

“(c) DEFINITIONS.—In this subsection:

“(1) The term ‘multiple source drug’ has the meaning given that term in section 1927(k)(7)(A)(i) of the Social Security Act (42 U.S.C. 1396r-8(k)(7)(A)(i)).

“(2) The term ‘AMP’ has the meaning given ‘average manufacturer price’ in section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-8(k)(1)) and ‘AMP’ in section 447.504(a) of title 42, Code of Federal Regulations as published on July 17, 2007 (72 Federal Register 39142).”

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108-173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under subchapter XVIII of this chapter, see section 303(j) of Pub. L. 108-173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108-173 (see note above), amendment by section 303 of Pub. L. 108-173 also applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology, see section 304 of Pub. L. 108-173, set out as a note under section 1395u of this title.

REPORTS ON BEST PRICE CHANGES AND PAYMENT OF REBATES

Pub. L. 102-585, title VI, §601(d), Nov. 4, 1992, 106 Stat. 4965, provided that not later than 90 days after the expiration of each calendar quarter beginning on or after Oct. 1, 1992, and ending on or before Dec. 31, 1995, Secretary of Health and Human Services was to submit to Congress a report containing information as to percentage of single source drugs whose best price either increased, decreased, or stayed the same in comparison to best price during previous calendar quarter, median and mean percentage increase or decrease of such price, and, with respect to drugs for which manufacturers were required to pay rebates under subsec. (c) of this section, Secretary’s best estimate, on State-by-State and national aggregate basis, of total amount of rebates paid under subsec. (c) of this section and percentages of such total amounts attributable to rebates paid under pars. (1) to (3) of subsec. (c) of this section, limited consideration to drugs which are considered significant expenditures under medicaid program, and contained requirements for initial report.

DEMONSTRATION PROJECTS TO EVALUATE EFFICIENCY AND COST-EFFECTIVENESS OF PROSPECTIVE DRUG UTILIZATION REVIEW

Pub. L. 101-508, title IV, §4401(c), Nov. 5, 1990, 104 Stat. 1388-159, directed Secretary of Health and Human Services to establish statewide demonstration projects to evaluate efficiency and cost-effectiveness of prospective drug utilization review and to evaluate impact on quality of care and cost-effectiveness of paying pharmacists under this subchapter whether or not drugs were dispensed for drug use review services, with two reports to be submitted to Congress, the first not later than Jan. 1, 1994, and the second not later than Jan. 1, 1995.

STUDY OF DRUG PURCHASING AND BILLING PRACTICES IN HEALTH CARE INDUSTRY; REPORT

Pub. L. 101-508, title IV, §4401(d), Nov. 5, 1990, 104 Stat. 1388-160, as amended by Pub. L. 104-316, title I, §122(i), Oct. 19, 1996, 110 Stat. 3837, provided for various studies and reports as follows: (1) directed Comptroller General to conduct study of drug purchasing and billing activities of various health care systems, and to submit report to Secretary of Health and Human Services and to Congress by not later than May 1, 1991; (2) directed Comptroller General to submit to Secretary

and Congress report on changes in prices charged by manufacturers for prescription drugs to Department of Veterans Affairs, other Federal programs, hospital pharmacies, and other purchasing groups and managed care plans; (3) directed Secretary, acting in consultation with Comptroller General, to study prior approval procedures utilized by State medical assistance programs conducted under this subchapter, and to submit report to Congress by not later than Dec. 31, 1991; (4) directed Secretary to conduct study on adequacy of current reimbursement rates to pharmacists under each State medical assistance program conducted under this subchapter, and to submit report to Congress by not later than Dec. 31, 1991; and (5) directed Secretary to undertake study of relationship between State medical assistance plans and Federal and State acquisition and reimbursement policies for vaccines and accessibility of vaccinations and immunization to children, and to report to Congress not later than one year after Nov. 5, 1990.

§ 1396s. Program for distribution of pediatric vaccines

(a) Establishment of program

(1) In general

In order to meet the requirement of section 1396a(a)(62) of this title, each State shall establish a pediatric vaccine distribution program (which may be administered by the State department of health), consistent with the requirements of this section, under which—

(A) each vaccine-eligible child (as defined in subsection (b) of this section), in receiving an immunization with a qualified pediatric vaccine (as defined in subsection (h)(8) of this section) from a program-registered provider (as defined in subsection (c) of this section) on or after October 1, 1994, is entitled to receive the immunization without charge for the cost of such vaccine; and

(B)(i) each program-registered provider who administers such a pediatric vaccine to a vaccine-eligible child on or after such date is entitled to receive such vaccine under the program without charge either for the vaccine or its delivery to the provider, and (ii) no vaccine is distributed under the program to a provider unless the provider is a program-registered provider.

