

109TH CONGRESS  
2D SESSION

# H. R. 5102

To amend title XVIII of the Social Security Act to prohibit removal of covered part D drugs from a prescription drug plan formulary during the plan year once an individual has enrolled in the plan.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 5, 2006

Mr. BECERRA (for himself, Mr. DEFAZIO, Mr. SALAZAR, Mr. HONDA, Mr. JEFFERSON, Mr. KENNEDY of Rhode Island, Mr. BOUCHER, Mr. WEXLER, Mr. CARDOZA, Mr. MCGOVERN, Mr. MOLLOHAN, Mr. GENE GREEN of Texas, Mr. GRIJALVA, Mr. RANGEL, Mr. STARK, Mr. CONYERS, Mr. MCDERMOTT, Ms. HERSETH, Mr. HINCHEY, Mr. BROWN of Ohio, Mr. REYES, Mr. RUPPERSBERGER, Mr. LARSON of Connecticut, Mr. McNULTY, Ms. MATSUI, Mr. COSTELLO, Mrs. MALONEY, Mr. MARSHALL, Mr. LEVIN, Ms. NORTON, Mr. INSLEE, Mr. LYNCH, Mr. DELAHUNT, Mr. OWENS, Mr. ORTIZ, Ms. SCHAKOWSKY, Mrs. NAPOLITANO, Mr. RYAN of Ohio, Mr. DOYLE, Mr. POMEROY, Mr. SCOTT of Virginia, Mr. BACA, Mr. SANDERS, Mr. CUMMINGS, Mr. OBERSTAR, Mr. PAYNE, Mr. GONZALEZ, Mr. EMANUEL, Mr. LANTOS, Mr. DOGGETT, Ms. WASSERMAN SCHULTZ, Mr. BRADY of Pennsylvania, Mrs. CAPPS, and Ms. MCCOLLUM of Minnesota) 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 title XVIII of the Social Security Act to prohibit removal of covered part D drugs from a prescription drug plan formulary during the plan year once an individual has enrolled in the plan.

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 “Medicare Drug For-  
5 mulary Protection Act”.

6 **SEC. 2. REMOVAL OF COVERED PART D DRUGS FROM THE**  
7 **PRESCRIPTION DRUG PLAN FORMULARY.**

8       (a) **LIMITATION ON REMOVAL OR CHANGE OF COV-**  
9 **ERED PART D DRUGS FROM THE PRESCRIPTION DRUG**  
10 **PLAN FORMULARY.**—Section 1860D–4(b)(3)(E) of the  
11 Social Security Act (42 U.S.C. 1395w–104(b)(3)(E)) is  
12 amended to read as follows:

13               “(E) **REMOVING A DRUG FROM FOR-**  
14 **MULARY OR IMPOSING A RESTRICTION OR LIM-**  
15 **TATION ON COVERAGE.**—

16               “(i) **LIMITATION ON REMOVAL, LIM-**  
17 **TATION, OR RESTRICTION.**—

18               “(I) **IN GENERAL.**—Subject to  
19 subclause (II) and clause (ii), begin-  
20 ning with 2006, the PDP sponsor of  
21 a prescription drug plan may not re-  
22 move a covered part D drug from the  
23 plan formulary or impose a restriction  
24 or limitation on the coverage of such  
25 a drug (such as through the applica-

1           tion of a preferred status, usage re-  
2           striction, step therapy, prior author-  
3           ization, or quantity limitation) other  
4           than at the beginning of each plan  
5           year except as the Secretary may per-  
6           mit to take into account new thera-  
7           peutic uses and newly covered part D  
8           drugs.

9           “(II) SPECIAL RULE FOR NEWLY  
10          ENROLLED INDIVIDUALS.—Subject to  
11          clause (ii), in the case of an individual  
12          who enrolls in a prescription drug  
13          plan on or after the date of the enact-  
14          ment of the Medicare Drug For-  
15          mulary Protection Act, the PDP spon-  
16          sor of such plan may not remove a  
17          covered part D drug from the plan  
18          formulary or impose a restriction or  
19          limitation on the coverage of such a  
20          drug (such as through the application  
21          of a preferred status, usage restric-  
22          tion, step therapy, prior authorization,  
23          or quantity limitation) during the pe-  
24          riod beginning on the date of such en-  
25          rollment and ending on December 31

1 of the immediately succeeding plan  
2 year except as the Secretary may per-  
3 mit to take into account new thera-  
4 peutic uses and newly covered part D  
5 drugs.

6 “(ii) EXCEPTIONS TO LIMITATION ON  
7 REMOVAL.—Clause (i) shall not apply with  
8 respect to a covered part D drug that—

9 “(I) is a brand name drug for  
10 which there is a generic drug ap-  
11 proved under section 505(j) of the  
12 Food and Drug Cosmetic Act (21  
13 U.S.C. 355(j)) that is placed on the  
14 market during the period in which  
15 there are limitations on removal or  
16 change in the formulary under sub-  
17 clause (I) or (II) of clause (i) if such  
18 generic drug is included in the for-  
19 mulary without any restriction or limi-  
20 tation placed on the coverage of such  
21 generic drug other than a restriction  
22 or limitation that would be placed on  
23 the coverage of the brand name drug  
24 during such period without the appli-  
25 cation of this subclause;

1                   “(II) is a brand name drug that  
2 goes off-patent during such period;

3                   “(III) is a drug for which the  
4 Commissioner of Food and Drugs  
5 issues a clinical warning that imposes  
6 a restriction or limitation on the drug  
7 during such period;

8                   “(IV) has been determined to be  
9 ineffective during such period;

10                   “(V) is a drug that the appro-  
11 priate pharmacy and therapeutic com-  
12 mittee determines, based on evidence  
13 from peer-reviewed research, to be un-  
14 safe or ineffective during such period;  
15 or

16                   “(VI) is any other drug that sat-  
17 isfies any other requirement deter-  
18 mined appropriate by the Secretary.

19                   “(iii) NOTICE OF REMOVAL UNDER  
20 APPLICATION OF EXCEPTION TO LIMITA-  
21 TION.—The PDP sponsor of a prescription  
22 drug plan shall provide appropriate notice  
23 (such as under subsection (a)(3)) of any  
24 removal or change under clause (ii) to the

1 Secretary, affected enrollees, physicians,  
2 pharmacies, and pharmacists.”.

3 (b) NOTICE FOR CHANGE IN FORMULARY AND  
4 OTHER RESTRICTIONS OR LIMITATIONS ON COVERAGE.—

5 (1) IN GENERAL.—Section 1860D–4(a) of such  
6 Act (42 U.S.C. 1395w–104(a)) is amended by add-  
7 ing at the end the following new paragraph:

8 “(5) ANNUAL NOTICE OF CHANGES IN FOR-  
9 MULARY AND OTHER RESTRICTIONS OR LIMITATIONS  
10 ON COVERAGE.—Each PDP sponsor offering a pre-  
11 scription drug plan shall furnish to each enrollee at  
12 the time of each annual coordinated election period  
13 (referred to in section 1860D–1(b)(1)(B)(iii)) for a  
14 plan year a notice of any changes in the formulary  
15 or other restrictions or limitations on coverage of a  
16 covered part D drug under the plan that will take  
17 effect for the plan year.”.

18 (2) EFFECTIVE DATE.—The amendment made  
19 by paragraph (1) shall apply to annual coordinated  
20 election periods beginning after the date of the en-  
21 actment of this Act.

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