

1 [Environment Code - Safe Drug Disposal]

2
3 **Ordinance amending the Environment Code to require any person who produces a**
4 **drug offered for sale in San Francisco to participate in an approved drug stewardship**
5 **program for the collection and disposal of unwanted drugs from residential sources;**
6 **to provide for implementation, enforcement, fees, and penalties; and making**
7 **environmental findings.**

8 NOTE: **Unchanged Code text and uncodified text** are in plain Arial font.
9 **Additions to Codes** are in *single-underline italics Times New Roman font*.
10 **Deletions to Codes** are in ~~*italics Times New Roman font*~~.
11 **Board amendment additions** are in double-underlined Arial font.
12 **Board amendment deletions** are in ~~Arial font~~.
13 **Asterisks (* * * *)** indicate the omission of unchanged Code
14 subsections or parts of tables.

15 Be it ordained by the People of the City and County of San Francisco:

16 Section 1. The Planning Department has determined that the actions contemplated in
17 this ordinance comply with the California Environmental Quality Act (California Public
18 Resources Code Sections 21000 et seq.). Said determination is on file with the Clerk of the
19 Board of Supervisors in File No. ____ and is incorporated herein by reference.

20 Section 2. The Environment Code is hereby amended by revising the name of Chapter
21 22, adding to Chapter 22 a Division II entitled "Safe Drug Disposal Information" consisting of
22 existing Sections 2250-2254, and adding to Chapter 22 a Division I entitled "Safe Drug
23 Disposal Stewardship" consisting of Sections 2200 through 2219, to read as follows:
24
25

1 CHAPTER 22: SAFE DRUG DISPOSAL *Information*

2 **DIVISION I: SAFE DRUG DISPOSAL STEWARDSHIP**

3 Sec. 2200. Title.

4 Sec. 2201. Findings.

5 Sec. 2202. Definitions.

6 Sec. 2203. Stewardship Plans – Participation.

7 Sec. 2204. Stewardship Plans – Components.

8 Sec. 2205. Stewardship Plans – Collection of Covered Drugs.

9 Sec. 2206. Stewardship Plans – Promotion.

10 Sec. 2207. Stewardship Plans – Disposal of Covered Drugs.

11 Sec. 2208. Stewardship Plans – Administrative and Operational Costs and Fees.

12 Sec. 2209. Stewardship Plans – Reporting Requirements.

13 Sec. 2210. Stewardship Plans – List of Producers of Covered Drugs.

14 Sec. 2211. Stewardship Plans – Review of Proposed Plans.

15 Sec. 2212. Stewardship Plans – Prior Approval for Change.

16 Sec. 2213. Stewardship Plans – Enforcement and Penalties.

17 Sec. 2214. Stewardship Plans – Rules, Performance Standards, and Report.

18 Sec. 2215. Plan Review and Annual Operation Fees.

19 Sec. 2216. Undertaking for the General Welfare.

20 Sec. 2217. No Conflict With Federal or State Law.

21 Sec. 2218. Severability.

22 Sec. 2219. Effect of Grant of Certiorari

1 **DIVISION I: SAFE DRUG DISPOSAL STEWARDSHIP**

2
3 **SEC. 2200. TITLE.**

4 *This Division I may be cited as the San Francisco Safe Drug Disposal Stewardship Ordinance.*

5
6 **SEC. 2201. FINDINGS.**

7 *(a) Legal medicinal drugs allow us to live longer, healthier, and more productive lives.*

8 *(b) A Mayo Clinic study issued in June 2013 found that nearly 70 percent of Americans take one*
9 *prescription drug, up from 48 percent in 2007-2008. According to the Centers for Disease Control and*
10 *Prevention, health care providers in the United States wrote 259 million prescriptions for painkillers in*
11 *2012, enough for every American adult to have a bottle of pills.*

12 *(c) Municipal wastewater treatment plants are not designed to treat complex drug compounds*
13 *that end up in the sewer system after being flushed down toilets and sinks. As a result, drugs can pass*
14 *through wastewater treatment systems and contaminate receiving waters.*

15 *(d) An Environmental Protection Agency report on drinking water released in December 2013*
16 *found samples of at least 25 different drugs, including medication to treat heart conditions, in supplies*
17 *coming out of wastewater treatment plants. Scientists examined samples from 50 large wastewater*
18 *plants testing for 56 drugs. Medication to treat high blood pressure was not only the most commonly*
19 *traced drug, but also found in the highest quantities. Properly disposing of leftover, expired, and*
20 *unwanted drugs would reduce the quantity of drugs that wind up in the San Francisco Bay and other*
21 *receiving waters.*

22 *(e) Properly disposing of leftover, expired, and unwanted drugs would also be a step forward*
23 *in preventing unintentional poisoning deaths attributable to drugs, by making such drugs less*
24 *accessible to persons who might abuse them. Deaths from drug overdose have been rising steadily*
25 *over the past two decades. Every day in the United States, 113 people die as a result of drug overdose,*

1 and another 6,748 are treated in emergency departments for the misuse or abuse of drugs. Nearly 9
2 out of 10 poisoning deaths are caused by drugs. In 2011, 80 percent of the 41,340 drug overdose
3 deaths in the United States were unintentional.

