

BOARD of SUPERVISORS



City Hall
1 Dr. Carlton B. Goodlett Place, Room 244
San Francisco 94102-4689
Tel. No. (415) 554-5184
Fax No. (415) 554-5163
TDD/TTY No. (415) 554-5227

MEMORANDUM

TO: Katy Tang, Director
Small Business Commission, City Hall, Room 448

FROM: Monique Crayton, Assistant Clerk, Public Safety and Neighborhood Services Committee, Board of Supervisors

DATE: May 22, 2024

SUBJECT: REFERRAL FROM BOARD OF SUPERVISORS
Public Safety and Neighborhood Services Committee

The Board of Supervisors' Public Safety and Neighborhood Services Committee has received the following legislation, which is being referred to the Small Business Commission for comment and recommendation. The Commission may provide any response it deems appropriate within 12 days from the date of this referral.

File No. 240502 Health Code - Requiring Retail Pharmacies to Stock Buprenorphine

Ordinance amending the Health Code to require each retail pharmacy in San Francisco that stocks controlled substance prescription drugs to stock sufficient buprenorphine to provide for at least two new prescriptions, provide for an affirmative defense for retail pharmacies that ordered replacement prescriptions, and establish penalties for violating the requirement to stock sufficient buprenorphine.

Please return this cover sheet with the Commission's response to me at the Board of Supervisors, City Hall, Room 244, 1 Dr. Carlton B. Goodlett Place, San Francisco, California 94102.

RESPONSE FROM SMALL BUSINESS COMMISSION - Date: _____

_____ **No Comment**

_____ **Recommendation Attached**

Chairperson, Small Business Commission

CC:
Office of Chair Stefani

1 [Health Code - Requiring Retail Pharmacies to Stock Buprenorphine]

2

3 **Ordinance amending the Health Code to require each retail pharmacy in San Francisco**
4 **that stocks controlled substance prescription drugs to stock sufficient buprenorphine**
5 **to provide for at least two new prescriptions, provide for an affirmative defense for**
6 **retail pharmacies that ordered replacement prescriptions, and establish penalties for**
7 **violating the requirement to stock sufficient buprenorphine.**

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 *strikethrough italics Times New Roman font*.
11 **Board amendment additions** are in double-underlined Arial font.
12 **Board amendment deletions** are in ~~strikethrough Arial font~~.
13 **Asterisks (* * * *)** indicate the omission of unchanged Code
14 subsections or parts of tables.

12

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

14

15 Section 1. Article 48 of the Health Code is hereby amended by revising Sections 4801,
16 4802, and 4803; adding new Section 4804; revising existing Sections 4804 and 4805 and
17 renumbering them as new Sections 4805 and 4806 respectively; renumbering existing
18 Sections 4806 and 4807 as new Sections 4807 and 4808 respectively; and revising existing
19 Section 4808 and renumbering it as new Section 4809, to read as follows:

20

ARTICLE 48:

21

REQUIRING RETAIL PHARMACIES TO STOCK OPIOID ANTAGONISTS AND

22

BUPRENORPHINE

23

24

SEC. 4801. FINDINGS.

25

1 (a) According to the U.S. Centers for Disease Control and Prevention, overdose
2 deaths remain a leading cause of injury-related deaths in the United States, and the majority
3 of overdose deaths involve opioids. From 2000 to 2015, more than half a million people died
4 from drug overdoses across the United States. In 2021, more than 71,000 people died from
5 synthetic opioid-related drug overdoses in the United States. On October 26, 2017, the *Acting*
6 *Secretary of the* U.S. Department of Health and Human Services declared the opioid crisis a
7 national public health emergency and has renewed such declaration every 90 days since
8 2017.

9 (b) According to the California Department of Public Health, based on preliminary
10 data, there were 6,843 opioid-related overdose deaths in California in 2021; 5,722 of these
11 deaths were related to fentanyl, and 224 of the fentanyl-related overdose deaths were teens,
12 ages 15–19 years old.

