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

Date: October 21, 2022

Plan Operator: Inmar Intelligence

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Determination:

Pursuant County Ordinance No. 04736 ("Ordinance") for Safe Medicine Disposal, the Director of the San Mateo County Environmental Health Division ("Division") approves Inmar Intelligence's ("Inmar") "San Mateo County Environmental Health Division, Safe Drug Disposal, Stewardship Plan" ("Plan") submitted on September 9, 2022, subject to conditions.

Plan Evaluation:

- Requirement: The Stewardship Plan for the collection, transportation, and disposal of Unwanted Covered Drugs shall meet the requirements of County Ordinance No. 04736.
 Evaluation: Section I. Introduction of the Plan cites Ordinance No. 4302. This does not pertain to the Safe Medicine Disposal Program.
 Condition #1: Inmar must revise the language in Section I of the Plan and delete the reference to Ordinance No. 4302.
- 2) <u>Requirement</u>: A Producer, either individually or jointly, shall pay all administrative and operational costs and fees associated with its Stewardship Plan, pursuant to **Section** 4.116.030(e)(6). In addition, a Person may offer to serve as a Collector voluntarily or may agree to serve as a Collector in exchange for incentives or payment offered by a Producer, group of Producers, or Stewardship Organization, pursuant to **Section 4.116.050 (b)(1)** of the Ordinance

<u>Evaluation</u>: Page 57 of the Plan includes instructions for drop-off site operators that indicate that "additional charges may apply for non-compliance." This implies that drop-off sites are charged a fee. Moreover, they could be charged penalties. This is not in compliance with the sections listed above, and it could deter the participation of collectors.

Condition #2: Inmar must revise the language and confirm that Section 4.116.030(e)(6). 4.116.050 (b)(1) of the Ordinance will be executed.



3) <u>Requirement</u>: The Stewardship must describe how any periodic collection events will be scheduled and located. Also, It must include the description of the collection service shall include a list of retail pharmacies and Law Enforcement Agencies (LEAs) contacted by the plan and a list of all collectors who offered to participate, pursuant to **Section 4.116.040 (b)** of the Ordinance.

Evaluation:

- The Plan does not describe periodic collection events and how these will be scheduled and located.
- The Plan includes a list of LEAs that currently do not participate as collectors with MED-Project and a list of potential drop-off locations (Appendix A-2), but it does not specify if these locations have already been contacted nor if they have offered to participate as collectors.

Condition #3: Inmar must revise the Plan to include the following:

- a) A description of how any periodic collection events will be scheduled and located,
- b) A description of procedures to contact retail pharmacies and LEAs to offer the opportunity to participate as collectors,
- c) A list of retail pharmacies and LEAs contacted by the Plan and a list of all collectors who offered to participate.
- 4) <u>Requirement</u>: The Plan should include identification of and contact information for collectors, transporters, and waste disposal facilities to be used, pursuant to **Section 4.116.040 (c)** of the Ordinance.

<u>Evaluation</u>: The Plan's information for collectors, transporters, and waste disposal facilities in Section IV includes incorrect information:

- The DEA registration number of 123 Compliant Logistics, LLC. is incorrect. It should be R90571364 based on the copy of the registration,
- Veolia Port Arthur is misspelled,
- The Plan didn't include a copy of the DEA registration certificate for Indianapolis Resource Recovery Facility and Covanta Manheim to confirm that these are authorized as reverse distributors.

Condition #4: Inmar must revise the Plan to include the following:

- a) The correct DEA registration number of 123 Compliant Logistics, LLC., and the spelling of Veolia Port Arthur,
- b) Copies of the DEA registration certificate for Indianapolis Resource Recovery Facility and Covanta Manheim.
- 5) Requirement: The Plan should include a description of how all collectors, transporters, and waste disposal facilities used will ensure that the collected Unwanted Covered Drugs are safely and securely tracked from collection through final disposal and how all entities participating in the Stewardship Plan will operate under and comply with all applicable federal and state laws, rules and guidelines, including but not limited to those of the United States Drug Enforcement Administration, and how any Pharmacy collection site will operate under applicable rules and guidelines of the State of California Board of Pharmacy, pursuant **Section 4.116.040 (d)** of the Ordinance.