(2) Delivery of sufficient quantities of pediatric vaccines to immunize federally vaccine-eligible children

(A) In general

The Secretary shall provide under subsection (d) of this section for the purchase and delivery on behalf of each State meeting the requirement of section 1396a(a)(62) of this title (or, with respect to vaccines administered by an Indian tribe or tribal organization to Indian children, directly to the tribe or organization), without charge to the State, of such quantities of qualified pediatric vaccines as may be necessary for the administration of such vaccines to all federally vaccine-eligible children in the State on or after October 1, 1994. This paragraph constitutes budget authority in advance of appropriations Acts, and represents the obligation of the Federal Government to provide for the purchase and delivery to States of

the vaccines (or payment under subparagraph (C)) in accordance with this paragraph.

**(B) Special rules where vaccine is unavailable**

To the extent that a sufficient quantity of a vaccine is not available for purchase or delivery under subsection (d) of this section, the Secretary shall provide for the purchase and delivery of the available vaccine in accordance with priorities established by the Secretary, with priority given to federally vaccine-eligible children unless the Secretary finds there are other public health considerations.

**(C) Special rules where State is a manufacturer**

**(i) Payments in lieu of vaccines**

In the case of a State that manufactures a pediatric vaccine the Secretary, instead of providing the vaccine on behalf of a State under subparagraph (A), shall provide to the State an amount equal to the value of the quantity of such vaccine that otherwise would have been delivered on behalf of the State under such subparagraph, but only if the State agrees that such payments will only be used for purposes relating to pediatric immunizations.

**(ii) Determination of value**

In determining the amount to pay a State under clause (i) with respect to a pediatric vaccine, the value of the quantity of vaccine shall be determined on the basis of the price in effect for the qualified pediatric vaccine under contracts under subsection (d) of this section. If more than 1 such contract is in effect, the Secretary shall determine such value on the basis of the average of the prices under the contracts, after weighting each such price in relation to the quantity of vaccine under the contract involved.

**(b) Vaccine-eligible children**

For purposes of this section:

**(1) In general**

The term “vaccine-eligible child” means a child who is a federally vaccine-eligible child (as defined in paragraph (2)) or a State vaccine-eligible child (as defined in paragraph (3)).

**(2) Federally vaccine-eligible child**

**(A) In general**

The term “federally vaccine-eligible child” means any of the following children:

- (i) A medicaid-eligible child.
- (ii) A child who is not insured.
- (iii) A child who (I) is administered a qualified pediatric vaccine by a federally-qualified health center (as defined in section 1396d(l)(2)(B) of this title) or a rural health clinic (as defined in section 1396d(l)(1) of this title), and (II) is not insured with respect to the vaccine.
- (iv) A child who is an Indian (as defined in subsection (h)(3) of this section).

**(B) Definitions**

In subparagraph (A):

(i) The term “medicaid-eligible” means, with respect to a child, a child who is entitled to medical assistance under a state<sup>1</sup> plan approved under this subchapter.

(ii) The term “insured” means, with respect to a child—

(I) for purposes of subparagraph (A)(ii), that the child is enrolled under, and entitled to benefits under, a health insurance policy or plan, including a group health plan, a prepaid health plan, or an employee welfare benefit plan under the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1001 et seq.]; and

(II) for purposes of subparagraph (A)(iii)(II) with respect to a pediatric vaccine, that the child is entitled to benefits under such a health insurance policy or plan, but such benefits are not available with respect to the cost of the pediatric vaccine.

**(3) State vaccine-eligible child**

The term “State vaccine-eligible child” means, with respect to a State and a qualified pediatric vaccine, a child who is within a class of children for which the State is purchasing the vaccine pursuant to subsection (d)(4)(B) of this section.

**(c) Program-registered providers**

**(1) Defined**

In this section, except as otherwise provided, the term “program-registered provider” means, with respect to a State, any health care provider that—

(A) is licensed or otherwise authorized for administration of pediatric vaccines under the law of the State in which the administration occurs (subject to section 254f(e) of this title), without regard to whether or not the provider participates in the plan under this subchapter;

(B) submits to the State an executed provider agreement described in paragraph (2); and

(C) has not been found, by the Secretary or the State, to have violated such agreement or other applicable requirements established by the Secretary or the State consistent with this section.

