



San Francisco Environment Department Regulation #SFE-23-02-SDDSO

Regulations Implementing the Safe Drug Disposal Stewardship Ordinance (Ordinance No. 31-15; 50-23)

Regulation Effective Date: Upon Director's Signature

A. Authorization

The Safe Drug Disposal Stewardship Ordinance ("Ordinance") was signed by Mayor Edwin Lee on March 26, 2015, and became effective on April 25, 2015. The Ordinance requires any person who produces a Covered Drug offered for sale in San Francisco to participate in an approved Stewardship Plan for the collection and disposal of unwanted drugs from residential sources, as codified in the San Francisco Environment Code, Chapter 22, Division I, Sections 2200 through 2219 ("Chapter 22").

The Director of the Environment Department promulgates these regulations pursuant to his authority to adopt rules necessary to implement and administer Chapter 22 under Section 2214(a).

B. Scope

These regulations apply to any Producer participating in a Stewardship Plan, as defined in Chapter 22, or the operator of a Stewardship Plan acting on behalf of a Producer, which has been approved by the Director of the Environment Department as required in Section 2211 of Chapter 22. These regulations replace San Francisco Department of the Environment Regulation #SFE-16-01-SDDSO.

These regulations do not duplicate the Chapter 22 and must be read together with Chapter 22.

C. Definitions

"Department" refers to the San Francisco Environment Department, or its successor agency.

"Biennial Surveys" refers to the biennial survey of City residents and biennial survey of pharmacists, veterinarians, and health professionals in the City required in Section 2206(a)(4) of Chapter 22.

"Help Desk" is the call center and/or email-in database operated by an approved Plan Operator for the purpose of providing support to Kiosk Drop-Off Sites, Mail-Back Envelope Distribution Sites, and other Stewardship Plan participants.

"Kiosk Drop-Off Site" means a federal Drug Enforcement Administration (DEA) authorized collector or law enforcement agency that hosts a secure collection kiosk for collecting Unwanted Covered Drugs through an approved Stewardship Plan.

"Kiosk Host-Managed Collection Service" refers to a collection kiosk service model where staff from the Kiosk Drop-Off Site are responsible for the installation of empty liners for collection of Unwanted Covered Drugs in collection kiosks and the subsequent removal and packaging of full liners prior to transport by common carrier to an authorized disposal facility.

“Mail-Back Envelope Distribution Site” means a location in the City, established as part of an approved Stewardship Plan, that provides Mail-Back Services for Unwanted Covered Drugs – not including pre-filled injector products and inhaler products – at no charge to City residents.

“Mail-Back Services” refers to postage prepaid and preaddressed packages for returning Unwanted Covered Drugs that are provided at no charge to City residents as part of an approved Stewardship Plan.

“Medium (plural, media)” means a communication vehicle that may or may not contain advertising, such as the internet, radio, magazines, mail, newspapers, out of home media, television, telephone directories, etc.

“Non-Substantive Change” refers to any changes to an approved Stewardship Plan that do not substantively alter achievement of the service convenience goal or substantively alter plan operations, as described in Section 2212(c) of Chapter 22.

“Outreach Program” means a series of activities undertaken to meet the requirements of Section 2206 of Chapter 22, including but not limited to commercials or advertisements, grass roots marketing, and community based social marketing.

“Proof of Performance” means documentation verifying that outreach described within the approved Stewardship Plan did in fact run. Examples of proof of performance can include a media kit, a media invoice, a photograph of a billboard, a copy of a published newspaper advertisement, reports of Internet usage, or other appropriate documentation.

“Plan Operator” means the entity designated by participating Producers to operate the activities described in an approved Stewardship Plan.

“Refuse” has the meaning set forth in the Refuse Collection and Disposal Ordinance adopted November 8, 1932, as amended, and includes recyclables, compostables, and trash.

“Single System of Promotion” refers to the single, coordinated system of outreach and promotion that all approved Plan Operators are required to develop and jointly implement so that collection options for Unwanted Covered Drugs are widely understood, as required in Section 2206 of Chapter 22.

“Substantive Change” refers to any changes to an approved Stewardship Plan that substantively alter plan operations, as described in Section 2212(a) of Chapter 22.

“Telephone Call Center” or “Call Center” means the resident-facing single toll-free telephone number an approved Plan Operator operates individually or jointly with other approved Plan Operators to publicize collection options and other information pertaining to safe medicine disposal.

“Target audience” means persons who are 18 years old or older and live in San Francisco.