Evaluation:

- The Plan does not describe the role of the Indianapolis Resource Recovery facility and Covanta Manheim facility, both listed in the table in Section IV of the Plan. Also, the

- Plan does not reference if these companies are alternative reverse distributor companies or if the three reverse distributors will operate simultaneously,
- The Plan does not mention that collectors, transporters, and waste disposal facilities besides 123 Compliant Logistics, Inc, TransChem Environmental, and FedEx will operate under and comply with all applicable federal and state laws, rules and guidelines,
- The Plan does not describe procedures in the event of an emergency to ensure safe operations,
- The Plan does not specify a maximum number of business days between the inner liner packing and the carrier pick-up to avoid overaccumulation at the drop-off site,
- The procedures for requesting maintenance do not specify the turnaround time to resolve issues. Any request should be resolved within three business days. In addition, the Plan does not describe a system to track requests received for appropriate response.

Condition #5: Inmar must revise the Plan to include the following:

- a) A description of the role of the Indianapolis Resource Recovery Facility and Covanta Manheim,
- b) A statement that all collectors, transporters, and waste disposal facilities will operate under and comply with all applicable federal and state laws, rules, and guidelines,
- c) Procedures in case of emergencies,
- d) Procedures to resolve maintenance requests within three business days.
- e) Inmar will track requests received through the public or drop-off sites, indicating the nature of the request and the response resolution time. These records will be included in the Annual Report as part of the records of safety and security problems and outreach activities.
- 6) Requirement: The Plan shall provide convenient and equitable access for County residents in all Supervisorial Districts trough drop-off sites. The system of drop-off sites shall provide at least one drop-off site for every 20,000 County residents in each Supervisorial District, geographically distributed to provide reasonably convenient and equitable access, but at no time shall there be less than five drop-off sites per Supervisorial District. If the service convenience goal in this subsection cannot be achieved due to a lack of drop-off sites at pharmacies, law enforcement, agencies, or other qualified collectors in each supervisorial district, then those areas shall be served through periodic collection events and/or mail-back services, pursuant to **Section 4.116.050 (b)(1)** of the Ordinance. Evaluation:
 - The Plan cites the "County of San Mateo 2017-2019 Profile from the City Manager's Office" as a source for the population data, but it does provide the city's name in reference or the sources.
 - The Plan describes mail-back distribution locations to supplement service in any underserved area by collection sites. In addition, Appendix A-1 includes a list of five confirmed drop-off sites, and Appendix A-3 includes twenty-three confirmed mail-back sites. The Ordinance allows periodic collection events and/or mail-back services only if the service convenience goal cannot be achieved due to a lack of drop-off sites at pharmacies, law enforcement, agencies, or other qualified collectors in each supervisorial district. The Plan does not present evidence of a lack of drop-off sites to opt for mail-back locations.
 - One confirmed mail-back distribution listed in sites is San Mateo MC O/P Pharmacy. However, there is an existing Med-Project drop-off site. Duplication of services at the

- same location will not benefit the goal of providing convenient and equitable access to the program for County residents. Therefore, Inmar should not set up drop-off boxes or mail-back distribution at locations already serviced by Med-Project to meet their service convenience goals.
- The Plan states that "the quantity of drop-off sites required will be evaluated and adjusted as Inmar consults with the Department for more detailed information on population centers and areas of need." The Ordinance describes the minimum number of drop-off sites in Section 4.116.050 (b)(1). Inmar should prioritize positioning drop-off sites in areas not served by Med-Project.