13 (c) According to the San Francisco Office of the Chief Medical Examiner, there were
14 647 accidental drug overdose deaths in San Francisco in 2022, and over 70% of those deaths
15 were attributable to fentanyl. ~~Between January and May 2023, p~~*Preliminary* reports indicate there
16 were ~~813346~~ accidental drug overdose deaths in San Francisco in 2023, a ~~more than 4025%~~
17 increase from ~~the same period in~~ 2022, with more than ~~8079%~~ of those deaths attributable to
18 fentanyl.

19 (d) Naloxone and other opioid antagonists are life-saving medications that are used
20 to reverse a drug overdose. They are safe to use, work almost immediately, and are not
21 addictive. According to peer-reviewed articles published in the journals “Drug and Alcohol
22 Dependence” and “JAMA Internal Medicine,” state laws allowing pharmacist dispensing of
23 naloxone have been associated with a 53% increase in naloxone dispensing, and a significant
24 reduction in overdose deaths. The California Public Health Officer has issued a standing order
25 to allow pharmacies, community organizations, and other approved entities to distribute

1 prescription naloxone and allow for the administration of prescription naloxone by a family
2 member, friend, or other person, to a person experiencing an overdose.

3 (e) On March 29, 2023, the U.S. Food and Drug Administration announced that it
4 approved NARCAN®, a four milligram (mg) naloxone hydrochloride nasal spray, for over-the-
5 counter, nonprescription use. It is the first naloxone product approved for use without a
6 prescription.

7 (f) Despite the efficacy of naloxone and other opioid antagonists, and the fact that
8 pharmacy distribution of naloxone is the second-most effective way—after community
9 distribution—to provide naloxone to people most likely to use it and reverse an overdose,
10 naloxone remains largely inaccessible.

11 (g) Buprenorphine is a medication approved for the treatment of Opioid Use Disorder
12 (“OUD”) and reduces the risk of dying from use of opioids by up to 50%. Buprenorphine can be
13 prescribed by physicians, nurse practitioners, and physician assistants who have a Drug Enforcement
14 Administration (“DEA”) license, as well as pharmacists with a DEA license (and who have state
15 authority to prescribe controlled substances independent of a physician). The medication can be
16 prescribed in an outpatient setting (in person or via telehealth) and dispensed at retail pharmacies.
17 Recent federal legislation (Section 1262 of the 2023 Consolidated Appropriations Act) removed
18 requirements for practitioners to obtain specific waivers to prescribe buprenorphine for the treatment
19 of OUD. Despite these efforts toward accessibility, data show that retail pharmacy availability is a
20 significant barrier to distributing buprenorphine to patients in the community.

21 (h) According to a peer-reviewed 2022 article published in the “Drug and Alcohol
22 Dependence” journal, between May 2020 and April 2021, only 31% of California pharmacies stocked
23 buprenorphine, limiting access for those who seek the medication for OUD treatment. To understand
24 the impact on San Franciscans, in January 2024, the Department of Public Health’s Office of Overdose
25 Prevention conducted a survey of all retail pharmacies in San Francisco. When surveyed, only 37 of

1 84 responding pharmacies (44%) were able to fill a day-of prescription for a 2-week supply of
2 buprenorphine. Of the 47 pharmacies that did not have buprenorphine in stock at the time of the
3 survey, just 17 (36%) indicated that they would be able to fill a prescription within one business day.

4 (i) Same-day access is particularly critical for Medication-Assisted Treatment (“MAT”) of
5 OUD. Any delay is a missed opportunity to get someone started on this lifesaving treatment. Ensuring
6 that individuals can immediately obtain buprenorphine at their local pharmacy will contribute to
7 citywide goals of increasing the number of patients on MAT and reducing overdose fatalities.

8 (g) The Board of Supervisors hereby finds that the public interest is served by
9 ensuring that retail pharmacies in San Francisco stock a minimum number of opioid
10 antagonists for purchase and a minimum number of buprenorphine doses to fill new prescriptions.