D. Stewardship Plan Participation, Review and Approval, Changes, and Discontinuation

1.0 Producer Participation. A Producer or group of Producers shall notify the Department of changes to their Plan Operator or participation in an approved Stewardship Plan as described in this section.

1.1 If a Producer intends to change Plan Operators and participate in an existing approved Stewardship Plan, the Producer shall submit a complete and signed form in a format prescribed by the Director that at minimum includes the information specified in Section 2203(g) of Chapter 22.

- 1.2 If a Producer or group of Producers intend to form a new Stewardship Plan that has not been approved by the Department, the Producer(s) shall:
 - 1.2.1 Submit a completed and signed form(s) in a format prescribed by the Director that at minimum includes the information specified in Section 2203(g) of Chapter 22.
 - 1.2.2 Within three months of submission of the form in Section D. 1.2.1 of these regulations, submit a proposed Stewardship Plan along with a plan review fee in an amount equal to 200 hours at the current approved hourly plan review fee.
- 1.3 A Producer or group of Producers that intend to form a new Stewardship Plan shall continue to participate in a currently approved Stewardship Plan until the new Stewardship Plan is approved by the Department and all elements of the new Stewardship Plan are fully implemented.
- 1.4 In the event that a Plan Operator discontinues operation of an approved Stewardship Plan, a Producer or group of Producers that participated in the discontinued Stewardship Plan and intend to form a new Stewardship Plan shall be exempted from the participation requirement in Section D. 1.3 of these regulations for 270 days.
- 2.0 Public Review and Comment on Proposed Stewardship Plans. The Director or her/his designee shall use the following procedures to provide the public an opportunity for review and comment on proposed Stewardship Plans:
 - 2.1 Within 30 calendar days of submission of a proposed Stewardship Plan, make the proposed Plan available for review on the Department's website and in-person by appointment. The Department shall also provide instructions for scheduling an appointment to review the proposed Stewardship Plan in-person and for submitting comments electronically and by mail.
 - 2.2 Within 30 calendar days of submission of a proposed Stewardship Plan, commence a comment period during which the Department will accept written comments on the proposed Plan from the public. The comment period shall be 30 calendar days in duration and conclude at 5:00 PM on the 30th day.
 - 2.3 If the 30th day of the comment period is a non-business day, the end of the public comment period shall be the first business day thereafter at 5:00 PM.
 - 2.4 The Department shall consider any public comments received during a 30-day public comment period. The Department may, but is not required to, consider public comments received after the comment period.
 - 2.5 Within 10 calendar days of the end of a public comment period, the Department shall make all comments received from the public available on the Department's website and in-person by appointment.
 - 2.6 The Department shall ensure that copies of all approved Stewardship Plans currently in operation and any related written plan approvals and/or rejections by the Department are available on the Department's website and in-person by appointment.
- 3.0 Minimum Collection System Requirements for Plan Approval. Prior to approval of a proposed Stewardship Plan, the Plan Operator shall demonstrate the proposed collection system will provide reasonably convenient and equitable access for all City residents within 90 calendar days of Stewardship Plan approval by:
 - 3.0.1 Demonstrating that the Plan Operator has obtained signed agreements with at least two Kiosk Drop-Off Sites in each Supervisorial District; and
 - 3.0.2 Demonstrating that the Plan Operator has obtained commitments to participate from a sufficient number of Mail-Back Envelope Distribution Sites to meet the Alternative Convenience Standard established in Section I. 3.0 of these regulations; and

