VFC Program Distribution of Pediatric Vaccines

This page lists the details on the specific legislation and the associated Congressional "Statement of Managers" as described on the VFC Program Management page.

The legislation provides general guidance for VFC program policy development, including eligibility, provider recruitment, and considerations for negotiating contracts with manufacturers.

SEC. 13631. Medicaid Pediatric Immunization Provisions

(a) State plan requirement for pediatric immunization distribution program. — Section 1902 (a) (42 U.S.C. 1396a(a)), as amended by sections 13623(a) and 13625(a), is amended —

(1) by striking "and" at the end of paragraph (60);
(2) by striking the period at the end of paragraph (61) and inserting "; and"; and
(3) by adding at the end the following new paragraph:
"(62) provide for a program for the distribution of pediatric vaccines to program-registered providers; for the immunization of vaccine-eligible children in accordance with section 1928.".

(b) Description of required program. — Title XIX is amended —

(1) by redesignating section 1928 as section 1931 and by moving such section to the end of such title, and
(2) by inserting after section 1927 the following new section "PROGRAM DISTRIBUTION OF PEDIATRIC VACCINES "SEC. 1982.

A PROGRAM FOR DISTRIBUTION OF PEDIATRIC VACCINES "SEC. 1928. (a) ESTABLISHMENT OF PROGRAM. —

(1) IN GENERAL. — In order to meet the requirement of section 1902(a)(62), 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)), in receiving an immunization with a qualified pediatric vaccine (as defined in subsection (h)(8)) from a program registered provider (as defined in subsection (c)) 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) for the purchase and delivery on behalf of each State meeting the requirement of section 1902(a)(62) (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 maybe 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), 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). 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 1905(1)(2)(B)) or a rural health clinic (as defined in section 1905(1)(1)), and (II) is not insured with respect to the vaccine.
(iv) A child who is an Indian (as defined in subsection (h)(3)).

(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 plan approved under this title.
(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 Act of 1974, 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).

(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 333(e) of the Public Health Service Act), without regard to whether or not the provider participates in the plan under this title;
(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. — provider agreement for a provider under this paragraph is an agreement (in which 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.
(iii) The provider will, upon request, make such records available to the State and to the Secretary, subject to section 1902(a)(7).

(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), except in such cases as, in the provider's medical judgement 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, 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 1915(b).

(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 thus 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 such is not provided for in advance in appropriations Acts, for the purchase and delivery of pediatric vaccines under subsection (a)(2)(A).

(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 317(j)(1) of the Public Health Service Act 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 the date of the enactment of the Omnibus Budget Reconciliation Act of 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 vaccine manufacturer involved agrees that the manufacturer will provide for the delivery of the vaccines on behalf of the State in accordance with such programs 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 State pursuant to paragraph (4)(B), the Secretary shall determine which of such contracts will be applicable to the purchase.

(e) USE OF PEDIATRIC VACCINE LISTS — 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 of Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).

(f) REQUIREMENTS 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 1902(a)(62), shall cease to be in effect beginning on such date as may be prescribed in Federal law providing for immunizations 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.
(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).
(7) The term ‘program registered provider’ has the meaning given such term in subsection (c).
(8) The term ‘qualified pediatric vaccine’ means a pediatric vaccine with respect to which a contract is in effect under subsection (d).
(9) The terms ‘vaccine eligible child’, ‘Federally vaccine-eligible child’, and ‘State vaccine eligible child’ have the meaning given such terms in subsection (b).

(c) LIMITATIONS ON MEDICAID PAYMENTS. — Section 20 1903(i) (42 U.S.C. 1396b(i)), as amended by section 21 2(b)(2) of the Medicaid Voluntary Contribution and Provider Specific Tax Amendments of 1991, is amended —

(1) in the paragraph (10) inserted by section 4401(a)(1)(B) of OBRA 1990, by striking all that follows “1927(g)” and inserting a semicolon;
(2) by redesignating the paragraph (12) inserted by section 4752(a)(2) of OBRA 1990 as paragraph (11), by transferring and inserting it after the paragraph (10) inserted by section 4401(a)(1)(B) of OBRA 1990, and by striking the period at the end and inserting a semicolon;
(3) by redesignating the paragraph (14) inserted by section 4752(e) of OBRA 1990 as paragraph (12), by transferring and inserting it after paragraph (11), as redesignated by paragraph (2), and by striking the period at the end and inserting a semicolon;
(4) by redesignating the paragraph (11) inserted by section 4801(e)(16)(A) of OBRA 1990 as paragraph (13), by transferring and inserting it after paragraph (12), as redesignated by paragraph (3), and by striking the period at the end and inserting “; or”; and
(5) by inserting after paragraph (13), as so redesignated, the following new paragraph:
“(14) with respect to any amount expended on administrative costs to carry out the program under section 1928.”.

