

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 3290  
OFFERED BY MR. BUCSHON OF INDIANA**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “340B Transparency  
3 Act”.

**4 SEC. 2. ENSURING TRANSPARENCY AND OVERSIGHT OF  
5 THE 340B DRUG DISCOUNT PROGRAM.**

6 (a) IN GENERAL.—Section 340B(a)(5) of the Public  
7 Health Service Act (42 U.S.C. 256b(a)(5)) is amended—

8 (1) in subparagraph (C)—

9 (A) by striking “A covered entity shall per-  
10 mit” and inserting:

11 “(i) DUPLICATE DISCOUNTS AND  
12 DRUG RESALE.—A covered entity shall per-  
13 mit”; and

14 (B) by adding at the end the following new  
15 clauses:

16 “(ii) USE OF SAVINGS.—A covered en-  
17 tity shall permit the Secretary to audit, at

1 the Secretary's expense, the records of the  
2 entity to determine—

3 “(I) how savings (as defined in  
4 subparagraph (E)(iv)) from covered  
5 outpatient drugs subject to an agree-  
6 ment under this section furnished by  
7 such entity are used by such entity;  
8 and

9 “(II) such entity's compliance  
10 with subparagraph (E).

11 “(iii) RECORDS RETENTION.—Covered  
12 entities shall retain such records and pro-  
13 vide such records and reports as deter-  
14 mined necessary by the Secretary for car-  
15 rying out this subparagraph.”; and

16 (2) by adding at the end the following new sub-  
17 paragraph:

18 “(E) REPORTING.—

19 “(i) IN GENERAL.—During the first  
20 year beginning on or after the date that is  
21 14 months after the date of enactment of  
22 this subparagraph and during each subse-  
23 quent year, each covered entity described  
24 in subparagraph (L) of paragraph (4) (and  
25 any other covered entity specified by the

1 Secretary) shall report to the Secretary (at  
2 a time and in a form and manner specified  
3 by the Secretary) the following information  
4 with respect to the preceding year:

5 “(I) With respect to such covered  
6 entity and each off-campus outpatient  
7 department, as applicable, of such en-  
8 tity—

9 “(aa) the total number of  
10 individuals who were dispensed or  
11 administered covered outpatient  
12 drugs during such preceding year  
13 that were subject to an agree-  
14 ment under this section; and

15 “(bb) the number of such in-  
16 dividuals described in a category  
17 specified in clause (iv), broken  
18 down by each such category.

19 “(II) With respect to such cov-  
20 ered entity and each off-campus out-  
21 patient department, as applicable, of  
22 such entity—

23 “(aa) the percentage of the  
24 total number of individuals fur-  
25 nished items and services during

1 such preceding year who were  
2 dispensed or administered cov-  
3 ered outpatient drugs during  
4 such preceding year that were  
5 subject to an agreement under  
6 this section; and

7 “(bb) for each category  
8 specified in clause (iii), the per-  
9 centage of the total number of  
10 individuals described in such cat-  
11 egory furnished items and serv-  
12 ices during such preceding year  
13 who were dispensed or adminis-  
14 tered covered outpatient drugs  
15 during such preceding year that  
16 were subject to an agreement  
17 under this section.

18 “(III) With respect to such cov-  
19 ered entity and each off-campus out-  
20 patient department, as applicable, of  
21 such entity, the total costs incurred  
22 during the year at each such site and  
23 the cost incurred at each such site for  
24 charity care (as defined in line 23 of

1 worksheet S-10 to the Medicare cost  
2 report, or in any successor form).

3 “(IV) With respect to such cov-  
4 ered entity and each off-campus out-  
5 patient department, as applicable, of  
6 such entity, the costs incurred during  
7 the year of furnishing items and serv-  
8 ices at each such department to pa-  
9 tients of such entity who were entitled  
10 to benefits under part A of title XVIII  
11 of the Social Security Act or enrolled  
12 under part B of such title, enrolled in  
13 a State plan under title XIX of such  
14 Act (or a waiver of such plan), or who  
15 were uninsured for services, minus the  
16 sum of—

17 “(aa) payments under title  
18 XVIII of such Act for such items  
19 and services (including any cost  
20 sharing for such items and serv-  
21 ices);

22 “(bb) payments under title  
23 XIX of such Act for such items  
24 and services (including any cost

1 sharing for such items and serv-  
2 ices); and

3 “(cc) payments by uninsured  
4 patients for such items and serv-  
5 ices.

