

Via Electronic Mail to safemeds@sfgov.org

November 4, 2020

San Francisco Department of the Environment
1455 Market Street, Suite 1200
San Francisco, CA 94103
Email: safemeds@sfgov.org

Re: Public Comments on Inmar Intelligence's October 13, 2020 Proposed Safe Drug Disposal Stewardship Plan

San Francisco Department of the Environment:

MED-Project LLC ("MED-Project") appreciates the opportunity to submit these public comments on the latest proposed Safe Drug Disposal Stewardship Plan, dated October 13, 2020, that was recently submitted to the San Francisco Department of the Environment ("SFE" or the "Department") by Inmar Intelligence (the "October Proposed Plan").

MED-Project develops, implements, and operates stewardship programs for unwanted medicine from households on behalf of over 250 "Producers" (as defined in San Francisco Safe Drug Disposal Stewardship Ordinance ("Ordinance") § 2202). 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 City and County of San Francisco ("San Francisco").

As described more fully in our comments set forth below, MED-Project continues to have serious concerns with certain aspects of the October Proposed Plan. Most importantly, the October Proposed Plan still does not adequately describe how the proposed collection system under the Plan will satisfy the mandatory convenience standards specified in the Ordinance at section 2205(b)(1). There are also significant omissions and/or inadequacies that remain in other aspects of the October Proposed Plan, which are described below.

Although section 2211(f) of the Ordinance provides that the Department "may exercise reasonable discretion to waive strict compliance with the requirements of [the Ordinance] ... in order to achieve the objectives [of the Ordinance]", MED-Project believes that it would not achieve the objectives of the Ordinance or be "reasonable" for SFE to exercise its "discretion" to approve the October Proposed Plan, as currently drafted, given the remaining issues with the Plan, which are described more fully below and in other stakeholder comment letters. It is neither reasonable nor consistent with the Ordinance's intent to approve a proposed Plan that is legally noncompliant and/or in conflict with the mandatory requirements imposed under the Ordinance and/or other applicable laws and regulations. This is particularly true here, where there is another approved Stewardship Plan that is operating at or above the standards imposed by the Ordinance. Such an

act of approval would not only be unreasonable and inconsistent with the objectives of the Ordinance, but also would create unfairness and inequities for not only MED-Project and the participating Producers, but also City residents.

SFE cannot provide final approval of the October Proposed Plan because, as currently drafted, approval would violate the intent of the Ordinance that alternative plan operators must independently meet all requirements of the Ordinance (except for the single system of promotion required by the Ordinance and Regulations). It would also be inequitable and unreasonable, as it would allow some Producers to save money by participating in a less robust plan, while relying on other, equally situated Producers to bear the increased costs of a more robust plan that provides the bulk of the product stewardship services to the residents of San Francisco. This, in turn, would create a “race to the bottom” scenario, which would incentivize Producers to switch to the less robust plan thereby reducing the level of product stewardship services provided to San Francisco residents. This is clearly inconsistent with the objectives and intent of the Ordinance, and therefore, should not be allowed to occur through the premature approval of the October Proposed Plan.

I. Every Stewardship Plan must independently satisfy the Ordinance’s convenience standard in an equally robust fashion.

- A. The October Proposed Plan does not adequately describe how it will work to meet the Ordinance’s convenience standard upon Plan approval.

The Ordinance requires that each “Stewardship Plan” (as defined in Ordinance section 2202) contain a description of how the proposed collection system under the Plan will provide “convenient ongoing collection service for all Unwanted Covered Drugs from City residents in compliance with the provisions and requirements in Section 2205.” Ordinance § 2204(b). The convenience standards specified in the Ordinance at Section 2205(b), in turn, require that each Plan’s collection system provide “reasonably convenient and equitable access for all City residents in all Supervisorial Districts” by requiring, namely, that: (1) there are at least five (5) drop-off sites in each of San Francisco’s 11 Supervisorial Districts; and (2) if the aforementioned convenience metric cannot be achieved in each Supervisory District, then those underserved areas must be alternatively served through periodic collection events and/or mail-back services. Ordinance § 2205(b)(1).

