
Via Electronic Mail to sccsafemeds@cep.sccgov.org

August 29, 2020

Consumer and Environmental Protection Agency
County of Santa Clara
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San Jose, CA 95112
Email: sccsafemeds@cep.sccgov.org

Re: Public Comments on Inmar Intelligence and Life in Check’s May 23, 2020 Proposed Safe Drug Disposal Stewardship Plan

To Whom It May Concern:

MED-Project LLC (“MED-Project”) appreciates the opportunity to submit these public comments on the proposed Safe Drug Disposal Stewardship Plan, dated May 23, 2020, submitted to the County of Santa Clara Consumer and Environmental Protection Agency (“CEPA” or “Department”) by Inmar Intelligence and Life in Check (the “Proposed Plan”).

MED-Project develops, implements, and operates stewardship programs for unwanted medicine from households on behalf of participating “Producers” (as defined in the Ordinance No. NS-517.91 amending Chapter XX of Division B11 of the Santa Clara County Ordinance Code relating to Safe Drug Disposal (“Ordinance”) § B11-540(p)). MED-Project has substantial, practical, on-the-ground experience implementing unwanted household medicine take-back programs in 21 jurisdictions across the country, including throughout California. MED-Project currently administers the only approved Product Stewardship Plan for Unwanted Medicine from Households in the County of Santa Clara (“Santa Clara” or “County”). Based on MED-Project’s experience developing and implementing unwanted medicine stewardship programs, including its experience in Santa Clara since 2017, MED-Project submits the following comments for CEPA’s consideration.

- I. CEPA must apply the same approval standards to all Stewardship Plans.**
 - a. Every Stewardship Plan must independently satisfy Ordinance convenience standards.**

The Ordinance requires that each “Stewardship Plan” (as defined in Ordinance § B11-540(u)) contain a description of how the proposed collection system under the Stewardship Plan will provide “convenient ongoing collection service for all Unwanted Covered Drugs from County residents in compliance with the provisions and requirements in Section B11-545. . . .” Ordinance § B11-542(b). The convenience standards specified in the Ordinance at Section B11-545(b)(1), in turn, require that each Stewardship Plan’s collection system provide “reasonably convenient and equitable access for County residents in all County of Santa Clara Supervisorial Districts” by requiring, namely, that: (1) the system provides at least one drop-off site for every

20,000 County residents; (2) there are, at no time, fewer than ten drop-off sites per County of Santa Clara Supervisorial District; and, (3) if the service convenience requirement cannot be met in any Supervisorial District, that Supervisorial District must be served by providing at least one reasonably convenient collection event or two additional reasonably convenient, publicly accessible distribution sites for mail-back services in lieu of each drop-off site needed to meet the convenience standard. Ordinance § B11-545(b)(1). Additionally, the Stewardship Plan must include as Collectors any Retail Pharmacies operated by the County of Santa Clara, or any law enforcement agency willing to serve voluntarily as a drop-off site and must make Mail-Back Services available, free of charge, to disabled and homebound County Residents through distribution of prepaid, preaddressed mailers at a minimum of five convenient distribution sites for Mail-Back Services per County of Santa Clara Supervisorial District. Ordinance §§ B11-545(b)(4) and (5). The Stewardship Plan must also include: (1) a list of all participating Collectors; (2) a list of drop-off sites; (3) a description of how any periodic events will be scheduled and located; (4) a description of how any mail-back services will be provided; and, (5) an example of the prepaid, preaddressed mailers the plan proposes to use. Ordinance § B11-542(b). These core components of a Stewardship plan are mandatory for “[e]ach Stewardship Plan” under the Ordinance and must apply equally to all “Stewardship Organizations” (as defined in Ordinance § B11-540(t)).

- i. Every Stewardship Plan must independently provide reasonably convenient and equitable access to kiosk drop-off sites.*

As described above, each Stewardship plan must provide reasonably convenient and equitable access for County residents in all County of Santa Clara Supervisorial Districts by providing at least one drop-off site for every 20,000 County residents and providing at least ten drop-off sites per County Supervisorial District. In doing so, each Stewardship Plan must give preference to having retail pharmacies and law enforcement agencies serve as drop-off sites. *See* Ordinance § B11-545(b)(3).

The Proposed Plan makes various statements regarding its intentions of meeting the Ordinance’s mandatory “reasonably convenient and equitable access” requirement but does not describe how the specific requirements enumerated above will be satisfied by the Proposed Plan in compliance with the Ordinance. In fact, the Proposed Plan establishes as its 6-month goal to “[h]elp achieve the convenience standard collectively with the existing provider.” Proposed Plan § VII. The Proposed Plan’s 12-month goal is “100 kiosks placed collectively across the County to provide equitable and reasonably convenient access to County Residents.” Proposed Plan § VII. The Ordinance is clear that a “collective” approach is not acceptable – “The collection system for *each* Stewardship Plan shall . . . [p]rovide reasonably convenient access for County Residents. . . .” Ordinance § B11-545(b) (emphasis added). Furthermore, MED-Project’s program already includes over 100 kiosks in Santa Clara, which seems to suggest that the Proposed Plan would be able to rely entirely on MED-Project’s kiosks to meet the convenience standard. That is not acceptable.