(d) CONTINUED COVERAGE OF COSTS OF A PEDIATRIC VACCINE UNDERCERTAIN GROUP HEALTH PLANS. —

(1) REQUIREMENT. — The requirement of this paragraph with respect to a group health plan for plan years beginning after the date of the enactment of this Act is that the group health plan not reduce coverage of the costs of pediatric vaccines (as defined under section 1928(h)(6) of the Social Security Act) below the coverage it provided as of May 1, 1993.
(2) ENFORCEMENT. — For purposes of section 2207 of the Public Health Service Act, the requirement of paragraph (1) is deemed a requirement of title XXII of such Act.

(e) AVAILABILITY OF MEDICAID PAYMENTS FOR CHILDHOOD VACCINE REPLACEMENT PROGRAMS. —

(1) IN GENERAL. — Section 1902(a)(32) (42 U.S.C. 1396a(a)(32)) is amended–

(A) by striking "and" at the end of subparagraph (B),
(B) by striking the period at the end of subparagraph (C) and inserting "; and", and
(C) by adding at the end the following new subparagraph:
(D) in the case of payment for a childhood vaccine administered before October 1, 1994, to individuals entitled to medical assistance under the State plan, the State plan may make payment directly to the manufacturer of the vaccine under a voluntary replacement program agreed to by the State pursuant to which the manufacturer

(i) supplies doses of the vaccine to providers administering the vaccine,
(ii) periodically replaces the supply of the vaccine, and
(iii) charges the State the manufacturer's price to the Centers for Disease Control and Prevention for the vaccine so administered (which price includes a reasonable amount to cover shipping and the handling of returns);'.

(2) EFFECTIVE DATE. — The amendments made by paragraph (1) shall take effect on the date of the enactment of this Act.

(f) OUTREACH AND EDUCATION. —

(1) IN GENERAL. — Section 1902(a) (42 U.S.C. 1396a(a)) is amended —

(A) in paragraph (11)(B) —

(i) by striking "effective July 1, 1969,",
(ii) by striking "and" before A(ii)", and
(iii) by striking "to him under section 1903" and inserting "to the individual under section 1903, and (iii) providing for coordination of information and education on pediatric vaccinations and delivery of immunization services";

(B) in paragraph (11)(C), by inserting ", including the provision of information and education on pediatric vaccinations and the delivery of immunization services," after "operations under this title"; and
(C) in paragraph (43)(A), by inserting before the comma at the end the following: "and the need for age-appropriate immunizations against vaccine preventable diseases".

(2) COVERAGE OF PUBLIC HOUSING HEALTH CENTERS AND CERTAIN INDIAN HEALTH CARE PROVIDERS AS FEDERALLY-QUALIFIED HEALTH CENTERS.

—Section 1905(1)(2)(B) (42 U.S.C. 1396d(1)(2)(B)) is amended —

(A) by striking “or 340” each place it appears and inserting “340, or 340A”, and
(B) by inserting “or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services” after “93 — 638)”.

(3) EFFECTIVE DATES. —

(A) Except as provided in subparagraph (B), the amendments made by this subsection shall apply to calendar quarters beginning on or after October 1, 1993, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.
(B) In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by the subsection, the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(g) SCHEDULE OF IMMUNIZATIONS UNDER EPSDT. —

(1) IN GENERAL. — Section 1905(r)(1) (42 U.S.C. 1396d(r)(1)) is amended —

(A) in subparagraph (A)(i), by inserting “and, with respect to immunizations under subparagraph (B)(iii), in accordance with the schedule referred to in section 1928(c)(2)(B)(i) for pediatric vaccines” after “child health care”; and
(B) in subparagraph (B)(iii), by inserting “(according to the schedule referred to in section 1928(c)(2)(B)(i) for pediatric vaccines)” after “appropriate immunizations”

(2) EFFECTIVE DATE. — The amendments made by subparagraph (A) and (B) of paragraph (1) shall first apply 90 days after the date the schedule referred to in subparagraphs (A)(i) and subparagraph (B)(iii) of section 1905(r)(1) of the Social Security Act (as amended by such respective subparagraphs) is first established.

