A and pursuant to LD 8 Chapter 94 and Sec 2. MRSA §1612. Pursuant to Sec. 2.38 MRSA §1612.6, Inmar will fully implement the Plan within 180 days of the Department’s approval of Inmar’s Plan. Inmar will set up a Collection System that is safe, secure, and convenient on an ongoing, year-round basis and provides equitable and reasonably convenient access for residents across the state consistent with Sec. 2.38 MRSA §1612.3(C).

1. Equitable and Reasonably Convenient Access

In accordance with Sec. 2.38 MRSA §1612.3(C), Inmar will establish a minimum of one Collection Location in each Service Center and one additional Collection Location for every ten thousand residents located within the Service Center which establishes collection opportunities that are geographically distributed and ensures access in rural and underserved areas. Using this formula, Inmar’s proposed Convenience Standard is the following:

Service Centers	79
Number of Collection Locations/Receptacles Needed	148

Inmar will give preference to establishing Collection Locations at Retail Pharmacies, hospitals or clinics with on-site pharmacies, long-term care facilities, substance misuse treatment centers and Law Enforcement Agencies while ensuring that Collection Locations are geographically distributed to provide reasonably convenient and equitable access to all residents of the Population Center.

Pursuant to Sec. 2.38 MRSA §1612.8(B), Inmar has notified potential Authorized Collectors of the opportunity to serve as an Authorized Collector voluntarily for the Program and will ensure that interested Authorized Collectors are added to the Program no later than 90 days after Inmar’s receipt

of the Authorized Collector's request to participate. Inmar enters into agreements with all willing Authorized Collectors ensuring their commitment to operation of the Collection Locations and shipping of contents in compliance with DEA regulations and all other state or federal laws and rules governing the collection of Covered Drugs.

Pharmacy Engagement/Enrollment

Extensive engagement has been made with pharmacies operating in Maine, each licensed with the Maine Board of Pharmacy. Through multi-pronged communications via email, telephone and onsite visits, Inmar has educated pharmacy operators on the benefit of Program enrollments by providing a safe and responsible drug disposal service to their patrons while operating within defined provisions of federal and state regulations.

Pharmacists were provided education on Title 21 CFR Part 1317 (Disposal) and guidance on how to update their current DEA registration to become an Authorized Collector Title 21 CFR Part 1317.40 (Registrants authorized to collect and authorized collection activities).

Law Enforcement Engagement/Enrollment

Extensive engagement with the leadership of state, local and tribal law enforcement agencies in Maine has been conducted via telephone, email, and onsite visits during which agency leadership were educated on the benefits of enrollment in the Maine Drug Stewardship Program to include:

- There is no cost to law enforcement for enrollment in the Program.
- Inmar provides a Collection Receptacle and all materials to support the Program
- Eliminates storage of boxes containing collected drugs in the law enforcement agencies secure evidence/property room for 6-months pending transfer to the DEA during a national bi-annual drug take-back collection event
- Eliminates the law enforcement agency from funding their own drug disposal at a local incineration facility due to limited evidence/property room storage capacity and the required transportation logistics
- For those law enforcement agencies with a certified law enforcement accreditation or seeking accreditation, the program mitigates violation of accreditation standards with commingling collected medications with evidence in the agency evidence/property room

To date, program enrollment by statewide law enforcement is currently over 88% of all locations and continues to grow.

Pharmacy Long-term Care Facility Engagement/Enrollment

Inmar is also engaging with pharmacies that service long-term care facilities in Maine and are licensed with the Maine Board of Pharmacy. By providing those pharmacy operators with both the operational details of Inmar's Stewardship Program, along with a fundamental understanding on how the Program operates within current established federal and state regulations, pharmacy operators have agreed to participate to facilitate the safe and responsible drug disposal at long-term care facilities that they service. Furthermore, the pharmacy operators are educated on the applicable federal regulations including Title 21 CFR Part 1317 (Disposal), guidance on how to update their

current DEA registration to “authorized collector” (Title 21 CFR Part 1317.40 - Registrants authorized to collect and authorized collection activities), and how to operate the Inmar Program within a long-term care facility (Title 21 CFR Part 1317.80 - Collection receptacles at long term care facilities).

These outreach efforts have been done in coordination with the Maine Department of Health and Human Services – Division of Licensing and Certification – Medical Facilities Unit that maintains oversight of drug disposal guidelines in long-term care facilities and nursing homes.

The disposal of controlled, non-controlled, and over-the-counter medications in assisted living facilities in Maine is proscribed in Maine’s “Regulations Governing the Licensing and Functioning of Assisted Housing Programs”, 10-144 Ch 113, sections 7.7 and 7.9 thru 7.10.5.

Similarly, the disposal of such medications in nursing homes is required in Maine’s “Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities,” 10-144 Ch 110, specifically Ch.17 “Pharmaceutical Services”.

Inclusion of Maine Tribes

Inmar has engaged with the Passamaquoddy Tribe and the Wabanaki Public Health & Wellness Centers, part of the Wabanaki Public Health District (WPHD) which serves four tribe locations in five communities (the Houlton Band of Maliseet Indians, The Aroostook Band of Micmac Indians, The Passamaquoddy at Indian Township and Pleasant Point, and the Penobscot Nations members on and off reservation). Inmar is in the process of finalizing agreements for Collection Receptacles and Mail-back Distribution Locations that will best serve the Tribes needs in the five communities.

2. Collection Locations

As stated and in accordance with Sec. 2.38 MRSA §1612.3(C), Inmar will establish a minimum of one Collection Location in each Service Center and one additional Collection Location for every ten thousand residents located within the Service Center.

To date, Inmar has established agreements with 203 Collection Locations and 15 Mail-back Distribution Locations distributed across 79 Service Centers in Maine. Appendix B provides the current list of Authorized Collectors with which Inmar has entered into agreements. Appendix C provides the current list of committed Mail-back Distribution Locations that have entered into agreements with Inmar. Inmar is committed to meeting the convenience standard within 180 days of approval through continued efforts described above to establish Collection Locations and Mail-back Distribution Locations.

Total # of Collection Receptacles Under Contract	203
Total # of Mail-Back Distribution Locations	15

The following map shows the geographical distribution of Collection Locations and Mail-back Distribution Locations that Inmar has entered into agreements with at the time of Plan submission. The circles represent a 15-mile radius around each Location to demonstrate convenient access for the surrounding area.

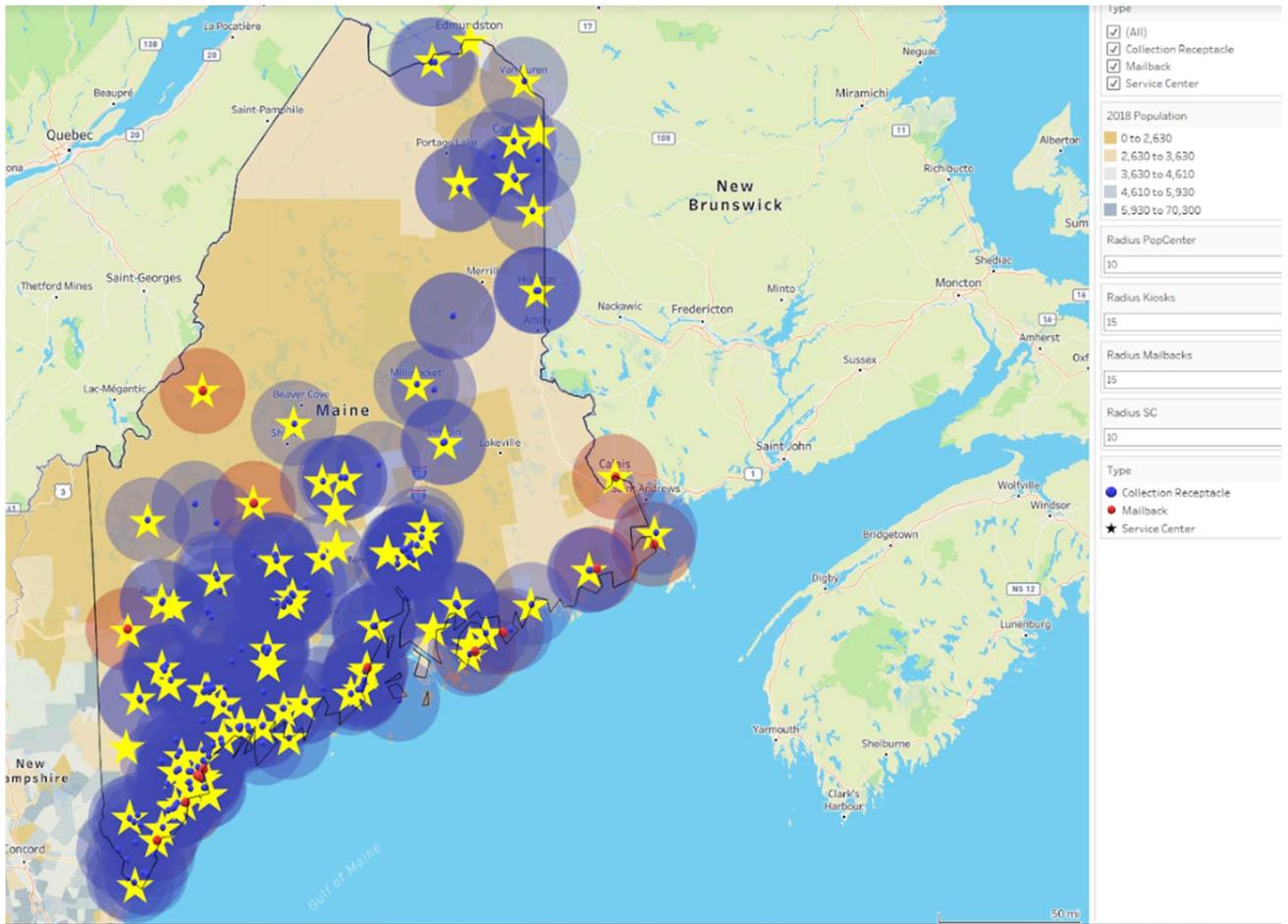


Figure 1: Map of Collection Locations and Mail-back Distribution Locations

Inmar continues to work to secure Collection Locations in each Service Center. The following process will continue until Inmar has secured the convenient number of Collection Locations to meet the standards set forth in Sec. 2.38 MRSA §1612.3(C).

1. Inmar will continue working with all interested Authorized Collectors to secure agreements, establish Collection Locations, and install Collection Receptacles.
2. Inmar will continue to reach out to potential Authorized Collectors who have not responded regarding a willingness to participate in the Maine Drug Take-back Program.

3. In Service Centers where a Collection Location has not yet been identified through the process described above, Inmar will provide Mail-back Distribution Locations
4. Inmar will continue to solicit potential Authorized Collectors and evaluate annually the need for additional Collection Locations based on population growth.

Convenience Tracking and Geographical Distribution

Inmar uses a tracking spreadsheet and maps to monitor the Convenience Standard requirement. The spreadsheet is updated weekly and records the required number of Collection Locations per Service Center in Maine, Inmar's established number of Collection Locations per Service Center and the number of supplemental services being established state-wide. The spreadsheet uses formulas to track the percentage of the population being serviced by a Collection Receptacle versus the population being serviced through Mail-back Distribution Locations. This spreadsheet identifies where there may be gaps in coverage so those areas can be targeted.

It is always Inmar's intention to establish a Collection Location wherever possible and as a first option in Service Centers. However, where space constraints or other factors make it challenging to establish a Collection Location, or where a Service Center does not meet the requirements to host a Collection Location, Mail-back Distribution Locations are sought out as an alternative and established in consultation with the local community. Inmar will continue to solicit Authorized Collectors beyond Plan approval and work to decrease the number of underserved Service Centers by Collection Locations and improve the geographical spread of Collection Receptacles throughout the state.

Inmar will seek to identify long-term care facility locations where Collection Receptacles can be installed in pursuant to CFR 1317.40 and CFR 1317.80 and in accordance to Maine's "Regulations Governing the Licensing and Functioning of Assisted Housing Programs", 10-144 Ch 113, sections 7.7 and 7.9 thru 7.10.5.

Collection Locations are available for use during normal business hours of the Authorized Collector and accept all Covered Drugs from residents. For Collection Locations that are added after Plan approval, Collection Receptacles will be installed and fully operational within 90 days of receiving an offer to participate from the Authorized Collector unless the Authorized Collector requests additional time for installations and operation of Collection Receptacle(s).

D. Collection Methods

Inmar's Collection System consists of two Collection Methods which are used to ensure that only Covered Drugs that are Household Pharmaceutical Waste will be collected by Authorized Collectors in such a way that is convenient to Maine residents. Pursuant to Sec. 2.38 MRSA §1612.3(D), the Collection Methods will include the use of 1) Collection Receptacles and 2) Mail-back Service and will not include home disposal methods involving packets, bottles or other containers that a person may use to render non-retrievable or destroy a Covered Drug that is household pharmaceutical waste by means of a chemical process.

In accordance with Sec. 2.38 MRSA §1612.8(F), the collection of Covered Drugs that are Household Pharmaceutical Waste at Collection Locations under Inmar's Program will be made available to consumers free of charge. Inmar nor any of its Authorized Collectors will 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.

Inmar will also employ outreach and education programs that encourage residents to separate Covered Drugs from packaging. More detail on these programs is covered in Section I.

1. Secure Collection Receptacles

Inmar's Collection Receptacle is made in the USA and is designed to be safe and secure. Produced from 16-gauge cold-rolled steel, and with an easy-to-use, Americans with Disabilities Act (ADA)-compliant Collection Receptacle design, residents can easily drop Covered Drugs through the Drop-door and into the shippable Container and Inner Liner inside. The Container is a 275 lb-rated box with a 6-mil, DEA-compliant Inner Liner. Inner Liners are either 18 gallons or 35 gallons dependent upon the geographical location and population density of the Collection Location. This volume rating is printed directly onto our Inner Liners and has passed the tests prescribed in accordance with ASTM D 1922 and ASTM D 1709.

The Collection Receptacle design exceeds standard safety requirements and will comply with all state and federal laws, including any applicable on-site storage and collection standards and DEA regulations. The top of the Collection Receptacle is sloped, limiting the ability to stack items on top. In addition, the Collection Receptacle features an extended metal Drop-door that lowers into the Container to detect when capacity is reached. When the Drop-door encounters resistance within the Collection Receptacle, it is an indication that it is time to change the Container. This manual capacity indicator eliminates the need to change batteries and/or sacrifice the location of the Collection Receptacle to be proximate to an electrical outlet. Lastly, the Collection Receptacle access door is reversible to allow for convenient placement in any appropriate location in the Collection Location.

Collection Receptacles will be securely installed inside an Authorized Collector's registered Collection Location in accordance with 21 CFR § 1317.75 to include:

- Pharmacies: 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 pharmacy counter).
- Hospitals/clinics: in an area regularly monitored by employees and shall not be located in the proximity of any area where emergency or urgent care is provided.
- Substance use disorder treatment program: in a room that does not contain any other controlled substances and is securely locked with controlled access.
- Long-term care facility: in a secured area regularly monitored by long-term care facility employees.

- Law Enforcement Facility: should be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances

The Collection Receptacle has pre-drilled holes in the bottom for secure installation. It also features a 4-point locking system with steel projections in two center locations and the top and bottom of the door that are activated when locked for strengthened security. Top and bottom deadbolt locations are hidden from the outside to prevent break-ins.

Inmar provides secure installation of Collection Receptacles for the Authorized Collector at the Collection Location. The Collection Location is requested to remove any physical barriers of the identified Collection Receptacle location in advance of the agreed upon installation date and time as well as the location to be identified on the floor with markings such as tape to ensure the Collection Receptacle is installed in the proper location. However, Authorized Collectors may request to install the Collection Receptacle themselves. In this scenario, Inmar will ship the Collection Receptacle to the Authorized Collector with instructions on how to properly install a Collection Receptacle according to DEA regulations. At the time of contract signing and receiving the order form for the Collection Receptacle, Inmar will send an electronic form to the Authorized Collector that provides an installation checklist and requires the Authorized Employee to sign acknowledging their inspection of installation according to those instructions.

Collection Receptacle signage will include signage with instructions regarding which items are allowed and prohibited for deposit into the Collection Receptacle ensuring that only household covered drugs that are household waste are deposited into the Collection Receptacle. Collection Receptacles will accept all Covered Drugs from residents during the hours that the Authorized Collector is normally open for business except for Pre-filled Injectors. Inmar will provide signage to the Authorized Collectors for display either on the Collection Receptacle or for display nearby that instructs residents on how to order a Pre-filled Injector Mail-back Package.

