



NOTICE OF DETERMINATION
Product Stewardship Plan Review
San Mateo County Ordinance No. 04736, Safe Medicine Disposal Ordinance

Date: July 11, 2023
Plan Operator: Med-Project LLC (Med-Project)
Dr. Victoria Travis, National Program Director
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Determination:

Pursuant County Ordinance No. 04736 ("Ordinance") for Safe Medicine Disposal, the Director of San Mateo County Environmental Health Services ("Department") approves Med-Project's four-year review of their Stewardship Plan for Safe Medicine Disposal submitted on April 19, 2023, subject to conditions.

Background:

On January 16, 2020, the Department issued a Notice of Determination to approve Med-Project's Stewardship Plan dated April 14, 2019.

On April 14, 2023, Med-Project submitted an updated Stewardship Plan ("Updated Plan") as required in Section 4.116.030(e)(5) of the Ordinance. The Updated Plan was published for a 30-day public comment, and one comment was received.

On May 31, 2023, the Director of the Division issued the Guidance for the Implementation of a Single System of Promotion and Program Goals ("Guidance Document") as authorized in sections 4.116.060(c) and 4.116.140 (b) of the Ordinance.

Plan Evaluation:

- 1) **Requirement:** Drop-off sites shall be geographically distributed to provide reasonable, convenient, and equitable access pursuant to Section 4.116.050 (b)(1) of the Ordinance. **Evaluation:** Although Med-Project has established at least one drop-off site for every 20,000 County residents, these are not geographically distributed, causing some areas to be underserved. Section V.A.4 and V.C of the Updated Plan fails to address how Med-Project will provide equitable access.



Condition #1: At a minimum, the Stewardship Plans must implement joint collection events at least annually in areas with no access to drop-off boxes within five miles in accordance with Section III.2.c of the Guidance Document.

- 2) Requirement: Stewardship Plans must include how entities participating in the Stewardship Plan will operate and comply with all applicable federal and state laws, rules, and regulations pursuant to Section 4.116.040 (d) & 4.116.050 (b)(4) of the Ordinance. In addition, the Guidance Document in Section III.2.c states that Stewardship Organizations must routinely verify compliance with laws and regulations and the timeframes and procedures for the service of the kiosks.

Evaluation: Section V.B.1 of the Updated Plan states that Med-Project's Kiosk Drop-off sites will be "able to meet all applicable laws, regulations, and other legal requirements within three months of their offer to participate." It is unclear if this language infers that there may be a period when the sites will be out of compliance.

Section V.B.2 and Section V.B.6 include a maintenance program for the drop-off site kiosk and procedures for kiosk service, respectively, which are under the responsibility of the two On-Demand Collection Service Kiosks Drop-Off Site employees or a Service Technician depending on the type of collection service. However, these procedures do not include how Med-Project will routinely verify compliance with laws and regulations and timeframes and procedures for the service of the kiosks.

Condition #2: The Stewardship Plan must clearly state that entities participating in the Stewardship Plan will operate and comply with all applicable federal and state laws, rules, and regulations and describe the procedures to accomplish this. These procedures must include routine verifications regardless of the type of Collection Service, as described in Section III.2.c of the Guidance Document, and the Department shall have access to these records.

- 3) Requirement: The Director provided guidance to Stewardship Organizations on the type of service to drop-off sites for collecting, replacing, and shipping containers with unwanted covered drugs; this is included in the Guidance Document Section III.2.

Evaluation: Section V.B.5 of the Updated Plan describes the two types of collection methods: Scheduled Collection Service and On-Demand Collection Service. Although the Department will allow both services, Med-Project shall use the Scheduled Collection service as a default service. And the collector may be allowed to self-service (On-Demand service) only if they can provide more expedited service, comply with applicable laws and regulations, and receives required training from the Stewardship Organization.

Also, Section V.B.2 of the Updates Plan states that for unplanned events vendor will typically respond to a service location within two to three business days of the event, which is inconsistent with the language on the Guidance Document, where if the collector requires an expedited service due to the kiosk filling up, it must be provided within 48 hours.

Condition #3: Med-Project must implement the procedures from Section III.2 of the Guidance Document.

- 4) Requirement: Covered drugs under the stewardship plan must be disposed of at a permitted hazardous waste disposal facility pursuant to Section 4.116.070 (a) of the Ordinance.

Evaluation: Med-Project requested approval to use municipal solid waste combustors to dispose of unwanted medicine pursuant to Section 4.116.070 (b)-(c) of the Ordinance.

