110TH CONGRESS
1ST SESSION

S. 28

To amend title XVIII of the Social Security Act to require the use of generic drugs under the Medicare part D prescription drug program when available unless the brand name drug is determined to be medically necessary.

IN THE SENATE OF THE UNITED STATES

JANUARY 4, 2007

Mr. KOHL introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To amend title XVIII of the Social Security Act to require the use of generic drugs under the Medicare part D prescription drug program when available unless the brand name drug is determined to be medically necessary.

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 "Generics First Act of 2007".

SEC. 2. REQUIRED USE OF GENERIC DRUGS UNDER THE MEDICARE PART D PRESCRIPTION DRUG PROGRAM.

(a) IN GENERAL.—Section 1860D–2(e)(2) of the Social Security Act (42 U.S.C. 1395w–102(e)(2)) is amended by adding at the end the following new subparagraph:

''(C) NON-GENERIC DRUGS UNLESS CERTAIN REQUIREMENTS ARE MET.—

''(i) IN GENERAL.—Such term does not include a drug that is a nongeneric drug unless—

''(I) no generic drug has been approved under the Federal Food, Drug, and Cosmetic Act with respect to the drug; or

''(II) the nongeneric drug is determined to be medically necessary by the individual prescribing the drug and prior authorization for the drug is obtained from the Secretary.

''(ii) DEFINITIONS.—In this subparagraph:

''(I) GENERIC DRUG.—The term 'generic drug' means a drug that is the subject of an application approved under subsection (b)(2) or (j) of sec-

tion 505 of the Federal Food, Drug, and Cosmetic Act, for which the Secretary has made a determination that the drug is the therapeutic equivalent of a listed drug under section 505(j)(7) of such Act.

"(II) NONGENERIC DRUG.—The term 'nongeneric drug' means a drug that is the subject of an application approved under—

"(aa) section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act; or

"(bb) section 505(b)(2) of such Act and that has been determined to be not therapeutically equivalent to any listed drug.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to drugs dispensed on or after the date of enactment of this Act.

○