Additionally, the Proposed Plan states: “Inmar will utilize hospitals with on-site retail pharmacies and law enforcement agencies as necessary to meet the goals of equitable and reasonably convenient access for County Residents, as outlined in §B11-545(b)(1). However, the Ordinance requires that each Stewardship Plan must give preference to having retail pharmacies and law enforcement agencies serve as drop-off sites. Proposed Plan § II.A. The Proposed Plan does not specifically address how it will provide one kiosk per 20,000 residents or ten kiosks per supervisorial district or how it will give preference to locating kiosks at retail pharmacies *and* law enforcement agencies. Instead, Inmar simply includes a list of “proposed” or “potential” locations for hosting a kiosk in Appendix A, where some sites are already included in the MED-Project program.

- ii. Each Stewardship Plan must independently provide convenient and equitable access to mail-back services.*

In addition to kiosk drop-off sites, the Proposed Plan must describe how convenient and equitable access to the Proposed Plan’s collection system will be provided to County residents via mail-back services. The Proposed Plan must describe “how any Mail-Back Services will be provided” and must include “an example of the prepaid, preaddressed mailers the plan proposes to use.” Ordinance § B11-542(b). The Ordinance requires that, at a minimum, mail-back services be available “to disabled and home-bound County Residents upon request through the Stewardship Plan’s toll-free telephone number and website, and through distribution of prepaid preaddressed mailers at a minimum of five convenient distribution sites for Mail-back Services per County of Santa Clara Supervisorial District.” Ordinance § B11-545(b)(5). In addition, mail-back services may be offered in areas underserved by kiosks – “If the service convenience requirement . . . cannot be achieved due to lack of drop-off sites . . . in any County of Santa Clara Supervisorial District, then that Supervisorial District shall be serviced by providing at least one reasonably convenient collection event or two additional reasonably convenient, publicly accessible distribution sites for Mail-Back Services in lieu of each drop-off site needed to meet the service convenience requirement in that Supervisorial District.” Ordinance § B11-545(b)(1).

The Proposed Plan does not adequately describe how reasonably convenient and equitable access to mail-back services will be provided to County residents, particularly those located in underserved areas. *See* Proposed Plan § II.B. The Proposed Plan indicates that it will prioritize “a collection system at Retail Pharmacies and law enforcement agencies as well as community collection events along with Mail-Back Services available at public buildings.” Proposed Plan § II. Not only must mail-back distribution sites be “publicly accessible” and prioritized at “public buildings,” at least three of each five distribution sites per Supervisorial District “shall be open each day of the week including weekends” with exception only available for major state and federal holidays. *See* “Final Notice of Determination – Approval of MED-Project, LLC’s proposed revised Stewardship Plan dated August 17, 2018” from J. Zientek, Director – CEPA, County of Santa Clara to V. Travis, National Program Director, MED-Project (Oct. 26, 2018) at 2 (hereinafter “October 26, 2018 NOD”); Ordinance §§ B11-545(b)(1), B11-545(b)(3).

Additionally, MED-Project was required to provide mail-back envelopes to the County for the two HHW facilities operated by the County (1,000 packages provided up front, followed by fulfillment of additional requests from the County for up to 5,000 packages in total, and then beyond the initial 5,000 on a more limited basis). See “Response to MED-Project letter of August 24, 2017 regarding 7/12/17 Final Notice of Determination” from W. Grimes, Safe Drug Disposal Liaison, CEPA, County of Santa Clara to V. Travis, National Program Director, MED Project (Aug. 31, 2017) at 1-2 (hereinafter “August 31, 2017 Response”). Any new Stewardship Plans should be required to provide the same offering to the County.

iii. Each Stewardship Plan must describe any take-back events offered to supplement drop-off sites.

As described above, take-back events may be offered to supplement services in areas underserved by kiosks. Ordinance § B11-545(b)(1). A proposed plan must provide “a description of how any periodic events to collect Unwanted Covered Drugs will be scheduled and located. . . .” Ordinance § B11-545(b)(1). The Proposed Plan does not describe how collection events will be scheduled and located. Instead, the Proposed Plan states: “Inmar will provide kiosks at regional locations convenient to the public and will conduct and promote Drug Take-Back Events in conjunction with a local law enforcement agency and in coordination with any National Consumer Drug Take-Back Day’s promoted by the DEA if requested by the Directors. . . .” Proposed Plan § II.B.ii. At one point, the Proposed Plan refers to prioritizing “community collection events,” as required under Ordinance § B11-545(b)(3) but does not provide further explanation. The Proposed Plan should also clarify that take-back events will not be held in conjunction with Household Hazardous Waste collection events, as prohibited by the Department. See “Notice of Determination – Conditional Approval of MED-Project, LLC’s Stewardship Plan” from S. Gallegos, County of Santa Clara to I. Butler, Plan Development Direct, MED-Project (Mar. 20, 2017) at 2 (hereinafter “March 20, 2017 NOD”).

iv. Each Stewardship Plan must provide convenient and equitable access to a collection system for all covered drugs, including inhalers and pre-filled injector products.

The Proposed Plan does not appear to provide for the collection of all “Unwanted Covered Drugs,” (as defined in Ordinance § B11-540(d)) as required by the Ordinance and provided for in MED-Project’s approved Stewardship Plan. “Covered Drug” is defined under the Ordinance broadly to include both prescription and nonprescription drugs, as well as inhalers and pre-filled injector products. See Ordinance § B11-540(d); see also August 31, 2017 Response at 2. However, the Proposed Plan does not clearly address the collection of inhalers and pre-filled injector products. The website linked throughout the Proposed Plan (i.e., <https://rxdisposal.lifeincheck.com/>) clearly excludes inhalers, needles, and aerosol cans without providing alternative collection options. We note that the website is also inconsistent with what is shown in Appendix B of the Proposed Plan. There is also a heading that mentions “auto-injector containers,” but the Proposed Plan does not describe any services for auto-injectors. Proposed Plan § II.B.ii.