4 (f) Proper drug disposal could also impact the number of people who become addicted to
5 prescription drugs. Results from the 2013 National Survey on Drug Use and Health indicate that about
6 15.3 million people aged 12 or older used prescription drugs non-medically in the past year, and 6.5
7 million did so in the past month. Seventy percent of those addicted to prescription drugs say they first
8 accessed drugs by taking them from friends and family who kept them unlocked in the house.

9 (g) Extended Producer Responsibility (EPR), also called Product Stewardship, is a strategy
10 that places some responsibility for end-of-life management of consumer products on the manufacturers
11 of the products, while encouraging product design that minimizes negative impacts on human health
12 and the environment at every stage of the product's lifecycle.

13 (h) San Francisco passed Producer Responsibility Resolutions in 2006 (Resolution No. 154-10)
14 and in 2010 (Resolution No. 94-06) to state its support for managing product waste under an EPR
15 system. Many other local and national government bodies support EPR, including CalRecycle
16 (formerly the California Integrated Waste Management Board), the National Association of Counties,
17 and the National League of Cities.

18 (i) California has passed four significant product stewardship laws for mercury thermostats (AB
19 2347, enacted as Chapter 572 of the statutes of 2008), carpet (AB 2398, enacted as Chapter 681 of the
20 statutes of 2010), paint (AB1343, enacted as Chapter 420 of the statutes of 2010), and mattresses (SB
21 254, enacted as Chapter 21 of the statutes of 2013). All four laws require producers to establish and
22 fund product stewardship programs for their waste stream.

23 (j) California Senate Bill 966, enacted as Chapter 542 of the Statutes of 2007, required
24 CalRecycle to survey existing drug collection programs, evaluate them for several factors including
25 cost effectiveness, and make recommendations for implementation of statewide programs.

1 (k) In 2010, Congress passed the “Secure and Responsible Drug Disposal Act of 2010,” Public
2 Law No. 111–273, which authorized the Attorney General to increase the methods—formerly restricted
3 to law enforcement—by which controlled substances may be collected, including collection at
4 pharmacies. The goal of the bill was to increase opportunities for drug collection in order to reduce
5 the instances of diversion and release of harmful substances into the environment. On October 9, 2014,
6 the Drug Enforcement Agency promulgated regulations implementing the bill. 21 C.F.R. Parts 1300,
7 1301, 1304, 1305, 1307, and 1317. These regulations, among other things, authorize retail
8 pharmacies to maintain secure collection receptacles for controlled substances.

9 (l) A number of Canadian provinces and other countries have active, well-established drug
10 product stewardship programs in place. British Columbia has had a manufacturer-funded drug
11 collection program in place since 1996. Ontario began a program in July 2010. And Manitoba began
12 its program in April 2011. France, Spain and Portugal, among other countries, have national, well-
13 established, manufacturer-funded drug collection programs.

14 (m) In 2012, Alameda County became the first local government in the United States to pass
15 legislation, Ordinance No. 0-2012-27, requiring pharmaceutical companies to design, fund, and
16 operate a safe drug collection and management program which could operate like the take-back
17 programs found in Canada’s pharmacies, which are paid for by drug companies and operated by the
18 Canadian Health Product Stewardship Association on their behalf. On September 30, 2014, the Ninth
19 Circuit Court of Appeal rejected a legal challenge to Alameda County’s ordinance brought by drug
20 manufacturers. Pharm. Research & Mfrs.of Am. v. Cty. of Alameda, 13-16833, 2014 WL 4814407 (9th
21 Cir. Sept. 30, 2014).

22 (n) On June 20, 2013, the King County Board of Health passed Rule and Regulation No. #13-
23 03 which created a drug take-back system for King County residents.

24 (o) To date, there is no voluntary or mandatory statewide product stewardship program for
25 unwanted drugs in California. In 2013, the California State Senate passed a bill, SB 1014, that would

1 have created authorized a voluntary program to collect and properly dispose of home-generated
2 pharmaceutical waste, but the California Assembly did not take up the bill for a vote.

3 (p) There is considerable demand in San Francisco for a permanent drug stewardship
4 program. Since 2012, the San Francisco Department of the Environment has operated a pilot program
5 for the collection of controlled and non-controlled substances. The program consists of 13 retail
6 pharmacies collecting non-controlled substances and all 10 of the City's police stations collecting both
7 controlled and non-controlled substances. The pilot program collects an average of 1,429 pounds of
8 controlled and non-controlled substances per month, and to date, has collected over 37,163 pounds.

9 (q) The pilot program, with only 23 drop-off locations, does not offer adequate convenient
10 disposal options for all City residents. Moreover, only 40 percent of the pilot program's cost is
11 covered by industry funding, and that funding is not reliable or sustainable.

12
13 **SEC. 2202. DEFINITIONS.**

14 For the purposes of this Division I, the following definitions apply:

15 "City" means the City and County of San Francisco.

16 "City residents" means human beings residing in the City.

17 "Collector" means a Person that gathers Unwanted Covered Drugs from City residents for the
18 purpose of collection, transportation, and disposal.

