

118TH CONGRESS
2D SESSION

S. 5021

To ensure the accessibility of drugs furnished through the drug discount program under section 340B of the Public Health Service Act.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 11, 2024

Mr. WELCH introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To ensure the accessibility of drugs furnished through the drug discount program under section 340B of the Public Health Service Act.

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 “340B Pharmaceutical
5 Access To Invest in Essential, Needed Treatments & Sup-
6 port Act of 2024” or the “340B PATIENTS Act of
7 2024”.

8 **SEC. 2. FINDINGS AND PURPOSES.**

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

1 (1) Section 340B of the Public Health Service
2 Act (42 U.S.C. 256b) enables covered entities to
3 stretch scarce resources as far as possible, reaching
4 more patients and providing more comprehensive
5 services than would be possible without such pro-
6 gram.

7 (2) Such section 340B requires drug manufac-
8 turers to offer discounted prices on covered out-
9 patient drugs to covered entities participating in the
10 program, as a condition of participating in the Med-
11 icaid program and part B of the Medicare program,
12 and drug manufacturers are required to offer drug
13 discount pricing to covered entities when requested.

14 (3) Savings on the purchase of drugs through
15 the program under section 340B of the Public
16 Health Service Act enables hospitals, clinics, and
17 health centers to provide comprehensive services to
18 the communities they serve, and covered entities are
19 in the best position to assess the use of their savings
20 for community needs.

21 (4) Since the early years of such program, cov-
22 ered entities have contracted with pharmacies to dis-
23 pense covered outpatient drugs purchased by a cov-
24 ered entity at drug discount program pricing to pa-
25 tients of the covered entity, consistent with how

1 Congress intended for covered entities to use the
2 program.

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

7 (6) Section 340B of the Public Health Service
8 Act requires drug manufacturers to offer drug dis-
9 count pricing for drugs purchased by covered enti-
10 ties regardless of the manner or location in which a
11 drug is dispensed, including drugs dispensed through
12 contract pharmacies.

13 (7) Section 340B of the Public Health Service
14 Act does not allow drug manufacturers to place con-
15 ditions on the ability of a covered entity to purchase
16 or use a covered outpatient drug at drug discount
17 program pricing regardless of the manner or location
18 in which a drug is dispensed, including by restricting
19 a covered entity's ability to dispense drugs pur-
20 chased through such program to patients through a
21 contractual relationship with a contracted pharmacy
22 or refusing to ship covered outpatient drugs to a
23 pharmacy or location identified by a covered entity.

24 (8) Such section 340B's inflationary penalty
25 provisions, which have saved part D of the Medicare

1 program \$7,000,000,000 between 2013 and 2017,
2 have a proven record of reducing drug price in-
3 creases, and use of contract pharmacies contributes
4 to these savings.

5 (9) Specialty drugs, which are often used to
6 treat chronic, serious, or life-threatening conditions
7 such as cancer, rheumatoid arthritis, growth hor-
8 mone deficiency, and multiple sclerosis, play a crit-
9 ical role in the care provided by covered entities.
10 These drugs often require specialized handling, are
11 not usually available to walk-in customers, and are
12 typically available only through specialty or mail
13 order pharmacies that are located hundreds of miles
14 from a covered entity. The use of contract pharmacy
15 arrangements under section 340B of the Public
16 Health Service Act is often the only means by which
17 covered entities can access these vital drugs.

18 (b) PURPOSES.—The purposes of this Act are the fol-
19 lowing:

20 (1) To clarify that section 340B of the Public
21 Health Service Act (42 U.S.C. 256b)—

22 (A) requires drug manufacturers to offer
23 drug discount pricing pursuant to an agreement
24 under subsection (a) of such section with re-
25 spect to drugs purchased by a covered entity re-

1 regardless of the manner or location in which the
2 drug is dispensed; and

3 (B) prohibits drug manufacturers from
4 placing conditions on the ability of covered enti-
5 ties to purchase drugs pursuant to an agree-
6 ment under subsection (a) of such section, re-
7 gardless of the manner or location in which
8 such drugs are dispensed.

9 (2) To clarify that—

10 (A) covered entities may contract with
11 pharmacies to dispense drugs purchased pursu-
12 ant to an agreement under section 340B(a) of
13 the Public Health Service Act (42 U.S.C.
14 256b(a)) on a covered entity's behalf, to assist
15 covered entities in stretching resources to pro-
16 vide care to more patients and provide more
17 comprehensive services; and

18 (B) the requirements and prohibitions that
19 apply to manufacturers under section 340B of
20 such Act apply in the case of a covered entity
21 that elects to contract with a pharmacy to dis-
22 pense 340B drugs.

1 **SEC. 3. ENSURING THE ACCESSIBILITY OF DRUGS FUR-**
 2 **NISHED UNDER THE DRUG DISCOUNT PRO-**
 3 **GRAM.**

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

6 (1) in paragraph (1)—

7 (A) by striking “that the manufacturer
 8 furnish” and inserting the following: “that—

9 “(A) the manufacturer furnish”;

10 (B) by striking “‘ceiling price’), and” and
 11 inserting “‘ceiling price’);”;

12 (C) by striking “shall require that the
 13 manufacturer offer” and inserting the following:

14 “(B) the manufacturer offer”; and

15 (D) by striking the period at the end and
 16 inserting the following: “, regardless of the
 17 manner or location in which the drug is dis-
 18 pensed; and

19 “(C) the manufacturer not place conditions
 20 on the ability of a covered entity to purchase
 21 and use a covered outpatient drug at or below
 22 the applicable ceiling price, regardless of the
 23 manner or location in which the drug is dis-
 24 pensed, including by placing limits on the deliv-
 25 ery of drugs, placing limits on the mechanisms
 26 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 the manufacturer may impose conditions described in this subparagraph 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 discount 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:

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

1 the applicable ceiling price described in paragraph
 2 (1).”.

3 (b) MANUFACTURER COMPLIANCE.—Section
 4 340B(d) of the Public Health Service Act (42 U.S.C.
 5 256b) is amended—

6 (1) in paragraph (1)(B)(vi), in the matter pre-
 7 ceding subclause (I), by inserting “, in the case of
 8 an overcharge” after “penalties”;

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

11 “(vii) The imposition of sanctions in
 12 the form of civil monetary penalties in the
 13 case of a violation of subsection (a)(1) or
 14 (a)(11), other than an overcharge, which—

15 “(I) shall be assessed according
 16 to standards established in regulations
 17 to be promulgated by the Secretary
 18 not later than 180 days after the date
 19 of enactment;

20 “(II) shall apply to any manufac-
 21 turer with an agreement under this
 22 section that knowingly and inten-
 23 tionally violates a requirement under
 24 subsection (a)(1) or (a)(11), other
 25 than an overcharge;

1 “(III) shall not exceed
2 \$2,000,000 for each day of such viola-
3 tion;

4 “(IV) shall be in an amount de-
5 termined by the Secretary, taking into
6 account factors such as the nature
7 and extent of the violation and harm
8 resulting from such violation, includ-
9 ing, where applicable, the number of
10 drugs affected and the number of cov-
11 ered entities affected; and

12 “(V) shall continue to be imposed
13 each day until such manufacturer is
14 no longer in violation of a requirement
15 under subsection (a)(1) or (a)(11).”;
16 and

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

19 “(D) Not later than 180 days after the
20 date of the enactment of this subparagraph, the
21 Secretary shall promulgate regulations to per-
22 mit covered entities to assert claims of viola-
23 tions of subsections (a)(1) and (a)(11) under

- 1 the process promulgated under subparagraph
- 2 (A).”.

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