- 3.0.3 Demonstrating that the Stewardship Plan has obtained agreements with a law enforcement agency and locations that will host collection events for Unwanted Covered Drugs in sufficient numbers to meet the Alternative Convenience Standard established in Section I. 3.0 of these regulations.
- 3.1 Kiosk Drop-Off Sites that agree to participate in a Stewardship Plan prior to approval of the Plan shall be installed and in operation within 90 calendar days of Stewardship Plan approval, unless the site requests a longer time frame.
- 3.2 In the event that a Kiosk Drop-Off Site that agreed to participate in a Stewardship Plan prior to approval of the Plan is not operating within 90 calendar days of Stewardship Plan approval, the Plan Operator shall supplement service in that Supervisorial District in accordance with the requirements in Section I. 3.0 of these regulations.
- 4.0 Substantive Changes to Existing Product Stewardship Plans. Plan Operators shall utilize the following procedures when submitting proposed Substantive Changes to the Department for review and written approval:
- 4.1 When providing written notification to the Department of a proposed Substantive Change to an approved Stewardship Plan, the written notification document shall be referred to as a "Substantive Change Proposal."
- 4.2 The Department shall make a determination on whether the proposed Substantive Change is subject to the review and public comment requirements in Section 2211 of Chapter 22 and notify the requesting Plan Operator within 7 business days.
- 5.0 Non-Substantive Changes to Existing Product Stewardship Plans. Plan Operators shall utilize the following procedures when notifying the Department of Non-Substantive Changes to an approved Stewardship Plan prior to implementation of the changes:
- 5.1 When providing written notification to the Department of a Non-Substantive Change, the written notification document shall be referred to as a "Non-Substantive Change Notification."
- 5.2 For Non-Substantive Changes made at the discretion of the Plan Operator, the Plan Operator shall provide the Department a Non-Substantive Change Notification at least 15 days before implementing the changes. The Department shall review the Non-Substantive Change Notification, make a determination on whether the proposed changes are Substantive Changes, and notify the requesting Plan Operator of the Department's determination within 5 business days. If the Department determines the proposed changes are Substantive Changes, the Plan Operator shall resubmit the proposed changes as a Substantive Change Proposal.
- 5.3 For Non-Substantive Changes made at the discretion of a Kiosk Drop-Off Site, Mail-Back Envelope Distribution Site, vendor, or other Stewardship Plan participant that is not the Plan Operator, the Plan Operator shall provide the Department a Non-Substantive Change Notification within 15 calendar days of the Plan Operator's knowledge.
- 6.0 Stewardship Plan Changes in Response to New Requirements. In the event that an approved Stewardship Plan no longer complies with federal and state laws, rules, or guidelines as a result of changes to the applicable requirements, the approved Plan Operator shall be required to update their Stewardship Plan.
- 6.1 In the event that the operator of an approved Stewardship Plan becomes aware that their Stewardship Plan no longer complies with applicable federal and state laws, rules, or guidelines, the Plan Operator shall notify the Department within 15 days of the Plan Operator's knowledge.

- 6.2 A Plan Operator that is required to update their Stewardship Plan to comply with changes to the applicable federal and state laws, rules, or guidelines shall either:
- 6.2.1 Submit a Substantive Change Proposal to the Department at least 30 days before the changes are scheduled to occur; or
 - 6.2.2 Notify the Department in writing of the Plan Operator's intent to submit an updated Stewardship Plan to the Department for review. Within 90 days of such notification, the Plan Operator shall submit an updated Stewardship Plan to the Department for review.
- 6.3 The Department may exercise reasonable discretion to waive strict compliance with the requirements of Sections D. 4.0 to 6.2 of these regulations to allow a Plan Operator to update their Stewardship Plan so it complies with changes to the applicable federal and state laws, rules or guidelines within the required timeframe(s).
- 7.0 Stewardship Plan Discontinuation. In the event that a Plan Operator discontinues operation of an approved Stewardship Plan, the following requirements shall apply to the Producer or group of Producers that participated in the discontinued Stewardship Plan:
- 7.1 The Producer or group of Producers shall inform the Director in writing within 15 calendar days of the Producer's or group of Producer's knowledge of their Plan Operator's intent to discontinue operation.
 - 7.2 Within 30 calendar days of notifying the Department of their Plan Operator's intent to discontinue operation, the Producer or group of Producers shall either:
 - 7.2.1 Identify the existing approved Stewardship Plan the Producer or group of Producers will participate in by submitting a complete and signed form in a format prescribed by the Director that at minimum includes the information specified in Section 2203(g) of Chapter 22; or
 - 7.2.2 Notify the Director in writing of the Producer's or group of Producers' intent to form a new Stewardship Plan and identify the new Plan Operator by submitting a complete and signed form in a format prescribed by the Director that at minimum includes the information specified in Section 2203(g) of Chapter 22.
 - 7.3 The Producer or group of Producers shall inform all participating Kiosk Drop-Off Sites, Mail-Back Envelope Distribution Sites, and other Stewardship Plan participants of their Stewardship Plan's discontinuation within 30 calendar days knowledge of the Plan Operator's intent to discontinue operation.
 - 7.4 The Producer or group of Producers shall ensure that collection kiosks are removed from Kiosk Drop-Off Sites participating in the discontinued Stewardship Plan within 90 calendar days knowledge of their Plan Operator's intent to discontinue operation.
 - 7.5 The Department shall notify all other approved Plan Operators of any Kiosk Drop-Off Sites participating in the discontinued Stewardship Plan that are willing to continue serving as Kiosk Drop-Off Sites. Those Kiosk Drop-Off Sites shall be included in one of the currently approved Stewardship Plans within 90 calendar days of the Department's notification unless the site requests a longer time frame.
 - 7.6 In the event that the existing approved Plan Operators are unable to come to agreement on which Kiosk Drop-Off Sites will be included in their respective Plans, the Department shall assign the Kiosk Drop-Off Sites equally among the approved Plan Operators through a randomized process approved by the Director.
- 8.0 Withdrawal of Stewardship Plan Approval. The Director of the Department may withdraw approval of an approved Stewardship Plan as described in this section.

