HOUSE DOCKET, NO. 3632 FILED ON: 2/19/2021

HOUSE . . . . . No. 1303

The Commonwealth of Massachusetts

PRESENTED BY:

James J. O'Day

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 compensation for victims of opioids.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
James J. O'Day	*14th Worcester*	*2/19/2021*
Christopher Hendricks	*11th Bristol*	*2/26/2021*

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HOUSE . . . . . No. 1303

By Mr. O'Day of West Boylston, a petition (accompanied by bill, House, No. 1303) of James J. O'Day and Christopher Hendricks relative to performance improvement plans of drug manufacturers and compensation for victims of opioids. Health Care Financing.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court
(2021-2022)

An Act relative to compensation for victims of opioids.

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. Chapter 6D of the General Laws, as so appearing in the 2018 Official Edition, is hereby amended by inserting after section 10 the following section:-

Section 10A. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Covered drug", any product included in the pharmacological class category of full opioid agonist, opioid agonist, partial opioid agonist or benzodiazepine in the National Drug Code (NDC) Directory NDC Product File that is ultimately dispensed in the commonwealth pursuant to a valid prescription issued under section 18 of chapter 94C; provided, however, that "covered drug" shall not include: (i) drugs intended for use solely in veterinary care; (ii) drugs that are compounded under a specialty license pursuant to sections 39G to 39J, inclusive, of chapter 112; or (iii) products approved by the United States Food and Drug Administration for the treatment of opioid use disorder.

"Manufacturer" shall mean an entity that manufactures a controlled substance under a United States Food and Drug Administration manufacturer's license, except for an institutional pharmacy, as defined in section 39D of chapter 112 or a wholesaler licensed pursuant to section 36B of chapter 112.

(b) The commission shall provide notice to any manufacturer referred to the commission by the commissioner of revenue under section 6 of chapter 63D. Such notice shall state that beginning in calendar year 2020, the commission may require certain actions, as established in this section, from manufacturers so identified.

(c) The commission shall establish procedures to support compliance with chapter 63D and to assist manufacturers in complying with said chapter without increasing the cost of covered drugs to consumers, the division of medical assistance, the state office of pharmacy services, the group insurance commission, carriers, pharmacies, or other purchasers of pharmaceutical drugs.

(d) In addition to the notice provided under subsection (b), if the commission has reason to believe that a manufacturer referred to the commission by the commissioner of revenue under section 6 of chapter 63D has increased the price of one or more covered drugs for the purposes of complying with chapter 63D, the commission may require such a manufacturer to file a performance improvement plan with the commission. The commission shall provide written notice to such manufacturer that they are required to file a performance improvement plan. Within 45 days of receipt of such written notice, the manufacturer shall either:

(1) file a performance improvement plan with the commission; or

(2) file an application with the commission to waive or extend the requirement to file a performance improvement plan.

(e) The manufacturer may file any documentation or supporting evidence with the commission to support the manufacturer's application to waive or extend the requirement to file a performance improvement plan. The commission shall require the manufacturer to submit any other relevant information it deems necessary in considering the waiver or extension application; provided, however, that such information shall be made public at the discretion of the commission.

(f) The commission may waive or delay the requirement for a manufacturer to file a performance improvement plan in response to a waiver or extension request filed under subsection (e) in light of all information received from the manufacturer, based on a consideration of factors specified by the commission in regulation.

(g) If the commission declines to waive or extend the requirement for the manufacturer to file a performance improvement plan, the commission shall provide written notice to the manufacturer that its application for a waiver or extension was denied and the manufacturer shall file a performance improvement plan.

(h) A manufacturer shall file a performance improvement plan: (1) within 45 days of receipt of a notice under subsection (d); (2) if the manufacturer has requested a waiver or extension, within 45 days of receipt of a notice that such waiver or extension has been denied; or (3) if the manufacturer is granted an extension, on the date given on such extension. The performance improvement plan shall be generated by the manufacturer and shall include but not be limited to, specific strategies, adjustments and action steps the entity proposes to implement to improve performance. The proposed performance improvement plan shall include specific

identifiable and measurable expected outcomes and a timetable for implementation. The timetable for a performance improvement plan shall not exceed 18 months.

(i) The commission shall approve any performance improvement plan that it determines will reasonably succeed in addressing the underlying reasons the manufacturer was referred to the commission by the commissioner of revenue under section 6 of chapter 63D.

