



SPONSOR: Sen. Hansen & Sen. Henry & Rep. Keeley &  
Rep. Hudson  
Sens. Ennis, McDowell, Poore, Sokola, Townsend,  
Walsh; Reps. Bennett, Hensley, Mitchell, Mulrooney,  
Paradee

DELAWARE STATE SENATE  
149th GENERAL ASSEMBLY

SENATE SUBSTITUTE NO. 1  
FOR  
SENATE BILL NO. 176

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE CREATING A PRESCRIPTION OPIOID IMPACT  
FUND.

1 WHEREAS, Delaware, like the rest of the United States, is in the midst of an opioid overdose epidemic; and

2 WHEREAS, in 2016, opioids killed more than 42,000 people and 40% of those deaths were from prescription  
3 opioids; and

4 WHEREAS, in 2016, the number of opioid overdose deaths were 5 times higher than the number of opioid  
5 overdose deaths in 1999; and

6 WHEREAS, the prescribing rates for prescription opioids among adolescents and young adults nearly doubled  
7 from 1994 to 2007; and

8 WHEREAS, from 2015 to 2016, Delaware had the second highest increase in drug overdose deaths; and

9 WHEREAS, in 2016, 308 Delawareans died from drug overdoses; and

10 WHEREAS, since 2009, more people in Delaware have died from a drug overdose than from a motor vehicle  
11 injury; and

12 WHEREAS, according to the Centers for Disease Control and Prevention's 2017 Annual Surveillance Report of  
13 Drug-Related Risks and Outcomes, Delaware's prescription rate of high dose opioids and prescription rate of long-  
14 acting/extended-release opioid pain relievers were both the highest in the nation; and

15 WHEREAS, in Delaware, opioids were prescribed at a rate of 870,046 prescriptions totaling 1,104,210,408  
16 morphine milligram equivalents ("MME") in 2015, 831,021 prescriptions totaling 1,050,799,858 MME in 2016, and  
17 759,521 prescriptions totaling 925,238,704 MME in 2017; and

18 WHEREAS, higher dosages of opioids are associated with a higher risk of overdose and death and higher dosages  
19 have not been shown to reduce pain over the long term; and

20 WHEREAS, 4 in 5 new heroin users started out misusing prescription painkillers; and

21 WHEREAS, in 2016, 3% of Delaware's eighth grade students reported using a prescription drug illegally; and

22 WHEREAS, nationally, Medicaid pays for 25% of the adults who receive residential treatment for opioid  
23 addiction, while 10% of the adults who receive residential treatment are unemployed; and

24 WHEREAS, nationally, Medicaid pays for 37% of the adults who receive outpatient treatment for opioid  
25 addiction, while 20% of the adults who receive outpatient treatment are unemployed; and

26 WHEREAS, buprenorphine, sold under the brand name Suboxone, is an opioid used to treat opioid addiction and  
27 40% of the total buprenorphine spending in Delaware in 2016 was by Medicaid; and

28 WHEREAS, the Behavioral Health Consortium provides oversight of behavioral healthcare and substance use  
29 treatment in Delaware and includes the Chair of the Addiction Action Committee, and the Addiction Action Committee  
30 coordinates a comprehensive approach to the addiction epidemic in this State; and

31 WHEREAS, the Prescription Monitoring Program does not include prescription opioids that are administered in  
32 hospitals, used to treat addiction, provided directly to patients by a hospice providers, or prescribed or dispensed by  
33 veterinarians; and

34 WHEREAS, a 1 penny or 1/4 of a penny fee on the MME dispensed in this State will not substantially increase the  
35 price of the prescription drug to Delaware consumers because pharmaceutical prices are set nationally; and

36 WHEREAS, the FY19 Governor's Recommended Budget requests \$100,000 for Substance Use Disorder Services  
37 and Naloxone for First Responders, \$328,500 for 20 additional Sober Living Beds, and \$990,000 for Emergency Room  
38 Consultations.

