

115TH CONGRESS
2D SESSION

H. R. 6071

To amend the Public Health Service Act to clarify the intent of the 340B program and provide for enhanced 340B program integrity, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 12, 2018

Ms. MATSUI introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act to clarify the intent of the 340B program and provide for enhanced 340B program integrity, and for other purposes.

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 “Stretching Entity Re-
5 sources for Vulnerable Communities Act” or the “SERV
6 Communities Act”.

1 **SEC. 2. SENSE OF CONGRESS RELATED TO PURPOSE OF**
2 **THE 340B PROGRAM.**

3 It is the sense of Congress that—

4 (1) the program under section 340B of the
5 Public Health Service Act (42 U.S.C. 256b) (in this
6 section referred to as the “340B program”) enables
7 covered entities to stretch scarce resources as far as
8 possible, reaching more patients and providing more
9 comprehensive services than without such program;

10 (2) the 340B program provides health care set-
11 tings that serve a disproportionate share of under-
12 served patient populations (referred to as covered
13 entities) a discount from drug manufacturers on the
14 covered outpatient drugs they purchase to meet
15 health care needs of the community;

16 (3) covered entities that qualify for participa-
17 tion under the 340B program meet rigorous eligi-
18 bility criteria, proving they are safety net health care
19 providers for many underserved patients;

20 (4) such discounts are provided to such covered
21 entities on the basis of meeting eligibility criteria
22 under the 340B program, and not directly to indi-
23 vidual patients;

24 (5) the 340B Program enables covered entities
25 to provide comprehensive services to the commu-
26 nities they serve, which may include providing free

1 or discounted drugs to vulnerable populations, but
2 providing free or discounted drugs to patients is not
3 the sole purpose of the program;

4 (6) the 340B Program is designed to help cov-
5 ered entities promote health for underserved commu-
6 nities and patients, regardless of a particular pa-
7 tient's insurance status or inability to pay;

8 (7) savings from the 340B program are used by
9 covered entities to reach more patients and provide
10 more comprehensive services, and covered entities
11 are in the best position to assess the use of their
12 savings for community needs; and

13 (8) drugs purchased under the 340B program
14 account for a small proportion of overall drug spend-
15 ing and the discounts described in paragraph (2)
16 provided through the 340B program are not funded
17 by taxpayers.

18 **SEC. 3. CODIFYING DEFINITION OF PATIENT UNDER 340B**
19 **PROGRAM.**

20 Section 340B(b) of the Public Health Service Act (42
21 U.S.C. 256b) is amended by adding at the end the fol-
22 lowing new paragraph:

23 “(3) PATIENT.—

24 “(A) IN GENERAL.—For purposes of car-
25 rying out this section, the term ‘patient’ shall

1 have the definition given to such term on pages
2 55156 through 55158 of title 61 of the Federal
3 Register published on October 24, 1996.

4 “(B) CLARIFICATION.—For purposes of
5 this section, the Secretary shall not implement
6 the definition under subparagraph (A) more
7 narrowly than the definition specified in sub-
8 paragraph (A), including by limiting the appli-
9 cation of the definition to particular individuals
10 based on their insurance status.”.

11 **SEC. 4. NON-DISCRIMINATION WITH RESPECT TO COVERED
12 ENTITIES.**

13 Section 340B of the Public Health Service Act (42
14 U.S.C. 256b) is amended by adding at the end the fol-
15 lowing new subsection:

16 “(f) NON-DISCRIMINATION WITH RESPECT TO COV-
17 ERED ENTITIES.—

18 “(1) TERMS OF AGREEMENT.—Subject to para-
19 graph (3), no entity that reimburses a covered entity
20 or its contract pharmacy for drugs that are subject
21 to an agreement under this section may discriminate
22 against such covered entity with respect to the terms
23 of such reimbursement, including terms relating to
24 the level and amount of reimbursement, on the basis

1 that the covered entity participates in the program
2 under this section.

