

AMENDED IN SENATE JUNE 18, 2018

AMENDED IN ASSEMBLY MARCH 23, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2486**

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**Introduced by Assembly Members McCarty and Gallagher**

February 14, 2018

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An act to add ~~Article 3.3 (commencing with Section 14124.50)~~ to Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code, relating to Medi-Cal; *Division 10.4 (commencing with Section 11730) to the Health and Safety Code, relating to opioids, and making an appropriation therefor, to take effect immediately, tax levy.*

LEGISLATIVE COUNSEL'S DIGEST

AB 2486, as amended, McCarty. ~~Medi-Cal~~ Opioid Prevention and Rehabilitation Act.

*Existing law establishes the State Department of Public Health, which has authority over various programs promoting public health. Existing law requires the department, upon appropriation by the Legislature, to award naloxone grant funding to local health departments, local government agencies, or other specified entities, in order to reduce the rate of fatal overdose from opioid drugs, including heroin and prescription opioids.*

*Under existing law, the department licenses and regulates manufacturers of drugs or devices in this state, and the California State Board of Pharmacy licenses and regulates wholesalers of dangerous drugs or devices, as specified.*

*This bill would, commencing with the 2020–21 fiscal year, require a manufacturer or wholesaler that sells or distributes opioid drugs in*

*this state to submit to the department a report, including specified information, that details all opioid drugs sold or distributed in this state during the preceding fiscal year. The bill would, commencing with the 2020–21 fiscal year, require the department, in consultation with the board, to calculate the ratable share of a manufacturer or wholesaler, which is the individual portion of the collective sum of \$100,000,000 to be paid by the manufacturers and wholesalers, based on the information reported. The bill would subject the manufacturer and wholesaler to specified civil penalties for failing to comply with the reporting or payment requirements.*

*The bill would require the deposit of the payments, less refunds and the department's administrative costs, into the continuously appropriated Opioid Prevention and Rehabilitation Program Fund, which the bill would create, thereby making an appropriation. The bill would require the department to distribute moneys in the fund to counties for purposes of opioid prevention and rehabilitation programs. The bill would base the distribution of moneys on county needs, using only specified information relating to opioid overdose in the counties.*

*This bill would include a change in state statute that would result in a taxpayer paying a higher tax within the meaning of Section 3 of Article XIII A of the California Constitution, and thus would require for passage the approval of  $\frac{2}{3}$  of the membership of each house of the Legislature.*

*This bill would take effect immediately as a tax levy.*

~~Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions.~~

~~Existing law provides for a schedule of benefits under the Medi-Cal program, which includes prescribed drugs subject to the Medi-Cal list of contract drugs. Existing law authorizes the department to enter into contracts with manufacturers of single-source and multiple-source drugs for drugs from each major therapeutic category. Existing law requires those contracts to provide for a state rebate to be remitted to the department quarterly. Existing law requires that the utilization data used to determine those rebates include data from all programs, including, but not limited to, fee-for-service Medi-Cal, and utilization data from health plans contracting with the department to provide services to Medi-Cal beneficiaries, as specified.~~

~~This bill would, on and after January 1, 2020, require a contract entered into by the department and a drug manufacturer under the Medi-Cal program, that includes a prescription drug that contains an active opioid ingredient, to provide for a state rebate, in addition to other existing rebates, which would be proportional to the utilization of prescription drugs containing active opioid ingredients, at a rate of \$0.01 per milligram of active opioid ingredient. The bill would require that the determination of drug utilization be based on the utilization data that the department prepares for purposes of the above-described state rebate. The bill would authorize the department to contract with a drug manufacturer without providing for the new state rebate, but would require the drug manufacturer's prescription drug that contains an active opioid ingredient to be made available only through prior authorization, to the extent that the prior authorization requirements are consistent with federal Medicaid Program provisions.~~

~~This bill would require the deposit of the collected state rebate amounts into the Medi-Cal Opioid Prevention and Rehabilitation Program Fund, which the bill would create. The bill would require the department, in consultation with the State Department of Public Health, and subject to appropriation, to annually distribute moneys in the fund to counties for purposes of opioid prevention and rehabilitation programs. The bill would base the distribution of moneys on county needs, using only specified information relating to opioid overdose in the counties.~~

~~This bill would implement these provisions only to the extent that any necessary federal approvals are obtained.~~

Vote: ~~majority~~<sup>2/3</sup>. Appropriation: ~~no~~<sup>yes</sup>. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

1     SECTION 1. Division 10.4 (commencing with Section 11730)  
2     is added to the Health and Safety Code, to read:

3

4                     DIVISION 10.4. OPIOID PREVENTION AND  
5                             REHABILITATION ACT

6

7     11730. This division shall be known, and may be cited, as the  
8     Opioid Prevention and Rehabilitation Act.

