Sec. 340C PUBLIC HEALTH SERVICE ACT: LIMITATION ON PRICES OF DRUGS PURCHASED BY CERTAIN COVERED ENTITIES.

(a) REQUIREMENTS FOR AGREEMENT WITH SECRETARY.

(1) IN GENERAL.—The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs which requires that:

(A) the amount required to be paid to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this section, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2), at the time of purchase. (This amount is referred to in this section as the 'ceiling price');

(B) the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price;

(C) all discounts anticipated by this statute shall be realized by such covered entities at the time they purchase 340B eligible drugs from drug wholesalers or drug manufacturers, at the ceiling prices described herein, unless the covered entity requests to have the discounts provided as a rebate after the drugs were purchased;

(D) such drugs are shipped without any delay or precondition to any licensed pharmacy or pharmacies that have entered into written agreement(s) with a covered entity that authorizes such licensed pharmacy or pharmacies to:

(i) perform dispensing activities to 340B eligible patients of the covered entity, and

(ii)receive and account for all 340B discounted drugs purchased by the covered entity, compliant with all applicable Federal and State laws, rules and regulations;

(E) the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities described in this section may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price').

(2) REBATE PERCENTAGE DEFINED.

(A) IN GENERAL.—For a covered outpatient drug purchased in a calendar quarter, the ''rebate percentage'' is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) OVER THE COUNTER DRUGS.—

(i) IN GENERAL.—For purposes of subparagraph (A), in the case of over the counter drugs, the ‘‘rebate percentage’’ shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) DEFINITION.—The term ‘‘over the counter drug’’ means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) COVERED ENTITY DEFINED.

In this section, the term ‘‘covered entity’’ means

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act);
(B) An entity receiving a grant under section 256a [1] of this title.
(C) A family planning project receiving a grant or contract under section 300 of this title.
(D) An entity receiving a grant under subpart II 1 of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).
(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.
(F) A black lung clinic receiving funds under section 937(a) of title 30.
(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].
(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.
(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].
(J) Any entity receiving assistance under subchapter XXVI (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).
(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) 1 of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).
(L) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act [42 U.S.C. 1395i–4(c)(2)]), and that
    (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(4) REQUIREMENTS FOR COVERED ENTITIES IN THIS SECTION.

(A) PROHIBITING DUPLICATE DISCOUNTS OR REBATES.—

(i) IN GENERAL.—A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) ESTABLISHMENT OF MECHANISM.—The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) PROHIBITING RESALE OF DRUGS.—With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) REINVESTMENT OF SAVINGS – Any funds generated from the benefits conferred under this section shall be reinvested into program operations, patient care, and other appropriate and beneficial activities, as determined by the covered entity leadership, to the populations served.

(D) AUDITING.—A covered entity shall permit the Secretary (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits, which shall be no more frequent than once every three years) to audit at the Secretary's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A), (B) and (C).

(D) ADDITIONAL SANCTION FOR NONCOMPLIANCE.—If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B), the covered entity shall be required to develop a corrective action plan that is approved by the Secretary and which must be completed within two years.

(5) CERTIFICATION OF CERTAIN COVERED ENTITIES

Covered entities described in this section are subject to the certification and recertification processes as defined in Section 340B.

(6) ACCESS TO PRIME VENDOR PROGRAM

Covered entities described in this section are eligible to enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(7) NOTICE TO MANUFACTURERS.

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(8) NO PROHIBITION ON LARGER DISCOUNT.

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(9) DRUGS PROVIDED UNDER STATE MEDICAID PLANS.

For drugs purchased by the covered entity for which payment is made, either directly or indirectly, by the State under the State plan for medical assistance under title XIX of the Social Security Act, such payment shall be no less than the cost as defined in Section 1847A(c)(6)(B) of the Social Security Act, in addition to an adequate and reasonable dispensing fee.

(10) PROHIBITION ON DISCRIMINATION.

(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 or its contracted pharmacy defined in this section by:

(1) 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 or 340C drugs, including by taking any action prohibited under subsection (b).

(2) imposing requirements, exclusions, copayments or other conditions on drugs that are purchased under this section that differ from those applied to the same drugs when purchased outside of this program.

(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 or a specified pharmacy 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 specified 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 or 340C 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) Refusing to provide coverage for a drug that was purchased under this section if it provides coverage for the same drug when it is purchased outside this section.

(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.

(11) REGULATORY AUTHORITY- The Secretary may issue regulations as necessary to implement this section.

(b) OTHER DEFINITIONS.

(1) IN GENERAL.—In this section, the terms ''average manufacturer price'', ''covered outpatient drug'', and ''manufacturer'' have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) COVERED DRUG.—In this section, the term 'covered drug'—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2022 and each succeeding fiscal year.