(h) DENIAL OF FEDERAL FINANCIAL PARTICIPATION FOR INAPPROPRIATE ADMINISTRATION OF SINGLE-ANTIGEN VACCINE. —

(1) IN GENERAL. — Section 1903(i) (42 U.S.C. 1396b(i)), as amended by subsection (c), is amended —

(A) in paragraph (13), by striking “or” at the end,
(B) in paragraph (14), by striking the period at the end and inserting “; or”, and
(C) by inserting after paragraph (14) the following new paragraph
“(15) with respect to any amount expended for a single antigen vaccine and its administration in

any case in which the administration of a combined antigen vaccine was medically appropriate (as determined by the Secretary).”.

(2) EFFECTIVE DATE. — The amendments made by paragraph (1) shall apply to amount expended for vaccines administered on or after October 1, 1993.

(i) EFFECTIVE DATE. — Except as otherwise provided in this section, the amendments made by this section shall apply to payments under State plans approved under title XIX of the Social Security Act for calendar quarters beginning on or after October 1, 1994.

Top of Page

SEC. 13632. National Vaccine Injury Compensation Program Amendments

(a) Amendment of vaccine injury table. —

(1) Filing. — Section 2116(b) of the Public Health Service Act (42 U.S.C. 300aa 16(b)) is amended by striking “such person may file” and inserting “or to significantly increase the likelihood of obtaining compensation, such person may, not withstanding section 2111(b)(2), file”.
(2) ADDITIONAL VACCINES. — Section 2114(e) of the Public Health Service Act (U.S.C. 300aa 14) is amended to read as follows:

“(e) ADDITIONAL VACCINES. —

(1) VACCINES RECOMMENDED BEFORE AUGUST 1, 1993. — By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include —
(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,
(B) the injuries, disabilities, illnesses, conditions. and deaths associated with such vaccines, and
(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) VACCINES RECOMMENDED AFTER AUGUST 1, 1993. — When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include —
(A) vaccines which were recommended for routine administration to children,
(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and
(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(3) EFFECTIVE DATE. — a revision by the Secretary under section 2114 (e) of the Public Health Service Act (42 U.S.C. 300aa 14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa 14(a)).”

(b) Increased spending. — Section 2115(j) of the Public Health Service Act (42 U.S.C. 300aa 15(j)) is amended by striking “$80,000,000 for each succeeding fiscal year” and inserting in lieu thereof “$110,000,000 for each succeeding fiscal year”.

(c) Extension of time for decision . — Section 2112(d)(3)(D) of the Public Health Service Act (42 U.S.C. 300aa 12(d) (3)(D)) is amended by striking “540 days” and inserting “30 months (but for not more than 6 months at a time)”.

Top of Page

Conference Notes on Vaccines for Children Legislation Summary

In broad terms, the agreement provides for the establishment of a new entitlement program that is a required part of each State’s Medicaid plan. Under this program, States are entitled to receive from the Federal government sufficient vaccine to provide fully for a limited class of children (Medicaid-eligible, uninsured, and Indian children and children receiving immunizations at Federally qualified health centers or rural health clinics). In turn, States must make this free vaccine available both (l) to all public and private health care providers who are authorized to administer vaccines under the laws of the State, who are willing to participate in the program, and who satisfy the Secretary’s requirements and (2) to all children who seek such vaccine through a willing health care provider. No charge may be made for the free vaccine, either by the State or by the providers, although providers may charge a limited fee for the administration of the vaccine (subject to prescribed limitations).

To provide the vaccine needed to carry out this program, the Secretary is to negotiate with manufacturers for a consolidated purchase price. For currently recommended vaccines, this price may not exceed the current purchase price under vaccine contracts administered under the Public Health Service Act, adjusted for inflation. For new vaccines, the Secretary is to negotiate a consolidated purchase price and no ceiling is specified. Special rules are provided for States that manufacture their own vaccines.

No change is made in other current law programs regarding immunization, including the program for grants to States for childhood immunization programs (under section 317(j) of the Public Health Service Act). The Conferees expect those Federal programs to continue in place. To the extent that discretionary funds provided by grants under these programs–or State immunization program funds–are no longer needed for the purchase of vaccines, the Conferees expect that these funds will be used to provide for the important infrastructure for vaccine delivery. Indeed, the Conferees note their belief that the provision of free vaccine must be done

together with essential immunization infrastructure improvements (such as longer clinic hours, more outreach workers, better parent education, innovative community-based activities, and improved physician fees).

