# 127th MAINE LEGISLATURE

## FIRST REGULAR SESSION-2015

**Legislative Document** **No. 1422**

H.P. 968 House of Representatives, May 19, 2015

**An Act To Allow Maine Residents To Personally Import Medications as Permitted under the Federal Food, Drug, and Cosmetic Act**

(AFTER DEADLINE)

(EMERGENCY)

Approved for introduction by a majority of the Legislative Council pursuant to Joint Rule 205.

Reference to the Committee on Health and Human Services suggested and ordered printed.

ROBERT B. HUNT
Clerk

Presented by Representative MARTIN of Eagle Lake.

**Emergency preamble. Whereas,** acts and resolves of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

**Whereas,** Maine residents benefitted until recently from a Maine law that allowed importation of prescription drugs from pharmacies in other countries; and

**Whereas,** a federal court ruled that the Maine law was in violation of federal law, a ruling that could cause many residents, including senior citizens and low-income residents, to forgo their medication because it is too costly; and

**Whereas,** this legislation, based on federal guidance regarding the personal importation of prescription drugs, allows the importation of certain prescription drugs from certain countries; and

**Whereas,** this legislation needs to take effect as soon as possible to provide some relief to those Maine residents who can no longer afford their prescription drugs; and

**Whereas,** in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

**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 Maine to import certain prescription drugs that are branded and registered in Canada and member countries of the European Union, but unapproved by the United States Food and Drug Administration in the Canadian or European branded or generic formula, will provide a level of safety to Maine consumers that they do not currently enjoy from unapproved foreign imports and the Food and Drug Administration personal importation policy.

### §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. "Member country" means Canada or a member country of the European Union. "Member country" does not include a country:

(1) In the European Union that was admitted into the European Union pursuant to the Treaty of Accession 2003 to which a transitional measure for the regulation of human pharmaceutical products applies and has expired;

(2) That the United States Secretary of State determines will not meet the requirements for the regulation of human pharmaceutical products by the date on which a transitional measure for the regulation of human pharmaceutical products expires;

(3) That the United States Secretary of State confirms to the Attorney General has failed to:

(a) Authorize the approval of those drugs that have been determined to be safe and effective by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations;

(b) Require the methods used in and the facilities and controls used for the manufacture, processing and packaging of drugs in that country to be adequate to preserve the drugs' identity, quality, purity and strength;

(c) Undertake the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective;

(d) Require the labeling and promotion of a drug to be in accordance with the approval of the drug;

(e) Adequately train pharmacists;

(f) Adequately regulate the practice of pharmacy; or

(g) Adequately protect the privacy of personal medical information; or

(4) From which the importation of drugs to the United States will adversely affect public health as determined by the United States Secretary of State.

B. "Pharmacist" means a person licensed by a member country to practice in a pharmacy, including the dispensing and selling of prescription drugs.

C. "Pharmacy" means a business licensed by a member country to engage in the selling of prescription drugs at retail that employs 50 or more licensed pharmacists.

D. "Prescription drug" means any 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.

E. "Unapproved new drug" means any drug, including a foreign-made version of a prescription drug, that has not been manufactured in accordance with and pursuant to the United States 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 a member country that is allowed to export prescription drugs under that member country's regulations.

**3. Prohibitions on importation of prescription drugs.** The following actions are prohibited.

A. An individual may not import a prescription drug about which the United States 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 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 Food and Drug Administration enforcement action.

B. An individual may not reimport a drug approved by the United States 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 Section 802 of the federal Controlled Substances Act.

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.

**Emergency clause.** In view of the emergency cited in the preamble, this legislation takes effect when approved.

## 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 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 Food and Drug Administration, enacts the Maine Pharmaceutical Drug Safety Act to allow an individual in Maine to import prescription drugs from Canada or certain member countries of the European Union for use by that individual or a member of that individual's immediate family. The country from which the prescription drug is to be imported must meet specific criteria regarding regulation of its pharmacies and pharmacists, as determined by the United States

Secretary of State. 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.