

Union Calendar No. 628

118TH CONGRESS
2D SESSION

H. R. 3290

[Report No. 118–757]

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

NOVEMBER 20, 2024

Reported with an amendment, committed to the Committee of the Whole
House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on May 15, 2023]

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 “340B Transparency*
 5 *Act”.*

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

8 *(a) IN GENERAL.—Section 340B(a)(5) of the Public*
 9 *Health Service Act (42 U.S.C. 256b(a)(5)) is amended—*
 10 *(1) in subparagraph (C)—*

11 *(A) by striking “A covered entity shall per-*
 12 *mit” and inserting:*

13 *“(i) DUPLICATE DISCOUNTS AND DRUG*
 14 *RESALE.—A covered entity shall permit”;*
 15 *and*

16 *(B) by adding at the end the following new*
 17 *clauses:*

18 *“(ii) USE OF SAVINGS.—A covered en-*
 19 *tity shall permit the Secretary to audit, at*
 20 *the Secretary’s expense, the records of the*
 21 *entity to determine—*

22 *“(I) how savings (as defined in*
 23 *subparagraph (E)(iv)) from covered*
 24 *outpatient drugs subject to an agree-*
 25 *ment under this section furnished by*

1 *such entity are used by such entity;*
 2 *and*

3 *“(II) such entity’s compliance*
 4 *with subparagraph (E).*

5 *“(iii) RECORDS RETENTION.—Covered*
 6 *entities shall retain such records and pro-*
 7 *vide such records and reports as determined*
 8 *necessary by the Secretary for carrying out*
 9 *this subparagraph.”; and*

10 *(2) by adding at the end the following new sub-*
 11 *paragraph:*

12 *“(E) REPORTING.—*

13 *“(i) IN GENERAL.—During the first*
 14 *year beginning on or after the date that is*
 15 *14 months after the date of enactment of*
 16 *this subparagraph and during each subse-*
 17 *quent year, each covered entity described in*
 18 *subparagraph (L) of paragraph (4) (and*
 19 *any other covered entity specified by the*
 20 *Secretary) shall report to the Secretary (at*
 21 *a time and in a form and manner specified*
 22 *by the Secretary) the following information*
 23 *with respect to the preceding year:*

24 *“(I) With respect to such covered*
 25 *entity and each off-campus outpatient*

1 *department, as applicable, of such enti-*
2 *ty—*

3 *“(aa) the total number of in-*
4 *dividuals who were dispensed or*
5 *administered covered outpatient*
6 *drugs during such preceding year*
7 *that were subject to an agreement*
8 *under this section; and*

9 *“(bb) the number of such in-*
10 *dividuals described in a category*
11 *specified in clause (iv), broken*
12 *down by each such category.*

13 *“(II) With respect to such covered*
14 *entity and each off-campus outpatient*
15 *department, as applicable, of such enti-*
16 *ty—*

17 *“(aa) the percentage of the*
18 *total number of individuals fur-*
19 *nished items and services during*
20 *such preceding year who were dis-*
21 *dispensed or administered covered*
22 *outpatient drugs during such pre-*
23 *ceding year that were subject to*
24 *an agreement under this section;*
25 *and*

1 “(bb) for each category speci-
2 fied in clause (iii), the percentage
3 of the total number of individuals
4 described in such category fur-
5 nished items and services during
6 such preceding year who were dis-
7 pensed or administered covered
8 outpatient drugs during such pre-
9 ceding year that were subject to
10 an agreement under this section.

11 “(III) With respect to such cov-
12 ered entity and each off-campus out-
13 patient department, as applicable, of
14 such entity, the total costs incurred
15 during the year at each such site and
16 the cost incurred at each such site for
17 charity care (as defined in line 23 of
18 worksheet S-10 to the Medicare cost re-
19 port, or in any successor form).

20 “(IV) With respect to such covered
21 entity and each off-campus outpatient
22 department, as applicable, of such enti-
23 ty, the costs incurred during the year
24 of furnishing items and services at
25 each such department to patients of

1 *such entity who were entitled to bene-*
2 *fits under part A of title XVIII of the*
3 *Social Security Act or enrolled under*
4 *part B of such title, enrolled in a State*
5 *plan under title XIX of such Act (or a*
6 *waiver of such plan), or who were un-*
7 *insured for services, minus the sum*
8 *of—*

9 *“(aa) payments under title*
10 *XVIII of such Act for such items*
11 *and services (including any cost*
12 *sharing for such items and serv-*
13 *ices);*

