

109TH CONGRESS
1ST SESSION

H. R. 563

To amend part D of title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate and disclose lowest possible prices for prescription drug prices for Medicare beneficiaries, and, with respect to the Federal Food, Drug, and Cosmetic Act, to provide waivers that permit such beneficiaries to import prescription drugs from Canada.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 2, 2005

Mr. LYNCH introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend part D of title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate and disclose lowest possible prices for prescription drug prices for Medicare beneficiaries, and, with respect to the Federal Food, Drug, and Cosmetic Act, to provide waivers that permit such beneficiaries to import prescription drugs from Canada.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Prescription Drug Af-
3 fordability Act of 2005”.

4 **SEC. 2. NEGOTIATION AND DISCLOSURE OF LOWEST POS-
5 SIBLE PRICES FOR PRESCRIPTION DRUGS
6 UNDER MEDICARE.**

7 Section 1860D–11 of the Social Security Act (42
8 U.S.C. 1395w–111) is amended by striking subsection (i)
9 (relating to noninterference) and by inserting the fol-
10 lowing:

11 “(i) **NEGOTIATION AND DISCLOSURE OF BEST
12 PRICES.**—

13 “(1) **NEGOTIATION.**—In order to ensure that
14 beneficiaries enrolled under prescription drug plans
15 and MA–PD plans pay the lowest possible price, the
16 Secretary shall have and exercise authority similar
17 to that of the Secretary of Veterans Affairs, the Sec-
18 retary of Defense, and the heads of other Federal
19 agencies and departments that purchase prescription
20 drugs in bulk to negotiate contracts with manufac-
21 turers of covered part D drugs, consistent with the
22 requirements and in furtherance of the goals of pro-
23 viding quality care and containing costs under this
24 part. In exercising such authority, the Secretary
25 shall negotiate the best possible prices for such
26 drugs.

1 “(2) DISCLOSURE.—The Secretary shall widely
2 disseminate information on the prices for covered
3 part D drugs negotiated under paragraph (1).”.

4 **SEC. 3. MEDICARE BENEFICIARIES; WAIVER REQUIREMENT**
5 **FOR PERSONAL IMPORTATION OF PRESCRIP-**
6 **TION DRUGS FROM CANADA.**

7 (a) IN GENERAL.— With respect to the importation
8 by Medicare beneficiaries of prescription drugs from Can-
9 ada, the Secretary of Health and Human Services, acting
10 through the Commissioner of Food and Drugs, shall in
11 accordance with this section establish by regulation a
12 waiver of prohibitions under the Federal Food, Drug, and
13 Cosmetic Act that apply to the importation of drugs. Such
14 a waiver shall permit such a beneficiary to import into
15 the United States any prescription drug that—

16 (1) is imported from Canada for personal use
17 by the beneficiary (not for resale);

18 (2) is approved by the Secretary under section
19 505 of such Act, is manufactured in an establish-
20 ment registered with the Secretary under section
21 510 of such Act, and is not a controlled substance
22 in schedule I, II, or III under section 202(c) of the
23 Controlled Substances Act;

24 (3) is imported from a Canadian pharmacy that
25 has submitted to the Secretary a registration that

1 identifies the pharmacy and provides documentation
2 that the pharmacy is licensed in Canada;

3 (4) is imported in a quantity that does not (for
4 that instance of importation) exceed a 90-day sup-
5 ply;

6 (5) at the time of importation, is accompanied
7 by a copy of a valid prescription for the drug for the
8 beneficiary, issued in the United States by a practi-
9 tioner in accordance with section 503(b) of the Fed-
10 eral Food, Drug, and Cosmetic Act, or is accom-
11 panied by documentation that verifies the issuance
12 of such a prescription for the beneficiary;

13 (6) is in the form of a final finished dosage;
14 and

15 (7) is imported under such other conditions as
16 the Secretary determines to be necessary to ensure
17 public safety.

18 (b) DEFINITIONS.—For purposes of subsection (a):

19 (1) The term “Medicare beneficiary” means an
20 individual who is entitled to benefits under, or en-
21 rolled in, part A of title XVIII of the Social Security
22 Act, enrolled under part B of such title, or both.

23 (2) The term “Secretary” means the Secretary
24 of Health and Human Services.

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