

118TH CONGRESS  
1ST SESSION

# H. R. 2534

To amend title XXVII of the Public Health Service Act to ensure the equitable treatment of covered entities and pharmacies participating in the 340B drug discount program, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2023

Ms. SPANBERGER (for herself and Mr. JOHNSON of South Dakota) 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 title XXVII of the Public Health Service Act to ensure the equitable treatment of covered entities and pharmacies participating in the 340B drug discount program, 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 “Preserving Rules Or-  
5 dered for The Entities Covered Through 340B Act of  
6 2023” or the “PROTECT 340B Act of 2023”.

1 **SEC. 2. FINDINGS AND PURPOSE.**

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

3 (1) The 340B drug pricing program is an es-  
4 sential part of the Nation’s health care safety net.

5 (2) 340B enables safety-net providers to stretch  
6 scarce resources further to offer services and treat  
7 patients through the savings these providers receive  
8 under the program.

9 (3) 340B savings support hospitals, clinics, and  
10 health centers’ care for patients who have low in-  
11 comes, including those with low incomes enrolled in  
12 Medicare and Medicaid.

13 (4) 340B savings are critically important to  
14 rural hospitals that operate on very slim margins  
15 and serve patients in isolated areas with limited ac-  
16 cess to health care.

17 (5) 340B supports care for those in need with-  
18 out using taxpayer dollars.

19 (6) Some commercial payers and pharmacy ben-  
20 efit managers are paying less to 340B covered enti-  
21 ties and their contract pharmacies for 340B drugs,  
22 requiring identification of 340B drug claims or oth-  
23 erwise discriminating against 340B covered entities  
24 and their contract pharmacies on the basis of their  
25 status as providers or pharmacies that dispense  
26 340B drugs.

1           (7) These types of discriminatory actions un-  
2           dermine the purpose of the 340B program and harm  
3           the patients served by 340B covered entities. Com-  
4           mercial payers and pharmacy benefit managers' im-  
5           position of requirements on a 340B pharmacy be-  
6           cause it is a pharmacy that dispenses 340B drugs,  
7           or requirements with respect to the use of and bill-  
8           ing for drugs purchased under 340B because they  
9           are 340B drugs is inconsistent with public policy be-  
10          cause of the deleterious effects on the nation's  
11          health care safety net.

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

14               (1) To prohibit discriminatory actions, includ-  
15               ing several specified actions, by a pharmacy benefit  
16               manager, a group health plan, a health insurance  
17               issuer offering group or individual health insurance,  
18               or a sponsor of a Medicare part D prescription drug  
19               plan against 340B covered entities and their phar-  
20               macies and requiring them to be treated as any  
21               other provider or pharmacy.

22               (2) To provide for the imposition of civil mone-  
23               etary penalties on pharmacy benefit managers that  
24               violate the new protections and require the Health

1 Services and Resources Administration to promul-  
2 gate implementing regulations.

3 (3) To authorize the Secretary to contract with  
4 a third-party entity to collect and review data from  
5 State Medicaid agencies and covered entities to pre-  
6 vent Medicaid duplicate discounts.

7 **SEC. 3. ENSURING THE EQUITABLE TREATMENT OF COV-**  
8 **ERED ENTITIES AND PHARMACIES PARTICI-**  
9 **PATING IN THE 340B DRUG DISCOUNT PRO-**  
10 **GRAM.**

11 (a) GROUP HEALTH PLAN AND HEALTH INSURANCE  
12 ISSUER REQUIREMENTS.—Subpart II of part A of title  
13 XXVII of the Public Health Service Act (42 U.S.C.  
14 300gg–11 et seq.) is amended by adding at the end the  
15 following new section:

16 **“SEC. 2730. REQUIREMENTS RELATING TO THE 340B DRUG**  
17 **DISCOUNT PROGRAM.**

18 “(a) IN GENERAL.—A group health plan, a health  
19 insurance issuer offering group or individual health insur-  
20 ance coverage, or a pharmacy benefit manager may not  
21 discriminate against a covered entity (as defined in sub-  
22 section (d)(1)), a specified pharmacy (as defined in sub-  
23 section (d)(2)), or a participant, beneficiary, or enrollee  
24 of such plan or coverage by imposing requirements, exclu-  
25 sions, reimbursement terms, or other conditions on such

1 entity or pharmacy that differ from those applied to enti-  
2 ties or pharmacies that are not covered entities or speci-  
3 fied pharmacies on the basis that the entity or pharmacy  
4 is a covered entity or specified pharmacy or that the entity  
5 or pharmacy dispenses 340B drugs, including by taking  
6 any action prohibited under subsection (b).