3 “(2) PATIENT’S CHOICE.—With respect to a pa-
4 tient eligible to receive drugs that are subject to an
5 agreement under this section from a covered entity
6 or its contract pharmacy, no entity that makes pay-
7 ment for such drugs shall discriminate against the
8 covered entity or its contract pharmacy in a manner
9 that prevents or interferes with the patient’s choice
10 to receive such drugs from the covered entity or con-
11 tract pharmacy.

12 “(3) EXCEPTION.—Paragraph (1) shall not
13 apply to States with respect to retail drugs that are
14 reimbursed by the State on a fee-for-service basis
15 pursuant to a State plan approved under title XIX
16 of the Social Security Act.”.

17 **SEC. 5. PROGRAM INTEGRITY.**

18 (a) FINDINGS.—Congress finds the following:

19 (1) In response to findings by the Office of the
20 Inspector General of the Department of Health and
21 Human Services that nearly 100 percent of covered
22 entities were overcharged by manufacturers for at
23 least one of the drugs reviewed, Congress directed
24 the Secretary of Health and Human Services in
25 2010 to publish the ceiling prices under section

1 340B of the Public Health Service Act (42 U.S.C.
2 256b) (in this section referred to as the “340B ceil-
3 ing price”) via Internet website so that covered enti-
4 ties could verify they were being charged the correct
5 price, however this website has not yet been estab-
6 lished, leaving covered entities vulnerable to con-
7 tinuing manufacturer overcharges.

8 (2) In response to findings by the Office of the
9 Inspector General of the Department of Health and
10 Human Services of widespread overcharges by man-
11 ufacturers and a lack of oversight and authority by
12 the Secretary of Health and Human Services to en-
13 sure that covered entities paid no more than the
14 340B ceiling price, Congress directed the Secretary
15 to develop standards for calculating 340B ceiling
16 prices and civil monetary penalties to apply to man-
17 ufacturers that violate these rules, however those
18 standards and penalties have not yet been developed,
19 significantly limiting the Secretary’s ability to over-
20 see manufacturer compliance with such section 340B
21 of the Public Health Service Act (42 U.S.C. 256b).

22 (3) There is no public transparency on drug
23 manufacturers’ average manufacturer price, best
24 price in the marketplace, or how much the average

1 manufacturer price of a drug has increased relative
2 to the rate of inflation.

3 (4) Information on the average manufacturer
4 price and best price are reported to the Centers for
5 Medicare & Medicaid Services, but rarely does the
6 Federal Government audit the raw data underlying
7 those calculations.

8 (5) Such data is not submitted and reviewed by
9 the Health Resources and Services Administration
10 as part of a 340B program audit.

11 (6) Furthermore, the Office of Pharmacy Af-
12 fairs has conducted only 11 total audits of manufac-
13 turers.

14 (b) PARITY IN AUDITS BETWEEN MANUFACTURER
15 AND HOSPITAL AUDITS.—Section 340B(d)(1)(B)(v) of
16 the Public Health Service Act (42 U.S.C.
17 256b(d)(1)(B)(v)) is amended to read as follows:

18 “(v) Selective auditing of manufactur-
19 ers and wholesalers to ensure the integrity
20 of the drug discount program under this
21 section, consistent with the following:

22 “(I) Such audits shall be con-
23 ducted in a form and manner that, to
24 the greatest extent practicable, results
25 in parity between such audits and au-

1 dits under subsection (a)(5)(C) of cov-
2 ered entities, as measured by com-
3 paring the percentage of total manu-
4 facturer audits under this clause to
5 the percentage of total audits con-
6 ducted under such subsection of cov-
7 ered entities described in subsection
8 (a)(4)(L).

(c) DEADLINE FOR INTERNET WEBSITE WITH APPLICABLE CEILING PRICES FOR COVERED OUTPATIENT DRUGS.—Section 340B(d)(1)(B)(iii) of the Public Health Service Act (42 U.S.C. 256b(d)(1)(B)(iii)) is amended by striking “The provision” and inserting “Not later than 90 days after the date of the enactment of the Stretching Entity Resources for Vulnerable Community Act, the provision”.