On page 7 of the October Proposed Plan, Inmar states that “[p]ursuant to §2205(b)(1), Inmar will establish a minimum of five Authorized Collection Sites in every Supervisorial District, geographically distributed to provide reasonably convenient and equitable access...” Later, on that same page, Inmar contradicts itself, stating that while its “goal” is to meet the above standard, “we also recognize that this may not be possible both logistically and physically.” Appendix A only identifies eight (8) kiosk locations in San Francisco that have “agreed” to become part of Inmar’s program. All other kiosk locations identified in the October Proposed Plan, and listed in Appendix B, have a status of “notified” or “in discussion.” Therefore, on the face of the October Proposed Plan, Inmar has not proven to SFE that it will, or can, satisfy the Ordinance’s convenience standard.

Furthermore, the October Proposed Plan does not provide any concrete details on *how* or *when* it will work, after SFE approval, to achieve the Ordinance’s mandatory convenience standard. For this reason, SFE cannot provide approval, as the October Proposed Plan falls far short of the Ordinance requirements.

- B. The October Proposed Plan does not adequately describe how it will comply with the Ordinance’s requirement to provide mail-back and/or take-back event services in underserved areas.

The October Proposed Plan attempts to argue that the Plan should still be approved because in addition to the small number of drop-off sites that will be operational (8 total across San Francisco), it will, at some point, after Plan approval, “secure Standard Mail-Back Envelope Distribution Sites” based on a formula presented on page 8 of the October Proposed Plan. However, the October Proposed Plan does not identify any sites that have actually agreed to be a Mail-Back Envelope Distribution site, if the Plan is approved. Although Appendix C is entitled “Appendix C: Standard Mail-Back Envelope Distribution Sites”, the text of the October Proposed Plan, at page 8, states that all of these sites are “identified as *potential* Standard Mail-Back Envelope Distribution Sites.” (emphasis added).

This is particularly notable because the October Proposed Plan *does not* propose providing any take-back events to San Francisco residents in underserved areas, and as is described in more detail below in Part I.C., it does not contemplate that mail-back services will be available upon request via toll-free number and/or website upon Plan approval (nor does it provide a timeline for when such services will be available after approval).

In contrast, MED-Project’s proposed Stewardship Plan, dated July 14, 2016, described in great detail *how* and *when* it would service underserved areas. For instance, the July 14, 2016, Plan states that:

90 days after Plan approval, MED-Project will conduct a gap assessment of established signed agreements with Kiosk Drop-Off Site Hosts. Within 30 days of the gap assessment, MED-Project will schedule quarterly Take-Back Events in any Supervisorial District where the service convenience goals are not met through signed Kiosk Drop-Off Site agreements. Take-Back Events will take place throughout the year, and MED-Project will continue to schedule quarterly until signed agreements have been obtained from a minimum of five Kiosk Drop-Off Site Hosts within the Supervisorial District.

In Supervisorial Districts where fewer than four agreements with Kiosk Drop-Off Site Hosts have been obtained, MED-Project will supplement Kiosk Drop-Off Sites and Take-Back Events through Mail-Back Services.

7/14/16 MED-Project Proposed Stewardship Plan, at p. 16.

The deficiencies in the October Proposed Plan in this regard fall well short of satisfying the Ordinance's requirements. SFE should not approve a plan with such minimum level of content on the critical convenience standard requirements.

- C. The October Proposed Plan does not adequately describe when it will begin providing mail-back services upon request via a toll-free number and website, as required by the Ordinance.

The approach set forth in the October Proposed Plan with regard to providing mail-back envelope services from a toll-free telephone number and website, as required by the Ordinance at Section 2205(b)(5), is also lacking. The October Proposed Plan makes only two general statements: (1) that Inmar's mail-back services will be available "directly" via MED-Project's existing website and toll-free number; and (2) "upon approval" Inmar is "committed to working with" MED-Project as required by the Ordinance's single system of promotion requirements, at Section 2206(a)(1)-(4), "to determine a fair and equitable method." October Proposed Plan, at p. 14.