As is required by the Department, the Proposed Plan should collect inhalers and pre-filled injector products. *See* August 31, 2017 Response at 2 (requiring a “plan for pre-loaded products containing a sharp and for collection of aerosol and inhaler pharmaceutical products”); March 20, 2017 NOD at 2 (“All Mail-Back Distribution Sites must be stocked with free, prepaid, preaddressed mailers for all types of Covered Drugs, including adequate mailers for auto-injectors, pre-loaded products with a sharp attached. . . .”); Letter from W. Grimes, Safe Drug Disposal Liaison, CEPA, County of Santa Clara to V. Travis, National Program Director, MED Project (Apr. 13, 2018) at 2 (“referring to the “requirement for all covered mail back constituents (pre-filled injectables, inhalers, iodine containing medications/standard mail back)”) (hereinafter “April 13, 2018 Letter”).

b. Every Stewardship Plan should have the opportunity to provide the same scope of services to kiosk drop-off sites.

MED-Project previously proposed to include a “host-assisted collection” option under its plan, whereby the kiosk host would be able to package and ship the inner liner and box from its kiosk. The Department rejected that approach. *See* October 26, 2018 NOD at 1. The Proposed Plan includes a similar collection model, tagged as “self-service returns.” *See* Proposed Plan § II.A. If the Department approves that approach under the Proposed Plan, the same should be approved for all other Stewardship Plans. The same is true for the “full-service returns” option provided in the Proposed Plan. *See* Proposed Plan § II.A.

c. Every Stewardship Plan must satisfy all legal requirements to ensure safe, secure, and compliant collection and disposal of all Unwanted Covered Drugs.

The Ordinance requires a Stewardship Plan to, among other things, provide a description of the policies and procedures that will be followed by persons handling Unwanted Covered Drugs collected under the Stewardship Plan, including a description of how “all Collectors, Transporters and Disposal Facilities used will ensure that the collected Unwanted Covered Drugs are safely and securely tracked from collection through final disposal”, as well as “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 . . . the State of California Board of Pharmacy.” Ordinance § B11-542(d). In order to ensure that the above requirements are met, the following components must be addressed in the Proposed Plan:

- i. All Stewardship Plans must describe how pharmacies will comply with all recordkeeping requirements imposed by the California Board of Pharmacy.*

The California Board of Pharmacy (“BOP”) regulations at 16 C.C.R. § 1776.6 require that pharmacies collecting unwanted prescription drugs maintain detailed records on collection receptacles and inner liners. However, the Proposed Plan does not always align with the BOP regulations, including in how it directs authorized collectors to maintain information for two

years. *See, e.g.*, Proposed Plan § IV. The BOP requires that pharmacies maintain these records for three years. 16 C.C.R. § 1776.6 (“Each entity authorized by this article to collect unwanted prescription drugs from consumers shall maintain the records required by this article for three years.”).

ii. All Stewardship Plans must provide a description of the emergency and rapid response services.

As stated above, the Ordinance requires that all proposed plans describe the policies and procedures that will be used to ensure that Unwanted Covered Drugs are safely, securely, and compliantly collected, transported, and disposed of. Ordinance § B11-542(d). To this end, all Stewardship Plans must describe the emergency and rapid response services that will be used in the event of an unplanned event or emergency requiring specialized rapid response services, such as a spill incident or other emergency or major event, including how such services can be initiated. *See* October 26, 2018 NOD at 2. The Proposed Plan currently states that “Inmar will also be at the ready with service technicians should emergency service be required” but then notes that, “[f]or a pickup request outside of the normal schedule, the standard response time is 48 hours.” Proposed Plan § II.A.

iii. Stewardship Plan collection models must comply with all other applicable laws, regulations, and other legal requirements.

Under the Ordinance, Stewardship Plans must describe 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. . . .” Ordinance § B11-542(d). If the Department evaluates one Stewardship Plan for compliance with all applicable laws, regulations, and other legal requirements, it must do so for all Stewardship Plans.

As the Department reviews the Proposed Plan for compliance with all applicable laws, regulations, and other legal requirements, MED-Project notes that Stewardship Plans must comply with United States Department of Transportation (“DOT”) requirements. For example, for Stewardship Plans relying only on DOT Special Permit 20255 for self-service returns at kiosk drop-off sites, MED-Project’s understanding is that the kiosk drop-off sites themselves must become party to Special Permit 20255. *See* Proposed Plan Appendix E. We note that the Proposed Plan also indicates that kiosk containers will be sent “using Inmar’s DOT Special Permit #20499” without explaining how such a system would comply with the terms of the special permit or how Special Permit 20255 would fit into the system.

d. Every Stewardship Plan must be subject to the same administrative standards.

The Ordinance and Regulations establish administrative standards applying to each Plan Operator, including Producer funding, Department funding, and public access requirements. *See, e.g.*, Ordinance §§ B11-539, B11-549. The Department has also imposed additional reporting

requirements on MED-Project. *See* October 26, 2018 NOD at 2-3. These requirements must apply equally to all Plan Operators.