PART 1. DEFINITIONS

1  
 2  
 3 11731. For purposes of this division, the following definitions  
 4 apply:  
 5 (a) “Department” means the State Department of Public Health.  
 6 (b) “Opioid stewardship payment” means the total amount to  
 7 be paid into the Opioid Prevention and Rehabilitation Program  
 8 Fund for each fiscal year, as described in Section 11734.  
 9 (c) “Ratable share” means the individual portion of the opioid  
 10 stewardship payment to be paid by each manufacturer or  
 11 wholesaler that is subject to this division.  
 12 (d) “Opioid” means an opiate or any synthetic or semisynthetic  
 13 narcotic that has opiate-like activities but is not derived from  
 14 opium and has effects similar to natural opium alkaloids, and any  
 15 derivatives thereof.  
 16 (e) “Opiate” means the dried, condensed juice of a poppy,  
 17 *Papaver somniferum*, that has a narcotic, soporific, analgesic,  
 18 and astringent effect.  
 19 (f) “Distribute” or “distribution” means the delivery for sale  
 20 of an opioid drug other than by administering or dispensing to the  
 21 ultimate user, including intracompany transfers between any  
 22 division, affiliate, subsidiary, parent, or other entity under complete  
 23 common ownership and control.

24  
 25 PART 2. OPIOID SALE OR DISTRIBUTION REPORTING

26  
 27 11732. Commencing with the 2020–21 fiscal year, and for each  
 28 fiscal year thereafter, a manufacturer or wholesaler that sells or  
 29 distributes opioid drugs in this state shall submit to the department  
 30 a report that details all opioid drugs sold or distributed by the  
 31 manufacturer or wholesaler in this state during the preceding  
 32 fiscal year. To the extent permitted by federal law, the report shall  
 33 include all of the following information:  
 34 (a) The name, address, telephone number, federal Drug  
 35 Enforcement Agency (DEA) registration number, and license  
 36 number of the manufacturer or wholesaler, as applicable.  
 37 (b) The name, address, and DEA registration number of the  
 38 entity to which the opioid drug was sold or distributed.  
 39 (c) The date of the sale or distribution of the opioid drug.

1 (d) The gross receipt total, in dollars, of all opioid drugs sold  
2 or distributed.

3 (e) The name and National Drug Code (NDC) of the opioid  
4 drug sold or distributed.

5 (f) The number of containers and the strength and metric  
6 quantity of controlled substances in each container of the opioid  
7 drug sold or distributed.

8 (g) The total number of morphine milligram equivalents (MMEs)  
9 attributed to the opioid drugs sold or distributed. MMEs shall be  
10 determined pursuant to a formulation that is issued by the  
11 department and updated as the department deems necessary to  
12 determine the ratable share pursuant to Section 11733.

13 (h) Any other elements relating to the sale or distribution of the  
14 opioid drug, as the department deems necessary to determine the  
15 ratable share pursuant to Section 11733.

16

17 **PART 3. RATABLE SHARE DETERMINATION**

18

19 11733. (a) Commencing with the 2020–21 fiscal year, and for  
20 each fiscal year thereafter, the department, in consultation with  
21 the California State Board of Pharmacy, shall calculate the ratable  
22 share of a manufacturer or wholesaler that is subject to Section  
23 11732, according to all of the following steps:

24 (1) The total number of morphine milligram equivalents (MMEs)  
25 attributed to opioid drugs sold or distributed in this state by the  
26 manufacturer or wholesaler for the preceding fiscal year, as  
27 reported pursuant to Section 11732, shall be divided by the total  
28 number of MMEs sold or distributed in this state by all  
29 manufacturers and wholesalers subject to this division for the  
30 preceding fiscal year, in order to determine the payment percentage  
31 for the manufacturer or wholesaler.

32 (2) The payment percentage shall be multiplied by the payment  
33 stewardship payment, as described in Section 11734.

34 (3) The product of the calculation described in paragraph (2)  
35 shall be the manufacturer or wholesaler’s ratable share.