Top of Page

Description and Intent

Subsection (a) — State plan requirement for pediatric immunization distribution program

Subsection (a) creates a new requirement of State Medicaid plans regarding immunizations as Section 1902 (a) (61) of the Social Security Act, and makes various conforming amendments.

Under the Conference Agreement, States must establish a pediatric vaccine distribution program as an amendment to their Medicaid plans, although (l) this program is available to a larger class of children than those who receive general Medicaid benefits and (2) the program providers may include a larger class of providers than those who agree to be Medicaid providers. (The Conferees note that providers who have not elected to be Medicaid providers may still participate in this new program.) Other than for those children whose eligibility for the program derives from their status as Medicaid beneficiaries, Medicaid eligibility requirements are not to be applied in determining which children are eligible for free vaccine.

Subsection (b) — Description of required program

Subsection (b) creates a new program for distribution of pediatric vaccines as Section 1928 of the Social Security Act.

“Section 1928 (a) — Establishment of Program”

Under the Conference Agreement, each State must establish a program of distribution of free vaccines to certain Federally vaccine-eligible children (defined below). This program may be administered by the State department of health or other agency designated by the State.

To facilitate these State-administered pediatric vaccine distribution programs, the Conference Agreement requires that the Secretary provide for the purchase and delivery for each State (or Indian tribe or tribal organization) sufficient vaccine to immunize certain children within the State (or tribe or tribal organization). This requirement constitutes the creation of a new entitlement and represents an obligation to provide for the purchase and delivery of vaccines that is undertaken by the Federal government in advance of appropriations acts and is binding on the Federal government regardless of the availability of appropriated funds or of discretely segregated or named funds or accounts.

The Conference Agreement provides special rules regarding the administration of this entitlement for situations in which a vaccine is unavailable or in which the State is a manufacturer.

The Conference Agreement also requires that States provide that any willing health care provider in the State, who meets enumerated registration requirements, be entitled to receive free vaccine to administer to Federally vaccine-eligible children. States may not impose additional qualifications or conditions for providers, except those approved by the Secretary to prevent fraud and abuse and for related purposes.

The Conferees intend that this program may be administered within States by the State health department, or by another department, if the State so designates. Because many providers who might see Federally vaccine-eligible children are not Medicaid providers and many Federally vaccine-eligible children are not Medicaid beneficiaries, failure to distinguish between this program and the Medicaid program could create confusion and result in fewer providers and children receiving free vaccine. In most cases, immunization programs have been administered within public health programs and thus, the Conferees believe that an administrative location in the public health program will benefit the increased immunization efforts outlined herein.

The Conferees do not intend that this new group (i.e., Federally vaccine-eligible children) be treated as Medicaid eligibles for purposes of Medicaid quality control eligibility and reviews.

The Conferees adopted an entitlement approach because they believe that the commitment to provide vaccine against preventable childhood diseases must be constant and certain and that States that come to rely on the Federal promise to provide vaccine must be protected against possible shortfalls. Funding by any other mechanism (such as a reliance on discretionary spending) is inherently less reliable than the guarantee authorized here and could place States and their citizens at risk of outbreaks of serious disease.

The Conferees have provided that States create entitlements for children and providers as a means to ensure that the program reaches all Federally vaccine-eligible children and all willing providers. While providers are not required to take part in the program, States may not restrict the availability of free vaccine if a provider is willing to participate and is otherwise qualified to administer vaccines under applicable law. The Conferees seek to forestall any attempt by a State to require that patients be referred from a qualified, willing provider to another site, because such referrals often result in a postponement of immunization or failure to immunize. The Conferees also seek to assure that Federally vaccine-eligible children are able to choose the provider that they wish to use for this benefit.

The Conferees recognize that the enforcement of the entitlement rights for providers may, in many cases, be of little value to providers, but of great value to the Federally vaccine-eligible children who may wish to be served by that provider. The Conferees intend, therefore, that Federally vaccine-eligible children be allowed to enforce a provider's rights on behalf of the provider.

