

**MED-PROJECT REQUEST FOR APPROVAL OF MAIL-BACK
PACKAGE DISPOSAL PROCESS**

Santa Clara County MED-Project
Medication Education & Disposal

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MED-PROJECT REQUEST FOR APPROVAL OF MAIL-BACK PACKAGE DISPOSAL PROCESS

Pursuant to County of Santa Clara Safe Drug Disposal Ordinance (“Ordinance”) § B11-546, Santa Clara County MED-Project LLC (“MED-Project”) requests the County of Santa Clara Consumer and Environmental Protection Agency’s (the “Agency’s”) approval to use the Covanta Indianapolis Inc., Indianapolis Resource Recovery Facility (the “Covanta Facility”), via the Stericycle, Inc., Indianapolis, Indiana Facility (the “Stericycle Facility”), for the disposal of mail-back packages. The Ordinance requires MED-Project to dispose of mail-back packages in accordance with all applicable laws, regulations, and other legal requirements at a hazardous or medical waste facility possessing the required permits and licenses. *See* Ordinance § B11-546(a), (b). As described below, conflicting United States Drug Enforcement Administration (“DEA”) and Resource Conservation and Recovery Act (“RCRA”) or similar state requirements and an inchoate market for mail-back package disposal make disposal of mail-back packages at hazardous and medical waste facilities in compliance with all applicable laws, regulations, and other legal requirements not feasible at this time.

To dispose of mail-back packages under these constraints, MED-Project requests the Agency’s approval for a two-phase process. In phase one, the Stericycle Facility accepts mail-back packages (including any controlled substances therein)¹ and renders them non-retrievable in compliance with DEA requirements. In phase two, the Covanta Facility incinerates any remaining non-retrievable materials from the Stericycle Facility. This two-phase process allows MED-Project to dispose of mail-back packages in compliance with all DEA and RCRA requirements and the Ordinance requirement that such disposal comply with all applicable laws, regulations, and other legal requirements. *See* Ordinance § B11-546(a). Given existing barriers to disposal of mail-back packages in compliance with all applicable laws, regulations, and other legal requirements at a hazardous waste facility, and a limited market for medical waste facility mail-back package disposal, MED-Project’s proposed Stericycle Facility and Covanta Facility two-phase process should be approved.

I. The Stericycle Facility and Covanta Facility Two-Phase Process for the Disposal of Mail-back Packages

Under the MED-Project Product Stewardship Plan’s (the “Plan’s”) mail-back program, differentially-abled or home-bound Santa Clara County residents can request a mail-back envelope by calling the MED-Project call center or using the MED-Project website. When MED-Project receives a request, MED-Project provides residents a pre-addressed, prepaid mail-back envelope. Mail-back services may also be available through certain distribution points. Residents fill the mail-back envelope according to provided instructions and return the mail-back package via United States Postal Service First Class Mail to the Stericycle Facility.² *See* Plan §

¹ The term “mail-back packages” as used in this submission means both the mail-back envelope itself and the contents therein.

² The Stericycle Facility’s mailing address is Stericycle Inc., 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901.

VI.D. MED-Project proposes the following two-phase process for managing and disposing of these mail-back packages.

A. Phase I – The Stericycle Facility Accepts Mail-back Packages from Santa Clara County Residents and Renders Them Non-Retrievable Pursuant to DEA Requirements

Phase one of the proposed two-phase disposal process is the acceptance of mail-back packages at the Stericycle Facility. The Stericycle Facility is a DEA registered collector and complies with all applicable DEA and RCRA requirements.³ As required by 21 C.F.R. §§ 1317.05(c) and 1317.70(a), the Stericycle Facility uses an on-site method to promptly render mail-back packages non-retrievable. Mail-back packages remain sealed throughout the destruction process.

The attached Standard Operating Procedures provides a step-by-step description of the Stericycle Facility mail-back package destruction process. *See* Appendix A. Generally, when the Stericycle Facility receives mail-back packages, Stericycle Environmental Solutions, Inc. (“Stericycle”) scans the mail-back packages’ unique barcode to record receipt and then takes the mail-back packages to a DEA vault for controlled substance storage. Approximately once per week (depending on volume received), Stericycle removes mail-back packages from the DEA vault for destruction and re-scans the mail-back packages to record their unique identifiers and destruction date.

Before destroying the mail-back packages, Stericycle passes all mail-back packages through a metallic screening process necessary to protect Stericycle employee safety and equipment.⁴ Stericycle then loads the mail-back packages into a container no larger than thirty gallons. The contents of this container are fed into the mechanical process. The end product of this mechanical process falls into a steel drum filled with fifteen gallons of an activated carbon-based solution that renders the remaining contents “non-retrievable,” as defined in 21 C.F.R. § 1300.05(b). As needed, Stericycle agitates the fifty-five gallon drum’s contents to ensure all mail-back packages are exposed to the activated carbon-based solution. Through this process, the Stericycle Facility renders all mail-back packages (and any contents therein) non-retrievable.