<u>Condition #6</u>: Inmar must revise the Plan to include the following:

- a) Provide the source of the "County of San Mateo 2017-2019 Profile from the City Manager's Office",
- b) Describe the efforts to contact and enroll collectors before the County considers any proposed drop-off sites or collection events for approval,
- c) Inmar will not approach sites already serviced by MED-Project until they meet their minimum convenience goals,
- d) Inmar will prioritize drop-off sites in areas not served by Med-Project.
- e) Delete the statement, "the quantity of drop-off sites required will be evaluated and adjusted as Inmar consults with the Department for more detailed information on population centers and areas of need."
- 7) <u>Requirement</u>: All stewardship plans shall jointly operate a drop-off site within each County-owned pharmacy, pursuant to **Section 4.116.050 (c)** of the Ordinance. Evaluation:
 - The Plan proposes to "operate a drop-off site within each county-owned pharmacy, either independently or in collaboration with other stewardship plans." MED-Project operates a drop-off box at the only County-owned pharmacy. Therefore, Inmar must coordinate with MED-Project and any future Stewardship Plan on jointly operating this drop-off site. Alternatively, this site can be operated by one stewardship plan upon agreement.

<u>Condition #7</u>: Inmar must revise the Plan to describe how the stewardship plans will jointly operate a drop-off site at the County-owned pharmacy.

8) <u>Requirement</u>: If more than one Stewardship Plan operates a drop-off site at a particular location, each drop-off site must accept all Covered Drugs, pursuant to **Section 4.116.050 (d)** of the Ordinance.

Evaluation:

- The Plan states, "It is Inmar's intention not to duplicate locations for kiosk placement with existing plan operators. If necessary and upon plan approval, Inmar will coordinate with existing plan operators on how to manage a kiosk at the same location. Inmar will not approach any currently operating sites for a minimum of three months after plan approval." Having more than one Stewardship Organization operating a drop-off site will not benefit the goal of providing convenient and equitable access to the program for County residents. Therefore, Inmar should not set up drop-off bin or mail-back distribution at locations already serviced by Med-Project to meet their service convenience goals.
- The Plan does not specify that all Covered Drugs will be accepted at drop-off sites operated by more than one Stewardship Plan.

Condition #8: Inmar must revise the Plan to include the following:

- a) Inmar will not approach sites already serviced by MED-Project until they meet their minimum convenience goals.
- b) All Covered Drugs will be accepted at drop-off sites operated by more than one Stewardship Plan.
- 9) <u>Requirement</u>: All Stewardship Plans shall coordinate with each other and develop a single system of promotion that shall 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 to **Section 4.116.060(a)(1)** of the Ordinance. Evaluation:
 - The proposed promotion system does not include measurable and deliverables elements to ensure full implementation. For example, it doesn't include the type of media (i.e., radio, email, social media, community events, etc.), audience, or promotion frequency.
 - The Plan proposes coordinating promotional activities with other approved plans within six months after the other program is approved. However, all promotional activities must be coordinated and agreed upon between Inmar and MED-Project as a requirement for the final approval of the Plan; therefore, the timeframe proposed in the Plan is not applicable.
 - None of the Stewardship Organizations should implement an individual promotion system; this could create inconsistent messaging and inequitable access to promotional information and adequate coverage in the Supervisorial Districts.

<u>Condition #9</u>: Inmar must revise the Plan to include the following:

- a) Provide details on the elements of the proposed promotion system, including but not limited to the type of media (i.e., radio, email, social media, community events, etc.), audience, or promotion frequency) for each type of promotion element,
- b) Eliminate the proposed timeframe for compliance with the requirements of this section.
- 10) <u>Requirement</u>: Coordinate with participating collectors to develop clear, standardized instructions for County residents on the use of collection bins and readily-recognizable, consistent design of collection bins, pursuant to **Section 4.116.060(a)(1)** of the Ordinance. <u>Evaluation</u>: The collection bin proposed in the Plan is green, which is not consistent with the color of the current drop-off bins. Stewardship Plans must offer a single promotion system. <u>Condition#10</u>: Inmar must revise the Plan to describe that they will coordinate with MED-Project to either adopt the current instructions and design of the collection bins or to develop a new single promotion system.
- 11) <u>Requirement</u>: The Plan shall establish a single toll-free telephone number and single website where collection options and locations of drop-off sites will be publicized, and prepare educational and outreach materials promoting safe storage of medicines and describing where and how to return Unwanted Covered Drugs to the Stewardship Plan. These materials must be provided to Pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to County residents. Plain language and explanatory images should be used to make use of medicine collection services readily understandable by all County residents, including individuals with limited English proficiency, pursuant to **Section 4.116.060(a)(3)** of the Ordinance.

