

# County of Santa Clara

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## 11/30/2023 FINAL NOTICE OF DETERMINATION

Safe Drug Disposal Ordinance  
Ordinance No. NS-517.91 Division B11, Chapter XX

DATE: 11/30/2023

To: Dr. Victoria Travis, National Program Director  
MED-Project, LLC  
4096 Piedmont Avenue Unit 174  
Oakland, CA 94611

FROM: Edgar Nolasco  
Director  
Consumer and Environmental Protection Agency  
County of Santa Clara  
1553 Berger Drive, Bldg 1, Suite 200  
San Jose, CA 95112

SUBJECT: Conditional Approval of Product Stewardship Plan for Unwanted Medicine from Households submitted by MED-Project, LLC ("Plan") dated on July 29, 2023

### DETERMINATION:

Pursuant to Division B11, Chapter XX of the County of Santa Clara Ordinance Code (Ordinance No. NS-517.91) and regulations adopted by the Director of the County of Santa Clara ("County") Consumer and Environmental Protection Agency ("Director") pursuant to Section B11-552(a) of the Ordinance ("Regulations"), the County conditionally approved the proposed Plan submitted on July 29, 2023 as required in Ordinance §B11-543(h) and requests the following corrections to be made:

- 1) The terms, HMR and FMCSA, shall be defined as Hazardous Materials Regulations and Federal Motor Carriers Safety Administration, respectively, in Section III. Plan Definitions.
- 2) All regulatory citations that were published under Volume 79 of Federal Register pages 53520 – 53570 on 9/9/2014 shall be specifically referred in the Plan as Title 21 Code of Federal Regulation (CFR) Sections 1300, 1301, 1304, 1305, 1307, and 1317.

The following examples are acceptable regulatory references:

- a. Title 21 CFR Section 1317.75
- b. T21 CFR §1317.75

3) Requirements from previously issued Notices of Determination (NODs) such as Quarterly Reports of (1) Mail-Back Packages for Unwanted Medication and (2) Service & Maintenance Logs must be incorporated as a separate section in the Plan. The Mail-Back Packages for Unwanted Medicine, Inhaler, and Injector Quarterly Report shall further be broken down to distinguish Mail-back packages for sharps waste from Safe Sharps Disposal Program. Here are examples:

Number of Mail-Back Packages for Unwanted Medicine Received at Destruction Facilities	Number of Mail-Back Packages for Unwanted Medicine Destroyed at Destruction Facilities	Weight of Mail-Back Packages for Unwanted Medicine Destroyed (lbs)
107	64	97

Number of Mail-Back Packages for Inhaler Received at Destruction Facilities	Number of Mail-Back Package for Inhaler Destroyed at Destruction Facilities	Weight of Mail-Back Packages for Inhaler Destroyed (lbs)
37	15	13

Number of Mail-Back Packages for Injector Received at Destruction Facilities	Number of Mail-Back Package for Injector Destroyed at Destruction Facilities	Weight of Mail-Back Packages for Injector Destroyed (lbs)
61	43	58

4) Based on the County’s survey of MED-Project established Unwanted Medicine Drop-Off Kiosks and Mail-Back Distribution Locations in 2022-2023, many Kiosks Drop-Off Site Hosts and Mail-Back Distribution Locations have high employee turnover rates, especially, at chain pharmacies. Employees at these locations had a lack of training in seeking Rapid Response, outreach materials, etc. from MED-Project. The Plan must include more regular training elements (i.e. guide, materials, frequency of training, etc.) to all the employees at the Kiosk Drop-Off Sites and Mail-Back Distribution Locations. A record of the training shall be kept on-site.

The County’s survey also revealed that veterinarian facilities and pet stores did not know about the Ordinance as well as the possibility of participating as Mail-Back Distribution Sites. These two issues must be addressed in the Plan.

5) After the passage of AB1286 (2023), the Plan must address methods to retain currently participating pharmacies and to recruit new pharmacies as Kiosk Drop-Off Sites in the County.