6 “(V) With respect to such cov-  
7 ered entity and each off-campus out-  
8 patient department, as applicable, of  
9 such entity, savings (as defined in  
10 clause (iv)) from covered outpatient  
11 drugs subject to an agreement under  
12 this section furnished by such entity  
13 or department.

14 “(ii) PUBLICATION.—The Secretary  
15 shall publish data reported under clause (i)  
16 with respect to a year annually on the pub-  
17 lic website of the Department of Health  
18 and Human Services in an electronic and  
19 searchable format, which may include the  
20 340B Office of Pharmacy Affairs Informa-  
21 tion System (or a successor to such sys-  
22 tem), in a manner that shows each cat-  
23 egory of data reported in the aggregate  
24 and identified by the specific covered entity  
25 submitting such data. The Secretary shall

1 include in such publication the dispropor-  
2 tionate patient percentage (as defined in  
3 section 1886(d)(5)(F)(vi) of the Social Se-  
4 curity Act) of each such covered entity (if  
5 applicable) for each cost reporting period  
6 occurring during such year.

7 “(iii) CATEGORIES SPECIFIED.—For  
8 purposes of clause (i), the categories speci-  
9 fied in this clause are the following:

10 “(I) Individuals covered under a  
11 group health plan or group or indi-  
12 vidual health insurance coverage (as  
13 such terms are defined in section  
14 2791).

15 “(II) Individuals entitled to bene-  
16 fits under part A or enrolled under  
17 part B of title XVIII of the Social Se-  
18 curity Act.

19 “(III) Individuals enrolled under  
20 a State plan under title XIX of such  
21 Act (or a waiver of such plan).

22 “(IV) Individuals enrolled under  
23 a State child health plan under title  
24 XXI of such Act (or a waiver of such  
25 plan).

1                   “(V) Individuals not described in  
2                   any preceding subclause and not cov-  
3                   ered under any Federal health care  
4                   program (as defined in section 1128B  
5                   of such Act but including the program  
6                   established under chapter 89 of title  
7                   5, United States Code).

8                   “(iv) DEFINITIONS.—For purposes of  
9                   this subparagraph:

10                   “(I) OFF-CAMPUS OUTPATIENT  
11                   DEPARTMENT.—The term ‘off-campus  
12                   outpatient department’ means a de-  
13                   partment of a provider (as defined in  
14                   section 413.65 of title 42, Code of  
15                   Federal Regulations, or any successor  
16                   regulation) that is not located—

17                   “(aa) on the campus (as de-  
18                   fined in such section) of such  
19                   provider; or

20                   “(bb) within the distance  
21                   (described in such definition of  
22                   campus) from a remote location  
23                   of a hospital facility (as defined  
24                   in such section).



1                   “(II) SAVINGS.—The term ‘sav-  
2                   ings’ means, with respect to a covered  
3                   outpatient drug purchased by a cov-  
4                   ered entity, the difference between—  
5                   “(aa) the price for such  
6                   drug that such entity would have  
7                   otherwise paid for such drug ob-  
8                   tained through a group pur-  
9                   chasing organization or other  
10                  group purchasing arrangement  
11                  had the requirement described in  
12                  paragraph (4)(L)(iii) not applied  
13                  (or, in the case such entity would  
14                  not have obtained covered out-  
15                  patient drugs through such an  
16                  organization or arrangement had  
17                  such requirement not applied or  
18                  information to determine such  
19                  price that such entity would have  
20                  so otherwise paid is not available,  
21                  the wholesale acquisition cost (as  
22                  defined            in            section  
23                  1847A(c)(6)(B) of the Social Se-  
24                  curity Act) for such drug); and

1                                   “(bb) the ceiling price for  
2                                   such drug.”.

3           (b) ENFORCEMENT.—Section 340B(d)(2)(B) of the  
4 Public Health Service Act (42 U.S.C. 256b(d)(2)(B)) is  
5 amended by adding at the end the following new clause:

6                                   “(vi) The imposition of civil monetary  
7                                   penalties in amounts determined appro-  
8                                   priate by the Secretary in the case that the  
9                                   Secretary determines that a covered entity  
10                                  is not in compliance with subsection  
11                                  (a)(5)(E) .”.

12           (c) RULEMAKING.—Not later than 180 days after the  
13 date of the enactment of this Act, the Secretary of Health  
14 and Human Services shall issue an interim final rule to  
15 carry out section 340B(a)(5)(E) of the Public Health  
16 Service Act, as added by subsection (a)(2).