In the event that available quantities of vaccine are insufficient to cover all children, both Federally and State eligible, the Conference Agreement provides that the Secretary is to establish priorities for purchase and distribution of the available vaccine, with priority given to Federally vaccine-eligible children unless the Secretary finds that there are other public health considerations. The Conferees believe that the Federally vaccine-eligible children are the most

vulnerable populations and, in the event of shortages, should be given highest priority. The Conferees recognize, however, that, in some instances, there may be other needs, such as the control of outbreaks of disease, which the Secretary may find are more pressing.

“Section 1928(b)-Vaccine-Eligible Children”

The Conference Agreement defines children eligible for the provision of free vaccine purchased by this program (known as “Federally vaccine-eligible children”) to be those children who are Medicaid-eligible, uninsured, Indians [SIC: American Indians or Alaskan Natives], or children who are administered vaccines in a Federally qualified health center or a rural health clinic and who are not insured for vaccine costs. Any child who meets these criteria is entitled to receive an immunization without charge for the vaccine.

In addition, the Conference Agreement establishes a category of children known as “State vaccine-eligible children” to be those children who are not Federally vaccine-eligible children but who are children that a State elects to provide with vaccine without charge for the vaccine. Such an optional category will include children in those States that currently purchase vaccines for all children, and potentially other States as well.

“Section 1928 (c) — Program-Registered Providers”

Under the terms of the Conference Agreement, to be program-registered providers, health care providers must agree to ask parents if a child is eligible for free vaccine, although the providers are not required independently to verify the answers to these question”. Providers must maintain certain records and comply with applicable State law, including laws relating to religious or other exemptions. Providers must administer vaccines according to the schedule recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention, unless in the provider’s medical judgment (subject to accepted medical practice) such compliance is medically inappropriate.

While providers may not charge for the vaccine per se, providers may charge a fee for the administration of the vaccine. Providers may not, however, charge an amount greater than the actual regional costs for such administration, as determined by the Secretary. Providers may not, under any circumstance, turn away a child because of the inability of the child’s parents to pay the administration fee. Providers need not, however, accept every request for immunization.

States are required (1) to encourage a variety of different providers to participate in the program and (2) to administer vaccines in an appropriate cultural context.

The Conferees note that the Conference Agreement’s provisions regarding providers are simple and underscore the intent that both the Secretary and the States implement these provisions in a similarly simple manner so as to encourage providers to participate and yet maintain accountability for the program. The Conferees recognize that different States have established a wide variety of distribution programs for vaccines and intend that existing effective distribution systems, including the use of independent wholesale distributors, be left in place.

The Conferees emphasize that this program in no way mandates immunization. This program deals with payment for vaccines. Individual State laws regarding immunization status are preserved, and the exemptions under these State laws for religious, medical, and other reasons are also preserved. The Conferees affirm their support of compliance with such laws and their exemptions. Acting under those laws, providers are to use their best medical judgment regarding an immunization and may decline to administer an immunization if it is medically inappropriate within the range of accepted medical practice.

The Conference Agreement does not require program-registered providers to administer a vaccine to each child seeking to be immunized. The Conferees clearly intend for this program to serve as many children as possible, but the Conferees believe that it is impractical to require that each provider who administers one shot to a vaccine-eligible child in his/her practice to immunize every other child who seeks vaccines whether in his/her practice or not. Such a requirement could quickly serve to drive all providers from the program. The Conferees do intend, however, that the Secretary seek to encourage program-registered providers to participate to the greatest extent possible.

The Conference Agreement provides for some restrictions on the fees that program-registered providers may charge to Federally vaccine-eligible children. Such fees may not exceed a schedule developed by the Secretary. The Conferees have included such a schedule because they believe that the cost of administration may serve as a significant roadblock for families of limited means that are eligible for this program. The Conferees recognize, however, that it fee limits are set too stringently, few providers may be willing to participate in the program and the Conferees intend for the Secretary to establish the schedule with these two problems in mind. The Conferees have not limited the fees for providers participating in a State-option programs. If States wish to limit such providers' fees, they are free to do so as part of their State option program.

The Conferees have also prohibited program-registered providers from denying vaccine to any vaccine-eligible child (whether State or Federal) because of the child's family's inability to pay for the administration of the vaccine. The Conferees believe that this protection is a fundamental standard to which providers may be reasonably expected to adhere.