- 6) In Section V. A. 3., discontinuation of Mail-Back Distribution Locations is not recommended after the minimum number of Kiosk Drop-Off Sites are established. Also, the standard Mail-Back Services shall not only be made available to all Residents, including owners of pets, within the County via the Call Center and MED-Project Website.
- 7) In Section V. A. 6., the County will not approve the On-Demand Collection Service Method (“Method”) unless the following items are addressed:
  - a) The County has the right to request and obtain a copy of the service contract between a Kiosk Drop-Off Site and MED-Project under this Method for review.
  - b) Kiosk Drop-Off Site Hosts retain the ability to request off-cycle services from Service Technicians to package the inner liners and prepare for shipment.
  - c) Maintenance Program of Kiosks was not addressed under this Method.
  - d) Rapid Response Support was not addressed under this Method.
  - e) Prior to implementing this Method, MED-Project shall submit to the County an outline of the training for the employees of Kiosk Drop-Off Sites. The training shall include, but not limited to, procedures of kiosk inspection, kiosk cleanliness, maintenance requests, proper inner liner setup and closure, preparation of shipment, and timely removal of the packaged inner liner from the Drop-Off Site. The outline must also specify the frequency of training and details of necessary initial and recurrent trainings.
  - f) Prior to utilizing this Method, each Drop-Off Site shall provide a written confirmation to the County that all staff members have been trained with procedures established in this Method and specify the relevant USDOT Special Permit(s) that each Drop-Off Site shall use as a legal Grantee. This written confirmation shall be submitted to the County at least 15 calendar days prior to participating in this Method.
  - g) Within 15 calendar days after each calendar quarter ends, the Producers represented by MED-Project shall submit a written report to the County listing the number of Kiosk Drop-Off Sites and the name of Kiosk Drop-Off Sites that utilized this Method in the preceding quarter.
  - h) All Kiosk Drop-Off Sites utilizing this Method shall retain an option to revert to the Scheduled Collection Service Method at any time when the Kiosk Drop-Off Sites encounter challenges leading to frequent unavailability of kiosks for public use. MED-Project shall not impose any penalties on those participating Kiosk Drop-Off Sites for exercising this option.

- 8) In Section V. A. 6. c., the last paragraph fails to address the DOT Special Permit compliance of no more than 66-pounds in the first leg of transportation of each sealed inner liner from a Kiosk Drop-Off Site to a reverse distributor. Each inner liner shall be weighed on a small, portal scale to meet DOT Special Permit compliance consistently throughout the required mode of transportation.
- 9) In Section B, the second paragraph shall update the number of Kiosk Drop-Off Sites due to recent closure of several locations.
- 10) In Section V. B. 1., the clause in parenthesis must include the exact language in T21 CFR §1317.75(d)(2), which states:  
  
“(e.g., can be seen from the pharmacy counter)”
- 11) In Section V. B. 3., the last paragraph references “a disposal facility listed in section X.C.” However, Section X. C. does not identify any disposal facility.
- 12) In Section V. C. 2., the last sentence refers to Section XIV.B. However, Section XIV.B. has a title of “California State Board of Pharmacy,” which has no relationship with Procedures at Take-Back Events.
- 13) In Section V. E. 4., “five permanent Mail-Back Distribution Locations in each Supervisorial District” were not identified.
- 14) In Section VI, Education & Promotion Goal was inadequately identified. The social media post has been the same for the last four years. Content must be changed once per month pursuant to Ordinance §§ B11-547(a)(5) and B11-547(e) and Regulation 7. B.
- 15) In Section VII, the same level of training on Patient Privacy was not addressed for the employees under On-Demand Collection Service Method.
- 16) In Section VIII, Appendix I was incorrectly referenced as a sample Call Center flow.
- 17) In Section IX., MED-Project or its Vendors must provide the necessary training and reference documents to the employees of Kiosk Drop-Off Site Hosts and Service Technicians as detailed in the list.  
  
Due to high turnover at chain pharmacies, the frequency of training must also be addressed.
- 18) Section X has incomplete or missing information as required in Ordinance §B11-542(c).
  - a) Appendix H was incorrectly referenced in this Section.

b) Copies of all permits and records of any penalties, violations, or regulatory orders are missing:

- i. Copy of valid DEA Registrations for DEA registered collectors and reverse distributors,
- ii. Applicable Carriers:
  1. USDOT ID#
  2. Hazardous Materials Certificate of Registration issued by USDOT – Pipeline and Hazardous Materials Safety Administration (PHMSA)
  3. Environmental Protection Agency Identification Number (EPA ID #)
  4. Hazardous Waste Transporter Registration ID # issued by CA Department of Toxic Substances Control, if operating in State of California.