**(2) Provider agreement**

A provider agreement for a provider under this paragraph is an agreement (in such form and manner as the Secretary may require) that the provider agrees as follows:

(A)(i) Before administering a qualified pediatric vaccine to a child, the provider will ask a parent of the child such questions as are necessary to determine whether the child is a vaccine-eligible child, but the provider need not independently verify the answers to such questions.

(ii) The provider will, for a period of time specified by the Secretary, maintain records of responses made to the questions.

<sup>1</sup> So in original. Probably should be capitalized.

(iii) The provider will, upon request, make such records available to the State and to the Secretary, subject to section 1396a(a)(7) of this title.

(B)(i) Subject to clause (ii), the provider will comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is established and periodically reviewed and, as appropriate, revised by the advisory committee referred to in subsection (e) of this section, except in such cases as, in the provider's medical judgment subject to accepted medical practice, such compliance is medically inappropriate.

(ii) The provider will provide pediatric vaccines in compliance with applicable State law, including any such law relating to any religious or other exemption.

(C)(i) In administering a qualified pediatric vaccine to a vaccine-eligible child, the provider will not impose a charge for the cost of the vaccine. A program-registered provider is not required under this section to administer such a vaccine to each child for whom an immunization with the vaccine is sought from the provider.

(ii) The provider may impose a fee for the administration of a qualified pediatric vaccine so long as the fee in the case of a federally vaccine-eligible child does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration).

(iii) The provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parent to pay an administration fee.

### **(3) Encouraging involvement of providers**

Each program under this section shall provide, in accordance with criteria established by the Secretary—

(A) for encouraging the following to become program-registered providers: private health care providers, the Indian Health Service, health care providers that receive funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.], and health programs or facilities operated by Indian tribes or tribal organizations; and

(B) for identifying, with respect to any population of vaccine-eligible children a substantial portion of whose parents have a limited ability to speak the English language, those program-registered providers who are able to communicate with the population involved in the language and cultural context that is most appropriate.

### **(4) State requirements**

Except as the Secretary may permit in order to prevent fraud and abuse and for related purposes, a State may not impose additional qualifications or conditions, in addition to the requirements of paragraph (1), in order that a provider qualify as a program-registered provider under this section. This subsection does not limit the exercise of State authority under section 1396n(b) of this title.

## **(d) Negotiation of contracts with manufacturers**

### **(1) In general**

For the purpose of meeting obligations under this section, the Secretary shall negotiate and enter into contracts with manufacturers of pediatric vaccines consistent with the requirements of this subsection and, to the maximum extent practicable, consolidate such contracting with any other contracting activities conducted by the Secretary to purchase vaccines. The Secretary may enter into such contracts under which the Federal Government is obligated to make outlays, the budget authority for which is not provided for in advance in appropriations Acts, for the purchase and delivery of pediatric vaccines under subsection (a)(2)(A) of this section.

### **(2) Authority to decline contracts**

The Secretary may decline to enter into such contracts and may modify or extend such contracts.

### **(3) Contract price**

#### **(A) In general**

The Secretary, in negotiating the prices at which pediatric vaccines will be purchased and delivered from a manufacturer under this subsection, shall take into account quantities of vaccines to be purchased by States under the option under paragraph (4)(B).

#### **(B) Negotiation of discounted price for current vaccines**

With respect to contracts entered into under this subsection for a pediatric vaccine for which the Centers for Disease Control and Prevention has a contract in effect under section 247b(j)(1) of this title as of May 1, 1993, no price for the purchase of such vaccine for vaccine-eligible children shall be agreed to by the Secretary under this subsection if the price per dose of such vaccine (including delivery costs and any applicable excise tax established under section 4131 of the Internal Revenue Code of 1986) exceeds the price per dose for the vaccine in effect under such a contract as of such date increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from May 1993 to the month before the month in which such contract is entered into.

#### **(C) Negotiation of discounted price for new vaccines**

With respect to contracts entered into for a pediatric vaccine not described in subparagraph (B), the price for the purchase of such vaccine shall be a discounted price negotiated by the Secretary that may be established without regard to such subparagraph.

