

MAINE STATE LEGISLATURE

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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.

Handwritten signature of Robert B. Hunt in cursive.

ROBERT B. HUNT
Clerk

Presented by Representative MARTIN of Eagle Lake.

1 A. "Member country" means Canada or a member country of the European Union.
2 "Member country" does not include a country:

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

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

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

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

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

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

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

23 (e) Adequately train pharmacists;

24 (f) Adequately regulate the practice of pharmacy; or

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

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

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

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

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

35 E. "Unapproved new drug" means any drug, including a foreign-made version of a
36 prescription drug, that has not been manufactured in accordance with and pursuant to
37 the United States Food and Drug Administration approval.

38 **2. Importation of prescription drugs.** An individual may import only for the use
39 of that individual or a member of that individual's immediate family a prescription drug

1 from a pharmacy in a member country that is allowed to export prescription drugs under
2 that member country's regulations.

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

5 A. An individual may not import a prescription drug about which the United States
6 Food and Drug Administration has issued a public notice stating that the prescription
7 drug:

8 (1) Lacks evidence of effectiveness;

9 (2) Is a health fraud drug product;

10 (3) Presents a direct challenge to the United States Food and Drug
11 Administration's new drug application and over-the-counter monograph
12 processes; or

13 (4) Has been reformulated by the manufacturer or exporter to evade an existing
14 United States Food and Drug Administration enforcement action.

15 B. An individual may not reimport a drug approved by the United States Food and
16 Drug Administration under the Federal Food, Drug, and Cosmetic Act that was
17 originally manufactured in the United States.

18 C. An individual may not import a controlled substance. As used in this paragraph,
19 "controlled substance" has the same meaning as in Section 802 of the federal
20 Controlled Substances Act.

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

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

23 **4. Rules.** The department shall adopt routine technical rules under Title 5, chapter
24 375, subchapter 2-A to implement the provisions of this chapter.

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

27 SUMMARY

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

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

1 Secretary of State. The prescription drug to be imported must also meet specific
2 requirements. The importation of controlled substances and prescription drugs for sale or
3 resale is specifically prohibited.