

109TH CONGRESS
2D SESSION

S. 2255

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.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 8, 2006

Mrs. FEINSTEIN (for herself, Ms. COLLINS, Mr. DORGAN, Ms. SNOWE, Mr. BINGAMAN, Mr. CHAFEE, Mrs. CLINTON, Mr. SCHUMER, Mrs. MURRAY, and Mrs. BOXER) 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 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 enactment
8 of this subparagraph, the PDP spon-
9 sor of such plan may not remove a
10 covered part D drug from the plan
11 formulary or impose a restriction or
12 limitation on the coverage of such a
13 drug (such as through the application
14 of a preferred status, usage restric-
15 tion, step therapy, prior authorization,
16 or quantity limitation) during the pe-
17 riod beginning on the date of such en-
18 rollment and ending on December 31
19 of the immediately succeeding plan
20 year except as the Secretary may per-
21 mit to take into account new thera-
22 peutic uses and newly covered part D
23 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);

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

15 “(III) is a drug for which the
 16 Commissioner of Food and Drugs
 17 issues a clinical warning that imposes
 18 a restriction or limitation on the drug
 19 during such period; or

20 “(IV) has been determined to be
 21 ineffective during such period.

22 “(iii) NOTICE OF REMOVAL UNDER
 23 APPLICATION OF EXCEPTION TO LIMITA-
 24 TION.—The PDP sponsor of a prescription
 25 drug plan shall provide appropriate notice

1 (such as under subsection (a)(3)) of any
 2 removal or change under clause (ii) to the
 3 Secretary, affected enrollees, physicians,
 4 pharmacies, and pharmacists.”.

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

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

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

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

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