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118TH CONGRESS
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H. R. 7635

To amend title III of the Social Security Act to ensure the accessibility of drugs furnished under the 340B drug discount program.

IN THE HOUSE OF REPRESENTATIVES

MARCH 12, 2024

Ms. MATSUI introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title III of the Social Security Act to ensure the accessibility of drugs furnished under the 340B drug discount program.

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 340B Pharmaceutical Access To Invest in Essential, Needed Treatments & Support Act of 2024'' or ''The 340B PATIENTS Act of 2024''.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress finds the following:

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

(2) Section 340B requires drug manufacturers to offer discounted prices on covered outpatient drugs to covered entities participating in the program, as a condition of participating in the Medicaid or Medicare Part B programs, and drug manufacturers must offer 340B pricing to covered entities and sell 340B and deliver 340B drugs to covered entities when requested irrespective of the manner or location through which a 340B drug is dispensed.

(3) Savings from section 340B enables hospitals, clinics, and health centers' to provide comprehensive services to the communities they serve, and covered entities are in the best position to assess the use of their savings for community needs.

(4) Since the early years of the 340B program, covered entities have contracted with pharmacies to dispense covered outpatient drugs purchased by a covered entity at 340B pricing to patients of the covered entity, consistent with how Congress intended for covered entities to use the program.

(5) Covered entities use savings generated through 340B contract pharmacy relationships to stretch scarce resources and support patient care, consistent with the purpose of the program.

(6) Section 340B requires drug manufacturers to offer 340B pricing for drugs purchased by covered entities regardless of the manner or location in which a drug is dispensed, including drugs dispensed through contract pharmacies.

(7) Section 340B does not allow drug manufacturers to place conditions on the ability of a covered entity to purchase or use a covered outpatient drug at 340B pricing regardless of the manner or location in which a drug is dispensed, including by restricting a covered entity's ability to dispense 340B drugs to patients through a contractual relationship with a contracted pharmacy or refusing to ship covered outpatient drugs to a pharmacy or location identified by a covered entity.

(8) Section 340B's inflationary penalty provisions, which have saved $7 billion in Medicare Part D spending between 2013 and 2017, have a proven record of reducing drug price increases, and use of 340B in contract pharmacies contributes to these savings.

(9) Specialty drugs, which are often used to treat chronic, serious, or life-threatening conditions such as cancer, rheumatoid arthritis, growth hormone deficiency, and multiple sclerosis, play a critical role in the care provided by covered entities. These drugs often require specialized handling, are not usually available to walk-in customers, and are typically available only through specialty or mail order pharmacies that are located hundreds of miles from a covered entity. The use of contract pharmacy arrangements under Section 340B are often the only means by which covered entities can access these vital drugs.

(b) PURPOSES.—The purposes of this Act are the following:

(1) To clarify that section 340B of the Public Health Service Act (42 U.S.C. 256b) requires drug manufacturers to offer 340B pricing for drugs purchased by a covered entity regardless of the manner or location in which the drug is dispensed, and section 340B prohibits drug manufacturers from placing conditions on the ability of covered entities to purchase and use 340B drugs, regardless of the manner or location in which they are dispensed.

(2) To clarify that covered entities under section 340B may contract with pharmacies to dispense on a covered entity's behalf drugs purchased by a covered entity under section 340B to generate savings to assist covered entities to stretch resources to provide care to more patients and provide more comprehensive services, and the requirements and prohibitions that apply to manufacturers under section 340B apply in the case of a covered entity that elects to contract with a pharmacy to dispense 340B drugs.

SEC. 3. ENSURING THE ACCESSIBILITY OF DRUGS FURNISHED UNDER THE 340B DRUG DISCOUNT PROGRAM.

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

(1) in paragraph (1)—

(A) by striking ''that the manufacturer furnish'' and inserting the following: ''that—

''(A) the manufacturer furnish'';

(B) by striking '' 'ceiling price'), and'' and inserting '' 'ceiling price');'';

(C) by striking ''shall require that the manufacturer offer'' and inserting the following:

''(B) the manufacturer offer''; and

(D) by striking the period at the end and inserting the following: ", regardless of the manner or location in which the drug is dispensed; and

"(C) the manufacturer not place conditions on the ability of a covered entity to purchase and use a covered outpatient drug at or below the applicable ceiling price, regardless of the manner or location in which the drug is dispensed, including but not limited to placing limits on the delivery of drugs, placing limits on the mechanisms through which drugs may be purchased, placing limits on where such drugs may be delivered, administered, or dispensed, requiring a covered entity's assurance of compliance with requirements under this section, or requiring the submission of claims data or other information, except that, notwithstanding this subparagraph, the manufacturer may impose such conditions after receiving advance approval from the Secretary (or, with respect to conditions specified by the Secretary, without such advance approval) if such conditions would not discourage covered entities from purchasing the manufacturer's drugs through the drug dis-

count program under this section or otherwise undermine the objective of this section, either by singling out covered entities from other customers for such conditions or by imposing conditions that disproportionately impact covered entities.''; and

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

''(11) CONTRACT PHARMACIES.—The requirements and prohibitions under subsection (a)(1) shall apply, in the case of a covered entity that elects to contract with one or more pharmacies to dispense covered outpatient drugs purchased by a covered entity at or below the applicable ceiling price described in paragraph (1), to patients of the covered entity.''.

(b) MANUFACTURER COMPLIANCE.—Section 340B(d) of the Public Health Service Act (42 U.S.C. 256b) is amended—

(1) in paragraph (1)(B)(vi), by inserting ''in the case of an overcharge'' after ''penalties'';

(2) in paragraph (1)(B), by adding at the end the following:

''(vii) The imposition of sanctions in the form of civil monetary penalties in the case of a violation of subsection (a)(1) or

subsection (a)(11), other than an overcharge, which—

"(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment;

"(II) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally violates a requirement under subsection (a)(1) or subsection (a)(11), other than an overcharge;

"(III) shall not exceed $2,000,000 for each day of such violation;

"(IV) shall be determined by the Secretary, taking into account factors such as the nature and extent of the violation and harm resulting from such violation, including, where applicable, the number of drugs affected and the number of covered entities affected; and

"(V) shall continue to be imposed each day until such manufacturer is no longer in violation of a requirement under subsection (a)(1) or subsection (a)(11), other than an overcharge."; and

(3) in paragraph (3), by adding at the end the following:

"(D) Not later than 180 days after the date of the enactment of this subparagraph, the Secretary shall promulgate regulations to permit covered entities to assert claims of violations of subsection (a)(1) and subsection (a)(11) under the process promulgated under subparagraph (A).".

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