
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 378 Session of
2023

INTRODUCED BY ISAACSON, BURGOS, CIRESI, GIRAL, HILL-EVANS,
HOHENSTEIN, MADDEN, SANCHEZ AND D. WILLIAMS, MARCH 14, 2023

REFERRED TO COMMITTEE ON HUMAN SERVICES, MARCH 14, 2023

AN ACT

1 Amending Title 35 (Health and Safety) of the Pennsylvania
2 Consolidated Statutes, providing for opioid stewardship;
3 establishing the Opioid Reparation and Accountability Fund
4 and the Opiate Epidemic Response Advisory Council; and
5 imposing duties on the Department of Health, the Department
6 of Human Services and the Department of Drug and Alcohol
7 Programs.

8 The General Assembly of the Commonwealth of Pennsylvania
9 hereby enacts as follows:

10 Section 1. Title 35 of the Pennsylvania Consolidated
11 Statutes is amended by adding a chapter to read:

12 CHAPTER 52C

13 OPIOID STEWARDSHIP

14 Sec.

15 52C01. Scope of chapter.

16 52C02. Definitions.

17 52C03. Licenses generally.

18 52C04. Fees and assessments.

19 52C05. Opioid Reparation and Accountability Fund.

20 52C06. Reports to department.

1 52C07. Opiate Epidemic Response Advisory Council.

2 52C08. Grants.

3 52C09. Annual reports.

4 52C10. Rules and regulations.

5 § 52C01. Scope of chapter.

6 This chapter relates to opioid stewardship.

7 § 52C02. Definitions.

8 The following words and phrases when used in this chapter
9 shall have the meanings given to them in this section unless the
10 context clearly indicates otherwise:

11 "Controlled substance." As defined in section 2(b) of the
12 Controlled Substance, Drug, Device and Cosmetic Act.

13 "Controlled Substance, Drug, Device and Cosmetic Act." The
14 act of April 14, 1972 (P.L.233, No.64), known as The Controlled
15 Substance, Drug, Device and Cosmetic Act.

16 "Cosmetic." As defined in section 2(b) of the Controlled
17 Substance, Drug, Device and Cosmetic Act.

18 "Council." The Opiate Epidemic Response Advisory Council.

19 "Department." The Department of Health of the Commonwealth.

20 "Device." As defined in section 2(b) of the Controlled
21 Substance, Drug, Device and Cosmetic Act.

22 "Distribute." As defined in section 2(b) of the Controlled
23 Substance, Drug, Device and Cosmetic Act.

24 "Distributor." As defined in section 2(b) of the Controlled
25 Substance, Drug, Device and Cosmetic Act.

26 "Drug." As defined in section 2(b) of the Controlled
27 Substance, Drug, Device and Cosmetic Act.

28 "Fund." The Opioid Reparation and Accountability Fund
29 established under section 52C05 (relating to Opioid Reparation
30 and Accountability Fund).

1 "Manufacture." As defined in section 2(b) of the Controlled
2 Substance, Drug, Device and Cosmetic Act.

3 "Manufacturer." A person lawfully authorized to manufacture
4 a drug or controlled substance.

5 "Opiate." As defined in section 2(b) of the Controlled
6 Substance, Drug, Device and Cosmetic Act.

7 "Opioid." Any of the following:

8 (1) A preparation or derivative of opium.

9 (2) A synthetic narcotic that has opiate-like effects
10 but is not derived from opium.

11 (3) A group of naturally occurring peptides that bind at
12 or otherwise influence opiate receptors, including an opioid
13 agonist.

14 "Pharmacy." As defined in section 2(12) of the act of
15 September 27, 1961 (P.L.1700, No.699), known as the Pharmacy
16 Act.

17 "Secretary." The Secretary of Health of the Commonwealth.

18 "Unit." The individual dosage form of a particular drug
19 product that is prescribed to a patient, with one unit being
20 equal to one tablet, capsule, patch, syringe, milliliter or
21 gram.

22 § 52C03. Licenses generally.

23 (a) Requirements.--A person may not act as a drug
24 manufacturer or distributor without first obtaining a license
25 from the department and paying an applicable fee under this
26 chapter.

27 (b) Term.--A license shall be valid for one year.

28 (c) Renewal.--The following shall apply:

29 (1) A license must be renewed annually.

30 (2) An application for a license renewal shall be

1 accompanied by the same fee as for initial license
2 application.

3 (d) Applications.--The following shall apply:

4 (1) A person seeking a license as a drug manufacturer or
5 distributor, or seeking to renew a license as a drug
6 manufacturer or distributor, shall complete an application
7 and submit the application to the department for review and
8 approval.

9 (2) Applications shall be on forms prescribed by the
10 secretary.

11 § 52C04. Fees and assessments.

12 (a) Initial license application fees.--The following shall
13 apply:

14 (1) The initial license application fee for a
15 manufacturer or distributor of a controlled substance
16 containing an opiate and listed in section 4 of the
17 Controlled Substance, Drug, Device and Cosmetic Act shall be
18 \$27,500.

19 (2) The initial license application fee for a
20 manufacturer or distributor of a drug that is not specified
21 under paragraph (1) or of a device only shall be \$2,500.

22 (b) Assessments.--The following shall apply:

23 (1) In addition to the fees specified under subsection
24 (a), the department shall annually assess an opiate product
25 registration fee on a manufacturer of an opiate that annually
26 sells, delivers or distributes within or into this
27 Commonwealth 2,000,000 or more units of an opiate, as
28 reported to the department under section 52C06 (relating to
29 reports to department).

30 (2) By April 1, 2023, and each April 1 thereafter, the

1 department shall notify each manufacturer described under
2 paragraph (1) that the manufacturer is required to pay an
3 annual assessment of \$250,000.

4 (c) Evaluation.--The department shall evaluate every two
5 years the fees and assessments under this section and whether
6 the fees and assessments under this section have impacted the
7 prescribing practices for opiates by reducing the number of
8 opiate prescriptions issued during the previous calendar year or
9 have caused any unintended consequences in the availability of
10 opiates for the treatment of chronic or intractable pain to the
11 extent that the department has the ability to effectively
12 identify a correlation. The following shall apply:

13 (1) The department may access the data reported under
14 section 52C06 to conduct the evaluation.

15 (2) As soon as practicable after completion of the
16 evaluation, the department shall submit the results of its
17 evaluation to the following:

18 (i) The chairperson and minority chairperson of the
19 Health and Human Services Committee of the Senate.

20 (ii) The chairperson and minority chairperson of the
21 Health Committee of the House of Representatives.

22 (iii) The chairperson and minority chairperson of
23 the Human Services Committee of the House of
24 Representatives.

25 (d) Notice.--Upon any change to the amount of the fee or
26 assessment under this section, the department shall transmit
27 notice to the Legislative Reference Bureau for publication in
28 the Pennsylvania Bulletin. The new fee or assessment shall take
29 effect upon publication in the Pennsylvania Bulletin.

30 (e) Refunds.--The following shall apply:

1 (1) Except as provided in paragraph (2), if the
2 department rejects a license application or license renewal
3 application, the department shall return the fee that
4 accompanied the application.

5 (2) The department may retain all or part of the fee if
6 the license application or license renewal application was
7 rejected based wholly or partially on false information
8 furnished by the applicant in the application.

9 (3) A manufacturer or distributor shall not be entitled
10 to a full or partial refund of a fee or assessment under this
11 section if the manufacturer or distributor ceases to do
12 business during the year covered by the fee or assessment.

13 § 52C05. Opioid Reparation and Accountability Fund.

14 (a) Establishment.--The Opioid Reparation and Accountability
15 Fund is established as a restricted account in the State
16 Treasury.

17 (b) Deposits.--

18 (1) The department shall deposit the fees remitted under
19 section 52C04 (relating to fees and assessments) into the
20 fund.

21 (2) Interest accrued on money received under section
22 52C04 shall be deposited into the fund.

23 (c) Use.--The money deposited into the fund may only be used
24 for the purposes specified under this chapter.

25 (d) Appropriations.--Money in the fund shall not lapse and
26 is appropriated on a continuing basis to the department for the
27 purposes stated in this section.

28 § 52C06. Reports to department.

29 (a) Manufacturers and distributors.--Beginning March 1,
30 2023, and each March 1 thereafter, each manufacturer and each

1 distributor shall report to the department every sale, delivery
2 or other distribution of an opiate within or into this
3 Commonwealth, which occurred during the previous calendar year,
4 to a practitioner, pharmacy, hospital, veterinary hospital or
5 other person that is permitted to possess controlled substances
6 for administration or dispensing to patients.

7 (b) Pharmacy owners.--Beginning March 1, 2023, and each
8 March 1 thereafter, each owner of a pharmacy with at least one
9 location within this Commonwealth shall report to the department
10 any intracompany delivery or distribution into this Commonwealth
11 of an opiate, to the extent that the delivery or distribution is
12 not reported to the department by a licensed distributor owned
13 by, under contract to or otherwise operating on behalf of the
14 owner of the pharmacy. The following shall apply:

15 (1) Reporting must be in the manner and format specified
16 by the department for deliveries and distributions that
17 occurred during the previous calendar year.

18 (2) The report must include the following:

19 (i) The name of the manufacturer or distributor from
20 which the owner of the pharmacy ultimately purchased the
21 opiate.

22 (ii) The amount of the purchase and date that the
23 purchase occurred.

24 § 52C07. Opiate Epidemic Response Advisory Council.

25 (a) Establishment.--The Opiate Epidemic Response Advisory
26 Council is established within the department.

27 (b) Purposes.--The council shall develop and implement a
28 comprehensive and effective Statewide effort to address the
29 opioid addiction and overdose epidemic in this Commonwealth,
30 with special attention given to the following:

1 (1) Prevention and education, including public education
2 and awareness for adults and youth, prescriber education, the
3 development and sustainability of opioid overdose prevention
4 and education programs and providing financial support to
5 local law enforcement agencies for opiate antagonist
6 programs.

7 (2) Training on the treatment of opioid addiction,
8 including the use of all United States Food and Drug
9 Administration-approved opioid addiction medications,
10 detoxification, relapse prevention, patient assessment,
11 individual treatment planning, counseling, recovery supports
12 and other best practices.

13 (3) The expansion and enhancement of a continuum of care
14 for opioid-related substance use disorders, including primary
15 prevention, early intervention, treatment, recovery and
16 aftercare services.

17 (4) The development of measures to assess and protect
18 the ability of cancer patients and survivors, individuals
19 with life-threatening illnesses, individuals suffering from
20 severe chronic pain and individuals at the end stages of
21 life, who legitimately need prescription pain medications, to
22 maintain their quality of life by accessing pain medications
23 without facing unnecessary barriers.

24 (c) Duties.--The council shall:

25 (1) Review Federal, State and local initiatives and
26 activities related to education, prevention, treatment and
27 services for individuals and families experiencing and
28 affected by opioid use disorder.

29 (2) Establish priorities to address this Commonwealth's
30 opioid epidemic, for the purpose of recommending initiatives

1 to be funded.

2 (3) Recommend to the secretary specific projects and
3 initiatives to be funded.

4 (4) Ensure that available funding is allocated to align
5 with other Federal and State funding to achieve the greatest
6 impact and ensure a coordinated State effort.

7 (5) Consult with the department, the Department of Human
8 Services and the Department of Drug and Alcohol Programs to
9 develop measurable outcomes to determine the effectiveness of
10 money allocated.

11 (6) Develop recommendations for an administrative and
12 organizational framework for the allocation, on a sustainable
13 and ongoing basis, of money deposited into the fund to
14 address opioid abuse and the overdose epidemic in this
15 Commonwealth and the areas of focus specified under
16 subsection (b).

17 (d) Membership.--The council shall consist of the following
18 members:

19 (1) The secretary or a designee, who shall serve as the
20 chairperson of the council.

21 (2) The Secretary of Human Services or a designee.

22 (3) The Secretary of Drug and Alcohol Programs or a
23 designee.

24 (4) A designee of the Safe and Effective Prescribing
25 Practices Task Force established by the department and the
26 Department of Drug and Alcohol Programs.

27 § 52C08. Grants.

28 (a) Report of proposed grants.--By March 1, 2023, and each
29 March 1 thereafter, the secretary shall submit a report of the
30 grants proposed by the council to be awarded for the upcoming

1 fiscal year to the following:

2 (1) The chairperson and minority chairperson of the
3 Finance Committee of the Senate.

4 (2) The chairperson and minority chairperson of the
5 Finance Committee of the House of Representatives.

6 (3) The chairperson and minority chairperson of the
7 Health and Human Services Committee of the Senate.

8 (4) The chairperson and minority chairperson of the
9 Health Committee of the House of Representatives.

10 (5) The chairperson and minority chairperson of the
11 Human Services Committee of the House of Representatives.

12 (b) Award.--Grants shall be awarded:

13 (1) based on the recommendations of the council;

14 (2) to the extent money is available through the fund or
15 other appropriations by the General Assembly; and

16 (3) in accordance with the purposes and duties specified
17 under section 52C07(b) and (c) (relating to Opiate Epidemic
18 Response Advisory Council).

19 (c) Limitation.--No more than 3% of grant money may be used
20 by a grantee for administrative costs.

21 § 52C09. Annual reports.

22 (a) Submittal.--By January 31, 2024, and each January 31
23 thereafter, the council shall report to the following:

24 (1) The chairperson and minority chairperson of the
25 Finance Committee of the Senate.

26 (2) The chairperson and minority chairperson of the
27 Finance Committee of the House of Representatives.

28 (3) The chairperson and minority chairperson of the
29 Health and Human Services Committee of the Senate.

30 (4) The chairperson and minority chairperson of the

1 Health Committee of the House of Representatives.

2 (5) The chairperson and minority chairperson of the
3 Human Services Committee of the House of Representatives.

4 (b) Contents.--The report under this section shall include
5 the following:

6 (1) Information regarding each project that receives a
7 grant from the department and the overall role of the project
8 in addressing the opioid addiction and overdose epidemic in
9 this Commonwealth.

10 (2) A description of the grantees and the activities
11 implemented, along with measurable outcomes as determined by
12 the council in consultation with the secretary.

13 (3) Recommendations regarding:

14 (i) whether the appropriations to the specified
15 entities under this chapter should be continued, adjusted
16 or discontinued;

17 (ii) whether funding should be appropriated for
18 other purposes related to opioid abuse prevention,
19 education and treatment;

20 (iii) the appropriate level of funding for existing
21 and new uses; and

22 (iv) any necessary or appropriate change in fees or
23 assessment under this chapter.

24 § 52C10. Rules and regulations.

25 The department shall promulgate rules and regulations as
26 necessary to implement the provisions of this chapter.

27 Section 2. This act shall take effect in 60 days.