

103D CONGRESS
1ST SESSION

S. 732

AN ACT

To provide for the immunization of all children in the United States against vaccine-preventable diseases, and for other purposes.

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To provide for the immunization of all children in the United States against vaccine-preventable diseases, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE, REFERENCES AND PURPOSE.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Comprehensive Child Immunization Act of 1993”.

1 (b) REFERENCES.—Except as otherwise expressly
 2 provided, whenever in this Act an amendment or repeal
 3 is expressed in terms of an amendment to, or repeal of,
 4 a section or other provision, the reference shall be consid-
 5 ered to be made to a section or other provision of the Pub-
 6 lic Health Service Act (42 U.S.C. 201 et seq.).

7 (c) PURPOSE.—It is the purpose of this Act to ensure
 8 that children in the United States are appropriately immu-
 9 nized against vaccine preventable infectious diseases at the
 10 earliest appropriate age.

11 **SEC. 2. MONITORING OF CHILDHOOD IMMUNIZATIONS.**

12 Title XXI of the Public Health Service Act (42
 13 U.S.C. 300aa–1 et seq.) is amended by adding at the end
 14 thereof the following new subtitle:

15 **“Subtitle 3—Improved Immuniza-**
 16 **tion Delivery and Monitoring**
 17 **Systems**

18 **“Part A—List of Vaccines and Administration**

19 **“SEC. 2141. LIST OF PEDIATRIC VACCINES; SCHEDULE FOR**
 20 **ADMINISTRATION.**

21 **“(a) RECOMMENDED PEDIATRIC VACCINES.—**

22 **“(1) IN GENERAL.—**The Secretary shall estab-
 23 lish a list of the vaccines that the Secretary rec-
 24 ommends for administration to all children for the
 25 purpose of immunizing the children, subject to such

1 contraindications for particular medical categories of
2 children as the Secretary may establish under sub-
3 section (b)(1)(D). The Secretary shall periodically
4 review the list, and shall revise the list as appro-
5 priate.

6 “(2) RULE OF CONSTRUCTION.—

7 “(A) The list of vaccines specified in sub-
8 paragraph (B) is deemed to be the list of vac-
9 cines maintained under paragraph (1).

10 “(B) The list of vaccines specified in this
11 subparagraph is the list of vaccines that, for
12 purposes of paragraph (1), is established (and
13 periodically reviewed and as appropriate re-
14 vised) by the Advisory Committee on Immuni-
15 zation Practices, an advisory committee estab-
16 lished by the Secretary, acting through the Di-
17 rector of the Centers for Disease Control and
18 Prevention.

19 “(b) RECOMMENDED SCHEDULE FOR ADMINISTRA-
20 TION.—

21 “(1) IN GENERAL.—Subject to paragraph (2),
22 in the case of a pediatric vaccine, the Secretary shall
23 establish (and periodically review and as appropriate
24 revise) a schedule of nonbinding recommendations
25 for the following:

1 “(A) The number of immunizations with
2 the vaccine that children should receive.

3 “(B) The ages at which children should re-
4 ceive the immunizations.

5 “(C) The dose of vaccine that should be
6 administered in the immunizations.

7 “(D) Any contraindications regarding ad-
8 ministration of the vaccine.

9 “(E) Such other guidelines as the Sec-
10 retary determines to be appropriate with re-
11 spect to administering the vaccine to children.

12 “(2) VARIATIONS IN MEDICAL PRACTICE.—In
13 establishing and revising a schedule under para-
14 graph (1), the Secretary shall ensure that, in the
15 case of the pediatric vaccine involved, the schedule
16 provides for the full range of variations in medical
17 judgment regarding the administration of the vac-
18 cine, subject to remaining within medical norms.

19 “(3) RULE OF CONSTRUCTION.—

20 “(A) The schedule specified in subpara-
21 graph (B) is deemed to be the schedule main-
22 tained under paragraph (1).

23 “(B) The schedule specified in this sub-
24 paragraph is the schedule that, for purposes of
25 paragraph (1), is established (and periodically

1 reviewed and as appropriate revised) by the ad-
2 visory committee specified in subsection
3 (a)(2)(B).

4 “(c) GENERALLY APPLICABLE RULES OF CONSTRUC-
5 TION.—This section does not supersede any State law or
6 requirements with respect to receiving immunizations (in-
7 cluding any such law relating to religious exemptions or
8 other exemptions under such State laws).

9 “(d) ISSUANCE OF LIST AND SCHEDULES.—Not
10 later than 180 days after the date of the enactment of
11 this section, the Secretary shall establish the initial list
12 required in subsection (a) and the schedule required in
13 subsection (b).

14 **“Part B—State Registry System for Immunization**
15 **Information**

16 **“SEC. 2145. PURPOSE.**

17 “It is the purpose of this part to authorize the Sec-
18 retary, in consultation with State public health officials,
19 to establish State registry systems to monitor the immuni-
20 zation status of all children.

