

2019 -- S 0798 SUBSTITUTE A

LC002256/SUB A/2

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2019

A N A C T

RELATING TO FOOD AND DRUGS -- OPIOID STEWARDSHIP ACT

Introduced By: Senators Ruggerio, Coyne, Miller, Sosnowski, and DiPalma

Date Introduced: April 10, 2019

Referred To: Senate Finance

It is enacted by the General Assembly as follows:

1 SECTION 1. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby
2 amended by adding thereto the following chapter:

3 CHAPTER 28.10

4 OPIOID STEWARDSHIP ACT

5 **21-28.10-1. Definitions.**

6 Unless the context otherwise requires, the following terms shall be construed in this
7 chapter to have the following meanings:

8 (1) "Department" means the Rhode Island department of health.

9 (2) "Director" means the director of the Rhode Island department of health.

10 (3) "Distribute" means distribute as defined in § 21-28-1.02.

11 (4) "Distributor" means distributor as defined in § 21-28-1.02.

12 (5) "Manufacture" means manufacture as defined in § 21-28-1.02.

13 (6) "Manufacturer" means manufacturer as defined in § 21-28-1.02.

14 (7) "Market share" means the total opioid stewardship fund amount measured as a
15 percentage of each manufacturer's, distributor's and wholesaler's gross, in-state, opioid sales in
16 dollars from the previous calendar year as reported to the U.S. Drug Enforcement Administration
17 (DEA) on its Automation of Reports and Consolidated Orders System (ARCOS) report.

18 (8) "Wholesaler" means wholesaler as defined in § 21-28-1.02.

19 **21-28.10-2. Opioid registration fee imposed on manufacturers, distributors, and**

1 **wholesalers.**

2 All manufacturers, distributors, and wholesalers licensed or registered under this title or
3 chapter 19.1 of title 5 (hereinafter referred to as "licensees"), that manufacture or distribute
4 opioids shall be required to pay an opioid registration fee. On an annual basis, the director shall
5 certify the amount of all revenues collected from opioid registration fees and any penalties
6 imposed, to the general treasurer. The amount of revenues so certified shall be deposited quarterly
7 into the opioid stewardship fund restricted receipt account established pursuant to § 21-28.10-10.

8 **21-28.10-3. Determination of market share and registration fee.**

9 (1) The total opioid stewardship fund amount shall be five million dollars (\$5,000,000)
10 annually, subject to downward adjustments pursuant to § 21-28.10-7.

11 (2) Each manufacturer's, distributor's, and wholesaler's annual opioid registration fee
12 shall be based on that licensee's in-state market share.

13 (3) The following sales will not be included when determining a manufacturer's,
14 distributor's, or wholesaler's market share:

15 (i) The gross, in-state opioid sales attributed to the sale of buprenorphine or methadone;

16 (ii) The gross, in-state opioid sales sold or distributed directly to opioid treatment
17 programs, data-waivered practitioners, or hospice providers licensed pursuant to chapter 17 of
18 title 23;

19 (iii) Any sales from those opioids manufactured in Rhode Island, but whose final point of
20 delivery or sale is outside of Rhode Island; and

21 (iv) Any sales of anesthesia or epidurals as defined in regulation by the department.

22 (4) The department shall provide to the licensee, in writing, on or before October 15,
23 2019, the licensee's market share for the 2018 calendar year. Thereafter, the department shall
24 notify the licensee, in writing, on or before October 15 of each year, of its market share for the
25 prior calendar year based on the opioids sold or distributed for the prior calendar year.

