

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.

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## 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

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## 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.

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 “Generics First Act of  
5 2007”.

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

4 (a) IN GENERAL.—Section 1860D–2(e)(2) of the So-  
 5 cial Security Act (42 U.S.C. 1395w–102(e)(2)) is amend-  
 6 ed by adding at the end the following new subparagraph:

7 “(C) NON-GENERIC DRUGS UNLESS CER-  
 8 TAIN REQUIREMENTS ARE MET.—

9 “(i) IN GENERAL.—Such term does  
 10 not include a drug that is a nongeneric  
 11 drug unless—

12 “(I) no generic drug has been ap-  
 13 proved under the Federal Food, Drug,  
 14 and Cosmetic Act with respect to the  
 15 drug; or

16 “(II) the nongeneric drug is de-  
 17 termined to be medically necessary by  
 18 the individual prescribing the drug  
 19 and prior authorization for the drug is  
 20 obtained from the Secretary.

21 “(ii) DEFINITIONS.—In this subpara-  
 22 graph:

23 “(I) GENERIC DRUG.—The term  
 24 ‘generic drug’ means a drug that is  
 25 the subject of an application approved  
 26 under subsection (b)(2) or (j) of sec-

1                   tion 505 of the Federal Food, Drug,  
2                   and Cosmetic Act, for which the Sec-  
3                   retary has made a determination that  
4                   the drug is the therapeutic equivalent  
5                   of a listed drug under section  
6                   505(j)(7) of such Act.

7                   “(II) NONGENERIC DRUG.—The  
8                   term ‘nongeneric drug’ means a drug  
9                   that is the subject of an application  
10                  approved under—

11                               “(aa) section 505(b)(1) of  
12                               the Federal Food, Drug, and  
13                               Cosmetic Act; or

14                               “(bb) section 505(b)(2) of  
15                               such Act and that has been de-  
16                               termined to be not therapeuti-  
17                               cally equivalent to any listed  
18                               drug.”.

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

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