



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

Date: December 21, 2023
Plan Operator: Med-Project LLC (Med-Project)
Dr. Victoria Travis, National Program Director
4096 Piedmont Ave., Unit 174, Oakland, CA 94611
victoria@med-project.org

Determination:

Pursuant to the County Ordinance No. 04736 ("Ordinance") for Safe Medicine Disposal, the Director of the San Mateo County Environmental Health Services ("Department") maintains the approval of Med-Project's four-year review of their Stewardship Plan for Safe Medicine Disposal submitted on September 18, 2023, subject to conditions.

Background:

On January 16, 2020, the Department approved Med-Project's Stewardship Plan, dated April 15, 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. On July 11, 2023, the Department issued a "Notice of Determination" to approve the Updated Plan subject to conditions.

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.

On August 10, 2023, MED-Project submitted to the Department a response to the conditions the Department included in the Notice of Determination sent to MED-Project on July 11, 2023. And on September 18, 2023, the Department received the resubmission of the Revised Stewardship Plan ("Revised Plan").

On October 09, 2023, the Department received a "Notice of Addition of Mail-Back Distribution Locations."



Plan Evaluation:

The Department has evaluated the Revised Plan for compliance with the conditions of the Notice of Determination issued on July 11, 2023, and the Ordinance. While some conditions have been resolved, others remain as conditions of this Second Notice of Determination. The following is the Department's determination:

- **Response to Condition #1:** Section 4.116.050(b)(1) of the Ordinance requires collection events and/or mail-back services when the convenience goals are not met, which includes a minimum number of drop-off sites geographically distributed to provide reasonable and equitable access. The Revised Plan meets the minimum number of drop-off sites, but these have not been geographically distributed to provide equitable access.

For example, District 3 lacked drop-off sites for the communities in the South of the district, such as the Towns of Portola Valley, Woodside, El Granada, and Pescadero, and only one Mail-Back Distribution Location was set up in Portola Valley. The Revised Plan on page 46 describes that "MED-Project operates kiosks within five miles of all incorporated cities." However, due to the geography of these areas, accessing the nearest drop-off site for these communities means a greater distance than communities in other more populated areas of the County, which becomes unequal.

The "Notice of Addition of Mail-Back Distribution Locations" was received on October 09, 2023; MED-Project Notified the Department of the addition of the following Mail-back sites:

Site Name	Site Type	Site Address
US Post Office San Gregorio	Mail-Back Distribution Location	7615 Stage Road, San Gregorio, CA 94074
Coastside Fire Protection District Station 44	Mail-Back Distribution Location	501 Stetson Street, Moss Beach, CA 94038
Coastside Fire Protection District Station 40	Mail-Back Distribution Location	1191 Main Street, Half Moon Bay, CA 94019
Coastside Fire Protection District Station 41	Mail-Back Distribution Location	555 Obispo Road, El Granada, CA 94018
San Mateo County Fire Skylonda Station 58	Mail-Back Distribution Location	17290 Skyline Boulevard, Woodside, CA 94062
Kings Mountain Fire Department	Mail-Back Distribution Location	13889 Skyline Boulevard, Woodside, CA 94062
La Honda Fire Brigade	Mail-Back Distribution Location	8945 La Honda Road, La Honda, CA 94020
San Mateo County Fire Department-Loma Mar	Mail-Back Distribution Location	8879 Pescadero Creek Road, Pescadero, CA 94021
San Mateo County Fire Station 59	Mail-Back Distribution Location	1200 Pescadero Creek Road, Pescadero, CA 94060

The Department has considered the additional mail-back distribution locations noted above and determined that the Revised Plan meets the requirements of Section 4.116.050 (b)(1) of the Ordinance. Condition #1 was met.

- **Response to Condition #2:** The Revised Plan includes policies and procedures to be followed by persons handling unwanted covered drugs collected under the Stewardship Plan, who will operate under and comply with all applicable federal and state laws, rules, and guidelines. MED-Project will verify compliance through periodic inspection. Condition #2 was met.
- **Response to Condition #3:** The collector may be allowed to self-serve the drop-off sites, referred to as On-Demand service, for the collection, replacement, and shipment of containers with unwanted covered drugs if they can provide a more expedited service than the Scheduled Collection Service, comply with applicable law and regulations, and receives required training from the Stewardship Organization, as noted on the Guidance Document. Otherwise, the Stewardship Organization must set up a scheduled collection. MED-Project must continue communicating these options to the drop-off site representatives.