23 (d) CIVIL MONETARY PENALTY.—

24 (1) IN GENERAL.—Clause (vi)(II) of section
25 340B(d)(1)(B) of the Public Health Service Act (42

1 U.S.C. 256b(d)(1)(B)) is amended to read as fol-
2 lows:

3 “(II) shall not exceed, for each
4 instance of overcharging a covered en-
5 tity that may have occurred, the
6 greater of—

7 “(aa) \$5,000; or
8 “(bb) 200 percent of the
9 amount of such overcharge; and”.

10 (2) CLARIFICATIONS.—Section 340B(d)(1) of
11 the Public Health Service Act (42 U.S.C.
12 256b(d)(1)) is amended by adding at the end the
13 following new subparagraph:

14 “(C) CLARIFICATIONS.—For purposes of
15 subparagraph (B)(vi)—

16 “(i) an instance of overcharging de-
17 scribed in subclause (II) of such subpara-
18 graph shall—

19 “(I) apply to each unit of a na-
20 tional drug code within an order,
21 whether placed directly with a manu-
22 facturer or through a wholesaler, au-
23 thorized distributor, or agent, and
24 may not be offset by other discounts
25 provided on any other National Drug

Code or discounts provided on the same National Drug Code on other transactions, orders or purchases; and

“(II) include a manufacturer’s failure, such as through a limited distribution network, to offer a covered outpatient drug to a covered entity at the 340B ceiling price to the same extent the manufacturer makes the drug available to non-340B providers, unless such action is taken to narrowly address an actual or imminent shortage and has been approved in advance by the Secretary pursuant to standards issued through an appropriate policy or regulatory issuance; and

“(ii) in applying subclause (III) of such subparagraph—

“(I) the term ‘knowingly’ shall have the meaning given the term ‘should know’ in section 1003.101 of title 42 of the Code of Federal Regulations (or any successor regulation); and

1 “(II) the term ‘intentionally’
2 means, with respect to an overcharge,
3 that such overcharge is not due to in-
4 advertent error.”.

5 (3) NON-APPLICATION OF 340B CEILING PRICE
6 AND CMP REGULATION.—The Secretary of Health
7 and Human Services shall not take any action to im-
8 plement, administer, or enforce the provision of the
9 final regulation titled “340B Drug Pricing Program
10 Ceiling Price and Manufacturer Civil Monetary Pen-
11 alties Regulation” published on June 5, 2018 (83
12 Fed. Reg. 25943 et seq.), that changes the effective
13 date of the 340B Drug Pricing Program Ceiling
14 Price and Manufacturer Civil Monetary Penalties
15 Regulation from July 1, 2018 to July 1, 2019. The
16 effective date shall be determined as if such final
17 regulation published on June 5, 2018, did not apply.

18 (4) IMPLEMENTATION.—The Secretary of
19 Health and Human Services shall implement the
20 amendments made by paragraphs (1) and (2) by
21 program instruction or otherwise such that such
22 amendment applies to instances of overcharges oc-
23 curring on or after the date that is 60 days after the
24 date of the enactment of this Act.

1 (5) GAO REPORT.—Not later than one year
2 after the date of the enactment of this Act, the
3 Comptroller General of the United States shall sub-
4 mit to Congress a report evaluating the extent to
5 which the Secretary of Health and Human Services
6 is carrying out the provisions of clause (vi) of section
7 340B(d)(1)(B) of the Public Health Service Act (42
8 U.S.C. 256b(d)(1)(B)), as amended by this sub-
9 section.

10 (e) MANUFACTURER TRANSPARENCY.—Section
11 340B(d)(1)(B) of the Public Health Service Act (42
12 U.S.C. 256b(d)(1)(B)) is amended by adding at the end
13 the following new clauses:

14 “(vii) The requirement that the appli-
15 cable ceiling price described in clause (iii)
16 for a covered outpatient drug, with respect
17 to a calendar quarter, shall be equal to the
18 average manufacturer price under section
19 1927(k)(1) of the Social Security Act from
20 the preceding calendar quarter for the
21 smallest unit of measure minus the unit
22 rebate amount and will be calculated using
23 six decimal places and will be published by
24 the Secretary rounded to two decimal
25 places, in accordance with the following:

1 “(I) In the case that the ceiling
2 price calculation results in an amount
3 less than \$0.01, the ceiling price will
4 be \$0.01.