(j) If the board determines that the performance improvement plan is unacceptable or incomplete, the commission may provide consultation on the criteria that have not been met and may allow an additional time period, up to 30 calendar days, for resubmission; provided, however, that all aspects of the performance improvement plan shall be proposed by the manufacturer and the commission shall not require specific elements for approval.

(k) Upon approval of the proposed performance improvement plan, the commission shall notify the manufacturer to begin immediate implementation of the performance improvement plan. Public notice shall be provided by the commission on its website, identifying that the manufacturer is implementing a performance improvement plan. All manufacturers implementing an approved performance improvement plan shall be subject to additional reporting requirements and compliance monitoring, as determined by the commission. The commission shall provide assistance to the manufacturer in the successful implementation of the performance improvement plan.

(l) All manufacturers shall, in good faith, work to implement the performance improvement plan. At any point during the implementation of the performance improvement plan the manufacturer may file amendments to the performance improvement plan, subject to approval of the commission.

(m) At the conclusion of the timetable established in the performance improvement plan, the manufacturer shall report to the commission regarding the outcome of the performance improvement plan. The manufacturer's report shall include a finding as to whether the performance improvement plan was successful or unsuccessful. If the manufacturer finds that the performance improvement plan was unsuccessful, the commission shall either: (i) extend the implementation timetable of the existing performance improvement plan; (ii) approve amendments to the performance improvement plan as proposed by the manufacturer; (iii) require the manufacturer to submit a new performance improvement plan under subsection (d) or (iv) waive or delay the requirement to file any additional performance improvement plans. If the manufacturer finds that the performance improvement plan was successful, the commission shall remove the identity of the manufacturer from the commission's website.

(n) The commission may submit a recommendation for proposed legislation to the joint committee on health care financing if the commission determines that further legislative authority is needed to assist manufacturers with the implementation of performance improvement plans or otherwise ensure compliance with the provisions of this section and with chapter 63D.

(o) If the commission determines that a manufacturer has: (i) willfully neglected to file a performance improvement plan with the commission within 45 days as required under subsection (d); (ii) failed to file an acceptable performance improvement plan in good faith with the commission; (iii) failed to implement the performance improvement plan in good faith; or (iv) knowingly failed to provide information required by this section to the commission or knowingly falsified the same, the commission may assess a civil penalty to the manufacturer of not more

than $500,000. The commission shall seek to promote compliance with this section and shall only impose a civil penalty as a last resort.

(p) The commission, in consultation with the secretary, shall promulgate regulations necessary to implement this section; provided, however, that notice of any proposed regulations shall be filed with the joint committee on state administration and regulatory oversight and the joint committee on health care financing at least 180 days before adoption.

SECTION 2. The General Laws, as so appearing, are hereby amended by inserting after chapter 63B the following chapter:-

Chapter 63D. Assessment on opioid and benzodiazepine manufacturers

Section 1. As used in this chapter, the following words shall have the following meanings unless the context clearly requires otherwise:

"Commissioner", the commissioner of revenue.

"Covered drug", any product included in the pharmacological class category of full opioid agonist, opioid agonist, partial opioid agonist or benzodiazepine in the National Drug Code (NDC) Directory NDC Product File that is ultimately dispensed in the commonwealth pursuant to a valid prescription issued under section 18 of chapter 94C; provided, however, that "covered drug" shall not include: (i) drugs intended for use solely in veterinary care; (ii) drugs that are compounded under a specialty license pursuant to sections 39G to 39J, inclusive, of chapter 112; or (iii) products approved by the United States Food and Drug Administration for the treatment of opioid use disorder.

"Drug stewardship payment" the total annual amount to be paid into the Substance Abuse Services Fund as set forth in section 3 .

"Gross receipts", receipts from sales of covered drugs made by a manufacturer to a purchaser that is not a related party. In the case of sales to a related party or parties for subsequent resale to an unrelated buyer, the gross receipts are the amount paid for the product by the first unrelated buyer.

“Manufacturer”, an entity that manufactures a controlled substance under a United States Food and Drug Administration manufacturer's license, except for an institutional pharmacy, as defined in section 39D of chapter 112 or a wholesaler licensed pursuant to section 36B of chapter 112.

"Person", any natural person or legal entity.

"Related parties", an entity that belongs to the same affiliated group as the person under section 1504 of the Internal Revenue Code, as amended and in effect for the taxable year, or if the entity and the person are otherwise commonly owned and controlled.

“Share of total gross receipts”, a manufacturer’s gross receipts for a calendar year divided by total gross receipts for said calendar year.

"Total gross receipts", the total of all gross receipts for all covered drugs dispensed in the commonwealth in a calendar year.

