

118TH CONGRESS
1ST SESSION

H. R. 3290

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

MAY 15, 2023

Mr. BUCSHON introduced the following bill; which was referred to the Committee on Energy and Commerce

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)—

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

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

4 (B) by adding at the end the following new
5 clauses:

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

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

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

21 “(E) REPORTING.—

22 “(i) IN GENERAL.—During the first
23 year beginning on or after the date that is
24 14 months after the date of enactment of
25 this subparagraph and during each subse-

1 quent year, each covered entity described
2 in subparagraph (L) of paragraph (4) (and
3 any other covered entity specified by the
4 Secretary) shall report to the Secretary (at
5 a time and in a form and manner specified
6 by the Secretary) the following information
7 with respect to the preceding year:

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

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

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

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

24 “(aa) the percentage of the
25 total number of individuals fur-

1 nished items and services during
2 such preceding year who were
3 dispensed or administered drugs
4 during such preceding year that
5 were subject to an agreement
6 under this section; and

7 “(bb) for each category
8 specified in clause (iv), 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 drugs during such pre-
15 ceeding year that were subject to
16 an agreement under this section.

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

1 “(IV) With respect to such cov-
2 ered entity and each off-campus out-
3 patient department of such entity, the
4 costs incurred during the year of fur-
5 nishing items and services at each
6 such department to patients of such
7 entity who were entitled to benefits
8 under part A of title XVIII of the So-
9 cial Security Act or enrolled under
10 part B of such title, enrolled in a
11 State plan under title XIX of such
12 Act (or a waiver of such plan), or who
13 were uninsured for services, minus the
14 sum of—

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

20 “(bb) payments under title
21 XIX of such Act for such items
22 and services (including any cost
23 sharing for such items and serv-
24 ices); and

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

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

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

23 “(iii) AUDIT OF RECORDS.—A covered
24 entity shall permit the Secretary to audit,
25 at the Secretary’s expense, the records of

1 the entity that directly pertain to the enti-
2 ty's compliance with the requirement of
3 clause (i).

4 “(iv) CATEGORIES SPECIFIED.—For
5 purposes of clause (i), the categories speci-
6 fied in this clause are the following:

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

12 “(II) Individuals who are entitled
13 to benefits under part A or enrolled
14 under part B of title XVIII of the So-
15 cial Security Act.

16 “(III) Individuals who enrolled
17 under a State plan under title XIX of
18 such Act (or a waiver of such plan).

19 “(IV) Individuals who were en-
20 rolled under a State child health plan
21 under title XXI of such Act (or a
22 waiver of such plan).

23 “(V) Individuals not described in
24 any preceding subclause and not cov-
25 ered under any Federal health care

1 program (as defined in section 1128B
2 of such Act but including the program
3 established under chapter 89 of title
4 5, United States Code).

5 “(v) DEFINITIONS.—For purposes of
6 this subparagraph:

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

14 “(aa) on the campus (as de-
15 fined in such section) of such
16 provider; or

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

22 “(II) SAVINGS.—The term ‘sav-
23 ings’ means, with respect to a drug
24 purchased by a covered entity, the dif-
25 ference between—

1 “(aa) the price for such
2 drug that such entity would have
3 otherwise paid for such drug ob-
4 tained through a group pur-
5 chasing organization or other
6 group purchasing arrangement
7 had the requirement described in
8 paragraph (4)(L)(iii) not applied
9 (or, in the case such entity would
10 not have obtained covered out-
11 patient drugs through such an
12 organization or arrangement had
13 such requirement not applied, the
14 wholesale acquisition cost (as de-
15 fined in section 1847A(c)(6)(B)
16 of the Social Security Act) for
17 such drug); and

18 “(bb) the ceiling price for
19 such drug.”.

20 (b) RULEMAKING.—Not later than 180 days after the
21 date of the enactment of this Act, the Secretary of Health
22 and Human Services shall issue an interim final rule to
23 carry out section 340B(a)(5)(E) of the Public Health
24 Service Act, as added by subsection (a)(3).

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