5 “(II) For a new covered out-
6 patient drug—

7 “(aa) manufacturers shall
8 estimate the ceiling price as of
9 the date the new drug is first
10 available for sale;

11 “(bb) the estimation shall be
12 calculated as wholesale acquisi-
13 tion cost minus the appropriate
14 rebate percentage until an aver-
15 age manufacturer price is avail-
16 able, which shall occur no later
17 than the 4th quarter that the
18 drug is available for sale; and

19 “(cc) manufacturers shall
20 calculate the actual ceiling price
21 and shall offer to refund or credit
22 the covered entity the difference
23 between the estimated ceiling
24 price and the actual ceiling price
25 within 120 days of the deter-

mination by the manufacturer involved that an overcharge occurred.

4 “(viii) The prohibition against dis-
5 criminatory distribution of drugs, con-
6 sistent with the following:

7 “(I) A manufacturer shall make
8 available each covered outpatient drug
9 to covered entities on the same terms
10 and conditions that the covered out-
11 patient drug is offered to purchasers
12 that are not covered entities except
13 that the manufacturer will charge the
14 covered entity for the covered out-
15 patient drug at or below the ceiling
16 price.

1 price in an amount equal to the reduc-
2 tion in the price of the drug provided
3 under the agreement between the enti-
4 ty and the manufacturer under this
5 section.”.

6 **SEC. 6. INCLUDING PROGRAMS FUNDED UNDER THE COM-**
7 **MUNITY MENTAL HEALTH SERVICES BLOCK**
8 **GRANT OR THE SUBSTANCE ABUSE PREVEN-**
9 **TION AND TREATMENT BLOCK GRANT AS**
10 **COVERED ENTITIES.**

11 (a) IN GENERAL.—Section 340B(a)(4) of the Public
12 Health Service Act (42 U.S.C. 256b(a)(4)) is amended by
13 adding at the end the following new subparagraph:

14 “(P) A program carried out through funds
15 received under a grant under the Community
16 Mental Health Services Block Grant or the
17 Substance Abuse Prevention and Treatment
18 Block Grant under part B of title XIX.”.

19 (b) EFFECTIVE DATE.—The amendment made by
20 subsection (a) shall apply beginning on the date of the
21 enactment of this Act.

1 **SEC. 7. PREVENTING MEDICARE HOSPITAL OUTPATIENT**
2 **PAYMENT CUTS FOR HOSPITALS THAT PUR-**
3 **CHASE DRUGS UNDER 340B PROGRAM.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services shall not take any action to implement,
6 administer, or enforce the provision of the final regulation
7 titled the Medicare Program: Hospital Outpatient Pro-
8 spective Payment and Ambulatory Surgical Center Pay-
9 ment Systems and Quality Reporting Programs published
10 on November 13, 2017 (82 Fed. Reg. 52356 et seq.), that
11 changes the payment amount under the Prospective Pay-
12 ment System for Hospital Outpatient Department Serv-
13 ices under section 1833(t) of the Social Security Act (42
14 U.S.C. 1395l(t)) for separately payable, nonpass-through
15 drugs and biologicals purchased under the 340B drug
16 pricing program under section 340B of the Public Health
17 Service Act (42 U.S.C. 256b). The payment amount under
18 such payment system under such section 1833(t) for such
19 a drug or biological provided on or after January 1, 2018,
20 shall be determined (or in the case of claims already proc-
21 essed, redetermined) through the same methodology as if
22 such final regulation did not apply.

23 (b) OPPS BUDGET NEUTRALITY ADJUSTMENT.—
24 The first sentence of section 1833(t)(9)(B) of the Social
25 Security Act (42 U.S.C. 1395l(t)(9)(B)) is amended by

- 1 striking “part” each place such term appears and insert-
- 2 ing “subsection” each such place.

○