19 "Covered Drug" means a Drug sold in any form and used by City residents, including
20 prescription, nonprescription, brand name and generic drugs. Notwithstanding the previous sentence,
21 "Covered Drug" does not include: (1) vitamins or supplements; (2) herbal-based remedies and
22 homeopathic drugs, products, or remedies; (3) cosmetics, shampoos, sunscreens, toothpaste, lip balm,
23 antiperspirants, or other personal care products that are regulated as both cosmetics and
24 nonprescription drugs under the federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. Chapter 9); (4)
25 Drugs for which Producers provide a pharmaceutical product stewardship or take-back program as

1 part of a federal Food and Drug Administration-managed risk evaluation and mitigation strategy (Title
2 21 U.S.C. Sec. 355-1); (5) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it
3 exists on the effective date of this Division I if the Producer already provides a pharmaceutical product
4 stewardship or take-back program; and (6) medical devices, their component parts or accessories, or a
5 Covered Drug contained in or on medical devices or their component parts or accessories.

6 “Department” means the Department of the Environment.

7 “Director” means the Director of the Department of the Environment or his or her designee.

8 “Drug Wholesaler” means a Person who buys Drugs for resale and distribution to
9 corporations, individuals, or entities other than consumers.

10 “Drug” means: (1) any article recognized in the official United States pharmacopoeia, the
11 official national formulary, the official homeopathic pharmacopoeia of the United States or any
12 supplement of the formulary or those pharmacopoeias as published by the U.S. Pharmacopeial
13 Convention and the Homeopathic Pharmacopoeia Convention of the United States; (2) any substance
14 intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or
15 other animals; (3) any substance, other than food, intended to affect the structure or any function of the
16 body of humans or other animals; or (4) any substance intended for use as a component of any
17 substance specified in (1), (2), or (3) of this definition, but not including medical devices, their
18 component parts or accessories, or a Covered Drug contained in or on medical devices or their
19 component parts or accessories.

20 “Manufacture” means the production, preparation, propagation, compounding, or processing
21 of a Drug or other substance or device or the packaging or repackaging of the substance or device, or
22 the labeling or relabeling of the commercial container of such substance or device, but does not include
23 the activities of a practitioner who, as an incident to his or her administration or dispensing such
24 substance or device in the course of his or her professional practice, prepares, compounds, packages,
25 or labels such substance or device.

1 "Manufacturer" means a Person engaged in the Manufacture of Drugs.

2 "Mail-back services" means a collection method for the return of Unwanted Covered Drugs
3 from City residents utilizing prepaid and preaddressed mailing envelopes.

4 "Nonprescription Drug" means a Drug that may be lawfully sold without a prescription.

5 "Person" means a human being, firm, sole proprietorship, corporation, limited liability
6 company, general partnership, limited partnership, limited liability partnership, association,
7 cooperative, or other entity of any kind or nature.

8 "Pharmacy" means a place licensed by the state of California Board of Pharmacy where the
9 practice of pharmacy is conducted.

10 "Prescription Drug" means any Drug, including any controlled substance, that is required by
11 federal or state law or regulation to be dispensed by prescription only or is restricted to use by
12 practitioners only.

13 "Producer" means a Manufacturer engaged in the Manufacture of a Covered Drug sold in the
14 City, including a brand-name or generic Drug. Notwithstanding the previous sentence, "Producer"
15 does not include: (1) a retailer whose store label appears on a Covered Drug or the drug's packaging
16 if the Manufacturer from whom the retailer obtains the drug is identified under Section 2203(c) of this
17 Division I; (2) a pharmacist who compounds a prescribed individual drug product for a consumer; or
18 (3) a Wholesaler who is not also a Manufacturer.

19 "Retail Pharmacy" means a Pharmacy licensed by the state of California Board of Pharmacy
20 for retail sale and dispensing of drugs.

21 "Stewardship Plan" means a plan for the collection, transportation and disposal of Unwanted
22 Covered Drugs required under Section 2204 of this Division I that is: (1) financed, developed,
23 implemented and participated in by one or more Producers; (2) operated by the participating
24 Producers or a Stewardship Organization; and (3) approved by the Director.

1 “Stewardship Organization” means an organization designated by a Producer or group of
2 Producers to act as an agent on behalf of one or more Producers to develop and implement and
3 operate a Stewardship Plan.

4 “Unwanted Covered Drug” means any Covered Drug that the owner has discarded or intends
5 to discard.

6
7 **SEC. 2203. STEWARDSHIP PLANS – PARTICIPATION.**

8 (a) Each Producer shall participate in a Stewardship Plan. Each Producer must: (1) operate,
9 individually or jointly with other Producers, a Stewardship Plan approved by the Director; or (2) enter
10 into an agreement with a Stewardship Organization to operate, on the Producer’s behalf, a
11 Stewardship Plan approved by the Director.

12 (b) Each Stewardship Plan must be approved by the Director before the entity administering
13 the plan starts collecting Unwanted Covered Drugs. Once approved, each Stewardship Plan must have
14 prior written approval of the Director for proposed changes as described under Section 2212.

15 (c) By six months after the effective date of this Division I, or by six months after a Producer
16 starts sale of a Covered Drug in the City, a Producer must notify the Director in writing of the
17 Producer’s intent to participate in a Stewardship Plan, or to form a new Stewardship Plan. A retailer
18 whose store label appears on a Covered Drug or the Covered Drug’s packaging must notify the
19 Director of the retailer’s intent to participate in a Stewardship Plan or provide written notification that
20 the Manufacturer from whom the retailer obtains the Covered Drug has provided its notice of intent to
21 participate.

