

Product Stewardship Plan Evaluation: San Francisco MED-Project - November 1, 2018 Revision (completed 4-5-2019)

Review Criteria for Evaluation of Stewardship Plans Submitted for the San Francisco Safe Drug Disposal Stewardship Ordinance				
Section 2204. Stewardship Plans - Components				
Ordinance Section	Requirement	Where in Plan?	Meets Req. (Y/N)	Issue/Information Requested
Sections 2204(a-h)	Each Stewardship Plan shall include:			
2204(a)	Contact information (name, address, phone number, email address) for all Producers participating in the Stewardship Plan and the contact information for a point of contact for each Producer.	Appendix A	N	<p>Producer contact info in Appendix A does not include phone number and email of “human being.”</p> <p>Proposed Condition #1: The Producers represented by the MED-Project shall provide a complete list of all Producers participating in the MED-Project Stewardship Plan for San Francisco containing all information, including contact name and email, required in Section 2204(a) of the Ordinance upon request within 10 business days.</p>
2204(b)	<p>A description of the proposed collection system to provide convenient ongoing collection service for all Unwanted Covered Drugs from City residents in compliance with the provisions and requirements in Section 2205, including a:</p> <ul style="list-style-type: none"> a. list of all collection methods and participating Collectors b. list of drop-off sites c. description of how any periodic collection events will be scheduled and located d. description of how any mail-back services will be provided e. example(s) of prepaid/preaddressed mailer(s) 	<ul style="list-style-type: none"> a. Appendix C b. Appendix C c. Sec V.C d. Sec V.E e. n/a f. Appendix D g. Appendix C 	N	<p>d. Instructions for use of mail-back services are not clear</p> <p>Proposed Condition #2: The Producers represented by the MED-Project shall submit a revised Appendix M - Call Center Scripts and a revised Appendix N - Website Webpages to clarify that injectors cannot be disposed in kiosks and that separate mail-back services must be used for inhalers and for injectors by June 30, 2019.</p>

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	<p>f. list of retail pharmacies and law enforcement agencies contacted by the plan under Section 2203(e)(2). (Note: This is the correct reference – ordinance has a typo which shows 2203(d)(2)).</p> <p>g. list of all Collectors who offered to participate</p>			<p>e. Example of small inhaler package (subject of new technology approval requested in Appendix L under Sec 2207(b)) not provided</p> <p>Proposed Condition #3: The Producers represented by the MED-Project shall submit an example of the Stericycle small inhaler mail-back package referenced in Appendix L by June 30, 2019.</p>
2204(c)	A description of the handling and disposal system, including identification of and contact information for collectors, transporters and waste disposal facilities to be used in accordance with Sections 2205 and 2207.	Sec X	Y	
2204(d)	<p>A description of the policies and procedures to be followed by persons handling collected Unwanted Covered drugs, including:</p> <p>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.</p> <p>b. how all entities participating in the Stewardship Plan will operate under and comply with all applicable federal state laws, rules and guidelines.</p>	<p>a. Sec V.B-E</p> <p>b. Sec XIV</p>	N	<p>b. Inhaler and injector mail back packages are not routed through a reverse distributor</p> <p>Proposed Condition #4: Within 10 business days of each calendar quarter, the Producers represented by the MED-Project as their Plan Operator shall report in writing to the Department whether any new Pre-Filled Injector Products and/or Inhaler Products brought to market contain Schedule II to V Controlled Substances, and accordingly require handling by a DEA-registered reverse distributor.</p>
2204(e)	A certification that any patient information on Drug packaging will be promptly destroyed.	Sec VII	Y	
2204(f)	A description of the public education effort and promotion strategy required in Section 2206, including a copy of standardized instructions for City residents, signage developed for collectors, and required promotional materials.	Sec XI & Appendices E (signage), M (call center script), N (website), and O (Flyer and mailer inserts)	Y	

