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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

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.

IN THE HOUSE OF REPRESENTATIVES

Mr. MCKINLEY introduced the following bill; which was referred to the
Committee on _____

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 2021” or the “PROTECT 340B Act of 2021”.

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)) or a specified pharmacy (as defined in sub-
23 section (d)(2)) by imposing requirements, exclusions, re-
24 imbursement terms, or other conditions on such entity or
25 pharmacy that differ from those applied to entities or

1 pharmacies that are not covered entities or specified phar-
2 macies on the basis that the entity or pharmacy is a cov-
3 ered entity or specified pharmacy or that the entity or
4 pharmacy dispenses 340B drugs, including by taking any
5 action prohibited under subsection (b).

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

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

21 “(2) Imposing any terms or conditions on cov-
22 ered entities or specified pharmacies with respect to
23 any of the following that differ from such terms or
24 conditions applied to other similarly situated entities
25 or pharmacies that are not covered entities or speci-

1 fied pharmacies on the basis that the entity or phar-
2 macy is a covered entity or specified pharmacy or
3 that the entity or pharmacy dispenses 340B drugs:

4 “(A) Fees, chargebacks, clawbacks, adjust-
5 ments, or other assessments.

6 “(B) Professional dispensing fees.

7 “(C) Restrictions or requirements regard-
8 ing participation in standard or preferred phar-
9 macy networks.

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

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

20 “(3) Interfering with an individual’s choice to
21 receive a 340B drug from a covered entity or speci-
22 fied pharmacy, whether in person or via direct deliv-
23 ery, mail, or other form of shipment.

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

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

9 “(A) the entity or pharmacy is a covered
10 entity or a specified pharmacy; or

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

14 “(c) ENFORCEMENT MECHANISM FOR PHARMACY
15 BENEFIT MANAGERS.—The Secretary shall impose a civil
16 monetary penalty on any pharmacy benefit manager that
17 violates the requirements of this section. Such penalty
18 shall not exceed \$5,000 per violation per day. The Sec-
19 retary shall issue proposed regulations to implement this
20 subsection not later than 60 days after the date of the
21 enactment of this subsection and shall finalize such regu-
22 lations not later than 180 days after such date of enact-
23 ment.

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

1 “(1) COVERED ENTITY.—The term ‘covered en-
2 tity’ has the meaning given such term in section
3 340B(a)(4).

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

9 “(3) 340B DRUG.—The term ‘340B drug’
10 means a drug that is—

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

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

15 (b) APPLICATION OF REQUIREMENTS TO MEDI-
16 CARE.—

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

21 “(8) APPLICATION OF REQUIREMENTS RELAT-
22 ING TO THE 340B DRUG DISCOUNT PROGRAM.—Each
23 contract entered into under this subsection with a
24 PDP sponsor shall provide that the requirements of
25 section 2730 of the Public Health Service Act apply

1 to such sponsor, and to any pharmacy benefit man-
2 ager that contracts with such sponsor, in the same
3 manner as such requirements apply with respect to
4 a group health plan, a health insurance issuer, or a
5 pharmacy benefit manager described in such sec-
6 tion.”.

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

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

13 (c) MEDICAID REQUIREMENTS.—

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

17 “(I) REVIEW TO PREVENT DUPLICATE DIS-
18 COUNTS.—

19 “(1) IN GENERAL.—Not later than 1 year after
20 the date of the enactment of this subsection, the
21 Secretary shall enter into a contract with a third-
22 party entity (who shall be free of conflicts of inter-
23 est, as specified by the Secretary) for purposes of—

24 “(A) identifying claims for 340B drugs (as
25 defined in section 2730(d) of the Public Health

1 Service Act) for which reimbursement was
2 made under a State plan (or waiver of such
3 plan); and

4 “(B) ensuring such claims are not included
5 in any State rebate request under this section
6 in violation of section 340B(a)(5)(A) of the
7 Public Health Service Act or section
8 1903(m)(2)(A)(xiii) or 1927(j)(1).

9 “(2) DUTIES OF CONTRACTING ENTITY.—

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

12 “(i) request and review, in the most
13 efficient and least burdensome manner
14 practicable—

15 “(I) claims level data from cov-
16 ered entities (as defined in section
17 340B of the Public Health Service
18 Act) itemizing 340B drugs dispensed
19 to individuals enrolled under a State
20 plan (or waiver of such plan); and

21 “(II) claims level rebate file data
22 from State agencies administering
23 such plan (or such waiver);

24 “(ii) request, receive, and maintain
25 data described in either of subclauses (I)

1 and (II) of clause (i) in a confidential man-
2 ner; and

3 “(iii) notify the State and the Sec-
4 retary of any violation described in para-
5 graph (1)(B) to ensure that such violation
6 is remedied.

7 “(B) RETROSPECTIVE SUBMISSION OF
8 DATA.—In requesting and reviewing claims level
9 data described in subparagraph (A)(i)(I) from a
10 covered entity, the entity with a contract in ef-
11 fect under paragraph (1) shall allow such cov-
12 ered entity the option of submitting such data
13 on a retrospective basis.”.

14 (2) ENSURING ACCESS TO INFORMATION.—

15 (A) COVERED ENTITY REQUIREMENT.—
16 Section 340B(a)(5) of the Public Health Serv-
17 ice Act (42 U.S.C. 256b(a)(5)) is amended by
18 adding at the end the following new subpara-
19 graph:

20 “(E) PROVISION OF INFORMATION TO CON-
21 TRACTED ENTITY FOR MEDICAID CLAIMS RE-
22 VIEW.—A covered entity shall furnish to the en-
23 tity with a contract in effect under section
24 1927(l) of the Social Security Act, upon request

1 of such entity, the data described in paragraph
2 (2)(A)(i) of such section.”.

3 (B) STATE PLAN REQUIREMENT.—Section
4 1902(a) of the Social Security Act (42 U.S.C.
5 1396a(a)) is amended—

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

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

10 (iii) by inserting after paragraph (87)
11 the following new paragraph:

12 “(88) provide for a mechanism to furnish to the
13 entity with a contract in effect under section
14 1927(l), upon request of such entity, the data de-
15 scribed in paragraph (2)(A)(ii) of such section and
16 remove from any rebate request described in para-
17 graph (1)(B) of such section any claim that is the
18 subject of a notice submitted by such entity under
19 paragraph (2)(C) of such section.”.

20 (d) PROHIBITION ON CERTAIN USE OF FUNDS.—No
21 funds appropriated under any Act may be used to imple-
22 ment Executive Order 13937 published on July 29, 2020,
23 or to otherwise specify or limit the amount that a covered
24 entity (as defined in section 340B(a)(4) of the Public
25 Health Service Act (42 U.S.C. 256b(a)(4))) charges pa-

1 tients for 340B drugs (as defined in section 2730(d) of
2 the Public Health Service Act, as added by subsection
3 (a)).