22 (d) A Producer, either individually or jointly with other Producers, shall:

23 (1) By nine months after the effective date of this Division I, or nine months after
24 starting sale of a Covered Drug in the City, identify in writing to the Director a Stewardship Plan
25

1 operator, including the operator's telephone, mailing address and email contact information, that is
2 authorized to be the official point of contact for the Stewardship Plan;

3 (2) By nine months after the effective date of this Division I, or nine months after
4 starting sale of a Covered Drug in the City, notify all Retail Pharmacies and law enforcement agencies
5 in the City of the opportunity to participate as a drop-off site in accordance with Sections 2205 of this
6 Division I and provide a process for forming an agreement between the Stewardship Plan and
7 interested Collectors; and annually thereafter, make the same notification to any nonparticipating or
8 new Retail Pharmacies in the City;

9 (3) By one year after the effective date of this Division I, or one year after starting sale
10 of a Covered Drug in the City, submit a proposed Stewardship Plan as described in Section 2204 to the
11 Director for review;

12 (4) Within three months after the Director's approval of the Stewardship Plan, operate
13 or participate in the Stewardship Plan in accordance with this Division I;

14 (5) At least every four years after the Stewardship Plan starts operations, submit an
15 updated Stewardship Plan to the Director explaining any substantive changes to components of the
16 Stewardship Plan required in Section 2204, and accompanied by the review fee in accordance with
17 Section 2215 of this Division I. The Director shall review updated Stewardship Plans using the process
18 described in Section 2210 of this Division I; and

19 (6) Pay all administrative and operational costs and fees associated with its
20 Stewardship Plan.

21 (e) A Producer, either individually or jointly with other Producers, may:

22 (1) Enter into contracts and agreements with Stewardship Organizations, other service
23 providers, or other entities as necessary, useful or convenient to carry out all or portions of their
24 Stewardship Plan;

1 (2) Notify the Director of any Producer selling Covered Drugs Manufactured by that
2 Producer or group of Producers in the City that is failing to participate in a Stewardship Plan; and

3 (3) Perform any other functions as may be necessary or proper to carry out the
4 Stewardship Plan and to fulfill any or all of the purposes for which the plan is organized.

5 (f) After the first full year of operation of a Stewardship Plan, a Producer or group of
6 Producers may notify the Director in writing of intent to form a new Stewardship Plan, and identify a
7 plan operator, including the plan operator's telephone, mailing address, and email contact
8 information, that is authorized to be the official point of contact for the proposed new Stewardship
9 Plan. Within three months of such notification, the Producer or group of Producers may submit a
10 proposed Stewardship Plan as described under Section 2204 to the Director for review.

11 (g) The Director may, on a case-by-case basis, approve in writing requests for extensions of
12 time for the submission dates and deadlines in this Section 2203.

13 (h) The Director may audit the records of a Producer, group of Producers, or Stewardship
14 Organization related to a Stewardship Plan or request that the Producer, group of Producers, or
15 Stewardship Organization arrange for the Director to inspect at reasonable times a Stewardship Plan's
16 or a Collector's facilities, vehicles, and equipment used in carrying out the Stewardship Plan.

17
18 **SEC. 2204. STEWARDSHIP PLANS – COMPONENTS.**

19 Each Stewardship Plan, which must be submitted and reviewed according to Section 2211, shall
20 include:

21 (a) Contact information for all Producers participating in the Stewardship Plan, including
22 each Drug Producer's name, address, phone number, and email address, and the name, address,
23 phone number, and email address of a human being to whom the Director may direct all inquires
24 regarding the Producer's participation in the Stewardship Plan;

1 (b) A description of the proposed collection system to provide convenient ongoing collection
2 service for all Unwanted Covered Drugs from City residents in compliance with the provisions and
3 requirements in Section 2205, including a list of all collection methods and participating Collectors, a
4 list of drop-off locations, a description of how any periodic collection events will be scheduled and
5 located, a description of how any mail-back services will be provided and an example of the prepaid,
6 preaddressed mailers the plan will use. The description of the collection service shall include a list of
7 Retail Pharmacies and law enforcement agencies contacted by the plan under Section 2203(d)(2) of
8 this Division I, and a list of all Collectors who offered to participate;

9 (c) A description of the handling and disposal system, including identification of and contact
10 information for Collectors, transporters and waste disposal facilities to be used by the Stewardship
11 Plan in accordance with Sections 2205 and Section 2207 of this Division I;

12 (d) A description of the policies and procedures to be followed by Persons handling Unwanted
13 Covered Drugs collected under the Stewardship Plan, including a description of how all Collectors,
14 transporters and waste disposal facilities used will ensure that the collected Unwanted Covered Drugs
15 are safely and securely tracked from collection through final disposal, and how all entities
16 participating in the Stewardship Plan will operate under and comply with all applicable federal and
17 state laws, rules and guidelines, including but not limited to those of the United States Drug
18 Enforcement Administration, and how any Pharmacy collection site will operate under applicable rules
19 and guidelines of the State of California Board of Pharmacy;

20 (e) A certification that that any patient information on Drug packaging will be promptly
21 destroyed;

22 (f) A description of the public education effort and promotion strategy required in Section 2206
23 of this Division I, including a copy of standardized instructions for City residents, signage developed
24 for Collectors, and required promotional materials;

1 (g) Proposed short-term and long-term goals of the Stewardship Plan for collection amounts,
2 education and promotion; and

3 (h) A description of how the Stewardship Plan will consider: (1) use of existing providers of
4 waste pharmaceutical services; (2) separating Covered Drugs from packaging to the extent possible to
5 reduce transportation and disposal costs; and (3) recycling of Drug packaging to the extent feasible.

