



City and County of San Francisco
Department of Public Health
Community Programs
COMMUNITY BEHAVIORAL HEALTH SERVICES

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CBHS Pharmacist Prescribing Naloxone Protocol

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Manual Number:
References:
California Codes
Civil Code
Section 1714.22

PURPOSE:

This San Francisco Department of Public Health (SFDPH) policy and procedure establishes guidelines for the dispensing to intranasal naloxone through the Community Behavioral Health Services (CBHS) in order to reduce fatal opioid overdose. CBHS pharmacists, under the supervising physician, will prescribe and dispense intranasal naloxone to participants meeting the inclusion criteria.

SCOPE:

This policy applies to all CBHS Clinical Pharmacists.

BACKGROUND:

1.) California Civil Code §1714.22 States:

- a. “A licensed health care provider who is permitted by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe and subsequently dispense or distribute an opioid antagonist in conjunction with an opioid overdose prevention and treatment training program, without being subject to civil liability or criminal prosecution. This immunity shall apply to the licensed health care provider even when the opioid antagonist is administered by and to someone other than the person to whom it is prescribed.”
- b. “A person who is not otherwise licensed to administer an opioid antagonist may administer an opioid antagonist in an emergency without fee if the person has received the training information specified in paragraph (2) of subdivision (a) and believes in good faith that the other person is experiencing a drug overdose. The person shall not, as a result of his or her acts or omissions, be liable for any violation of any professional licensing statute, or subject to any criminal prosecution arising from or related to the unauthorized practice of medicine or the possession of an opioid antagonist.”
- c. To summarize, California Civil Code Section 1714.22 authorizes persons, other than licensed health care professionals, to administer the opioid antagonist naloxone to another person if:
 - i. He/she, in good faith, believes the other person is experiencing a drug overdose; and
 - ii. He/she has received specified training information specified as an *Opioid Overdose Prevention and Treatment Training Program*.

2.) Definitions

- a. **Program Director(s)**

- i. The designated program director(s) shall be identified within CBHS who shall be responsible for overseeing and ensuring compliance with all aspects of this protocol including, but not limited to:
 - 1. Ensure that Opioid Overdose Prevention Educators are trained that meet the criteria set forth in California Civil Code Section 1714.22(2) and routinely evaluated for effectiveness and adherence to these guidelines; and
 - 2. Ensure proper collection of participant data and subsequent required reporting in accordance with California Civil Code Section 1714.22(d):
 - a. Number of individuals who have received a prescription for, and training to administer, an opioid antagonist;
 - b. Number of opioid antagonist doses prescribed;
 - c. Number of opioid antagonist doses administered;
 - d. Number of individuals who received opioid antagonist injections who were properly revived;
 - e. Number of individuals who received opioid antagonist injections who were not revived; and
 - f. Number of adverse events associated with an opioid antagonist dose that was distributed as part of an opioid overdose prevention and treatment training program, including a description of the adverse events.
 - b. **Supervising Physician**
 - i. Shall be a licensed CBHS physician.
 - ii. The supervising physician shall:
 - 1. Ensure that all Opioid Overdose Prevention Educators are properly trained and their skills are maintained through periodic assessments; and
 - 2. Periodically review this policy and procedures as indicated.
- 3.) **Opioid Overdose Prevention and Treatment Training Program (“Training Program”)**
 - a. According to California Civil Code 1714.22(2)
 - i. Means any program operated by a local health jurisdiction or that is registered by a local health jurisdiction to train individuals to prevent, recognize, and respond to an opiate overdose, and that provides, at a minimum, training in all of the following:
 - (A) The causes of an opiate overdose.
 - (B) Mouth to mouth resuscitation.
 - (C) How to contact appropriate emergency medical services.
 - (D) How to administer an opioid antagonist.
- 4.) **Opioid Overdose Prevention Educators (“Trainers”)**
 - a. All overdose prevention educators who will be training participants must attend a training program that meets the criteria set forth in California Civil Code 1714.22(2).
- 5.) **Opioid Overdose Responders (“Patients” or “Responders”)**
 - a. Overdose prevention educators shall be responsible for training responders using the requirements listed in California Civil Code 1714.22(2).
 - b. A *Naloxone Verification of Training and Enrollment* Form (see Attachment A) shall be completed by the trainer upon the successful completion of training the participant.

PROCEDURES:

1.) Naloxone Kit Contents

- a. Contents of the naloxone kit shall be dispensed by CBHS in accordance with this protocol. CBHS Pharmacy Services is responsible for properly assembling the kits.
- b. Each intranasal naloxone kit shall include:
 - i. Two (2) prefilled syringes of 2mg/2mL naloxone hydrochloride;
 - ii. Two (2) mucosal atomization devices;
 - iii. Step-by-step instructions for intranasal naloxone administration; and
 - iv. Other program materials.

2.) Participant Forms

- a. A participant registration form, *Naloxone Verification of Training and Enrollment Form* (see Attachment A), shall be completed for each trained overdose responder.
- b. An *Overdose Report Back and Naloxone Refill Form* (see Attachment B) shall be completed for each refill request.
- c. The data collected from the participant forms shall be entered into the Microsoft Excel spreadsheet titled "Buprenorphine Naloxone Intranasal Reporting."

3.) Naloxone

a. Prescribing

- i. CBHS clinical pharmacists shall prescribe in accordance with this protocol, naloxone for the purpose of opioid overdose prevention within the inclusion and exclusion criteria.

b. Inclusion criteria

- i. Patients enrolled in services from CBHS Pharmacy Outpatient Based Opioid Treatment (OBOT) methadone; and/or
- ii. Patients enrolled in Integrated Buprenorphine Intervention Services (IBIS).

c. Exclusion criteria include:

1. Known allergy to naloxone

d. Dispensing

i. New Participants

1. All participants must complete an opioid overdose prevention and treatment training program in accordance with California Civil Code Section 1714.22(2).
2. A participant registration form, *Naloxone Verification of Training and Enrollment Form* (see Attachment A), shall be completed for each trained overdose responder.

ii. Refill Requests

1. The pharmacy staff associate shall complete the required reporting form, *Overdose Report-Back and Naloxone Refill Form* (see Attachment B).

- iii. Each box of intranasal naloxone shall be affixed with a patient specific prescription label in accordance with labeling requirements set forth in the California Business and Professions Code Section 4076.

Program Director, Clinical Pharmacist – Michelle Geier, PharmD

Date

Clinical Pharmacist – James Gasper, PharmD

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Clinical Pharmacist – Betsy Yuan, PharmD

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Clinical Pharmacist – Suzannah Patterson, PharmD

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Clinical Pharmacist – Sandra Suzaki, PharmD

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Clinical Pharmacist – Jeanette Cavano, PharmD

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Clinical Pharmacist – Kim So-Che, PharmD

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Clinical Pharmacist

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APPROVED BY:

Supervising Physician – Judith Martin, MD

Date

AMENDMENTS:

Any specific modifications to this protocol made by a specific site are to be placed here.

ATTACHMENTS:

A.) Naloxone Verification of Training and Enrollment Form

B.) Overdose Report-Back and Naloxone Refill Form