11
12 **SEC. 4802. DEFINITIONS.**

13 For purposes of this Article 48, the following terms have the following meanings:

14 “Buprenorphine” means the drug buprenorphine including any official name, common or
15 usual name, chemical name, or brand name used to describe buprenorphine prescribed for the
16 treatment of Opioid Use Disorder.

17 “City” means the City and County of San Francisco.

18 “Controlled Substance” means those substances referred to in the Federal Controlled
19 Substances Act, Chapter 13 (commencing with Section 801) of Title 21 of the United States Code and
20 the California Uniformed Controlled Substances Act, Division 10 (commencing with Section 11000) of
21 the California Health and Safety Code.

22 “Department” means the San Francisco Department of Public Health.

23 “Director” means the Director of the San Francisco Department of Public Health or
24 the Director’s designee.

25 “FDA” means the United States Food and Drug Administration.

1 “Opioid Antagonist” means Naloxone nasal spray (*such as* NARCAN®) or any other
2 formulation of naloxone hydrochloride or similar drug approved or authorized by the FDA for
3 the treatment of an opioid overdose.

4 “Pharmacist” means an individual licensed by the California State Board of Pharmacy
5 to engage in the practice of pharmacy.

6 “Retail Pharmacy” means a licensed pharmacy, as defined in subdivision (a) of
7 Section 4037 of the California Business and Professions Code, that is located in the City and
8 dispenses drugs for retail sale.

9
10 **SEC. 4803. OPIOID ANTAGONIST STOCKING REQUIREMENT.**

11 (a) Each Retail Pharmacy shall maintain a pharmaceutical stock of Opioid
12 Antagonists sufficient to fill at least two purchases of Opioid Antagonists by consumers.

13 (b) The following shall constitute a sufficient stock of Opioid Antagonist for purposes
14 of this Section 4803: (1) two boxes of nonprescription Opioid Antagonist; (2) two boxes of
15 prescription Opioid Antagonist; or (3) one box of prescription Opioid Antagonist and one box
16 of nonprescription Opioid Antagonist.

17 (c) It shall be an affirmative defense to a violation of subsection (a) of this Section
18 4803 for a Retail Pharmacy to demonstrate by a preponderance of the evidence that:

19 (1) No more than three days had elapsed since the Retail Pharmacy maintained a
20 pharmaceutical stock of Opioid Antagonists sufficient to fill at least two requests for Opioid
21 Antagonists; and

22 (2) During that three-day grace period, the Retail Pharmacy had ordered
23 replacement stock and was waiting for the supplier *or wholesaler* to fill the order.

24 (d) Retail Pharmacies shall post clear and legible signage advising customers of the
25 availability of Opioid Antagonists at the following locations:

- 1 (1) At all points of sale at which a Pharmacist dispenses pharmaceuticals; and
2 (2) If the Retail Pharmacy stocks nonprescription, over-the-counter Opioid
3 Antagonists, at all points of sale where the Retail Pharmacy sells nonprescription medication.
4 (e) The Department may develop model signage for use by Retail Pharmacies.

5
6 **SEC. 4804. BUPRENORPHINE STOCKING REQUIREMENT.**

7 (a) Each Retail Pharmacy that stocks Controlled Substances shall maintain a
8 pharmaceutical stock of Buprenorphine sufficient to fill all active existing prescriptions for
9 Buprenorphine for patients of the Retail Pharmacy as of the effective date of the ordinance in Board of
10 Supervisors File No. 240502 enacting this Section 4804 and at least two additional prescriptions for
11 Buprenorphine.

12 (b) For purposes of this Section 4804, “prescription for Buprenorphine” means sufficient
13 Buprenorphine tablets or film or both to provide a patient with 24 milligrams per day for one week.