21 **“SEC. 2146. GRANTS FOR IMMUNIZATION REGISTRIES.**

22 “(a) IN GENERAL.—For the purpose described in
23 section 2145, the Secretary, acting through the Director
24 of the Centers for Disease Control and Prevention, shall
25 make an allotment each fiscal year for each State in an

1 amount determined in accordance with section 2151. The
2 Secretary shall make a grant to the State of the allotment
3 made for the State for the fiscal year if the State submits
4 to the Secretary an application in accordance with section
5 2150 on behalf of the chief executive officer of such State.

6 “(b) DESIGN OF STATE REGISTRIES.—To carry out
7 the purpose described in section 2145, a State registry es-
8 tablished under this part shall be designed to—

9 “(1) provide accurate and up to date surveil-
10 lance data regarding immunization rates at the
11 State and local levels;

12 “(2) assist in identifying localities with inad-
13 equate immunization rates to target for necessary
14 remedial assistance;

15 “(3) assist in the effective administration and
16 management of immunization programs at State and
17 local levels by providing data to guide immunization
18 program efforts;

19 “(4) assist the State in providing and receiving
20 information on the immunization status of children
21 who move across geographic boundaries that are cov-
22 ered by different State or local registries; and

23 “(5) facilitate the linkage of vaccine dosage in-
24 formation to adverse events reported to the Centers
25 for Disease Control and Prevention under section

1 2125(b) and disease outbreak patterns, for the pur-
2 pose of monitoring vaccine safety and effectiveness.

3 “(c) ELIGIBLE USE OF FUNDS.—The Secretary may
4 make a grant under subsection (a) only if the State agrees
5 to expend the grant for the purpose of—

6 “(1) collecting the data described in section
7 2147;

8 “(2) operating registries to maintain the data
9 (and establishing such registries, in the case of a
10 State that is not operating such a registry);

11 “(3) utilizing the data to monitor the extent to
12 which children have received immunizations in ac-
13 cordance with the schedule established under section
14 2141;

15 “(4) notifying parents, as appropriate, if chil-
16 dren have not received immunizations in accordance
17 with such schedule;

18 “(5) coordinating and exchanging information
19 with other State registries to allow the monitoring of
20 the immunization status of children changing State
21 of residence; and

22 “(6) such other activities as the Secretary may
23 authorize with respect to achieving the objectives es-
24 tablished by the Secretary for the year 2000 for the

1 immunization status of children in the United
2 States.

3 “(d) REQUIREMENT REGARDING STATE LAW.—

4 “(1) IN GENERAL.—The Secretary may make a
5 grant under subsection (a) only if the State in-
6 volved—

7 “(A) provides assurances satisfactory to
8 the Secretary that, not later than October 1,
9 1996, the State will be operating a registry in
10 accordance with this part, including having in
11 effect such laws and regulations as may be nec-
12 essary to so operate such a registry;

13 “(B) agrees that, prior to such date, the
14 State will make such efforts to operate a reg-
15 istry in accordance with this part as may be au-
16 thorized in the law and regulations of the State;
17 and

18 “(C) has in effect such laws and regula-
19 tions as may be necessary to ensure the follow-
20 ing safeguards for the rights of parents:

21 “(i) An exemption for the parent,
22 upon the request of the parent, from the
23 requirements established by the State, pur-
24 suant to this part, for the collection of
25 data described in subsections (b) and (c) of

1 section 2147, or the collection of any other
2 data regarding any child of the parent that
3 the State may require for incorporation in
4 the State immunization registry.

5 “(ii) Restrictions ensuring that no in-
6 formation relating to a child or to the par-
7 ent or guardian of a child that is collected
8 or maintained by the State immunization
9 registry pursuant to this part, or the na-
10 tional immunization surveillance program
11 established under section 2153, will be
12 used as a basis for the criminal prosecu-
13 tion or the commencement of a criminal in-
14 vestigation of a parent or guardian.

15 “(2) RULES OF CONSTRUCTION.—

16 “(A) With respect to the agreements made
17 by a State under this part, other than para-
18 graph (1)(B), the Secretary may require com-
19 pliance with the agreements only to the extent
20 consistent with such paragraph.

21 “(B) The provisions of this part do not au-
22 thorize the Secretary, as a condition of the re-
23 ceipt of a grant under subsection (a) by a
24 State, to prohibit the State from providing any
25 parent, upon the request of the parent, with an

1 exemption from the requirements established by
2 the State pursuant to this part for the collec-
3 tion of data regarding any child of the parent.

4 **“SEC. 2147. REGISTRY DATA.**

5 “(a) IN GENERAL.—For purposes of section
6 2146(c)(1), the data described in this section are the data
7 described in subsection (b) and the data described in sub-
8 section (c).