14 *“(bb) payments under title*
15 *XIX of such Act for such items*
16 *and services (including any cost*
17 *sharing for such items and serv-*
18 *ices); and*

19 *“(cc) payments by uninsured*
20 *patients for such items and serv-*
21 *ices.*

22 *“(V) With respect to such covered*
23 *entity and each off-campus outpatient*
24 *department, as applicable, of such enti-*
25 *ty, savings (as defined in clause (iv))*

1 *from covered outpatient drugs subject*
2 *to an agreement under this section fur-*
3 *nished by such entity or department.*

4 “(ii) *PUBLICATION.—The Secretary*
5 *shall publish data reported under clause (i)*
6 *with respect to a year annually on the pub-*
7 *lic website of the Department of Health and*
8 *Human Services in an electronic and*
9 *searchable format, which may include the*
10 *340B Office of Pharmacy Affairs Informa-*
11 *tion System (or a successor to such system),*
12 *in a manner that shows each category of*
13 *data reported in the aggregate and identi-*
14 *fied by the specific covered entity submit-*
15 *ting such data. The Secretary shall include*
16 *in such publication the disproportionate pa-*
17 *tient percentage (as defined in section*
18 *1886(d)(5)(F)(vi) of the Social Security*
19 *Act) of each such covered entity (if applica-*
20 *ble) for each cost reporting period occurring*
21 *during such year.*

22 “(iii) *CATEGORIES SPECIFIED.—For*
23 *purposes of clause (i), the categories speci-*
24 *fied in this clause are the following:*

1 “(I) *Individuals covered under a*
2 *group health plan or group or indi-*
3 *vidual health insurance coverage (as*
4 *such terms are defined in section*
5 *2791).*

6 “(II) *Individuals entitled to bene-*
7 *fits under part A or enrolled under*
8 *part B of title XVIII of the Social Se-*
9 *curity Act.*

10 “(III) *Individuals enrolled under*
11 *a State plan under title XIX of such*
12 *Act (or a waiver of such plan).*

13 “(IV) *Individuals enrolled under*
14 *a State child health plan under title*
15 *XXI of such Act (or a waiver of such*
16 *plan).*

17 “(V) *Individuals not described in*
18 *any preceding subclause and not cov-*
19 *ered under any Federal health care*
20 *program (as defined in section 1128B*
21 *of such Act but including the program*
22 *established under chapter 89 of title 5,*
23 *United States Code).*

24 “(iv) *DEFINITIONS.—For purposes of*
25 *this subparagraph:*

1 “(I) *OFF-CAMPUS OUTPATIENT*
 2 *DEPARTMENT.*—*The term ‘off-campus*
 3 *outpatient department’ means a de-*
 4 *partment of a provider (as defined in*
 5 *section 413.65 of title 42, Code of Fed-*
 6 *eral Regulations, or any successor reg-*
 7 *ulation) that is not located—*

8 *“(aa) on the campus (as de-*
 9 *defined in such section) of such pro-*
 10 *vider; or*

11 *“(bb) within the distance (de-*
 12 *scribed in such definition of cam-*
 13 *pus) from a remote location of a*
 14 *hospital facility (as defined in*
 15 *such section).*

16 “(II) *SAVINGS.*—*The term ‘sav-*
 17 *ings’ means, with respect to a covered*
 18 *outpatient drug purchased by a covered*
 19 *entity, the difference between—*

20 *“(aa) the price for such drug*
 21 *that such entity would have other-*
 22 *wise paid for such drug obtained*
 23 *through a group purchasing orga-*
 24 *nization or other group pur-*
 25 *chasing arrangement had the re-*

1 requirement described in paragraph
2 (4)(L)(iii) not applied (or, in the
3 case such entity would not have
4 obtained covered outpatient drugs
5 through such an organization or
6 arrangement had such require-
7 ment not applied or information
8 to determine such price that such
9 entity would have so otherwise
10 paid is not available, the whole-
11 sale acquisition cost (as defined in
12 section 1847A(c)(6)(B) of the So-
13 cial Security Act) for such drug);
14 and

15 “(bb) the ceiling price for
16 such drug.”.

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

20 “(vi) The imposition of civil monetary
21 penalties in amounts determined appro-
22 priate by the Secretary in the case that the
23 Secretary determines that a covered entity
24 is not in compliance with subsection
25 (a)(5)(E) .”.

1 (c) *RULEMAKING.*—Not later than 180 days after the
2 date of the enactment of this Act, the Secretary of Health
3 and Human Services shall issue an interim final rule to
4 carry out section 340B(a)(5)(E) of the Public Health Serv-
5 ice Act, as added by subsection (a)(2).

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