[~117H4390]

.....

(Original Signature of Member)

118TH 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

Ms. SPANBERGER 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.

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 ''Preserving Rules Ordered for The Entities Covered Through 340B Act of 2023'' or the ''PROTECT 340B Act of 2023''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress finds the following:

(1) The 340B drug pricing program is an essential part of the Nation's health care safety net.

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

(3) 340B savings support hospitals, clinics, and health centers' care for patients who have low incomes, including those with low incomes enrolled in Medicare and Medicaid.

(4) 340B savings are critically important to rural hospitals that operate on very slim margins and serve patients in isolated areas with limited access to health care.

(5) 340B supports care for those in need without using taxpayer dollars.

(6) Some commercial payers and pharmacy benefit managers are paying less to 340B covered entities and their contract pharmacies for 340B drugs, requiring identification of 340B drug claims or otherwise discriminating against 340B covered entities and their contract pharmacies on the basis of their status as providers or pharmacies that dispense 340B drugs.

(7) These types of discriminatory actions undermine the purpose of the 340B program and harm the patients served by 340B covered entities. Commercial payers and pharmacy benefit managers' imposition of requirements on a 340B pharmacy because it is a pharmacy that dispenses 340B drugs, or requirements with respect to the use of and billing for drugs purchased under 340B because they are 340B drugs is inconsistent with public policy because of the deleterious effects on the nation's health care safety net.

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

(1) To prohibit discriminatory actions, including several specified actions, by a pharmacy benefit manager, a group health plan, a health insurance issuer offering group or individual health insurance, or a sponsor of a Medicare part D prescription drug plan against 340B covered entities and their pharmacies and requiring them to be treated as any other provider or pharmacy.

(2) To provide for the imposition of civil monetary penalties on pharmacy benefit managers that violate the new protections and require the Health

Services and Resources Administration to promulgate implementing regulations.

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

SEC. 3. ENSURING THE EQUITABLE TREATMENT OF COVERED ENTITIES AND PHARMACIES PARTICIPATING IN THE 340B DRUG DISCOUNT PROGRAM.

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

"SEC. 2730. REQUIREMENTS RELATING TO THE 340B DRUG DISCOUNT PROGRAM.

''(a) IN GENERAL.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager may not discriminate against a covered entity (as defined in subsection (d)(1)), a specified pharmacy (as defined in subsection (d)(2)), or a participant, beneficiary, or enrollee of such plan or coverage by imposing requirements, exclusions, reimbursement terms, or other conditions on such

entity or pharmacy that differ from those applied to entities or pharmacies that are not covered entities or specified pharmacies on the basis that the entity or pharmacy is a covered entity or specified pharmacy or that the entity or pharmacy dispenses 340B drugs, including by taking any action prohibited under subsection (b).

''(b) SPECIFIED PROHIBITED ACTIONS.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager may not discriminate against a covered entity, a specified pharmacy, or a participant, beneficiary, or enrollee of such plan or coverage by doing any of the following:

''(1) Reimbursing a covered entity or specified pharmacy for a quantity of a 340B drug (as defined in subsection (d)) in an amount less than such plan, issuer, or manager (as applicable) would pay to any other similarly situated (as specified by the Secretary) entity or pharmacy that is not a covered entity or a specified pharmacy for such quantity of such drug on the basis that the entity or pharmacy is a covered entity or specified pharmacy or that the entity or pharmacy dispenses 340B drugs.

''(2) Imposing any terms or conditions on covered entities or specified pharmacies with respect to

any of the following that differ from such terms or conditions applied to other similarly situated entities or pharmacies that are not covered entities or specified pharmacies on the basis that the entity or pharmacy is a covered entity or specified pharmacy or that the entity or pharmacy dispenses 340B drugs:

''(A) Fees, chargebacks, clawbacks, adjustments, or other assessments.

''(B) Professional dispensing fees.

''(C) Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

''(D) Requirements relating to the frequency or scope of audits or to inventory management systems using generally accepted accounting principles.

''(E) Any other restrictions, conditions, practices, or policies that, as specified by the Administrator of the Health Resources and Services Administration, interfere with the ability of a covered entity to maximize the value of discounts provided under section 340B.