26 **21-28.10-4. Reports and records.**

27 (a) Each manufacturer, distributor, and wholesaler licensed to manufacture or distribute
28 opioids in the state of Rhode Island shall provide to the director a report detailing all opioids sold
29 or distributed by such manufacturer or distributor in the state of Rhode Island. Such report shall
30 include:

31 (1) The manufacturer's, distributor's, or wholesaler's name, address, phone number, DEA
32 registration number, and controlled substance license number issued by the department;

33 (2) The name, address, and DEA registration number of the entity to whom the opioid
34 was sold or distributed;

- 1 (3) The date of the sale or distribution of the opioids;
- 2 (4) The gross receipt total, in dollars, of all opioids sold or distributed;
- 3 (5) The name and National Drug Code of the opioids sold or distributed;
- 4 (6) The number of containers and the strength and metric quantity of controlled substance
- 5 in each container of the opioids sold or distributed; and
- 6 (7) Any other elements as deemed necessary or advisable by the director.

7 (b) Initial and future reports.

8 Such information shall be reported annually to the department via ARCOS or in such
9 other form as defined or approved by the director; provided, however, that the initial report
10 provided pursuant to subsection (a) of this section shall consist of all opioids sold or distributed in
11 the state of Rhode Island for the 2018 calendar year, and shall be submitted by August 1, 2019.
12 Subsequent annual reports shall be submitted by April 1 of each year based on the actual opioid
13 sales and distributions of the prior calendar year.

14 **21-28.10-5. Payment of market share.**

15 The licensee shall make payments quarterly to the department with the first payment of
16 its market share due on January 1, 2020; provided, that the amount due on January 1, 2020 shall
17 be for the full amount of the payment for the 2018 calendar year, with subsequent payments to be
18 due and owing on the first day of every quarter thereafter.

19 **21-28.10-6. Rebate of market share.**

20 In any year for which the director determines that a licensee failed to report information
21 required by this chapter, those licensees complying with this chapter shall receive a reduced
22 assessment of their market share in the following year equal to the amount in excess of any
23 overpayment in the prior payment period.

24 **21-28.10-7. Licensee opportunity to appeal.**

25 (a) A licensee shall be afforded an opportunity to submit information to the department
26 documenting or evidencing that the market share provided to the licensee (or amounts paid
27 thereunder), pursuant to § 21-28.10-3(4), is in error or otherwise not warranted. The department
28 may consider and examine such additional information that it determines to be reasonably related
29 to resolving the calculation of a licensee's market share, which may require the licensee to
30 provide additional materials to the department. If the department determines thereafter that all or
31 a portion of such market share, as determined by the director pursuant to § 21-28.10-3(4), is not
32 warranted, the department may:

33 (1) Adjust the market share;

34 (2) Adjust the assessment of the market share in the following year equal to the amount in

1 excess of any overpayment in the prior payment period; or

2 (3) Refund amounts paid in error.

3 (b) Any person aggrieved by a decision of the department relating to the calculation of
4 market share may appeal that decision to the superior court, which shall have power to review
5 such decision, and the process by which such decision was made, as prescribed in chapter 35 of
6 title 42.

7 (c) A licensee shall also have the ability to appeal its assessed opioid registration fee if
8 the assessed fee amount exceeds the amount of profit the licensee obtains through sales in the
9 state of products described in § 21-28.10-3. The department may, exercising discretion as it
10 deems appropriate, waive or decrease fees as assessed pursuant to § 21-28.10-3 if a licensee can
11 demonstrate that the correctly assessed payment will pose undue hardship to the licensee's
12 continued activities in state. The department shall be allowed to request, and the licensee shall
13 furnish to the department, any information or supporting documentation validating the licensee's
14 request for waiver or reduction under this subsection. Fees waived under this section shall not be
15 reapportioned to other licensees which have payments due under this chapter.

16 **21-28.10-8. Departmental annual reporting.**

17 By January of each calendar year, the department of behavioral healthcare,
18 developmental disabilities and hospitals (BHDDH), the executive office of health and human
19 services (EOHHS), the department of children, youth and families (DCYF), the Rhode Island
20 department of education (RIDE), the Rhode Island office of veterans' affairs (RIOVA), the
21 department of corrections (DOC), and the department of labor and training (DLT) shall report
22 annually to the governor, the speaker of the house, and the senate president which programs in
23 their respective departments were funded using monies from the opioid stewardship fund and the
24 total amount of funds spent on each program.

