Date of Hearing: September 13, 2023

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Marc Berman, Chair
AB 663 (Haney) – As Amended August 21, 2023

NOTE: This bill is being heard pursuant to Assembly Rule 77.2 for concurrence in Senate amendments only.

SUBJECT: Pharmacy: mobile units.

SUMMARY: Allows for certain controlled substances approved for the treatment of opioid use disorder to be carried and dispensed at county-operated mobile pharmacy units and authorizes the operation of multiple mobile units within one jurisdiction.

EXISTING LAW:

1) Establishes the Board of Pharmacy (BOP) to administer and regulate the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 *et seq.*)

2) Defines "dispense" as the furnishing of drugs or devices upon a prescription from a physician, nurse practitioner, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor acting within the scope of their practice. (BPC § 4024)

3) Defines "pharmacy" as an area, place, or premises licensed by the BOP in which the profession of pharmacy is practiced and where prescriptions are compounded. (BPC § 4037)

4) Defines a "remote dispensing site pharmacy" as a licensed pharmacy located in California that is exclusively overseen and operated by a supervising pharmacy and staffed by qualified registered pharmacy technicians, where pharmaceutical care services are remotely monitored or provided by a pharmacist through telepharmacy technology. (BPC § 4044.3)

5) Defines "telepharmacy" as a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs by a remote dispensing site pharmacy and provides for related drug regimen review and patient counseling by an electronic method. (BPC § 4044.7)

6) Authorizes the BOP to allow for the employment of a mobile pharmacy or clinic in areas impacted during a declared federal, state, or local emergency to ensure the continuity of patient care if certain conditions are met. (BPC § 4062(c))

7) Authorizes the BOP to allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged, the mobile pharmacy is necessary to protect the health and safety of the public, and certain conditions are met. (BPC § 4110(c))

8) Allows for a county, city and county, or special hospital authority to operate a mobile unit operated as an extension of its pharmacy license to provide prescription medication within its jurisdiction to individuals without fixed addresses, individuals living in county-owned or city-and-county-owned housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority; allows a mobile unit to dispense prescription medication if all of the following requirements are met:

a) A licensed pharmacist is on the premises and the mobile unit is under the control and management of a pharmacist while prescription medications are being dispensed.

b) All activities of the pharmacist, including the furnishing of medication by the pharmacist, are consistent with the Pharmacy Law.

c) If a physician is practicing in the mobile unit, all prescribing by the physician meets the requirements of the Medical Practice Act.

d) The mobile unit does not carry or dispense controlled substances.

e) Dangerous drugs shall not be left in the mobile unit during the hours that the mobile unit is not in operation.

f) At least 30 days prior to commencing operation of a mobile unit, a county, city and county, or special hospital authority shall notify the board of its intention to operate a mobile unit. Notice shall also be given to the BOP at least 30 days prior to discontinuing operation of a mobile unit.

(BPC § 4110.5)

THIS BILL:

1) Exempts Schedule III, Schedule IV, or Schedule V controlled substances approved by the federal Food and Drug Administration (FDA) for the treatment of opioid use disorder from the prohibition against mobile units carrying or dispensing controlled substances.

2) Requires any controlled substance for the treatment of opioid use disorder that is carried or dispensed by a mobile unit to be carried in reasonable quantities based on prescription volume and stored securely in the mobile unit.

3) Authorizes a county, city and county, or special hospital authority to operate more than one mobile unit and empowers the pharmacist-in-charge to determine the number of mobile units that are appropriate for a particular pharmacy license.

4) Revises the requirements for a local government to notify the BOP of its intention to operate or discontinue operation of a mobile unit to require notification as soon as possible but no later than five business days after commencing operation and as soon as possible but at least one business day before discontinuing operation.

FISCAL EFFECT: Pursuant to Senate Rule 28.8, negligible state costs.

COMMENTS:

Purpose. This bill is sponsored by the **City and County of San Francisco**. According to the author:

"We are currently in an opioid overdose crisis. The State needs to do everything possible to expand access to life saving treatment, including getting medication for opioid use disorder to communities that need it most. While local governments can operate mobile pharmacies to provide health care to communities that lack access to "brick and mortar" pharmacies, they

cannot dispense medication for opioid use disorder. To provide those suffering with opioid use disorder access to effective treatment, AB 663 will allow local governments who operate mobile pharmacies to dispense medications for opioid use disorders."

Background.

Overview of the Opioid Crisis. Opioids are a class of drugs prescribed and administered by health professionals to manage pain. The term "opioid" is commonly used to describe both naturally occurring opiates derived from the opium poppy as well as their manufactured synthetics. Common examples of prescription opioids include oxycodone (OxyContin, Percocet); hydrocodone (Vicodin, Norco, Lorcet); codeine; and morphine. Heroin is also an opioid, but is ineligible for lawful prescription in the United States.

