AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 3290
OFFERED BY MR. BUCSHON OF INDIANA

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “340B Transparency Act”.

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

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

(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—

“(I) how savings (as defined in subparagraph (E)(iv)) from covered outpatient drugs subject to an agreement under this section furnished by such entity are used by such entity; and

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

“(iii) RECORDS RETENTION.—Covered entities shall retain such records and provide such records and reports as determined necessary by the Secretary for carrying out this subparagraph.”; and

(2) by adding at the end the following new subparagraph:

“(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, as applicable, of such entity—

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

“(bb) for each category specified in clause (iii), 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 covered outpatient 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, as applicable, 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, as applicable, 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 of 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, as applicable, of such entity, savings (as defined in clause (iv)) from covered outpatient 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) with respect to a year 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), in a manner that shows each category of data reported in the aggregate and identified by the specific covered entity submitting such data. The Secretary shall
include in such publication the disproportionate patient percentage (as defined in section 1886(d)(5)(F)(vi) of the Social Security Act) of each such covered entity (if applicable) for each cost reporting period occurring during such year.

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

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

“(IV) Individuals 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).

“(iv) 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 covered outpatient 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 or information to determine such price that such entity would have so otherwise paid is not available, the wholesale acquisition cost (as defined in section 1847A(e)(6)(B) of the Social Security Act) for such drug); and
“(bb) the ceiling price for such drug.”.

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

“(vi) The imposition of civil monetary penalties in amounts determined appropriate by the Secretary in the case that the Secretary determines that a covered entity is not in compliance with subsection (a)(5)(E).”.

(c) 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)(2).