25 **21-28.10-9. Penalties.**

26 (a) The department may assess a civil penalty in an amount not to exceed one thousand
27 dollars (\$1,000) per day against any licensee that fails to comply with this chapter.

28 (b)(1) In addition to any other civil penalty provided by law, where a licensee has failed
29 to pay its market share in accordance with § 21-28.10-5, the department may also assess a penalty
30 of no less than ten percent (10%) and no greater than three hundred percent (300%) of the market
31 share due from such licensee.

32 (2) In addition to any other criminal penalty provided by law, where a licensee has failed
33 to pay its market share in accordance with § 21-28.10-5, the department may also assess a penalty
34 of no less than ten percent (10%) and no greater than fifty percent (50%) of the market share due

1 from such licensee.

2 **21-28.10-10. Creation of opioid stewardship fund.**

3 (a) There is hereby established, in the custody of the department, a restricted receipt
4 account to be known as the "opioid stewardship fund."

5 (b) Monies in the opioid stewardship fund shall be kept separate and shall not be
6 commingled with any other monies in the custody of the department.

7 (c) The opioid stewardship fund shall consist of monies appropriated for the purpose of
8 such account, monies transferred to such account pursuant to law, contributions consisting of
9 promises or grants of any money or property of any kind or value, or any other thing of value,
10 including grants or other financial assistance from any agency of government and monies
11 required by the provisions of this chapter or any other law to be paid into or credited to this
12 account.

13 (d) Monies of the opioid stewardship fund shall be available to provide opioid treatment,
14 recovery, prevention, education services, and other related programs, subject to appropriation by
15 the general assembly.

16 **21-28.10-11. Allocation.**

17 The monies, when allocated, shall be paid out of the opioid stewardship fund and subject
18 to the approval of the director and the approval of the director of the department of behavioral
19 healthcare, developmental disabilities and hospitals (BHDDH), pursuant to the provisions of this
20 chapter.

21 **21-28.10-12. Severability.**

22 If any clause, sentence, paragraph, subdivision, or section of this act shall be adjudged by
23 any court of competent jurisdiction to be invalid, such judgment shall not affect, impair, or
24 invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence,
25 paragraph, subdivision, or section directly involved in the controversy in which such judgment
26 shall have been rendered. It is hereby declared to be the intent of the legislature that this act
27 would have been enacted even if such invalid provisions had not been included herein.

28 **21-28.10-13. Rules and regulations.**

29 The director may prescribe rules and regulations, not inconsistent with law, to carry into
30 effect the provisions of chapter 28.10 of title 21, which rules and regulations, when reasonably
31 designed to carry out the intent and purpose of this chapter, are prima facie evidence of its proper
32 interpretation. Such rules and regulations may be amended, suspended, or revoked, from time to
33 time and in whole or in part, by the director. The director may prescribe, and may furnish, any
34 forms necessary or advisable for the administration of this chapter.

1 SECTION 2. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
A N A C T
RELATING TO FOOD AND DRUGS -- OPIOID STEWARDSHIP ACT

1 This act would establish an opioid stewardship payment program requiring manufacturers
2 and distributors of opioids to pay an amount, based on the amount of opioids manufactured or
3 distributed, into a fund which would be used to support programs operated by the department of
4 behavioral healthcare, developmental disabilities and hospitals (BHDDH), the executive office of
5 health and human services (EOHHS), the department of children, youth and families (DCYF), the
6 Rhode Island department of education (RIDE), the Rhode Island office of veterans' affairs
7 (RIOVA), the department of corrections (DOC), the department of labor and training (DLT) or
8 agencies certified, authorized, approved or otherwise funded by the Rhode Island department of
9 health (DOH) to provide opioid treatment, recovery and prevention and education services.

10 This act would take effect upon passage.

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