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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stretching Entity Resources for Vulnerable Communities Act'' or the ''SERV Communities Act''.

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

It is the sense of Congress that—

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

(2) the 340B program provides health care settings that serve a disproportionate share of underserved patient populations (referred to as covered entities) a discount from drug manufacturers on the covered outpatient drugs they purchase to meet health care needs of the community;

(3) covered entities that qualify for participation under the 340B program meet rigorous eligibility criteria, proving they are safety net health care providers for many underserved patients;

(4) such discounts are provided to such covered entities on the basis of meeting eligibility criteria under the 340B program, and not directly to individual patients;

(5) the 340B Program enables covered entities to provide comprehensive services to the communities they serve, which may include providing free

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

(6) the 340B Program is designed to help covered entities promote health for underserved communities and patients, regardless of a particular patient's insurance status or inability to pay;

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

(8) drugs purchased under the 340B program account for a small proportion of overall drug spending and the discounts described in paragraph (2) provided through the 340B program are not funded by taxpayers.

SEC. 3. CODIFYING DEFINITION OF PATIENT UNDER 340B PROGRAM.

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

''(3) PATIENT.—

''(A) IN GENERAL.—For purposes of carrying out this section, the term 'patient' shall

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

''(B) CLARIFICATION.—For purposes of this section, the Secretary shall not implement the definition under subparagraph (A) more narrowly than the definition specified in subparagraph (A), including by limiting the application of the definition to particular individuals based on their insurance status.''.

SEC. 4. NON-DISCRIMINATION WITH RESPECT TO COVERED ENTITIES.

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

''(f) NON-DISCRIMINATION WITH RESPECT TO COVERED ENTITIES.—

''(1) TERMS OF AGREEMENT.—Subject to paragraph (3), no entity that reimburses a covered entity or its contract pharmacy for drugs that are subject to an agreement under this section may discriminate against such covered entity with respect to the terms of such reimbursement, including terms relating to the level and amount of reimbursement, on the basis

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

''(2) PATIENT'S CHOICE.—With respect to a patient eligible to receive drugs that are subject to an agreement under this section from a covered entity or its contract pharmacy, no entity that makes payment for such drugs shall discriminate against the covered entity or its contract pharmacy in a manner that prevents or interferes with the patient's choice to receive such drugs from the covered entity or contract pharmacy.

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

SEC. 5. PROGRAM INTEGRITY.

(a) FINDINGS.—Congress finds the following:

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

340B of the Public Health Service Act (42 U.S.C. 256b) (in this section referred to as the ''340B ceiling price'') via Internet website so that covered entities could verify they were being charged the correct price, however this website has not yet been established, leaving covered entities vulnerable to continuing manufacturer overcharges.

(2) In response to findings by the Office of the Inspector General of the Department of Health and Human Services of widespread overcharges by manufacturers and a lack of oversight and authority by the Secretary of Health and Human Services to ensure that covered entities paid no more than the 340B ceiling price, Congress directed the Secretary to develop standards for calculating 340B ceiling prices and civil monetary penalties to apply to manufacturers that violate these rules, however those standards and penalties have not yet been developed, significantly limiting the Secretary's ability to oversee manufacturer compliance with such section 340B of the Public Health Service Act (42 U.S.C. 256b).

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

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

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

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

(6) Furthermore, the Office of Pharmacy Affairs has conducted only 11 total audits of manufacturers.

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

"(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section, consistent with the following:

"(I) Such audits shall be conducted in a form and manner that, to the greatest extent practicable, results in parity between such audits and au-

dits under subsection (a)(5)(C) of covered entities, as measured by comparing the percentage of total manufacturer audits under this clause to the percentage of total audits conducted under such subsection of covered entities described in subsection (a)(4)(L).

''(II) Such audits shall include review of average manufacturer price, best price, and the inflationary penalty to ensure that manufacturers are calculating the ceiling price accurately.''.

(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''.

(d) CIVIL MONETARY PENALTY.—

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

U.S.C. 256b(d)(1)(B)) is amended to read as follows:

"(II) shall not exceed, for each instance of overcharging a covered entity that may have occurred, the greater of—

"(aa) $5,000; or

"(bb) 200 percent of the amount of such overcharge; and".

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

"(C) CLARIFICATIONS.—For purposes of subparagraph (B)(vi)—

"(i) an instance of overcharging described in subclause (II) of such subparagraph shall—

"(I) apply to each unit of a national drug code within an order, whether placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent, and may not be offset by other discounts 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

"(II) the term 'intentionally' means, with respect to an overcharge, that such overcharge is not due to inadvertent error.".

(3) NON-APPLICATION OF 340B CEILING PRICE AND CMP REGULATION.—The Secretary of Health and Human Services shall not take any action to implement, administer, or enforce the provision of the final regulation titled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation" published on June 5, 2018 (83 Fed. Reg. 25943 et seq.), that changes the effective date of the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation from July 1, 2018 to July 1, 2019. The effective date shall be determined as if such final regulation published on June 5, 2018, did not apply.

(4) IMPLEMENTATION.—The Secretary of Health and Human Services shall implement the amendments made by paragraphs (1) and (2) by program instruction or otherwise such that such amendment applies to instances of overcharges occurring on or after the date that is 60 days after the date of the enactment of this Act.

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

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

''(vii) The requirement that the applicable ceiling price described in clause (iii) for a covered outpatient drug, with respect to a calendar quarter, shall be equal to the average manufacturer price under section 1927(k)(1) of the Social Security Act from the preceding calendar quarter for the smallest unit of measure minus the unit rebate amount and will be calculated using six decimal places and will be published by the Secretary rounded to two decimal places, in accordance with the following:

"(I) In the case that the ceiling price calculation results in an amount less than $0.01, the ceiling price will be $0.01.

"(II) For a new covered outpatient drug—

"(aa) manufacturers shall estimate the ceiling price as of the date the new drug is first available for sale;

"(bb) the estimation shall be calculated as wholesale acquisition cost minus the appropriate rebate percentage until an average manufacturer price is available, which shall occur no later than the 4th quarter that the drug is available for sale; and

"(cc) manufacturers shall calculate the actual ceiling price and shall offer to refund or credit the covered entity the difference between the estimated ceiling price and the actual ceiling price within 120 days of the deter-

mination by the manufacturer involved that an overcharge occurred.

''(viii) The prohibition against discriminatory distribution of drugs, consistent with the following:

''(I) A manufacturer shall make available each covered outpatient drug to covered entities on the same terms and conditions that the covered outpatient drug is offered to purchasers that are not covered entities except that the manufacturer will charge the covered entity for the covered outpatient drug at or below the ceiling price.

''(II) If the Secretary finds, after audit as described in subparagraph (B)(v) and after notice and hearing, that a manufacturer is in violation of the requirement described in subclause (I), the manufacturer shall be liable to the covered entity that was not able to purchase the covered outpatient drug involved at a discounted

price in an amount equal to the reduction in the price of the drug provided under the agreement between the entity and the manufacturer under this section.''.

SEC. 6. INCLUDING PROGRAMS FUNDED UNDER THE COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT OR THE SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT AS COVERED ENTITIES.

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

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

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

SEC. 7. PREVENTING MEDICARE HOSPITAL OUTPATIENT PAYMENT CUTS FOR HOSPITALS THAT PURCHASE DRUGS UNDER 340B PROGRAM.

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

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

striking ''part'' each place such term appears and inserting ''subsection'' each such place.

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