The end product from the mechanical process is “pea sized.” Stericycle seals these remaining non-retrievable mail-back package materials in the fifty-five gallon drum for secure transportation to the Covanta Facility. Stericycle places a security seal on the trailer transporting the non-retrievable materials and verifies this seal upon arrival at the Covanta Facility. A

³ The Stericycle Facility’s DEA Registration Number is RS0331607; its RCRA Permit Number is INR000110197.

⁴ If metal is found and does not appear consistent with a pharmaceutical product (i.e., an inhaler), the mail-back package is segregated and returned to storage. These segregated mail-back packages are held pending notification to the DEA Field Division Office for further direction regarding the receipt of an envelope that likely contains materials Stericycle did not agree to receive. *See* 21 C.F.R. § 1317.70.

Stericycle witness follows the non-retrievable materials to the Covanta Facility and witnesses their incineration.

B. Phase II – The Covanta Facility Incinerates the Non-Retrievable Materials

Phase-two of MED-Project’s mail-back package destruction process is incineration of the non-retrievable materials from the Stericycle Facility, including mail-back packages and their contents, at the Covanta Facility. As the Covanta Facility is not registered with the DEA, it cannot receive mail-back packages until they are first rendered non-retrievable at the Stericycle Facility. *See* 21 C.F.R. § 1317.70(a).⁵

The Covanta Facility is a permitted large municipal waste combustor.⁶ An “energy-from-waste” facility, the Covanta Facility uses municipal solid waste, like non-retrievable mail-back packages, to generate renewable energy. Steam recovered from incineration at the Covanta Facility helps power the Indianapolis downtown heating loop, which includes Indiana University and Purdue University’s Indianapolis campus. *See* Covanta, Covanta Indianapolis, <https://www.covanta.com/Our-Facilities/Covanta-Indianapolis>.

II. Standards Governing the Approval of MED-Project’s Mail-Back Package Disposal Process

Any disposal of mail-back packages must comply with the overarching Ordinance disposal requirement that “[e]ach Stewardship Plan shall comply with all local, state, and federal laws and regulations applicable to disposal of pharmaceutical waste and controlled substances.” Ordinance § B11-546(a); *see also* Ordinance § B11-553 (“This Chapter shall be construed so as not to conflict with applicable federal or State laws, rules or regulations.”). The Ordinance also provides that “[e]ach Stewardship Plan shall dispose of collected Covered Drugs by incineration at a medical waste or hazardous waste facility. The medical waste or hazardous waste facility must possess all required regulatory permits and licenses. Ordinance § B11-546(b).

⁵ Stericycle is a DEA-registered collector. *See supra* note 3.

⁶ *See* Indiana Department of Environmental Management, Permitted Solid Waste Facilities List (June 6, 2016), <http://www.in.gov/idem/landquality/2412.htm> (Permitted Solid Waste Facilities List, PDF page 25).

III. The Stericycle Facility and Covanta Facility Two-Phase Process Should Be Approved under Ordinance § B11-546.

MED-Project and its vendor, Stericycle, spent months attempting to identify a hazardous waste facility capable of disposing mail-back packages in compliance with all DEA and RCRA requirements. MED-Project and Stericycle also investigated the possibility of mail-back package disposal at medical waste facilities. Both efforts remain ongoing. Unfortunately, this investigation identified barriers to destroying mail-back packages at hazardous or medical waste facilities.

Under DEA regulations, only law enforcement or certain DEA registrants may conduct mail-back programs. *See* 21 C.F.R. § 1317.70(a). MED-Project is only aware of a few hazardous waste facilities that have a DEA registration. Unfortunately, hazardous waste facility RCRA permits typically require the sampling and/or inspection of controlled substances before destruction. Such sampling or inspection is prohibited by DEA regulations, which state that “[u]pon receipt of a mail-back package by a collector conducting a mail-back program, the package shall not be opened . . .” 21 C.F.R. § 1317.70(f). These conflicting DEA and RCRA regulatory regimes make it infeasible for MED-Project to dispose of mail-back packages at a hazardous waste facility in compliance with “all local, state, and federal laws and regulations applicable to disposal of pharmaceutical waste and controlled substances.” Ordinance § B11-546(a). The same barriers exist regarding incineration at a hazardous waste facility “possess[ing] all required regulatory permits and licenses.” Ordinance § B11-546(b).