- 8.1 The Director of the Department may withdraw approval of a Stewardship Plan if, after receiving a written warning of violation(s) under Section 2213(b) of Chapter 22, the Plan Operator has not corrected all cited violations within 30 days of the written warning of violation(s), and the Director determines that one or more of the uncorrected violations has the effect of significantly undermining the effectiveness of the Stewardship Plan in accomplishing the goals of Chapter 22.
- 8.2 The Director shall provide the Plan Operator with written notice of their intent to withdraw approval of a Stewardship Plan under Section D. 8.1 of these regulations at least 30 days prior to the date the Director designates for withdrawal of approval, and the notice shall include reasons for the proposed withdrawal of approval. Within 15 days of receiving such notice, the Plan Operator may submit written objections to the withdrawal of approval. The Director shall review any such written objections, shall determine whether or not withdrawal of approval remains warranted in light of the objections, and shall notify the Plan Operator in writing of the Director's determination and, if applicable, the date on which the Director's withdrawal of approval of the Stewardship Plan will go into effect.
- 8.3 If the Director of the Department withdraws approval of a Stewardship Plan, the Plan Operator – or the Producer or group of Producers it represents – shall discontinue operation of the Stewardship Plan in accordance with the requirements of Section D. 7.0 of these regulations.

E. Outreach Program Design

- 1.0 Outreach Program Design. Each Plan Operator shall utilize the following design parameters in meeting the requirements of Section 2206 of Chapter 22:
 - 1.1 The Outreach Program shall convey disposal instructions only for the types of collection and disposal options offered through all approved Stewardship Plans.
 - 1.2 All written outreach materials, including collection kiosk signage, shall be available in English, Spanish, Chinese, Russian, and Filipino, and shall be designed to be readily understandable by all residents, including individuals with limited literacy.
 - 1.3 The messages used in outreach activities shall be designed and implemented to achieve the following goals:
 - 1.3.1 Promote safe storage of all drugs, wanted or unwanted, by residents in their home;
 - 1.3.2 Discourage stockpiling and storage in the home of Unwanted Covered Drugs;
 - 1.3.3 Describe where and how to return Unwanted Covered Drugs under all approved Stewardship Plans;
 - 1.3.4 Describe Mail-Back Services and any other disposal options offered under all approved Stewardship Plans;
 - 1.3.5 Discourage the disposal of Unwanted Covered Drugs in any refuse collection container, including a collection cart, receptacle, bin, or debris box;
 - 1.3.6 Discourage the disposal of Unwanted Covered Drugs through an indoor plumbing or on-site septic system;
 - 1.3.7 Identify all Mail-Back Envelope Distribution Sites in San Francisco that are operated by an approved Stewardship Plan;
 - 1.3.8 Identify all collection kiosk locations and collection events in San Francisco which are authorized by the DEA and at which Unwanted Covered Drugs can be disposed, whether operated by an approved Stewardship Plan or not.
- 2.0 Outreach Materials. Each Plan Operator shall provide printed outreach materials promoting their Stewardship Plan in the manner described below, pursuant to Section 2206 of Chapter 22:

- 2.1 Plan Operators shall provide the Department printed outreach materials for distribution to City residents and/or Stewardship Plan participants following a request by the Director or her/his designee. The requested materials shall be provided within 30 calendar days of the request, in the languages specified in Section E. 1.2 of these regulations.
- 2.2 Plan Operators shall provide interested San Francisco pharmacies, health care facilities, veterinarians, and veterinary clinics printed outreach materials upon request by the Department. Within 30 calendar days of provision of a list by the Department, a Plan Operator shall contact each entity listed to inform them of outreach material availability and how to reply with desired quantities. The Plan Operator shall provide interested entities outreach materials in the desired quantities and languages within 60 days of the entity's reply.
- 2.3 At least annually, each approved Plan Operator shall offer all San Francisco retail pharmacies outreach materials promoting the Stewardship Plan's collection and disposal options, website, and call center. The Department shall provide a list of locations that will be offered materials and a schedule based on the number of approved Stewardship Plans. The printed outreach materials shall be designed for display at the pharmacy counter or other location where Covered Drugs are dispensed and may additionally promote the outreach messages in Section E. 1.3 of these regulations.