- i. Producer funding requirements apply independently to all Stewardship Plans.*

The requirement that Producers fund Stewardship Plans is foundational to the Ordinance. *See, e.g.*, Ordinance § B11-540(u) (“‘Stewardship Plan’ means a plan . . . that is: (1) Financed, developed, implemented and participated in by one or more Producers. . . .”); Ordinance § B11-541(e)(6) (“A Producer, either individually or jointly with other Producers, shall: . . . Pay all costs and fees associated with its Stewardship Plan. . . .”); Ordinance § B11-539 (“This Chapter requires Drug Manufacturers to develop, operate, and fund a program or programs to safely and properly dispose of County Residents’ unwanted pharmaceuticals.”). The Ordinance defines “Producer” to mean “a Manufacturer engaged in the Manufacture of a Covered Drug sold in the County, including a brand-name or generic Drug” subject to certain exemptions. Ordinance § B11-540(p). It then makes clear that these Producers must pay for virtually all aspects of the Stewardship Plan. Specifically, the Ordinance provides that:

A Producer, group of Producers, or Stewardship Organization participating in a Stewardship Plan shall pay all administrative and operational costs related to its Stewardship Plan, except as provided under this Section B11-549. Administrative and operational costs related to the Stewardship Plan *include, but are not limited to*, the following: [enumerating cost categories].

Ordinance § B11-549(a) (emphasis added).

Stewardship Plans must meet these funding requirements to be approved. The Proposed Plan includes only one “Producer(s).” *See* Proposed Plan § I. It is difficult to imagine a single Producer self-funding a Stewardship Plan of the scope and scale that the Ordinance and Regulations require. That is the obligation, however, that any Producer(s) participating in any Stewardship Plan assumes.

Additionally, the Proposed Plan is not clear that it would cover all of the costs identified in Ordinance § B11-549. A Stewardship Organization must be responsible for all administrative, maintenance, and operational costs of installing and removing the kiosks it provides. Further, in light of the Ordinance’s Producer-funding requirements, it appears that the Proposed Plan’s reference to certain “[a]dditional charges” is an oversight. *See* Proposed Plan at PDF page 50 (“Additional charges may apply for non-compliance.”). If the Department interprets the Ordinance such that Stewardship Plans need not fund and manage costs associated with their kiosks and mail-back services or such that other organizations may fund Stewardship Plans, then due process requires that it apply the same interpretation to MED-Project.

ii. Department funding requirements apply independently to each Stewardship Organization.

Ordinance § B11-550 authorizes the Department to charge fees to cover costs of administering and enforcing the Ordinance, and Regulations § 3 provides more information about the fees to be charged, particularly for the initial submission of a proposed Stewardship Plan and an annual fee. Each Stewardship Organization should be required to pay any fees for the review of its own Stewardship Plan and the annual fee submitted with its own annual report. *See* Regulations § 3.B. Likewise, each Stewardship Organization must also be responsible for the “costs that the County of Santa Clara incurs in administering and enforcing this Chapter” insofar as they are associated with its Stewardship Plan. *See* Ordinance § B11-550. Administration and enforcement costs that are not associated with a specific Stewardship Plan must be divided evenly among Stewardship Organizations.

iii. Public access requirements apply independently to each Stewardship Plan.

Stewardship Plans are public documents. The Ordinance requires that the Director “make all approved and proposed Stewardship Plans submitted under this Section B11-543 available to the public.” Ordinance § B11-543(i). Despite this plain language and the public interest in Stewardship Plans, the Proposed Plan attempts to self-impose restrictions on how it can be used. On the bottom of nearly every page of the Proposed Plan, the following statement is included:

© Inmar 2020 Inmar authorizes the posting of the plan dated May 23, 2020 in accordance with the California Public Records Act, as well as Section B11-543 of the County of Santa Clara Ordinance Code for the purposes of making it available to the public for review and comment. Any other use requires express written consent of Inmar.

Proposed Plan *passim*. The Ordinance does not provide that the Director shall make all Stewardship Plans and proposed plans submitted under Section 2211 available to the public, *except as limited* by the Plan Operator. It requires the Director to make Stewardship Plans public, period. The Department should not approve a Stewardship Plan attempting to side-step requirements for public access.¹

The Proposed Plan was submitted pursuant to the Ordinance as part of the requirements for implementing and operating a drug take-back program in Santa Clara County. As such, the Proposed Plan is a public document and a public record under California law. Given the goal of publicly beneficial transparency around drug take-back programs, it is and should be available to

¹ It may be in the public interest to withhold certain Stewardship Plan information from public disclosure in limited circumstances consistent with all applicable laws, regulations, and other legal requirements (*e.g.*, information related to controlled substance diversion risks). The Proposed Plan’s claims go far beyond that, however.

the public for any purpose. The MED-Project stewardship plan, the only approved drug stewardship plan in the County, is posted on the Santa Clara Safe Medication Disposal website, <https://www.sccgov.org/sites/rwr/hhw/Documents/54%20-%20Santa%20Clara%20County%20MED-Project%20Revised%20Plan%2003.04.2019.pdf>. The Proposed Plan's attempt to self-impose usage restrictions on the public's use of the Proposed Plan and the information contained in it lacks any support under California or Santa Clara law.

