

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

# H. R. 6123

To include costs incurred by the Indian Health Service, a federally qualified health center, an AIDS drug assistance program, certain hospitals, or a pharmaceutical manufacturer patient assistance program in providing prescription drugs toward the annual out of pocket threshold under part D of title XVIII of the Social Security Act and to provide a safe harbor for assistance provided under a pharmaceutical manufacturer patient assistance program.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2006

Mr. HOLT 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 include costs incurred by the Indian Health Service, a federally qualified health center, an AIDS drug assistance program, certain hospitals, or a pharmaceutical manufacturer patient assistance program in providing prescription drugs toward the annual out of pocket threshold under part D of title XVIII of the Social Security Act and to provide a safe harbor for assistance provided under a pharmaceutical manufacturer patient assistance program.

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 “Helping Fill the Medi-  
5 care Rx Gap Act of 2006”.

6 **SEC. 2. INCLUDING COSTS INCURRED BY THE INDIAN**  
7                    **HEALTH SERVICE, A FEDERALLY QUALIFIED**  
8                    **HEALTH CENTER, AN AIDS DRUG ASSISTANCE**  
9                    **PROGRAM, CERTAIN HOSPITALS, OR A PHAR-**  
10                   **MACEUTICAL MANUFACTURER PATIENT AS-**  
11                   **SISTANCE PROGRAM IN PROVIDING PRE-**  
12                   **SCRIPTION DRUGS TOWARD THE ANNUAL**  
13                   **OUT OF POCKET THRESHOLD UNDER PART D.**

14        (a) IN GENERAL.—Section 1860D–2(b)(4)(C) of the  
15 Social Security Act (42 U.S.C. 1395w–102(b)(4)(C)) is  
16 amended—

17                    (1) in clause (i), by striking “and” at the end;

18                    (2) in clause (ii)—

19                                (A) by striking “such costs shall be treated  
20 as incurred only if” and inserting “subject to  
21 clause (iii), such costs shall be treated as in-  
22 curred if”;

23                                (B) by striking “, under section 1860D–  
24 14, or under a State Pharmaceutical Assistance  
25 Program”; and

1 (C) by striking the period at the end and  
2 inserting “; and”; and

3 (3) by inserting after clause (ii) the following  
4 new clause:

5 “(iii) such costs shall be treated as in-  
6 curred and shall not be considered to be  
7 reimbursed under clause (ii) if such costs  
8 are borne or paid—

9 “(I) under section 1860D–14;

10 “(II) under a State Pharma-  
11 ceutical Assistance Program;

12 “(III) by the Indian Health Serv-  
13 ice, an Indian tribe or tribal organiza-  
14 tion, or an urban Indian organization  
15 (as defined in section 4 of the Indian  
16 Health Care Improvement Act);

17 “(IV) by a federally qualified  
18 health center (as defined in section  
19 1861(aa)(4));

20 “(V) under an AIDS Drug As-  
21 sistance Program under part B of  
22 title XXVI of the Public Health Serv-  
23 ice Act;

24 “(VI) by a subsection (d) hos-  
25 pital (as defined in section

1 1886(d)(1)(B)) that meets the re-  
2 quirements of clauses (i) and (ii) of  
3 section 340B(a)(4)(L) of the Public  
4 Health Service Act; or

5 “(VII) by a pharmaceutical man-  
6 ufacturer patient assistance program,  
7 either directly or through the distribu-  
8 tion or donation of covered part D  
9 drugs, which shall be valued at the  
10 negotiated price of such covered part  
11 D drug under the enrollee’s prescrip-  
12 tion drug plan or MA–PD plan as of  
13 the date that the drug was distributed  
14 or donated.”.

15 (b) EFFECTIVE DATE.—The amendments made by  
16 subsection (a) shall apply to costs incurred on or after  
17 January 1, 2006.

18 **SEC. 3. PROVIDING A SAFE HARBOR FOR PHARMA-**  
19 **CEUTICAL MANUFACTURER PATIENT ASSIST-**  
20 **ANCE PROGRAMS.**

21 (a) SAFE HARBOR.—Section 1128B(b)(3) of the So-  
22 cial Security Act (42 U.S.C. 1320a–7b(b)(3)) is amend-  
23 ed—

24 (1) in subparagraph (G), by striking “and” at  
25 the end;

1           (2) in subparagraph (H), as added by section  
2           237(d) of the Medicare Prescription Drug, Improve-  
3           ment, and Modernization Act of 2003 (Public Law  
4           108–173; 117 Stat. 2213)—

5                   (A) by moving such subparagraph 2 ems to  
6           the left; and

7                   (B) by striking the period at the end and  
8           inserting a semicolon;

9           (3) by redesignating subparagraph (H), as  
10          added by section 431(a) of the Medicare Prescrip-  
11          tion Drug, Improvement, and Modernization Act of  
12          2003 (Public Law 108–173; 117 Stat. 2287), as  
13          subparagraph (I);

14          (4) in subparagraph (I), as so redesignated—

15                   (A) by moving such subparagraph 2 ems to  
16          the left; and

17                   (B) by striking the period at the end and  
18          inserting “; and”; and

19          (5) by adding at the end the following new sub-  
20          paragraph:

21                   “(J) any remuneration paid by a pharma-  
22          ceutical manufacturer patient assistance program,  
23          either in cash or through the distribution or dona-  
24          tion of covered Part D drugs (as defined in section  
25          1860D–2(e)), to an individual enrolled in a prescrip-

1       tion drug plan under part D of title XVIII or in an  
2       MA–PD plan under part C of such title.”.

3       (b) **EFFECTIVE DATE.**—The amendments made by  
4 subsection (a) shall apply to remuneration paid on or after  
5 January 1, 2006.

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