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2204(g)	Proposed short-term and long-term goals of the Stewardship Plan for collection amounts, education and promotion.	Sec VI	Y	Proposed Condition 12: The Producers represented by the MED-Project shall report the numerical results of the Plan's Education & Public Outreach short term goals as described in Section VI (pg 18) for CY 2018 by June 30, 2019 and update these results for future reporting periods in the applicable Annual Report.
2204(h)	A description of how the Stewardship Plan will consider (1) use of existing providers of waste pharmaceutical services; (2) separating Covered Drugs from packaging to the extent possible to reduce transportation and disposal costs; and (3) recycling of Drug packaging to the extent feasible.	1) Sec V.B.2 2) Sec XIII 3) Sec XIII	Y	
Section 2205. Stewardship Plans – Collection of Covered Drugs				
Sections 2205(b)(1-5)	The collection system for each Stewardship Plan shall:			
2205(b)(1)	Provide reasonably convenient and equitable access for all City residents in all Supervisorial Districts. The system of drop-off sites shall provide at least five drop-off sites in every Supervisorial District, geographically distributed to provide reasonably convenient and equitable access. 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, then those areas shall be served through periodic collection events and/or mail-back services	Sec V.A-E & Appendix C	Y	Proposed Condition #5: Notification of non-substantive changes in Program Operation described in Section 2212(c) which are made at the discretion of MED-Project on behalf of the Producers they represent, including the closure of any of the standard mail-back envelope distribution points listed in Appendix C of the 11-1-2018 Revised Plan, shall be made in writing to the Director 15 days in advance of the change.
2205(b)(2)	Be safe and secure, including providing for the prompt destruction of patient information on Drug packaging.	Sec VII	Y	
2205(b)(3)	Give preference to having retail pharmacies and law enforcement agencies serve as drop-off sites.	Sec V.B	Y	
2205(b)(4)	Include, as Collectors, any retail pharmacy or any law enforcement agency willing and able to serve voluntarily as a drop-off site for Unwanted Covered Drugs within three months of their offer to participate, unless the Collector requests a longer time frame. A Stewardship Plan may also accept other Collectors willing to serve as a drop-off site for Unwanted Covered Drugs and able to meet the requirements.	Sec V.B.1	Y	

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2205(b)(5)	Make mail-back services available, free of charge, to disabled and home-bound residents upon request through the Stewardship Plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mailers to persons providing services to such residents. The toll-free telephone number and website required shall be in English, Spanish, Chinese, Russian, and Tagalog.	Sec V.E.4	Y	Proposed Condition #6: For each type and size of mail-back packages, the Producers represented by the MED-Project shall report the total of actual, not average, weights of mail-back packages received by the disposal vendor, starting with the 2019 Annual Report due April 25, 2020.
2205(c)	All stewardship plans shall jointly operate a drop-off site within each City-owned pharmacy.	n/a	Y	City-owned pharmacies are listed in Appendix C
2205(d)	Drop-off sites shall accept all Covered Drugs from City residents during all hours that the retail pharmacy, law enforcement agency, or other Collector is normally open for business with the public. Drop-off sites not operated by a law enforcement agency shall utilize secure collection bins in compliance with all applicable requirements. In the event that more than one Stewardship Plan operates a drop-off site at a particular location, each drop-off site must accept all Covered Drugs.	Sec V.B	Y	Proposed Condition #7: Within 10 business days of the end of each calendar quarter, the Producers represented by MED-Project shall report, through their Plan Operator, in writing to the Director 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.
Section 2206. Stewardship Plans – Promotion				
Section 2206(a)(1-4)	All Stewardship Plans shall coordinate with each other and develop a single system of promotion that shall:			
2206(a)(1)	Promote the Stewardship Plans so that collection options for Covered Drugs are widely understood by 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 City residents.	Sec XI	N	Outreach Program does not include specifics of outreach to health care practitioners, veterinarians, and veterinary hospitals Proposed Condition #9: The Producers represented by the 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 each of the San Francisco pharmacies, health-care facilities, veterinarians, and veterinary clinics within 60 days of provision of a list of these entities by the Director.