9 “(b) DATA REGARDING BIRTH OF CHILD.—With re-
10 spect to the birth of a child, the data described in this
11 subsection is as follows:

12 “(1) The name of each child born in the State
13 involved after the date of the implementation of the
14 registry (in no event shall such date be later than
15 October 1, 1996).

16 “(2) Demographic data on the child.

17 “(3) The name of one or both of the parents of
18 the child. If the child has been given up for adop-
19 tion, any information regarding the identity of the
20 birth parent or parents of the child may not be en-
21 tered into the registry, or if entered, shall be deleted.

22 “(4) The address, as of the date of the birth of
23 the child, of each parent whose name is received in
24 the registry pursuant to paragraph (3).

1 “(c) DATA REGARDING INDIVIDUAL IMMUNIZA-
2 TIONS.—With respect to a child to whom a pediatric vac-
3 cine is administered in the State involved, the data de-
4 scribed in this subsection is as follows:

5 “(1) The name, age, and address of the child.

6 “(2) The date on which the vaccine was admin-
7 istered to the child.

8 “(3) The name and business address of the
9 health care provider that administered the vaccine.

10 “(4) The address of the facility at which the
11 vaccine was administered.

12 “(5) The name and address of one or both par-
13 ents of the child as of the date on which the vaccine
14 was administered, if such information is available to
15 the health care provider.

16 “(6) The type of vaccine.

17 “(7) The lot number or other information iden-
18 tifying the particular manufacturing batch of the
19 vaccine.

20 “(8) The dose of vaccine that was administered.

21 “(9) A notation of the presence of any adverse
22 medical reactions that the child experienced in rela-
23 tion to the vaccine and of which the health care pro-
24 vider is aware, in accordance with section 2125.

1 “(10) The presence of contraindications noted
2 by the health care provider with respect to adminis-
3 tration of the vaccine to the child.

4 “(11) Such other data regarding immunizations
5 for the child, including identifying data, as the Sec-
6 retary, in consultation with State public health offi-
7 cials, may require consistent with applicable law (in-
8 cluding social security account numbers furnished
9 pursuant to section 205(c)(2)(E) of the Social Secu-
10 rity Act).

11 “(d) LIMITATION.—The Secretary may not establish
12 information reporting requirements in addition to those
13 described in subsection (c) if such requirements are un-
14 duly burdensome.

15 “(e) DATE CERTAIN FOR SUBMISSION TO REG-
16 ISTRY.—The Secretary may make a grant under section
17 2146 only if the State involved agrees to ensure that, with
18 respect to a child—

19 “(1) the data described in subsection (b) are
20 submitted to the registry under such section as soon
21 as possible but in no event later than 8 weeks after
22 the date on which the child is born; and

23 “(2) the data described in subsection (c) with
24 respect to a vaccine are submitted to such registry
25 as soon as possible but in no event later than 4

1 weeks after the date on which the vaccine is admin-
2 istered to the child.

3 “(f) UNIFORMITY IN METHODOLOGIES.—The Sec-
4 retary shall, in consultation with State public health offi-
5 cials, establish standards regarding the methodologies
6 used in establishing and operating registries under section
7 2146, and may make a grant under such section only if
8 the State agrees to comply with the standards. The Sec-
9 retary shall provide maximum flexibility to the States
10 while also retaining a reasonable degree of uniformity
11 among the States in such methodologies for the purpose
12 of ensuring the utility, comparability, and exchange of the
13 data maintained in such registries.

14 “(g) COORDINATION AMONG STATES.—The Sec-
15 retary may make a grant under section 2146 to a State
16 only if, with respect to the operation of the registry of
17 the State under such section, the State agrees to transfer
18 that information contained in the State registry pursuant
19 to section 2146 to other States upon the request of such
20 States for such information.

21 **“SEC. 2148. FEDERAL STANDARDS ON CONFIDENTIALITY.**

22 “(a) ESTABLISHMENT.—

23 “(1) IN GENERAL.—The Secretary, in consulta-
24 tion with the States, shall by regulation establish
25 standards providing for maintaining the confidential-

1 ity of the identity of individuals with respect to
2 whom data are maintained in registries under sec-
3 tion 2146. Such standards shall, with respect to a
4 State, provide that the State is to have in effect laws
5 or regulations regarding such confidentiality, includ-
6 ing appropriate penalties for violation of the laws.
7 The Secretary may make a grant under such section
8 only if the State involved agrees to comply with the
9 standards.