14 (c) It shall be an affirmative defense to a violation of subsection (a) of this Section 4804 for a
15 Retail Pharmacy to demonstrate by a preponderance of the evidence that:

16 (1) No more than three days had elapsed since the Retail Pharmacy maintained a
17 pharmaceutical stock of Buprenorphine sufficient to fill at least two additional prescriptions for
18 Buprenorphine; and

19 (2) During that three-day grace period:

20 (A) the Retail Pharmacy had ordered replacement stock and was waiting for the
21 supplier or wholesaler to fill the order, or

22 (B) the Retail Pharmacy had requested the supplier or wholesaler increase the Retail
23 Pharmacy’s allotment of Controlled Substances and, once the supplier or wholesaler approved the
24 increase, ordered replacement stock within three days of approval, or

1 (3) The Retail Pharmacy had requested the supplier or wholesaler increase the Retail
2 Pharmacy's allotment of Controlled Substances and the supplier or wholesaler denied the request.

3
4 **SEC. 4804~~5~~. ADMINISTRATION AND ENFORCEMENT.**

5 (a) This Article 48 shall be administered and enforced by the Department. The
6 Director may adopt regulations, guidelines, and forms to carry out the provisions and
7 purposes of this Article 48.

8 (b) For purposes of assessing penalties for violation of this Article 48, each of the
9 following shall constitute a separate violation: (1) each day in which a Retail Pharmacy fails to
10 maintain a sufficient stock of Opioid Antagonists as required under ~~s~~Section 4803(a), subject
11 to the affirmative defense set forth in Section 4803(c); (2) each day in which a Retail Pharmacy
12 that stocks Controlled Substances fails to maintain a sufficient stock of Buprenorphine as required
13 under Section 4804(a), subject to the affirmative defense set forth in Section 4804(c); and ~~(23)~~ each
14 day in which a Retail Pharmacy fails to display the signage required under Section 4803(d).

15 (c) The Director shall issue a notice of violation for violations of subsections (a) and
16 (d) of Section 4803 or subsection (a) of Section 4804. The Director may impose an administrative
17 penalty of not less than \$250 and not more than \$1,000 per violation. Administrative Code
18 Chapter 100, "Procedures Governing the Imposition of Administrative Fines," is hereby
19 incorporated in its entirety, except as it relates to the definition of a violation and the
20 calculation of penalty amounts, addressed in Sections 4804~~5~~(b) and (c), and that the Director
21 shall appoint the hearing officer to conduct hearings for appeals.

22
23 **SEC. 4805~~6~~. ENFORCEMENT BY CITY ATTORNEY.**

24 (a) The City Attorney may at any time institute civil proceedings for injunctive and
25 monetary relief, including civil penalties, against any person for violations of this Article 48,

1 without regard to whether the Director has issued a notice of violation, instituted abatement
2 proceedings, scheduled or held a hearing on a notice of violation, or issued a final decision.

3 (b) At any time, the Director may refer a case to the City Attorney's Office for civil
4 enforcement, but a referral is not required for the City Attorney to bring a civil action under this
5 Section ~~4805~~4806.

6 (c) Any person that violates any provision of this Article 48 shall be enjoined and
7 shall be subject to a civil penalty of not less than \$250 and not more than \$1,000 for each
8 violation, as defined in Section 48045(b), which penalty shall be assessed and recovered in a
9 civil action brought in the name of the people of the City and County of San Francisco by the
10 City Attorney in any court of competent jurisdiction. In assessing the amount of the civil
11 penalty, the court shall consider any one or more of the relevant circumstances presented by
12 any of the parties to the case, including but not limited to, the following: the nature and
13 seriousness of the misconduct giving rise to the violation, the number of violations, the
14 persistence of the misconduct, the length of time over which the misconduct occurred, the
15 willfulness of the defendant's misconduct, and the defendant's assets, liabilities and net worth.

16 (d) The prevailing party in any court case or special proceeding to enforce this
17 Article 48 shall recover reasonable attorneys' fees if the City Attorney elects, at the initiation of
18 the action, to seek recovery of attorneys' fees and provides notice of such intention to the
19 adverse party or parties. In no court case or special proceeding shall an award of attorneys'
20 fees to a prevailing party exceed the amount of reasonable attorneys' fees incurred by the
21 City.