6
7 **SEC. 2205. STEWARDSHIP PLANS – COLLECTION OF COVERED DRUGS.**

8 (a) This Division I does not require any Person to serve as a Collector in a Stewardship Plan.
9 A Person may offer to serve as a Collector voluntarily, or may agree to serve as a Collector in
10 exchange for incentives or payment offered by a Producer, group of Producers or Stewardship
11 Organization. Collectors may include law enforcement agencies, Pharmacies, mail-back services or
12 other entities, operating in accordance with state and federal laws and regulations for the handling of
13 Covered Drugs, including but not limited to those of the United States Drug Enforcement
14 Administration, and in compliance with this Division I. A Pharmacy collection site shall operate under
15 applicable rules and guidelines of the State of California Board of Pharmacy.

16 (b) The collection system for each Stewardship Program shall:

17 (1) Provide reasonably convenient and equitable access for all City residents in all
18 Supervisory Districts. The system of drop-off sites shall provide at least five drop-off sites in every
19 Supervisory District, geographically distributed to provide reasonably convenient and equitable
20 access. If the service convenience goal in this subsection (b)(1) cannot be achieved due to a lack of
21 drop-off sites at pharmacies, law enforcement agencies, or other qualified Collectors in each
22 Supervisory District, then those areas shall be served through periodic collection events and/or or
23 mail-back services;

24 (2) Be safe and secure, including providing for the prompt destruction of patient
25 information on Drug packaging.

1 (3) Give preference to having Retail Pharmacies and law enforcement agencies serve as
2 drop-off sites.

3 (4) Include, as Collectors, any Retail Pharmacy or any law enforcement agency willing to
4 serve voluntarily as a drop-off site for Unwanted Covered Drugs and able to meet the requirements of
5 this Division I within three months of their offer to participate, unless the Collector requests a longer
6 time frame. A Stewardship Plan may also accept other Collectors willing to serve as a drop-off site for
7 Unwanted Covered Drugs and able to meet the requirements of this Division I; and

8 (5) Make mail-back services available, free of charge, to disabled and home-bound
9 residents upon request through the Stewardship Plan's toll-free telephone number and web site, and
10 through distribution of prepaid, preaddressed mailers to Persons providing services to such residents.
11 The toll-free telephone number and web site required by this subsection (b)(5) shall be in English,
12 Spanish, and Chinese.

13 (c) Drop-off sites shall accept Covered Drugs from City residents during all hours that the
14 Retail Pharmacy, law enforcement agency, or other Collector is normally open for business with the
15 public. Drop-off sites not operated by a law enforcement agency shall utilize secure drop boxes in
16 compliance with all applicable requirements, including but not limited to those of the United States
17 Drug Enforcement Administration and the State of California Board of Pharmacy.

18
19 **SEC. 2206. STEWARDSHIP PLANS – PROMOTION.**

20 Each Stewardship Plan shall:

21 (1) Promote the Stewardship Plan so that collection options for Covered Drugs are
22 widely understood by residents, pharmacists, retailers of Covered Drugs and health care practitioners
23 including doctors and other prescribers, and promote the safe storage of Covered Drugs by City
24 residents before secure disposal through the Stewardship Plan;

1 (2) Work with Collectors participating in the Stewardship Plan to develop clear,
2 standardized instructions for City residents on the use of drop boxes and a readily-recognizable,
3 consistent design of drop boxes. The Director may provide guidance on the development of the
4 instructions and design;

5 (3) Establish a toll-free telephone number and web site where collection options and
6 current locations of drop-off sites will be publicized, and prepare educational and outreach materials
7 promoting safe storage of medicines and describing where and how to return Unwanted Covered
8 Drugs to the Stewardship Plan. These materials must be provided to Pharmacies, health care facilities
9 and other interested parties for dissemination to City residents. Plain language and explanatory images
10 should be used to make use of medicine collection services readily understandable by all residents,
11 including individuals with limited English proficiency;

12 (4) Annually evaluate the effectiveness of its outreach and Stewardship Plan activities;
13 and

14 (5) Conduct bi-annual surveys of City residents and a survey of pharmacists and health
15 professionals in the City who interact with patients on use of medicines after the first full year of
16 operation of the plan. Survey questions shall measure percent awareness of the Stewardship Plan,
17 assess to what extent drop-off sites and other collection methods are convenient and easy to use, and
18 assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and
19 nonprescription medicines used in the home. Draft survey questions shall be submitted to the Director
20 for review and comment at least 30 days prior to initiation of the survey. Results of the survey shall be
21 reported to the Director and made available to the public on the Stewardship Plan's website. The
22 privacy of all survey respondents shall be maintained.