Finally, the Conferees note that they have prohibited States from imposing additional qualifications for eligibility as a program-registered provider. The Conferees have done this because, as was discussed above regarding enforcement of entitlement rights, they seek to forestall any attempt by a State to require that patients be referred from a qualified, willing provider to another site. The Conferees also seek to assure that Federally vaccine-eligible children are able to choose the provider that they wish to use for this benefit.

"Section 1928(d) — Negotiation of Contracts with Manufacturers"

The Conference Agreement requires that the Secretary negotiate and enter into contracts with manufacturers of vaccines to meet the requirements of this program. The Secretary is required to consolidate these negotiations and contracts with other such activities. These contracts may be for multiple years.

The Conference Agreement specifies that the Secretary may not agree to a contract for these purposes under which the price of the vaccine would exceed the cost of the vaccine under the contract of the Centers for Disease Control and Prevention on May 1, 1993, adjusted for inflation. If, however, a new vaccine is recommended for routine use in children, the Secretary is required to negotiate for the purchase price of that vaccine and is not bound by prices set for current vaccines. Contract prices are to include the price for shipping and handling. In carrying out these negotiations, the Secretary is to take into account the needs that States have identified (and provided in advance of negotiations to the Secretary) for State vaccine-eligible children under their own programs. The Secretary is also to take into account the need to maintain a 6-month supply of pediatric vaccines to meet unanticipated needs and to consider the potential for disease outbreaks.

The Conference Agreement further provides that the Secretary shall, as appropriate, enter into a contract with each manufacturer of the vaccine that meets the terms and conditions of the Secretary. The Secretary also may have multiple prices.

The Conferees intend that negotiations proceed according to the Federal Acquisition Regulation, subject to specific provisions of this section, including the price ceiling. The Conferees note that the maximum price allowed under the Conference Agreement is intended to be a ceiling and not a floor or a presumptive price. The Conferees understand that in recent years, the increase in the public price on some vaccines has not kept up with the Consumer Price Index. They intend to retain Secretary's ability to negotiate savings below the maximum price that is established in this section.

The Conferees also intend, however, that the Secretary conduct negotiations in a manner that will ensure the continuation of research and development toward new, better, and safer vaccines. The Conferees recognize that most vaccine innovation is conducted in the private sector by manufacturers and intend that the Secretary act to foster such innovation through every means available. While the program provides substantial fiscal relief to the States and is cost-effective for the Federal government and the public at large, the Conferees have not adopted the new vaccine program principally as a cost-cutting measure but rather as a public health measure. To the extent that increases in negotiated prices can be justified as subsidizing research and development necessary for the improvement of public health, the Conferees intend for the Secretary to allow such increases. Indeed, recognizing that research and development in vaccines are vital to public health, the Conferees have not attempted to cap the cost of new vaccines but have chosen to leave such negotiations to the Secretary to be done on an ad hoc basis. Moreover, if the Secretary comes to believe that the statutory limitation on prices for current vaccines does not allow for sufficient research and development subsidies, the Conferees expect her to report that belief to the Congress and to request an amendment to the limitation.

The Conferees intend that vaccine manufacturers retain their ability under these contract provisions to distribute pediatric vaccines through independent drug wholesalers. Manufacturers may elect to subcontract the shipping, handling, and related distribution functions to such wholesalers. Independent drug wholesalers frequently have served these functions in the past and the Conferees do not intend to disrupt such practices. The Conferees further intend that States be allowed to retain their distribution systems.

In carrying out the responsibilities of this subsection, the Secretary is intended to consolidate these negotiations with all others that she carries out for the purchase of vaccine, including those for the use of grants funds under the Public Health Service Act. The Conferees believe that this consolidation is an efficient means of assuring that the largest possible number of children have access to vaccines and do not intend the explicit description of authority in this program to limit the Secretary's authority in any others.

The Conference Agreement also provides for an emergency stockpile of vaccines to be negotiated and purchased under these provisions. While the Conferees recognize that this is an increased cost in the short run, they believe it is necessary to avoid situations in which potentially life-saving vaccines are unavailable because of natural disasters or manufacturing problems.

The Conference Agreement provides authority for the Secretary to decline to enter into contracts. The Conferees have provided this authority for extreme circumstances only and, again, would emphasize the importance of continuity of vaccine supplies for Federally vaccine-eligible children and States.

Recognizing that the manufacturing process for vaccines is complex and has specific physical plant requirements, the Conferees understand that manufacturers may need the reassurance of contracts for a time longer than the traditional one-year period. The Conferees have, therefore, provided the Secretary with the unusual authority, traditionally reserved for defense issues, to provide multi-year contracts to allow for stability of vaccine supply.

