

Sec. 340B PUBLIC HEALTH SERVICE ACT

LIMITATION ON PRICES OF DRUGS PURCHASED BY 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 under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) 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). Each such agreement shall require that 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 may permissibly be required to pay for the drug (referred to in this section as the ‘ceiling price’), and shall require that 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.

(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) DRUGS PROVIDED UNDER STATE MEDICAID PLANS.

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) COVERED ENTITY DEFINED.

In this section, the term “covered entity” means an entity that meets the requirements described in paragraph (5) and is one of the following:

- (A) A Federally-qualified health center (as defined in section 1905(1)(2)(B) of the Social Security Act).
- (B) An entity receiving a grant under section 340A.

- (C) A family planning project receiving a grant or contract under section 1001.
- (D) An entity receiving a grant under subpart II of part C of title XXVI (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 title XXVI.
- (F) A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act.
- (G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.
- (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.
- (J) Any entity receiving assistance under title 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 318 (relating to treatment of sexually transmitted diseases) or section 317(j)(2) (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) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) 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 or eligible for assistance under the State plan under this title;
 - (ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and
 - (iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.
- (M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v)

of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) REQUIREMENTS FOR COVERED ENTITIES.

(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) AUDITING.—A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

(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 liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) TREATMENT OF DISTINCT UNITS OF HOSPITALS.

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) CERTIFICATION OF CERTAIN COVERED ENTITIES.

(A) DEVELOPMENT OF PROCESS.—Not later than 60 days after the date of enactment of this subsection, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) INCLUSION OF PURCHASE INFORMATION.—The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) CRITERIA.—The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) LIST OF PURCHASERS AND DISPENSERS.—The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) RECERTIFICATION.—The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) DEVELOPMENT OF PRIME VENDOR PROGRAM.

The Secretary shall establish a prime vendor program under which covered entities may 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.

(9) 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).

(10) 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).

(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.

(d) IMPROVEMENTS IN PROGRAM INTEGRITY.

(1) MANUFACTURER COMPLIANCE.—

(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive

adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which—

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act;

(II) shall not exceed \$5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) COVERED ENTITY COMPLIANCE.

(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors,

covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS.

(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) DEADLINES AND PROCEDURES.—Regulations promulgated by the Secretary under subparagraph (A) shall—

(i) designate or establish a decision making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to

demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) **FINALITY OF ADMINISTRATIVE RESOLUTION.**—The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of Orphan Drugs for Certain Covered Entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term 'covered outpatient drug' shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.

****Sec. 340B of the Public Health Service Act (Pub. L. 102-585), as amended by the Patient Protection and Affordable Care Act (Pub. L. 111-148), Health Care and Education Reconciliation Act (Pub. L. 111-152) and Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111-309)**