Collection Receptacle signage will feature the Program Toll-free Phone Number and Program Website publicizing Collection Methods, and Collection Locations, encouraging the separation of Covered Drugs from packaging prior to disposal and discouraging improper disposal practices for Covered Drugs, such as flushing them or placing them in the garbage. Inmar will work with the Department to design any additional signage that meets the needs and requirements of the Program. Appendix F provides examples of signage to be used in Collection Receptacles.

Upon installation of the Collection Receptacle, Authorized Collectors are provided enough supplies for 3 returns and instructions for ordering and receiving additional supplies. Supplies include:

- Pre-addressed, pre-paid, serialized Container
- Serialized Inner Liners to protect against puncture and provide a liquid barrier
- Easy-to-use zip ties to compliantly seal Inner Liner
- Absorbent pad for placement in the bottom of the Inner Liner.

2. Returns Process

Inmar offers the opportunity for Authorized Collectors to choose which returns process works best for them. In each case, Inmar establishes a service and transportation schedule with each Collection Location. The schedule will depend on which Collection Method is being used and may be adjusted with the agreement of the Authorized Collector based on Collection Receptacle usage. As required by Sec. 2.38 MRSA §1612.8(C), Inmar will 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. Authorized Collectors may elect to change their chosen Collection Method at any time and Inmar will ensure completion of such a change within 30 days of written request by the Collection Location, unless more time is requested.

Self-Service Returns

Inmar will train Authorized Collectors to service the Collection Receptacles on their own to allow for expedited servicing as desired. For the safe on-site removal of contents and servicing of Collection Receptacles, Inmar abides by the DEA regulations in 21 CFR 1300 et al. Pursuant to Sec. 2.38 MRSA §1612.8(C). Inmar provides a service schedule that meets the needs of each Collection Location to ensure that each Collection Receptacle is serviced as often as necessary to avoid reaching capacity. The steps to service a Collection Receptacle are fast, efficient, and DEA-compliant. Inmar will provide Authorized Collectors with training materials* including step-by-step instructions for tracking, sealing, shipping, and replacing Containers. The process for Authorized Collectors, once a Collection Receptacle is installed, is as follows:

- Authorized Collector receives the Liner Kit
- Authorized Employee constructs the Container with Inner Liner, inserts and securely locks the Collection Receptacle
- Authorized Collector team unlocks the Collection Receptacle Drop-door to enable resident use
- Installation date of Inner Liner is documented and witnessed by the Authorized Employee on a tracking sheet
- Once Collection Receptacle is full, Authorized Employee will open the Collection Receptacle in accordance with 21 CFR § 1317.05(c), 21 CFR § 1317.80(c) and 21 CFR § 1317.35(c)
- Container and Inner Liner are removed and documented on the tracking sheet
- Container is packaged (Inner Liner is zip-tied, outer box is taped) to be compliant with all DOT Hazardous Materials Regulations
- The sealed Inner Liner will not be opened, x-rayed, analyzed, or otherwise penetrated
- Replacement Container and Inner Liner is constructed, inserted, secured with locking system into Collection Receptacle and documented on the tracking sheet
- Authorized Employee contacts FedEx for pickup of Packaged Container for shipping to the Reverse Distributor for ultimate destruction.

Authorized Collectors receive training materials that provide detailed instructions on how to manage a Collection Receptacle, including but not limited to: installation (if applicable), safety and security, recognizing capacity, replacing Inner Liners (if applicable), storage of Packaged Containers and the rules and regulations pertaining to these items and the operation of a Collection Receptacle in general. Sample training material is provided in Appendix E but does not represent final state-specific

material. Training materials will be customized upon approval to include, but not limited to, the following changes:

- The purchase and installation of Collection Receptacles by Inmar as the default option
- References to Maine and Federal law where applicable
- Clarification of where Authorized Collectors are to ship Packaged Containers
- Inclusion of requirements for every type of potential Authorized Collector and Collection Location
- Single Program Website that has been coordinated and agreed upon with other approved Program Operators
- Removal of references to other Inmar programs/offers and placing of client logos on Collection Receptacle
- Updating Inner Liner storage requirements to reflect 21 CFR 1317.60(b)
- Removal of content pertaining to weight limits

The Authorized Collector will be responsible for packaging the Container and Inner Liner for shipment and contacting FedEx for pickup. FedEx will respond within 48 hours of request by phone. Authorized Collectors utilizing the FedEx shipping portal are able to request in the “Notes” field a specific pick-up time. Inmar will also reach out to its contacts at FedEx to ensure that local contacts are aware of Collection Locations and their needs related to quick turnaround. During this time, Authorized Collectors will be required to store the Packaged Container in accordance with all applicable laws including 21 CFR § 1317.05(c), 21 CFR § 1317.35(c), and 21 CFR § 1317.80(d).

Technician Assisted Returns

Inmar will provide employees who are trained specifically in servicing Collection Receptacles in Maine. Pursuant to Sec. 2.38 MRSA §1612.8(C), Inmar provides a service schedule that meets the needs of each Collection Location to ensure that each Collection Receptacle is serviced as often as necessary to avoid reaching storage capacity and that collected Covered Drugs are transported to final disposal in a timely manner.

The service will include the following:

- Observation of the condition of the Collection Receptacle upon arrival
- Notification to the Authorized Collector of arrival
- Coordination of 2 Authorized Employees to witness the change out of Collection Receptacle Inner Liner supplies
- Removal, packaging, and documentation of the Inner Liner and Container from the Collection Receptacle
- Replenishment of new supplies for renewed operation
- General clean-up and wipe down of Collection Receptacle
- Notation of Inner Liner serial number removed, and replacement Inner Liner serial number installed along with signatures by 2 Authorized Employees (witnesses)
- Removal of Packaged Container to be placed behind the pharmacy counter to await FedEx pick-up

- Technician calls FedEx to schedule pickup of the Packaged Container unless otherwise agreed upon by Authorized Collector
- Final signature from Authorized Employee of completion of service event.

Service Standards

Inmar has established several processes for Authorized Collectors to seek assistance for service issues including a process for additional prompt Collection Receptacle supplies replenishment upon notification from the Collection Location. Aside from visual inspection when locking and unlocking the Collection Receptacle for use during business hours, Authorized Collectors are provided with the following resources should they experience issues with the Collection Receptacle:

- Email the take-back@inmar.com inbox, which is monitored by a team of full-time workers, and the issues can be quickly triaged and handled. This inbox is the quickest and most effective way for us to respond to any issues with Collection Receptacles.
- Authorized Collectors can also call 1-800-350-0396, option 5 for urgent issues.

The above resources can also be used to request additional supplies when a Collection Receptacle becomes full prior to a scheduled service date.

Inmar's Operations team has direct relationships with personnel at FedEx corporate offices. Should an issue arise with the standard 48-hour service level agreement, these contacts will be leveraged daily for mitigation of further issues as well as any needed general support. Detailed FedEx contact information can be found in Section II.I below.

All Packaged Container FedEx shipment tracking numbers will be periodically monitored from Collection Locations to the designated Reverse Distributor as designated in Section II.I below. Typically, any Packaged Container that is shipped has a 3-5 day ground shipment time frame from the moment it is scanned by a FedEx driver to the delivery point. Should a Packaged Container not arrive at our Reverse Distributor within an acceptable time frame (seven days), Inmar will do the following:

- Reach out to Authorized Collector to determine when Packaged Container was picked up
- Track via tracking ID portal at FedEx.com
- Contact regional representative for FedEx to investigate the root cause of delay
- Investigate the location of Packaged Container and identify updated arrival date at Reverse Distributor site.

3. Collection Receptacle Maintenance and Cleaning

Collection Locations are able to email a monitored email inbox that is operated by a team who triage Authorized Collector requests. Should a Collection Receptacle require maintenance outside of the quarterly service schedule, service is provided within 48-72 hours of the initial request.

- Requests can be made by emailing the team at take-back@inmar.com inbox, which is monitored by a team and issues can be quickly triaged and handled. This inbox is the quickest and most effective way for Inmar to respond to any issues with Collection Receptacles.
- Authorized Collectors can also call 1-800-350-0396, option 5 for urgent issues.

4. Auto-replenishment of Collection Receptacle Supplies

The supplies used to collect and transport Covered Drugs are provided in automatically-replenished Liner Kits of three Containers. Each Liner Kit includes pre-labeled and pre-paid cardboard box Containers, liquid barriers, and Inner Liners. The Liner Kits, when packaged with the interior components, are approximately 6 inches thick. The Container is cinched tightly around the inner components, which makes for a very easy-to-store kit. Liner Kits are then stored in accordance with 21 CFR § 1317.60(b), 21 CFR § 1317.05(c), 21 CFR § 1317.35(c), and 21 CFR § 1317.80(d).

Upon receipt of the Packaged Container at the Reverse Distributor, an electronic raw data file via SSH File Transfer Protocol (SFTP) with the weight, serialized barcoded label information, and tracking information is passed to Inmar. This information is then received and entered into an Order Management log and Inbound Receipts log. The system tracks when the second of the three Containers is received at the Reverse Distributor. Inmar then initiates a reorder trigger for the next Liner Kit to be shipped. The delivery of the Liner Kits occurs according to the following schedule:

- After the second full Container is received, the new Liner Kit would be received by the Collection Location within 14 days. This timeline allows Inmar to complete the processes described above where the SFTP file is logged and a reorder trigger is initiated.
- Collection Locations can contact Inmar at any time through the Program Website or Program Toll-free Phone Number to request additional Liner Kits. Inmar responds to such requests within 2 business days of receipt of the request. If a Collection Location contacts Inmar requesting an additional Liner Kit for any reason outside the normal process described above, the Liner Kit would be received by the Collection Location within 7 days. Turnaround of requests for additional Liner Kits outside the auto-replenishment process are quicker because there is no SFTP file, logging, etc.

It should be noted that only after the second Container is received from a Collection Location will a new Liner Kit be sent. Auto replenishment reduces the amount of inventory maintained at the Collection Location while maintaining sufficient supplies to keep the Collection Receptacle continuously operable.

The resources below can be used to request additional Collection Receptacle supplies prior to a scheduled auto-replenishment service date:

- Email the take-back@inmar.com inbox, which is monitored by a team of full-time workers, and the issues can be quickly triaged and handled. This inbox is the quickest and most effective way for Inmar to respond to any issues with Collection Receptacles.
- Authorized Collectors can also call the Program Toll-free Phone Number.

5. Mail-back Services

Upon Request Service

Inmar will provide Mailers free of charge to all residents. Three types of Mailers, including Standard Mail-back Envelopes, Inhaler Mail-back Envelopes and Pre-filled Injector Mail-back Packages will be

available for request to all residents on the approved Program Website and by calling the Program Toll-free Phone Number. Standard Mail-back Envelopes will accept all Covered Drugs, with the exception of inhalers and Pre-filled Injectors (not including emptied injector products) for which Inmar provides separate envelopes or containers. The Mailers provide written instructions for returning Covered Drugs, inhalers or Pre-filled Injectors as required by Sec. 2.38 MRSA §1612.3(I).

Residents are able to request up to three (3) Standard Mail-back Envelopes, three (3) Inhaler Mail-back Envelopes and (3) Pre-filled Injector Mail-back Packages at a time via the Program Website or Program Toll-free Phone Number. Residents will receive the Envelopes no later than 10 business days from the date of request.

When a resident calls the Program Toll-free Phone Number, Inmar will take the required information from the resident over the phone. The required information for shipment will be entered into the system and the Mailer, which is free, prepaid and pre-addressed, will be shipped directly to the resident, which they can then ship to Inmar's Service Provider, free of charge.

Mail-back Distribution Locations Service

Inmar will provide a Mail-back Program for the distribution of pre-paid, pre-addressed mailing envelopes for the Drug Take-back Program. Inmar will establish Mail-back Distribution Locations in addition to the required Collection Locations and where the minimum number of Collection Locations cannot be met. Mail-back Distribution Locations may include, but are not limited to, town halls, libraries, health/medical offices and retail locations.

Inmar obtains signed order forms where Mail-back Distribution Locations will be established. Each Location will agree to maintain compliance with the Drug Take-back Laws and will remain in compliance to that end. Each Mail-back Distribution Location is required to provide access to residents during normal business hours, display signage and instructions regarding proper use of all Envelopes and Packages and comply with all applicable state and federal laws. Pursuant to Sec. 2.38 MRSA §1612.3(I) and Sec. 2.38 MRSA §1612.8(D) Inmar will provide to each Mail-back Distribution Location educational information to provide to residents regarding Covered Drug collection and the safe disposal of Covered Drugs.

Once a location has been accepted as a Mail-back Distribution Location, Inmar will send a Mail-back Starter Kit. Standard Mail-back Envelopes will accept all Covered Drugs, including pills, creams and liquids, and Schedule II-V controlled substances. The Starter Kit will include 20 Standard Mail-back Envelopes and 5 Inhaler Mail-back Envelopes. The Starter Kit is a countertop display that comes pre-assembled. The front of the box displays information about what can and cannot be included in the Mailers and how the resident may request more Mailers or specifically request a Pre-filled Injector Mail-back Package via the Program Website or Program Toll-free Phone Number. There is currently no limit on the number of Mailers that a resident may take from a Mail-back Distribution Location. The Mailers provide written instructions for returning Covered Drugs.

Inmar will track the unique identifier for all Mailers sent to each Location for fulfillment and logistical purposes. Inmar will add a visual reorder trigger in the box of Standard Mail-back Envelopes. Once the Location gets to the reorder trigger in the box, the visual reorder trigger will instruct the Location to email Inmar for another kit. This service model ensures that there is no 'down time' at the Location for Standard Mail-back Envelopes. If a Location begins to use a larger number of Standard Mail-back Envelopes, the number of fulfilled Standard Mail-back Envelopes sent to that Location will be increased. As needed, Inmar will assess the need to increase the quantity of Envelopes sent to each Mail-back Distribution Location. This will be monitored by the request frequency data per Location and will be assessed on an as needed and per Location basis. Each Location will be reassessed yearly or as needed should the frequency of fulfillment from one particular Location increase dramatically. Additionally, Mail-back Distribution Locations may order Mailers, outside of the standard 20 units, in units of 50.

Inmar is committed to providing all Authorized Collectors an option to supply residents with information regarding mail-back options. Inmar will provide both Mail-back Distribution Locations and Authorized Collectors with promotional brochures in accordance with Sec. 2.38 MRSA §1612.3(I).

Description of Mailers

A description of Mailers used for both requested and Mail-back Distribution Locations Mail-back services is provided below.

The Standard Mail-back Envelopes and Inhaler Mail-back Envelopes will meet DEA Rule requirements under § 1317.70(c)(2), specifically:

- Pre-addressed, postage paid
- Nondescript and does not indicate what may be inside
- Waterproof, spill proof, tamper-evident, tear-resistant, and sealable; the envelopes also contain an absorbent pad
- Contain a unique ID number that allows for tracking
- Include instructions for the user that indicate the process for mailing the package, substances that can be sent, notice that packages can only be mailed in the US customs territory and notice that only packages provided by the Authorized Collector will be accepted
- No Personally Identifiable Information will be required.

Both Envelopes are white in color with a gray interior and are 7" x 10". The Envelopes include a 3" perforated lip security seal.

