MAINE STATE LEGISLATURE

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129th MAINE LEGISLATURE

FIRST REGULAR SESSION-2019

Legislative Document

No. 793

S.P. 237

In Senate, February 12, 2019

An Act To Improve Accountability of Opioid Manufacturers

Reference to the Committee on Judiciary suggested and ordered printed.

DAREK M. GRANT Secretary of the Senate

Presented by President JACKSON of Aroostook.
Cosponsored by Representative MADIGAN of Waterville and
Senators: CLAXTON of Androscoggin, GRATWICK of Penobscot, LIBBY of Androscoggin,
VITELLI of Sagadahoc, Representatives: BAILEY of Saco, HYMANSON of York.

1	Be it enacted by the People of the State of Maine as follows:
2	Sec. 1. 5 MRSA c. 525 is enacted to read:
3	CHAPTER 525
4	OPIOID CRISIS ACCOUNTABILITY ACT
5	§20101. Short title
6	This chapter may be known and cited as "the Opioid Crisis Accountability Act."
7	§20102. Definitions
8 9	As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.
10 11 12	1. Abuse liability. "Abuse liability" means the potential of an opioid medication to result in physical or psychological dependence on the opioid medication that is likely to lead to substance use disorder as described in section 20003, subsection 17-A.
13 14	2. Commissioner. "Commissioner" means the Commissioner of Health and Human Services.
15 16	3. Department. "Department" means the Department of Health and Human Services.
17 18 19	4. Opioid medication manufacturer or distributor. "Opioid medication manufacturer or distributor" means a business operating in this State that manufactures or distributes opioid medication to another person or business in this State.
20	§20103. Illegal marketing or distribution of opioid medication prohibited
21	1. Prohibited acts. An opioid medication manufacturer or distributor may not:
22 23	A. Falsely represent in this State, by means of distributing marketing materials or otherwise advertising, that an opioid medication:
24	(1) Does not have abuse liability; or
25	(2) Has a lower abuse liability than another opioid medication;
26 27	B. Distribute a quantity of opioid medications in this State that is not medically reasonable; or
28 29 30	C. Fail to report to the commissioner pursuant to section 20104 an order or pattern of orders for the distribution of opioid medication in this State that is not medically reasonable.

§20104. Reporting required

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An opioid medication manufacturer or distributor shall report to the commissioner an order or pattern of orders for the distribution of opioid medication in this State that is not medically reasonable.

§20105. Medically reasonable standard

The department shall establish by rule the medically reasonable standard applicable to section 20103, subsection 1, paragraphs B and C. In adopting the standard, the department shall consult data from the automated reports and consolidated ordering system of the United States Department of Justice.

§20106. Investigation

The Attorney General, upon the Attorney General's own initiative or upon petition of the commissioner or of 50 or more residents of the State, shall investigate suspected violations of this chapter.

§20107. Violations

- 1. Penalty for individual. Notwithstanding any other law to the contrary, a person employed by an opioid medication manufacturer or distributor who directly and knowingly violates section 20103 or 20104 commits a civil violation for which a fine of not more than the total of the following may be adjudged:
- A. The amount of the person's salary from the period in which the person was in violation; and
- B. The amount by which the person's stock or other certificates of ownership interest in the opioid medication manufacturer or distributor increased in value during the period in which the person was in violation.
 - 2. Penalty for business. An opioid medication manufacturer or distributor that knowingly violates section 20103 or 20104 commits a civil violation for which a fine of not more than 25% of the total profit of the opioid medication manufacturer or distributor from the sale of opioid medication in the United States during the period in which the opioid medication manufacturer or distributor was in violation.

§20108. Fund

- 1. Fund established. The Opioid Reimbursement Fund, referred to in this section as
 "the fund," is established as a nonlapsing fund in the department for the purposes
 specified in this section.
- 2. Source of funds. The State Controller shall credit to the fund any penalties and
 fines assessed for violations of this chapter.
- 35 **3.** Uses of the fund. The fund may be used for activities of the department relating to substance use disorder pursuant to chapter 521.

§20109. Rules

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The department may adopt rules necessary to implement this chapter. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

§20110. Retroactivity

This Act applies retroactively to January 1, 1985.

7 SUMMARY

This bill prohibits opioid medication manufacturers and distributors from falsely advertising that an opioid medication does not have abuse liability or has a lower abuse liability than another opioid medication; distributing a quantity of opioid medications that is not medically reasonable; or failing to report orders that are not medically reasonable. It establishes a civil violation and authorizes the Attorney General to investigate violations. It creates a fund into which the penalties and fees must be paid. This legislation applies retroactively to January 1, 1985.