

SENATE No.

The Commonwealth of Massachusetts

PRESENTED BY:

Jason M. Lewis

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to the establishment of and payments into an opioid stewardship fund.

PETITION OF:

NAME:

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SENATE No.

[Pin Slip]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-First General Court
(2019-2020)

An Act relative to the establishment of and payments into an opioid stewardship fund.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Over the past few years across the state we have become all too aware of
2 the prevalence of opioid use disorders. Despite increased public awareness and prevention
3 efforts, all of our communities have been impacted by the ongoing opioid epidemic.

4 Law enforcement and first responders have had much success reviving people who have
5 overdosed with the use of nasal naloxone. Naloxone has been credited as a significant factor in
6 the decrease in the number of fatal overdoses in the last year in the Commonwealth.

7 Recognizing the impact that access to this drug has on saving lives, now people across
8 the state can go to a pharmacy and get naloxone. Having access is not enough, however, if--
9 even with insurance--the cost of the co-pay is prohibitive.

10 Every overdose death is the loss of someone's child, someone's parent, someone's
11 brother or sister, someone's friend; and it need not happen. We must work to get naloxone into
12 the hands of everyone who needs it.

13 SECTION 2: Chapter 94C of the General Laws, as appearing in the 2016 Official
14 Edition, is hereby amended by adding the following new section 50:

15 (a) Naloxone Co-Pay Assistance Program.

16 The department of public health shall establish and promulgate regulations for
17 administration of a Naloxone Co-Pay Assistance Program, a program to improve access to those
18 who seek to obtain naloxone and other medications approved by the United States Food and
19 Drug Administration that, when administered, negates or neutralizes in whole or in part the
20 pharmacological effects of an opioid in the body. The program shall supplement the cost of
21 insurance copayments so that the cost of Naloxone is greatly reduced or free of charge to those
22 who need it.

23 (b)(1) There shall be established in the Commonwealth a separate trust fund to be known
24 as the Opioid Stewardship Fund to support the Naloxone Co-Pay Assistance Program established
25 in subsection 50(a).

26 (b)(2) Monies in the Opioid Stewardship Fund shall be kept separate and shall not be
27 commingled with any other monies in the custody of the State Comptroller and the
28 Commissioner of Administration and Finance. The fund shall be maintained by the
29 Commissioner of Public Health or a designee. The monies shall be expended under the direction
30 of the department of public health, without prior appropriation. Any balance in the fund at the
31 close of a fiscal year shall be available for expenditure in subsequent fiscal years and shall not be
32 transferred to any other fund or revert to the General Fund. The Commissioner of Public Health
33 or a designee shall annually report the amount of funds collected and any expenditures made
34 from the fund to the clerks of the house of representatives and senate to be forwarded on to the

35 house and senate committees on ways and means, the house and senate chairs of the joint
36 committee on public health and the house and senate chairs of the joint committee on health care
37 financing.

38 (b)(3) The Opioid Stewardship Fund shall consist of the opioid stewardship payments
39 made by each manufacturer and distributor as directed in subsection 50(c)(3), monies
40 appropriated for the purpose of such fund, and monies transferred to such fund pursuant to law.

41 (c)(1) Definitions:

42 (i) "Opioid stewardship payment" shall mean the total amount to be paid into the Opioid
43 Stewardship Fund for each state fiscal year as set forth in subsection (d)(4);

44 (ii) "Ratable share" shall mean the individual portion of the opioid stewardship payment
45 to be paid by each manufacturer and distributor registered with the Commissioner of Public
46 Health pursuant to section 7(a) of this chapter or registered with the board of registration in
47 pharmacy pursuant to section 12(a) of this chapter (hereinafter "registrants") that sells or
48 distributes or delivers opioids in the Commonwealth;

49 (c)(2) Reports and records of Registrants. Annually each registrant shall provide to the
50 Commissioner of Public Health a report detailing all opioids sold or distributed by such
51 manufacturer or distributor in the Commonwealth. Such information shall be reported to the
52 department of public health in such form as designed by the Commissioner, provided however
53 that the initial report provided upon the establishment of the Opioid Stewardship Fund shall
54 report all opioids sold or distributed by the registrant in the Commonwealth for the 2019
55 calendar year, and must be submitted by August 1, 2020. Subsequent annual reports shall be

56 submitted on April first of each year based on the actual opioid sales and distributions of the
57 prior calendar year.

58 Such report shall include:

59 (i) the manufacturer's or distributor's name, address, phone number, federal Drug
60 Enforcement Agency (DEA) registration number and controlled substance registration number
61 issued by the department of public health or board of registration in pharmacy;

62 (ii) the name, address and DEA registration number of the entity to whom the opioid was
63 sold or distributed;

64 (iii) the date of the sale or distribution of the opioid;

65 (iv) the gross receipt total, in dollars, of all opioids sold or distributed;

66 (v) the name and National Drug Code (NDC) of the opioid sold or distributed;

67 (vi) the number of containers and the strength and metric quantity of controlled substance
68 in each container of the opioid sold or distributed;

69 (vii) the total number of morphine milligram equivalents (MMEs) sold or distributed; and

70 (viii) any other elements as deemed necessary by the commissioner.

