

112TH CONGRESS  
1ST SESSION

# H. R. 1055

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.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 11, 2011

Mr. THORNBERRY (for himself, Mr. CARNAHAN, Mr. BURGESS, and Ms. HAYWORTH) 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 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, 2012.

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