County residents, businesses, and other institutions may access and use a Stewardship Plan in many ways. Separate from the requirement for written public comment, the Ordinance also requires that the Director "make all approved and proposed Stewardship Plans submitted under this Section B11-543 available to the public." Ordinance § B11-543(i). As discussed above, this requirement does not limit how the public can use the plan, but rather it implicitly recognizes the multitude of ways the public may use a Stewardship Plan. Potential kiosk hosts and County residents will want to educate themselves about all aspects of the Proposed Plan before getting involved with the program under the Proposed Plan. Moreover, County residents may want to access the Proposed Plan and any other Stewardship Plan for any number of other reasons, including: school (e.g., lessons about Extended Producer Responsibility ("EPR") programs); advocacy (e.g., supporting access to collection services); scholarship (e.g., evaluating stewardship plan success); etc. Upon seeing the Proposed Plan's language claiming to limit public use, County residents could well be inclined to not hire an attorney to determine their rights to use the Proposed Plan or portions thereof. Rather, the teacher planning an EPR lesson will find a different example, the advocate will use another citation, and the scholar will gather other data; public engagement will likely be suppressed.

If Inmar can retain the Proposed Plan's language cited above attempting to limit public access to and use of the Proposed Plan, it will have a chilling effect in a number of ways on the performance of governmental functions. First, as you know, upon receipt of a proposed Stewardship Plan, the Department is required to first review it for the purpose of determining whether it meets the requirements of the Ordinance, and then in ninety days, decide whether to accept or reject the proposed plan. *See* Ordinance § B11-543(b). If the Inmar self-imposed usage restrictions were followed, the Department would be prevented from discussing the proposed plan with outside parties that it sought information from with regard to the Proposed Plan. Second, as recognized in Regulations § 4.B, the County is a public agency subject to the disclosure requirements of the California Public Records Act. These attempted usage restrictions would have the potential to decrease transparency by frustrating California Public Records Act compliance, and necessarily require the Department to disregard the restrictions in order to properly comply with the California Public Records Act. They would be contrary to the Regulations, which would require the Department to provide a Stewardship Plan upon request, subject only to exceptions under the California Public Records Act. *See* Regulations § 4.B. Finally, the self-imposed usage restrictions language would create problems for the County since it purports to require Inmar's written permission for any use of the Proposed Plan in a County report, County outreach, etc. *See* Ordinance § B11-552 (requiring the Director to report to the Board of Supervisors on request concerning the status of all Stewardship Plans and recommendations for changes to the Ordinance).

With respect to other Stewardship Organizations, the claimed restrictions in the Proposed Plan create an uneven playing field. MED-Project, the only Stewardship Organization currently approved in Santa Clara, considers its Santa Clara plan to be a public document, available for public review. The public nature of MED-Project's Santa Clara plan and the level of detail it contains affects MED-Project's negotiations with potential vendors; Plan Operators able to limit public access to their Stewardship Plan would have a competitive advantage over MED-Project with regard to their contracting processes. Furthermore, limiting how another Plan Operator can use a proposed Stewardship Plan could affect the efficiency and success of the coordination among Stewardship Organizations required by the Ordinance. *See* Ordinance § B11-547.

Drug take-back plans submitted pursuant to the Ordinance are public documents, including the Proposed Plan. For the reasons set forth above, the Department should not approve any stewardship plan, including the Proposed Plan, which attempts to restrict public access through self-imposed usage restrictions. The Department should instead mandate that the self-imposed usage restrictions in the Proposed Plan be eliminated and removed, encouraging transparency in the drug take-back programs in the County.

iv. Reporting requirements apply independently to all Stewardship Plans.

In addition to annual reporting required under Ordinance § B11-548 and Regulations § 8, the Plan Operator must notify the Department of "any known security or safety incidents at Drop-Off Sites, Take-Back Events, and Mail-Back Distribution Sites, or during transportation or disposal of Unwanted Covered Drugs as soon as reasonably practicable but no later than ten business days after the incident." Regulations § 4.C. The Proposed Plan simply indicates that "[a]ny discrepancies will be included as required in the annual reports" and does not address this requirement for more immediate reporting if there are safety or security incidents.

Additionally, the Department, through its notices of determination and written correspondence, has imposed several reporting requirements on MED-Project that must also extend to other Plan Operators. For example, the Department requires MED-Project to report quarterly on (1) kiosk host service calls and correspondence, (2) kiosk maintenance service logs, and (3) mail-back package weights and quantities. *See* October 26, 2018 NOD at 2-3; *see also* April 13, 2018 Letter at 2-3. Relatedly, the Department has required that MED-Project provide detail on its attempts to reach out to potential host sites. *See* April 13, 2018 Letter at 1 ("Please provide a meaningful table of comments, dates and specifics on outreach attempts."). If the Department interprets the Ordinance and Regulations as requiring this information, then those same requirements apply with equal force to any Plan Operator.

v. Each Stewardship Plan must endeavor to meet the implementation deadlines established in the Ordinance and by the Department.