A sample Standard Mail-back Envelope is shown below:

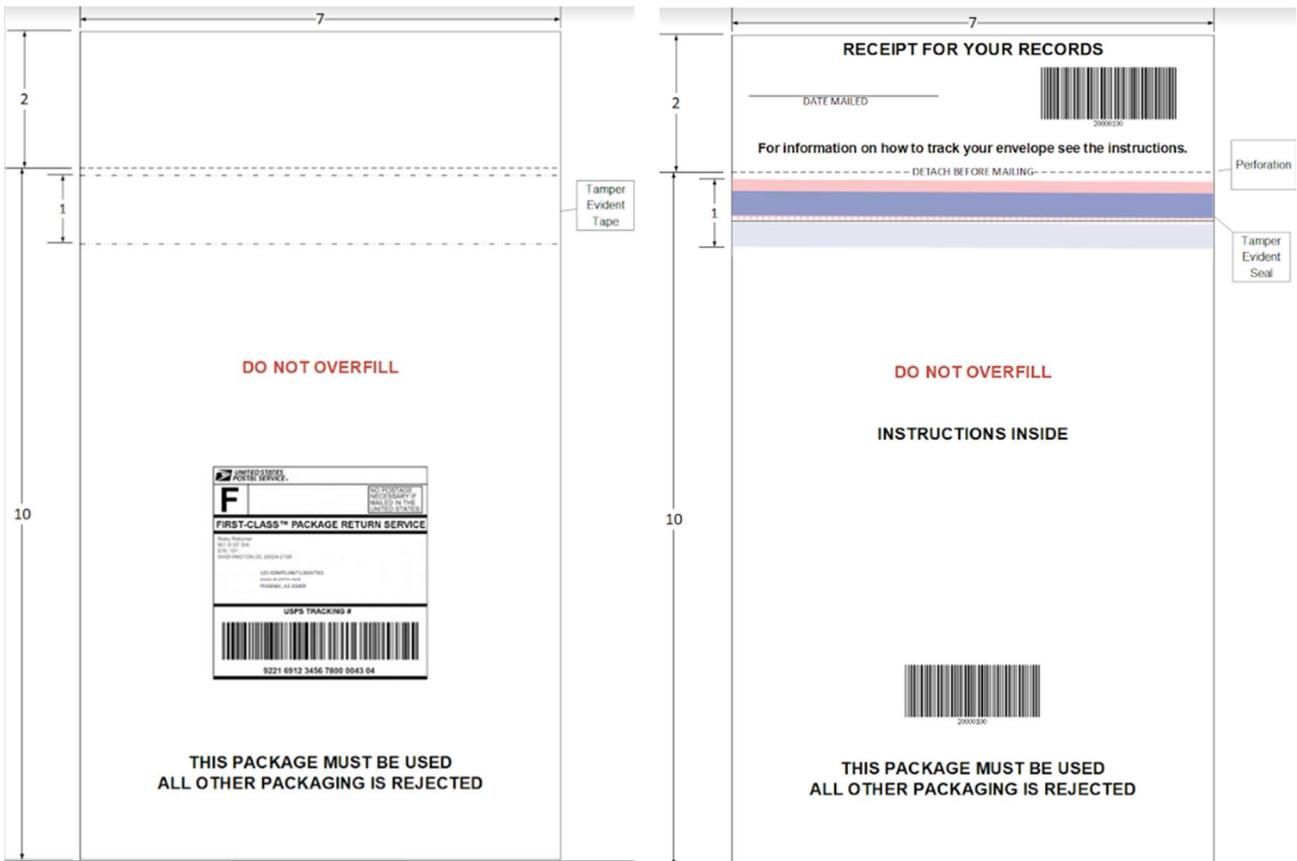


Figure 2: Sample Standard Mail-back Envelope

Sample Inhaler Mail-back Envelope

Residents will be able to request three (3) Inhaler Mail-back Envelopes at a time via the Program Website or Program Toll-free Phone Number. Residents will receive the Inhaler Mail-back Envelopes no later than 10 business days from date of request.

A sample Inhaler Mail-back Envelope is shown below:

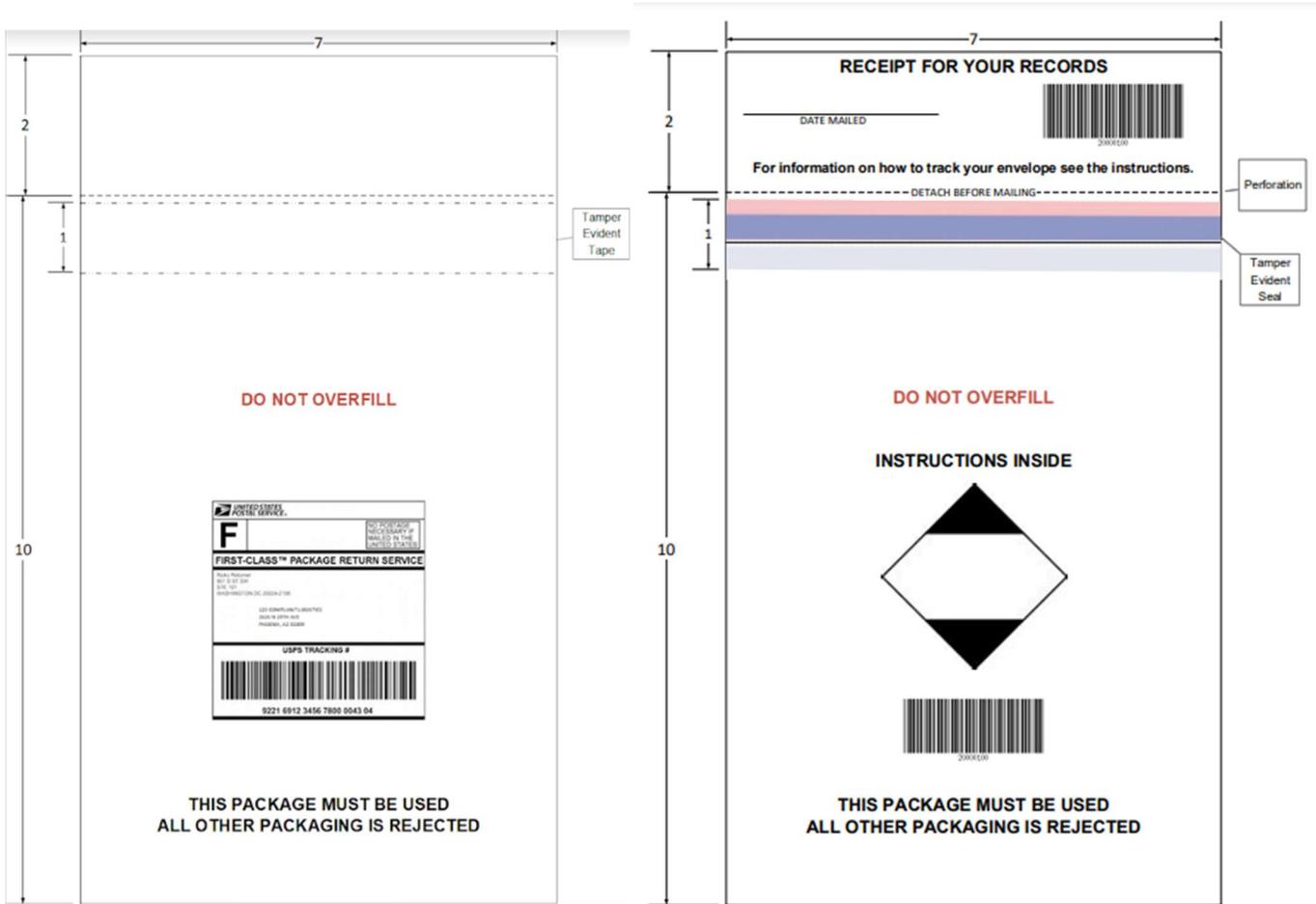


Figure 3: Sample Inhaler Mail-back Envelope

Sample Pre-filled Injector Mail-back Package

Residents will also be able to request three (3) Pre-filled Injector Mail-back Packages at a time via the Program Website or Program Toll-free Phone Number. Residents will receive the Pre-filled Injector Mail-back Packages no later than 10 business days from date of request. Pre-filled Injector Mail-back Packages will meet all DOT requirements. See below for specifications and sample.

Specifications	
Access	Petals
Dimensions (in.)	7.5 x 3.6 x 3.6 in.
Color	Red
Lid Type	Hinge Cap
Liquid Absorbing Pad	Product has liquid absorbing pad
Universal Biohaz Sym	Product has universal biohaz symbol
Volume (L)	1.4 qt



Figure 4: Sample Pre-filled Injector Mail-back Package

E. Publicly Accessible Website

Pursuant to Sec. 2.38 MRSA §1612.3(E), Inmar will, upon implementation of the plan, jointly with the operators of other approved plans, 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; and
- A statement that the stewardship program or programs are designed for the collection of covered drugs that are household pharmaceutical waste only;

F. Tracking, Handling and Disposal

As described in Section II.D, Inmar provides technician-assisted returns or the option for Authorized Collectors to manage the returns process on their own. In both of these return options, Packaged Containers are properly sealed, securely stored, and pick-up is arranged from the Collection Location in a manner consistent with the DEA Rule. The Packaged Container will include a pre-addressed and pre-paid shipping label. The FedEx representative will take possession of the Packaged Container and deliver it to the Service Provider for witnessed transportation to witnessed incineration. All Mailers received at the Service Provider will also be taken via witnessed transportation to witnessed incineration.

Service Providers operate in full compliance with DEA § 1317.75(c), which prohibits handling substances after they have been deposited into a Collection Receptacle.

All Covered Drugs shipped directly to the Service Provider will be transported using their contracted, licensed transporter to the appropriate disposal facility to be incinerated quickly, securely, efficiently, and in accordance with all DEA requirements. The Service Provider will be responsible for all DEA Form 41 recordkeeping requirements.

All Service Providers comply with all local, state, and federal laws and regulations surrounding the transportation and disposal of Covered Drugs.

The following is a list of Service Providers who will be providing transportation and disposal to fulfill the requirements of this Plan.

Company Name	Contact Information	Registration Information	Service Provided
123 Compliant Logistics, LLC 2626 N 29th Avenue Phoenix, AZ 85009	Rory Buske 602-612-4140	DEA Reverse Distributor-Collector: R90571264	Reverse Distributor - Packaged Containers from Authorized Collectors using either returns process option
Indianapolis Resource Recovery Facility in Indiana, operating as Covanta Indianapolis, Inc. 2515 S Holt Rd, Suite 200 Indianapolis, IN 46221	Alex Davila 317-478-0670	DEA Reverse Distributor-Collector RC0620496 EPA ID No: IND984882365	Reverse Distributor & Municipal Waste Combustor – All Covered Drugs(Mail-back Packages & Packaged Containers from Authorized Collectors)
Covanta Manheim dba Chesapeake Waste Solutions	Ken Wilson 717-653-8882	DEA Registration No. RC0322595	Reverse Distributor & Municipal Waste Combustor – All Covered Drugs(Mail-back Packages & Packaged Containers from Authorized Collectors)
Curtis Bay Medical Waste Services 3200 Hawkins Point Road, Baltimore City, MD 21226	Sam Blanchard (855) 228-1715	EPA ID No. MDD985404318	Hazardous Waste Incinerator Covered Drugs-Kiosks & Mailers
Ross Incineration Services 36790 Giles Road, Grafton, OH 44044	Chris Fada 440-748-5800	EPA ID No. OHD048415665	Hazardous Waste Incinerator Covered Drugs-Kiosks & Mailers
Clean Harbors Aragonite 11600 N Aptus Road Aragonite, UT 94029	Michael Marlow 435-884-8100	EPA ID: UTD981552177	Hazardous Waste Incinerator- All Covered Drugs
Clean Harbors El Dorado, LLC 309 American Circle El Dorado, AR 71730	Dan Roblee 870-863-7173	EPA ID: ARD069748192	Hazardous Waste Incinerator- All Covered Drugs
Veolia ES Technical Solutions, LLC 7665 Highway 73 Port Arthur, TX 77640	David Michaelis 281-216-9618	EPA ID: TXD000838896	Hazardous Waste Incinerator- All Covered Drugs

TransChem Environmental 542 East 27 th Street Tucson, AZ 85713	Don Huey 602-513-6528	DOT Registration: 052119550060B Hazardous Materials Safety Permit: US-1341480-AZ- HMSP	Hazardous Waste Transporter – All Covered Drugs
FedEx	Eric Stillson Shane McAbee		Transporter – Packaged Containers
USPS	Jackie Purcell 919-501-9394		Transporter– All Mailers and Containers

Containers and Inner Liners will have a serialized identification number to enable tracking at all stages of the return process illustrated below.



Figure 5: Return Process Tracking

Tracking is well-documented as evidenced by the serialization tracking forms referenced below. This form must be completed and witnessed by two Authorized Employees, which assures compliance and safety across the Program, and internally by both the Program Operator and the Authorized Collector.

DRUG DISPOSAL SERIALIZATION TRACKING SHEET INNER LINER TRACKING FORM

Serialization Tracking Sheet should be validated by 2 authorized individuals - See (21 CFR §1317.80, 21 CFR §1317.35, 21 CFR §1317.75)

Name of Collection Site		Address of Collection Site				Collection Site DEA # (if applicable):			
Size of Liner		Address of Reverse Distributor/Disposal Site				Reverse Distributor/Disposal Site DEA #			
1 SERIAL NUMBER (unique)	2 Date Liner Acquired (1 Signature)	3 Date Liner Installed (2 Names & Signatures)		4 Date Removed (2 Names & Signatures)		5 Date Transferred to Storage (2 Names & Signatures)		6 Date Shipped (2 Names & Signatures)	
Ex: 32587	4/26/19	4/26/19		5/26/19		5/26/19		5/27/19	
	John Jones <i>John Jones</i>	John Jones <i>John Jones</i>	John Jones <i>John Jones</i>	John Jones <i>John Jones</i>	John Jones <i>John Jones</i>	John Jones <i>John Jones</i>	John Jones <i>John Jones</i>	John Jones <i>John Jones</i>	John Jones <i>John Jones</i>
	Sally Smith <i>Sally Smith</i>	Sally Smith <i>Sally Smith</i>	Sally Smith <i>Sally Smith</i>	Sally Smith <i>Sally Smith</i>	Sally Smith <i>Sally Smith</i>	Sally Smith <i>Sally Smith</i>	Sally Smith <i>Sally Smith</i>	Sally Smith <i>Sally Smith</i>	Sally Smith <i>Sally Smith</i>

Figure 6: Inmar Serialization Tracking Form

The purpose of this form is to document the use of the serialized Inner Liner throughout the collection process and to help the Authorized Collector meet DEA and Board of Pharmacy recordkeeping requirements. Inmar will require each Authorized Collector to understand and comply with all federal, state, and local regulatory requirements pertaining to Covered Drugs applicable at the Collection Location, including but not limited to applicable rules from the Maine State Pharmacy Quality Assurance Commission. Inmar requires signed contracts stating the requirements with which Authorized Collectors must comply and giving Inmar the right to audit for compliance at any time. More information about the specific policies and procedures included in Inmar's contracts with Authorized Collectors are described below in Section III.A.

The serial numbers, date acquired, and signature of Authorized Employee must be completed upon receipt of the Container and Inner Liner. As illustrated above, the date installed is to be completed by two Authorized Employees with their names and signatures. The date the Container and Inner Liner are removed from the Collection Receptacles is also to be noted with names and signatures. Finally, the date the Packaged Container and Inner Liner are shipped is noted with authorized names and signatures.

Authorized Collectors must maintain a copy of the completed form, a copy of the FedEx tracking information, and other records as applicable, on file at the Authorized Collector's registered location for at least two years pursuant to 21 CFR 1304.04.

Authorized Collectors are provided detailed instructions on how to manage a Collection Receptacle, including but not limited to: installation (if applicable), safety and security, recognizing capacity, replacing Inner Liners (if applicable), storage of Packaged Containers and the rules and regulations pertaining to these items and the operation of a Collection Receptacle in general. Sample training material is provided in Appendix E but does not represent final state-specific material. Training materials will be customized upon approval to include, but not limited to, the following changes:

- Removal of LifeInCheck branding
- Inmar's purchasing and installing Collection Receptacles as the default option
- References to Maine and Federal law where applicable
- Clarification of where Authorized Collectors are to ship Packaged Containers
- Inclusion of requirements for every type of potential Authorized Collector and Collection Location
- Single Program Website and Program Toll-free Phone Number that has been coordinated and agreed upon with other approved Program Operators
- Removal of references to other Inmar programs/offers and placing of client logos on Collection Receptacle
- Updating Inner Liner storage requirements to reflect 21 CFR 1317.60(b)
- Removal of content pertaining to weight limits.

Recycling and Separation of Covered Drugs from Packaging

DEA §1317.75(c) prohibits handling substances after they have been deposited into a Collection Receptacle. For this reason, Inmar is unable to separate and recycle drug packaging. However, Inmar will

execute educational programs, as outlined in Section IV, to encourage residents to separate Covered Drugs from their packaging and recycle the packaging prior to disposal.

Even though regulations prevent us from recycling drug packaging, Inmar still has a vested interest in reducing waste and improving our environment. We will continue to look for opportunities to expand our eco-friendly efforts in the state.

Federal

1. DEA, The Controlled Substance Act (CSA) - 21 USC Chapter 13 §§ 801 - 971
 - Responsible Parties - Authorized Collectors, Collection Locations, and Service Providers
2. DEA, 21 CFR Section 1317
 - Responsible Parties - Authorized Collectors, Collection Locations, and Service Providers
3. US Department of Transportation (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) - 49 CFR Subtitle B Chapter 1 §§ 100 - 185
 - Responsible Parties - Authorized Collectors, Collection Locations, and Service Providers

1. Policies and Procedures

In accordance with Sec. 2.38 MRSA §1612.3(F), Inmar has established policies and procedures to be followed by persons handling Covered Drugs collected under the Program to ensure safety, security, and compliance with regulations that establish collection and transportation standards.