23 All surveys, outreach, education, promotion, websites, and toll-free phone numbers required by
24 this Section 2206 shall be in English, Spanish, and Chinese.

1 **SEC. 2207. STEWARDSHIP PLANS – DISPOSAL OF COVERED DRUGS.**

2 (a) Covered Drugs collected under a Stewardship Plan must be disposed of at a permitted
3 hazardous waste disposal facility as defined by the United States Environmental Protection Agency
4 under 40 C.F.R. parts 264 and 265.

5 (b) The Director may grant approval for a Stewardship Plan to dispose of some or all collected
6 Covered Drugs at a permitted large municipal waste combustor, as defined by the United States
7 Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if the Director deems the use of a
8 hazardous waste disposal facility described under subsection (a) of this Section 2207 to be infeasible
9 for the Stewardship Plan based on cost, logistics or other considerations.

10 (c) A Stewardship Plan may petition the Director for approval to use final disposal
11 technologies that provide superior environmental and human health protection than provided by the
12 disposal technologies in subsections (a) and (b) of this Section 2207, or equivalent protection at lesser
13 cost. The proposed technology must provide equivalent or superior protection in each of the following
14 areas: (1) monitoring of any emissions or waste; (2) worker health and safety; (3) reduction or
15 elimination of air, water or land emissions contributing to persistent, bioaccumulative, and toxic
16 pollution; and (4) overall impact on the environment and human health.

17
18 **SEC. 2208. STEWARDSHIP PLANS – ADMINISTRATIVE AND OPERATIONAL COSTS AND**
19 **FEES.**

20 (a) A Producer or group of Producers participating in a Stewardship Plan shall pay all
21 administrative and operational costs related to their Stewardship Plan, except as provided under this
22 Section 2208. Administrative and operational costs related to the Stewardship Plan include but are not
23 limited to the following:

24 (1) Collection and transportation supplies for each drop-off site;

25 (2) Acquisition of all secure drop boxes for drop-off sites;

1 (3) Ongoing maintenance or replacement of secure drop boxes, as requested by

2 Collectors;

3 (4) Prepaid, preaddressed mailers provided to disabled and/or home-bound residents;

4 (5) Operation of periodic collection events, including costs of law enforcement staff
5 time if necessary;

6 (6) Transportation of all collected Covered Drugs to final disposal, including costs of
7 law enforcement escort if necessary;

8 (7) Environmentally sound disposal of all collected Covered Drugs under Section 2207
9 of this Division I;

10 (8) Program promotion under Section 2206 of this Division I; and

11 (9) Costs related to any review of a Product Stewardship Program for purposes of
12 obtaining compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et
13 seq.).

14 (b) No Person or Producer may charge a point-of-sale fee to consumers to recoup the costs of
15 their Stewardship Plan, nor may they charge a specific point-of-collection fee at the time the Covered
16 Drugs are collected.

17 (c) Producers are not required to pay for costs of staff time at drop-off sites provided by
18 Collectors volunteering for a Stewardship Plan.

19
20 **SEC. 2209. STEWARDSHIP PLANS – REPORTING REQUIREMENTS.**

21 (a) Within six months after the end of the first 12-month period of operation, and annually
22 thereafter, the plan operator of a Stewardship Plan shall submit a report to the Director on behalf of
23 participating Producers describing their plan's activities during the previous reporting period. The
24 report must include:

25 (1) A list of Producers participating in the Stewardship Plan;

1 (2) The amount, by weight, of Covered Drugs collected, including the amount by weight
2 from each collection method used;

3 (3) A list of drop-off locations, the number of mailers provided for disabled and/or
4 home-bound residents, locations where mailers were provided, if applicable, dates and locations of
5 collection events held, if applicable, transporters used and the disposal facility or facilities used;

6 (4) Whether any safety or security problems occurred during collection, transportation
7 or disposal of Unwanted Covered Drugs during the reporting period and, if so, what changes have or
8 will be made to policies, procedures or tracking mechanisms to alleviate the problem and to improve
9 safety and security in the future;

10 (5) A description of the public education, outreach and evaluation activities
11 implemented during the reporting period;

12 (6) A description of how collected packaging was recycled to the extent feasible,
13 including the recycling facility or facilities used;

14 (7) A summary of the Stewardship Plan's goals, the degree of success in meeting those
15 goals in the past year, and, if any goals have not been met, what effort will be made to achieve the
16 goals in the next year; and

17 (8) The total expenditures of the Stewardship Plan during the reporting period.

18 (b) The Director shall make reports submitted under this Section 2209 available to the public.

19 (c) For the purposes of this Section 2209, "reporting period" means the period from January 1
20 through December 31 of the same calendar year, unless otherwise specified to the plan operator by the
21 Director.

22
23 **SEC. 2210. STEWARDSHIP PLANS – LIST OF PRODUCERS OF COVERED DRUGS.**

24 Beginning 60 days after the effective date of this Division I, each Drug Wholesaler that sells any
25 Covered Drug in the City must provide a list of the Producers of those Covered Drugs to the Director

1 in a form prescribed by the Director. Wholesalers must update and resubmit the list by January 15
2 each year.