Pursuant to California Health & Safety Code Sections 118025 & 118029, all medical waste haulers must be registered as a hazardous waste transporter in California. As a requirement of the hazardous waste transporter pursuant to Section 66263.11 (i.e. DTSC Form 187) of Title 22 California Code of Regulations, each hazardous waste transporter is required to obtain EPA ID number(s).

Also, copies of all Issued Permits and Penalty Record for each Carrier must be attached in the Plan for verification. Hyperlinks to FMCSA – Safety Measurement System (SMS) are not acceptable as a complete submission of the Plan.

iii. Disposal Facilities:

1. Not all Detailed Facility Reports from USEPA Enforcement and Compliance History Online (ECHO) were attached to the Plan.
2. Copies of all Clean Air Act (CAA) Title V Operating Permits are missing.
3. Copies of applicable Resource Conservation and Recovery Act (RCRA) Hazardous Waste Incinerator Permits are missing that must show both permit number and permit expiration date.
4. Copies of applicable Medical Waste Incinerators or Municipal Waste Combustor Operating Permits are missing that must show both permit number and permit expiration date.
5. Hazardous Waste Facilities must also have valid EPA ID.

c) In Subsection A. Vendors, Stericycle, Inc. had an incorrect website.

d) In Subsection B. Reverse Distributors,

- i. Covanta Environmental Solutions, LLC has a missing Suite number at this address. The phone number was also incorrect.
- ii. DEA Registration No RC0322595 belongs to a different registrant's name.

e) In Subsection C. Carriers, pursuant to USDOT public records:

- i. Covanta Environmental Solutions Carriers II, LLC has an incorrect address and has a different phone number.
- ii. USDOT# 327574 does not match Covanta Environmental Solutions dba Chesapeake Waste Solutions, LLC.
- iii. EMS Dispatch, Inc. has a different phone number.
- iv. Sharps Solutions, LLC has incorrect addresses and missing its website.
- v. Tri-State Motor Transit Co. has a different phone number.

f) In Subsection D. Disposal Facilities,

- i. Clean Harbors Aragonite, LLC has an incorrect Title V Operating Permit number.
- ii. Heritage Thermal Services – Ohio has an incorrect Title V Operating Permit number.
- iii. 2320 S. Harding Street, Indianapolis, IN 46221 shows a different registered facility's name. The phone number and Title V Operating Permit number are also incorrect.
- iv. Title V Operating Permit number of Lancaster County Waste to Energy Facility was not able to be verified.
- v. Ross Incineration Services, Inc. has an incorrect EPA ID. Also, there were two penalties on 8/23/2021 and 9/27/2022 verified from ECHO report.
- vi. Stericycle, Inc., Warren, Ohio Facility has an incorrect phone number.

19) In Section XI, the educational and outreach program failed to address unwanted medications for pets. The promotional information shall include explanatory images (i.e. graphics, signage, posters, websites, etc.) and in plain language to promote the proper disposal of unwanted medications for pets at the Drop-Off Kiosks and Mail-Back Distribution Sites pursuant to Ordinance §B11-547(b).

20) In Section XI. B., referencing Section XI.D.1 was incorrect. Required Languages must be available on all educational and outreach materials, not just Call Center.

21) In Section XI. C., the key points of emphasis shall include:

“How to properly dispose of Unwanted Medications for pets.”

22) In Section XI. D., the toll-free telephone number to Call Center and website shall maintain a single system of promotion of providing convenient and equitable access to proper disposal options for all County Residents pursuant to Ordinance §B11-547(a). The current MED-Project's telephone number and website shall immediately be changed to a non-branded, neutral telephone number and non-branded, neutral website for Residents within 30-days after any future Plan Operator(s) (as defined in Ordinance Section B11-540(n)) were either conditionally approved or fully approved to operate stewardship plan(s) to collect and dispose of County Residents' unwanted pharmaceuticals.

The Plan did not address in-person outreach events done in the local community. The County would like to request a minimum of ten (10) tabling events coordinated with the guidance provided by the Director to promote the Plan pursuant to Ordinance Section B11-547(e). Additional in-person outreach may be done at the local communities where the Kiosks were underutilized based on collection data.