The Updated Plan provided information on how using a permitted hazardous waste disposal facility presents challenges due to cost and logistics. Still, it did not describe why using a hazardous waste disposal facility would be "infeasible," as required in Section 4.116.070 (b) of the Ordinance. Moreover, the data presented to discuss the logistics consideration centralized the shipments in Ohio, providing a disadvantage for facilities located between San Mateo County and Ohio. No alternative analysis was provided to use the Warren, Ohio facility. Therefore, authorization under this Section 4.116.070 (b) is denied.

The Updated Plan included discussion and documentation to claim that municipal waste combustors provide superior environmental and human health protection or equivalent at a lesser cost to meet the requirements in Section 4.116.070 (c) of the Ordinance. However, the information was not complete in the following aspects:

- **Worker health and safety:** The ERM report in Appendix C only included information for some of the permitted hazardous disposal sites and did not include the type of incident. Limited information does not allow the Department to evaluate this criterion.
- **Reduction or elimination of air, water, or land emissions contributing to persistent, bio-accumulative, and toxic (PBT) pollution:** Given the lack of more extensive requirements for Municipal Waste Combustors or Hospital Medical Infectious Waste Incinerators, the more stringent permit limits provide measurable metrics for some PBTs but no comparable metrics for the other PBTs. Provide more comparable data.
- **Costs:** The ERM report in Appendix C references costs for a medical waste incinerator versus hazardous waste incineration. Med-Project requests approval for a municipal waste combustor, not a medical waste incinerator.

Therefore, authorization under this Section 4.116.070 (c) is denied.

Condition #4: Med-Project must continue to use a permitted hazardous waste disposal facility to dispose of the unwanted medicine. Additional information shall be submitted for further consideration for approval of municipal waste combustors.

- 5) Requirement: All Stewardship Plans shall develop clear, standardized instructions for County residents on the use of collector bins and a readily recognizable, consistent design of collection bins, pursuant to Section 4.116.060 (a)(2) of the Ordinance

Evaluation: The Updated Plan has conflicting information on the disposal of inhalers. Section V.E.3 states that inhalers will be received via mail-back services, but graphics in Appendix B for Sample Kiosk signage depicts an inhaler.

Condition #5: Med-Project must update the kiosk signs to include pictures of only those items allowed to be dropped into kiosks.

- 6) Requirement: A single system of promotion must promote the Stewardship Plans so that collection options for Covered Drugs are widely understood by County residents, pharmacists, retailers of Covered Drugs, and health care practitioners, including doctors and other prescribers, veterinarians, and veterinary hospitals, and promote the safe storage of Covered Drugs by County residents, pursuant Section 4.116.060 (a)(1) of the Ordinance. Educational and outreach materials must be provided to pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to County residents, pursuant to Section 4.116.060 (a)(3) of the Ordinance.

Evaluation: Section XI.C.3 of the Updated Plan stated that educational materials would be provided to the kiosks drop-off sites, potential third partners, and community organizations upon request. The Ordinance requires that educational and outreach material must be provided; therefore, Med-Project fails to meet the requirements.

Condition #6: Med-Project must provide educational and promotional material to pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to County residents in accordance with the requirements of the Ordinance and the guidance provided by the Director in Section IV.2 of the Guidance Document.

- 7) Requirement: All Stewardship Plans shall coordinate with each other and develop a single promotion system, pursuant to Section 4.116.060 of the Ordinance.
Evaluation: Section XVI of the Updated Plan states that Med-Project will coordinate with other approved Stewardship Plans but does not include specific procedures.
Condition #7: Med-Project must implement a single system of promotion in accordance with the requirements of the Ordinance and the guidance provided by the Director in Section IV of the Guidance Document.

In addition to the conditions listed above, VI. Plan and Collection Goals and Section IX. Training must align with the language in Section III of the Guidance Document, published after the Updated Plan was submitted to the Division.

The conditional approval of the Plan is contingent upon Med-Project providing a letter within 10 calendar days of the issuance of this Notice committing to revise and resubmit the Stewardship Plan to meet conditions on this Notice of Determination and to include guidance provided by the Director in the Guidance for the Implementation of a Single System of Promotion and Program Goals published on May 31, 2023.

The revised Stewardship Plan must be submitted to the Department within 90 days of the issuance of this Notice.

Failure to comply with all conditions may result in the Department's rejection of the Plan and the Producers represented by Med-Project being out of compliance with the Ordinance and subject to the Ordinance's enforcement provisions.

If you have any questions, please contact Liliana Mejia, Program Supervisor, at (650) 339-9791, or lmejia@smcgov.org.

Sincerely,

Heather Forshey
Director, Environmental Health Services

Cc: Liliana Mejia, Program Supervisor, San Mateo County Environmental Health Services