

LAWS OF DELAWARE
VOLUME 82
CHAPTER 37
150th GENERAL ASSEMBLY
FORMERLY
SENATE BILL NO. 34
AS AMENDED BY
SENATE AMENDMENT NO. 1

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

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

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

WHEREAS, in 2017, opioids killed more than 70,200 people and 68% of those deaths were from prescription opioids;
and

WHEREAS, in 2016, the number of opioid overdose deaths were 5 times higher than the number of opioid overdose deaths in 1999 and, in 2017, the number of opioid overdose deaths were 6 times higher than in 1999; and

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

WHEREAS, from 2015 to 2016, Delaware had the second highest increase in drug overdose deaths and, from 2016 to 2017, had a statistically-significant increase in drug overdose deaths; and

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

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

WHEREAS, in 2003, 38 babies were cared for in Delaware hospitals because of neonatal abstinence syndrome, drug withdrawal in a newborn; and

WHEREAS, in 2014, 215 babies were cared for in Delaware hospitals because of neonatal abstinence syndrome, at a cost of \$9,600,000; and

WHEREAS, according to the Centers for Disease Control and Prevention's Annual Surveillance Report of Drug-Related Risks and Outcomes, in 2017 and 2018, Delaware's prescription rate of high dose opioids and prescription rate of long-acting/extended-release opioid pain relievers were both the highest in the nation; and

WHEREAS, in Delaware, opioids were prescribed at a rate of 870,017 prescriptions totaling 1,104,171,268 morphine milligram equivalents ("MME") in 2015; 831,005 prescriptions totaling 1,050,147,346 MME in 2016; 750,944 prescriptions totaling 921,842,143 MME in 2017; and 750,691 prescriptions totaling 826,770,680 MME in 2018; and

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

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

WHEREAS, in 2017, 3% of Delaware's eighth grade students reported using a prescription drug illegally; and

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

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

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

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

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

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

WHEREAS, the FY19 Governor's Recommended Budget requested and the General Assembly appropriated \$100,000 for Substance Use Disorder Services and Naloxone for First Responders, \$328,500 for 20 additional Sober Living Beds, and \$990,000 for Emergency Room Consultations; and

WHEREAS, the FY20 Governor's Recommended Budget requests \$1.8 million for behavioral health and the opioid epidemic, including recommendations from the Behavioral Health Consortium, as follows: \$50,000 for Youth Prevention, Education, & Treatment; \$100,000 for Narcan Community Access; \$125,000 for Medication Assisted Treatment; \$350,000 for Needle Exchange Expansion; \$400,000 for Withdrawal Management; and \$800,000 for Level IV Recovery Homes.

NOW, THEREFORE:

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

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

Chapter 48B. Prescription Opioid Impact Fund.

§ 4801B. Findings and purpose.

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

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

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

(3) In the 4 years prior to the creation of the Prescription Opioid Impact Fund, prescription opioids were dispensed to Delaware residents as follows:

a. In 2015, 870,017 prescriptions for 59,138,601 individual doses totaling 1,104,171,268 MMEs.

b. In 2016, 831,005 prescriptions for 56,440,474 individual doses totaling 1,050,147,346 MMEs.

c. In 2017, 750,944 prescriptions for 49,875,000 individual doses totaling 921,842,143 MMEs.

d. In 2018, 750,691 prescriptions for 46,125,690 individual doses totaling 826,770,680 MMEs.

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

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

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

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

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

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

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

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

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

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

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

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

§ 4802B. Definitions.

For purposes of this chapter:

(1) "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".

(2) "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.

(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.

§ 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 1 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 pharmaceuticals used to reverse the effect of an opioid overdose.

d. Peer support programs.

(3) 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 of the Department of Health and Services or the Secretary of State for administration of this chapter.

c. Costs incurred by the Attorney General to bring an action to enforce this chapter must 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) The Secretary of the Department of Health and Social Services shall allocate the money in this Fund by awarding grants and entering into contracts. Before allocating money in this Fund, the Secretary shall review any recommendations provided by January 1 of the most recent calendar year from the Behavioral Health Consortium, Addiction Action Committee, and the Overdose System of Care Committee.

(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 of State shall calculate the total amount of the impact fee on a quarterly basis using the information in the PMP.

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

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

§ 4807B. Annual report.

Beginning November 1, 2020, the Secretary of the Department of Health and Social Services 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 Secretary of the Department of Health and Social Services, 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.

Section 3. This Act expires on January 1, 2025, unless terminated sooner or extended by the General Assembly.

Approved June 12, 2019