F. Single System of Promotion

- 1.0 Coordinated Single System of Promotion. All approved and prospective Plan Operators shall develop and implement a Single System of Promotion as described in Section 2206 of Chapter 22 and these regulations.
- 1.1 Within 180 calendar days of submission of a new Stewardship Plan to the Department for review, the Director or her/his designee may convene a meeting of the Plan Operators of all Stewardship Plans approved and proposed as of that date. The purpose of the meeting shall be to coordinate the new proposed Stewardship Plan's integration into the existing Single System of Promotion.
- 1.2 In the event that agreement among the proposed and currently approved Plan Operators cannot be achieved within 60 calendar days of the Director convening the meeting described in Section F. 1.1 of these regulations, the Director or her/his designee may develop and impose a final outreach program design and Single System of Promotion which meets the requirements of Section 2206 of Chapter 22 and these regulations.
- 1.3 All costs of implementing the Single System of Promotion including, but not limited to, the design and implementation of the Outreach Program and ongoing operation and administration, shall be divided among all plan operators of approved Stewardship Plans, according to a formula which shall be included in the Annual Report required of all operators of an approved Stewardship Plan in Section 2209 of Chapter 22.
- 2.0 Telephone Call Center. Each Program Operator's resident-facing telephone Call Center and any resident-facing Call Center operated jointly by approved Plan Operators shall meet the requirements of this section.
- 2.1 A resident-facing Call Center shall have the following capabilities:
 - 2.1.1 Customer service representatives answer calls twenty-four hours a day, seven days a week;
 - 2.1.2 Provides multi-lingual support in the languages specified in Section E. 1.2 of these regulations;
 - 2.1.3 Allows residents to request Mail-Back Services be sent to the address of the resident's choice at no cost to the resident;
 - 2.1.4 Provides support to residents that have a hearing or speech impairment through text telephone ("TTY") or similar accessibility technology.

- 2.2 In the event that Plan Operators cannot reach agreement on jointly operating a single resident-facing Call Center, Plan Operators may operate Call Centers individually, provided that each meets the following specifications intended to simulate a single Call Center:
 - 2.2.1 Utilizes a single coordinated toll-free telephone number for residents to call;
 - 2.2.2 Utilizes the same call scripts and process flows;
 - 2.2.3 Routes incoming calls to each approved Plan Operator's Call Center on an equal basis;
 - 2.2.4 Provides information on locations and services for disposing of Unwanted Covered Drugs from all approved Stewardship Plans.
- 2.3 Any proposed changes to the operation or functionality of a Call Center shall be submitted to the Director or her/his designee for review in accordance with Section 2212(a) of Chapter 22 and Section D. 4.0 of these regulations. Plan Operators may request an advance determination from the Department whether a proposed change would be deemed to alter operation or functionality of a Call Center.
- 3.0 Resident-Facing Website. Each Plan Operator's resident-facing website and any resident-facing website operated jointly by Plan Operators shall be operated in accordance with this section.
- 3.1 All approved Plan Operators shall jointly operate a single resident-facing website that:
 - 3.1.1 Utilizes a single coordinated website URL for residents to access the website;
 - 3.1.2 Provides the single coordinated toll-free telephone number of the resident-facing Call Center;
 - 3.1.3 Provides residents a method to request Mail-Back Services be sent to the address of the resident's choice either directly through the website or by directing residents to an approved Plan Operator's own website.
- 3.2 A resident-facing website shall have the following capabilities:
 - 3.2.1 Provides a functionally equivalent user experience, including content, access, and navigability, in the languages specified in Section E. 1.2 of these regulations;
 - 3.2.2 Allows residents to request Mail-Back Services be sent to the address of the resident's choice at no cost to the resident;
 - 3.2.3 Provides information on locations and services for disposing of Unwanted Covered Drugs from all approved Stewardship Plans;
 - 3.2.4 Complies with Web Content Accessibility Guidelines ("WCAG") or similar accessibility standards to provide support for residents that have a visual or physical impairment.
- 3.3 Any proposed changes to the operation or functionality of a resident-facing website shall be submitted to the Director or her/his designee for review in accordance with Section 2212(a) of Chapter 22 and Section D. 4.0 of these regulations. Plan Operators may request an advance determination from the Department whether a proposed change would be deemed to alter operation or functionality of a resident-facing website.
- 4.0 Collection Kiosk Design and Signage. Each Plan Operator shall utilize the following design parameters when establishing Kiosk Drop-Off Sites as part of an approved Stewardship Plan:
 - 4.1 All approved Plan Operators shall implement a coordinated design for collection kiosks, including but not limited to, kiosk color, kiosk signage, and other visual elements.
 - 4.2 The collection kiosk signage shall be designed to provide a functionally equivalent user experience in the languages specified in Section E. 1.2 of these regulations. Text and other language-specific visual elements shall be of similar size and prominence to that of the other required languages.