### **(4) Quantities and terms of delivery**

Under such contracts—

(A) the Secretary shall provide, consistent with paragraph (6), for the purchase and delivery on behalf of States (and tribes and tribal organizations) of quantities of pediatric vaccines for federally vaccine-eligible children; and

(B) each State, at the option of the State, shall be permitted to obtain additional quantities of pediatric vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through purchasing the vaccines from the manufacturers at the applicable price negotiated by the Secretary consistent with paragraph (3), if (i) the State agrees that the vaccines will be used to provide immunizations only for children who are not federally vaccine-eligible children and (ii) the State provides to the Secretary such information (at a time and manner specified by the Secretary, including in advance of negotiations under paragraph (1)) as the Secretary determines to be necessary, to provide for quantities of pediatric vaccines for the State to purchase pursuant to this subsection and to determine annually the percentage of the vaccine market that is purchased pursuant to this section and this subparagraph.

The Secretary shall enter into the initial negotiations under the preceding sentence not later than 180 days after August 10, 1993.

**(5) Charges for shipping and handling**

The Secretary may enter into a contract referred to in paragraph (1) only if the manufacturer involved agrees to submit to the Secretary such reports as the Secretary determines to be appropriate to assure compliance with the contract and if, with respect to a State program under this section that does not provide for the direct delivery of qualified pediatric vaccines, the manufacturer involved agrees that the manufacturer will provide for the delivery of the vaccines on behalf of the State in accordance with such program and will not impose any charges for the costs of such delivery (except to the extent such costs are provided for in the price established under paragraph (3)).

**(6) Assuring adequate supply of vaccines**

The Secretary, in negotiations under paragraph (1), shall negotiate for quantities of pediatric vaccines such that an adequate supply of such vaccines will be maintained to meet unanticipated needs for the vaccines. For purposes of the preceding sentence, the Secretary shall negotiate for a 6-month supply of vaccines in addition to the quantity that the Secretary otherwise would provide for in such negotiations. In carrying out this paragraph, the Secretary shall consider the potential for outbreaks of the diseases with respect to which the vaccines have been developed.

**(7) Multiple suppliers**

In the case of the pediatric vaccine involved, the Secretary shall, as appropriate, enter into a contract referred to in paragraph (1) with each manufacturer of the vaccine that meets the terms and conditions of the Secretary for an award of such a contract (including terms and conditions regarding safety and quality). With respect to multiple contracts entered into pursuant to this paragraph, the Secretary may have in effect different prices under each of such contracts and, with respect to a purchase by States pursuant to paragraph (4)(B),

the Secretary shall determine which of such contracts will be applicable to the purchase.

**(e) Use of pediatric vaccines list**

The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).

**(f) Requirement of State maintenance of immunization laws**

In the case of a State that had in effect as of May 1, 1993, a law that requires some or all health insurance policies or plans to provide some coverage with respect to a pediatric vaccine, a State program under this section does not comply with the requirements of this section unless the State certifies to the Secretary that the State has not modified or repealed such law in a manner that reduces the amount of coverage so required.

**(g) Termination**

This section, and the requirement of section 1396a(a)(62) of this title, shall cease to be in effect beginning on such date as may be prescribed in Federal law providing for immunization services for all children as part of a broad-based reform of the national health care system.

**(h) Definitions**

For purposes of this section:

(1) The term “child” means an individual 18 years of age or younger.

(2) The term “immunization” means an immunization against a vaccine-preventable disease.

(3) The terms “Indian”, “Indian tribe” and “tribal organization” have the meanings given such terms in section 4 of the Indian Health Care Improvement Act [25 U.S.C. 1603].

(4) The term “manufacturer” means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any pediatric vaccine. The term “manufacture” means to manufacture, import, process, or distribute a vaccine.

(5) The term “parent” includes, with respect to a child, an individual who qualifies as a legal guardian under State law.

(6) The term “pediatric vaccine” means a vaccine included on the list under subsection (e) of this section.

(7) The term “program-registered provider” has the meaning given such term in subsection (c) of this section.

(8) The term “qualified pediatric vaccine” means a pediatric vaccine with respect to which a contract is in effect under subsection (d) of this section.

(9) The terms “vaccine-eligible child”, “federally vaccine-eligible child”, and “State vaccine-eligible child” have the meaning given such terms in subsection (b) of this section.

(Aug. 14, 1935, ch. 531, title XIX, §1928, as added Pub. L. 103-66, title XIII, §13631(b)(2), Aug. 10, 1993, 107 Stat. 637.)