Firstly, contrary to Inmar's proposed approach in the October Proposed Plan, MED-Project has not agreed to provide Inmar with free and unfettered use of its branded website and toll-free telephone number. Rather, as stated in MED-Project's letter, dated August 7, 2020, responsive to SFE's request for MED-Project's "vision" of a single system of promotion in San Francisco, MED-Project stated that it proposed that modifications be made to MED-Project's current website platform, as necessary, including making a neutrally unbranded landing page for San Francisco residents, and that costs of the modifications and future operations should be shared equally by approved Plan Operators. Likewise, with regards to MED-Project's existing toll-free number, the August 7, 2020, letter proposed modifying the initial script provided to San Francisco residents via the toll-free number in order to make it program operator neutral, and suggested that calls could then be directed out to each approved Program Operator, via designated phone numbers, or otherwise routed accordingly for processing by approved Program Operators.

Secondly, the October Proposed Plan makes no effort to provide any specificity as to how it proposes to implement the single website and toll-free telephone number required by the Ordinance. It also fails to address MED-Project's specific proposals offered to date, as described above. Given the absence of an adequate amount of specificity in the October Proposed Plan on this critical issue of how Inmar will satisfy the Ordinance's convenience standard requirements, and by when, SFE cannot approve the October Proposed Plan, as currently proposed, without requiring some type of interim approach to provide required services for the residents of San Francisco during the time period where the terms of providing a single program-operator-neutral website and toll-free telephone number are negotiated and agreed upon by the approved Program Operators, which addresses, among other things: (1) how mail-back services will be available directly to San Francisco residents upon request; (2) how details for collection services at drop-off sites and mail-back distribution locations will be sufficiently accessible to San Francisco residents; (3) the details of when take-back events will be conducted (a relatively expensive form of take-back that the October Proposed Plan eliminates as an option) for San Francisco residents; and (4)

how subsequent modifications to said existing services are made. Otherwise, an inequitable result will ensue, where one plan operator would be essentially relying on the existing operator's program to provide the necessary services to San Francisco residents, while still getting its incomplete proposed Plan approved.

II. Clarity is needed regarding the October Proposed Plan's approach to operating kiosks at City-owned pharmacies.

Section 2205(c) of the Ordinance states all Stewardship Plans "shall jointly operate a drop-off site within each City-owned pharmacy." However, contrary to this clear mandate, the October Proposed Plan states, on page 8, that "Inmar proposes to assume servicing one of the two City-owned pharmacy Kiosk Drop-off Sites." The October Proposed Plan also states on page 8, in a somewhat confusing and contradictory fashion, that "[u]pon Plan approval, Inmar commits to coordinating with the current approved Program Operator in determining a fair and equitable approach for the operation and/or servicing of the two City-owned pharmacy Kiosk Drop-off Sites." Inmar should clarify its proposal in this regard, as it is unclear what it is proposing and/or whether it is compliant with the Ordinance.

III. Every Stewardship Plan must independently satisfy the education and outreach requirements in the Ordinance and Regulation.

The Ordinance and Regulation establish comprehensive Stewardship Plan promotion requirements. *See* Ordinance § 2206; Regulation §§ B-D. Each Plan Operator must independently meet promotion content, reach and frequency, materials distribution, and other promotion requirements for Stewardship Plan approval. *See, e.g.*, Regulation § D.1.0 ("*Each Plan Operator shall utilize the following design parameters in meeting the requirements of Section 2206 of the Ordinance.*") (emphasis added). The Department cannot apply these standards differently among Plan Operators.

