and resource use, sharing information, treatment decision support, and organizing care to avoid duplication of service and other medical management approaches intended to improve quality and value of health care services;

(H) provide local access to the continuum of health care services in the most appropriate setting, including access to individuals that implement the care plans of patients and coordinate care, such as integrative health care practitioners;

(I) collect and report data that permits evaluation of the success of the collaborative effort on patient outcomes, including collection of data on patient experience of care, and identification of areas for improvement; and

(J) establish a coordinated system of early identification and referral for children at risk for developmental or behavioral problems such as through the use of infolines, health information technology, or other means as determined by the Secretary;

(7) provide 24-hour care management and support during transitions in care settings including—

(A) a transitional care program that provides onsite visits from the care coordinator,[1] assists with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospitals,[2] nursing home, or other institution setting;

(B) discharge planning and counseling support to providers, patients, caregivers, and authorized representatives;

(C) assuring that post-discharge care plans include medication management, as appropriate;

(D) referrals for mental and behavioral health services, which may include the use of infolines; and

(E) transitional health care needs from adolescence to adulthood;

(8) serve as a liaison to community prevention and treatment programs;

(9) demonstrate a capacity to implement and maintain health information technology that meets the requirements of certified EHR technology (as defined in section 300jj of this title) to facilitate coordination among members of the applicable care team and affiliated primary care practices; and

(10) where applicable, report to the Secretary information on quality measures used under section 280j–2 of this title.

(d) Requirement for primary care providers

A provider who contracts with a care team shall—

(1) provide a care plan to the care team for each patient participant;

(2) provide access to participant health records; and

(3) meet regularly with the care team to ensure integration of care.

[1] So in original. The comma probably should be ''and''.

[2] So in original. Probably should be ''hospital,''.

(e) Reporting to Secretary

An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out by the entity under subsection (c).

(f) Definition of primary care

In this section, the term ''primary care'' means the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

(Pub. L. 111–148, title III, § 3502, title X, § 10321, Mar. 23, 2010, 124 Stat. 513, 952.)

REFERENCES IN TEXT

Section 2703, referred to in subsec. (b)(5), means section 2703 of Pub. L. 111–148.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2010—Subsec. (c)(2)(A). Pub. L. 111–148, § 10321, inserted ''or other primary care providers'' after ''physicians''.

SUBPART VII—DRUG PRICING AGREEMENTS

§ 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 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 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). 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 percent-

age'' 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)(3) 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[1] 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)[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) 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.

(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 [42 U.S.C. 1395ww(d)(1)(B)(iii)], 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 [42 U.S.C. 1395i–4(c)(2)]), 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 [42 U.S.C. 1395ww(d)(5)(C)(i)], 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.

[1] See References in Text note below.

(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[2] (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[2] (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

(1) In general

In this section, the terms ''average manufacturer price'', ''covered outpatient drug'', and

[2] So in original. Probably should be ''subparagraph''.

''manufacturer'' have the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C. 1396r–8(k)].

(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 [42 U.S.C. 1396r–8(k)(2)]); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act [42 U.S.C. 1396r–8(k)(3)(A)], 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) Repealed. Pub. L. 111–152, title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(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 March 23, 2010;

(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).[1]

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, 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[3] (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

[3] So in original. Probably should be ''subsection''.

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 360bb of title 21 for a rare disease or condition.

(July 1, 1944, ch. 373, title III, § 340B, as added Pub. L. 102–585, title VI, § 602(a), Nov. 4, 1992, 106 Stat. 4967; amended Pub. L. 103–43, title XX, § 2008(i)(1)(A), June 10, 1993, 107 Stat. 212; Pub. L. 111–148, title II, § 2501(f)(1), title VII, §§ 7101(a)–(d), 7102, Mar. 23, 2010, 124 Stat. 309, 821–823; Pub. L. 111–152, title II, § 2302, Mar. 30, 2010, 124 Stat. 1082; Pub. L. 111–309, title II, § 204(a)(1), Dec. 15, 2010, 124 Stat. 3289.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(1), (3), (4)(L)(i), (5)(A)(i), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, which is classified generally to chapter 7 (§ 301 et seq.) of this title. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§ 1395 et seq.) and XIX (§ 1396 et seq.) of chapter 7 of this title, respectively. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 256a of this title, referred to in subsec. (a)(4)(B), was in the original a reference to section 340A of act July 1, 1944, which was repealed by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645. Subsequently, a new section 340A was added to the act of July 1, 1944, by Pub. L. 109–18, § 2, June 29, 2005, 119 Stat. 340, which is also classified to section 256a of this title.