- 4.3 Plan Operators shall ensure that signage excluding sharps or pre-filled injector products from collection kiosk disposal and providing direction to the public on how to obtain Mail-Back Services for pre-filled injector products is available at or near each collection kiosk.

G. Biennial Surveys

- 1.0 Biennial Survey Coordination. All approved Plan Operators shall coordinate with each other and conduct the Biennial Surveys as described in Section 2206 of Chapter 22 and these regulations.
- 1.1 Within one year of approval of a new Stewardship Plan, the Director or her/his designee may convene a meeting of operators of all Stewardship Plans approved as of that date to discuss coordination of the Biennial Surveys.
- 1.2 In the event that the approved Plan Operators cannot come to agreement on jointly conducting the Biennial Surveys within 90 calendar days of the Director's meeting in Section G. 1.1 of these regulations, each Plan Operator shall be required to conduct the Biennial Surveys individually.
- 1.3 Each Biennial Survey of City residents shall include all questions utilized in any baseline survey completed prior to or within the first six months of operation of any Stewardship Plan, unless changes to the survey questions are approved by the Department.
- 1.4 Final draft survey questions and methodology for the Biennial Surveys shall be submitted to the Director, or her/his designee, for review, comment, and approval at least 30 calendar days prior to the initiation of the Biennial Surveys.
- 1.5 The Biennial Survey of City residents shall be designed in a manner that targets the racial and language usage demographics of survey respondents that is proportional to the racial and language usage demographics of City residents.
- 1.6 The Biennial Surveys shall be conducted in a manner such that the survey has a margin of error of +/- 3.5 percentage points or less.
- 1.7 Results from the Biennial Surveys shall be made available to the public on the single resident-facing website required in Section F. 3.1 of these regulations, unless this requirement is waived by the Director.
- 1.8 Complete survey responses or other un-tabulated survey response data from the Biennial Surveys shall be provided to the Director or her/his designee upon request.

H. Outreach Effectiveness

- 1.0 Outreach Effectiveness. The effectiveness of a Plan Operator's outreach activities shall be measured by target audience awareness of the collection program for Unwanted Covered Drugs, as demonstrated by results from the most recent Biennial Survey of City residents.
- 1.1 The minimum resident awareness requirements shall be:
 - 1.1.1 50% of the total survey participants shall be aware of the collection program;
 - 1.1.2 50% of the survey participants that responded to the survey in Spanish shall be aware of the collection program;
 - 1.1.3 50% of the survey participants that responded to the survey in Chinese shall be aware of the collection program;

- 1.2 If the results of any Biennial Survey of City residents show that any of the minimum resident awareness requirements in Section H. 1.1 of these regulations are not being met, additional outreach activities must be undertaken by each Plan Operator in the following two years to increase awareness until the minimum resident awareness requirements are met, as demonstrated in subsequent Biennial Surveys of City residents.
- 1.3 Within 30 calendar days of posting the results of a Biennial Survey of City residents on the single resident-facing website, each approved Plan Operator shall submit a written proposal to the Department to undertake additional outreach activities, if required by Section H. 1.2 of these regulations. The Department shall review and either approve, conditionally approve, or reject the proposal.
- 1.4 At least every four years, each approved Plan Operator shall conduct a review of their existing outreach materials, including any public-facing websites and all printed and electronic outreach materials, and update the design and other visual elements of the outreach materials. Each approved Plan Operator shall coordinate with the other approved Plan Operators to ensure the updates are consistent with the Single System of Promotion required by Section 2206 of Chapter 22 and these regulations. The Department shall review and approve any proposed changes to ensure consistency with the coordinated Single System of Promotion.

