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(Original Signature of Member)

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. \_\_\_\_\_

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

Mr. BECERRA (for himself and [see attached list of cosponsors]) introduced the following bill; which was referred to the Committee on

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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”.



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

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

8 “(E) REMOVING A DRUG FROM FOR-  
9 MULARY OR IMPOSING A RESTRICTION OR LIM-  
10 TATION ON COVERAGE.—

11 “(i) LIMITATION ON REMOVAL, LIM-  
12 TATION, OR RESTRICTION.—

13 “(I) IN GENERAL.—Subject to  
14 subclause (II) and clause (ii), begin-  
15 ning with 2006, the PDP sponsor of  
16 a prescription drug plan may not re-  
17 move a covered part D drug from the  
18 plan formulary or impose a restriction  
19 or limitation on the coverage of such  
20 a drug (such as through the applica-  
21 tion of a preferred status, usage re-  
22 striction, step therapy, prior author-  
23 ization, or quantity limitation) other  
24 than at the beginning of each plan  
25 year except as the Secretary may per-  
26 mit to take into account new thera-



1           peutic uses and newly covered part D  
2           drugs.

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

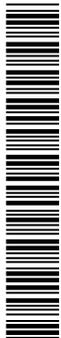


1           “(ii) EXCEPTIONS TO LIMITATION ON  
2           REMOVAL.—Clause (i) shall not apply with  
3           respect to a covered part D drug that—

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

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

23                   “(III) is a drug for which the  
24                   Commissioner of Food and Drugs  
25                   issues a clinical warning that imposes



1 a restriction or limitation on the drug  
2 during such period;

3 “(IV) has been determined to be  
4 ineffective during such period;

5 “(V) is a drug that the appro-  
6 priate pharmacy and therapeutic com-  
7 mittee determines, based on evidence  
8 from peer-reviewed research, to be un-  
9 safe or ineffective during such period;

10 or

11 “(VI) is any other drug that sat-  
12 isfies any other requirement deter-  
13 mined appropriate by the Secretary.

14 “(iii) NOTICE OF REMOVAL UNDER  
15 APPLICATION OF EXCEPTION TO LIMITA-  
16 TION.—The PDP sponsor of a prescription  
17 drug plan shall provide appropriate notice  
18 (such as under subsection (a)(3)) of any  
19 removal or change under clause (ii) to the  
20 Secretary, affected enrollees, physicians,  
21 pharmacies, and pharmacists.”

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



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

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

14           (2) EFFECTIVE DATE.—The amendment made  
15 by paragraph (1) shall apply to annual coordinated  
16 election periods beginning after the date of the en-  
17 actment of this Act.