Also recognizing that the Federal market share in the vaccine industry will be increased under the new program, the Conferees have provided that the Secretary shall, as appropriate, enter into a contract with each of the manufacturers that meets the terms and conditions of the Secretary, attempting to ensure that each manufacturer obtains an appropriate share of the contract. The Conferees have adopted this provision to assure that Federal contracts under the program encourage competition, innovation, and efficiency. In order to do so, the Secretary may, at her discretion, also allow for different prices from different manufacturers.

The Conferees intend that manufacturers involved agree to submit to the Secretary such reports as the Secretary determines to be appropriate with respect to compliance with the contract.

"Section 1928(e)–Use of Pediatric Vaccines List"

In carrying out the requirements of this section, the Secretary is to purchase vaccines from the list established, maintained, and revised by the Advisory Committee on Immunization Practices. The Conferees understand that this list includes the guidelines and schedule of appropriate immunization as outlined by the Advisory Committee on Immunization Practices.

The Conferees note that they do not intend that this list and these guidelines be considered guidelines, standards, performance measures or review criteria for purposes of the Agency for Health Care Policy and Research under Title IX of the Public Health Service Act or under Section 1142 of the Social Security Act.

In carrying out negotiations under this subsection and all duties of this section, the Secretary is to rely on the ACIP list of recommended vaccines. The Conferees intend that the Secretary provide for Federally vaccine-eligible children the same vaccines that are recommended for children with their own source of payment.

The Conferees intend that the Advisory Committee on Immunization Practices be allowed to conduct its work in an objective manner, concerned only with issues of public health and medicine. While decisions regarding the listing of recommended vaccines will, undoubtedly, have some budget implications for the program and the Secretary, it is the Conferees' intention that the ACIP's- work be rigorously separated from such concerns. The Conferees are troubled by past examples of budgetary influence in matters of science and has chosen the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention as a committee less vulnerable than some others to such influence. So, for example, if the ACIP were to decide that one vaccine that produces side effects and reactions should be replaced with a more expensive vaccine that does not, neither the Secretary nor any other public officer should attempt to affect that judgment. If proposed changes present a budget implication so serious as to cause the Secretary to question their validity, the Secretary should present that concern and a proposed legislative change to the Congress, but until legislative change is made, the entitlements of States to ACIP-recommended vaccines are to continue in effect.

"Section 1928(f)–Requirement of State Maintenance of Immunization Laws"

The Conference Agreement requires the maintenance of State laws that were in effect on May 1, 1993, that require health insurance policies or plans to provide some coverage with respect to pediatric vaccines. In addition, the Conference Agreement prohibits any group health plan that is covered by the requirements of Title XXII of the Public Health Service Act from reducing its coverage for the costs of pediatric vaccines.

In keeping with other provisions in this Act regarding the maintenance of insurance immunization benefits (whether private, ERISA, or State-run), the Conferees have adopted this requirement to forestall any attempts to decrease the amount of private insurance coverage that currently exists for vaccines. The Conference Agreement necessarily includes only a limited pool of eligible children and the Conferees do not intend for States or private insurers to shift costs now borne by private third-party payors onto the new program

"Section 1928 (g) — Termination"

The Conference Agreement provides that the new plan requirement and this program terminate upon the enactment of additional Federal law providing for immunization services for all children as part of a broad-based reform of the national health care system.

"Section 1928(h)– Definitions"

Section 1928(h) provides definitions for the terms used in the creation of the vaccine distribution program

Other Provisions Relation to Immunizations

Current Law

(a) Outreach and Education – States participating in Medicaid are required to cover Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services for all eligible children under 21. States are required to inform all Medicaid-eligible children under age 21 of the availability of EPSDT services.

(b) Schedule of Immunizations under EPSDT – The screening services element of the EPSDT benefit must, at a minimum, include appropriate immunizations according to age and health history, at intervals which meet reasonable standards of medical practice, as determined by each State.

(c) Assuring Adequate Payment Rates for Administration of Vaccines to Children – States are required to reimburse for EPSDT and other pediatric services at levels which are sufficient to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent that they are available to the general population in the geographic area. With respect to pediatric services, States must submit, by April 1 of each year, a State plan amendment that specifies, by procedure, the payment rates to be used for pediatric services in the year beginning the following July 1 and that includes data to assist the Secretary in evaluating the State's compliance with the provider participation requirement.