First, the Department's Notice of Determination requires that "[t]he Producers represented by MED-Project shall provide a minimum of 50 copies of the tri-fold flyer in Appendix O in English and 25 copies in each other language specified in the Ordinance on an annual basis and upon request" to certain pharmacies, health care facilities, veterinarians, and veterinary clinics. Notice of Determination Item 9 (June 5, 2019). Because, as it applies to MED-Project, the Department interprets the Ordinance and Regulation as mandating that specific quantities and types of promotional materials be distributed to certain locations on an annual basis, as well as upon request, it must apply those same requirements to all Plan Operators to ensure a level playing field. The October Proposed Plan does not address this Department mandate. *See e.g.*, October Proposed Plan at p. 42 (stating only that the sample promotional brochure "will be *available* in the Required Languages") (emphasis added).

Second, the October Proposed Plan does not adequately describe, with sufficient specificity, its proposed media plan, as required by the Ordinance and Regulation. Instead, page 20 of the October Proposed Plan generally states that "in coordination with other Program Operators and the Director, Inmar will develop, or coordinate to develop, a strategy for promoting

the program through traditional media ... Inmar will provide an example of a detailed traditional media plan *upon request.*” (emphasis added). This level of detail is insufficient and Inmar, like all potential Program Operators, must provide such a plan as part of the plan review and approval process.

IV. The biennial survey process proposed in the October Proposed Plan does not align with the Ordinance and Regulation.

Page 21 of the October Proposed Plan states that, “Inmar will conduct a biennial survey of City residents as well as pharmacists, veterinarians, and health professionals who interact with patients on use of medicines after the first full year of operation of the Stewardship Plan.” Page 21 also explains that “[d]raft survey questions will be submitted to the Director for review and comment at least 30 days prior to the initiation of the survey”, “[r]esults of the survey will be reported to the Director and made available to the public on the website required within 90 calendar days of the end of the survey period”, and “[t]he initial biennial survey will be completed within four months of the completion of the first year of the collection program operation.”

The above quoted language does not comply with Section 2206(a)(4) of the Ordinance and Section D.3.1 of the Regulation, which requires that all Program Operators with approved Stewardship Plans “coordinate” on completing a single biennial survey of City residents. The October Proposed Plan appears to propose that each approved Program Operator will conduct separate biennial surveys without coordination. This is inconsistent with the Ordinance and Regulation and must be revised accordingly.

V. Coordination must require licensing agreements.

Pages 19 – 22 of the October Proposed Plan indicate that Inmar will coordinate with all Plan Operators to develop a single system of promotion for the Stewardship Plan, including kiosk signage, outreach materials, and promotional messaging. Appendix D of the October Proposed Plan contains depictions of sample kiosk signage and other program materials, all of which feature MED-Project’s toll-free number and website (www.med-project.org), as well as the “look and feel” of MED-Project’s proprietary artwork, designs, branding, and other intellectual property (“MED-Project Property”). As MED-Project has stated repeatedly, Inmar will be welcome to use MED-Project property upon executing a licensing agreement allowing such use, as further discussed in this section.

MED-Project has invested substantial time, energy, and resources in creating goodwill in artwork and branding related to MED-Project’s mission and services. MED-Project owns intellectual property (registered and unregistered) and proprietary rights in and to the “look and feel” of its kiosks and related signage, and in its name, artwork, branding, website, and other materials. Any unauthorized/unlicensed reference to MED-Project’s toll-free number and website or use of related promotional materials or elements with a similar “look and feel” to that of MED-Project would infringe on MED-Project’s intellectual property rights. *AT&T Corp. v. Vision One Security Sys.*, 1995 WL 476251, at *5, n.4 (S.D. Cal. July 27, 1995) (“A claim for federal

trademark infringement may be brought against any person who, without license from the holder of the protected mark, uses any ‘reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive...’”) (citing 15 U.S.C. 1114(1)(a)).

