

1 [Health Code - Surplus Medication Repository and Distribution Program]

2
3 **Ordinance amending the Health Code to establish a Surplus Medication Repository and**
4 **Distribution Program, to be overseen by the Department of Public Health.**

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

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

13 Section 1. The Health Code is hereby amended by adding Article 43, consisting of
14 Sections 4300 through 4311, to read as follows:

15 **ARTICLE 43: SURPLUS MEDICATION REPOSITORY AND DISTRIBUTION**

16
17 **SEC. 4300. TITLE.**

18 *This Article 43 may be cited as the San Francisco Surplus Medication Repository and*
19 *Distribution Ordinance.*

20
21 **SEC. 4301. FINDINGS.**

22 *(a) Legal prescription medications are an integral part of health care and can help people live*
23 *longer, healthier, and more productive lives. Notwithstanding programs that have improved access to*
24 *health insurance and health care services, many San Franciscans still lack access to prescription*
25 *medications.*

1 **(b) According to a report by the Kaiser Family Foundation, in 2016, 18% of uninsured non-**
2 **elderly adults nationally did not obtain, or postponed obtaining, needed prescription medications due**
3 **to cost.**

4 **(c) Neighborhood health care centers play a significant role in San Francisco by providing**
5 **care to patients who do not qualify for subsidized insurance, people who are between jobs and cannot**
6 **afford to purchase health insurance, and recent immigrants who have not lived in the United States**
7 **long enough to qualify for subsidized insurance programs.**

8 **(d) Division 116 of the California Health and Safety Code authorizes counties to establish**
9 **voluntary drug repository and distribution programs for distributing surplus medications to low-**
10 **income people in need of prescription medications. In enacting Division 116, the Legislature intended**
11 **that the health and safety of Californians be protected and promoted through such programs, while**
12 **reducing unnecessary waste at licensed health and care facilities, by allowing those facilities to donate**
13 **unused and unexpired medications.**

14 **(e) A surplus medication collection and distribution intermediary is an entity that is licensed by**
15 **the State to facilitate the donation of medications to or transfer of medications between participating**
16 **entities in a voluntary drug repository and distribution program. Since 2015, a Bay Area company**
17 **named Sirum has been licensed to serve this function, and has facilitated the transfer of enough**
18 **prescriptions medications to allow 150,000 patients to receive medicine they need to be healthy, and**
19 **has prevented at least 241,000 pounds of waste by eliminating the need to produce new medicines.**

20 **(f) Santa Clara County, San Mateo County, and Sonoma County have established surplus**
21 **medication collection and distribution programs that authorize county-owned pharmacies to dispense**
22 **medications donated through those programs.**

23
24 **SEC. 4302. DEFINITIONS.**

25 **“City” means the City and County of San Francisco.**

1 "Department" means the Department of Public Health.

2 "Director" means the Director of the Department of Health, or the Director's designee.

3 "Donor Organization" has the meaning set forth in Section 150201 of the California Health
4 and Safety Code, as may be amended from time to time.

5 "Eligible Entity" has the meaning set forth in Section 150201 of the California Health and
6 Safety Code, as may be amended from time to time.

7 "Medication" has the meaning set forth in Section 150201 of the California Health and Safety
8 Code, as may be amended from time to time.

9 "Participating Entity" has the meaning set forth in Section 150201 of the California Health and
10 Safety Code, as may be amended from time to time.

11 "Reverse Distributor" has the meaning set forth in Section 4040.5 of the California Business
12 and Professions Code, as may be amended from time to time.

13
14 **SEC. 4303. ESTABLISHMENT OF SURPLUS MEDICATION REPOSITORY AND**
15 **DISTRIBUTION PROGRAM.**

16 There is hereby established a Surplus Medication Repository and Distribution Program
17 ("Surplus Medication Program") to be administered by the Department for the purpose of distributing
18 surplus Medications to persons in need of financial assistance to ensure access to pharmaceutical
19 therapies.