Section IX. of the Revised Plan discusses the training for vendors and drop-off Sites. It states that "Operational Procedures, including training, are the responsibility of the Kiosk Drop-Off Site Host. MED-Project supports training if agreed to with the kiosk Drop-Off Site Host." The type of support that MED-Project will provide is not specified.

MED-Project must make available to drop-off site staff training required for their roles and responsibilities; this includes training required by laws and regulations and training on operational procedures. The Stewardship Plans shall not overburden the host sites that participate voluntarily with the full responsibility for meeting regulatory requirements, especially if specific training is required solely because of the duties related to collecting unwanted covered drugs. For example, if sites choose the On-Demand service, MED-Project must provide free-of-charge access to the training detailed in 49 CFR 172.704 Subpart H.

The Revised Plan states that MED-Project will provide a 48-hour expedited service when a kiosk fills up.

Condition #3 has not been met. MED-Project's Stewardship Plan must specify the Stewardship Organization's and the drop-off site host's responsibilities for training based on the collection method, as described in Section III.2. of the Guidance Document.

- **Response to Condition #4:** The Department approved MED-Project's initial Stewardship Plan on January 16, 2020, which included approving Medical Waste Incinerators and Municipal Combustors to dispose of unwanted covered drugs. This approval was provided per Section 4.116.070(b).

On April 1, 2021, MED-Project requested the approval of "Additional Permitted Hazardous Waste Incinerators." This letter also included a revised Appendix X. Vendor, Transporter, and Disposal Facility Information of the Stewardship Plan, which differed from the list approved on January 16, 2020. Please note that a change of disposal sites is considered a substantial change to the Stewardship Plan per Section 4.116.120. Due to this discrepancy, the Department approved only the two hazardous waste incinerators on request, Heritage Thermal Ohio and Ross Incineration Services, on December 9, 2021.

Appendix X of the Revised Plan includes two Medical Waste Incinerators, Stericycle, Inc., Warren, Ohio, and Curtis Bay Energy, LP, as disposal facilities. Although these two Medical Waste Incinerators were approved on January 16, 2020, the basis for approval under Section 4.116.070(c) of the Ordinance must also be updated to confirm continued compliance with the conditions for approval. The Notice of Determination, dated July 11, 2023, includes comments on the required information.

MED-Project is allowed to use the Disposal Facilities listed in Appendix X of the Revised Plan and must submit updated information required in Section 4.116.070(c) of the Ordinance to maintain approval for the four-year Stewardship Plan update. Condition #4 was not met.

- **Response to Condition #5:** Condition #5 was met.
- **Response to Condition #6:** The Ordinance requires that educational "materials must be provided to Pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to County residents." MED-Project proposes to provide material only when requested by these entities. This method puts the burden on these businesses and their staff. This method also promotes passive outreach and will reduce the amount of material available for the residents.

Condition #6 was not met. MED-Project must directly provide outreach material to pharmacies, healthcare facilities, veterinary facilities, and other interested parties. Businesses shall be encouraged to display and keep this material visible and available for their customers. The Guidance Document further explains different printed material options that could be more suitable for each business. MED-Project shall ensure outreach material is available through periodic checks and respond to requests for replenishment.

- **Response to Condition #7:** Section XVI of the Revised Plan stated that the "single system of promotion will be implemented pursuant to the Terms of Coordination agreed to by MED-Project and the other approved program operators on September 7, 2023".

The Terms of Coordination included in Appendix H demonstrate coordination with other approved Stewardship Plans. Please note that the language on this document does not satisfy the requirements in the Ordinance nor aligns with the Guidance Document for a Single System of Promotion alone but in conjunction with the language in the Stewardship Plan.

Condition #7 has been met.

In addition to the conditions listed above, MED-Project was required to revise the plan goals per the guidance provided by the Department. Section VI of the Revised Plan, "Plan and Collection Goals," fails to include the goal described in section III. 4. B of the Guidance Document.

In conclusion, Conditions #1, #2, #5, and #7 from the Notice of the Determination dated July 11, 2023. Conditions #3, #4, and #6 and the plan goals failed to meet the Ordinance requirements and align with the Department's Guidance.

The conditional approval of the Plan is contingent upon Med-Project providing a letter within 15 calendar days of the issuance of this Notice committing to implement the Revised Stewardship Plan per the conditions listed above and to revise and resubmit the Plan.

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.

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Sincerely,

Charles Ice

Director, Environmental Health Services

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