

Tab 1-1

42 U.S.C. § 256b - 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 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 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 November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. § 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

(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 [42 U.S.C. § 1396r-8(c)] 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 [42 U.S.C. § 1396r-8(c)] is based on the applicable percentage provided under section 1927(c)(4) of such Act.

(ii) "Over the counter drug" defined. 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 [42 U.S.C. § 1396 et seq.].

(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(l)(2)(B) of the Social Security Act [42 U.S.C. § 1396d(l)(2)(B)]).

(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 of part C of subchapter XXIV of this chapter (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 of this chapter.

(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 XXIV of this chapter (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) 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) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. § 1395ww(d)(1)(B)]) 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;

(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 [42 U.S.C. § 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. § 1395ww(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(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 [42 U.S.C. § 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C. § 1396d(a)(12)] 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 [42 U.S.C. § 1396r-8].

(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 [42 U.S.C. § 1396r-8(a)(5)(C)] 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 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 November 4, 1992, 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 [42 U.S.C. § 1396a(a)(5)] 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. 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 [42 U.S.C. § 1396r-8(k)].

(c) References to Social Security Act. Any reference in this section to a provision of the Social Security Act [42 U.S.C. § 301 et seq.] shall be deemed to be a reference to the provision as in effect on November 4, 1992.

(d) Compliance with requirements. A manufacturer is deemed to meet the requirements of subsection (a) of this section if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after November 4, 1992), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after November 4, 1992.