129th MAINE LEGISLATURE

FIRST REGULAR SESSION-2019

Legislative Document **No. 1387**

S.P. 431 In Senate, March 26, 2019

An Act To Increase Access to Safe and Affordable Prescription Drugs

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by President JACKSON of Aroostook.
Cosponsored by Representative DILLINGHAM of Oxford and
Senators: CLAXTON of Androscoggin, SANBORN, H. of Cumberland, VITELLI of Sagadahoc, Representatives: FECTEAU of Biddeford, Speaker GIDEON of Freeport, MOONEN of Portland, STEWART of Presque Isle, TEPLER of Topsham.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 603-A is enacted to read:

CHAPTER 603-A

MAINE PHARMACEUTICAL DRUG SAFETY ACT

§2699-A. Short title

This chapter may be known and cited as "the Maine Pharmaceutical Drug Safety Act."

§2699-B. Findings

The Legislature finds that allowing the citizens of the State to import certain prescription drugs that are branded and registered in Canada, but unapproved by the United States Department of Health and Human Services, Food and Drug Administration in the Canadian branded or generic formula, will not present an unreasonable risk to individuals or public health and will result in a significant reduction in the cost of necessary drugs for consumers in the State.

§2699-C. Personal importation policy

1. Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Pharmacy" means a business licensed by Canada to engage in the selling of prescription drugs at retail.

B. "Prescription drug" means a drug required to be reported to a state prescription monitoring program and includes but is not limited to substances listed in the federal Controlled Substances Act and unapproved new drugs.

C. "Unapproved new drug" means a drug, including a foreign-made version of a prescription drug, that has not been manufactured in accordance with and pursuant to United States Department of Health and Human Services, Food and Drug Administration approval.

2. Importation of prescription drugs. An individual may import only for the use of that individual or a member of that individual's immediate family a prescription drug from a pharmacy in Canada that is allowed to export prescription drugs under Canada's regulations as long as:

A. The drug is clearly for personal use;

B. The drug does not present an unreasonable risk to the user;

C. No more than a 90-day supply is imported during any 90-day period; and

D. The individual or member of the individual's immediate family for whom the drug is intended possesses a valid prescription for the imported drug.

3. Prohibitions on importation of prescription drugs. The following prohibitions on the importation of prescription drugs pursuant to this section apply.

A. An individual may not import a prescription drug about which the United States Department of Health and Human Services, Food and Drug Administration has issued a public notice stating that the prescription drug:

(1) Lacks evidence of effectiveness;

(2) Is a health fraud drug product;

(3) Presents a direct challenge to the United States Department of Health and Human Services, Food and Drug Administration's new drug application and over-the-counter monograph processes; or

(4) Has been reformulated by the manufacturer or exporter to evade an existing United States Department of Health and Human Services, Food and Drug Administration enforcement action.

B. An individual may not reimport a drug approved by the United States Department of Health and Human Services, Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act that was originally manufactured in the United States.

C. An individual may not import a controlled substance. As used in this paragraph, "controlled substance" has the same meaning as in the federal Controlled Substances Act, 21 United States Code, Section 802.

D. An individual may not import a prescription drug for sale or resale.

An individual who violates this subsection commits a Class D crime.

4. Rules. The department shall adopt routine technical rules under Title 5, chapter 375, subchapter 2-A to implement the provisions of this chapter.

SUMMARY

Under the Federal Food, Drug, and Cosmetic Act, the importation of unapproved new prescription drugs, including foreign-made versions of prescription drugs that have been approved by the federal Department of Health and Human Services, Food and Drug Administration, is prohibited. However, the Food and Drug Administration has developed guidance that allows the personal importation of certain drugs.

This bill, using the guidance developed by the federal Department of Health and Human Services, Food and Drug Administration, enacts the Maine Pharmaceutical Drug Safety Act to allow an individual in Maine to import prescription drugs from Canada as long as specific criteria are met, including that the drug is imported for personal use, that the individual importing the drug has a valid prescription, that the drug does not present an unreasonable risk to the individual and that no more than a 90-day supply of the drug is imported. The prescription drug to be imported must also meet specific requirements. The importation of controlled substances and prescription drugs for sale or resale is specifically prohibited.