39 NOW, THEREFORE:

40 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE (Three-fifths of all  
41 members elected to each house thereof concurring therein):

42 Section 1. Amend Part IV, Title 16 of the Delaware Code by making deletions as shown by strike through and  
43 insertions as shown by underline as follows:

44 Chapter 48B. Prescription Opioid Impact Fund.

45 § 4801B. Findings and purpose.

46 (a) It is the intent of the General Assembly that the Prescription Opioid Impact Fund be established under this  
47 chapter to fund prevention and treatment of opioid addiction. In establishing the Prescription Opioid Impact Fund, the  
48 General Assembly finds as follows:

49 (1) The Prescription Opioid Impact Fund is needed to prevent and respond to the dramatic increase in  
50 opioid addiction in this State.

51                   (2) The Prescription Opioid Impact Fund is needed to protect the public health, safety, and general  
52                   welfare of the citizens of this State.

53                   (3) In the 3 years prior to the creation of the Prescription Opioid Impact Fund, prescription opioids were  
54                   dispensed to Delaware residents as follows:

55                   a. In 2015, 870,046 prescriptions for 59,198,611 individual doses totaling 1,104,210,40 MMEs.

56                   b. In 2016, 831,021 prescriptions for 56,502,249 individual doses totaling 1,050,799,858 MMEs.

57                   c. In 2017, 759,521 prescriptions for 50,339,666 individual doses totaling 925,238,704 MMEs.

58                   (4) There is a direct connection between the quantity and strength of opioids prescribed to citizens of this  
59                   State and the rates of opioid addiction and overdose deaths.

60                   (5) There is a substantial nexus between the opioid manufacturers subject to the impact fee and the State  
61                   of Delaware, in part because only those manufacturers whose prescription opioids are dispensed in the State in  
62                   amounts sufficient to meet the quarterly threshold in § 4804B(b) of this chapter are subject to the impact fee.

63                   (6) Opioid manufacturers receive revenues in connection with prescription opioids dispensed in in this  
64                   State.

65                   (6) The Prescription Opioid Impact Fund will pay for a share of the cost incurred by the State of opioid  
66                   substance abuse treatment and prevention.

67                   (8) The impact fee does not discriminate against interstate commerce, because both in-state and out-of-  
68                   state opioid manufacturers are equally subject to its provisions.

69                   (9) The impact fee is fairly apportioned because it is based upon the volume of an opioid manufacturer's  
70                   product dispensed within Delaware, with recognition of the fact that some manufacturers' products have different  
71                   underlying costs and are sold at substantially different prices.

72                   (10) By paying a share of the cost of opioid addiction treatment and prevention, the opioid manufacturers  
73                   receive assistance in promoting responsible product use and offset negative effect that these products have on  
74                   Delaware residents.

75                   (b) It is the intent of this chapter to ensure that adequate public funds are available to do all of the following:

76                   (1) Prevent more individuals from becoming addicted to opioids.

77                   (2) Provide funding to defray expenses incurred by the Prescription Monitoring Program under this  
78                   chapter.

79                   (3) Provide opioid addiction treatment to all Delawareans who have opioid addiction.

80                   (4) Fund emergency medical assistance to treat opioid overdoses.

§ 4802B. Definitions.

For purposes of this chapter:

(1) “Impact fee” means a payment of money imposed upon an opioid manufacturer, as a result of the provisions of this chapter, to pay for a share of the cost of preventing and treating opioid addiction.

(2) “Generic substitution” means a drug that is the same active ingredient, equivalent in strength to the strength written on the prescription, and is classified as being therapeutically equivalent to another drug in the latest edition or supplement of the Federal Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, sometimes referred to as the “Orange Book”.

(3) “Manufacturer of prescription opioids” or “opioid manufacturer” means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription opioid drug, but does not include a person who is engaged in the preparation and dispensing of a drug pursuant to a prescription.

(4) “Morphine milligram equivalent” or “MME” means the conversion factor used to calculate the strength of an opioid using morphine dosage as the comparative unit of measure.

(5) “Prescription opioid” means a drug that is a controlled substance under Chapter 47 of this title and is either an opiate, derived from the opium poppy, or an opiate-like synthetic drug. “Prescription opioid” does not include buprenorphine.

