L.D. 793

Date: (Filing No. S-)

JUDICIARY

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STATE OF MAINE

SENATE

129TH LEGISLATURE

FIRST REGULAR SESSION

COMMITTEE AMENDMENT " " to S.P. 237, L.D. 793, Bill, "An Act To Improve Accountability of Opioid Manufacturers"

Amend the bill by striking out everything after the enacting clause and inserting the following:

'**Sec. 1. 5 MRSA §20010** is enacted to read:

§20010. Opioid Use Disorder Prevention and Treatment Fund

1. Fund established. The Opioid Use Disorder Prevention and Treatment Fund, referred to in this section as "the fund," is established for the purpose of supporting opioid use disorder analysis, prevention and treatment and is administered by the department. The fund consists of:

A. Money received from proceeds from the registration fee under Title 32, section 13800-C;

B. Money received from proceeds from the fee under Title 32, section 13724, less $325, which may be retained by the Department of Professional and Financial Regulation; and

C. Appropriations, allocations and contributions from private and public sources.

The fund must be held separate and apart from all other money, funds and accounts. Eligible investment earnings credited to the assets of the fund become part of the assets of the fund. Any unexpended balances remaining in the fund at the end of any fiscal year do not lapse and must be carried forward to the next fiscal year.

2. Uses of fund proceeds. The proceeds of the fund must be used for the following purposes:

A. Opioid use disorder prevention services;

B. Opioid use disorder treatment services, including:

(1) Inpatient and outpatient treatment programs and facilities, including short-term and long-term residential treatment programs and sober living facilities;

(2) Treating substance use disorder for the underinsured and uninsured; and

(3) Research regarding opioid use disorder prevention and treatment;

C. The department's reasonable expenses in administering the fund; and

D. The Maine Board of Pharmacy's reasonable expenses in administering Title 32, section 13800-C and in providing the report required under Title 32, section 13800-C.

The department shall award grants and contracts from proceeds of the fund to persons and organizations to carry out the purposes of the fund.

Sec. 2. 22 MRSA §7249-B is enacted to read:

§7249-B. Opioid medication distribution monitoring information

A manufacturer of an opioid medication that is available in this State and a wholesaler that sells or distributes an opioid medication in this State shall submit to the department, by electronic means or other format specified in a waiver granted by the department, information for this State submitted to the United States Drug Enforcement Administration's Automation of Reports and Consolidated Orders System pursuant to 21 United States Code, Subchapter I and 21 Code of Federal Regulations, Section 1304.33 at the time that information is submitted to the United States Drug Enforcement Administration. As used in this section, the terms "manufacturer" and "opioid medication" have the same meanings as in Title 32, section 13702-A.

Sec. 3. 32 MRSA §13724, as amended by PL 2007, c. 402, Pt. DD, §11 and PL 2011, c. 286, Pt. B, §5, is repealed and the following enacted in its place:

§13724. Fees

The Director of the Office of Professional and Occupational Regulation may establish by rule fees for purposes authorized under this chapter in amounts that are reasonable and necessary for their respective purposes in accordance with this section. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

1. General fees. Except as provided in subsection 2, the fee for any one purpose may not exceed $325.

2. Manufacturer of an opioid medication fee. The fee for a manufacturer of an opioid medication is $55,000.

Sec. 4. 32 MRSA §13800-C is enacted to read:

§13800-C. Opioid medication product registration fee

This section governs opioid medication product registration fees. As used in this section, "unit of an opioid medication" means the lowest identifiable quantity of the opioid medication that is dispensed.

1. Registration fee. Except as provided in subsection 2, a manufacturer that sells, delivers or distributes an opioid medication in this State shall pay an annual registration fee of $250,000 to the board on December 31st of each year.