20
21 **Sec. 4304. QUALIFIED PARTICIPANTS.**

22 (a) Only the following entities may participate in the Surplus Medication Program as
23 donors of Medications:

24 (1) A Donor Organization;

1 (2) A pharmacy, licensed in California and not on probation with the California
2 State Board of Pharmacy, whose primary or sole type of pharmacy practice is limited to a skilled
3 nursing facility, home health care, board and care, or mail order, provided that the Medication it
4 donates was received directly from a manufacturer or wholesaler or was returned from a health facility
5 to the issuing pharmacy, in a manner consistent with state and federal law;

6 (3) A wholesaler licensed pursuant to Article 11 (commencing with Section 4160) of
7 Chapter 9 of Division 2 of the California Business and Professions Code; and

8 (4) A drug manufacturer that is legally authorized under federal law to manufacture
9 and sell pharmaceutical drugs.

10 (b) Only Participating Entities may receive and dispense donated Medications as part of the
11 Surplus Medication Program.

12
13 **SEC. 4305. STANDARDS FOR DONATED MEDICATIONS.**

14 (a) A Medication donated as part of the Surplus Medication Program shall meet all of the
15 following criteria:

16 (1) The Medication must be unexpired.

17 (2) The Medication may not be a controlled substance, as defined in Section 11007
18 of the California Health and Safety Code, as may be amended from time to time.

19 (3) The Medication may not have been adulterated, misbranded, or stored under
20 conditions contrary to standards set by the United States Pharmacopoeia ("USP") or the product
21 manufacturer.

22 (4) The Medication may not have been in the possession of a patient or any
23 individual member of the public, and in the case of Medications donated by a health or care facility, as
24 described in Section 150202 of the California Health and Safety Code, must have been under the
25 control of a staff member of the health or care facility who is licensed in California as a health care

1 professional or has completed, at a minimum, the training requirements specified in Section 1569.69 of
2 the California Health and Safety Code.

3 (5) The Medication must be in unopened, tamper-evident packaging or modified unit
4 dose containers that meet USP standards, and both lot numbers and expiration dates must be affixed.

5 (6) If the Medication is the subject of a United States Food and Drug Administration
6 managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United
7 States Code, inventory transfer must not be prohibited by that strategy.

8 (7) In the case of a Medication donated by a health or care facility, as described in
9 Section 150202 of the California Health and Safety Code:

10 (A) The Medication must have been under the control of a staff member of the
11 health or care facility who is licensed in California as a health care professional or has completed, at a
12 minimum, the training requirements specified in Section 1569.69 of the California Health and Safety
13 Code;

14 (B) The Medication must be one that would have been destroyed by the
15 facility or another appropriate entity, if not for the opportunity to donate the Medication to the Surplus
16 Medication Program; and

17 (C) The Medication must have been directly delivered from the dispensing
18 pharmacy, wholesaler or manufacturer to the health or care facility, and subsequently centrally stored.

19
20 **SEC. 4306. DISPENSING REQUIREMENTS.**

21 A pharmacist or physician at a Participating Entity shall:

22 (a) Use his or her professional judgment in determining whether a donated Medication
23 meets the standards of this Article 43 before accepting or dispensing any Medication under the Surplus
24 Medication Program.

1 **(b) Adhere to standard pharmacy practices, as required by state and federal law, when**
2 **dispensing all donated Medications.**

3 **(c) In the case of a Medication that is the subject of a United States Food and Drug**
4 **Administration managed risk evaluation and mitigation strategy under Section 355-1 of Title 21 of the**
5 **United States Code, the donation of which is not prohibited pursuant to subparagraph (A) of Section**
6 **355-1, dispense the Medication according to the requirements of that strategy.**

7
8 **SEC. 4307. MEDICATION HANDLING.**

9 **(a) Medication donated as part of the Surplus Medication Program may be handled in the**
10 **following ways:**