All outreach materials must be made durable, weather-proof and must be readily distributed to all interested parties for both indoor and outdoor promotion of the Plan to comply with Ordinance Section B11-547(a)(5). The outreach materials are included, but not limited to, brochures, labels, posters, signages on the collection kiosks, etc.

Quick-Response (QR) code to the approved website shall be included in all outreach materials for quick access pursuant to Ordinance Section B11-547(e).

Pursuant to Ordinance Section B11-547(a)(5), other interested parties shall include, but not limited to, the points of sales locations of pet medication, veterinary facilities, shopping malls, airports, etc. within the County.

23) In Section XII, the methodology of conducting a survey must be specified. Representations in each professional category (i.e. health office administrator, pharmacist, dentist, doctor, nurse, veterinarian, etc.) shall never have a difference of 10% or more from any one professional category in the survey. All representations shall be relatively the same in the survey.

MED-Project conducted a survey in July – August 2022 showed that the sample size was not representative sample when only n = 202 were chosen as Santa Clara County Healthcare Provider Type. The survey result showed a broad range from as low as 1% Long-term care facility (n = 2) to as high as 33% health office administrator (n = 67). Veterinarian (2%; n = 4), doctor (9%; n = 18), nurse (10%; n = 20), and pharmacist (12%; n = 24) were far less than health office administrator representation in the survey. The difference between the highest and lowest professional categories was 32%.

24) In Section XV, Appendix L (Principles of Coordination) was referenced. However, survey was missing to address in Appendix L, which was in conflict of the reference in Section XII.

25) In Section XVI, the list of Kiosk Drop-Off Sites in the Annual Report must be broken down in the following format:

Supervisory District	Unique Identifier	Weight (lbs)	Number of Box Liners Picked Up	Number of Pickups	Rush Services
3	101811	402	10	13	1

Supplemental list of Unique Site ID:

Supervisory District	Unique Identifier	Site Name	Street	City	Zip
3	102585	County Service Center	1555 Berger Drive	San Jose	95122

List of Mail-Back Distribution Locations and Unwanted Medicine collected information:

Supervisory District	Site Name	Street	City	Zip	Mail-Back Packages Distributed	Mail-Back Returned for Destruction	Weight (lbs)
3	County Service Center	1555 Berger Drive	San Jose	95122	17 Inhaler	5 Inhaler	18
					41 Standard	27 Standard	131

26) In both Appendices B and C, the list shall be broken down with a counter and notated with corresponding Supervisory Districts (District) in the following format:

Count	District	Site Name	Street	City	Zip
13	3	CVS Pharmacy 00422	4110 North 1 <sup>st</sup> Street	San Jose	95134
14	2	CVS Pharmacy 03061	3475 McKee Road	San Jose	95127

27) In Appendix C, two CVS Pharmacies were deactivated in October 2023. The list of Participating Kiosk Drop-Off Sites must be updated.

The lack of participation from veterinary facilities served as Mail-Back Distribution Sites does not provide equitable access for Residents with pets as only one facility, The Whole Pet Vet, was listed.



In Santa Clara County, a total of 643 active, licensed veterinarians is listed in California Department of Consumer Affairs database. The County expects every effort to be made to increase the total number of Mail-Back Distribution Sites at veterinary facilities. Veterinary facilities must be recruited and maintained at a minimum of 25% of the total number of Mail-Back Distribution Sites pursuant to Ordinance Section B11-545(b)(1).

Any pet store that sells or dispenses medications to treat pets can be a substitute for veterinary facility as a Mail-Back Distribution Sites at a one-to-one ratio.

For example, when the list contains 100 Mail-Back Distribution Sites, 25 of those sites must be veterinary facilities and/or pet stores selling pet medications.


- 28) In Appendix D, sample signages must include graphics of medications for pets as well as provide information on dangers of pets' exposure to unwanted human medications.
- 29) In Appendix I, all copies of regulatory permits and records of any penalties, violations, or regulatory orders must be updated and reconciled with Section X of the Plan.

Pursuant to Ordinance Section B11-543, MED-Project shall prepare a revised Plan addressing and correcting these identified deficiencies no later than 60 days after the date of this official NOD was issued.

Please address any questions regarding this Notice to:

Billy Puk  
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Sincerely,

DocuSigned by:  
  
9A7F52EB1925473...

Edgar Nolasco  
Director - Consumer and Environmental Protection Agency