Subpart II of part C of subchapter XXIV of this chapter, referred to in subsec. (a)(4)(D), was redesignated subpart I of part C of subchapter XXIV of this chapter by Pub. L. 106–345, title III, § 301(b)(1), Oct. 20, 2000, 114 Stat. 1345, and is classified to section 300ff–51 et seq. of this title.

The Native Hawaiian Health Care Act of 1988, referred to in subsec. (a)(4)(H), was Pub. L. 100–579, Oct. 31, 1988, 102 Stat. 2916, and subtitle D of title II of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4222, which were classified generally to chapter 122 (§ 11701 et seq.) of this title prior to being amended generally and renamed the Native Hawaiian Health Care Improvement Act by Pub. L. 102–396. For complete classification of this Act to the Code, see Tables.

The Indian Health Care Improvement Act, referred to in subsec. (a)(4)(I), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400, as amended. Title V of the Act is classified generally to subchapter IV (§ 1651 et seq.) of chapter 18 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

Section 247b(j)(2) of this title, referred to in subsec. (a)(4)(K), was repealed and section 247b(j)(1)(B) was redesignated section 247b(j)(2) by Pub. L. 103–183, title III, § 301(b)(1)(A), (C), Dec. 14, 1993, 107 Stat. 2235.

The Prescription Drug Marketing Act, referred to in subsec. (d)(2)(B)(v)(III), probably means the Prescription Drug Marketing Act of 1987, Pub. L. 100–293, Apr. 22, 1988, 102 Stat. 95, which amended sections 331, 333, 353, and 381 of Title 21, Food and Drugs, and enacted provisions set out as notes under sections 301 and 353 of Title 21. For complete classification of this Act to the Code, see Short Title of 1988 Amendments note set out under section 301 of Title 21 and Tables.

CODIFICATION

Another section 340B of act July 1, 1944, was renumbered section 340C and is classified to section 256c of this title.

AMENDMENTS

2010—Subsec. (a)(1). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug'' and ''covered outpatient drugs'' for ''covered drugs'' wherever appearing.

Pub. L. 111–148, § 7102(b)(1), inserted at end ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered 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 drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''

Subsec. (a)(2)(A). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug'' in introductory provisions.

Pub. L. 111–148, § 7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug'' in introductory provisions.

Subsec. (a)(2)(B)(i). Pub. L. 111–148, § 2501(f)(1)(A), substituted ''1927(c)(3)'' for ''1927(c)(4)''.

Subsec. (a)(4)(L). Pub. L. 111–152, § 2302(1)(B), struck out ''and'' at end of cl. (i), substituted ''; and'' for period at end of cl. (ii), and added cl. (iii).

Pub. L. 111–148, § 7101(c)(1), in cl. (i), inserted ''and'' at end, in cl. (ii), substituted period for ''; and'' at end, and struck out cl. (iii) which read as follows: ''does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.''

Subsec. (a)(4)(M) to (O). Pub. L. 111–148, § 7101(a), added subpars. (M) to (O).

Subsec. (a)(5)(B). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, § 7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(C). Pub. L. 111–152, § 2302(1)(C)(i), (ii), redesignated subpar. (D) as (C) and struck out former subpar. (C). Prior to amendment, text of subpar. (C) read as follows:

''(i) IN GENERAL.—A hospital described in subparagraph (L), (M), (N), or (O) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided for pursuant to clauses (ii) or (iii).

''(ii) INPATIENT DRUGS.—Clause (i) shall not apply to drugs purchased for inpatient use.

''(iii) EXCEPTIONS.—The Secretary shall establish reasonable exceptions to clause (i)—

''(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug shortage problem, manufacturer noncompliance, or any other circumstance beyond the hospital's control;

''(II) to facilitate generic substitution when a generic covered outpatient drug is available at a lower price; or

''(III) to reduce in other ways the administrative burdens of managing both inventories of drugs subject to this section and inventories of drugs that are not subject to this section, so long as the exceptions do not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).

''(iv) PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS.—The Secretary shall ensure that 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 shall have multiple options for purchasing covered outpatient drugs for inpatients, including by utilizing a group purchasing organization or other group purchasing arrangement, establishing and utilizing its own group purchasing program, purchasing directly from a manufacturer,

and any other purchasing arrangements that the Secretary determines is appropriate to ensure access to drug discount pricing under this section for inpatient drugs taking into account the particular needs of small and rural hospitals.''

Pub. L. 111–148, §7101(c)(2)(B), added subpar. (C). Former subpar. (C) redesignated (D).

Pub. L. 111–148, §7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(C)(iv). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs''.

Subsec. (a)(5)(D). Pub. L. 111–152, §2302(1)(C)(ii), (iii), redesignated subpar. (E) as (D) and substituted ''subparagraph (C)'' for ''subparagraph (D)''. Former subpar. (D) redesignated (C).

Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, §7101(c)(2)(A), redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Pub. L. 111–148, §7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(E). Pub. L. 111–152, §2302(1)(C)(ii), redesignated subpar. (E) as (D).

Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, §§7101(c)(2)(A), 7102(b)(2), redesignated subpar. (D) as (E) and inserted ''after audit as described in subparagraph (D) and'' after ''finds,''.

Subsec. (a)(7). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs'' wherever appearing.

Pub. L. 111–148, §7101(b)(1), substituted ''covered drugs'' for ''covered outpatient drugs'' wherever appearing.

Subsec. (a)(9). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs''.

Pub. L. 111–148, §7101(b)(1), substituted ''covered drugs'' for ''covered outpatient drugs''.

Subsec. (b). Pub. L. 111–148, §7101(b)(2)(A), which directed substitution of ''Other definitions'' for ''Other definition'' in subsec. heading, designation of existing provisions as par. (1), and insertion of par. (1) heading, was executed by reenacting subsec. heading without change, designating existing provisions as par. (1), and inserting par. (1) heading, to reflect the probable intent of Congress.

Subsec. (b)(2). Pub. L. 111–148, §7101(b)(2)(B), added par. (2).

Subsec. (c). Pub. L. 111–152, §2302(2), struck out subsec. (c). Text read as follows: ''Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients.''

Pub. L. 111–148, §7101(d), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: ''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.''

Pub. L. 111–148, §2501(f)(1)(B), (C), redesignated subsec. (d) as (c) and struck out former subsec. (c). Text of former subsec. (c) read as follows: ''Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on November 4, 1992.''

Subsec. (d). Pub. L. 111–152, §2302(3), substituted ''covered outpatient drugs'' for ''covered drugs'' wherever appearing and substituted ''(a)(5)(C)'' for ''(a)(5)(D)'' and ''(a)(5)(D)'' for ''(a)(5)(E)'' in two places.

Pub. L. 111–148, §7102(a), which directed general amendment of subsec. (d), was executed by adding subsec. (d) after subsec. (c) to reflect the probable intent of Congress, because no subsec. (d) appeared subsequent to amendment by Pub. L. 111–148, §2501(f)(1)(C). See below.

Pub. L. 111–148, §2501(f)(1)(C), redesignated subsec. (d) as (c).

Subsec. (e). Pub. L. 111–309 substituted ''covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M))'' for ''covered entities described in subparagraph (M)''.

Pub. L. 111–152, §2302(4), added subsec. (e).

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–585, §602(a), which enacted this section.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–309, title II, §204(a)(2), Dec. 15, 2010, 124 Stat. 3289, provided that: ''The amendment made by paragraph (1) [amending this section] shall take effect as if included in the enactment of section 2302 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152).''

Pub. L. 111–148, title II, §2501(f)(2), Mar. 23, 2010, 124 Stat. 310, provided that: ''The amendments made by this subsection [amending this section] take effect on January 1, 2010.''

Pub. L. 111–148, title VII, §7101(e), Mar. 23, 2010, 124 Stat. 823, provided that:

''(1) IN GENERAL.—The amendments made by this section [amending this section] and section 7102 [amending this section] shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010.

''(2) EFFECTIVENESS.—The amendments made by this section and section 7102 shall be effective and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), notwithstanding any other provision of law.''

STUDY OF TREATMENT OF CERTAIN CLINICS AS COVERED ENTITIES ELIGIBLE FOR PRESCRIPTION DRUG DISCOUNTS

Section 602(b) of Pub. L. 102–585 directed Secretary of Health and Human Services to conduct a study of feasibility and desirability of including specified entities receiving funds from a State as covered entities eligible for limitations on prices of covered outpatient drugs under 42 U.S.C. 256b(a) and, not later than 1 year after Nov. 4, 1992, to submit a report to Congress on the study, including in the report a description of the entities that were the subject of the study, an analysis of the extent to which such entities procured prescription drugs, and an analysis of the impact of the inclusion of such entities as covered entities on the quality of care provided to and the health status of the patients of such entities.

SUBPART VIII—BULK PURCHASES OF VACCINES FOR CERTAIN PROGRAMS

AMENDMENTS

1993—Pub. L. 103–43, title XX, §2008(i)(2)(A)(i), June 10, 1993, 107 Stat. 213, made technical amendment relating to placement of subpart VIII within part D of this subchapter.

§ 256c. Bulk purchases of vaccines for certain programs

(a) Agreements for purchases

(1) In general

Not later than 180 days after October 27, 1992, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator of the Health Resources and Services Administration, shall enter into negotiations