

(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.

(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.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(1), (3), (4)(L)(i), (5)(A)(i), and (c), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended, which is classified generally to chapter 7 (§301 et seq.) of this title. Titles XVIII and XIX of the Act are classified generally to sub-

chapters 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 repealed by Pub. L. 104-299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

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.

CODIFICATION

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

AMENDMENTS

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

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 Preven-

tion and in consultation with the Administrator of the Health Resources and Services Administration, shall enter into negotiations with manufacturers of vaccines for the purpose of establishing and maintaining agreements under which entities described in paragraph (2) may purchase vaccines from the manufacturers at the prices specified in the agreements.

(2) Relevant entities

The entities referred to in paragraph (1) are entities that provide immunizations against vaccine-preventable diseases with assistance provided under section 254b of this title.

(b) Negotiation of prices

In carrying out subsection (a) of this section, the Secretary shall, to the extent practicable, ensure that the prices provided for in agreements under such subsection are comparable to the prices provided for in agreements negotiated by the Secretary on behalf of grantees under section 247b(j)(1) of this title.

(c) Authority of Secretary

In carrying out subsection (a) of this section, the Secretary, in the discretion of the Secretary, may enter into the agreements described in such subsection (and may decline to enter into such agreements), may modify such agreements, may extend such agreements, and may terminate such agreements.

(d) Rule of construction

This section may not be construed as requiring any State to reduce or terminate the supply of vaccines provided by the State to any of the entities described in subsection (a)(2) of this section.

(July 1, 1944, ch. 373, title III, §340C, formerly §340B, as added Pub. L. 102-531, title III, §305, Oct. 27, 1992, 106 Stat. 3494; renumbered §340C, Pub. L. 103-43, title XX, §2008(i)(2)(A)(ii), June 10, 1993, 107 Stat. 213; amended Pub. L. 104-299, §4(a)(2), Oct. 11, 1996, 110 Stat. 3645.)

AMENDMENTS

1996—Subsec. (a)(2). Pub. L. 104-299 substituted “with assistance provided under section 254b of this title” for “under the programs established in sections 254b, 254c, 256, and 256a of this title.”

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104-299 effective Oct. 1, 1996, see section 5 of Pub. L. 104-299, as amended, set out as a note under section 233 of this title.

§ 256d. Breast and cervical cancer information

(a) In general

As a condition of receiving grants, cooperative agreements, or contracts under this chapter, each of the entities specified in subsection (c) of this section shall, to the extent determined to be appropriate by the Secretary, make available information concerning breast and cervical cancer.

(b) Certain authorities

In carrying out subsection (a) of this section, an entity specified in subsection (c) of this section—

(1) may make the information involved available to such individuals as the entity determines appropriate;

(2) may, as appropriate, provide information under subsection (a) of this section on the need for self-examination of the breasts and on the skills for such self-examinations;

(3) shall provide information under subsection (a) of this section in the language and cultural context most appropriate to the individuals to whom the information is provided; and

(4) shall refer such clients as the entities determine appropriate for breast and cervical cancer screening, treatment, or other appropriate services.

(c) Relevant entities

The entities specified in this subsection are the following:

(1) Entities receiving assistance under section 247b-7¹ of this title (relating to tuberculosis).

(2) Entities receiving assistance under section 247c of this title (relating to sexually transmitted diseases).

(3) Migrant health centers receiving assistance under section 254b¹ of this title.

(4) Community health centers receiving assistance under section 254c¹ of this title.

(5) Entities receiving assistance under section 254b(h) of this title (relating to homeless individuals).

(6) Entities receiving assistance under section 256a¹ of this title (relating to health services for residents of public housing).

(7) Entities providing services with assistance under subchapter III-A of this chapter or subchapter XVII of this chapter.

(8) Entities receiving assistance under section 300 of this title (relating to family planning).

(9) Entities receiving assistance under subchapter XXIV of this chapter (relating to services with respect to acquired immune deficiency syndrome).

(10) Non-Federal entities authorized under the Indian Self-Determination Act [25 U.S.C. 450f et seq.].

(July 1, 1944, ch. 373, title III, §340D, as added Pub. L. 103-183, title I, §104, Dec. 14, 1993, 107 Stat. 2230; amended Pub. L. 106-310, div. A, title XXV, §2502(b), Oct. 17, 2000, 114 Stat. 1163; Pub. L. 107-251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664.)