7       “(b) SPECIFIED PROHIBITED ACTIONS.—A group  
8 health plan, a health insurance issuer offering group or  
9 individual health insurance coverage, or a pharmacy ben-  
10 efit manager may not discriminate against a covered enti-  
11 ty, a specified pharmacy, or a participant, beneficiary, or  
12 enrollee of such plan or coverage by doing any of the fol-  
13 lowing:

14               “(1) Reimbursing a covered entity or specified  
15 pharmacy for a quantity of a 340B drug (as defined  
16 in subsection (d)) in an amount less than such plan,  
17 issuer, or manager (as applicable) would pay to any  
18 other similarly situated (as specified by the Sec-  
19 retary) entity or pharmacy that is not a covered en-  
20 tity or a specified pharmacy for such quantity of  
21 such drug on the basis that the entity or pharmacy  
22 is a covered entity or specified pharmacy or that the  
23 entity or pharmacy dispenses 340B drugs.

24               “(2) Imposing any terms or conditions on cov-  
25 ered entities or specified pharmacies with respect to

1 any of the following that differ from such terms or  
2 conditions applied to other similarly situated entities  
3 or pharmacies that are not covered entities or speci-  
4 fied pharmacies on the basis that the entity or phar-  
5 macy is a covered entity or specified pharmacy or  
6 that the entity or pharmacy dispenses 340B drugs:

7 “(A) Fees, chargebacks, clawbacks, adjust-  
8 ments, or other assessments.

9 “(B) Professional dispensing fees.

10 “(C) Restrictions or requirements regard-  
11 ing participation in standard or preferred phar-  
12 macy networks.

13 “(D) Requirements relating to the fre-  
14 quency or scope of audits or to inventory man-  
15 agement systems using generally accepted ac-  
16 counting principles.

17 “(E) Any other restrictions, conditions,  
18 practices, or policies that, as specified by the  
19 Administrator of the Health Resources and  
20 Services Administration, interfere with the abil-  
21 ity of a covered entity to maximize the value of  
22 discounts provided under section 340B.

23 “(3) Interfering with an individual’s choice to  
24 receive a 340B drug from a covered entity or speci-

1       fied pharmacy, whether in person or via direct deliv-  
2       ery, mail, or other form of shipment.

3           “(4) Requiring a covered entity or specified  
4       pharmacy to identify, either directly or through a  
5       third party, 340B drugs.

6           “(5) Refusing to contract with a covered entity  
7       or specified pharmacy for reasons other than those  
8       that apply equally to entities or pharmacies that are  
9       not covered entities or specified pharmacies, or on  
10      the basis that—

11           “(A) the entity or pharmacy is a covered  
12      entity or a specified pharmacy; or

13           “(B) the entity or pharmacy is described in  
14      any of subparagraphs (A) through (O) of sec-  
15      tion 340B(a)(4).

16           “(6) With respect to a group health plan or  
17      health insurance issuer for health insurance cov-  
18      erage, denying coverage of a drug on the basis that  
19      such drug is a 340B drug.

20           “(c) ENFORCEMENT MECHANISM FOR PHARMACY  
21      BENEFIT MANAGERS.—The Secretary shall impose a civil  
22      monetary penalty on any pharmacy benefit manager that  
23      violates the requirements of this section. Such penalty  
24      shall not exceed \$5,000 per violation per day. The Sec-  
25      retary shall issue proposed regulations to implement this

1 subsection not later than 60 days after the date of the  
2 enactment of this subsection and shall finalize such regu-  
3 lations not later than 180 days after such date of enact-  
4 ment.

5 “(d) DEFINITIONS.—For purposes of this section:

6 “(1) COVERED ENTITY.—The term ‘covered en-  
7 tity’ has the meaning given such term in section  
8 340B(a)(4).

9 “(2) SPECIFIED PHARMACY.—The term ‘speci-  
10 fied pharmacy’ means a pharmacy with which a cov-  
11 ered entity has contracted to dispense 340B drugs  
12 on behalf of the covered entity whether distributed  
13 in person or via mail.

14 “(3) 340B DRUG.—The term ‘340B drug’  
15 means a drug that is—

16 “(A) a covered outpatient drug (as defined  
17 for purposes of section 340B); and

18 “(B) purchased under an agreement in ef-  
19 fect under such section.”.

20 (b) APPLICATION OF REQUIREMENTS TO MEDI-  
21 CARE.—

22 (1) PART D.—Section 1860D–12(b) of the So-  
23 cial Security Act (42 U.S.C. 1395w–112(b)) is  
24 amended by adding at the end the following new  
25 paragraph:



1           “(8) APPLICATION OF REQUIREMENTS RELAT-  
 2           ING TO THE 340B DRUG DISCOUNT PROGRAM.—Each  
 3           contract entered into under this subsection with a  
 4           PDP sponsor shall provide that the requirements of  
 5           section 2730 of the Public Health Service Act apply  
 6           to such sponsor, and to any pharmacy benefit man-  
 7           ager that contracts with such sponsor, in the same  
 8           manner as such requirements apply with respect to  
 9           a group health plan, a health insurance issuer, or a  
 10          pharmacy benefit manager described in such sec-  
 11          tion.”.