Inmar requires that Authorized Collectors, Collection Locations, Mail-back Distribution Locations and Service Providers involved in collection services, transportation, or disposal comply with The Drug Take-back Program Laws, The Controlled Substances Act, 21 USC §§ 801-971 and 21 CFR § 1317; United States Department of Transportation Hazardous Materials Regulation, 49 CFR § 100-185; Board of Pharmacy, and all applicable state and federal laws.

Inmar requires a signed agreement with Authorized Collectors and Service Providers ensuring their commitment to compliant operation of the Collection Receptacle and shipping of contents in compliance with the DEA regulations. A refusal to sign the agreement or comply with the DEA regulations would be a reason why a Pharmacy could be excluded from the Program.

Inmar's agreement with Authorized Collectors generally includes:

- Service Overview
- Term
- Client obligations
 - Compliance with all applicable federal, state and local regulatory requirements, including but not limited to, DEA, DOT, and Environmental Protection Agency (EPA) regulations
 - Maintaining all applicable governmental permits and licenses
 - Inmar has the right to inspect site and records upon request to ensure compliance

- Provide residents access to the Collection Receptacle during business hours, unless it is locked due to any safety, security, maintenance or any other reason
- Inmar must be promptly notified of any unserviced Collection Receptacle or safety or security concerns.
- Safety and security procedures
- Training and qualified personnel
- Description of supplies provided and replenishment
- Shipping and Tracking
- Cancellation procedures
- Confidentiality
- Limitations
- Indemnification
- Signatures

Inmar's agreement with Service Providers who handle Covered Drugs generally includes:

- Scope of work
- Delivery schedule
- Delivery procedures
- Delivery vehicles and identification
- Term
- Fees
- Descriptions of acceptable and unacceptable waste
- Quality assurance/quality control
- Billing and payments
- Insurance
- Compliance with government regulations
- Suspension and termination of service
- Right to audit.

Obligations of Mail-back Distribution Locations under agreement with Inmar generally include:

- Maintain compliance with all regulations stated above including required documentation
- Provide access to residents during normal business hours
- Display signage and instructions regarding proper use of all Envelopes and Packages
- Provide to residents information regarding safe disposal of Covered Drugs
- Do not charge residents for the Envelopes or Packages
- Display the Mail-back Starter Kit for easy access for residents
- Promptly reorder supplies as necessary
- Notify Inmar immediately of any service issue or desire to no longer serve as a Mail-back Distribution Location
- Inmar must be promptly notified of any safety or security concerns.
- Do not limit residents on the amount of Envelopes or Packages they take
- Never accept Envelopes or Packages from residents for any reason
- Do not collect any resident personal information

- Do not modify any part of the Mail-back Starter Kit
- Inmar has the right to inspect sites upon request to ensure compliance

2. Patient Privacy

Inmar provides significant training to our participating Authorized Collectors and strictly follows the DEA Rule for the proper handling of the Collection Receptacles and Inner Liners. This begins with the training of the Authorized Collector in the compliant operation of the Collection Receptacle and proper preparation, removal and packaging of the Container. It also involves the training of staff that may come into contact with the Packaged Containers to ensure proper handling. Inmar strictly complies with state and federal statutes and regulations, including but not limited to the DEA regulations cited below.

Inner Liners are opaque and contents will not be visible when sealed. According to the DEA - As provided in §§ 1317.60(c) and 1317.70(f), Inner Liners shall be sealed immediately upon removal from the Collection Receptacle; sealed Inner Liners and Standard Mail-back Envelopes shall not be opened, x-rayed, analyzed, or otherwise penetrated. Accordingly, their contents shall not be sorted or inventoried subsequent to being placed into Collection Receptacles or Mailers. To clarify this, § 1317.75(c) was modified to add the prohibition against individually handling substances after they have been deposited into Collection Receptacles.

Inmar, contracted Service Providers and Authorized Collectors will comply with all regulations regarding the protection of patient privacy and will be HIPAA and Protected Healthcare Information (PHI) compliant. Any and all patient information on drug packaging will be promptly destroyed in the unlikely event of exposure.

Inmar will also execute educational programs, as outlined in Section IV, to educate residents on the importance of redacting individually identifiable information and safeguarding their private patient information prior to depositing Covered Drugs in Collection Receptacles or Mailers.

G. Security

Collection Receptacles

Collection Receptacles will be securely installed inside an Authorized Collector's registered Collection Location in accordance with 21 CFR § 1317.75 to include:

- Pharmacies: 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 pharmacy counter).
- Hospitals/clinics: in an area regularly monitored by employees and shall not be located in the proximity of any area where emergency or urgent care is provided.
- Substance use disorder treatment program: in a room that does not contain any other controlled substances and is securely locked with controlled access.

- Long-term care facility: in a secured area regularly monitored by long-term care facility employees.
- Law Enforcement Facility: should be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances
- Instructions are provided to Authorized Collectors outlining how to change the Inner Liner when it becomes full which includes inspecting the kiosks for any tampering that may create a risk for diversion and reporting any issues to Inmar immediately

The Collection Receptacle has pre-drilled holes in the bottom for easier installation. It also features a 4-point locking system with steel projections in two center locations and the top and bottom of the door that are activated when locked for strengthened security. Top and bottom deadbolt locations are hidden from the outside to prevent break-ins.

Mail-Back Envelopes

The Standard Mail-back Envelopes and Inhaler Mail-back Envelopes will meet DEA Rule requirements under § 1317.70(c)(2), specifically:

- Pre-addressed, postage paid
- Nondescript and does not indicate what may be inside
- Waterproof, spill proof, tamper-evident, tear-resistant, and sealable; the envelopes also contain an absorbent pad
- Contain a unique ID number that allows for tracking
- Include instructions for the user that indicate the process for mailing the package, substances that can be sent, notice that packages can only be mailed in the US customs territory and notice that only packages provided by the Authorized Collector will be accepted
- No Personally Identifiable Information will be required.

Both types of envelopes are white in color with a gray interior and are 7" x 10". The Envelopes include a 3" perforated lip security seal.

The Auto-Injector Mail-back Package is red in color, includes a hinge cap, liquid absorbing pad, petal access and includes the universal biohaz symbol for safe shipment to the Service Provider.

H. Metrics

In accordance with Sec. 2.38 MRSA §1612.10, Inmar will submit, within 90 days after the first full year of implementation, and annually thereafter, a report describing the activities of the program during the prior calendar year, which must include, at a minimum:

- A list of manufacturers participating in the stewardship program, including contact information;

- The amount by weight of material collected under the stewardship program in the prior calendar year, including the amount by weight from each collection method used (i.e. Collection Receptacle, Mailers) both in total and by county;
- Details regarding the stewardship program's collection system, including a list of authorized collectors and associated collection locations with addresses; a list of locations where mail-back envelopes were provided under the program; a list of collection locations where collection receptacles were made available under the program; dates and locations of collection events held under the program; and 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 pursuant to subsection 3, paragraph
- For the 2nd year and 3rd year of stewardship program implementation, and every 2 years after that 3rd year, the report must include the results of the 3rd-party assessment required under subsection 9;
- A description of how packaging collected under the program was recycled, to the extent feasible;
- A description of the methods used under the stewardship program to collect, transport and dispose of covered drugs that are household pharmaceutical waste, including information regarding efforts by the operator to ensure that only covered drugs that are household pharmaceutical waste were collected, and how the methods are consistent with the federal hazardous waste regulations identified in subsection 3, paragraph F;
- A summary of the stewardship program's achievement of its performance goals as set forth in the approved plan pursuant to subsection 3, paragraph J. If any performance goals were not achieved, the report must include a description of the efforts that will be made to achieve those goals the following year;
- An analysis of the convenience of the collection system under the stewardship 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 stewardship program in the prior calendar year, which must include an accounting of the program's expenditures in the prior calendar year, as verified through an independent 3rd-party audit;
- Any recommendations for changes to the stewardship program to improve the convenience of the collection system, to increase consumer awareness and education or to better evaluate program performance; and
- 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 subsection 5.

I. Promotion

Inmar will execute a comprehensive and measurable promotion, education and public outreach strategy to drive awareness of the Program and maximize participation pursuant to Sec. 2.38 MRSA §1612.3(I). In addition to preventative education, Inmar's strategy is designed to ensure that where and how to return Covered Drugs is widely understood by residents.

Prior to Plan submission, Inmar has been conducting education sessions in person and virtually to leadership of the public health sector and drug-free community (DFC) coalitions operating in Maine. By providing the leadership of these organizations with a history of the drug take-back programming in Maine, Inmar's goal was to better-prepare these groups to integrate Inmar's Drug Stewardship Program with their local law enforcement partners, pharmacies, and long-term care facilities through community outreach.

Pursuant to Sec. 2.38 MRSA §1612.3(I) the individual components of Inmar's promotion strategy are detailed below. Across all tactics, key messages will include, but not be limited to, the following:

- Promote the safe storage of Covered Drugs by residents before secure disposal through a Drug Take-back Program
- Discourage residents from disposing of Covered Drugs in solid waste collection, sewer, or septic systems
- Promote the use of the Drug Take-back Program so that where and how to return Covered Drugs is widely understood by residents, pharmacists, health care facilities and providers, veterinarians, and veterinary hospitals
- Establish a Program Toll-free Phone Number and Program Website publicizing collection options and Collection Locations and discouraging improper disposal practices for Covered Drugs, such as flushing them or placing them in the garbage
- Importance of redacting individually identifiable information and safeguarding private patient information prior to depositing Covered Drugs in Collection Receptacles or Mailers.

1. Tools for Promotion

Printed Materials

In accordance with Sec. 2.38 MRSA §1612.3(I), Inmar will make available on the Program Website and distribute promotional printed materials to Pharmacies, health care facilities, and other interested parties so that they can provide these materials to residents. Distribution methods include providing material at the time of Collection Receptacle installation, with the Mail-back Starter Kit or by request on the Program Website or by calling the Program Toll-free Phone Number. The media communication methods of promotion described in this section will encourage any interested party, including but not limited to, pharmacies, healthcare facilities and veterinary clinics, to request materials via the Program Website or Program Toll-free Phone Number. The process for requesting materials is the same for all entities whether or not they are considered Authorized Collectors.

These materials will:

- Provide instruction on how to safely store Covered Drugs at home
- Inform of the risks of disposing of Covered Drugs in inappropriate waste streams (e.g., solid waste collection, sewer, or septic systems) and discourage improper disposal such as flushing or placing them in the garbage
- Outline how to participate in the Drug Take-back Program for safe disposal of Covered Drugs
- Inform residents about Collection Locations, hours of operation, and Mail-back Services

All materials will leverage explanatory graphics to aid in comprehension, will be easily understandable by interested parties with varying levels of English proficiency, and can be translated into other languages at the Department's request.

Inmar will provide a creative advertising template for print publications. To drive public relation impression, Inmar will develop press release templates and perform outreach to local media.

Additionally, in support of the requirements outlined in Sec. 2.38 MRSA §1612.8(D), Inmar will provide printed materials to all Authorized Collectors participating in the Program which outlines information on Covered Drug collection and safe drug disposal options that can be provided to consumers upon dispensing a Covered Drug, including the availability of Mailers upon request. In accordance with Sec. 2.38 MRSA §1612.8(E) these materials will be provided to the Authorized Collectors free of charge.

Collection Receptacle Signage

Inmar will work with Authorized Collectors at the time of agreement negotiation to develop a readily recognizable and consistent design for Collection Receptacles to be used at Collection Locations and to develop clear, standardized instructions to residents on how to use those Collection Receptacles. Each Collection Receptacle is equipped with clear graphical instructions for proper use in the form of magnets and stickers that are placed on the Collection Receptacle at the time of implementation. Please see Appendix D for a sample image of the Collection Receptacle and disposal instructions.

Outreach Demographics

Inmar has a system in place that allows us to efficiently deploy local media using traditional tactics for general awareness and programmatic media to sustain a presence throughout the year. Below are details that have been gathered to inform the outreach process. Inmar will reach all demographics including the elderly and underserved.

The below population data was gathered from U.S. Census Bureau 2020 data. (<https://www.census.gov/quickfacts/fact/table/ME/POP010220>).

Maine

Population 1,362,359

- Ages 0-17 18.5%
- Ages 18-64 60.3%
- Ages over 65 21.2%

Households 2,848,396

- White alone 93.0%
- Asian 1.3%
- Hispanic or Latino 1.8%
- Black or African American 1.7%
- American Indian or Native Alaskan 0.7%

Median HHI \$59,489

Target Demographics:

- General public
- At risk populations including the elderly and homeless population
- Minority, low-income, rural and other historically underserved communities
- Pharmacies
- Retailer of Covered Drugs
- Health care providers and patients
- Skilled nursing and long-term care facilities
- Veterinary providers and animal lovers
- Public health facilities
- Community Agencies

Media Communication Methods

Inmar will reach out to residents through direct mail in a campaign deployed twice a year around the National Consumer Drug Take-Back (NCDTB) days. The campaign will focus on promoting the Maine Safe Medication Return Program. The majority of the direct mail will go to underserved and rural areas and expand outwards to the larger cities. The semiannual direct mail campaign will occur for the first two years with adjustments to the campaign being made in year three.

Programmatic advertising refers to the data and technology-driven process by which buyers and sellers of digital advertising space purchase or sell that inventory in real time. The programmatic campaigns will run twice each year. The programmatic campaign will occur for the first two years with adjustments to the campaign being made in year three.

Inmar will provide Influencer Marketing services. The Social Media Influencer campaigns will also occur quarterly throughout the year. Adjustments to campaigns will be made in year three.

Beyond the above, Inmar will also post about the Program twice monthly on our social media channels and promote the posts with amplified media when deemed necessary.

Below is a breakdown of the media communication methods being proposed:

1. Press Release

- Sent at Plan Approval
- Local Media Outlets/Partners
- National PR Wire

2. Direct Mail

- PSA Announcement Postcard sent to residents (5x7 Postcard) twice a year leading up to NCDTB day

3. Print Ads

- Run ads in major newspapers quarterly

4. Programmatic Media

- Provide targeted display and/or video ads on browser sites on internet capable devices (smart phones, computers, tablets, etc.). To do this, Inmar uses Geo-targeting that uses the physical locations of the Collection Receptacles to target residents within close proximity
- Inmar will run ads across a prequalified list of over 200K domains
- Inmar will run targeted ads twice a year for the 6 weeks leading up the NCDTB days (last Saturday in April and October each year)
- Metrics - Impressions - These metrics are reported directly from the individual websites that the ads are placed on and are reported on a per campaign bases (once per quarter)

Definitions:

- Impressions - Potential views/interactions of your content or media.

5. Influencer Marketing

- Inmar will run several social media influencer campaigns. Campaigns will include one activation every quarter for the first two years with evaluation for effectiveness starting in year three
- Metrics - Impressions and Content Views. These metrics are reported directly from the social platforms themselves and are reported on a per campaign bases (once per quarter)

Definitions:

- Impressions - Potential views/interactions of your content or media.
- Content Views - Actual views of the campaign content on the influencers sites or social channels since campaign launch.

Program Website

Inmar will provide a single, neutrally branded, mobile-optimized website, in coordination with other approved Program Operators, which will publicize collection options and educate all residents, including individuals with limited English proficiency, on proper disposal practices. Inmar will use enhanced search engine optimization to ensure easy location and access.

Specifically, the Program Website will:

- Allow residents, LEAs, health jurisdictions and community members to contact Inmar to provide feedback on the Program.
- Allow residents to find the nearest Collection Location or Mail-back Distribution Location via an interactive map. The list of locations will be updated quarterly to ensure accuracy. The location list will be inclusive of all Collection Receptacles and Mail-back Distribution Locations operated by Department-approved Program Operators.
- Allow residents to request Mailers.
- Clearly indicate what substances are and are not accepted. Graphics of unacceptable substances are provided for additional clarity.
- Include educational and outreach materials for the safe storage and disposal of Covered Drugs.
- Feature links to Drug Take-back social media pages for more useful content.

Potential Authorized Collectors interested in participating in the Program will be able to request more information through the Website. In addition, participating Authorized Collectors will have access to resources for compliant Collection Receptacle management (including installation, tracking, and shipping) and will be able to request on-site Collection Receptacle maintenance and support. Similarly, Mail-back Distribution Locations will be able to request educational and promotional materials, additional supplies to prevent a break in service, request bulk orders, obtain support and report issues via the Program Website.

Inmar will update the list of Authorized Collectors, Collection Locations and Mail-back Distribution Locations at least quarterly on the Program Website.

