

114TH CONGRESS  
1ST SESSION

# S. 122

To amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable drugs from approved pharmacies in Canada.

---

## IN THE SENATE OF THE UNITED STATES

JANUARY 8, 2015

Mr. McCAIN (for himself and Ms. KLOBUCHAR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable drugs from approved pharmacies in Canada.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe and Affordable  
5 Drugs from Canada Act of 2015”.

6 **SEC. 2. SAFE AND AFFORDABLE DRUGS FROM CANADA.**

7 Chapter VIII of the Federal Food, Drug, and Cos-  
8 metic Act (21 U.S.C. 381 et seq.) is amended by adding  
9 at the end the following:

1 **“SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIP-**  
2 **TION DRUGS FROM CANADA.**

3 “(a) IN GENERAL.—Notwithstanding any other pro-  
4 vision of this Act, not later than 180 days after the date  
5 of enactment of this section, the Secretary shall promul-  
6 gate regulations permitting individuals to safely import  
7 into the United States a prescription drug described in  
8 subsection (b).

9 “(b) PRESCRIPTION DRUG.—A prescription drug de-  
10 scribed in this subsection—

11 “(1) is a prescription drug that—

12 “(A) is purchased from an approved Cana-  
13 dian pharmacy;

14 “(B) is dispensed by a pharmacist licensed  
15 to practice pharmacy and dispense prescription  
16 drugs in Canada;

17 “(C) is purchased for personal use by the  
18 individual, not for resale, in quantities that do  
19 not exceed a 90-day supply;

20 “(D) is filled using a valid prescription  
21 issued by a physician licensed to practice in a  
22 State in the United States; and

23 “(E) has the same active ingredient or in-  
24 gredients, route of administration, dosage form,  
25 and strength as a prescription drug approved  
26 by the Secretary under chapter V; and

1 “(2) does not include—

2 “(A) a controlled substance (as defined in  
3 section 102 of the Controlled Substances Act  
4 (21 U.S.C. 802));

5 “(B) a biological product (as defined in  
6 section 351 of the Public Health Service Act  
7 (42 U.S.C. 262));

8 “(C) an infused drug (including a peri-  
9 toneal dialysis solution);

10 “(D) an intravenously injected drug;

11 “(E) a drug that is inhaled during surgery;

12 “(F) a parenteral drug;

13 “(G) a drug manufactured through 1 or  
14 more biotechnology processes, including—

15 “(i) a therapeutic DNA plasmid prod-  
16 uct;

17 “(ii) a therapeutic synthetic peptide  
18 product of not more than 40 amino acids;

19 “(iii) a monoclonal antibody product  
20 for in vivo use; and

21 “(iv) a therapeutic recombinant DNA-  
22 derived product;

23 “(H) a drug required to be refrigerated at  
24 any time during manufacturing, packing, proc-  
25 essing, or holding; or

1                   “(I) a photoreactive drug.

2                   “(c) APPROVED CANADIAN PHARMACY.—

3                   “(1) IN GENERAL.—In this section, an ap-  
4                   proved Canadian pharmacy is a pharmacy that—

5                   “(A) is located in Canada; and

6                   “(B) that the Secretary certifies—

7                   “(i) is licensed to operate and dis-  
8                   pense prescription drugs to individuals in  
9                   Canada; and

10                   “(ii) meets the criteria under para-  
11                   graph (3).

12                   “(2) PUBLICATION OF APPROVED CANADIAN  
13                   PHARMACIES.—The Secretary shall publish on the  
14                   Internet Web site of the Food and Drug Administra-  
15                   tion a list of approved Canadian pharmacies, includ-  
16                   ing the Internet Web site address of each such ap-  
17                   proved Canadian pharmacy, from which individuals  
18                   may purchase prescription drugs in accordance with  
19                   subsection (a).

20                   “(3) ADDITIONAL CRITERIA.—To be an ap-  
21                   proved Canadian pharmacy, the Secretary shall cer-  
22                   tify that the pharmacy—

23                   “(A) has been in existence for a period of  
24                   at least 5 years preceding the date of such cer-  
25                   tification and has a purpose other than to par-

1            participate in the program established under this  
2            section;

3            “(B) operates in accordance with phar-  
4            macy standards set forth by the provincial  
5            pharmacy rules and regulations enacted in Can-  
6            ada;

7            “(C) has processes established by the phar-  
8            macy, or participates in another established  
9            process, to certify that the physical premises  
10           and data reporting procedures and licenses are  
11           in compliance with all applicable laws and regu-  
12           lations, and has implemented policies designed  
13           to monitor ongoing compliance with such laws  
14           and regulations;

15           “(D) conducts or commits to participate in  
16           ongoing and comprehensive quality assurance  
17           programs and implements such quality assur-  
18           ance measures, including blind testing, to en-  
19           sure the veracity and reliability of the findings  
20           of the quality assurance program;

21           “(E) agrees that laboratories approved by  
22           the Secretary shall be used to conduct product  
23           testing to determine the safety and efficacy of  
24           sample pharmaceutical products;

1           “(F) has established, or will establish or  
2 participate in, a process for resolving grievances  
3 and will be held accountable for violations of es-  
4 tablished guidelines and rules;

5           “(G) does not resell products from online  
6 pharmacies located outside Canada to cus-  
7 tomers in the United States; and

8           “(H) meets any other criteria established  
9 by the Secretary.”.

○