(d) Denial of Federal Financial Participation for Inappropriate Administration of Single-Antigen Vaccine – Federal Medicaid matching funds are available for the costs of single-antigen vaccines and their administration.

(e) Requiring Medicaid Managed Care Plans to Comply with Immunization and Other EPSDT Requirement– States may contract on a risk basis with managed care plans to deliver covered services including appropriate immunizations and other EPSDT benefits, to Medicaid-eligible children and other beneficiaries

House Provision (Section 5183)(a)

Outreach and Education – Requires the States to inform all Medicaid-eligible children under age 21 of the need for age-appropriate immunizations against vaccine-preventable conditions. Requires State Medicaid agencies to enter into agreements with State agencies and other institutions or organizations receiving Maternal and Child Health (MCH) Block Grant funds under Title V providing for coordination of information and education on childhood vaccinations and to coordinate delivery of immunization services. Requires State Medicaid agencies to provide, or assure the provision of, information and education on childhood vaccinations and the delivery of immunization services with the State's operations under the Special Supplemental Food Program for Women, Infants and Children (WIC).

Effective Date: Enactment.

(b) Schedule of Immunizations Under EPSDT – Requires that States, as part of the screening services element of the EPSDT benefit package, cover appropriate immunizations according to the schedule recommended by the Secretary under the Public Health Service Act.

Effective Date: 90 days after the issuance of the Secretary's recommended schedule of immunizations.

(c) Assuring Adequate Payment Rates for Administration of Vaccines to Children – Clarifies that, for purposes of determining whether pediatric service payment levels are sufficient, pediatric services include the administration of vaccines by health care practitioners.

Effective Date – Applies with respect to State amendments submitted by April 1, 1994.

(d) Denial of Federal Financial Participation for Inappropriate Administration of Single-Antigen Vaccine – The House bill denies Federal Medicaid matching funds for single-antigen vaccines, and the administration of such vaccines, in any case in which the administration of a combined-antigen vaccine was medically appropriate (as determined by the Secretary)

Effective Date: Applies with respect to vaccines administered on or after October 1, 1993.

(e) Requiring Medicaid Managed Care Plan to Comply with Immunization and Other EPSDT Requirements – Requires that a risk contract between a State Medicaid agency and an entity: (l) specify which EPSDT services are to be provided under the contract to children enrolled with the entity; (2) specify, with respect to those EPSDT services that are not to be provided under the contract, the steps the entity will take (through referrals, scheduling appointments with appropriate providers, monitoring the receipt of referred services, or other arrangements) to assure that such individuals will receive such services; and (3) require the entity to submit periodic reports as necessary to enable the State to meet its reporting requirements under sections 1902(a)(43)(D) (relating to EPSDT screening and referral rates and State participation goals) and 506(a)(2) (relating to progress in achieving the national Year 2000 health status objectives relating to mothers and children). Provides for the imposition of a civil monetary penalty in an amount of up to $25,000 for each instance in which an entity fails substantially to provide EPSDT service to the extent specified in its contract with the State.

Effective Date: Applies to contract years beginning on or after October 1, 1993.

Senate Amendment

The Senate amendment contains no comparable provision.

Conference Agreement

(a) Outreach and Education – The Conference Agreement follows the House bill with a modification.

(b) Schedule of Immunizations Under EPSDT – The Conference Agreement follows the House bill.

(c) Assuring Adequate Payment Rate, for Administration of Vaccines to Children – The Conference Agreement does not contain the House language regarding Medicaid vaccine administration fees. The Conferees agree with the Secretary's view that, under current law, she has the authority and the Conferees understand that it is the Secretary's intent to accomplish what the House bill would have required.

(d) Denial of FFP for Inappropriate Administration of Single-Antigen Vaccines – The Conference Agreement follows the House bill.

(e) Requiring Medicaid Managed Care Plan to Comply with Immunization Other EPSDT Requirements – The conferees have been informed that a point of order could be raised in the Senate, under the so-called "Byrd rule" (section 313 of the Congressional Budget Act of 1974), to the substance of the House provision if included in the conference agreement. In order to avoid such a possible point of order, the conference agreement does not include the House provision. The conferees express no views on the merits of the provision.

https://www.cdc.gov/vaccines/programs/vfc/about/distribution.html