The Ordinance requires that "[w]ithin three months of the Director's approval or conditional approval of the Stewardship Plan, whichever is earlier, and thereafter, operate or participate in the Stewardship Plan in accordance with this Chapter. . . ." Ordinance § B11-541(e)(5). Additionally, the County has instructed MED-Project as follows: "Short Term

Collection goal – 90 days seems excessive to implement. Within 30 should be the standard.” The Proposed Plan, however, seems to establish program collection and promotion goals over a much longer time horizon. *See* Proposed Plan § VII. We assume that the program goals in the Proposed Plan are tied to the date of an approval or conditional approval, as in Ordinance § B11-541(e)(5), although the Proposed Plan is not clear on that point. In direct contradiction with the Ordinance, the Proposed Plan has scheduled initiation of program operation for 6 months after program approval. Other critical components of the program are not scheduled for at least one year after program approval. MED-Project recognizes that extenuating circumstances may affect a Stewardship Organization’s ability to operate certain elements of its program by a specific deadline, but all Stewardship Plans should aim to meet the requirements in the Ordinance and only stray from those for legitimate and transparent reasons.

vi. Each Stewardship Plan must include the minimum information required for each disposal facility.

The Ordinance requires that a Stewardship Plan describe the handling and disposal system for unwanted covered drugs, including “identification of and contact information for Collectors, Transporters and Disposal Facilities to be used . . . , as well as their . . . permit status, as applicable; and record of any penalties, violations, or regulatory orders received in the previous five years. . . .” Ordinance § B11-542(c). The Proposed Plan identifies several disposal facilities it proposes to use but does not provide penalty records for all of the facilities.

II. All Stewardship Plans must coordinate to satisfy Ordinance and Regulations outreach requirements.

Since the Department first approved MED-Project’s Stewardship Plan, MED-Project has worked with the Department to implement its Stewardship Plan for County residents in compliance with the Ordinance, Regulations, and all other applicable laws, regulations, and other legal requirements. Because of its work with the Department and its commitment to compliance, MED-Project now provides 108 kiosk drop-off sites and 46 mail-back distribution locations throughout Santa Clara so that disposing of Unwanted Covered Drugs is convenient, safe, and accessible for residents in each Supervisorial District. MED-Project will continue these efforts regardless of whether the Department approves another Stewardship Plan.

Consistent with its commitment to compliance, if the Department approves another Stewardship Plan, MED-Project will coordinate with that Stewardship Plan to develop a single system of promotion as required under Ordinance § B11-547 and Regulations § 7. A Stewardship Plan must include “an explanation of how the Plan Operator will collaborate with all other Plan Operators to develop a single system of promotion for all Stewardship Plans. . . .” Ordinance § B11-542(f). Stewardship Organizations must coordinate to provide a single system of promotion, which must include: (1) promotion of the Stewardship Plans’ collection options; (2) promotion of safe storage of Covered Drugs; (3) clear, standardized instructions for County residents and a readily-recognizable, consistent kiosk design; (4) a single toll-free telephone number and single website; (5) educational and outreach materials promoting safe storage and disposal of unwanted covered drugs; (6) geographically targeted advertising of collection events;

and, (7) collaboration with home health care providers to promote mail-back services. Ordinance § B11-547(a); Regulations § 7. All approved Stewardship Plans must conduct a biennial survey. Ordinance § B11-547(c). And, the promotion system established by the Stewardship Plans must include a detailed marketing plan designed to achieve reach and frequency targets defined in the Regulations. Regulations § 7.B.

MED-Project will look to the Department for guidance on the development of a single system of promotion for all Stewardship Plans, if there is more than one Stewardship Plan. *See* Ordinance § B11-547(e). MED-Project expects that the required coordination would involve an equal division of costs for shared promotional activities and alignment on the content of messaging and materials for residents and host sites. MED-Project understands that a single system of promotion involves the provision of consistent information to residents, but it does not require identical branding or matching materials and products.

a. Costs for shared promotional activities required under Ordinance § B11-547 and Regulations § 7 should be divided equally among Stewardship Organizations.

Where promotional activities required under the Ordinance are shared (e.g., a shared website landing page, a shared toll-free phone number, and a single biennial survey), MED-Project expects that any costs would be divided equally between Stewardship Organizations (i.e., each Stewardship Organization would pay half of the costs if there were two Stewardship Organizations). This is consistent with the Proposed Plan’s assurance that any coordination will include “the fair and equitable division of resources. . . .” Proposed Plan § VI. Furthermore, the equal sharing of costs is the most reasonable approach, particularly in light of the Ordinance’s requirement that each Stewardship Organization pay all administrative and operational costs related to its Stewardship Plan, including “[p]rogram promotion under Section B11-547. . . .” *See* Ordinance § B11-549(a)(8). MED-Project provides more detail on what it would expect for such a system below and encourages the Department to require that the Proposed Plan be revised to reflect such an approach.

On the topic of a single website, MED-Project’s current web platform for the County has been in place for 3 years and is familiar to Santa Clara residents. The Proposed Plan, on the other hand, would use a national website that is not targeted to Santa Clara residents and does not address how its website would meet the full scope of requirements under the Santa Clara Ordinance. For example, the Proposed Plan should:

- Provide screenshots that demonstrate it is available in all of the required languages and how it will be displayed on the site. *See* April 13, 2018 Letter at 5. The required languages are English, Spanish, Vietnamese, Mandarin, Tagalog, Korean, Japanese and Hindi. April 13, 2018 Letter at 1.
- Describe how the website will allow visually impaired residents to request mail-back services or search for kiosk locations. *See* April 13, 2018 Letter at 4.

- Describe the frequency of website updates to ensure the most current take-back event dates, kiosk locations, and other information are on the website. *See* April 13, 2018 Letter at 4.