I. Collection System Requirements

- 1.0 Kiosk Drop-Off Site Operation. An approved Plan Operator shall establish and operate Kiosk Drop-Off Sites in accordance with this section.
- 1.1 A Kiosk Drop-Off Site that desires to utilize a Kiosk Host-Managed Collection Service model shall provide written confirmation to the Department that their staff have received training in the procedures established for the Kiosk Host-Managed Collection Service model and identify the specific Federal Department of Transportation Special Permit that they will be party to while utilizing the Kiosk Host-Managed Collection Service model. Such written confirmation shall be provided at least 15 calendar days before a site begins collecting Unwanted Covered Drugs under a Kiosk Host-Managed Collection Service model.
- 1.2 An approved Plan Operator shall contact each participating Kiosk Drop-Off Site on a quarterly basis to provide staff with training and support as needed. An approved Plan Operator shall conduct an in-person visit to each participating Kiosk Drop-Off Site at least every six months to provide staff with training and support as needed. The training shall include review of the Kiosk Drop-Off Site's role and responsibilities in the approved Stewardship Plan, inspection of the collection kiosk for maintenance and cleanliness, procedures for requesting collection kiosk maintenance, and procedures to ensure that a packaged collection kiosk liner is removed from the Kiosk Drop-Off Site within established timeframes.
- 2.0 Mail-Back Envelope Distribution Site Operation. An approved Plan Operator shall establish and operate Mail-Back Envelope Distribution Sites in accordance with this section.
- 2.1 A location that wishes to participate as a Mail-Back Envelope Distribution Site in an approved Stewardship Plan shall provide written confirmation to the Department of their intent to participate and that their staff have received training in the procedures established for participating Mail-Back Envelope Distribution Sites. Such written confirmation to the Department shall be provided at least 15 calendar days before the location is activated as a Mail-Back Envelope Distribution Site.
- 2.2 An approved Plan Operator shall contact each participating Mail-Back Envelope Distribution Site on a quarterly basis to confirm the site's continued participation and provide staff with training and support as needed. An approved Plan Operator shall conduct an in-person visit to each participating Mail-Back Envelope Distribution Site at least every six months to confirm the site's continued participation and provide staff with training and support as needed. The training shall include instructions on what types of Unwanted Covered Drugs are allowed in the different types of Mail-Back Services and how the site can order additional mail-back packages.

- 3.0 Alternative Convenience Standard. In the event that an approved Plan Operator is not providing five Kiosk Drop-Off Sites in a Supervisorial District, the Plan Operator shall supplement service in that District in the following manner:
- 3.0.1 In Supervisorial Districts where the approved Plan has four Kiosk Drop-Off Sites, the Plan Operator shall provide the District at least three Mail-Back Envelope Distribution Sites;
 - 3.0.2 In Supervisorial Districts where the approved Plan has three Kiosk Drop-Off Sites, the Plan Operator shall provide the District at least four Mail-Back Envelope Distribution Sites or one collection event per calendar year;
 - 3.0.3 In Supervisorial Districts where the approved Plan has two Kiosk Drop-Off Sites, the Plan Operator shall provide the District at least six Mail-Back Envelope Distribution Sites or two collection events per calendar year;
 - 3.0.4 In Supervisorial Districts where the approved Plan has one Kiosk Drop-Off Site, the Plan Operator shall provide the District at least six Mail-Back Envelope Distribution Sites and one collection event per calendar year;
 - 3.0.5 In Supervisorial Districts where the approved Plan has zero Kiosk Drop-Off Sites, the Plan Operator shall provide the District at least six Mail-Back Envelope Distribution Sites and two collection events per calendar year.
- 3.1 If, due to a lack of law enforcement agency participation, a Plan Operator is unable to provide collection events as required by the Alternative Convenience Standard established in Section I. 3.0 of these regulations, that Plan Operator shall submit a proposal to the Department for review and approval that describes an alternative plan for supplementing service in the required Supervisorial Districts.
- 3.2 In the event that changes in the number of participating Kiosk Drop-Off Sites or Mail-Back Envelope Distribution Sites results in a Stewardship Plan no longer meeting the service convenience goal in Section 2205(b)(1) of Chapter 22 or the Alternative Convenience Standard established in Section I. 3.0 of these regulations, the Plan Operator shall have 60 days to establish additional Kiosk Drop-Off Sites or supplement service in that Supervisorial District in accordance with the Alternative Convenience Standard in Section I. 3.0 of these regulations.
- 4.0 Collection Event Requirements. Any collection event held pursuant to Section 2205(b)(1) of Chapter 22 or Section I. 3.0 of these regulations shall meet the following requirements:
- 4.0.1 Event dates shall be selected so that events are held periodically throughout the calendar year;
 - 4.0.2 At least half of events shall be held on weekends;
 - 4.0.3 Events shall be at least 4 hours in duration and accept Unwanted Covered Drugs for the entire event;
 - 4.0.4 Events shall accept all types of Unwanted Covered Drugs to the maximum extent practicable under federal and state laws and regulations;
 - 4.0.5 Events shall have available information on how residents can dispose of any Unwanted Covered Drugs that are not accepted at the event.
- 4.1 Collection events shall be broadly promoted at least 30 calendar days prior to the event date. Promotion activity for each event shall:
- 4.1.1 When considered together, reach 50% of City residents within the Supervisorial District in which the event will be held;
 - 4.1.2 Include media activities in the three languages that residents most commonly use in the Supervisorial District in which the event will be held;
 - 4.1.3 Include at least one outreach activity in digital media and at least one outreach activity in print media.