2. Exception. A manufacturer that does not sell, deliver or distribute 2,000,000 or more units of an opioid medication within this State in the year in which a registration fee is due is not required to pay the registration fee. To qualify for the exception under this subsection, a manufacturer must demonstrate to the board, by January 31st of the year following the year in which the registration fee is due, in a manner determined by the board, that the manufacturer did not sell, deliver or distribute 2,000,000 or more units of an opioid medication within this State in the year in which the manufacturer seeks to claim the exception. The board may adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

3. Calculation of units of an opioid medication sold, delivered or distributed. When calculating the number of units of an opioid medication sold, delivered or distributed by a manufacturer under subsection 2, units of an opioid medication may be excluded when prescribed for the purpose of medication-assisted treatment of substance use disorder. The board periodically shall provide to the Department of Health and Human Services a list of medications exempted under this subsection.

4. Registration fee review and report. By March 1st of each year following calendar years 2020, 2021 and 2022, the board shall evaluate and report whether the registration fee due under this section and the fee due under section 13724 have affected the prescribing practices of opioid medications by reducing the number of opioid medication prescriptions issued during calendar years 2020, 2021 and 2022 or whether the fees have created any unintended consequences in the availability of opioid medications for the treatment of chronic or intractable pain, to the extent the board has the ability to identify a correlation. The board shall provide the report to the joint standing committee of the Legislature having jurisdiction over health and human services matters, which may report out legislation based upon the report.

This subsection is repealed September 1, 2023.

Sec. 5. Appropriations and allocations. The following appropriations and allocations are made.

HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Opioid Use Disorder Prevention and Treatment Fund N307

Initiative: Provides base allocation for the Opioid Use Disorder Prevention and Treatment Fund.

OTHER SPECIAL REVENUE FUNDS	**2019-20**	**2020-21**
All Other	$500	$500
OTHER SPECIAL REVENUE FUNDS TOTAL	$500	$500

HEALTH AND HUMAN SERVICES, DEPARTMENT OF DEPARTMENT TOTALS	2019-20	2020-21
OTHER SPECIAL REVENUE FUNDS	$500	$500
DEPARTMENT TOTAL - ALL FUNDS	$500	$500

PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF

Licensing and Enforcement 0352

Initiative: Allocates funds for the contracting and general operating costs associated with the development of the registration fee review report, determination and report of exempted medications, rulemaking and additional board meetings.

OTHER SPECIAL REVENUE FUNDS	2019-20	2020-21
All Other	$53,000	$53,000
OTHER SPECIAL REVENUE FUNDS TOTAL	$53,000	$53,000

PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF DEPARTMENT TOTALS	2019-20	2020-21
OTHER SPECIAL REVENUE FUNDS	$53,000	$53,000
DEPARTMENT TOTAL - ALL FUNDS	$53,000	$53,000

SECTION TOTALS	2019-20	2020-21
OTHER SPECIAL REVENUE FUNDS	$53,500	$53,500
SECTION TOTAL - ALL FUNDS	$53,500	$53,500

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SUMMARY

This amendment replaces the bill.

The amendment raises the annual fee for a manufacturer of opioid medication to $55,000. The amendment establishes a registration fee due from manufacturers of opioid medications of $250,000 if the manufacturer sells, delivers or distributes 2,000,000 or more units of an opioid medication within this State, not including units that are prescribed for the purpose of medication-assisted treatment of substance use disorder. The fees are deposited into the Opioid Use Disorder Prevention and Treatment Fund,

which is established to provide opioid use disorder prevention and treatment services and administered by the Department of Health and Human Services.

The amendment also requires manufacturers and wholesale distributors of opioid medications to provide to the State the same information as provided to the United States Drug Enforcement Administration under its Automation of Reports and Consolidated Orders System regarding controlled substances transactions in this State on the same schedule that information is provided to the Federal Government.

The amendment requires the Maine Board of Pharmacy to evaluate and report whether the fees have affected the prescribing practices for opioid medications by reducing the number of opioid medication prescriptions issued during calendar years 2020, 2021 and 2022 or whether the fees have created any unintended consequences in the availability of opioid medications for the treatment of chronic or intractable pain, to the extent the board has the ability to identify a correlation. The board shall provide the report to the joint standing committee of the Legislature having jurisdiction over health and human services matters, which may report out legislation based upon the report. The reports must be submitted annually by March 1st.

FISCAL NOTE REQUIRED

(See attached)