11 **(1) Dispensed to an eligible patient.**

12 **(2) Destroyed.**

13 **(3) Returned to a Reverse Distributor or licensed waste hauler.**

14 **(4) Transferred to another Participating Entity within the City, after which it shall**
15 **be dispensed to an eligible patient, destroyed, or returned to a Reverse Distributor or licensed waste**
16 **hauler. Medication transferred pursuant to this subsection (a)(4) shall be transferred with**
17 **documentation that identifies the drug name, strength, and quantity of the Medication, and the donation**
18 **facility from where the Medication originated shall be identified on Medication packaging or in**
19 **accompanying documentation. A copy of all documentation required under the previous sentence shall**
20 **be kept by the Participating Entity transferring the Medication and the Participating Entity receiving**
21 **the Medication.**

22 **(b) Medication donated as part of the Surplus Medication Program shall be maintained in**
23 **the donated packaging units until dispensed to an eligible patient under the program, who presents a**
24 **valid prescription. When dispensed, the Medication shall be in a new and properly labeled container,**
25

1 specific to the eligible patient and ensuring the privacy of the individual for whom the Medication was
2 initially dispensed.

3 (c) Medication donated as part of the Surplus Medication Program shall be physically
4 segregated from the Participating Entity's other drug stock, for purposes of inventory, accounting, and
5 inspection.

6 (d) Medication donated under this Article 43 in opened containers shall not be dispensed,
7 and once identified, shall be quarantined immediately and handled and disposed of in accordance with
8 the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104 of the
9 California Health and Safety Code).

10 (e) A Participating Entity shall follow the same procedural drug pedigree requirements for
11 donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug
12 manufacturer.

13
14 **SEC. 4308. SURPLUS MEDICATION COLLECTION AND DISTRIBUTION**

15 **INTERMEDIARY.**

16 (a) A surplus medication collection and distribution intermediary that is licensed pursuant
17 to Section 4169.5 of the California Business and Professions Code, may facilitate the donation of
18 Medications to and transfer of Medications between Participating Entities under this Article 43.

19 (b) A surplus medication collection and distribution intermediary shall comply with all of
20 the following:

21 (1) It shall not take possession, custody, or control of dangerous drugs and
22 dangerous devices, as those terms are defined in Section 4022 of the California Business and
23 Professions Code, as may be amended from time to time.

24 (2) It shall ensure that notification is provided to Participating Entities that a
25 package has been shipped when the surplus medication collection and distribution intermediary has

1 knowledge of the shipment and has provided logistical support to facilitate a shipment directly from a
2 Donor Organization to a Participating Entity.

3 (3) It shall not select, or direct a Donor Organization to select, a specific
4 Participating Entity to receive surplus Medications.

5 (c) No Participating Entity may receive donated Medication directly from the surplus
6 medication collection and distribution intermediary.

7
8 **SEC. 4309. RULES AND REGULATIONS.**

9 (a) Before the Surplus Medication Program may operate, the Director shall establish
10 written procedures and protocols to ensure compliance with Division 116 of the California Health and
11 Safety Code and this Article 43. At a minimum, these written procedures and protocols shall:

12 (1) Establish eligibility for medically indigent patients who may participate in the
13 program;

14 (2) Ensure that patients eligible for the program will not be charged for any
15 Medications provided under the program;

16 (3) Develop a formulary of Medications appropriate for the Surplus Medication
17 Program;

18 (4) Ensure proper safety and management of any Medications collected by and
19 maintained under the authority of a Participating Entity;

20 (5) Ensure the privacy of individuals for whom the Medications were originally
21 prescribed.

22 (6) Conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of
23 Division 2 of the California Business and Professions Law) regarding packaging, transporting, storing,
24 and dispensing all Medications.

1 (7) Include specific procedures to ensure that Medications that require
2 refrigeration, including, but not limited to, any biological product as defined in Section 351 of the
3 Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, are
4 packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP
5 standards and the Pharmacy Law.

6
7 **SEC. 4310. ADMINISTRATION.**

8 (a) An Eligible Entity that seeks to participate in the Surplus Medication Program shall
9 submit an application to the Department, on a form to be prescribed by the Director. An Eligible
10 Entity may not participate in the program until it has received written or electronic documentation
11 from the Director confirming that the Department has received its application and has confirmed that it
12 qualifies as a Participating Entity.