In addition to providing pain relief, opioids can be used as a cough suppressant, an antidiarrheal, a method of sedation, and a treatment for shortness of breath. The majority of pharmaceutical opioids are Schedule II drugs under the federal Controlled Substances Act, considered by the federal Drug Enforcement Administration (DEA) to have a high potential for abuse that may lead to severe psychological or physical dependence. However, combination drugs containing lower doses of opioids combined with other active ingredients are typically less restricted; for example, cough syrups containing low doses of codeine are frequently classified Schedule V medications.

In October of 2017, the White House declared the opioid crisis a national public health emergency, formally recognizing what had long been understood to be a growing epidemic responsible for devastation in communities across the country. According to the Centers for Disease Control and Prevention (CDC), as many as 50,000 Americans died of an opioid overdose in 2016, representing a 28 percent increase over the previous year. The California Department of Public Health estimated that nearly 2,000 Californians died of an opioid overdose in 2016.

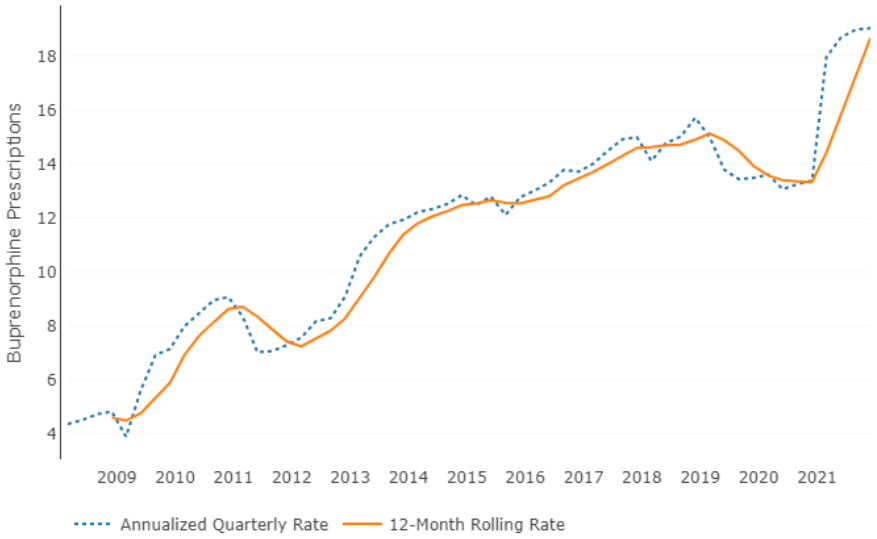
The nature of the country's opioid crisis has evolved over the past several years as illicitly manufactured fentanyl has replaced prescribed pain management medication as the dominant source of opioid-related overdoses. Fentanyl is a synthetic opioid that is up to 100 times stronger than morphine. Fentanyl is often pressed into pills to imitate more common (and less potent) pharmaceutical products, and other drugs can be unknowingly "laced" with fentanyl. Over 70,000 Americans died of a fentanyl overdose in 2021, including 5,961 deaths in California – approximately 83% of all opioid-related deaths in California.

The abuse of prescription drugs was historically viewed as a criminal concern analogous to street narcotics cases regularly investigated by law enforcement. In recent years, however, an expert consensus has evolved around the opinion that the opioid crisis must be addressed through the lens of public health policy. It is widely accepted that health professionals must continue to play a critical role in any meaningful solutions through safe-prescribing and the medication-assisted treatment of opioid use disorder.

Buprenorphine. Itself a type of opioid, buprenorphine is a Schedule III controlled substance used in treatment of opioid use disorder. Buprenorphine is what is referred to as a partial opioid agonist; this essentially means that it provides a much lower degree of euphoria than other opioids like oxycodone and heroin, and is considered to be less prone to abuse or dependence. In medication-assisted treatment of addiction, buprenorphine is used similarly to methadone, but with reduced side effects. Buprenorphine is frequently marketed under the brand name Subutex, as well as Suboxone when combined with naloxone, an opioid antagonist.

As an opioid classified as a Schedule III controlled substance, buprenorphine can only be prescribed or administered by a licensed practitioner in possession of a DEA registration. Prior federal restrictions on buprenorphine under the federal Drug Addiction Treatment Act of 2000 allowed for only specially trained physicians to prescribe buprenorphine through an "X-waiver" process. Further restricting the availability of buprenorphine treatments was federal law limiting the number of patients a physician in receipt of an X-waiver may treat. The Drug Addiction Treatment Act of 2000 originally capped the number of patients per physician at ten; this cap was raised under the Obama administration to allow up to 100 patients to be treated with buprenorphine per approved physicians who have held the waiver for two years, and up to 275 patients at three years. In January of 2021, the federal Department of Health and Human Services announced that it was eliminating the X-waiver entirely.

As the federal restrictions on prescribing buprenorphine have incrementally loosened, the number of prescriptions has gone up substantially. The following chart is available through the California Department of Public Health's Opioid Overdose Surveillance Dashboard, which utilizes data from the CURES database. The chart shows the rate of buprenorphine prescriptions per 1,000 residents statewide.



