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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2019

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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) "Distribute" means to deliver a controlled substance other than by administering or
9 dispensing to the ultimate user, including intra-company transfers between any division, affiliate,
10 subsidiary, parent or other entity under complete common ownership and control.

11 (2) "Opioid stewardship payment" means the total amount to be paid into the opioid
12 stewardship fund for each state fiscal year as set forth in § 21-28.10-2.

13 (3) "Ratable share" means the individual portion of the opioid stewardship payment to be
14 paid by each manufacturer and distributor licensed under this title that sells or distributes opioids
15 in the state of Rhode Island.

16 **21-28.10-2. Opioid stewardship payment imposed on manufacturers and**
17 **distributors.**

18 All manufacturers and distributors licensed or registered under this title or chapter 19.1 of
19 title 5 (hereinafter referred to as "licensees"), that sell or distribute opioids in the state of Rhode

1 Island shall be required to pay an opioid stewardship payment. On an annual basis, the director of
2 the department of health shall certify to the state treasurer the amount of all revenues collected
3 from opioid stewardship payments and any penalties imposed. The amount of revenues so
4 certified shall be deposited quarterly into the opioid stewardship fund restricted receipt account
5 established pursuant to § 21-28.10-11.

6 **21-28.10-3. Determination of opioid stewardship payment.**

7 The total opioid stewardship payment amount shall be seven million five hundred
8 thousand dollars (\$7,500,000) annually, subject to downward adjustments pursuant to § 21-28.10-
9 9.

10 **21-28.10-4. Reports and records.**

11 (a) Each manufacturer and distributor licensed to sell or distribute opioids in the state of
12 Rhode Island shall provide to the director of the department of health a report detailing all opioids
13 sold or distributed by such manufacturer or distributor in the state of Rhode Island. Such report
14 shall include:

15 (1) The manufacturer's or distributor's name, address, phone number, federal Drug
16 Enforcement Agency (DEA) registration number and controlled substance license number issued
17 by the department;

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

20 (3) The date of the sale or distribution of the opioid;

21 (4) The gross receipt total, in dollars, of all opioids sold or distributed;

22 (5) The name and National Drug Code (NDC) of the opioid sold or distributed;

23 (6) The number of containers and the strength and metric quantity of controlled substance
24 in each container of the opioid sold or distributed;

25 (7) The total number of morphine milligram equivalents (MMEs) sold or distributed; and

26 (8) Any other elements as deemed necessary by the director.

27 (b) Initial and future reports.

28 (1) Such information shall be reported annually to the department of health in such form
29 as defined by the director; provided, however, that the initial report provided pursuant to
30 subsection (a) of this section shall consist of all opioids sold or distributed in the state of Rhode
31 Island for the 2018 calendar year, and must be submitted by August 1, 2019. Subsequent annual
32 reports shall be submitted on April 1 of each year based on the actual opioid sales and
33 distributions of the prior calendar year.

34 (2) For the purpose of such annual reporting, MMEs shall be determined pursuant to a

1 formulation to be issued by the department and updated as the department deems appropriate.

2 **21-28.10-5. Determination of ratable share.**

3 Each manufacturer and distributor licensed to sell or distribute opioids in the state of
4 Rhode Island shall pay a portion of the total opioid stewardship payment amount. The ratable
5 share shall be calculated as follows:

6 (1) The total amount of MMEs sold or distributed in the state of Rhode Island by the
7 licensee for the preceding calendar year, as reported by the licensee pursuant to § 21-28.10-4,
8 shall be divided by the total amount of MMEs sold in the state of Rhode Island by all licensees
9 pursuant to this chapter to determine the licensee payment percentage. The licensee payment
10 percentage shall be multiplied by the total opioid stewardship payment. The product of such
11 calculation shall be the licensee's ratable share. The department shall have the authority to adjust
12 the total number of a licensee's MMEs to account for the nature and use of the product, as well as
13 the type of entity purchasing the product from the licensee, when making such determination and
14 adjust the ratable share accordingly.

15 (2) The licensee's total amount of MMEs sold or distributed, as well as the total amount
16 of MMEs sold or distributed by all licensees under this chapter, used in the calculation of the
17 ratable share, shall not include the MMEs of those opioids which are:

18 (i) Manufactured in Rhode Island, but whose final point of delivery or sale is outside of
19 Rhode Island;

20 (ii) Sold or distributed to entities certified to operate as chemical dependency
21 professionals, or hospice providers licensed pursuant to chapter 17 of title 23; or

22 (iii) The MMEs attributable to buprenorphine, methadone or morphine.