13 (b) A Participating Entity shall disclose to the Department on a quarterly basis the name
14 and location of the source of all donated Medications it receives.

15 (c) A participating primary care clinic, as described in Section 150201 of the California
16 Health and Safety Code, shall disclose to the Department the name of the licensed physician who will
17 be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant
18 to Division 116 of the California Health and Safety Code and this Article 43. This physician must be the
19 professional director, as defined in subdivision (c) of Section 4182 of the California Business and
20 Professions Code.

21 (d) A Participating Entity shall keep complete records of the acquisition and disposition of
22 Medication donated to, and transferred, dispensed, or destroyed under, the Surplus Medication
23 Program. These records shall be kept separate from the Participating Entity's other acquisition and
24 disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section
25 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

1 (e) The Board of Supervisors, the County Health Officer, and the California State Board of
2 Pharmacy may prohibit an Eligible Entity or Participating Entity from participating in the Surplus
3 Medication Program if the entity does not comply with the provisions of the program, pursuant to
4 Division 116 of the California Health and Safety Code and this Article 43. If any one of the Board of
5 Supervisors, the County Health Officer, or the California State Board of Pharmacy prohibits an
6 Eligible Entity or Participating Entity from participating in the Surplus Medication Program, it shall
7 provide written notice to the prohibited entity within 15 days of making this determination, and shall
8 ensure that this notice also is provided to the other two (of the Board of Supervisors, County Health
9 Officer, and California State Board of Pharmacy) not making the determination.

10
11 **SEC. 4311. UNDERTAKING FOR THE GENERAL WELFARE.**

12 In enacting and implementing this Article 43, the City is assuming an undertaking only to
13 promote the general welfare. It is not assuming, nor is it imposing on its officers and employees, an
14 obligation for breach of which it is liable in money damages to any person who claims that such breach
15 proximately caused injury.

16
17 Section 2. Effective Date. This ordinance shall become effective 30 days after
18 enactment. Enactment occurs when the Mayor signs the ordinance, the Mayor returns the
19 ordinance unsigned or does not sign the ordinance within ten days of receiving it, or the Board
20 of Supervisors overrides the Mayor's veto of the ordinance.

21 APPROVED AS TO FORM:
22 DENNIS J. HERRERA, City Attorney

23 By:


24 ANNE PEARSON
25 Deputy City Attorney

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City and County of San Francisco
Tails
Ordinance

City Hall
1 Dr. Carlton B. Goodlett Place
San Francisco, CA 94102-4689

File Number: 180804

Date Passed: October 16, 2018

Ordinance amending the Health Code to establish a Surplus Medication Repository and Distribution Program, to be overseen by the Department of Public Health.

September 26, 2018 Public Safety and Neighborhood Services Committee -
RECOMMENDED

October 02, 2018 Board of Supervisors - PASSED ON FIRST READING


Ayes: 10 - Brown, Cohen, Fewer, Kim, Mandelman, Peskin, Ronen, Safai, Tang
and Yee
Excused: 1 - Stefani

October 16, 2018 Board of Supervisors - FINALLY PASSED

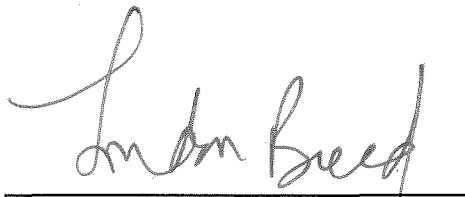
Ayes: 11 - Brown, Cohen, Fewer, Kim, Mandelman, Peskin, Ronen, Safai, Stefani,
Tang and Yee

File No. 180804

I hereby certify that the foregoing
Ordinance was **FINALLY PASSED** on
10/16/2018 by the Board of Supervisors of
the City and County of San Francisco.



Angela Calvillo
Clerk of the Board



London N. Breed
Mayor

10/26/18

Date Approved