

111TH CONGRESS
2^D SESSION

H. R. 5732

To amend title XVIII of the Social Security Act to permit coverage of certain covered part D drugs for uses that are determined to be for medically accepted indications based upon clinical evidence in peer reviewed medical literature.

IN THE HOUSE OF REPRESENTATIVES

JULY 14, 2010

Ms. KILROY (for herself, Mr. THORNBERRY, and Mr. BURGESS) 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

A BILL

To amend title XVIII of the Social Security Act to permit coverage of certain covered part D drugs for uses that are determined to be for medically accepted indications based upon clinical evidence in peer reviewed medical literature.

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 “Part D Off-Label Pre-
5 scription Parity Act”.

1 **SEC. 2. REVISED DEFINITION OF MEDICALLY ACCEPTED IN-**
2 **DICATION FOR MEDICARE COVERED PART D**
3 **DRUGS.**

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

7 “(D) CLARIFICATION.—Notwithstanding
8 subparagraph (A)(ii), none of the provisions of
9 this subsection shall prevent a PDP sponsor of-
10 fering a prescription drug plan or an MA orga-
11 nization offering an MA–PD plan from deter-
12 mining (whether through a determination, re-
13 consideration of such a determination, or an ap-
14 peal of such a determination under section
15 1852(g) or subsection (g) or (h) of section
16 1860D–4, as applicable) that a use of a covered
17 part D drug is for a medically accepted indica-
18 tion for purposes of coverage of such drug
19 under such plan if such determination is based
20 upon guidance provided by the Secretary for de-
21 termining accepted uses of covered part D
22 drugs and on supportive clinical evidence in
23 peer reviewed medical literature.”.

1 (b) **EFFECTIVE DATE.**—The amendment made by
2 this section shall apply to plan years beginning on or after
3 January 1, 2011.

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