(6) “Prescription Monitoring Program” or “PMP” means the program established under § 4798 of this title.

(7) “Secretary” means the Secretary of the Department of State.

§ 4803B. Prescription Opioid Impact Fund.

(a) A special fund known as the Prescription Opioid Impact Fund (“Fund”) is established and the State Treasurer shall invest the Fund consistent with the investment policies established by the Cash Management Policy Board. The State Treasurer shall credit interest to the Fund on a monthly basis consistent with the rate established by the Cash Management Policy Board.

(b) The following moneys must be deposited in the Fund:

(1) All impact fees collected by the State under to § 4804B of this title.

(2) All funds received by the State as the result of a civil action relating to opioids unless otherwise specifically designated by a court order or written agreement arising from the civil action.

(3) Any other money appropriated or transferred to the Fund by the General Assembly.

(c) Money in the Fund must be used for activities in one or more of the following categories:

(1) Opioid addiction prevention.

(2) The following opioid addiction services:

a. Inpatient and outpatient treatment programs and facilities, including short-term and long-term residential treatment programs and sober living facilities.

b. Services relating to treating substance use disorder for the under-insured and uninsured.

c. Emergency assistance relating to prescription opioids, including purchasing Naloxone.

(3) Research regarding opioid addiction and treatment.

(4) The cost of administering this chapter, as follows:

a. No more than 15% of the money annually deposited into the Fund may be used for administering this chapter, including expenses incurred by the Prescription Monitoring Program under this chapter.

b. Entering into contracts to implement this chapter, including contracts entered into by the Secretary for administration of this chapter.

c. Costs incurred by the Attorney General to bring an action to enforce this chapter shall be covered by the Fund and are not subject to or included in the 15% cap on administrative expenses.

(d) Money in the Fund may not be used to supplant existing State funding.

(e)(1) The Addiction Action Committee ("AAC"), as established under § 5198 of this title, in consultation with respect to priorities with the Behavioral Health Consortium, shall appropriate the money in this Fund by awarding grants and entering into contracts.

(2) The ACC shall create a standing subcommittee to make recommendations regarding appropriations under this section. A member of the standing subcommittee may not be an employee or officer of this State.

(3) Grants and contracts made pursuant to this section must be made exclusively by the AAC in accordance with § 6982(b) of Title 29 or its successor provision.

(f) Money appropriated by the General Assembly to implement this chapter must be reimbursed from money received under this section.

§ 4804B. Prescription opioid impact fee.

(a) A manufacturer of a prescription opioid must pay a prescription opioid impact fee to the State of Delaware if more than 100,000 MME of the manufacturer's prescription opioid products are dispensed in this State in a quarter.

(b) The prescription opioid impact fee is calculated as follows:

(1) The impact fee is \$0.01 per MME for a prescription opioid dispensed and reported in the PMP.

(2) The impact fee is \$0.0025 per MME for a prescription opioid that is a generic substitution.

(c) The Secretary shall calculate the total amount of the impact fee on a quarterly basis using the information in the PMP.

(d) The Secretary shall send an invoice to manufacturers of prescription opioids dispensed in this State for the impact fee due under this section quarterly, beginning after the close of the first full quarter after [the effective date of this Act].

(e) Manufacturers of prescription opioids shall pay the impact fee 1 month after the date of an invoice.

(f) When a manufacturer of prescription opioids fails to pay the impact fee within 1 month after the date of an invoice, the penalty is \$100 a day or 10% of the impact fee due, whichever is greater. In addition, any unpaid impact fee bears interest at the rate of 1% a month.

(g) A manufacturer who disputes the amount an invoice sent under this chapter may request a hearing under § 4736 of this title.

§ 4805B. Enforcement.

The Attorney General may bring an action on behalf of the State to enforce this chapter. The Attorney General may recover interest and reasonable attorney fees and expenses as a result of a successful action to enforce this chapter. Any attorney fees recovered in an action to enforce this chapter must be remitted to the Fund.

§ 4806B. Policies and procedures.