Mobile Pharmacy Units. In 2022, legislation sponsored by the County of San Diego and the County of Santa Clara was enacted to expand the authority for pharmacies to operate within mobile units. Previously, mobile units were only authorized as a way to temporarily provide pharmacy services during a natural disaster when brick-and-mortar pharmacies were damaged or destroyed. The language of the bill allowed for any county, city and county, or special hospital authority to operate a mobile unit for purposes of providing prescription medication to unhoused and low-income individuals.

Current law places certain limitations on how counties and special hospital authorities may operate mobile pharmacy units. One provision of the law specifically prohibits mobile units from carrying or dispensing controlled substances. While this prohibition was intended to prevent mobile units from carrying classes of medication that are considered at high risk or abuse or diversion, several drugs approved for treatment of opioid use disorder are currently classified as controlled substances, making them unavailable through a mobile unit.

This bill seeks to create an exemption to the prohibition in current law that prevents mobile units operated by counties from carrying and dispensing controlled substances. The bill would specifically exempt controlled substances approved by the FDA for the treatment of opioid use disorder that have been placed on either Schedule III, Schedule IV, or Schedule V pursuant to the Controlled Substances Act. This would include buprenorphine (Schedule III) but would exclude methadone (Schedule II). The bill would further provide that any controlled substance must be carried in reasonable quantities based on prescription volume and stored securely in the mobile pharmacy unit.

Current law also provides that a local government can only operate "*a* mobile unit," implying that only one mobile unit may be operated by that local government. This bill would clarify that a local government may operate one or more mobile units. The bill would authorize the pharmacist-in-charge to determine the number of mobile units that are appropriate for a particular pharmacy license.

Finally, current law requires a local government to notify the BOP of its intention to operate a mobile unit at least 30 days prior to commencing operation, and requires notification at least 30 days prior to discontinuing operation of a mobile unit. This bill would adjust those notification times to allow for less advance notice to be provided prior to commencement or discontinuation. Language in the bill would require a local government to notify the BOP of its intention to operate a mobile unit as soon as possible, and no later than five business days after commencing operation of a mobile unit. The bill would then require a local government to notify the BOP of its intention to discontinue operation of a mobile unit as soon as possible, and at least one business day before discontinuing operation of a mobile unit.

Prior Related Legislation. AB 269 (Berman, Chapter 1, Statutes of 2023) authorizes an entity approved by the Department of Public Health to operate a designated COVID-19 testing and dispensing site to acquire, dispense, and store COVID-19 oral therapeutics.

AB 1731 (Santiago, Chapter 144, Statutes of 2023) exempts a health practitioner who prescribes, orders, administers, or furnishes buprenorphine in the emergency department of a hospital from the duty to consult the state's prescription drug monitoring program.

SB 872 (Dodd, Chapter 220, Statutes of 2022) authorizes a county, city and county, or special hospital authority to operate a licensed mobile unit under certain conditions.

ARGUMENTS IN SUPPORT:

The **City and County of San Francisco** is sponsoring this bill. San Francisco Mayor London Breed writes: "Treatment with buprenorphine, and other medications for opioid use disorder, is a foundational part of our efforts to reduce overdose deaths and connect our most vulnerable residents to ongoing care. One of the challenges faced by clinical outreach teams attending to people experiencing homelessness is providing prescription medications to people in a convenient and accessible location. Until recently, California law required that most pharmacies must operate in a fixed location, such as a retail pharmacy. While a recently passed law, SB 872 (Dodd, 2022) expanded medication access by allowing jurisdictions to operate mobile pharmacies, the law does not currently allow dispensing of key medications for opioid use disorder." Mayor Breed argues that "with new tools like mobile pharmacies available to provide medications for the treatment of opioid use disorder, the City will be better able to address the needs of individuals suffering from substance use disorders."

Attorney General Rob Bonta also supports this bill, writing: "OUD medication, including buprenorphine, are an important part of successful OUD treatment. Buprenorphine has shown a decrease in overdose deaths by 50% in individuals with OUD compared to treatment without those medications. In populations with barriers to accessing traditional healthcare, such as those experiencing homelessness, buprenorphine availability is key for reducing overdose deaths." Attorney General Bonta argues that the bill "would help expand local efforts to prevent overdose deaths and improve access to healthcare for some of our most vulnerable populations."

ARGUMENTS IN OPPOSITION:

None on file.

REGISTERED SUPPORT:

City and County of San Francisco *(Sponsor)*
Alameda County Board of Supervisors
Attorney General Rob Bonta
California Academy of Family Physicians
California Association of Public Hospitals & Health Systems
California Pharmacists Association
California Society of Addiction Medicine
California Society of Health System Pharmacists
California State Board of Pharmacy
County Behavioral Health Directors Association
County Health Executives Association of California
County of San Diego
County of Santa Clara
Mayor of City & County of San Francisco London Breed
Office of Lieutenant Governor Eleni Kounalakis
R Street Institute
Steinberg Institute

REGISTERED OPPOSITION:

None on file.

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