Section 2. Any manufacturer who sells one or more covered drugs, directly or through another person, for distribution in the commonwealth shall be subject to the drug stewardship assessment levied under this chapter. Any such manufacturer shall, on a schedule determined by

the commissioner, pay an amount equal to the lesser of the following: (i) the manufacturer's share of total gross receipts in the preceding calendar year multiplied by the drug stewardship payment; or, (ii) 40 per cent of the manufacturer's gross receipts in the preceding calendar year. The department shall annually notify in writing each manufacturer subject to this section of its obligations under this chapter. The assessment imposed under this chapter shall be in addition to, and not a substitute for or credit against any other tax or excise imposed under the General Laws. On an annual basis, the commissioner shall certify to the state comptroller the total amount of all revenues from all payments collected and any penalties imposed under this chapter. The amount of revenues so certified shall be deposited annually into the Substance Abuse Services Fund established under section 2I of chapter 111.

Section 3. (a) Unless otherwise decreased pursuant to subsection (b), the drug stewardship payment amount for each fiscal year shall be $75,000,000.

(b) The executive office of health and human services shall annually review the amount of state operating funds spent for opioid and benzodiazepine prevention, intervention, treatment and recovery. The secretary of health and human services shall annually certify to the department the amount expended for such services in the preceding fiscal year, utilizing available information on patient demographics and the actual cost of services delivered by the state and by state-funded providers, and shall provide the total amount of such spending to the department no later than August first of each year. If the amount expended for such services in the preceding fiscal year is less than $75,000,000, the commissioner shall reduce the drug stewardship payment by the difference between such amount expended and $75,000,000.

Section 4. Annually, not later than a date specified by the commissioner, each manufacturer subject to the assessment under section 2 shall file a report with the commissioner and the commissioner of public health, which shall include:

(i) the manufacturer's name, address, phone number, federal Drug Enforcement Administration registration number and controlled substance registration number issued by the department of public health under chapter 94C;

(ii) the name and national drug code of each covered drug it manufactures;

(iii) the unit of measure and quantity of covered drugs;

(iv) the name, address and DEA registration number of the first unrelated buyer of covered drugs;

(v) the date of the sale of covered drugs;

(vi) whether the covered drug was ultimately dispensed in the commonwealth pursuant to a valid prescription issued under section 18 of chapter 94C;

(vii) the gross receipt total, in dollars, for all covered drugs sold; and

(viii) any other elements required by the commissioner.

The commissioner may disclose to the health policy commission amounts paid under section 2 and may disclose information contained in returns and reports filed under this chapter. Information reported under this section shall remain confidential and shall not be public record; provided however, that the health policy commission and the department of public health may issue reports which include aggregate, de-identified data and findings based on such information.

Section 5. A manufacturer subject to the assessment under section 2 shall be afforded an opportunity to submit information to the department to justify why the amounts paid thereunder are in error or otherwise not warranted. If the department determines thereafter that all or a portion of such payment is not warranted, the department may: (a) adjust the manufacturer's payment in the following year equal to the amount in excess of any overpayment in the prior payment period; or (b) refund amounts paid in error.

Section 6. The commissioner shall confidentially provide to the health policy commission a list of manufacturers that increase prices for one or more covered drugs so that the health policy commission may pursue further action under section 10A of chapter 6D.

Section 7. The department may assess a civil penalty in an amount not to exceed $10,000 per day against any manufacturer that fails to comply with the provisions of this chapter.

Section 8. The commissioner may promulgate regulations or issue guidance to facilitate the implementation of this chapter.

SECTION 3. Section 2I of chapter 111 of the General Laws, as so appearing, is hereby amended by striking out, in line 11, the words "and (iv)" and inserting in place thereof the following words:- (iv) revenues from the assessment imposed under chapter 63D; and (v)

SECTION 4. Said section 2I of said chapter 111, as so appearing, is hereby further amended by striking out subsections (b) to (d), inclusive, and inserting in place thereof the following subsections:-

(b) All expenditures from the fund shall support prevention, intervention, recovery, and treatment strategies to reduce the prevalence of substance use disorder in the commonwealth.

(c) Annually, not later than January 1, the commissioner shall report on the activities of the fund to the clerks of the house of representatives and senate, the chairs of the house and senate committees on ways and means, and the chairs of the joint committee on mental health, substance use and recovery. The report shall include: (i) an accounting of money received by the fund broken down by source; (ii) an itemized accounting of expenditures from the fund; (iii) the amount of any unexpended balance; and (iv) anticipated expenditures and goals for the subsequent year.