Accordingly, MED-Project proposes the continued use of its website as the single website under Ordinance § B11-547(a)(4), with any modifications needed to reflect the operation of multiple Stewardship Plans. More specifically, MED-Project would propose to provide a neutrally branded landing page for Santa Clara residents seeking to dispose of unwanted medicine. When residents reach the neutrally branded landing page, they would select which services they seek, and that selection would route them to information on one of the Stewardship Organization's independently branded websites for Santa Clara. MED-Project is still considering how residents will be routed (e.g., every other person looking to search for an unwanted medicine kiosk will be sent to each Stewardship Organization's website) while also considering the routing of residents interested in how to dispose of unwanted sharps. The costs of modifications and operations of the neutral landing page would be shared equally by all Stewardship Organizations.

Similarly, with regard to the call center, MED-Project's toll-free phone number is well established in Santa Clara and is widely published, including on each current kiosk sign. Changing the existing phone number could cause confusion and unnecessary cost to MED-Project. Additionally, MED-Project's call center has already met the requirements imposed by the Ordinance and the Department, including ensuring translation to the required languages and availability for hearing impaired residents. *See* April 13, 2018 Letter at 1, 3; Ordinance § B11-547(d); Regulations § 7.C. MED-Project would propose continued use of MED-Project's existing call center number as the single toll-free telephone number required under Ordinance § B11-547(a)(4). MED-Project would propose modifications to the initial segment of the unwanted medicine script for Santa Clara residents so it would be neutral with regard to program operator. Callers inquiring about unwanted medicine would be directed out to call centers operated separately by each Stewardship Program; the call center to which callers are directed would be determined based on an algorithm yet to be developed. For example, every other call inquiring about unwanted medicine mail-back services could be directed to the call center operated by each Stewardship Organization. The Stewardship Organizations would each pay half of the costs for modifying the script and operating the system for receiving and directing calls.

Lastly, for the biennial surveys required under Ordinance § B11-547(c) and Regulations § 9, MED-Project would propose that a single vendor perform the surveys, with each Stewardship Organization paying half of the associated costs, including any costs for review and approval of the survey by the Department. The Department could select the vendor to perform the surveys and could also provide guidance on ensuring that the survey schedules are synced across the Stewardship Plans so that no Stewardship Organization is disadvantaged by the survey schedule (e.g., MED-Project's survey is underway and the Ordinance does not require it to provide another survey for two years from that survey).

b. Some promotional activities must be specific to an individual Stewardship Plan, in coordination with others.

Based on the text of the Ordinance and Regulations, there are a few promotional activities that should be conducted individually by each Stewardship Organization, in coordination with others. These activities include, for example: (1) achievement of the reach and frequency targets identified in Regulations § 7.B; (2) development and distribution of educational and outreach materials, as required under Ordinance § B11-547(a)(5) and Regulations § 7.A; (3) standardized instructions for kiosks and readily-recognizable, consistent kiosk designs, as required under Ordinance § B11-547(a)(3); (4) collaboration with home health care providers to promote the use of mail-back services by disabled and homebound County residents under Ordinance § B11-547(a)(7); and, (5) geographically targeted advertising of collection events under Ordinance § B11-547(6).

- i. Each Stewardship Plan is responsible for independently meeting the reach and frequency targets in the Regulations.*

The Regulations lay out a very specific schedule for reach and frequency targets, and that schedule depends on the time that has passed since a particular Stewardship Plan was approved. More specifically, the promotion system “must include a detailed marketing plan with targeted Media run dates designed to achieve a Combined Target Reach Percent of: 75% at a 3+ Frequency for the duration of one month at least three times per year over the first twelve months of Stewardship Plan operation; 50% at a 2+ Frequency for the duration of one month at least three times per year for following years; and 75% at a 3+ Frequency for the duration of one month at least three times per year for every fifth year of program operation.” Regulations § 7.B. These targets are necessarily specific to an individual Stewardship Plan, as they depend on the date that Stewardship Plan began operating. Accordingly, the Proposed Plan must address how it would meet the target reach percentages and frequencies, and if the Proposed Plan can satisfy these standards through promotions not readily susceptible to reach calculations, through alternative metrics, or if they do not need to satisfy these requirements at all, then the Department must allow such flexibility for all Stewardship Organizations. *See Proposed Plan § VI.*

For a number of reasons, including the importance of ensuring that any shared costs are distributed equally among Stewardship Organizations, MED-Project objects to the suggestion that “Inmar will coordinate with other Plan Owners to execute the Digital Media outreach and Social Influencer outreach, while the other plan operator focuses on traditional print and television media.” Proposed Plan § VI. Given that, in MED-Project’s experience, “traditional print and television media” are among the most expensive promotion methods, the Proposed Plan’s approach appears inequitable. MED-Project would instead coordinate on messaging and content of materials as described below, and each Stewardship Plan would be required to meet the reach and frequency targets itself.

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- ii. New Stewardship Plans should align their messaging and materials with the existing Stewardship Plan, but each Stewardship Plan should bear its own associated costs and should use its own branding.*

Where MED-Project has already undertaken significant work to develop certain materials and designs that are part of its approved promotion system, MED-Project expects that any other Stewardship Organizations would generally align the content to essential messaging. More specifically, MED-Project believes that materials and designs developed as part of a single system of promotion may generally include the information listed below but should be independently branded and distributed by each approved Stewardship Organizations.

