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(Original Signature of Member)

118TH CONGRESS  
1ST SESSION

**H. R.**

To amend title III of the Public Health Service Act to ensure transparency  
and oversight of the 340B drug discount program.

IN THE HOUSE OF REPRESENTATIVES

Mr. BUCSHON introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

**A BILL**

To amend title III of the Public Health Service Act to  
ensure transparency and oversight of the 340B drug  
discount 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. ENSURING TRANSPARENCY AND OVERSIGHT**  
4 **OF THE 340B DRUG DISCOUNT PROGRAM.**

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

7 (1) in subparagraph (C)—

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

3 “(i) DUPLICATE DISCOUNTS AND  
4 DRUG RESALE.—A covered entity shall per-  
5 mit”; and

6 (B) by adding at the end the following new  
7 clauses:

8 “(ii) USE OF SAVINGS.—A covered en-  
9 tity shall permit the Secretary to audit, at  
10 the Secretary’s expense, the records of the  
11 entity to determine how savings (as defined  
12 in subparagraph (E)(iii)) from drugs sub-  
13 ject to an agreement under this section  
14 furnished by such entity is used by such  
15 entity.

16 “(iii) RECORDS RETENTION.—Covered  
17 entities shall retain such records and pro-  
18 vide such records and reports as deter-  
19 mined necessary by the Secretary for car-  
20 rying out this subparagraph.”; and

21 (2) by adding at the end the following new sub-  
22 paragraph:

23 “(E) REPORTING.—

24 “(i) IN GENERAL.—During the first  
25 year beginning on or after the date that is

1           14 months after the date of enactment of  
2           this subparagraph and during each subse-  
3           quent year, each covered entity described  
4           in subparagraph (L) of paragraph (4) (and  
5           any other covered entity specified by the  
6           Secretary) shall report to the Secretary (at  
7           a time and in a form and manner specified  
8           by the Secretary) the following information  
9           with respect to the preceding year:

10                   “(I) With respect to such covered  
11                   entity and each off-campus outpatient  
12                   department of such entity—

13                           “(aa) the total number of  
14                           individuals who were dispensed or  
15                           administered drugs during such  
16                           preceding year that were subject  
17                           to an agreement under this sec-  
18                           tion; and

19                           “(bb) the number of such in-  
20                           dividuals described in a category  
21                           specified in clause (iv), broken  
22                           down by each such category.

23                   “(II) With respect to such cov-  
24                   ered entity and each off-campus out-  
25                   patient department of such entity—

1                   “(aa) the percentage of the  
2                   total number of individuals fur-  
3                   nished items and services during  
4                   such preceding year who were  
5                   dispensed or administered drugs  
6                   during such preceding year that  
7                   were subject to an agreement  
8                   under this section; and

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

19                  “(III) With respect to such cov-  
20                  ered entity and each off-campus out-  
21                  patient department of such entity, the  
22                  total costs incurred during the year at  
23                  each such site and the cost incurred  
24                  at each such site for charity care (as  
25                  defined in line 23 of worksheet S-10

1 to the Medicare cost report, or in any  
2 successor form).

3 “(IV) With respect to such cov-  
4 ered entity and each off-campus out-  
5 patient department of such entity, the  
6 costs incurred during the year of fur-  
7 nishing items and services at each  
8 such department to patients of such  
9 entity who were entitled to benefits  
10 under part A of title XVIII of the So-  
11 cial Security Act or enrolled under  
12 part B of such title, enrolled in a  
13 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 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 of such entity,  
9 savings (as defined in clause (v)) from  
10 drugs subject to an agreement under  
11 this section furnished by such entity  
12 or department.

13 “(ii) PUBLICATION.—The Secretary  
14 shall publish data reported under clause (i)  
15 annually on the public website of the De-  
16 partment of Health and Human Services  
17 in an electronic and searchable format,  
18 which may include the 340B Office of  
19 Pharmacy Affairs Information System (or  
20 a successor to such system), and in a man-  
21 ner that shows each category of data re-  
22 ported in the aggregate and identified by  
23 the specific covered entity submitting such  
24 data.

1           “(iii) AUDIT OF RECORDS.—A covered  
2           entity shall permit the Secretary to audit,  
3           at the Secretary’s expense, the records of  
4           the entity that directly pertain to the enti-  
5           ty’s compliance with the requirement of  
6           clause (i).

7           “(iv) 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 who entitled to  
16           benefits under part A or enrolled  
17           under part B of title XVIII of the So-  
18           cial Security Act.

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

22           “(IV) Individuals who were en-  
23           rolled under a State child health plan  
24           under title XXI of such Act (or a  
25           waiver of such 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                   “(v) 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 drug  
3                   purchased by a covered entity, the dif-  
4                   ference 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, the  
18                  wholesale acquisition cost (as de-  
19                  fined in section 1847A(c)(6)(B)  
20                  of the Social Security Act) for  
21                  such drug); and

22                  “(bb) the ceiling price for  
23                  such drug.”.

24                  (b) RULEMAKING.—Not later than 180 days after the  
25                  date of the enactment of this Act, the Secretary of Health

1 and Human Services shall issue an interim final rule to  
2 carry out section 340B(a)(5)(E) of the Public Health  
3 Service Act, as added by subsection (a)(3).