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

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

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

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

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

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

“(E) **REPORTING.**—

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

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

“(aa) the total number of individuals who were dispensed or administered drugs during such preceding year that were subject to an agreement under this section; and

“(bb) the number of such individuals described in a category specified in clause (iv), broken down by each such category.

“(II) With respect to such covered entity and each off-campus outpatient department of such entity—
“(aa) the percentage of the total number of individuals furnished items and services during such preceding year who were dispensed or administered drugs during such preceding year that were subject to an agreement under this section; and

“(bb) for each category specified in clause (iv), the percentage of the total number of individuals described in such category furnished items and services during such preceding year who were dispensed or administered drugs during such preceding year that were subject to an agreement under this section.

“(III) With respect to such covered entity and each off-campus outpatient department of such entity, the total costs incurred during the year at each such site and the cost incurred at each such site for charity care (as defined in line 23 of worksheet S–10
to the Medicare cost report, or in any successor form).

“(IV) With respect to such covered entity and each off-campus outpatient department of such entity, the costs incurred during the year of furnishing items and services at each such department to patients of such entity who were entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title, enrolled in a State plan under title XIX of such Act (or a waiver of such plan), or who were uninsured for services, minus the sum of—

“(aa) payments under title XVIII such Act for such items and services (including any cost sharing for such items and services);

“(bb) payments under title XIX of such Act for such items and services (including any cost
sharing for such items and services); and

“(cc) payments by uninsured patients for such items and services.

“(V) With respect to such covered entity and each off-campus outpatient department of such entity, savings (as defined in clause (v)) from drugs subject to an agreement under this section furnished by such entity or department.

“(ii) Publication.—The Secretary shall publish data reported under clause (i) annually on the public website of the Department of Health and Human Services in an electronic and searchable format, which may include the 340B Office of Pharmacy Affairs Information System (or a successor to such system), and in a manner that shows each category of data reported in the aggregate and identified by the specific covered entity submitting such data.
“(iii) Audit of Records.—A covered entity shall permit the Secretary to audit, at the Secretary’s expense, the records of the entity that directly pertain to the entity’s compliance with the requirement of clause (i).

“(iv) Categories Specified.—For purposes of clause (i), the categories specified in this clause are the following:

“(I) Individuals covered under a group health plan or group or individual health insurance coverage (as such terms are defined in section 2791).

“(II) Individuals who entitled to benefits under part A or enrolled under part B of title XVIII of the Social Security Act.

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

“(IV) Individuals who were enrolled under a State child health plan under title XXI of such Act (or a waiver of such plan).
“(V) Individuals not described in any preceding subclause and not covered under any Federal health care program (as defined in section 1128B of such Act but including the program established under chapter 89 of title 5, United States Code).

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

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

“(aa) on the campus (as defined in such section) of such provider; or

“(bb) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section).
“(II) SAVINGS.—The term ‘savings’ means, with respect to a drug purchased by a covered entity, the difference between—

“(aa) the price for such drug that such entity would have otherwise paid for such drug obtained through a group purchasing organization or other group purchasing arrangement had the requirement described in paragraph (4)(L)(iii) not applied (or, in the case such entity would not have obtained covered outpatient drugs through such an organization or arrangement had such requirement not applied, the wholesale acquisition cost (as defined in section 1847A(c)(6)(B) of the Social Security Act) for such drug); and

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

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