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

27 **21-28.10-6. Payment of ratable share.**

28 The licensee shall make payments quarterly to the department with the first payment of
29 the ratable share; provided that, the amount due on January 1, 2020 shall be for the full amount of
30 the first annual payment, with additional payments to be due and owing on the first day of every
31 quarter thereafter.

32 **21-28.10-7. Rebate of ratable share.**

33 In any year for which the director determines that a licensee failed to report required
34 information as required by this chapter, those licensees complying with this chapter shall receive

1 a reduced assessment of their ratable share in the following year equal to the amount in excess of
2 any overpayment in the prior payment period.

3 **21-28.10-8. Licensee opportunity to appeal.**

4 A licensee shall be afforded an opportunity to submit information to the department to
5 justify why the ratable share provided to the licensee, pursuant to § 21-28.10-5, or amounts paid
6 thereunder are in error or otherwise not warranted. If the department determines thereafter that all
7 or a portion of such ratable share, as determined by the director pursuant to §21-28.10-5, is not
8 warranted, the department may:

9 (1) Adjust the ratable share;

10 (2) Adjust the assessment of the ratable share in the following year equal to the amount in
11 excess of any overpayment in the prior payment period; or

12 (3) Refund amounts paid in error.

13 **21-28.10-9. Department annual review.**

14 The department shall annually review the amount of state operating funds spent in the
15 offices dedicated to substance use disorders within the department of behavioral healthcare,
16 developmental disabilities and hospitals (BHDDH), the executive office of health and human
17 services (EOHHS), the department of children, youth and families (DCYF), the Rhode Island
18 department of education (RIDE), the Rhode Island office of veterans' affairs (RIOVA), the
19 department of corrections (DOC), and the department of labor and training (DLT), for opioid
20 prevention, treatment and recovery. The directors of BHDDH, EOHHS, DCYF, RIDE, RIOVA,
21 DOC, and DLT shall certify to the department the amount of annual spending for such services,
22 utilizing available information on patient demographics and the actual cost of services delivered
23 by the state and by state-funded providers. The certification of such spending shall begin in state
24 fiscal year 2019, and continue annually thereafter. The total amount of such spending shall be
25 provided to the department by the directors of BHDDH, EOHHS, DCYF, RIDE, RIOVA, DOC,
26 and DLT no later than June 30 of each year. The director shall certify to the governor the amount
27 of annual spending for such services, utilizing available information on patient demographics and
28 the actual cost of services delivered by the state and by state-funded providers.

29 **21-28.10-10. Penalties.**

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

32 (b) In addition to any other civil or criminal penalty provided by law, where a licensee
33 has failed to pay its ratable share in accordance with § 21-28.10-6, the department may also
34 assess a penalty of no less than ten percent (10%) and no greater than three hundred percent

1 (300%) of the ratable share due from such licensee.

2 **21-28.10-11. Opioid stewardship fund - restricted receipt account.**

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

6 (b) Monies in the opioid stewardship fund shall be kept separate and shall not be
7 commingled with any other monies in the custody of the state treasurer and the administrator of
8 the division of taxation.

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

15 (d) Monies of the opioid stewardship fund, when allocated, shall be available, subject to
16 the approval of the director of the budget, to support programs operated by the Rhode Island
17 department of behavioral healthcare, developmental disabilities and hospitals (BHDDH), the
18 executive office of health and human services (EOHHS), the department of children, youth and
19 families (DCYF), the Rhode Island department of education (RIDE), the Rhode Island office of
20 veterans' affairs (RIOVA), the department of corrections (DOC), the department of labor and
21 training (DLT) or agencies certified, authorized, approved or otherwise funded by the Rhode
22 Island department of health to provide opioid treatment, recovery and prevention and education
23 services.

24 (e) At the request of the budget director, the state comptroller shall transfer monies to
25 support the costs of opioid treatment, recovery, prevention, education services, and other related
26 programs, from the opioid stewardship fund to any other fund of the state to support this purpose.

27 (f)(1) Notwithstanding the provisions of any general or special law, no monies shall be
28 available from the opioid stewardship fund until a certificate of allocation and a schedule of
29 amounts to be available therefor shall have been issued by the director, and a copy of such
30 certificate filed with the general treasurer's office, the chairperson of the house finance committee
31 and the chairperson of the senate finance committee.

32 (2) Such certificate may be amended from time to time by the director, and a copy of
33 such amendment shall be filed with the treasurer, the chairperson of the house finance committee
34 and the chairperson of the senate finance committee.

1 **21-28.10-12. Allocation.**

2 The monies, when allocated, shall be paid out of the opioid stewardship fund, and subject
3 to the approval of the director pursuant to the provisions of this chapter.

4 **21-28.10-13. Severability.**

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

11 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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