71 For the purpose of such annual reporting, MMEs shall be determined pursuant to a
72 formulation to be issued by the department of public health and updated as the department deems
73 appropriate.

74 (c)(3) Determination of ratable share. Each registered manufacturer and distributor that
75 sells or distributes opioids in the Commonwealth shall pay a portion of the total opioid
76 stewardship payment amount. The department shall notify the registrant in writing annually on
77 or before October fifteenth of each year of the registrant's ratable share, based on the report of
78 opioids sold or distributed for the prior calendar year. The ratable share shall be calculated as
79 follows:

80 (i) The total amount of MMEs sold or distributed in the Commonwealth by the registrant
81 for the preceding calendar year, as reported by the registrant pursuant to subsection (c)(2), shall
82 be divided by the total amount of MME sold or distributed in the Commonwealth by all
83 registrants to determine the registrant payment percentage. The registrant payment percentage
84 shall be multiplied by the total opioid stewardship payment. The product of such calculations
85 shall be the registrant's ratable share. The department of public health shall have the authority to
86 adjust the total number of a registrant's MMEs to account for the nature and use of the product,
87 as well as the type of entity purchasing the product from the registrant, when making such
88 determination and adjust the ratable share accordingly.

89 (ii) The registrant's total amount of MME sold or distributed, as well as the total amount
90 of MME sold or distributed by all registrants under this chapter, used in the calculation of the
91 ratable share shall not include the MME of those opioids which are: (a) manufactured in the
92 Commonwealth, but whose final point of delivery or sale is outside of the Commonwealth; (b)
93 sold or distributed to entities certified to operate pursuant to section 5 of chapter 111E, or section
94 57D of chapter 111; or (c) the MMEs attributable to buprenorphine, methadone or morphine.

95 (c)(4) Opioid stewardship payment imposed on manufacturers and distributors. All
96 registered manufacturers and distributors that sell or distribute opioids in the Commonwealth
97 shall be required to pay an opioid stewardship payment. On an annual basis, the Commissioner
98 of Public Health shall certify to the State Comptroller the amount of all revenues collected from
99 opioid stewardship payments and any penalties imposed. The amount of revenues so certified
100 shall be deposited quarterly into the opioid stewardship fund established pursuant to subsection
101 50(b). No registrant shall pass the cost of their ratable share amount to a purchaser, including the
102 ultimate user of the opioid, or such registrant shall be subject to penalties pursuant to subsection
103 (c)(8).

104 (c)(5). Payment of ratable share. The registrant shall make payments of the ratable share
105 quarterly to the department of public health with the first quarter's due on January 1 following
106 the annual notice as set forth in subsection (d)(3); additional quarterly payments shall be due and
107 owing on the first day of every quarter thereafter.

108 (c)(6). Rebate of ratable share. In any year for which the Commissioner of Public Health
109 determines that any registrant has failed to make a timely report of required information pursuant
110 to subsection (c)(2), then those registrants who comply by making a timely report pursuant to
111 subsection (c)(2) shall receive a reduced assessment of their ratable share in the following year
112 equal to the amount in excess of any overpayment in the prior year's payment.

113 (c)(7). Registrant's opportunity to appeal. A registrant shall be afforded an opportunity
114 to submit information to the department of public health to justify why the ratable share
115 calculated for the registrant pursuant to subsection (c)(3), or amounts paid thereunder, are in
116 error or otherwise not warranted. If the department determines thereafter that all or a portion of

117 such ratable share, as determined by the Commissioner pursuant to subsection (c)(3), is not
118 warranted, the department may: (a) adjust the ratable share; (b) adjust the assessment of the
119 ratable share in the following year equal to the amount in excess of any overpayment in the prior
120 payment period; or (c) refund amounts paid in error.

121 (c)(8) Penalties.

122 (i) The department may assess a civil penalty in an amount not to exceed one thousand
123 dollars per day against any registrant that fails to comply with subsections (d)(2) or (d)(5).

124 (ii) In addition to any other civil or criminal penalty provided by law, where a registrant
125 has failed to pay its ratable share in accordance with subsection (d)(5), the department may also
126 assess a penalty of no less than ten percent and no greater than three hundred percent of the
127 ratable share due from such registrant.

128 (iii) Where the ratable share, or any portion thereof, has been passed on to a purchaser by
129 a registrant as prohibited in subsection (d)(3), the commissioner may impose a penalty not to
130 exceed one million dollars per incident.