The market for mail-back package disposal is still developing following the passage of the DEA final rule, Disposal of Controlled Substances, 79 Fed. Reg. 53520, in September 2014. As a result, MED-Project is aware of few (if any) permitted hazardous waste facilities available to destroy mail-back packages with the required permits and licenses at this time. MED-Project is also unaware of medical waste facilities willing and able to destroy Stericycle mail-back packages. MED-Project and Stericycle will continue exploring mail-back package disposal at permitted hazardous or medical waste facilities as such options become available. However, current regulatory and market barriers make it infeasible for MED-Project to dispose of mail-back packages “by incineration at a medical waste or hazardous waste facility. . . . possess[ing] all required regulatory permits and licenses.” Ordinance § B11-546(b).

The only disposal method for mail-back packages complying with all DEA and RCRA requirements and available to MED-Project and Stericycle at this time is the two-phased disposal process proposed above. Satisfying the Ordinance’s overarching requirement that mail-back package disposal comply with all DEA and RCRA requirements, the Agency should approve the disposal of mail-back packages via the Stericycle Facility and Covanta Facility two phase process.⁷

⁷ King County, Washington, recently approved MED-Project’s request to use of this same disposal process for similar reasons. *See* Approved Standard Stewardship Plan, Secure Medicine Return Regulations King County, Washington, <https://kingcountysecuremedicinereturn.org/standard-stewardship-plan-2/> (King County MED-Project Plan § VIII.C.)

IV. Conclusion

For the foregoing reasons, MED-Project's proposed Stericycle Facility and Covanta Facility two-phase process for the disposal of mail-back packages should be approved.

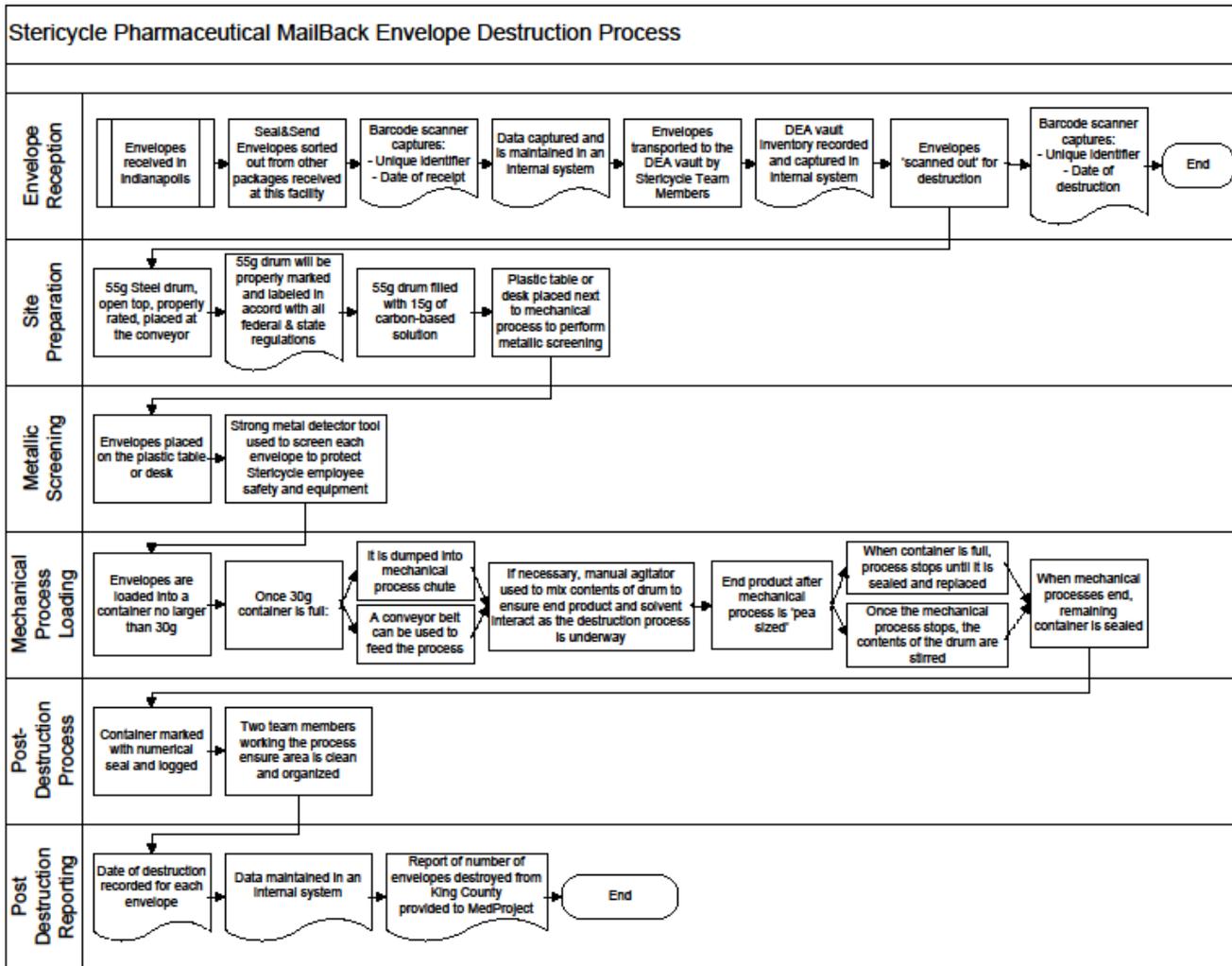
Appendix A: Stericycle Facility Standard Operating Procedures

