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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).