SENATE DOCKET, NO. 957 FILED ON: 1/18/2023

SENATE . . . . . No. 1259

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:	DISTRICT/ADDRESS:
Jason M. Lewis	*Fifth Middlesex*
Marian T. Ryan	*15 Commonwealth Avenue, Woburn, MA 01801*

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SENATE . . . . . No. 1259

By Mr. Lewis, a petition (accompanied by bill, Senate, No. 1259) of Jason M. Lewis and Marian T. Ryan for legislation relative to the establishment of and payments into an opioid stewardship fund. Mental Health, Substance Use and Recovery.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. *1302* OF 2021-2022.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Third General Court
(2023-2024)

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:

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

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

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

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

SECTION 2: Chapter 94C of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by adding the following new section 50:

(a) Naloxone Co-Pay Assistance Program.

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

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

(b)(2) Monies in the Opioid Stewardship Fund shall be kept separate and shall not be commingled with any other monies in the custody of the State Comptroller and the Commissioner of Administration and Finance. The fund shall be maintained by the Commissioner of Public Health or a designee. The monies shall be expended under the direction of the department of public health, without prior appropriation. Any balance in the fund at the close of a fiscal year shall be available for expenditure in subsequent fiscal years and shall not be

transferred to any other fund or revert to the General Fund. The Commissioner of Public Health or a designee shall annually report the amount of funds collected and any expenditures made from the fund to the clerks of the house of representatives and senate to be forwarded on to the house and senate committees on ways and means, the house and senate chairs of the joint committee on public health and the house and senate chairs of the joint committee on health care financing.

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

(c)(1) Definitions:

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

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

(c)(2) Reports and records of Registrants. Annually each registrant shall provide to the Commissioner of Public Health a report detailing all opioids sold or distributed by such manufacturer or distributor in the Commonwealth. Such information shall be reported to the department of public health in such form as designed by the Commissioner, provided however that the initial report provided upon the establishment of the Opioid Stewardship Fund shall

report all opioids sold or distributed by the registrant in the Commonwealth for the 2025 calendar year, and must be submitted by August 1, 2026. Subsequent annual reports shall be submitted on April first of each year based on the actual opioid sales and distributions of the prior calendar year.

Such report shall include:

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

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

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

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

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

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

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

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

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

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

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

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

(c)(4) Opioid stewardship payment imposed on manufacturers and distributors. All registered manufacturers and distributors that sell or distribute opioids in the Commonwealth shall be required to pay an opioid stewardship payment. On an annual basis, the Commissioner of Public Health shall certify to the State Comptroller the amount of all revenues collected from opioid stewardship payments and any penalties imposed. The amount of revenues so certified shall be deposited quarterly into the opioid stewardship fund established pursuant to subsection 50(b).

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

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

(c)(7). Registrant's opportunity to appeal. A registrant shall be afforded an opportunity to submit information to the department of public health to justify why the ratable share calculated for the registrant pursuant to subsection (c)(3), or amounts paid thereunder, are in error or otherwise not warranted. If the department determines thereafter that all or a portion of such ratable share, as determined by the Commissioner pursuant to subsection (c)(3), is not warranted, the department may: (a) adjust the ratable share; (b) adjust the assessment of the

ratable share in the following year equal to the amount in excess of any overpayment in the prior payment period; or (c) refund amounts paid in error.

(c)(8) Penalties.

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

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