

119TH CONGRESS
1ST SESSION

H. R. 4581

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

IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2025

Ms. MATSUI (for herself, Mrs. TRAHAN, Mr. TONKO, Ms. DAVIDS of Kansas, Ms. MCCOLLUM, Mr. THANEDAR, Ms. TLAIB, Mr. FROST, and Ms. CASTOR of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 **SEC. 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 2025” or the “340B PATIENTS Act of
7 2025”.

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, and, as a condition of participating in the
11 Medicaid program and part B of the Medicare pro-
12 gram, drug manufacturers are required to offer drug
13 discount pricing to covered entities when requested.

14 (3) Savings on the purchase of drugs under the
15 drug discount program under section 340B of the
16 Public Health Service Act enables hospitals, clinics,
17 and health centers to provide comprehensive services
18 to the communities they serve, and covered entities
19 are in the best position to assess the use of their
20 savings 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 saving 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 discount
9 pricing for drugs purchased by covered entities re-
10 gardless of the manner or location in which a drug
11 is dispensed, including drugs dispensed through con-
12 tract pharmacies.

13 (7) Such section 340B does not allow drug
14 manufacturers to place conditions on the ability of
15 a covered entity to purchase or use a covered out-
16 patient drug at discounted pricing regardless of the
17 manner or location in which a drug is dispensed, in-
18 cluding by restricting a covered entity's ability to
19 dispense drugs purchased at such discount to pa-
20 tients through a contractual relationship with a con-
21 tracted pharmacy or refusing to ship covered out-
22 patient drugs to a pharmacy or location identified by
23 a covered entity.

24 (8) The inflationary penalty provisions under
25 section 340B of the Public Health Service Act,

1 which have saved \$7,000,000,000 in spending under
2 part D of the Medicare program between 2013 and
3 2017, have a proven record of reducing drug price
4 increases, and use of the drug discount program in
5 contract pharmacies contributes to these savings.

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

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

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

23 (A) requires drug manufacturers to offer
24 drug discount pricing pursuant to an agreement
25 under subsection (a) of such section with re-

1 spect to drugs purchased by a covered entity re-
2 gardless of the manner or location in which the
3 drug is dispensed; and

4 (B) prohibits drug manufacturers from
5 placing conditions on the ability of covered enti-
6 ties to purchase covered outpatient drugs pur-
7 suant to an agreement under subsection (a) of
8 such section, regardless of the manner or loca-
9 tion in which they are dispensed.

10 (2) To clarify that—

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

19 (B) the requirements and prohibitions that
20 apply to manufacturers under section 340B of
21 such Act apply in the case of a covered entity
22 that elects to contract with a pharmacy to dis-
23 pense covered outpatient 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 man-
17 ner or location in which the drug is dispensed;
18 and

19 “(C) the manufacturer not place any con-
20 ditions on the ability of a covered entity to pur-
21 chase and use a covered outpatient drug at or
22 below the applicable ceiling price, regardless of
23 the manner or location in which the drug is dis-
24 pensed, if such conditions—

25 “(i) would place limits on the delivery
26 of drugs, place limits on the mechanisms

1 through which drugs may be purchased,
2 place limits on where such drugs may be
3 delivered, administered, or dispensed, re-
4 quire a covered entity's assurance of com-
5 pliance with requirements under this sec-
6 tion, or require the submission of claims
7 data or other information;

8 “(ii) would not reflect customary busi-
9 ness practices;

10 “(iii) would discourage covered enti-
11 ties from purchasing the manufacturer's
12 drugs through the drug discount program
13 under this section or otherwise undermine
14 the objective of this section, either by sin-
15 gling out covered entities from other cus-
16 tomers for such conditions or by imposing
17 conditions that disproportionately impact
18 covered entities; or

19 “(iv) have not been approved in ad-
20 vance by the Secretary.”; and

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

23 “(11) CONTRACT PHARMACIES.—The require-
24 ments and prohibitions under paragraph (1) shall
25 apply in the case of a covered entity that elects to

1 contract with one or more pharmacies to dispense, to
2 patients of the covered entity, covered outpatient
3 drugs purchased by the covered entity at or below
4 the applicable ceiling price described in paragraph
5 (1).”.

6 (b) MANUFACTURER COMPLIANCE.—Section
7 340B(d) of the Public Health Service Act (42 U.S.C.
8 256b) is amended—

9 (1) in paragraph (1)(B)—

10 (A) in clause (vi), in the matter preceding
11 subclause (I), by inserting “, in the case of a
12 manufacturer overcharging a covered entity for
13 covered outpatient drugs” after “penalties”;
14 and

15 (B) by adding at the end the following:

16 “(vii) The imposition of sanctions in
17 the form of civil monetary penalties in the
18 case of a violation of subsection (a)(1)(C)
19 or (a)(11), other than an overcharge,
20 which—

21 “(I) shall be assessed according
22 to standards established in regulations
23 to be promulgated by the Secretary
24 not later than 180 days after the date
25 of enactment;

1 “(II) shall apply to any manufac-
2 turer with an agreement under this
3 section that intentionally violates a re-
4 quirement under subsection (a)(1)(C)
5 or (a)(11), other than an overcharge;

6 “(III) shall not exceed
7 \$2,000,000 for each day of such viola-
8 tion;

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

17 “(V) shall continue to be imposed
18 each day until such manufacturer is
19 no longer in violation of a requirement
20 under subsection (a)(1)(C) or (a)(11),
21 other than an overcharge.”; and

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

24 “(D) CLAIMS OF VIOLATIONS.—Not later
25 than 180 days after the date of the enactment

1 of this subparagraph, the Secretary shall pro-
2 mulgate regulations to permit covered entities
3 to assert claims of violations of subsections
4 (a)(1) and (a)(11) under the process established
5 under subparagraph (A).”.

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