Evaluation:

- The Plan agrees to use the MED-Project's website "Medproject.org" and a toll-free number (844)633-7765 as one option to meet the requirements of this section. However, the website cited on the Plan is incorrect. The correct website for the approved Stewardship Plan is Med-Project.org.
- As an alternative, the Plan proposes to use its website and toll-free phone number. The final system must be coordinated and agreed upon with MED-Project and any future stewardship plans.
- The Plan states that educational brochures will be provided at collection sites at least two times per year in quantities of 50 in English and 25 in the other required languages or upon request of the collector. The brochures also should be distributed to other stakeholders as described in the referenced section of the Ordinance on an annual basis and upon request. This should be recorded and reported in the Annual Report as part of the outreach activities implemented during the reporting period.
- Also, the Plan states, "upon approval, Inmar is committed to working with any approved Stewardship Plan Operator(s) as required to determine a fair and equitable method in jointly meeting the requirements under the Ordinance. Such coordination will be complete within 6 months of approval of the Plan." A single toll-free telephone number and single website must be coordinated and agreed upon between Inmar and MED-Project as a requirement for the final approval of the Plan; therefore, the timeframe proposed in the Plan is not applicable. The Director will provide guidance on the development of a single system of promotion.

<u>Condition #11</u>: Inmar must revise the Plan to include the following:

- a) Correct MED-Project's website,
- b) The single toll-free telephone number and a single website to be used to meet the requirements of Section 4.116.060(a)(3) of the Ordinance,
- c) Educational material will be provided to pharmacies, health care facilities, veterinary facilities, and other interested parties annually and upon request. Inmar must document each stakeholder provided educational material and include this information in their annual report,
- d) Eliminate the proposed timeframe for compliance with the requirements of this section.
- 12) <u>Requirement</u>: Covered Drugs collected under a Stewardship Plan must be disposed of at a permitted hazardous waste disposal facility as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 264 and 265, pursuant to **Section 4.116.070(a)** of the Ordinance.

Evaluation:

- The Plan does not include documentation to support that all five incinerators listed (Curtis Bay Medical Waste Services, Ross Incineration Services, Clean Harbors; Aragonite & El Dorado, Veolia Port Arthur) have a valid EPA Part B permit.
- The RCRA Info database shows the Permit for Clean Harbors Argonite as expired.

Condition #12: Inmar must revise the Plan to include the following:

- a) Copy of the EPA Part B permits for all incinerator facilities,
- b) Copy of the TSDF Permit for Clean Harbors Argonite.
- 13) <u>Requirement</u>: The requirements for proposed changes to an approved Stewardship Plan are detailed in **Section 4.116.120** of the Ordinance.
 - Evaluation: The Plan does not address the requirements in this section.

<u>Condition #13</u>: Inmar must revise the Plan to include language on how changes to their Plan upon approval will comply with Section 4.116.120 of the Ordinance.

San Mateo County solicited public comments on the Plan and received one comment.

The conditional approval of the Plan is contingent upon Inmar providing a letter, within 30 calendar days of the issuance of this Notice of Determination (NOD), committing to revise and resubmit the Plan to meet conditions #1 through #13 listed in the evaluation section of this letter within 90 calendar days of the issuance of this NOD.

Failure to comply with all conditions may result in the Department's rejection of the Plan and the Producers represented by Inmar Intelligence 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