36 (4) For purposes of the calculation of the ratable share, the  
37 total number of MMEs attributed to opioid drugs sold or distributed  
38 by a manufacturer or wholesaler shall not include either of the  
39 following:

1 (A) *The number of MMEs attributed to opioid drugs that are*  
2 *manufactured in this state but the final point of delivery or sale of*  
3 *which is outside this state.*

4 (B) *The number of MMEs attributed to buprenorphine,*  
5 *methadone, or morphine.*

6 (b) *The department shall notify the manufacturer or wholesaler,*  
7 *in writing, of the value of the ratable share for that manufacturer*  
8 *or wholesaler.*

9 (c) (1) *The manufacturer or wholesaler shall have the*  
10 *opportunity to appeal the ratable share determination by submitting*  
11 *information to the department explaining why the ratable share*  
12 *determined pursuant to this section is erroneous or otherwise not*  
13 *warranted.*

14 (2) *Upon receipt of the information described in paragraph (1),*  
15 *if the department determines that all or a portion of the ratable*  
16 *share is not warranted, the department may do one of the*  
17 *following:*

18 (A) *Adjust the ratable share if the payment has not yet been*  
19 *made.*

20 (B) *Adjust the assessment of the ratable share in the following*  
21 *fiscal year by decreasing the ratable share by the amount that was*  
22 *overpaid in the current fiscal year.*

23 (C) *Refund the amount that was overpaid.*

24

#### 25 PART 4. RATABLE SHARE PAYMENT

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27 11734. (a) *Commencing with the 2020–21 fiscal year, and for*  
28 *each fiscal year thereafter, a manufacturer or a wholesaler subject*  
29 *to this division shall make quarterly payments, to the department,*  
30 *of the manufacturer's or wholesaler's corresponding ratable share*  
31 *of the opioid stewardship payment.*

32 (b) *A manufacturer or wholesaler shall not pass the cost of the*  
33 *ratable share payment to the purchaser of the opioid drug,*  
34 *including the ultimate user of the opioid drug.*

35 (c) *All ratable share payments described in subdivision (a), less*  
36 *refunds and the department's administrative costs, shall be*  
37 *deposited quarterly into the Opioid Prevention and Rehabilitation*  
38 *Program Fund established pursuant to Section 11736.*

39 (d) (1) *The opioid stewardship payment shall be equal to one*  
40 *hundred million dollars (\$100,000,000) for each fiscal year, which*

1 shall be the amount used to calculate the ratable share for a  
2 manufacturer or wholesaler pursuant to Section 11733.

3 (2) Notwithstanding paragraph (1), the combined sum of ratable  
4 share payments by manufacturers and wholesalers may be less  
5 than one hundred million dollars (\$100,000,000) in a fiscal year,  
6 if the department makes adjustments to the ratable share of a  
7 manufacturer or wholesaler pursuant to Section 11733.

8

9

PART 5. PENALTIES

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11 11735. (a) A manufacturer or wholesaler that fails to comply  
12 with the reporting requirements described in Section 11732 shall  
13 be subject to a civil penalty not exceeding one thousand dollars  
14 (\$1,000) per calendar day.

15 (b) A manufacturer or wholesaler that fails to make a ratable  
16 share payment pursuant to subdivision (a) of Section 11734 shall  
17 be subject to a civil penalty of not less than 10 percent of, and not  
18 greater than 300 percent of, the ratable share payment that is due.

19 (c) A manufacturer or wholesaler that fails to comply with  
20 subdivision (b) of Section 11734, by passing the cost of the ratable  
21 share payment to the purchaser of the opioid drug, shall be subject  
22 to a civil penalty not exceeding one million dollars (\$1,000,000)  
23 per incident.

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PART 6. OPIOID PREVENTION AND REHABILITATION  
PROGRAM FUND

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28 11736. (a) There is hereby created in the State Treasury the  
29 Opioid Prevention and Rehabilitation Program Fund.

30 (b) Notwithstanding Section 13340 of the Government Code,  
31 all moneys in the fund are continuously appropriated to the  
32 department to carry out the purposes described in Section 11736.5.

33 11736.5. (a) The department shall distribute moneys in the  
34 fund to counties on an annual basis pursuant to subdivision (b)  
35 for purposes of opioid prevention and rehabilitation programs.

36 (b) Distribution of moneys in the fund to counties shall be based  
37 on county needs, using the most recent data of only the following  
38 information, as provided by the department:

39 (1) The ratio of opioid overdose deaths per county population.

1 (2) *The ratio of opioid overdose emergency department visits*  
2 *per county population.*

3 (3) *The ratio of opioid overdose hospitalizations per county*  
4 *population.*

5 SEC. 2. *This act provides for a tax levy within the meaning of*  
6 *Article IV of the California Constitution and shall go into*  
7 *immediate effect.*

8 SECTION 1. ~~Article 3.3 (commencing with Section 14124.50)~~  
9 ~~is added to Chapter 7 of Part 3 of Division 9 of the Welfare and~~  
10 ~~Institutions Code, to read:~~

11  
12 ~~Article 3.3. Medi-Cal Opioid Prevention and Rehabilitation~~  
13 ~~Act~~  
14