This SOP explains Stericycle's Seal & Send pharmaceutical Mail Back envelope service.

Scope and Applicability

This SOP applies to all Stericycle Environmental Solutions Team Members who are considered a Subject Matter Expert (SME) for the Seal & Send pharmaceutical Mail Back envelope service.

Process Flow



Procedure

Part 1 Envelope Reception

- 1a) The Seal&Send envelopes shall be received at the Stericycle facility in Indianapolis, via mail, and will be scanned into a tracking spreadsheet. The envelopes shall remain sealed and closed at all times.
 - i) Seal&Send envelopes sorted out from all packages received at the Indianapolis facility.
 - ii) Barcode scanner captures data:
 - Unique identifier
 - Date that the envelope is received
 - iii) Data captured and is maintained in an internal system
- 1b) The envelopes will be transported by Stericycle Team Members to the DEA vault where all controlled substances are held prior to destruction.
 - i) DEA vault inventory recorded and captured in internal system.

Part 2 Envelope Destruction

- 2a) Bi-weekly or as necessary, the envelopes will be “scanned out” for destruction.
 - i) Barcode scanner captures data:
 - Unique identifier
 - Date that the envelope is destroyed
- 2b) Site Preparation
 - i) A new or properly reconditioned 55g steel drum, open top, properly rated for the hazard of the product being used to render the pharmaceuticals non-retrievable, shall be placed at the end of the conveyor where the end product will be accumulated. The 55g steel drum shall be properly marked and labeled in accord with all federal and state regulations.
 - ii) The accumulation drum will be filled with 15 gallons of the carbon-based solution being used to render the pharmaceuticals non-retrievable.
 - iii) A plastic table or desk that contains no metal will be placed next to the mechanical process to perform metallic screening prior to feeding any material into the mechanical process.
- 2c) Metallic Screening
 - i) A team member shall place the envelopes on the plastic table or desk.
 - ii) The team member will use a strong metal detector tool to screen each envelope for metal objects to protect employee safety and company equipment.
- 2d) Mechanical Process Loading

- i) No medicine containers are removed from MailBack envelopes before destruction (and thus no medicines are removed from medicine containers before destruction).
- ii) Envelopes will then be loaded into a small container, no larger than 30 gallons capacity, prior to loading into the mechanical process.
- iii) Once the 30g container is full, it can be dumped into the chute of the mechanical process.
- iv) Alternately, a conveyor belt shall be placed next to the mechanical process to allow envelopes to be placed onto it for conveyance up to the chute above the mechanical process, where they will be dropped by conveyor belt into the mechanical process.
- v) Stericycle team members will monitor the end product material drum, the conveyor line, and monitor for fires. As the mechanical process is underway, if necessary, Stericycle team members will also use a manual agitator to mix the contents of the drum to ensure all product is in contact with the solvent. The end product of envelopes and their contents that go through the mechanical process is pea sized. Any medicine containers (whether containing drugs or not) that residents may have returned inside a MailBack envelope are also destroyed to a pea size.
- vi) The mechanical process shall be stopped if the accumulation drum fills past 9/10ths full.
- vii) Once mechanical process operations stop, the end product material drum contents are stirred to ensure that the solvent mixes with the pharmaceuticals and renders them 'non retrievable'.
- viii) Once the container is filled, mechanical process operations shall stop until the end product material drum is sealed and a replacement container is prepared, following the requirements in the site preparation section of this SOP.

2e) Post-Destruction Process

- i) Once all mechanical process activities have been completed for the shift, the remaining end product material drum shall be closed and sealed according to the container's closure specifications as detailed by the container manufacturer.
- ii) This container shall be marked with a numerical seal and noted on a log present in the area to ensure the container is not reopened.
- iii) After all mechanical process operations are complete, the team members working the mechanical process shall ensure the working area is cleaned up and tidy, so that the next shift operating the mechanical process finds everything in clean and working order.

Part 3 Post-Destruction Reporting

3a) Tracking

- i) Date of destruction is recorded for each envelope in an internal system and linked to its original location by linking the unique tracking number