Program Toll-free Phone Number

Inmar will operate a toll-free call center that interested parties can call to learn more about the Program and drug disposal best practices. Residents will also be able to request information about the nearest Collection Location or Mail-back Distribution Location, request that a Mailer be sent to them or acquire information about other collection processes. The call center is operated with live operators and will be staffed with a third-party service to assist with live translation in requested languages. All call center operators are trained to assist and answer questions related to the Program operation including but not limited to Authorized Collector Collection Receptacle support and service requests.

Callers with medical emergencies will be directed to call 911. Patients with medication-related questions will be directed to contact their health care provider(s).

Authorized Collectors will also be able to call the Program Toll-free Phone Number to request on-site Collection Receptacle maintenance and support.

Public Awareness and Outreach Reporting

Pursuant to Sec. 2.38 MRSA §1612.9, during the 2nd and 3rd years of implementation of a Stewardship Program, and every two (2) years thereafter, Inmar will fund an independent 3rd-party assessment of the effectiveness of the Program’s outreach and public education activities per the Performance Goals identified in Sec. 2.38 MRSA §1612.3(J). Inmar will work with the Department to develop the assessment’s method and scope, and will implement changes in its efforts to engage the public as deemed appropriate per the findings.

J. Performance Goals

	Short-term (one year after Program implementation)	Long-term (Ongoing)
Collection	Continue to increase convenience to Collection Locations through additional Collection Receptacles and Mail-back Distribution	Continue to increase convenience to Collection Locations through additional Collection Receptacles and Mail-back Distribution

	<p>Locations to increase geographical distribution.</p> <p>Collection goal of 20 lbs average of collected Covered Drugs per Collection Location based on total pounds of Covered Drugs collected.</p>	<p>Locations to increase geographical distribution.</p> <p>Inmar’s long-term goal would be to see an increase in pounds of Covered Drugs collected relevant to the increase in number of Collection Locations and improved outreach and education programs in years 2-4 of Program implementation.</p>
Education & Promotion	<p>Continue public awareness and outreach campaign as described in Section I of Plan with a goal of reaching 60% of Maine residents after one year of the Program implementation.</p> <p>Education programs will 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.</p> <p>Inmar will use the baseline survey from Section K of the Plan to measure promotion goals for year one.</p>	<p>Continue public awareness and outreach campaign as described in Section I of Plan with a goal of reaching 70% of residents after 2 years of the Program implementation and sustained reach of 75% of Maine residents after four years of Program implementation.</p> <p>Education programs will 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.</p> <p>Inmar will use the ongoing surveys described in Section K of the Plan to measure promotion goals.</p>

K. Survey

In accordance with Sec. 2.38 MRSA §1612.3(K), Inmar will arrange for and fund a survey conducted by a 3rd party prior to the implementation of the Stewardship Program of residents, pharmacists, and healthcare professionals in the state of Maine who interact with residents. The goal of the survey is to measure public awareness regarding proper disposal methods for unwanted drugs.

The survey will measure how these above groups currently dispose of unwanted drugs and assess knowledge and attitudes regarding the risks, such as abuse, poisoning, and overdose from improperly storing and improperly discarding or abandoning Covered Drugs. Inmar commits to providing survey responses to the Department for review in the that will describe the following data points:

- Overall number of potential survey respondents

- How those surveyed are representative of the state such as in terms of race, gender, income and location of residence
- Additional details about the survey and method of delivery

Results from the survey will be used by Inmar as a baseline to improve the effectiveness of the Plan in subsequent Plan years.

Additionally, in accordance with Sec. 2.38 MRSA §1612.9, during the 2nd and 3rd years of implementation Inmar’s Program, and every 2 years after that 3rd year, Inmar will fund an independent 3rd-party assessment of the effectiveness of the Program’s education and outreach efforts including progress achieving the performance goals described in Sec. 2.38 MRSA §1612.3(J) and section J of the Plan.

Inmar will implement improvements to the Program’s collection, education and outreach efforts if the need is demonstrated by the results of the assessment. Examples of such improvements could include adjusting the number or location of Collection Locations, providing additional services in underserved communities, improving outreach to and education for residents, and/or identifying other methods for improving service and outreach.

L. Budget

Inmar has long-term commitments from Manufacturers who will cover all costs associated with the Program. Inmar uses data on Covered Drugs to inform Program costs. Data sets from Covered Drugs sold include volume estimates, relative value, comparisons to states with similar populations, and actual historical data from Maine. The Program operational costs will be apportioned as fees among each participating Manufacturer based upon the volume and value estimates below. Participating Manufacturers are invoiced and remit funds according to their contracts.

Year 1	
Administrative Costs	\$515,920
Collection and Disposal Cost	\$1,633,392.00
Communication Costs	\$328,800.00
Total Program Costs	\$2,478,112

Category 1: Administrative costs. A total for all administrative costs includes, but is not limited to:

- (i) Contracted and employed personnel overhead costs;
- (ii) Legal fees;
- (iii) Local and state business licensing fees;
- (iv) Local, state, and federal taxes;
- (v) Property costs, including rentals;
- (vi) Utilities, phone, and internet; and
- (vii) General equipment and supplies.

Category 2: Collection and disposal costs. A total for all collection and disposal costs includes, but is not limited to:

- (i) Collection, transportation, and disposal of drugs;
- (ii) Purchase, maintenance, and replacement of collection receptacles;
- (iii) Compensation of Authorized Collectors, if separate from personnel costs and
- (iv) Production, distribution, and postage of Mailers.

Category 3: Communication costs. A total for all communication costs includes, but is not limited to:

- (i) Advertising;
- (ii) Marketing;
- (iii) Website creation and maintenance; and
- (iv) Operation of a Toll-free Phone Number.

Assumptions

This budget estimate provided by Inmar is an estimate of the total expenditure to implement the Program by Inmar across the entire state of Maine. This estimate is based upon Inmar's experience and national footprint in servicing the pharmaceutical industry and applying the Maine regulations to this effort. As such, the actual performance results may differ from those projected in this Program Budget. No guarantee is implied as to the accuracy of this estimate.

Inmar will be responsible for all costs incurred in the Program and will be performing all the work in-house with the exception of transportation and disposal, which will be the only services Inmar will subcontract. Inmar has long-standing agreements for these services, which Inmar will leverage for performance of this Program.

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Appendix A: List of Participating Manufacturers

1. Lannett Company Inc.

Michael Gankiewicz
Director DEA & Security
1101 C Avenue West, Seymour, IN 47274
Email: mgankiewicz@lannett.com
Phone: 215-333-9000

2. Unichem Pharmaceuticals (USA), INC.

Kartik M. Keertikar
Senior Manager, Regulatory Affairs
One Tower Center Boulevard, Suite 2200, East Brunswick, NJ 08816
Email: kkeertikar@unichemusa.com
Phone: 732-253-5954

3. Ascend Laboratories

Hindy Schiff
Vice President Regulatory Affairs/Compliance
339 Jefferson Road, Suite 101, Parsippany, NJ 07054 USA
Email: HSchiff@ascendlaboratories.com
Phone: 908.612.3079

4. Strides Pharma Inc.

Michael Altamuro
SVP, Sales & Marketing (US)
1 Ram Ridge Rd, Chestnut Ridge, NY 10977
Email: mike.altamuro@stridesusa.com
Phone: 845-682-3251

5. Dr. Reddy's Laboratories Inc.

Brian Kilmartin
Lead Risk Management PV
107 College Road East, Princeton, NJ 08540
Email: bkilmartin@drreddys.com
Phone: 609-806-3963

6. Hikma Pharmaceuticals USA Inc.

Heather S. Patrick
Sr. Analyst, Legal Affairs
200 Connell Drive, 4th Floor, Berkeley Heights, NJ 07922
Email: hpatrick@hikma.com

Phone: 908.673.1030

7. Sun (Taro) Pharmaceutical Industries, Inc.

Rick Lewellyn
Assoc. Dir. Supply Chain
2 Independence Way, Princeton, NJ 08540
Email: Richard.lewellyn@taro.com
Phone 914-345-9001

8. Novadoz Pharmaceuticals, LLC

Michael Clark
Director Sales Operations
20 DUKE ROAD, SUITE A, PISCATAWAY, NJ 08854-3714
Email:michael.clark@NovadozPharma.com
Phone:848-200-1910

9. Avet-Heritage Pharmaceuticals, Inc

Jamie Berlanska
VP Chief Financial Officer
1 Tower Center Boulevard, Suite 1700, East Brunswick, NJ 08816
Email: Jamie.Berlanska@avetpharma.com
Phone: 732-429-1000

10. Fosun Pharma USA, Inc

Huong Nguyen
General Counsel
104 Carnegie Center Drive, Suite 204, Princeton, New Jersey 08540
Email: huong.nguyen@fosunpharmausa.com
Phone: 408-200-9891

11. TruPharma, LLC

John E. Mooney
President
4100 W Kennedy Blvd, Suite 220, Tampa, FL 33609
Email: jmooney@trupharma.com
Phone: 312-953-2600

12. NextSource Biotechnology

Thomas Hunter
General Counsel, Chief Compliance Officer, Secretary
80 SW 8th Street, Suite 2660, Miami, FL 33130
Email: tomhunter@trisourceph.com
Phone: 855-672-2468

13. Micro Labs USA, Inc

Gaurang Bhavsar, RAC
Associate Director - Regulatory Affairs
220 Davidson Ave, Suite 402, Somerset, NJ 08873
Email: gaurangbhavsar@microlabs.in
Phone: 908-484-7410

14. Leading Pharma, LLC

Tal Lev
Chief Financial Officer
3 Oak Rd, Fairfield, NJ 07004
Email: tlev@leadingpharma.com
Phone: 973-276-9600

15. Camber Pharmaceuticals, Inc.

Ron Cerminaro
Director, Commercial Strategy and Operations
1031 Centennial Ave., Piscataway, NJ 08854
Email: rcerminaro@camberpharma.com
Phone: 732.529.0430

16. ProvePharm

Tania Tardif
Office Operations Specialist
100 Springhouse Drive Suite 105, Collegeville, PA 19426
Email: tania.tardif@provepharm.com
Phone: 610-601-8600

17. Westminster Pharmaceuticals, LLC

Adrienne Fink
Financial Controller
3450 Buschwood Park Dr, Suite 110, Tampa, FL 33618
Email: finance@wprx.com
Phone: 727-300-1376

18. USpharma, Ltd

13900 Northwest 57th Ct, Miami Lakes, FL 33014
Email: info@uspharmaltd.com
Phone: 305-698-4600

Appendix B: List of Confirmed Authorized Collectors

Below is the list of confirmed locations that have signed contracts with Inmar to be Authorized Collectors. This list continues to grow as we continue outreach.

Authorized Collector	Mailing Street	Mailing City	Postal Code	County
Androscoggin County Sheriff's Office	2 Turner Street	Auburn	04210	Androscoggin
Auburn Police Department	60 Court Street	Auburn	04210	Androscoggin
Bedard Pharmacy, Inc	359 Minot Avenue Suite B	Auburn	04210	Androscoggin
Bedard Senior Care Inc.	359 Minot Ave. Suite C	Auburn	04210	Androscoggin
Bolster Heights	26 Bolster Street	Auburn	04210	Androscoggin
Coastal Community Care	95 Main Street	Auburn	04210	Androscoggin
Hannaford 8347	95 Spring St.	Auburn	04210	Androscoggin
OSCO PHARMACY #2550	600 Center Street	Auburn	04210	Androscoggin
Bedard Medical Inc.	61 College Street	Lewiston	04240	Androscoggin
Hannaford 8265	692 Sabattus St.	Lewiston	04240	Androscoggin
Lewiston Police Department	171 Park Street	Lewiston	04240	Androscoggin
OSCO PHARMACY #4559	27 East Avenue	Lewiston	04240	Androscoggin
Woodlands Memory Care of Lewiston	45 Mollison Way	Lewiston	04240	Androscoggin
Lisbon Police Department	300 Lisbon Street	Lisbon	04250	Androscoggin
Livermore Falls Police Department	2 Main Street	Livermore Falls	04254	Androscoggin
Sabattus Police Department	190 Middle Road	Sabattus	04280	Androscoggin
Ashland Drug Store	73 Presque Isle Rd	Ashland	04732	Aroostook
Ashland Police Department	17 Bridgham St	Ashland	04732	Aroostook
Caribou Nursing Home	10 Bernadette Street	Caribou	04736	Aroostook

Caribou Police Department	25 High Street	Caribou	04736	Aroostook
Fort Fairfield Police Department	18 Community Center Drive	Fort Fairfield	04742	Aroostook
Fort Kent Police Department	416 West Main Street	Fort Kent	04743	Aroostook
St. John Valley Pharmacy LLC	182 Market Street	Fort Kent	04743	Aroostook
Aroostook County Sheriff's Office	25 School Street, Suite 216	Houlton	04730	Aroostook
Houlton Police Department	97 Military Street	Houlton	04730	Aroostook
Kvhc Pharmacy	59 Bangor St	Houlton	04730	Aroostook
Limestone Police Department	93 Main Street	Limestone	04750	Aroostook
The Aroostook Medical Center	15 Highland Ave	Mars Hill	04758	Aroostook
Aroostook Apothecary LLC	159 Academy Street	Presque	04769	Aroostook
Presque Isle Police Department	43 North Street, Suite 2	Presque Isle	04769	Aroostook
Borderview Rehab	208 State Street	Van Buren	04785	Aroostook
Hebert Rexall Pharmacy	31 Main St	Van Buren	04785	Aroostook
Washburn Police Department	1287 Main Street	Washburn	04786	Aroostook
Bridgton Police Department	8 Iredale Street	Bridgton	04009	Cumberland
Hannaford 8167	109 Portland Rd.	Bridgton	04009	Cumberland
Brunswick Police Department	85 Pleasant Street	Brunswick	04011	Cumberland
Coastal Shores	142 Neptune Dr.	Brunswick	04011	Cumberland
Dionne Commons	24 Maurice Drive	Brunswick	04011	Cumberland
Guardian Pharmacy of Maine	3 Business Parkway Suite 2	Brunswick	04011	Cumberland
OSCO PHARMACY #0628	147 Bath Road	Brunswick	04011	Cumberland
Cape Elizabeth Police Department	325 Ocean House Road	Cape Elizabeth	04107	Cumberland
Cape Memory Care	126 Scott Dyer Rd	Cape Elizabeth	04107	Cumberland

Cumberland Police Department	290 Tuttle Road	Cumberland	04021	Cumberland
The Heron House	92 Us Route 1	Cumberland	04110	Cumberland
Falmouth Police Department	2 Marshall Drive	Falmouth	04105	Cumberland
Walmart #2659	206 Us Rt 1	Falmouth	04105	Cumberland
Freeport Police Department	16 Main Street	Freeport	04032	Cumberland
OSCO PHARMACY #0608	200 Lower Main Street	Freeport	04032	Cumberland
Gorham Police Department	270 Main Street	Gorham	04038	Cumberland
Hannaford 8350	99 Main St.	Gorham	04038	Cumberland
Day One New Gloucester	934 Intervale Road	New Gloucester	04260	Cumberland
Cumberland County Sheriff's Office	36 County Way	Portland	04102	Cumberland
Hannaford 8351	295 Forest Ave. Suite 7	Portland	04101	Cumberland
HarborChase of South Portland	26 Country Club Lane	Portland	04106	Cumberland
Northern Light Pharmacy Fore River	195 Fore River Pkwy Ste 170	Portland	04102	Cumberland
OSCO PHARMACY #2541	Northgate Center, 91 Auburn St.	Portland	04103	Cumberland
Portland Police Department	26 Portland Street	Portland	04101	Cumberland
Portland Police Department - Middle Street	109 Middle Street	Portland	04101	Cumberland
OSCO PHARMACY #2547	417 Payne Road	Scarborough	04074	Cumberland
Scarborough Police Department	275 Us Route 1	Scarborough	04074	Cumberland
Walmart #1788	500 Gallery Blvd	Scarborough	04074	Cumberland
Hannaford 8279	50 Cottage Rd.	South Portland	04106	Cumberland
South Portland Police Department	30 Anthoine Street	South Portland	04106	Cumberland
Hannaford 8349	71 Colonial Dr	Standish	04084	Cumberland

