

MEDICAL BOARD OF CALIFORNIA  
LEGISLATIVE ANALYSIS

BILL NUMBER: AB 1468  
AUTHOR: McCarty and Gallagher  
BILL DATE: May 8, 2019, Amended  
SUBJECT: Opioid Prevention and Rehabilitation Act  
SPONSOR: Author  
POSITION: Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill would establish the Opioid Prevention and Rehabilitation Act (OPRA), which would be funded by manufacturers and wholesalers of opioid drugs and would become inoperative on July 1, 2027 and be repealed as of January 1, 2028.

BACKGROUND:

According to the Centers for Disease Control and Prevention, drug overdose deaths continue to increase in the United States. From 1999 to 2017, more than 700,000 people have died from a drug overdose. Around 68% of the more than 70,200 drug overdose deaths in 2017 involved an opioid. In 2017, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 6 times higher than in 1999. On average, 130 Americans die every day from an opioid overdose.

The Medical Board of California (Board) developed a Prescribing Task Force that held multiple meetings to identify best practices, hear from speakers regarding this issue, and update the Board's Guidelines for Prescribing Controlled Substances for Pain. This task force had numerous meetings with interested parties and discussions with experts in the field of pain management to develop this document, which was adopted by the Board in November 2014. These Guidelines are intended to educate physicians on effective pain management in California by avoiding under treatment, overtreatment, or other inappropriate treatment of a patient's pain. The Guidelines' primary objective is improved patient outcomes and reduction of prescription overdose deaths. The Guidelines contain a significant amount of information and are supplemented with as many resources as practical via the appendices and links to websites that further assist a physician when prescribing controlled substances for pain. The Guidelines discuss several areas, including understanding pain, special patient populations, patient evaluation and risk stratification, consultation, treatment plan and objectives, patient consent, pain management agreements, counseling patient on overdose risk and response, initiating an opioid trial, ongoing patient assessment, and several other areas.

## ANALYSIS:

This bill would define several terms for the purpose of OPRA. This bill would define “department” as the California Department of Public Health (CDPH). This bill would define “opioid stewardship payment” as the total amount to be paid into the Opioid Prevention and Rehabilitation Program Fund (Fund) for each fiscal year. This bill would define “ratable share” as the individual portion of the opioid stewardship payment to be paid by each manufacturer or wholesaler that is subject to this bill. This bill would define “opioid” as an opiate or any synthetic or semisynthetic narcotic that has opiate-like activities but is not derived from opium and has effects similar to natural opium alkaloids, and any derivatives thereof. This bill would define “opiate” as the dried, condensed juice of a poppy, *Papaver somniferum* that has a narcotic, soporific, analgesic, and astringent effect. This bill would define “distribute” or “distribution” as the delivery for sale of an opioid drug other than by administering or dispensing to the ultimate user, including intracompany transfers between any division, affiliate, subsidiary, parent, or other entity under complete common ownership and control.

This bill would require, beginning with the 2021-22 fiscal year and for each fiscal year thereafter, a manufacturer or wholesaler that sells or distributes opioid drugs in California to submit to CDPH a report that details all opioid drugs sold or distributed in California during the preceding fiscal year. This bill would require the report to include the following:

- The name, address, telephone number, federal Drug Enforcement Agency (DEA) registration number, and license number of the manufacturer or wholesaler, as applicable.
- The name, address, and DEA registration number of the entity to which the opioid drug was sold or distributed.
- The date of the sale or distribution of the opioid drug.
- The gross receipt total, in dollars, of all opioid drugs sold or distributed.
- The name and National Drug Code (NDC) of the opioid drug sold or distributed.
- The number of containers and the strength and metric quality of controlled substances in each container of the opioid drug sold or distributed.
- The total number of morphine milligram equivalents (MMEs) attributed to the opioid drugs sold or distributed. MMEs shall be determined pursuant to a formulation that is issued by CDPH and updated as CDPH deems necessary to determine the ratable share.
- Any other elements relating to the sale or distribution of the opioid drug, as CDPH deems necessary to determine the ratable share.

Beginning with the 2021–22 fiscal year, and for each fiscal year thereafter, this bill would require CDPH, in consultation with the California State Board of Pharmacy, to calculate the ratable share of a manufacturer or wholesaler, according to all of the following steps:

- The total number of MMEs attributed to opioid drugs sold or distributed in this state by the manufacturer or wholesaler for the preceding fiscal year, divided by the total number of MMEs attributed to opioid drugs sold or distributed in

California by all manufacturers and wholesalers for the preceding fiscal year, in order to determine the payment percentage for the manufacturer or wholesaler.

- The payment percentage shall be multiplied by the opioid stewardship payment.
- The product of the above-described calculation would be the manufacturer's or wholesaler's ratable share.

For purposes of the calculation of the ratable share, the total number of MMEs attributed to opioid drugs sold or distributed by a manufacturer or wholesaler shall not include the number of MMEs attributed to opioid drugs that are manufactured in this state but the final point of delivery or sale is outside this state or the number of MMEs attributed to buprenorphine, methadone, or morphine.

