
42 U.S. Code § 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)), 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 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), 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.

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