Westbrook Police Department	570 Main Street	Westbrook	04092	Cumberland
Hannaford 8345	797 Roosevelt Trail	Windham	04062	Cumberland
New Communities - Windham Pines	20 Bishop Drive	Windham	04062	Cumberland
Windham Police Department	375 Gray Road	Windham	04062	Cumberland
Yarmouth Police Department	178 North Road	Yarmouth	04096	Cumberland
Community Pharmacy of Gorham	365 Main Street	Gorham	04038	Cumberland
Carrabassett Valley Police Department	9000 Maine Street	Carrabassett Valley	04947	Franklin
Farmington Police Department	116 Farmington Avenue	Farmington	04938	Franklin
Franklin County Sheriff's Office	123 County Way	Farmington	04938	Franklin
Woodlands Senior Living of Farmington	175 Knowlton Corner Rd.	Farmington	04938	Franklin
Jay Police Department	340 Main Street	Jay	04239	Franklin
Spruce Mountain Pharmacy Inc.	148 Main Street	Jay	04239	Franklin
Western Maine Pharmacy, Inc.	238 Main Street	Kingfield	04947	Franklin
Rangeley Police Department	15 School Street	Rangeley	04970	Franklin
Wilton Police Department	874 Main Street	Wilton	04294	Franklin
Bar Harbor Police Department	37 Firefly Lane	Bar Harbor	04609	Hancock
Bucksport Police Department	89 Franklin Street	Bucksport	04416	Hancock
Community Pharmacy of Bucksport	75 Main Street	Bucksport	04416	Hancock
Ellsworth Police Department	1 City Hall Plaza	Ellsworth	04605	Hancock
Hancock County Sheriff's Office	50 State Street	Ellsworth	04605	Hancock
Hannaford 8123	225 High St., Suite 1	Ellsworth	04605	Hancock
OSCO PHARMACY #0057	175 High Street	Ellsworth	04605	Hancock

Gouldsboro Police Dept.	59 Main Street	Prospect Harbor	04669	Hancock
Southwest Harbor Police Department	26 Village Green Way	Southwest Harbor	04679	Hancock
Augusta Police Department	33 Union Street	Augusta	04330	Kennebec
Hannaford 8239	29 Whitten Rd.	Augusta	04330	Kennebec
Kennebec County Sheriff's Office	125 State Street	Augusta	04330	Kennebec
OSCO PHARMACY #2552	150 Western Avenue	Augusta	04330	Kennebec
Clinton Police Department	27 Baker St	Clinton	04927	Kennebec
Hallowell Police Department	1 Winthrop Street	Hallowell	04347	Kennebec
Woodlands Senior Living of Hallowell	152 Winthrop St.	Hallowell	04347	Kennebec
Monmouth Polica Department	847 Main Street	Monmouth	04259	Kennebec
Oakland Pharmacy	43 Main Street	Oakland	04963	Kennebec
Oakland Police Department	7 Fairfield Street	Oakland	04963	Kennebec
Hannaford 8229	140 Elm Plaza	Waterville	04901	Kennebec
OSCO PHARMACY #3551	251 Kennedy Memorial Drive	Waterville	04901	Kennebec
Waterville Police Department	10 Colby Street,	Waterville	04901	Kennebec
Woodlands Senior Living of Waterville	147 West River Rd.	Waterville	04901	Kennebec
Winslow Police Department	114 Benton Avenue	Winslow	04901	Kennebec
Winthrop Police Department	15 Town Hall Lane	Winthrop	04364	Kennebec
Camden Police Department	31 Washington Street	Camden	04843	Knox
Knox County Sheriff's Office	301 Park Street	Rockland	04841	Knox
OSCO PHARMACY #3548	235 Camden Street	Rockland	04841	Knox
Rockland Police Department	1 Police Plaza	Rockland	04841	Knox
Woodlands Memory Care of Rockland	201 Camden St.	Rockland	04841	Knox

Kennebec Pharmacy & Home Care LLC	839 Commercial St	Rockport	04856-4243	Knox
Rockport Police Department	85 Main Street	Rockport	04856	Knox
Thomaston Police Department	13 Valley Street	Thomaston	04861	Knox
Public Safety Building	56 West Maine Street	Vinalhaven	04863	Knox
Boothbay Harbor Police Department	11 Howard Street	Boothbay Harbor	04538	Lincoln
Damariscotta Police Department	21 School Street	Damariscotta	04543	Lincoln
Hannaford 8141	469 Main St.	Damariscotta	04543	Lincoln
Waldoboro Police Department	1600 Atlantic Highway	Waldoboro	04572	Lincoln
Lincoln County Sheriff's Office	42 Bath Road	Wiscasset	04578	Lincoln
Wiscasset Police Department	51 Bath Road	Wiscasset	04578	Lincoln
Fryeburg Police Department	89 Bridgton Road	Fryeburg	04037	Oxford
Mexico Police Department	134 Main Street	Mexico	04257	Oxford
Norway Police Department	19 Danforth Street	Norway	04268	Oxford
Hannaford 8338	1603 Main St.	Oxford	04270	Oxford
Oxford Police Department	701 Maine Street	Oxford	04270	Oxford
Rumford Police Department	150 River Street	Rumford	04276	Oxford
Paris Police Department	35 Market Square	South Paris	04281	Oxford
Bangor Drug Company	711 Broadway Ste 1	Bangor	04401	Penobscot
Bangor Drug LTC	711 Broadway Ste 2	Bangor	04401	Penobscot
Bangor Police Department	240 Main Street	Bangor	04401	Penobscot
Hannaford 8109	1133 Union St.	Bangor	04401	Penobscot
M Drug LLC	915 Union Street	Bangor	04401	Penobscot
Northern Light Pharmacy Riverside	417 State St Ste 130	Bangor	04401	Penobscot

Northern Light Pharmacy State Street	210 State St	Bangor	04401	Penobscot
OSCO PHARMACY #4556	353 Main Street	Bangor	04401	Penobscot
Walmart #1856	900 Stillwater Ave	Bangor	04401	Penobscot
Brewer Police Department	151 Parkway South	Brewer	04412	Penobscot
Hannaford 8173	383 Wilson St.	Brewer	04412	Penobscot
M Drug LLC	33 Whiting Hill Road Suite 4	Brewer	04412	Penobscot
Woodlands Senior Living of Brewer	53 Colonial Circle	Brewer	04412	Penobscot
East Millinocket Police Department	125 Main Street	East Millinocket	04430	Penobscot
Hampden Police Department	106 Western Avenue	Hampden	04444	Penobscot
Hannaford 8140	22 Goding Ave.	Lincoln	04457	Penobscot
Lincoln Police Department	21 Fleming Street	Lincoln	04457	Penobscot
Kvhc Pharmacy Millinocket	50 Summer Street	Millinocket	04462	Penobscot
Newport Police Department	21 Water Street	Newport	04953	Penobscot
Hannaford 8133	500 Stillwater Ave. Ste 1	Old Town	04468	Penobscot
Orono Police Department	63 Main Street	Orono	04473	Penobscot
Kvhc Pharmacy Patten	30 Houlton St	Patten	04765	Penobscot
Patten Drug Company	20 Main St	Patten	04765	Penobscot
Veazie Police Department	1084 Main Street	Veazie	04401	Penobscot
Dover Foxcroft PD	182 East Main Street	Dover-Foxcroft	04426	Piscataquis
OSCO PHARMACY #0629	1073 West Main Street	Dover-Foxcroft	04426	Piscataquis
Piscataquis County Sheriff's Office - Dover-Foxcroft	52 Court Street	Dover-Foxcroft	04426	Piscataquis
Greenville Police Department	7 Minden Street	Greenville	04441	Piscataquis

Harris Drug	10 Pritham Ave	Greenville	04441	Piscataquis
Piscataquis County Sheriff's Office - Guilford	2 Hudson Ave	Guilford	04443	Piscataquis
Milo Police Dept	6 Pleasant Street	Milo	04463	Piscataquis
Bath Police Department	250 Water Street	Bath	04530	Sagadahoc
Sagadahoc County Sheriff's Office	752 High Street	Bath	04530	Sagadahoc
Phippsburg Police Department	1042 Main Street	Phippsburg	04562	Sagadahoc
Richmond Police Department	26 Gardiner St	Richmond	04357	Sagadahoc
Topsham Police Department	100 Main Street	Topsham	04086	SagadAhoc
Fairfield Pharmacy	66 Western Ave	Fairfield	04937	Somerset
Fairfield Police Department	One Police Plaza	Fairfield	04937	Somerset
Somerset County Sheriff's Office - East Madison Road	131 East Madison Road	Madison	04950	Somerset
Somerset County Sheriff's Office - Weston Avenue	26 Weston Avenue	Madison	04950	Somerset
Woodlands Memory Care of Madison	110 East Madison Rd.	Madison	04950	Somerset
Pittsfield Police Department	112 Somerset Avenue	Pittsfield	04967	Somerset
Skowhegan Police Department	225 Water Street	Skowhegan	04976	Somerset
Variety Drug	12 High St	Skowhegan	04976	Somerset
Belfast Drug Company	15 Starrett Dr. Unit G	Belfast	04915	Waldo
Belfast Police Department	112 Church Street	Belfast	04915	Waldo
Waldo County Sheriff's Office	6 Public Safety Way	Belfast	04915	Waldo
Searsport Police Department	3 Union Street	Searsport	04974	Waldo
Unity Pharmacy	33 Plaza Drive	Unity	04988	Waldo
Eastport Police Department	22 Washington Street	Eastport	04631	Washington

Machias Police Department	17 Stackpole Drive	Machias	04654	Washington
Washington County Sheriff's Office	83 Court Street	Machias	04654	Washington
Milbridge Police Department	22 School Street	Milbridge	04658	Washington
York County Sherriffs Office	1 Layman Way	Alfred	04002	York
Berwick Police Department	20 Wilson Street	Berwick	03901	York
Biddeford Police Department	39 Alfred Street	Biddeford	04005	York
Hannaford 8225	299 Elm St.	Biddeford	04005	York
Walmart #2153	50 Boulder Way	Biddeford	04005	York
Buxton Police Department	185 Portland Road	Buxton	04093	York
Eliot Police Department	27 Dixon Road	Eliot	03903	York
Kennebunk Police Department	4 Summer Street	Kennebunk	04033	York
Kittery Police Department	200 Rogers Road	Kittery	03904	York
North Berwick Police Department	21 Main Street	North Berwick	03906	York
Ogunquit Police Department	20 Cottage Street	Ogunquit	03907	York
Old Orchard Beach Police Department	16 E. Emerson Cummings Blvd.	Old Orchard Beach	04064	York
Community Pharmacy of Saco	244 Main Street	Saco	04072	York
Hannaford 8138	532 Main St.	Saco	04072	York
OSCO PHARMACY #2626	4 Scammon St Ste 10	Saco	04072	York
Saco Police Department	20 Storer Street	Saco	04072	York
OSCO PHARMACY #4560	1364 Main Street	Sanford	04073	York
Sanford Police Department	935 Main Street	Sanford	04073	York
Walmart #1954	1930 Main St	Sanford	04073	York

South Berwick Police Department	1 Farmgate Road	South Berwick	03908	York
Oxford County Sheriff's Office	26 Western Avenue	South Paris	04281	York
Wells Police Department	1563 Post Road	Wells	04090	York
York Hospital Apothecary	15 Hospital Drive	York	03909	York
York Police Department	9 Hannaford Drive	York	03909	York

Appendix C: List of Confirmed Mail-back Distribution Locations

Below is the list of confirmed locations that have agreed to be Mail-back Distribution Locations with Inmar. This list continues to grow as we continue outreach.

Mail-back Location	Mailing Street	Mailing City	Postal Code	County
Elara Caring	22 Cushman Street, Suites 2A & 2B	PORTLAND	04102	Cumberland
Eyecare Medical Group	53 Sewall Street	PORTLAND	04102	Cumberland
Martin's Point Pharmacy	331 Veranda Street	PORTLAND	04103	Cumberland
Mount Desert Police Dept.	21 Sea Street	Northeast Harbor	04662	Hancock
Winter Harbor Police Department	20 School Street	Winter Harbor	04693	Hancock
Camden Public Library	55 Main Street	Camden	04843	Knox
bethel family health center	32 Railroad St	Bethel	04216	Oxford
Bingham Area Health Center	237 Main St	Bingham	04920	Somerset
Penobscot Community Health Care	376 Main Street	Jackman	04945	Somerset
Bingham Area Health Center	237 Main St	Bingham	04920	Somerset
Calais City Building	11 Church Street	Calais	04619	Washington
East Machias Location	893 Main Street	East Machias	04630	Washington
Healthways/RMCL Lubec Location	43 South Lubec Road	Lubec	04652	Washington
Rice Public Library	8 Wentworth Street	Kittery	03904	York
Edith Belle Libby Memorial Library	27 Staples Street	Old Orchard Beach	04064	York
Wells Public Library	1434 Post Rd	Wells	04090	York

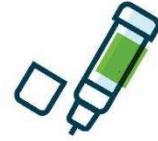
Appendix D: Sample Promotional Material

All promotional and educational material provided here are samples and do not represent the final version to be used in Maine.



Sample Collection Receptacle Prototype and Signage

**MAIL-BACK SERVICES ARE AVAILABLE IN YOUR AREA FOR
PRE-FILLED INJECTORS. FOR MORE INFORMATION, PLEASE CALL
OR VISIT OUR WEBSITE: [SAFEMEDICINEDROP.COM](https://www.safemedicinedrop.com) | 888-371-0717**



Front Door Sticker that can be added to the Collection Receptacle to instruct residents on how to return Pre-filled Injectors.



SAFE DRUG DISPOSAL

*ELIMINACIÓN SEGURA
DE MEDICAMENTOS*

**RETURN YOUR UNUSED
PRESCRIPTION MEDICATIONS HERE**

*DEPOSITE AQUÍ SUS MEDICAMENTOS
RECETADOS NO UTILIZADOS*

Help protect your family, your community and our water supply
Ayude a proteger a su familia, a su comunidad y a nuestro suministro de agua



ACCEPTED

MEDICATIONS IN ANY DOSAGE FORM, EXCEPT FOR THOSE LISTED 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, AND ILLICIT-DRUGS.

Front Panel Drop-door Collection Receptacle Signage



CONSUMER DRUG TAKE-BACK
(PROGRAMA DE ELIMINACIÓN DE MEDICAMENTOS)



ACCEPTED [ACEPTADOS]

Unused or expired prescription medication
(Including Schedule II-V controlled substances)
Medicamentos con receta no consumidos o vencidos (incluidas las sustancias controladas de clasificación II a V)

Unused or expired over-the-counter medication
Medicamentos de venta libre, no consumidos o vencidos

Pet Medication
Medicamentos para mascotas



NOT ACCEPTED [NO ACEPTADOS]

Schedule I controlled substances
Sustancias controladas de clasificación I

Illegal drugs
Drogas ilegales



Thermometers
Termómetros



Needles
Agujas



Aerosol Cans
Latas de aerosoles

Top of Collection Receptacle Sticker



MAIL-BACK SERVICES
ARE AVAILABLE
IN YOUR AREA FOR:
INJECTORS



For more information, please call or visit our website
safemedicinedrop.com • 888-371-0717



This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of Inmar Intelligence or the Producers participating in the Inmar Intelligence Product Stewardship Plan.

Sample Mail-back Services Signage

MAIL-BACK PACKAGE IS FOR

**UNWANTED
OR EXPIRED
MEDICATIONS**



ACCEPTED

Medications in any dosage form, except those listed below, in their original container or sealed bag.*

*If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.

NOT ACCEPTED

Herbal remedies, vitamins, supplements, cosmetics, other personal care products, inhalers, medical devices, batteries, mercury-containing thermometers, sharps, and illicit drugs.

To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the disposal options listed above.

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of Inmar Intelligence or the Producers participating in the Inmar Intelligence Product Stewardship Plan.

Sample Mail-back Insert for Covered Drugs



MAIL-BACK PACKAGE IS FOR
INHALERS



ACCEPTED

Inhalers

NOT ACCEPTED

Unwanted medicines that are not inhalers, herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, sharps, and illicit drugs.

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.

To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the disposal options listed above.

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of Inmar Intelligence or the Producers participating in the Inmar Intelligence Product Stewardship Plan.

Sample Inhaler Mail-back Insert



**MAIL-BACK PACKAGE IS FOR
PRE-FILLED INJECTORS**



ACCEPTED

Pre-filled injectors

NOT ACCEPTED

Unwanted medicines that are not pre-filled injectors, inhalers, herbal remedies, vitamins, supplements, cosmetics, other personal care products, batteries, mercury-containing thermometers, sharps, and illicit drugs.

Note: Injector Mail-Back Packages can only be used for pre-filled injector products and cannot accept other types of items.

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of Inmar Intelligence or the Producers participating in the Inmar Intelligence Product Stewardship Plan.

Sample Pre-filled Injector Mail-back Insert



PROTECT YOUR FAMILIES,
COMMUNITIES, AND THE ENVIRONMENT
**SAFELY DISPOSE
OF UNUSED MEDICINES**

WHAT SHOULD YOU DO WITH YOUR
EXPIRED OR UNWANTED MEDICINES

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

Go to www.safemedicinedrop.com to learn more.