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2206(a)(2)	Work with Collectors participating in the Stewardship Plans to develop clear, standardized instructions for City residents on the use of collection bins and a readily-recognizable, consistent design of collection bins.	Sec V.B.3 & Appendix E	N	<p>Instructions for injector disposal are not clear.</p> <p>Proposed Condition #8: The Producers represented by the MED-Project shall provide signage similar to the injector mail-back signage shown in Appendix E (pg 94) on each kiosk operating in San Francisco. Proposed kiosk signage or an alternative on-site method of informing residents of the need to use mail-back services for injector disposal shall be submitted to the Director by June 30, 2019 and implemented within 60 days of the Director's approval.</p>
2206(a)(3)	Establish a single toll-free telephone number and single web site where collection options and current 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 City residents. Plain language and explanatory images should be used to make use of medicine collection services readily understandable by all residents, including individuals with limited English proficiency.	Sec XI & Appendices M, N & O	N	<p>Outreach Materials are not provided to health care facilities, veterinary facilities and other interested parties.</p> <p>Proposed Condition #9: See above</p>
2206(a)(4)	Conduct a biennial survey of City residents and a survey of pharmacists, veterinarians, and health professionals in the City who interact with patients on use of medicines after the first full year of operation of the plans. Survey questions shall measure percent awareness of the stewardship plans, assess to what extent drop-off sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription medicines used in the home. Draft survey questions shall be submitted to the Director for review and comment at least 30 days prior to initiation of the survey. Results of the survey shall be reported to the Director and made available to the public on the required website within 90 days of the end of the survey period. The privacy of all survey respondents shall be maintained.	Sec XII	Y	

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2206(b)	All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by this section shall be in English, Spanish, Chinese, Russian, and Tagalog.	Sec XI & XII & Appendices E, M, N & O	N	<p>Website mail-back order form and Kiosk & standard envelope locator screens are not available in Spanish, Chinese, Russian or Filipino</p> <p>Proposed Condition #10: The Producers represented by MED-Project shall update MED-Project's San Francisco webpages for mail-back service order form and for the kiosk & standard mail-back envelope distribution point locator so that the webpages shall be available and fully functional in Spanish, Chinese, Filipino, and Russian, as well as English by June 30, 2019.</p>
Section 2207. Stewardship Plans – Disposal of Covered Drugs				
2207(a)	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 [unless approved as in 2207(b)].	Sec X	N	<p>Heritage Thermal Services – Ohio appears on EPA's Echo website (www.echo.epa.gov) as a High Priority Violator of the Clean Air Act on a continuous basis for the past three years.</p> <p>Proposed Condition #11: Use of Heritage Thermal Services – Ohio as a Disposal Facility for Kiosk Drop-Off Site and Take Back Collection Services is <u>not</u> approved. The Producers represented by the MED-Project shall utilize only the secondary and tertiary disposal facilities listed in Section X.D of the Plan for covered drugs disposed at a kiosk drop-off site until a Request for Approval of an Alternate Disposal Facility is approved by the Director as described in Section 2207 of the Ordinance, or an explanation of Heritage Thermal Services' Clean Air Act High Priority Violation Compliance Status is approved by the Director.</p>
2207(b)	The Director may grant approval for a Stewardship Plan to dispose of some or all collected Covered Drugs at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if the Director deems the use of a hazardous waste disposal facility described under	Appendices J, K & L	Y	These approvals are for medical waste incineration for standard mail-back packages and MSW incineration for inhaler and injector mail-back packages

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	subsection (a) of this section to be infeasible for the Stewardship Plan based on cost, logistics or other considerations.			
2207(c)	A Stewardship Plan may petition the Director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in this section, or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas: (1) monitoring of any emissions or waste; (2) worker health and safety; (3) reduction or elimination of air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and (4) overall impact on the environment and human health. (n/a)	n/a	n/a	No petition for approval submitted with Plan