

[DISCUSSION DRAFT]

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. SHORT TITLE.**

4 This Act may be cited as the “_____ Act
5 of 2023”.

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

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

5 (1) in subparagraph (C)—

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

8 “(i) DUPLICATE DISCOUNTS AND
9 DRUG RESALE.—A covered entity shall per-
10 mit”; and

11 (B) by adding at the end the following new
12 clauses:

13 “(ii) USE OF SAVINGS.—A covered en-
14 tity shall permit the Secretary to audit, at
15 the Secretary’s expense, the records of the
16 entity to determine how net revenue from
17 drugs subject to an agreement under this
18 section furnished by such entity is used by
19 such entity.

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

25 (2) by adding at the end the following new sub-
26 paragraph:

1 “(E) REPORTING.—

2 “(i) IN GENERAL.—During the first
3 year beginning on or after the date that is
4 14 months after the date of enactment of
5 this subparagraph and during each subse-
6 quent year, each covered entity described
7 in subparagraph (L) of paragraph (4) (and
8 any other covered entity specified by the
9 Secretary) shall report to the Secretary (at
10 a time and in a form and manner specified
11 by the Secretary) the following information
12 with respect to the preceding year:

13 “(I) With respect to such covered
14 entity and each child site of such enti-
15 ty—

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

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

1 “(II) With respect to such cov-
2 ered entity and each child site of such
3 entity—

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

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

22 “(III) With respect to such cov-
23 ered entity and each child site of such
24 entity, the total costs incurred during
25 the year at each such site and the cost

1 incurred at each such site for charity
2 care (as defined in line 23 of work-
3 sheet S-10 to the Medicare cost re-
4 port, or in any successor form).

5 “(IV) With respect to such cov-
6 ered entity each child site of such en-
7 tity, the costs incurred during the
8 year of furnishing items and services
9 at the child site to patients of such
10 entity who were entitled to benefits
11 under part A of title XVIII of the So-
12 cial Security Act or enrolled under
13 part B of such title, enrolled in a
14 State plan under title XIX of such
15 Act (or a waiver of such plan), or who
16 were uninsured for services, minus the
17 sum of—

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

23 “(bb) payments under title
24 XIX of such Act for such items
25 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 child site of such
8 entity, the net revenue from drugs
9 subject to an agreement under this
10 section furnished by such entity or
11 child site and how such revenue was
12 used by the covered entity.

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

24 “(iii) AUDIT OF RECORDS.—A covered
25 entity shall permit the Secretary to audit,

1 at the Secretary's expense, the records of
2 the entity that directly pertain to the enti-
3 ty's compliance with the requirement of
4 clause (i).

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

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

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

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

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

24 “(V) Individuals not described in
25 any preceding subclause and not cov-

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

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