3
4 **SEC. 2211. STEWARDSHIP PLANS – REVIEW OF PROPOSED PLANS.**

5 (a) By one year after the effective date of this Division I, each Producer, group of Producers or
6 Stewardship Organization shall submit its proposed Stewardship Plan to the Director for review,
7 accompanied by the plan review fee in accordance with Section 2215 of this Division I. The Director
8 may upon request provide information, counseling, and technical assistance about the requirements of
9 this Division I to assist with the development of a proposed Stewardship Plan.

10 (b) The Director shall review the proposed Stewardship Plan and determine whether it meets
11 the requirements of this Division I. In reviewing a proposed Stewardship Plan, the Director shall
12 provide an opportunity for written public comment on the proposed Stewardship Plan and consider any
13 comments received.

14 (c) After the review under subsection (b) of this Section 2211 and within 90 days after receipt
15 of the proposed Stewardship Plan, the Director shall either approve or reject the proposed Stewardship
16 Plan in writing and, if rejected, provide reasons for the rejection.

17 (d) If the Director rejects a proposed Stewardship Plan, a Producer, group of Producers, or
18 Stewardship Organization must submit a revised Stewardship Plan to the Director within 60 days after
19 receiving written notice of the rejection. The Director shall review and approve or reject a revised
20 Stewardship Plan as provided under subsections (b) and (c) of this Section 2211.

21 (e) If the Director rejects a revised Stewardship Plan, or any subsequently revised plan, the
22 Director may deem the Producer or group of Producers out of compliance with this Division I and
23 subject to the enforcement provisions in this Division I.

1 (f) In approving a proposed Stewardship Plan, the Director may exercise reasonable discretion
2 to waive strict compliance with the requirements of this Division I that apply to Producers in order to
3 achieve the objectives of this Division I.

4 (g) The Director shall make all Stewardship Plans and proposed plans submitted under this
5 Section 2211 available to the public.

6
7 **SEC. 2212. STEWARDSHIP PLANS – PRIOR APPROVAL FOR CHANGE.**

8 (a) Proposed changes to an approved Stewardship Plan that substantively alter plan
9 operations, including, but not limited to, changes to participating Manufacturers, collection methods,
10 achievement of the service convenience goal, policies and procedures for handling Unwanted Covered
11 Drugs, or education and promotion methods or disposal facilities, must be approved in writing by the
12 Director before the changes are implemented.

13 (b) A Producer or group of Producers participating in a Stewardship Plan shall submit to the
14 Director any proposed change to a Stewardship Plan as described under subsection (a) of this
15 Section 2212 in writing at least 30 days before the change is scheduled to occur and accompanied by
16 the review fee in accordance with Section 2215 of this Division I.

17 (c) The plan operator of an approved Stewardship Plan shall notify the Director at least
18 15 days before implementing any changes to drop-off site locations, methods for scheduling and
19 locating periodic collection events, or methods for distributing prepaid, preaddressed mailers, that do
20 not substantively alter achievement of the service convenience goal under Section 2205(c) of this
21 Division I, or other changes that do not substantively alter plan operations under subsection (a) of this
22 Section 2212.

23 (d) The plan operator may request an advance determination from the Director whether a
24 proposed change would be deemed to substantively alter plan operations.

1 SEC. 2213. STEWARDSHIP PLANS – ENFORCEMENT AND PENALTIES.

2 (a) The Director shall administer the penalty provisions of this Division I.

3 (b) If the Director determines that any Person has violated this Division I or a regulation
4 adopted pursuant to this Division I, the Director shall send a written warning, as well as a copy of this
5 Division I and any regulations adopted pursuant to this Division I, to the Person or Persons who
6 violated it. The Person or Persons shall have 30 days after receipt of the warning to come into
7 compliance and correct all violations.

8 (c) If the Person or Persons fail to come into compliance or correct all violations, the Director
9 may impose administrative fines for violations of this Division I or of any regulation adopted pursuant
10 to this Division I. San Francisco Administrative Code Chapter 100, "Procedures Governing the
11 Imposition of Administrative Fines," as amended, is hereby incorporated in its entirety and shall
12 govern the imposition, enforcement, collection, and review of administrative citations issued to enforce
13 this Division I or any rule or regulation adopted pursuant to this Division I. Each day shall constitute
14 a separate violation for these purposes.

15 (d) Upon the failure of any Person to comply with any requirement of this Division I or any
16 rule or regulation adopted pursuant to this Division I, the City Attorney may petition any court having
17 jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including
18 restraining such Person from continuing any prohibited activity and compelling compliance with lawful
19 requirements.

20 (e) Any Person who knowingly and willfully violates the requirements of this Division I or any
21 rule or regulation adopted pursuant to this Division I is guilty of a misdemeanor and upon conviction
22 thereof is punishable by a fine of not less than fifty dollars (\$50) and not more than five hundred (\$500)
23 for each day per violation, or by imprisonment in the County Jail for a period not to exceed six months,
24 or by both such fine and imprisonment.

1 (f) Any Person in violation of this Division I or any rule or regulation adopted pursuant to this
2 Division I shall be liable to the City for a civil penalty in an amount not to exceed one thousand dollars
3 (\$1,000) per day per violation. Each day in which the violation continues shall constitute a separate
4 violation. Civil penalties shall not be assessed pursuant to this subsection (f) for the same violations for
5 which the Director assessed an administrative penalty pursuant to subsection (c) of this Section 2213.