CONVENIENT
KIOSK
LOCATIONS



MAIL-BACK



TAKE-BACK
EVENTS

For more information about the program,
go to www.safemedicinedrop.com
or call 1-888-371-0717



WHY IS SAFE DRUG
DISPOSAL IMPORTANT
FOR PUBLIC HEALTH?

Proper disposal of unused
drugs saves lives and
protects the environment.

- Unused or expired prescription medications can lead to accidental poisoning, overdose, and abuse.
- Unused prescription drugs thrown in the trash can be retrieved and abused or illegally sold.
- Unused drugs that are flushed contaminate the water supply.

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of Inmar Intelligence or the Producers participating in the Inmar Intelligence (Source: U.S. Food and Drug Administration) Product Stewardship Plan

ICT1289 CDTB SC.CC 07162021

Educational Brochure for residents - Front



**PROTECT YOUR FAMILIES,
COMMUNITIES, AND THE ENVIRONMENT**
**SAFELY DISPOSE
OF UNUSED MEDICINES**

BEFORE DISPOSAL CHECK THE PACKAGE

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

DISPOSAL OPTIONS



CONVENIENT KIOSK DROP OFF LOCATIONS

To find drug disposal kiosk drop-off sites in your area, visit www.safemedicatedrop.com.



MAIL-BACK ENVELOPES

Mail-Back Services for Unwanted Medicines. Visit the Mail-Back section of www.safemedicatedrop.com to order a Mail-Back Package.



TAKE-BACK EVENTS

Local Take-Back events offer residents a free and convenient way to dispose of expired or Unwanted Medicines. Visit the Take-Back Events section of the DEA site at takebackday.dea.gov for information on events in your area.

For more information about the program, go to www.safemedicatedrop.com or call 1-888-371-0717

**WHAT CAN YOU
DISPOSE OF IN A
KIOSK OR MAILBACK
ENVELOPE?**



ACCEPTED:

Medications in any dosage form, except for those listed below, in their original container or sealed.*

*If transferring medications to a sealed bag, please be sure to recycle all remaining packaging



NOT ACCEPTED:

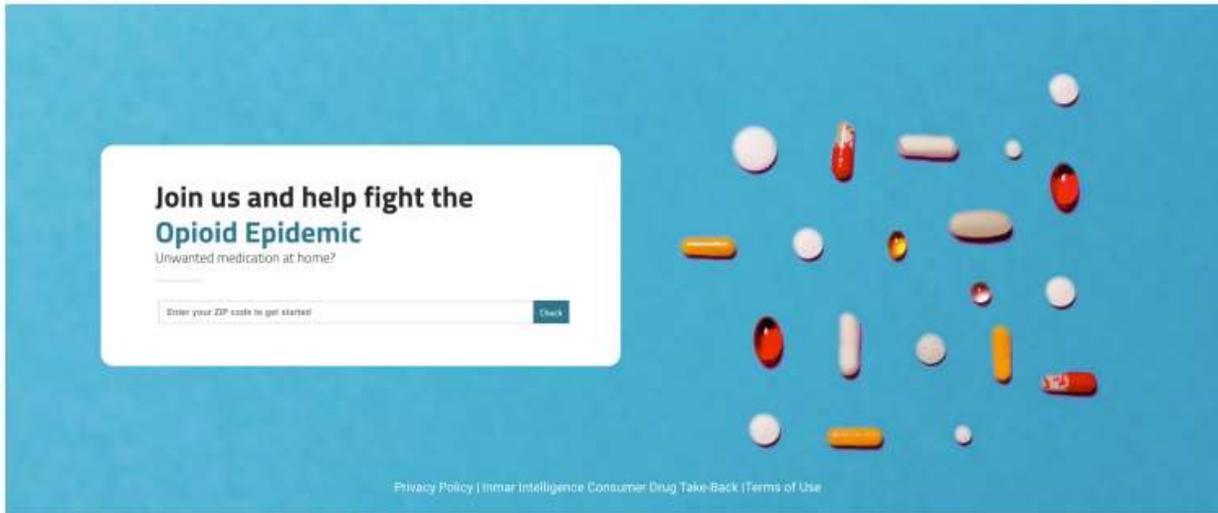
Herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, sharps, and illicit drugs.



This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of Inmar Intelligence or the Producers participating in the Inmar Intelligence (Source: U.S. Food and Drug Administration) Product Stewardship Plan
ICT1289 CDTB SC CC 07162021

Educational Brochure for residents - Back

Sample Website which will be customized upon approval and in coordination with existing Plan Operators.



Join us and help fight the Opioid Epidemic
Unwanted medication at home?

Enter your ZIP code to get started [Check](#)

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About Us

[Home](#) > [About Us](#)



Safe Medicine Drop Consumer Drug Take-Back Program

The opioid epidemic is impacting communities and families across the US – from rural farm towns to highly populated urban areas and across every demographic.

Inmar Intelligence is working to help educate Americans on the dangers of leaving prescription drugs unattended in the home, specifically opioids and benzodiazepines. Disposing of your medication properly makes your community a healthier and safer place.

- **Why** – Unused and expired drugs in the house can be dangerous
- **What** – Dispose them safely and for free at a place convenient to you
- **Who** – SafeMedicineDrop.com – Inmar's consumer take back program

Inmar Intelligence

Inmar Intelligence is a data and tech-enabled services company. We create insights and turn them into actions — to help boards, retailers and healthcare providers do more, save more, connect more and earn more — in the face of changing markets and consumer behaviors.



Mail Back Request

Home > > Massachusetts > Mail Back Request

Choose your package type: **Medicine** | How many packages do you need: **1**

Contact Information

First Name*	Last Name*	Email Address*
Address Line 1*	Address Line 2	
City*	MA	01001

Submit

[Back To Massachusetts](#)



Massachusetts

Home > Locations > Massachusetts

- 
**Kiosks
Nearby**
- 
**Mail Back
Request**
- 
**In Home
Services**
- 
**Check the
Package**
- 
FAQ



Check the Package

Home > ... > Massachusetts > Check the Package

To protect the environment, unwanted medicines should never be flushed down the toilet, put down the sink, or thrown in the trash. Proper disposal of medication helps to reduce the risk of environmental contamination as well as reducing the chance of abuse.

When destroying medication, please make every attempt to protect your Patient Health Information (PHI) and remove any personally identifiable information on medication labels or product packaging before disposing.

For further information about safe medication storage and destruction practices, please see the U.S. Food & Drug Administration information page, Poison Control Center information page and the DEA information page.

FDA information

Poison Control Center

DEA information

Back To Massachusetts

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Kiosks Nearby

Home > ... > Massachusetts > Kiosks Nearby

Locations Listing

0 1001

Select Category Select Radius



APOTHECARE OF CAPE COD Medbank Supplies
Get Directions and Location Information
140 Barnstable Road Barnstable MA 02601

ATTH: PHUONG NGUYEN OUTPATIENT PHARMACY Medbank Supplies
Get Directions and Location Information
5 Orchard Street Northampton MA 01060

BRIGHAM AND WOMAN'S HEALTH CARE CENTER Medbank Supplies
Get Directions and Location Information
20 Park Plaza Falmouth MA 01935

BRIGHAM AND WOMAN'S HOSPITAL OUTPATIENT PHARMACY Medbank Supplies
Get Directions and Location Information
800 Bay Street Lowell Pharmacy Dept. 200 Lowell MA 01851

BRIGHAM AND WOMAN'S HOSPITAL OUTPATIENT PHARMACY Medbank Supplies
Get Directions and Location Information
70 Francis Street, 4th, Outpatient Pharmacy Boston MA 02115

CAPE COD HEALTHCARE PHARMACY AT CDH Medbank Supplies
Get Directions and Location Information
87 Park Street Hyannis MA 02601

CAPE COD HEALTHCARE PHARMACY AT FALMOUTH Medbank Supplies
Get Directions and Location Information



FAQ
Home > FAQ



- What does Inmar Intelligence trace about me?
- Is this service free?
- Do we open the package?
- What does Inmar Intelligence report?
- What does this program offer?

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FAQ
Home > ... > Oregon > FAQ

■ What Can I Put in the Kiosk?

LIFECHECK™ CONSUMER DRUG TAKE-BACK
(PROGRAMA DE ELIMINACIÓN DE MEDICAMENTOS)

1 Pull to open drawer / *Ale para abrir el cajón*
▶
2 Place medications inside / *Coloque los medicamentos adentro*
▶
3 Close the drawer / *Cierre el cajón*

<p>✓ ACCEPTED (ACEPTADOS)</p> <p>Unused or expired prescription medication (including Schedule II-V controlled substances) <i>Medicamentos con receta no consumidos o vencidos (Incluyen las sustancias controladas de clasificación II a V)</i></p> <p>Unused or expired over-the-counter medication <i>Medicamentos de venta libre, no consumidos o vencidos</i></p>	<p>✗ NOT ACCEPTED (NO ACEPTADOS)</p> <p>Schedule I controlled substances <i>Sustancias controladas de clasificación I</i></p> <p>Illegal drugs / <i>Drugs ilegales</i> Pet Medication / <i>Medicamentos para mascotas</i></p> <p> ✗ Theracemide / <i>Teracemida</i> ✗ Needles / <i>Agujas</i> ✗ Animal Care / <i>Cuidado de animales</i> </p>
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EDUCATIONAL MATERIALS: English | Español

Please contact support at : 800-361-9946

Back To Oregon

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Authorized Collector

Home > Authorized Collector



CDTB Steps to Start

[Download Now](#)

CDTB Expanded Serial Tracker

[Download Now](#)

CDTB Visual Instructions

[Download Now](#)

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Contact Us

Home > Contact Us



Get In Touch

For more info about our other consumer drug take back programs please visit:
<https://redisposal.lifeincheck.com/>

In case of queries, please write to us at:
take-back@inmar.com

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Appendix E: Sample Training Material

Authorized Collectors receive training materials that provide detailed instructions on how to manage a Collection Receptacle, including but not limited to, installation (if applicable), safety and security, recognizing capacity, replacing Inner Liners (if applicable), storage of Packaged Containers, the rules and regulations pertaining to these items, and the operation of a Collection Receptacle in general. Sample training material is provided but does not represent final state-specific material. Training materials will be customized upon approval to include, but not limited to, the following changes:

- Removal of LifeInCheck branding
- Inmar's purchasing and installing Collection Receptacles as the default option
- References to Maine and Federal law where applicable
- Clarification of where Authorized Collectors are to ship Packaged Containers
- Inclusion of requirements for every type of potential Authorized Collector and Collection Location
- Single Program Website and Program Toll-free Phone Number which has been coordinated and agreed upon with other approved Program Operators
- Removal of references to other Inmar programs/offers and placing of client logos on Collection Receptacle
- Updating Inner Liner storage requirements to reflect 21 CFR 1317.60(b)
- Removal of content pertaining to weight limits.



FAQS FOR CONSUMER DRUG TAKE-BACK

CONSUMER DRUG TAKE-BACK CLIENT SERVICE TEAM

take-back@inmar.com
(800) 350-0396 Option 6
Mon-Fri 8am - 5pm EST

WHAT TO EXPECT AS A NEW INMAR CONSUMER DRUG TAKE-BACK PROGRAM CLIENT



1. You will receive a “welcome” email from take-back@inmar.com. This email will include “Steps to Start,” a Consumer Drug Take-Back Serialization Tracking Sheet and Receptacle Installation Instructions.



2. You will receive your CDTB receptacle and the collection container supplies via separate shipments within 5-7 business days after returning the Agreement. The collection container supplies should allow you to operate your program for three months.



3. Be sure to install your receptacle in strict accordance with instructions provided to help ensure you remain compliant with the Secure and Responsible Drug Disposal Act.



4. Prepare and install the collection container according to instructions provided. Track the serialized inner liner from receipt to return on the Serialization Tracking Sheet.



5. Return collection container to Inmar. When we receive your second returned container, we will send you another three-month supply of collection containers, liners and zip ties.

FREQUENTLY ASKED QUESTIONS

Note: Two pharmacy personnel are required to install, remove, store and transfer the corrugate collection container.

Consumer Drug Take-Back Client Service Team • Take-Back@inmar.com
(800) 350-0396 Option 6 • Mon - Fri 8am-5pm EST

Installation / Removal

Question	Answer
1 How is the receptacle installed?	The receptacle must be affixed to a wall or bolted to the floor for compliance with the Responsible Disposal Act. Inmar provides a printed guide for easy installation.
2 Where are the keys located for the receptacle?	The keys are located in the top bin of the receptacle. Please note there are two sets of keys provided for each lock. We suggest these duplicates be immediately separated and each set stored in a safe place.
3 If I need replacement keys, where is the lock number located?	Each lock has a lock number printed on the outside of the lock. When ordering replacement keys, you will need to reference the receptacle PC number which is located on the inside left of the drop-door.
4 When should I ship the collection container to Inmar?	Full containers should be shipped immediately after the inner liner is sealed and packaged for shipping. The container is sent to you already prepared with a prepaid FedEx shipping label.
5 How will I know when the collection container is full?	The drop-door has an extended tongue that lowers down into the container when the drop-door is closed. When the product builds to a certain height, the door will have some resistance in operation. This will indicate it is time to change the container.
6 Where is the serial number located?	The inner liner is serialized and the outside of the cardboard shipping container is serialized. These serial numbers match and are packaged as a kit. Therefore, it is critical that the pieces of the kit stay together throughout usage and return shipping.

Installation / Removal Continued

Note: Two pharmacy personnel are required to install, remove, store and transfer the corrugate collection container.

Consumer Drug Take-Back Client Service Team • Take-Back@inmar.com
(800) 350-0396 Option 6 • Mon - Fri 8am-5pm EST

Question	Answer
7 Do I need to wait until the shipping company is on-site for pickup before I change the container?	As the pickup is standard FedEx, most of our customers change the container and then call FedEx. Please be aware that the DEA requires that the sealed container be held in the controlled substances area during the time between liner removal and pickup.
8 When ordering multiple receptacles, is it required that each receptacle be shipped to the location where they will be installed or can they be shipped to a central location and then transported?	The metal receptacles can be shipped to whatever location you choose. The supplies are shipped separately from our facility in Fort Worth, TX. It will be important to notify your staff to be on the lookout for these supplies so they are not inadvertently discarded.
9 How do I order more collection containers?	Upon receipt of your second returned container, Inmar will automatically send you a supply kit for your next three returns. If you need additional supplies, please contact Inmar via the email address or phone number listed below.

Compliance / Regulatory

Question	Answer
10 Is there a statement from the DEA allowing for video monitoring of the receptacle?	There is no statement allowing video surveillance. However, the regulations state that regular monitoring by employees is required. This is the exact text from the Regulation Part 1317 Subpart B (1317.75 2(i)): "(i) At a hospital/clinic: A collection receptacle shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided." VIDEO MONITORING IS NOT ALLOWED IN CALIFORNIA (not part of DEA regulation).
11 Are the items collected considered medical waste?	Household pharmaceuticals collected by take-back programs are not considered medical waste and, therefore, not subject to EPA RCRA rules. The items collected are considered household waste as long as the take-back program rules are followed. That is, no sharps, non-pharmaceuticals, etc. allowed in the receptacles.

Compliance / Regulatory Continued

Note: Two pharmacy personnel are required to install, remove, store and transfer the corrugate collection container.

Consumer Drug Take-Back Client Service Team • Take-Back@inmar.com

(800) 350-0396 Option 6 • Mon - Fri 8am-5pm EST

Question	Answer
<p>12 What should the pharmacist do if they see someone put a “not allowed” substance or item in the receptacle?</p>	<p>Those responsible for monitoring the receptacle should do their best to keep this from occurring. However, the DEA specifies opening the inner liner is not allowed.</p>
<p>13 Can non-controlled medications and controlled substances be placed in the LifeInCheck Consumer Drug Take-Back receptacle?</p>	<p>Yes. Comingling of controlled and non-controlled substances is allowed in the take-back receptacle.</p>
<p>14 If a patient asks the pharmacist to place their medications in the receptacle, can they do so?</p>	<p>With an exception for personnel in a long term care facility, the drug owner or a member of his/her household are the only persons allowed to place items in the take-back receptacle.</p>
<p>15 Where can I find information on DEA regulations?</p>	<p>You can access links for DEA registrants, LTCFs and more here: https://www.deadiversion.usdoj.gov/drug_disposal/index.html.</p>
<p>16 Are there any regulations limiting the number of keys I can replicate for these units?</p>	<p>The DEA does not specify anything regarding the keys, only that the receptacle is secure, monitored and that two staff members are present when it is opened.</p>

Marketing / Promotion

Question	Answer
<p>17 Can the pharmacy add a logo to, or brand, the receptacle?</p>	<p>The magnet provided by Inmar must be placed on the front door of the receptacle. The sides can be used for your logo/brand. If the full-price subscription was purchased, then the pharmacy can place a logo/brand on the sides or front.</p>
<p>18 Are there marketing materials available to help me promote my take-back program?</p>	<p>Please contact Inmar for the latest marketing materials. These include signage, social media copy and images as well as language for press releases and ads.</p>

Note: Two pharmacy personnel are required to install, remove, store and transfer the corrugate collection container.