12           (2) PART C.—Section 1857(f)(3) of the Social  
 13          Security Act (42 U.S.C. 1395w–27(f)(3)) is amend-  
 14          ed by adding at the end the following new subpara-  
 15          graph:

16                   “(E) 340B DRUG DISCOUNT PROGRAM.—  
 17                   Section 1860D–12(b)(8).”.

18          (c) MEDICAID REQUIREMENTS.—

19           (1) IN GENERAL.—Section 1927 of the Social  
 20          Security Act (42 U.S.C. 1396r–8) is amended by  
 21          adding at the end the following new subsection:

22                   “(1) REVIEW TO PREVENT DUPLICATE DIS-  
 23          COUNTS.—

24                   “(1) IN GENERAL.—Not later than 1 year after  
 25          the date of the enactment of this subsection, the

1 Secretary shall enter into a contract with a third-  
2 party entity (who shall be free of conflicts of inter-  
3 est, as specified by the Secretary) for purposes of—

4 “(A) identifying claims for 340B drugs (as  
5 defined in section 2730(d) of the Public Health  
6 Service Act) for which reimbursement was  
7 made under a State plan (or waiver of such  
8 plan); and

9 “(B) ensuring such claims are not included  
10 in any State rebate request under this section  
11 in violation of section 340B(a)(5)(A) of the  
12 Public Health Service Act or section  
13 1903(m)(2)(A)(xiii) or 1927(j)(1).

14 “(2) DUTIES OF CONTRACTING ENTITY.—

15 “(A) IN GENERAL.—The entity with a con-  
16 tract in effect under paragraph (1) shall—

17 “(i) request and review, in the most  
18 efficient and least burdensome manner  
19 practicable—

20 “(I) claims level data from cov-  
21 ered entities (as defined in section  
22 340B of the Public Health Service  
23 Act) itemizing 340B drugs dispensed  
24 to individuals enrolled under a State  
25 plan (or waiver of such plan); and

1 “(II) claims level rebate file data  
2 from State agencies administering  
3 such plan (or such waiver);

4 “(ii) request, receive, and maintain  
5 data described in either of subclauses (I)  
6 and (II) of clause (i) in a confidential man-  
7 ner; and

8 “(iii) notify the State and the Sec-  
9 retary of any violation described in para-  
10 graph (1)(B) to ensure that such violation  
11 is remedied.

12 “(B) RETROSPECTIVE SUBMISSION OF  
13 DATA.—In requesting and reviewing claims level  
14 data described in subparagraph (A)(i)(I) from a  
15 covered entity, the entity with a contract in ef-  
16 fect under paragraph (1) shall allow such cov-  
17 ered entity the option of submitting such data  
18 on a retrospective basis through a data file or  
19 another method that does not exclusively re-  
20 quire point-of-sale identification.”.

21 (2) ENSURING ACCESS TO INFORMATION.—

22 (A) COVERED ENTITY REQUIREMENT.—  
23 Section 340B(a)(5) of the Public Health Serv-  
24 ice Act (42 U.S.C. 256b(a)(5)) is amended by

1 adding at the end the following new subpara-  
2 graph:

3 “(E) PROVISION OF INFORMATION TO CON-  
4 TRACTED ENTITY FOR MEDICAID CLAIMS RE-  
5 VIEW.—A covered entity shall furnish to the en-  
6 tity with a contract in effect under section  
7 1927(l) of the Social Security Act, upon request  
8 of such entity, the data described in paragraph  
9 (2)(A)(i) of such section.”.

10 (B) STATE PLAN REQUIREMENT.—Section  
11 1902(a) of the Social Security Act (42 U.S.C.  
12 1396a(a)) is amended—

13 (i) in paragraph (86), by striking  
14 “and” at the end;

15 (ii) in paragraph (87)(D), by striking  
16 the period and inserting “; and”; and

17 (iii) by inserting after paragraph (87)  
18 the following new paragraph:

19 “(88) provide for a mechanism to furnish to the  
20 entity with a contract in effect under section  
21 1927(l), upon request of such entity, the data de-  
22 scribed in paragraph (2)(A)(ii) of such section and  
23 remove from any rebate request described in para-  
24 graph (1)(B) of such section any claim that is the

1 subject of a notice submitted by such entity under  
2 paragraph (2)(C) of such section.”.

3 (d) PROHIBITION ON CERTAIN USE OF FUNDS.—No  
4 funds appropriated under any Act may be used to imple-  
5 ment Executive Order 13937 published on July 29, 2020,  
6 or to otherwise specify or limit the amount that a covered  
7 entity (as defined in section 340B(a)(4) of the Public  
8 Health Service Act (42 U.S.C. 256b(a)(4))) charges pa-  
9 tients for 340B drugs (as defined in section 2730(d) of  
10 the Public Health Service Act, as added by subsection  
11 (a)).

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