6 (g) In determining the appropriate penalties, the court or the Director shall consider the extent
7 of harm caused by the violation, the nature and persistence of the violation, the frequency of past
8 violations, any action taken to mitigate the violation, and the financial burden to the violator.

9
10 **SEC. 2214. STEWARDSHIP PLANS – RULES, PERFORMANCE STANDARDS, AND REPORT.**

11 (a) The Director, following public notice and a hearing, may adopt rules necessary to
12 implement, administer, and enforce this Division I.

13 (b) The Director may work with the Stewardship Plan operator to define goals for collection
14 amounts, education, and promotion for a Stewardship Plan.

15 (c) The Director shall report annually to the Board of Supervisors concerning the status of all
16 Stewardship Plans and recommendations for changes to this Division I. The annual report shall include
17 a summary of available data on indicators and trends of abuse, poisonings and overdoses from
18 prescription and nonprescription drugs and a review of comprehensive prevention strategies to reduce
19 risks of drug abuse, overdoses, and preventable poisonings. The first report shall be due one year from
20 the effective date of this Division I.

21
22 **SEC. 2215. PLAN REVIEW AND ANNUAL OPERATION FEES.**

23 (a) A Producer or group of Producers participating in a Stewardship Plan shall pay to the
24 Director plan review fees to be established under subsection (d) of this Section 2215 for:

25 (1) Review of a proposed Stewardship Plan;

1 (2) Resubmittal of a proposed Stewardship Plan;

2 (3) Review of changes to an approved Stewardship Plan;

3 (4) Submittal of an updated Stewardship Plan at least every four years under
4 Section 2203(d)(5) of this Division I; or

5 (5) Review of any petition for approval to use alternative final disposal technologies
6 under Section 2207(c) of this Division I.

7 (b) In addition to plan review fees, a Producer or group of Producers participating in a
8 Stewardship Plan shall pay to the Director annual operating fees to be established under subsection (d)
9 of this Section 2215.

10 (c) A plan operator or a Stewardship Organization may remit the plan review fee on behalf of
11 participating Producers.

12 (d) As soon as practicable, the Director shall propose to the Commission on the Environment a
13 schedule of fees to be adopted by rule and charged to a Producer or group of Producers to cover costs
14 of administering and enforcing this Division I. Fees shall be calculated to recover but not exceed
15 actual costs to the City.

16
17 **SEC. 2216. UNDERTAKING FOR THE GENERAL WELFARE.**

18 In adopting and implementing this Division I, the City is assuming an undertaking only to
19 promote the general welfare. It is not assuming, nor is it imposing on its officers and employees, an
20 obligation for breach of which it is liable in money damages to any Person who claims that such
21 breach proximately caused injury.

22
23 **SEC. 2217. NO CONFLICT WITH FEDERAL OR STATE LAW.**

24 This Division I shall be construed so as not to conflict with applicable federal or State laws,
25 rules or regulations. Nothing in this Division I shall authorize any City agency or department to

1 impose any duties or obligations in conflict with limitations on municipal authority established by State
2 or federal law at the time such agency or department action is taken. The City shall suspend
3 enforcement of this Division I to the extent that said enforcement would conflict with any preemptive
4 State or federal legislation subsequently adopted. Nothing in this Division I is intended or shall be
5 construed to protect anticompetitive or collusive conduct, or to modify, impair, or supersede the
6 operation of any of the antitrust or unfair competition laws of the State of California or the Unites
7 States.

8
9 **SEC. 2218. SEVERABILITY.**

10 If any of the provisions of this Division I or the application thereof to any Person or
11 circumstance is held invalid, the remainder of those provisions, including the application of such part
12 or provisions to persons or circumstances other than those to which it is held invalid, shall not be
13 affected thereby and shall continue in full force and effect. To this end, the provisions of this Division I
14 are severable.

15
16 **SEC. 2219 . EFFECT OF GRANT OF CERTIORARI.**

17 If, prior to the effective date of this Division I, the United States Supreme Court grants a
18 petition for a writ of certiorari in the case of Pharmaceutical Research & Manufacturers of America v.
19 County of Alameda, 13-16833, 2014 WL 4814407 (9th Cir. Sept. 30, 2014), then this Division I shall
20 not become operative until 30 days after judgment has been entered in that case. Once judgment has
21 been entered in that case, the City Attorney's Office shall notify the Department that judgment has been
22 entered.

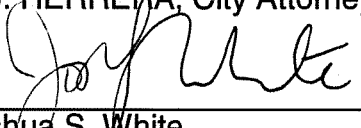
23
24 **DIVISION II: SAFE DRUG DISPOSAL INFORMATION**

25 * * * *

1
2 Section 3. Effective Date. Except as specified in Section 2219, this ordinance shall
3 become effective 30 days after enactment. Enactment occurs when the Mayor signs the
4 ordinance, the Mayor returns the ordinance unsigned or does not sign the ordinance within
5 ten days of receiving it, or the Board of Supervisors overrides the Mayor's veto of the
6 ordinance.

7
8
9 APPROVED AS TO FORM:
10 DENNIS J. HERRERA, City Attorney

11 By:


12 Joshua S. White
13 Deputy City Attorney

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