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

fied pharmacy, whether in person or via direct delivery, mail, or other form of shipment.

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

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

''(A) the entity or pharmacy is a covered entity or a specified pharmacy; or

''(B) the entity or pharmacy is described in any of subparagraphs (A) through (O) of section 340B(a)(4).

''(6) With respect to a group health plan or health insurance issuer for health insurance coverage, denying coverage of a drug on the basis that such drug is a 340B drug.

''(c) ENFORCEMENT MECHANISM FOR PHARMACY BENEFIT MANAGERS.—The Secretary shall impose a civil monetary penalty on any pharmacy benefit manager that violates the requirements of this section. Such penalty shall not exceed $5,000 per violation per day. The Secretary shall issue proposed regulations to implement this

subsection not later than 60 days after the date of the enactment of this subsection and shall finalize such regulations not later than 180 days after such date of enactment.

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

''(1) COVERED ENTITY.—The term 'covered entity' has the meaning given such term in section 340B(a)(4).

''(2) SPECIFIED PHARMACY.—The term 'specified pharmacy' means a pharmacy with which a covered entity has contracted to dispense 340B drugs on behalf of the covered entity whether distributed in person or via mail.

''(3) 340B DRUG.—The term '340B drug' means a drug that is—

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

''(B) purchased under an agreement in effect under such section.''.

(b) APPLICATION OF REQUIREMENTS TO MEDICARE.—

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

''(8) APPLICATION OF REQUIREMENTS RELATING TO THE 340B DRUG DISCOUNT PROGRAM.—Each contract entered into under this subsection with a PDP sponsor shall provide that the requirements of section 2730 of the Public Health Service Act apply to such sponsor, and to any pharmacy benefit manager that contracts with such sponsor, in the same manner as such requirements apply with respect to a group health plan, a health insurance issuer, or a pharmacy benefit manager described in such section.''.

(2) PART C.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

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

(c) MEDICAID REQUIREMENTS.—

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

''(l) REVIEW TO PREVENT DUPLICATE DISCOUNTS.—

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

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

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

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

"(2) DUTIES OF CONTRACTING ENTITY.—

"(A) IN GENERAL.—The entity with a contract in effect under paragraph (1) shall—

"(i) request and review, in the most efficient and least burdensome manner practicable—

"(I) claims level data from covered entities (as defined in section 340B of the Public Health Service Act) itemizing 340B drugs dispensed to individuals enrolled under a State plan (or waiver of such plan); and

''(II) claims level rebate file data from State agencies administering such plan (or such waiver);

''(ii) request, receive, and maintain data described in either of subclauses (I) and (II) of clause (i) in a confidential manner; and

''(iii) notify the State and the Secretary of any violation described in paragraph (1)(B) to ensure that such violation is remedied.

''(B) RETROSPECTIVE SUBMISSION OF DATA.—In requesting and reviewing claims level data described in subparagraph (A)(i)(I) from a covered entity, the entity with a contract in effect under paragraph (1) shall allow such covered entity the option of submitting such data on a retrospective basis through a data file or another method that does not exclusively require point-of-sale identification.''.

(2) ENSURING ACCESS TO INFORMATION.—

(A) COVERED ENTITY REQUIREMENT.—Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. 256b(a)(5)) is amended by

adding at the end the following new subparagraph:

''(E) PROVISION OF INFORMATION TO CONTRACTED ENTITY FOR MEDICAID CLAIMS REVIEW.—A covered entity shall furnish to the entity with a contract in effect under section 1927(l) of the Social Security Act, upon request of such entity, the data described in paragraph (2)(A)(i) of such section.''.

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

(i) in paragraph (86), by striking ''and'' at the end;

(ii) in paragraph (87)(D), by striking the period and inserting ''; and''; and

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

''(88) provide for a mechanism to furnish to the entity with a contract in effect under section 1927(l), upon request of such entity, the data described in paragraph (2)(A)(ii) of such section and remove from any rebate request described in paragraph (1)(B) of such section any claim that is the

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

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