(a) The Secretary shall develop necessary policies and procedures and promulgate necessary regulations to implement § 4804B of this title.

(b) The Secretary of the Department of Health and Social Services shall work with the AAC to develop necessary policies and procedures and promulgate necessary regulations to implement § 4803B of this title.

§ 4807B. Annual report.

Beginning November 1, 2019, the AAC shall prepare and submit to the Governor and the General Assembly a report on the income and specific expenditures of the Fund.

Section 2. Amend § 4798, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 4798. The Delaware Prescription Monitoring Program.

(l) The Office of Controlled Substances shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed, except as provided for in this section.

(2) The Office of Controlled Substances may provide data in the prescription monitoring program in the form of a report to the following persons:

n. The Addiction Action Committee, the Secretary of State, and the Attorney General for purposes of administering and enforcing the Prescription Opioid Impact Fund under Chapter 48B of this title.

### SYNOPSIS

This Act creates a Prescription Opioid Impact Fund ("Fund") through a prescription opioid impact fee ("Fee") that is assessed on manufacturers of prescription opioids as follows:

1. The fee is based on the total of the Morphine Milligram Equivalent ("MME") in each manufacturer's products dispensed in Delaware, based upon data already reported to the Prescription Monitoring Program ("PMP"). The PMP data contains the mandatory reports by pharmacists of every prescription opioid dispensed in the State. The PMP data does not include prescription opioids administered in hospitals, provided directly to patients by hospice, or dispensed by veterinarians.

2. The fee is assessed against manufacturers who exceed a threshold of MME dispensed each quarter.

3. The Fee is assessed as follows:

- One penny per MME for a prescription opioid dispensed and reported in the PMP.
- One-quarter of a penny per MME for a prescription opioid that is a generic.

The money in the Prescription Opioid Impact Fund must be spent on the following activities:

1. Opioid addiction prevention.

2. The following opioid addiction services:

• Inpatient and outpatient treatment programs and facilities, including short-term and long-term residential treatment programs and sober living facilities.

• Treating substance use disorder for the under-insured and uninsured.

• Emergency assistance relating to prescription opioids, including purchasing Naloxone.

3. Research regarding opioid addiction and treatment.

4. Administrative costs of implementing the Fee and Fund, up to 15% of the amount in the Fund.

The Addiction Action Committee will award grants and contracts from the money in the Fund, based upon priorities developed in consultation with the Behavioral Health Consortium. A standing subcommittee of the Addiction Action Committee that does not contain any State employees will make the recommendations regarding the awards of the grants and contracts.

This Substitute Bill differs from Senate Bill No. 176 as follows:

• Adds additional whereas clauses to further explain the background for the Fund and Fee.

• Gives responsibility for the Fee to the Secretary of State instead of the Secretary of the Department of Health and Social Services, because the PMP and the Controlled Substances Act are under the Secretary of State.

• Removes the ability to use the funds from the Fee for Medicaid, and restricts appropriations to specifically-listed activities.

• Prohibits using the Fund to supplant existing State funding.

• Permits a manufacturer to challenge an invoice for a prescription opioid impact fee through the existing appeal process under the Controlled Substances Act.

• Gives responsibility for appropriating funds from the Fund to the Addiction Action Committee.

• Lowers the amount of the impact fee for generic drugs.

• Establishes a minimum threshold before manufacturers are assessed the Fee.

• Removes the restriction on raising prices to consumers because the Fee is unlikely to materially increase the price of prescription drugs because those prices are set on a national basis.

• Provides explicitly that the Attorney General may recover interest and reasonable attorney fees and costs in a successful lawsuit to enforce this Act.

• Clarifies that the Secretary of State develops the rules and regulations for implementing the Fee. And the Addiction Action Committee, with the Secretary of the Department of Health and Social Services, develops the rules and regulations for implementing the Fund.

• Revises the reporting requirements on how money from the Fund is spent.

• Provides clear permission to share the PMP data with the Addiction Action Committee, Secretary of State, and Attorney General for the purposes of administering and enforcing this chapter.