Accordingly, in order to preserve MED-Project’s Property, any circumstances under which Inmar references MED-Project’s toll-free number or website or otherwise uses or imitates any of MED-Project’s “look and feel” or other proprietary rights (including any marks, materials, artwork, signage, branding, website domain names, call center references, or other intellectual property) must be subject to a licensing agreement governing the use of these rights and properties. *Audigier Brand Mgmt. v. Perez*, 2012 WL 5470888, at *7 (C.D. Cal. Nov. 5, 2012) (“where the trademark holder has authorized another to use its mark, there [generally] can be no likelihood of confusion—the prerequisite to any trademark infringement claim.”). The intent of the license agreement is to establish reasonable and customary limits that set forth terms to guard and protect MED-Project’s proprietary rights and the goodwill associated therewith. MED-Project has previously indicated to SFE and Inmar (via written communications, and at an October 14, 2020, meeting) that MED-Project is willing to license (on a royalty-free basis) the use of such rights and properties pursuant to a customary licensing agreement. The October Proposed Plan does not provide any description of these necessary licensing arrangements. As discussed, Inmar will be welcome to reference MED-Project’s toll-free number, its website, or elements of (or otherwise imitate) the “look and feel” of MED-Project’s proprietary artwork, designs, branding and other intellectual property, upon executing a licensing agreement with MED-Project.

VI. Every Stewardship Plan must provide a description of its proposed emergency and rapid response services.

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 § 2204(d). To this end, all 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. The October Proposed Plan does not describe what, if any, emergency and rapid response services are proposed to be used, and the policies and procedures that will be in place, should an emergency event requiring immediate response be needed.

VII. 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 § 2202 (“‘Stewardship Plan’ means a plan . . . that is: (1) financed, developed, implemented and participated in by one or more Producers”); Ordinance § 2203(e)(6) (“A Producer, either individually or jointly with other Producers, shall: Pay all administrative and operational costs and fees associated with its Stewardship Plan.”); *see also* SF Environment, Second Biennial Report on the San Francisco Safe Drug Disposal Stewardship Ordinance (July

2019) (“The Ordinance is based on an Extended Producer Responsibility (EPR) model in which manufacturers of products that are difficult or expensive to dispose of are responsible for the costs of collection and disposal at the end of their product’s useful lives.”).

The Ordinance defines “Producer” to mean “a Manufacturer engaged in the Manufacture of a Covered Drug sold in San Francisco, including a brand-name or generic Drug,” subject to certain exceptions. Ordinance § 2202. It then makes clear that these Producers must pay for virtually all aspects of the Stewardship Plan. Specifically, the Ordinance provides that:

A Producer or group of Producers participating in a Stewardship Plan shall pay *all* administrative and operational costs related to their Stewardship Plan, except as provided under this Section 2208. Administrative and operational costs related to the Stewardship Plan *include but are not limited to* the following: [enumerating cost categories].

Ordinance § 2208(a) (emphasis added). There are no exceptions allowing other organizations to pay these costs on the Producers’ behalf.

Proposed Stewardship Plans must meet these funding requirements to be approved. Inmar’s draft Stewardship Plan includes only three “Producer(s).” *See* October Proposed Plan at p. 6. It is difficult to imagine three Producers somehow funding a Stewardship Plan of the scope and scale that the Ordinance and Regulations require for all household covered drugs in San Francisco. That is the obligation, however, that any Producer(s) participating in any Stewardship Plan assume(s). If, contrary to the Ordinance’s plain language, the Department interprets the Ordinance such that other organizations, not Producers, may fund Stewardship Plan costs in total or in part, then due process requires that it apply the same interpretation to MED-Project.

VIII. Department funding requirements apply independently to each Plan Operator.

Section 2215 of the Ordinance establishes Stewardship Plan review and annual operating fees. Each Plan Operator must, of course, pay its own plan review fees under Ordinance 2215(a). *See* Ordinance § 2215(a) (“A Producer or group of Producers participating in a Stewardship Plan shall pay to the Director plan review fees to be established . . .”). Likewise, each Plan Operator must also be responsible for an equal share of the Department’s “annual operating fees” (*e.g.*, if the annual operating fee is \$95,000 and there are two approved Stewardship Plans, each Plan Operator would pay \$47,500). Because each Plan Operator has an independent obligation to meet the same collection and disposal, promotion, and administrative requirements, each Plan Operator also has an independent obligation to pay the equivalent amount of annual operating fees.