22 (e) Remedies under this Section ~~4805~~ 4806 are non-exclusive and cumulative to all
23 other remedies available at law or equity.

24
25 **SEC. 4806~~7~~. UNDERTAKING FOR THE GENERAL WELFARE.**

1 In enacting and implementing Article 48, the City is assuming an undertaking only to
2 promote the general welfare. It is not assuming, nor is it imposing on its officers and
3 employees, an obligation for breach of which it is liable in money damages to any person who
4 claims that such breach proximately caused injury.

5
6 **SEC. 48078. SEVERABILITY.**

7 If any section, subsection, sentence, clause, phrase, or word of Article 48, or any
8 application thereof to any person or circumstance, is held to be invalid or unconstitutional by a
9 decision of a court of competent jurisdiction, such decision shall not affect the validity of the
10 remaining portions or applications of this Article. The Board of Supervisors hereby declares
11 that it would have passed this Article and each and every section, subsection, sentence,
12 clause, phrase, and word not declared invalid or unconstitutional without regard to whether
13 any other portion of these sections or application thereof would be subsequently declared
14 invalid or unconstitutional.

15
16 **SEC. 48089. NO CONFLICT WITH FEDERAL OR STATE LAW.**

17 Nothing in this ~~ordinance~~ Article 48 shall be interpreted or applied so as to create any
18 requirement, power, or duty in conflict with any federal or state law.

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

1 Section 3. Scope of Ordinance. In enacting this ordinance, the Board of Supervisors
2 intends to amend only those words, phrases, paragraphs, subsections, sections, articles,
3 numbers, punctuation marks, charts, diagrams, or any other constituent parts of the Municipal
4 Code that are explicitly shown in this ordinance as additions, deletions, Board amendment
5 additions, and Board amendment deletions in accordance with the “Note” that appears under
6 the official title of the ordinance.

7

8 APPROVED AS TO FORM:
9 DAVID CHIU, City Attorney

10 By: /s/ Henry L. Lifton
11 HENRY L. LIFTON
 Deputy City Attorney

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LEGISLATIVE DIGEST

[Health Code - Requiring Retail Pharmacies to Stock Buprenorphine]

Ordinance amending the Health Code to require each retail pharmacy in San Francisco that stocks controlled substance prescription drugs to stock sufficient buprenorphine to provide for at least two new prescriptions, provide for an affirmative defense for retail pharmacies that ordered replacement prescriptions, and establish penalties for violating the requirement to stock sufficient buprenorphine.

Existing Law

The Proposed Ordinance has not previously been codified. Currently, Article 48 of the Health Code requires each retail pharmacy in San Francisco to stock sufficient opioid antagonists, such as naloxone, to fulfill at least two purchases by consumers.

Amendments to Current Law

The Proposed Ordinance would amend Article 48 to require each retail pharmacy in San Francisco that stocks controlled substance prescription drugs to maintain sufficient stock of buprenorphine to fill existing prescriptions as of the effective date of the ordinance and at least two additional prescriptions. The Proposed Ordinance would also allow a 3-day grace period for retail pharmacies to reorder two additional prescriptions subject to supplier and wholesaler availability and approval. Finally, the Proposed Ordinance would provide for penalties for violations of not less than \$250 per violation and not more than \$1,000 per violation.

Background Information

Buprenorphine is a medication approved for the treatment of Opioid Use Disorder and reduces the risk of dying from use of opioids by up to 50%. According to an article published in the “Drug and Alcohol Dependence” journal, only 31% of California pharmacies stocked buprenorphine. In January of 2024 the Department of Public Health conducted a survey among retail pharmacies in San Francisco and found only 37 of the 84 responding pharmacies were able to fill a day-of prescription for a 2-week supply of buprenorphine. The availability of buprenorphine is critical to ensuring individuals can immediately obtain lifesaving treatment.

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