REFERENCES IN TEXT

Section 247b-7 of this title, referred to in subsec. (c)(1), relates to loan repayment program and not to assistance relating to tuberculosis.

Sections 254b and 254c of this title, referred to in subsec. (c)(3), (4), were in the original references to sections 329 and 330, meaning sections 329 and 330 of act July 1, 1944, which were omitted in the general amendment of subpart I (§254b et seq.) of this part by Pub. L. 104-299, §2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104-299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

Section 256a of this title, referred to in subsec. (c)(6), was repealed by Pub. L. 104-299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

¹ See References in Text note below.

The Indian Self-Determination Act, referred to in subsec. (c)(10), is title I of Pub. L. 93-638, Jan. 4, 1975, 88 Stat. 2206, as amended, which is classified principally to part A (§450f et seq.) of subchapter II of chapter 14 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 450 of Title 25 and Tables.

AMENDMENTS

2002—Subsec. (c)(5). Pub. L. 107-251 substituted “254b(h)” for “256”.

2000—Subsec. (c)(1). Pub. L. 106-310 substituted “section 247b-7 of this title” for “section 247b-6 of this title”.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center, considered reference to health center, see section 4(c) of Pub. L. 104-299, set out as a note under section 254b of this title.

SUBPART IX—SUPPORT OF GRADUATE MEDICAL EDUCATION PROGRAMS IN CHILDREN’S HOSPITALS

§ 256e. Program of payments to children’s hospitals that operate graduate medical education programs

(a) Payments

The Secretary shall make two payments under this section to each children’s hospital for each of fiscal years 2000 through 2005 and each of fiscal years 2007 through 2011, one for the direct expenses and the other for indirect expenses associated with operating approved graduate medical residency training programs. The Secretary shall promulgate regulations pursuant to the rulemaking requirements of title 5 which shall govern payments made under this subpart.

(b) Amount of payments

(1) In general

Subject to paragraphs (2) and (3), the amounts payable under this section to a children’s hospital for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) Direct expense amount

The amount determined under subsection (c) of this section for direct expenses associated with operating approved graduate medical residency training programs.

(B) Indirect expense amount

The amount determined under subsection (d) of this section for indirect expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

(2) Capped amount

(A) In general

The total of the payments made to children’s hospitals under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the funds appropriated under paragraph (1) or (2), respectively, of subsection (f) of this section for such payments for that fiscal year.

(B) Pro rata reductions of payments for direct expenses

If the Secretary determines that the amount of funds appropriated under sub-

section (f)(1) of this section for a fiscal year is insufficient to provide the total amount of payments otherwise due for such periods under paragraph (1)(A), the Secretary shall reduce the amounts so payable on a pro rata basis to reflect such shortfall.

(3) Annual reporting required

(A) Reduction in payment for failure to report

(i) In general

The amount payable under this section to a children’s hospital for a fiscal year (beginning with fiscal year 2008 and after taking into account paragraph (2)) shall be reduced by 25 percent if the Secretary determines that—

(I) the hospital has failed to provide the Secretary, as an addendum to the hospital’s application under this section for such fiscal year, the report required under subparagraph (B) for the previous fiscal year; or

(II) such report fails to provide the information required under any clause of such subparagraph.

(ii) Notice and opportunity to provide missing information

Before imposing a reduction under clause (i) on the basis of a hospital’s failure to provide information described in clause (i)(II), the Secretary shall provide notice to the hospital of such failure and the Secretary’s intention to impose such reduction and shall provide the hospital with the opportunity to provide the required information within a period of 30 days beginning on the date of such notice. If the hospital provides such information within such period, no reduction shall be made under clause (i) on the basis of the previous failure to provide such information.

(B) Annual report

The report required under this subparagraph for a children’s hospital for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

(i) The types of resident training programs that the hospital provided for residents described in subparagraph (C), such as general pediatrics, internal medicine/pediatrics, and pediatric subspecialties, including both medical subspecialties certified by the American Board of Pediatrics (such as pediatric gastroenterology) and non-medical subspecialties approved by other medical certification boards (such as pediatric surgery).

(ii) The number of training positions for residents described in subparagraph (C), the number of such positions recruited to fill, and the number of such positions filled.

(iii) The types of training that the hospital provided for residents described in