#### REFERENCES IN TEXT

The Employee Retirement Income Security Act of 1974, referred to in subsec. (b)(2)(B)(ii)(I), is Pub. L. 93-406, Sept. 2, 1974, 88 Stat. 829, as amended, which is classified principally to chapter 18 (§1001 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 1001 of Title 29 and Tables.

The Indian Health Care Improvement Act, referred to in subsec. (c)(3)(A), 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.

The Internal Revenue Code of 1986, referred to in subsec. (d)(3)(B), is classified generally to Title 26, Internal Revenue Code.

#### PRIOR PROVISIONS

A prior section 1396s, act Aug. 14, 1935, ch. 531, title XIX, §1928, formerly §1920, as added Apr. 7, 1986, Pub. L. 99-272, title IX, §9526, 100 Stat. 218, and renumbered and amended, which related to references to laws directly affecting medicaid program, was renumbered section 1931 of act Aug. 14, 1935, by Pub. L. 103-66, title XIII, §13631(b)(1), Aug. 10, 1993, 107 Stat. 637, and transferred to section 1396v of this title.

#### EFFECTIVE DATE

Section applicable to payments under State plans approved under this subchapter for calendar quarters beginning on or after Oct. 1, 1994, see section 13631(i) of Pub. L. 103-66, set out as an Effective Date of 1993 Amendment note under section 1396a of this title.

### § 1396t. Home and community care for functionally disabled elderly individuals

#### (a) "Home and community care" defined

In this subchapter, the term "home and community care" means one or more of the following services furnished to an individual who has been determined, after an assessment under subsection (c) of this section, to be a functionally disabled elderly individual, furnished in accordance with an individual community care plan (established and periodically reviewed and revised by a qualified community care case manager under subsection (d) of this section):

- (1) Homemaker/home health aide services.
- (2) Chore services.
- (3) Personal care services.
- (4) Nursing care services provided by, or under the supervision of, a registered nurse.
- (5) Respite care.
- (6) Training for family members in managing the individual.
- (7) Adult day care.
- (8) In the case of an individual with chronic mental illness, day treatment or other partial hospitalization, psychosocial rehabilitation services, and clinic services (whether or not furnished in a facility).
- (9) Such other home and community-based services (other than room and board) as the Secretary may approve.

#### (b) "Functionally disabled elderly individual" defined

##### (1) In general

In this subchapter, the term "functionally disabled elderly individual" means an individual who—

(A) is 65 years of age or older,

(B) is determined to be a functionally disabled individual under subsection (c) of this section, and

(C) subject to section 1396a(f) of this title (as applied consistent with section 1396a(r)(2) of this title), is receiving supplemental security income benefits under subchapter XVI of this chapter (or under a State plan approved under subchapter XVI of this chapter) or, at the option of the State, is described in section 1396a(a)(10)(C) of this title.

##### (2) Treatment of certain individuals previously covered under a waiver

(A) In the case of a State which—

(i) at the time of its election to provide coverage for home and community care under this section has a waiver approved under section 1396n(c) or 1396n(d) of this title with respect to individuals 65 years of age or older, and

(ii) subsequently discontinues such waiver, individuals who were eligible for benefits under the waiver as of the date of its discontinuance and who would, but for income or resources, be eligible for medical assistance for home and community care under the plan shall, notwithstanding any other provision of this subchapter, be deemed a functionally disabled elderly individual for so long as the individual would have remained eligible for medical assistance under such waiver.

(B) In the case of a State which used a health insuring organization before January 1, 1986, and which, as of December 31, 1990, had in effect a waiver under section 1315 of this title that provides under the State plan under this subchapter for personal care services for functionally disabled individuals, the term "functionally disabled elderly individual" may include, at the option of the State, an individual who—

(i) is 65 years of age or older or is disabled (as determined under the supplemental security income program under subchapter XVI of this chapter);

(ii) is determined to meet the test of functional disability applied under the waiver as of such date; and

(iii) meets the resource requirement and income standard that apply in the State to individuals described in section 1396a(a)(10)(A)(ii)(V) of this title.

##### (3) Use of projected income

In applying section 1396b(f)(1) of this title in determining the eligibility of an individual (described in section 1396a(a)(10)(C) of this title) for medical assistance for home and community care, a State may, at its option, provide for the determination of the individual's anticipated medical expenses (to be deducted from income) over a period of up to 6 months.