IX. Stewardship Plans must provide accurate and reliable means of identifying Authorized Collection Sites, Mail-Back Distribution Locations and Take-Back Events under a Stewardship Plan.

Page 6 of the October Proposed Plan does not provide for an accurate and reliable means for residents to search for locations to dispose of unwanted medicine. Based on our extensive

experience in this industry, MED-Project believes that current, accurate mapping of locations and events is essential in providing San Francisco residents with an up-to-date list of accessible kiosks, mail-back distribution locations and take-back events under a Stewardship Plan. This is particularly true now, in light of COVID-related access restrictions or interruptions and related modifications that are being made by businesses in light of the COVID pandemic.

Further, in the October Proposed Plan, the searchable method provided does not yield accurate or complete results. This is why MED-Project has compiled a list of collection locations on its website, for each jurisdiction where it operates, so that residents have a readily-available accurate source of information regarding the locations of convenient kiosks and mail-back distribution locations in their area. *See*, MED-Project San Francisco City and County, CA Convenient Locations webpage, available at: <https://med-project.org/locations/san-francisco/convenient-locations>.

X. SFE must apply the same approval conditions and standards to all Plan Operators.

A. Reporting requirements apply independently to all Stewardship Plans.

The Department, through its Notices of Determination, imposes several reporting requirements on MED-Project that must also extend to any other Plan Operators. The Notices of Determination require MED-Project to report, “[w]ithin 10 business days of the end of each calendar quarter . . . a summary of Help Desk requests by type made in the previous quarter, including the number of each type, average days to close and the range (min/max days) in length of time to close.” 7/29/20 Revised Notice of Determination, Item 7. In addition, it requires MED-Project to provide a list of all participating Producers, including their contact names and emails, upon Department request within 10 business days. 7/29/20 Revised Notice of Determination, Item 1. These same requirements must apply with equal force to any Plan Operator.

B. Additional change management notifications apply to all Stewardship Plans.

The Department, through its Notices of Determination, require that MED-Project shall report any changes which occur due to location closure or withdrawal from the program in writing to the Department within 15 days of MED-Project’s knowledge. 7/29/20 Revised Notice of Determination, Item 4. Such a requirement must be applied to all Plan Operators.

C. Public access requirements apply independently to each proposed Stewardship Plan.

Proposed stewardship plans are public documents. Section 2211(g) of the Ordinance requires that “[t]he Director shall make all Stewardship Plans and proposed plans submitted under this Section 2211 available to the public.” SFE has properly made the October Proposed Plan available on its website.

This is the third version of the Inmar proposed stewardship plan that has been made available by San Francisco for public comment. Although Inmar has modified the language used

in earlier draft proposed Plans, which attempted to impose self-proclaimed usage restrictions on any use of the draft proposed Plan by the public except for formal public comment, Inmar still states the following claim on every page of the October Proposed Plan:

© Inmar 2020. Inmar authorizes the posting of the plan dated October 13, 2020 in accordance with Section 2211(b) and 2211(g) of the San Francisco Ordinance 31-15 for Safe Drug Disposal Stewardship for the purposes of making it available to the public for review and comments.

Proposed Plan *passim*.

The Ordinance does not provide that the Director shall make all proposed Plans submitted under Section 2211 available to the public only for public review and comment, or otherwise as limited by a Plan Operator. See, Ordinance, § 2211(g). It requires the Director to make proposed Stewardship Plans public, period. To the extent that Inmar intends that its October Proposed Plan “authorizes the posting” language is somehow meant to limit the use of the October Proposed Plan by the public in other contexts, the Department should not approve or endorse Inmar’s efforts to attempt to side-step requirements for the full public access provided by statute.¹

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 SFE going forward to provide San Francisco residents with safe, convenient and effective services under our approved Stewardship Plan.

Sincerely yours,



Dr. Victoria Travis, PharmD, MS, MBA
National Program Director

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 substances diversion risks). The October Proposed Plan’s claims go far beyond that, however.