For purposes of the calculation of the ratable share, opioid drugs sold or distributed in California shall not be double-counted. The total number of MMEs attributed to opioid drugs sold or distributed by a wholesaler shall not include the number of MMEs attributed to opioid drugs that a manufacturer has sold or distributed in California. Those opioid drugs shall be counted only for the calculation of the manufacturer's ratable share.

This bill would require CDPH to notify the manufacturer or wholesaler, in writing, of the value of the ratable share for that manufacturer or wholesaler. In any fiscal year that CDPH determines that a manufacturer or wholesaler failed to report information required by this bill, CDPH shall estimate, based on available data, the number of MMEs attributed to opioid drugs sold or distributed by that manufacturer or wholesaler. The other manufacturers and wholesalers complying with the requirements in this bill would receive a decreased assessment of their corresponding ratable share in the following fiscal year, with the decrease equaling the amount that was overpaid by that compliant manufacturer or wholesaler in the current fiscal year.

This bill would allow the manufacturer or wholesaler to have the opportunity to appeal the ratable share determination by submitting information to CDPH explaining why the ratable share determined pursuant to this section is erroneous or otherwise not warranted.

Beginning with the 2021–22 fiscal year, and for each fiscal year thereafter, a manufacturer or a wholesaler subject to the requirements in this bill would be required to make quarterly payments to CDPH, of the manufacturer's or wholesaler's corresponding ratable share of the opioid stewardship payment.

This bill would specify that all ratable share payments, minus refunds and the CDPH's administrative costs, would be deposited quarterly into the Fund. This bill would specify that the opioid stewardship payment shall be equal to fifty million dollars (\$50,000,000) for each fiscal year, which shall be the amount used to calculate the ratable share for a manufacturer or wholesaler. This bill would specify that if the total number of MMEs attributed to opioid drugs sold or distributed in California by all manufacturers and wholesalers subject to this bill during the 2021-22 fiscal year, or any fiscal year

thereafter, is smaller than the total number of MMEs attributed to opioid drugs sold or distributed in California by all manufacturers and wholesalers subject to this bill during the 2020-21 fiscal year, the opioid stewardship payment shall be reduced from fifty million dollars (\$50,000,000) by a percentage equal to the percentage of that reduction in the total number of MMEs. This bill would specify that the combined sum of ratable share payments by manufacturers and wholesalers may be less than the amount of the opioid stewardship payment in a fiscal year, if CDPH makes adjustments to the ratable share of a manufacturer or wholesaler.

This bill would specify that a manufacturer or wholesaler that fails to comply with the reporting requirements in this bill would be subject to a civil penalty not exceeding five hundred dollars (\$500) per calendar day. This bill would specify that a manufacturer or wholesaler that fails to make a ratable share quarterly payment pursuant to this bill would be subject to a civil penalty of not less than 10 percent of, and not greater than 300 percent of, the ratable share quarterly payment that is due. This bill would specify that any penalties collected pursuant to this bill shall be deposited in the Fund.

This bill would create the Fund in the State Treasury. This bill would specify that all moneys in the fund are continuously appropriated to CDPH to carry out the requirements in this bill. This bill would require CDPH to distribute moneys in the Fund to counties or local non-profit community-based organizations, including, but not limited to, community clinics, on an annual basis for purposes of opioid prevention and rehabilitation programs, based on applications submitted by those counties or organizations that elect to participate. This bill would specify that distribution of moneys in the Fund to counties or local non-profit community-based organizations would be based on county needs, using the most recent data of the following information, as provided by CDPH:

- The ratio of opioid overdose deaths per county population.
- The ratio of opioid overdose emergency department visits per county population.
- The ratio of opioid overdose hospitalizations per county population.

According to the author, the opioid epidemic is an ongoing and growing problem that desperately needs assistance for both prevention and treatment. The Fund will generate an important, on-going source of funding for prevention and treatment centers in order to save lives. The money collected will be distributed based on need and population. Dealing with the opioid epidemic requires a holistic approach and participation from all involved parties, including the drug manufacturers and wholesalers.

The growing opioid abuse epidemic remains a matter of concern for the Board and it is a priority for the Board to help prevent inappropriate prescribing and misuse and abuse of opioids. This bill will impose fees on manufacturers and wholesalers of opioid drugs, based on the amount of opioid drugs they sold and distributed, to fund community-based organizations for purposes of opioid prevention and rehabilitation programs, which is a reasonable funding source to contribute to the elimination of opioid abuse and misuse. For these reasons, the Board is pleased to support this important bill.

FISCAL: None

SUPPORT: County Behavioral Health Directors Association  
California Health+ Advocates  
County Health Executives Association of California

OPPOSITION: Association for Accessible Medicines.; Biocom; California Chronic Care Coalition; California Dental Association; California Hospice & Palliative Care Association; California Society of Health-System Pharmacists; and Healthcare Distribution Alliance