15 ~~14124.50. This article shall be known, and may be cited, as~~  
16 ~~the Medi-Cal Opioid Addiction Prevention and Rehabilitation Act.~~

17 ~~14124.51. For purposes of this article, the following definitions~~  
18 ~~shall apply:~~

19 ~~(a) "State rebate" shall have the same meaning as provided in~~  
20 ~~Section 14105.31.~~

21 ~~(b) "Manufacturer" shall have the same meaning as provided~~  
22 ~~in Section 14105.31.~~

23 ~~(c) "Single-source drug" shall have the same meaning as~~  
24 ~~provided in Section 14105.31.~~

25 ~~(d) "Multiple-source drug" shall have the same meaning as~~  
26 ~~applied to the term in Section 14105.33.~~

27 ~~(e) "Active opioid ingredient" means that portion of a product~~  
28 ~~that is an opioid.~~

29 ~~(f) "Opioid" means an opiate or any synthetic or semisynthetic~~  
30 ~~narcotic that has opiate-like activities but is not derived from opium~~  
31 ~~and has effects similar to natural opium alkaloids, and any~~  
32 ~~derivatives thereof.~~

33 ~~(g) "Opiate" means the dried, condensed juice of a poppy,~~  
34 ~~Papaver somniferum, that has a narcotic, soporific, analgesic, and~~  
35 ~~astrigent effect.~~

36 ~~14124.52. (a) On and after January 1, 2020, except as specified~~  
37 ~~in subdivision (f), a contract entered into by the department and a~~  
38 ~~manufacturer of single-source or multiple-source drugs under the~~  
39 ~~Medi-Cal program pursuant to Section 14105.33, that includes a~~  
40 ~~prescription drug that contains an active opioid ingredient, shall~~

1 provide for a state rebate as described in subdivision (b), in addition  
2 to rebates pursuant to other provisions of state or federal law.

3 ~~(b) The manufacturer described in subdivision (a) shall make a~~  
4 ~~state rebate payment to the department proportional to the~~  
5 ~~utilization of prescription drugs provided by the manufacturer that~~  
6 ~~contain active opioid ingredients, at a rate of one cent (\$0.01) per~~  
7 ~~milligram of active opioid ingredient.~~

8 ~~(c) Determination of prescription drug utilization shall be based~~  
9 ~~on the utilization data that the department prepares for purposes~~  
10 ~~of the state rebate described in Section 14105.33.~~

11 ~~(d) The department may adopt any regulations necessary or~~  
12 ~~appropriate to carry out the purposes of this article.~~

13 ~~(e) All state rebate amounts collected pursuant to this section,~~  
14 ~~less refunds and the department's administrative costs, shall be~~  
15 ~~deposited into the Medi-Cal Opioid Prevention and Rehabilitation~~  
16 ~~Program Fund established pursuant to Section 14124.53.~~

17 ~~(f) Notwithstanding subdivision (a), the department may enter~~  
18 ~~into a contract with a manufacturer without providing for the state~~  
19 ~~rebate described in this section, in which case the manufacturer's~~  
20 ~~prescription drug that contains an active opioid ingredient shall be~~  
21 ~~made available only through prior authorization, to the extent that~~  
22 ~~the prior authorization requirements are consistent with federal~~  
23 ~~Medicaid Program provisions.~~

24 ~~(g) This section shall apply only to new contracts, and renewals~~  
25 ~~of existing contracts, entered into by the department and a~~  
26 ~~manufacturer pursuant to Section 14105.33, on or after January 1,~~  
27 ~~2020.~~

28 ~~(h) This article shall be implemented only to the extent that any~~  
29 ~~necessary federal approvals are obtained.~~

30 ~~14124.53. (a) There is hereby created in the State Treasury~~  
31 ~~the Medi-Cal Opioid Prevention and Rehabilitation Program Fund.~~

32 ~~(b) (1) The department, in consultation with the State~~  
33 ~~Department of Public Health, shall, subject to appropriation by~~  
34 ~~the Legislature, distribute moneys in the fund to counties, on an~~  
35 ~~annual basis pursuant to paragraph (2), for purposes of opioid~~  
36 ~~prevention and rehabilitation programs.~~

37 ~~(2) Distribution of moneys in the fund to counties shall be based~~  
38 ~~on county needs, using the most recent data of only the following~~  
39 ~~information, as provided by the State Department of Public Health:~~

40 ~~(A) The ratio of opioid overdose deaths per county population.~~

- 1     ~~(B) The ratio of opioid overdose emergency department visits~~
- 2     ~~per county population.~~
- 3     ~~(C) The ratio of opioid overdose hospitalizations per county~~
- 4     ~~population.~~

O