J. Reporting Requirements:

- 1.0 Quarterly Reporting. Each Plan Operator shall report the following information to the Department on a quarterly basis:
 - 1.1 Within 10 business days of the end of each calendar quarter, any Plan Operator whose collection system includes Mail-Back Services for pre-filled injector products and/or inhaler products that are not returned to a DEA-registered reverse distributor shall provide a written assessment of whether the Federal Food and Drug Administration has approved any new pre-filled injector products and/or inhaler products which contain Schedule II through V Controlled Substances and accordingly require handling on disposal by a DEA-registered reverse distributor.
 - 1.2 Within 10 business days of the end of each calendar quarter, each Plan Operator shall provide a written summary of Help Desk requests by type made in the previous quarter, including the number of each type of request, the average number of days to close the request, and the range (minimum and maximum days) in length of time to close the request.
 - 1.3 Within 10 business days of the end of each calendar quarter, each Plan Operator shall provide a written summary of the number of Kiosk Drop-Off Sites that utilized the different types of collection kiosk service options offered under the Operator's approved Stewardship Plan.
 - 1.4 Within 30 calendar days of the end of each calendar quarter, each Plan Operator shall report the total weight of Unwanted Covered Drugs collected at each Kiosk Drop-Off Site and the number of collection kiosk liners utilized to transport Unwanted Covered Drugs for disposal.
 - 1.5 Within 30 calendar days of the end of each calendar quarter, each Plan Operator shall provide the Department a complete list of all Producers participating in the approved Stewardship Plan that contains all information, including contact name and email address, required in Section 2204(a) of Chapter 22. Each Plan Operator shall additionally provide a complete list of all Producers participating in the approved Stewardship Plan within 10 business days of a request from the Department.
- 2.0 Annual Reporting. Each Plan Operator shall include the following information on collection and disposal activities in the Annual Report, in addition to that required in Section 2209 of Chapter 22:
 - 2.1 For each Kiosk Drop-Off Site: the total weight of Unwanted Covered Drugs collected and the number of collection kiosk liners utilized to transport Unwanted Covered Drugs for disposal.
 - 2.2 For each collection event held: the district in which the collection event was held, the number of City residents who dropped off Unwanted Covered Drugs, and the total weight of Unwanted Covered Drugs collected.
 - 2.3 For each type and size of Mail-Back Service offered by a Plan Operator: the number of mail-back packages distributed, the number of mail-back packages received by the disposal vendor, and the total of actual, not average, package weights received by the vendor.
 - 2.4 For each final disposal site utilized: the total weight of Unwanted Covered Drugs destroyed by service type (Drop-Off Kiosk Site, Mail-Back Services, collection event).
- 3.0 Outreach Program Reporting. Each Plan Operator shall include the following information on outreach activities in the Annual Report, as required in Section 2209(a)(9) of Chapter 22:
 - 3.1 The identity of all media used to promote the collection program in the reporting year.
 - 3.2 Proof of Performance for each medium utilized in the outreach activities undertaken during the reporting year.

- 3.3 In years where a Biennial Survey of City residents was conducted, a discussion of whether the survey results confirm that the minimum resident awareness requirements in Section H. 1.1 of these regulations were achieved.
- 3.4 A description of any additional outreach activities undertaken in accordance with Section H. 1.2 of these regulations, if applicable.
- 3.5 Numerical results of the Program Goals described in the approved Program Plan for outreach activities conducted during the reporting year, including but not limited to:
 - 3.5.1 Number of page visits and unique visits to the Stewardship Operator's own website and the single resident-facing website required in Section F. 3.3 of these regulations;
 - 3.5.2 List of law enforcement agencies, retail pharmacies, other pharmacies, community groups, and other third parties where outreach was conducted;
 - 3.5.3 List of media outlets receiving press advisories or other media communications;
 - 3.5.4 List of all community centers in San Francisco reached;

The Director of the Environment Department hereby adopts these regulations as of the date specified below.

Tyrone Jue
Director

Approved:
Date: