
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 340 Session of
2021

INTRODUCED BY ISAACSON, CIRESI, DELLOSO, DRISCOLL, FREEMAN,
GALLOWAY, HOHENSTEIN, HOWARD, WEBSTER AND ZABEL,
JANUARY 29, 2021

REFERRED TO COMMITTEE ON HUMAN SERVICES, JANUARY 29, 2021

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

1 "Manufacturer." A person lawfully authorized to manufacture
2 a drug or controlled substance.

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

5 "Opioid." Any of the following:

6 (1) A preparation or derivative of opium.

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

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

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

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

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

20 § 52C03. Licenses generally.

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

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

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

27 (1) A license must be renewed annually.

28 (2) An application for a license renewal shall be
29 accompanied by the same fee as for initial license
30 application.

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

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

7 (2) Applications shall be on forms prescribed by the
8 secretary.

9 § 52C04. Fees and assessments.

10 (a) Initial license application fees.--The following shall
11 apply:

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

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

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

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

28 (2) By April 1, 2021, and each April 1 thereafter, the
29 department shall notify each manufacturer described under
30 paragraph (1) that the manufacturer is required to pay an

1 annual assessment of \$250,000.

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

11 (1) The department may access the data reported under
12 section 52C06 (relating to reports to department) to conduct
13 the evaluation.

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

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

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

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

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

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

30 (1) Except as provided in paragraph (2), if the

1 department rejects a license application or license renewal
2 application, the department shall return the fee that
3 accompanied the application.

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

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

12 § 52C05. Opioid Reparation and Accountability Fund.

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

16 (b) Deposits.--

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

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

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

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

27 § 52C06. Reports to department.

28 (a) Manufacturers and distributors.--Beginning March 1,
29 2021, and each March 1 thereafter, each manufacturer and each
30 distributor shall report to the department every sale, delivery

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

6 (b) Pharmacy owners.--Beginning March 1, 2021, and each
7 March 1 thereafter, each owner of a pharmacy with at least one
8 location within this Commonwealth shall report to the department
9 any intracompany delivery or distribution into this Commonwealth
10 of an opiate, to the extent that the delivery or distribution is
11 not reported to the department by a licensed distributor owned
12 by, under contract to or otherwise operating on behalf of the
13 owner of the pharmacy. The following shall apply:

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

17 (2) The report must include the following:

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

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

23 § 52C07. Opiate Epidemic Response Advisory Council.

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

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

30 (1) Prevention and education, including public education

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 § 52C08. Grants.

27 (a) Report of proposed grants.--By March 1, 2021, and each
28 March 1 thereafter, the secretary shall submit a report of the
29 grants proposed by the council to be awarded for the upcoming
30 fiscal year to the following:

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

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

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

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

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

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

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

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

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

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

20 § 52C09. Annual reports.

21 (a) Submittal.--By January 31, 2022, and each January 31
22 thereafter, the council shall report to the following:

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

25 (2) The chairperson and minority chairperson of the
26 Health and Human Services Committee of the Senate.

27 (3) The chairperson and minority chairperson of the
28 Finance Committee of the House of Representatives.

29 (4) The chairperson and minority chairperson of the
30 Health Committee of the House of Representatives.

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

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

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

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

12 (3) Recommendations regarding:

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

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

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

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

23 § 52C10. Rules and regulations.

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

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