LIFE **IN** CHECK™
CONSUMER DRUG TAKE-BACK

COLLECTION CONTAINER VISUAL INSTRUCTIONS

CONSTRUCTION, INSTALLATION, REMOVAL AND SHIPPING OF COLLECTION CONTAINER

Questions: Contact Consumer Drug Take-Back Client Service Team
take-back@inmar.com

1-800-350-0396 Option 6, Mon-Fri 8am-5pm EST

KIT CONTENTS

Each shipment contains 3 individually packaged kits with unique components to each kit.

DO NOT rearrange contents between kits.

THE KIT:

- 1 The kit will arrive in a package similar to this.
- 2 The kit will include three numbered and pre-labeled boxes.



Each kit contains one of each of the following items:

- 1 Zip tie
- 2 Absorption pad
- 3 Inner liner
- 4 Numbered and pre-labeled box



IMPORTANT:

For every shipment – serial number on inner liner & serial number on cardboard container **MUST MATCH**.

NOTE: All direct contact with the LifeInCheck Consumer Drug Take-Back Container should be performed by two pharmacy personnel.

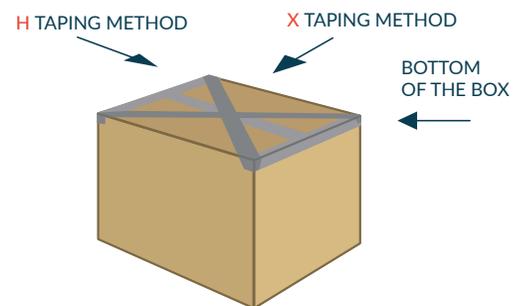
KIT INSTRUCTIONS— INSTALLING A NEW COLLECTION CONTAINER

1 Document the serial number and receipt of each inner liner on the Drug Disposal Serialization Tracking Sheet.



SERIAL NUMBERS	Date Received by (2 Signatures)	Date In Use (2 Signatures)	Date Removed (2 Signatures)	Date Shipped (2 Signatures)
Ex: 32587	4/20/19 <i>John Jones</i>	4/26/19 <i>John Jones</i> <i>Sally Smith</i>	5/26/19 <i>John Jones</i> <i>Sally Smith</i>	5/27/19 <i>John Jones</i> <i>Sally Smith</i>

2 Close and tape the box bottom. Seal the middle seam and both outside seams. Leave no un-taped spaces along the seams. We recommend 1 strip of tape across the bottom seam, 2 strips of tape over the edge seams and 2 strips of tape across the bottom of the box placed diagonally. See illustration to right.



3 Place inner liner into the box and fold excess material at top over box flaps.



KIT INSTRUCTIONS— INSTALLING A NEW COLLECTION CONTAINER

- 4** Tape the zip tie to the inside of the door for later use.



- 5** Place absorbent pad into the installed inner liner.



- 6** Install the lined box (now the “Container”) into the collection kiosk.



KIT INSTRUCTIONS— INSTALLING A NEW COLLECTION CONTAINER

7 Immediately document installation of Container on the Drug Disposal Serialization Tracking Sheet.



INMAR intelligence + LIFE IN CHECK CONSUMER DRUG TAKE-BACK

DRUG DISPOSAL SERIALIZATION TRACKING SHEET - Inner Liner Tracking Form

Serialization Tracking Sheet should be validated by 2 pharmacy employees.

SERIAL NUMBERS	Date Received by (1 Signature)	Date In Use (2 Signatures)	Date Removed (2 Signatures)	Date Shipped (2 Signatures)
Ex: 32587	4/20/19 <i>Jade Jones</i>	4/26/19 <i>Jade Jones</i> <i>Judy Smith</i>	5/26/19 <i>Jade Jones</i> <i>Judy Smith</i>	5/27/19 <i>Jade Jones</i> <i>Judy Smith</i>

8 Lock the bottom door and unlock the drop door at the top of the kiosk to begin drug disposal collection.



9 Store remaining spare kits securely for future use.



10 Use the Drug Disposal Serialization Tracking Sheet to document all “inner liner events.”



INMAR intelligence + LIFE IN CHECK CONSUMER DRUG TAKE-BACK

DRUG DISPOSAL SERIALIZATION TRACKING SHEET - Inner Liner Tracking Form

Serialization Tracking Sheet should be validated by 2 pharmacy employees.

SERIAL NUMBERS	Date Received by (1 Signature)	Date In Use (2 Signatures)	Date Removed (2 Signatures)	Date Shipped (2 Signatures)
Ex: 32587	4/20/19 <i>Jade Jones</i>	4/26/19 <i>Jade Jones</i> <i>Judy Smith</i>	5/26/19 <i>Jade Jones</i> <i>Judy Smith</i>	5/27/19 <i>Jade Jones</i> <i>Judy Smith</i>

NOTE: All direct contact with the LifeInCheck Consumer Drug Take-Back Container should be performed by two pharmacy personnel.

KIT INSTRUCTIONS— REMOVING AND SEALING A FULL COLLECTION CONTAINER

Note: The total weight of the Container ready for shipping may not exceed 66 pounds.

- 1 Unlock and open bottom door.



- 2 Remove full Container from collection kiosk. **DO NOT** sort, count or inventory pharmaceuticals or touch contents of inner liner prior to sealing.



KIT INSTRUCTIONS— REMOVING AND SEALING A FULL COLLECTION CONTAINER

- 3** Immediately seal the inner liner by gathering the top of the liner.
- 4** Bend the gathered portion at the halfway point and fold the top half alongside the bottom half.
- 5** Repeat Step 4 - Again bend the gathered portion at the halfway point and fold the top half alongside the bottom half.

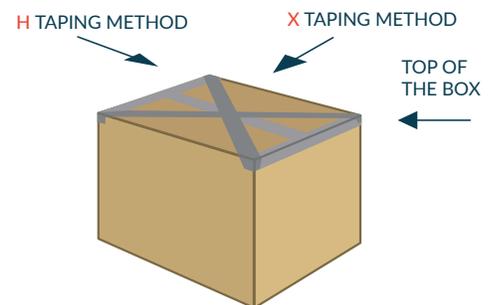


KIT INSTRUCTIONS— REMOVING AND SEALING A FULL COLLECTION CONTAINER

- 6** Cinch and fully tighten the provided zip tie around both halves of the gathered portion of the liner to secure the top.



- 7** Close and tape the box top. Seal the middle seam and both outside seams. Leave no un-taped spaces along the seams. We recommend 1 strip of tape across the top seam, 2 strips of tape over the edge seams and 2 strips of tape across the top of the Container placed diagonally. See illustration to right.



KIT INSTRUCTIONS— REMOVING AND SEALING A FULL COLLECTION CONTAINER

8 Document removal of Container on the Drug Disposal Serialization Tracking Sheet.



SERIAL NUMBERS	Date Received by (1 Signature)	Date In Use (2 Signatures)	Date Removed (2 Signatures)	Date Shipped (2 Signatures)
Ex: 32587	4/20/19 <i>Sally Smith</i>	4/26/19 <i>Sally Smith</i>	5/26/19 <i>Sally Smith</i>	5/27/19 <i>Sally Smith</i>

9 Store the sealed Container in a secure location until shipped. The Container is pre-labeled for shipping. Document the shipping of the Container on the Drug Disposal Serialization Tracking Sheet.



SERIAL NUMBERS	Date Received by (1 Signature)	Date In Use (2 Signatures)	Date Removed (2 Signatures)	Date Shipped (2 Signatures)
Ex: 32587	4/20/19 <i>Sally Smith</i>	4/26/19 <i>Sally Smith</i>	5/26/19 <i>Sally Smith</i>	5/27/19 <i>Sally Smith</i>

PLEASE NOTE:

Your cardboard container is pre-labeled for shipping. This label is pre-paid with FedEx and must not be copied.

Additional charges may apply for non-compliance.

Questions: Contact Consumer Drug Take-Back Client Service Team
take-back@inmar.com

1-800-350-0396 Option 6, Mon-Fri 8am-5pm EST

GETTING STARTED

RECEPTACLE

You will receive your Consumer Drug Take-Back receptacle and your supplies in separate shipments. After unpacking the Consumer Drug Take-Back receptacle, it must be installed according to the “Responsible Disposal Act” Rule which means it must be connected to a wall or the floor ensuring the receptacle is secure. Your receptacle will come pre-drilled in the bottom to make installation easier. Please see the installation instructions included in this email.

Your usage of the Inmar Consumer Drug Take-Back Program indicates your agreement to accept responsibility for following the Federal Guidelines. DEA’s Final Rule, which implements the Secure and Responsible Drug Disposal Act of 2010 (“the Disposal Act”).

SUPPLIES

After completing the proper installation of your Consumer Drug Take-Back receptacle, you should unpack your supplies.

Included are supplies to operate your Consumer Drug Take-Back program for 3 shipments. Upon Inmar’s receipt of your second container (return) shipment, we will automatically send your next 3 shipment supply package so you will always have the necessary supplies on hand. Staged shipping of your supplies alleviates your need to store large supply quantities.

Each shipment contains 3 individually-packaged kits with unique components to each kit. DO NOT rearrange contents between kits.

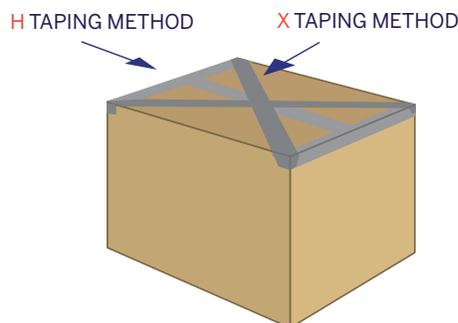
Each kit contains one of each of the following:

- Serialized Inner Liner
- Absorption pad
- Serialization Tracking Sheet (emailed separately)
- Black Zip Tie
- Set of instructions (Single Page)
- Numbered and pre-labeled cardboard box

It is important for you to document receipt of the serialized Inner Liners on your tracking form. To assist, Inmar has provided the Serialization Tracking sheet (Inner Liner Tracking Form). Maintain a copy of the completed Serialization Tracking Sheet in your files for at least 2 years (at the collector’s registered location). Refer to 21 CFR § 1304.04(a).

CONSTRUCTING YOUR INNER CONTAINER

Construct 1 cardboard container applying an appropriate amount of tape to the bottom to ensure safe transportation. Seal the middle seam and both outside seams. Leave no untaped spaces along the seams and no less than 3 inches of tape overhang on each side. We recommend 2 strips of tape across the bottom seam and 2 strips of tape over the edge seams and 2 strips of tape across the bottom of the container placed diagonally. See illustration to right.



NOTE: All direct contact with the unsealed Consumer Drug Take-Back liner must be performed by two pharmacy personnel.

PREPARING YOUR CONTAINER FOR USAGE

1. Place Serialized Inner Liner into the box and fold excess material at top over box flaps. Leave Black Zip Tie taped to the Liner for later use. (When inserting Inner Liner, check to ensure Serial Number on Serialized Inner Liner matches Serial Number on the shipping container.)
2. Place absorbent pad into the installed Liner.
3. Install the lined box (now the "Container") into the Collection Receptacle.
4. Immediately document installation of Container (column 3 of the Serialization Tracking Sheet).
5. Store remaining spare kits securely for future use.
6. Lock bottom door and unlock top door to begin CDTB collection.

NOTE: All direct contact with the unsealed Consumer Drug Take-Back liner must be performed by two pharmacy personnel.

PREPARING YOUR CONTAINER FOR SHIPPING

Note: The total weight of the Container ready for shipping MAY NOT EXCEED 66 POUNDS IN WEIGHT.

1. Unlock and open bottom door.
2. Remove full Container from Collection Receptacle. DO NOT sort, count or inventory pharmaceuticals or touch contents of Liner prior to sealing.
3. Immediately seal the Serialized Inner Liner by gathering the top of the Liner, bending the gathered portion at the halfway point and folding the top half alongside the bottom half. For extra security, bend the gathered portion at the halfway point a 2nd time. While folding Liner, keep Serial Number on Liner visible. Securely cinch the provided Black Zip Tie around both halves of the gathered portion of the Liner to secure the top. Ensure that the zip tie is completely above the exposed end of the top half of the gathered portion and that the zip tie is fully tightened. This will provide an airtight seal at the open end of the Liner to prevent leakage of any trace liquids that may be inside.
4. Close and tape the box top. Seal the middle seam and both outside seams. Leave no untaped spaces along the seams and no less than 3 inches of tape overhang on each side. We recommend 2 strips of tape across the top seam and 2 strips of tape over the edge seams and 2 strips of tape across the top of the container placed diagonally. See illustration of taping method above.
5. Document removal of Container (in column 4 of Serialization Tracking Sheet).
6. Store the sealed Container in a secure location until shipped.

SHIPPING AND RECORD KEEPING

Note: Container is pre-labeled and ready to return. The marking requirements of 49 CFR 172.301(c) do not apply. The container shall not contain any markings to indicate that the contents contain controlled substances.

1. Ship in accordance with the DOT Special Permit. Container comes pre-paid and pre-labeled for shipping.
2. When the Liner is shipped, complete column 5 on the Serialization Tracking Sheet. The completed Serialization Tracking Sheet is a record of Liner Events and should be filed in accordance with DEA guidelines.
3. Maintain a copy of the completed Serialization Tracking Sheet in your files for at least 2 years (at the collector's registered location). Refer to 21 CFR § 1304.04(a).
4. Inmar will maintain your modified Form 41 noting destruction date and time on file and will provide it to you upon request.

QUICK STEPS

TO START

- 01** Install the Consumer Drug Take-Back Receptacle per DEA guidelines.

- 02** Properly tape container at bottom.

- 03** Place Serialized Inner Liner inside with top folded over container flaps.
(When inserting Serialized Inner Liner, check to ensure Serial Number on Inner Liner matches Serial Number on the shipping container.)

- 04** Place absorbent pad in bottom of Serialized Inner Liner.

- 05** Document the installation of the container on the Serialization Tracking Sheet.

- 06** Install container inside Consumer Drug Take-Back receptacle.

- 07** Lock bottom door and unlock top door to begin drug take-back collection.

TO CLOSE

- 01** Open bottom door.

- 02** Remove full container, total weight of container **may not exceed 66lbs in weight.**

- 03** Ensure the Serial Number is visible before using a zip tie to secure Serialized Inner Liner bag top.

- 04** Document the removal of the container on the Serialization Tracking Sheet.

- 05** Properly tape container at top.

- 06** Container is pre-labeled for return shipment.

NOTE: All direct contact with the unsealed Consumer Drug Take-Back liner must be performed by two pharmacy personnel.



DRUG DISPOSAL SERIALIZATION



TRACKING SHEET INNER LINER TRACKING FORM

Serialization Tracking Sheet should be validated by 2 authorized individuals - See (21 CFR §1317.80, 21 CFR §1317.35, 21 CFR §1317.75)

Name of Collection Site	Address of Collection Site	Collection Site DEA #(if applicable):
Size of Liner	Address of Reverse Distributor/Disposal Site	Reverse Distributor/Disposal Site DEA #

1 SERIAL NUMBER (unique)	2 Date Liner Acquired (1 Signature)	3 Date Liner Installed (2 Names & Signatures)		4 Date Removed (2 Names & Signatures)		5 Date Transferred to Storage (2 Names & Signatures)		6 Date Shipped (2 Names & Signatures)	
Ex: 32587	4/26/19 <i>John Jones</i>	4/26/19 John Jones <i>John Jones</i>	Sally Smith <i>Sally Smith</i>	5/26/19 John Jones <i>John Jones</i>	Sally Smith <i>Sally Smith</i>	5/26/19 John Jones <i>John Jones</i>	Sally Smith <i>Sally Smith</i>	5/27/19 John Jones <i>John Jones</i>	Sally Smith <i>Sally Smith</i>

Instructions: Each Inner Liner (container) will bear a permanent, unique identification number to enable tracking on the Inner Liner form. Columns 1 and 2 are to be completed upon receipt of Inner Liner. Column 3 is to be completed upon installation of the container into the collection receptacle. Column 4 is to be completed upon removal of the container from the collection receptacle. Column 5 is to be completed if the Inner Liner is removed from the receptacle.