I

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug Affordability Act of 2005''.

SEC. 2. NEGOTIATION AND DISCLOSURE OF LOWEST POSSIBLE PRICES FOR PRESCRIPTION DRUGS UNDER MEDICARE.

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

''(i) NEGOTIATION AND DISCLOSURE OF BEST PRICES.—

''(1) NEGOTIATION.—In order to ensure that beneficiaries enrolled under prescription drug plans and MA–PD plans pay the lowest possible price, the Secretary shall have and exercise authority similar to that of the Secretary of Veterans Affairs, the Secretary of Defense, and the heads of other Federal agencies and departments that purchase prescription drugs in bulk to negotiate contracts with manufacturers of covered part D drugs, consistent with the requirements and in furtherance of the goals of providing quality care and containing costs under this part. In exercising such authority, the Secretary shall negotiate the best possible prices for such drugs.

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

SEC. 3. MEDICARE BENEFICIARIES; WAIVER REQUIREMENT FOR PERSONAL IMPORTATION OF PRESCRIPTION DRUGS FROM CANADA.

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

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

(2) is approved by the Secretary under section 505 of such Act, is manufactured in an establishment registered with the Secretary under section 510 of such Act, and is not a controlled substance in schedule I, II, or III under section 202(c) of the Controlled Substances Act;

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

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

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

(5) at the time of importation, is accompanied by a copy of a valid prescription for the drug for the beneficiary, issued in the United States by a practitioner in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act, or is accompanied by documentation that verifies the issuance of such a prescription for the beneficiary;

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

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

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

(1) The term ''Medicare beneficiary'' means an individual who is entitled to benefits under, or enrolled in, part A of title XVIII of the Social Security Act, enrolled under part B of such title, or both.

(2) The term ''Secretary'' means the Secretary of Health and Human Services.

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