- A single website and phone number for Santa Clara residents to learn about take-back services for unwanted medicines.
- Promotion of safe storage and disposal of covered drugs.
- Details on the types of collection services available in Santa Clara, including where and how to access take-back services for unwanted medicines.
- How to request additional information from a Stewardship Organization.

This aligned messaging would be used, for example, in written materials and brochures distributed to residents and collection sites, outreach to home health care providers, kiosk signage and designs, and mail-back inserts. Each Stewardship Plan would have its own specific messaging, educational materials, and kiosk designs that would be prepared, branded, printed, and distributed at that Stewardship Plan's own costs. This approach appears to be consistent with what is included in the Proposed Plan, which offers its own branded educational materials, kiosks, and other materials.

On the issue of readily-recognizable, consistent kiosk design required under Ordinance § B11-547(a)(3), MED-Project would expect that all Stewardship Organizations use kiosks (1) made of similar materials, (2) with similar, stand-alone design including medicine doors and double locks on the access doors, (3) using internal disposal boxes and liners, and (4) with identifying markings indicating they are unwanted medicine collection bin and instructions for what is and is not accepted. Each plan operator should bear its own costs regarding its kiosks and kiosk signage and be responsible for the maintenance and support of its kiosks.

The materials and designs used under MED-Project's plan may be trademarked, patent pending, or otherwise protected, so it may not be feasible to for a new Stewardship Plan to adopt the existing materials and designs offered under MED-Project's plan. Additionally, MED-Project has invested time, money, and sweat equity in developing many of the materials and designs and establishing brand recognition across Santa Clara, so it would not be fair or equitable for another Stewardship Organization to benefit from MED-Project's effort and expenses without compensating MED-Project for as much. Lastly, as you know, MED-Project is

operating programs in multiple jurisdictions, and its current branded system promotes resident familiarity with programs across jurisdictional boundaries.

We note that this is not an endorsement of the materials or designs in the Proposed Plan, which may need to be tailored to Santa Clara and revised to respond to the requirements in the Ordinance – for example:

- The materials must “[c]onvey instructions and information only for the types of disposal options offered through the Collection System” in Santa Clara, meaning they should include services for all inhalers and pre-filled injector products, in addition to other unwanted medicine. *See* Regulations § 7.A.ii; April 13, 2018 Letter at 3 (“Provide details on how education and outreach will be modified to include resident education as to methods of proper disposal of injectors, iodine-containing [medications] and inhalers through separate mail back services.”).
- Kiosk signage must include information about services for covered drugs that are not accepted in kiosks, such as pre-filled injector products. April 13, 2018 Letter at 4; October 26, 2018 NOD at 2.
- Instructional flyers that will accompany inhaler mail-back packages must be included in the Proposed Plan. April 13, 2018 Letter at 4.
- Materials must be translated into English, Spanish, Vietnamese, Mandarin, Tagalog, Korean, Japanese and Hindi. Ordinance § B11-547(d); Regulations § 7.C; April 13, 2018 Letter at 1.

Promotion content requirements the Department applies to MED-Project must apply to all Plan Operators. If Plan Operators can bypass these content requirements by providing generic promotions not specific to Santa Clara or through decentralized promotion approaches, then the Department must apply that interpretation of the Ordinance and Regulations equally to all Stewardship Plans.

iii. Each Stewardship Plan should be responsible for advertising its own collection events.

The Ordinance requires that the system of promotion include undertaking “geographically targeted advertising of collection events at least one month in advance of each scheduled collection event. . . .” Ordinance § B11-547(a)(6). Each Stewardship Organization should be responsible for advertising its own events under this requirement and bearing the related costs. A Stewardship Organization should not be required to advertise an event sponsored by another Stewardship Organization beyond including information about that event via the toll-free call center and website. This is consistent with the Ordinance requirement that each Stewardship Organization pay all administrative and operational costs related to its Stewardship Plan, including “[p]rogram promotion under Section B11-547. . . .” *See* Ordinance § B11-549(a)(8).

c. Coordination among Stewardship Organizations must be done in compliance with all applicable laws.

In coordinating with another Stewardship Plan, MED-Project will comply with all applicable laws, regulations, and legal requirements, including federal and state antitrust requirements. While MED-Project will, of course, coordinate with other Plan Operators as required under the Ordinance and Regulations, MED-Project does not accept the Proposed Plan’s unusual trade association proposal. For unknown reasons, “Inmar suggests the Plan Owners form a trade association to ensure that there are no inefficiencies or distortions due to collaboration. A trade association protects against the types of illegal agreements that can distort competition.” Proposed Plan § VI. Despite these claims, establishing a trade association does not somehow bestow competitor organizations with antitrust immunities. *See* Federal Trade Commission, *Spotlight on Trade Associations*, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/spotlight-trade> (last visited August 17, 2020) (“But forming a trade association does not shield joint activities from antitrust scrutiny: Dealings among competitors that violate the law would still violate the law even if they were done through a trade association.”). For its part, MED-Project will implement Ordinance § B11-547, Regulations § 7, and all other aspects of the Ordinance and Regulations in compliance with all antitrust laws, regulations, and other legal requirements.

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Thank you again, in advance, for your consideration of MED-Project’s comments. Please feel free to contact us with any comments or questions, and we look forward to continuing to work with CEPA going forward to provide Santa Clara residents with safe, convenient and effective services under our approved Stewardship Plan.

Sincerely yours,



Dr. Victoria Travis
National Program Director