10 “(2) USE OF DISCLOSURE.—

11 “(A) No personally identifiable information
12 relating to a child or to the parent or guardian
13 of such child that is collected or maintained by
14 the State registry may be used or disclosed by
15 any holder of such information except as per-
16 mitted for—

17 “(i) the monitoring of a child’s immu-
18 nization status;

19 “(ii) oversight, audit, and evaluation
20 of the immunization delivery and registry
21 systems;

22 “(iii) activities relating to establishing
23 and maintaining a safe and effective sup-
24 ply of recommended childhood vaccine;

1 “(iv) processing of insurance claims
2 for payment for vaccine administration
3 (but only to the extent necessary for proc-
4 essing claims); and

5 “(v) administration of the National
6 Vaccine Injury Compensation Program
7 under subtitle 2.

8 “(B) Information regarding immunizations
9 provided as described in subparagraph (A)(i)
10 may be used or disclosed only with the written
11 authorization of the individual to whom it refers
12 or to the parent with custody of such individual.

13 “(b) USE OF SOCIAL SECURITY ACCOUNT NUM-
14 BERS.—Any usage or disclosure of data in registries under
15 section 2146 that consists of social security account num-
16 bers and related information which is otherwise permitted
17 under this part may be exercised only to the extent per-
18 mitted under section 205(c)(2)(E) of the Social Security
19 Act. For purposes of the preceding sentence, the term ‘re-
20 lated information’ has the meaning given such term in
21 clause (iv)(II) of such section.

22 **“SEC. 2149. PROVIDER PARTICIPATION.**

23 “(a) IN GENERAL.—The State shall monitor and en-
24 force compliance by health care providers with the require-
25 ments of sections 2147 and 2148 and section 2155(b) for

1 all doses of pediatric vaccine administered in the State.
2 The State shall establish procedures satisfactory to the
3 Secretary for discontinuing the distribution of federally
4 purchased or State purchased vaccine for any health care
5 provider who fails to comply with the requirements of sec-
6 tion 2147 and for reinstating such vaccine supply to such
7 provider upon receiving from such provider—

8 “(1) the reports necessary to make current and
9 complete the information that would have been fur-
10 nished to the State registry between the dates of the
11 provider’s termination and reinstatement; and

12 “(2) satisfactory assurances regarding the pro-
13 vider’s future compliance.

14 “(b) **REPORTS TO SECRETARY.**—The Secretary may
15 make a grant under section 2146 only if the State involved
16 agrees to submit to the Secretary such reports as the Sec-
17 retary determines to be appropriate with respect to the
18 activities of the State under this part.

19 **“SEC. 2150. APPLICATION FOR GRANT.**

20 “An application by a State for a grant under section
21 2146 is in accordance with this section if the application—

22 “(1) is submitted not later than the date speci-
23 fied by the Secretary;

24 “(2) contains each agreement required in this
25 part;

1 “(3) contains any information required in this
2 part to be submitted to the Secretary; and

3 “(4) is in such form, is made in such manner,
4 and contains such agreements, assurances, and in-
5 formation as the Secretary determines to be nec-
6 essary to carry out this part.

7 **“SEC. 2151. DETERMINATION OF AMOUNT OF ALLOTMENT.**

8 “The Secretary shall determine the amount of the al-
9 lotments required in section 2146 for States for a fiscal
10 year in accordance with a formula established by the Sec-
11 retary that allots the amounts appropriated under section
12 2152 for the fiscal year on the basis of the costs of the
13 States in establishing and operating registries under sec-
14 tion 2146.

15 **“SEC. 2152. AUTHORIZATION OF APPROPRIATIONS.**

16 “For the purpose of carrying out this part, other than
17 section 2153, there are authorized to be appropriated
18 \$152,000,000 for fiscal year 1994, \$125,000,000 for fis-
19 cal year 1995, and \$35,000,000 for each of the fiscal years
20 1996 through 1999.

21 **“SEC. 2153. NATIONAL IMMUNIZATION SURVEILLANCE PRO-**
22 **GRAM.**

23 “(a) IN GENERAL.—The Secretary shall establish a
24 national immunization surveillance program for the pur-
25 pose of assessing the effects of the programs and activities

1 provided for in this subtitle towards appropriately immu-
2 nizing children and facilitating State immunization reg-
3 istries. The national immunization surveillance program
4 shall—

5 “(1) provide technical assistance to States for
6 the development of vaccination registries and mon-
7 itoring systems; and

8 “(2) receive aggregate epidemiologic data (that
9 is in a format that is not person specific) collected
10 by States as provided for in section 2147 at inter-
11 vals determined appropriate by the Secretary for the
12 purpose of—

13 “(A) compiling accurate and up-to-date
14 surveillance data regarding immunization rates
15 at the State level in order to assess the progress
16 made towards achieving nationally established
17 immunization goals;

18 “(B) assisting in the effective administra-
19 tion and management of immunization pro-
20 grams at the State level by providing technical
21 assistance to guide immunization program ef-
22 forts at the request of the State;

23 “(C) providing technical assistance to
24 States and localities to facilitate monitoring the
25 immunization status of children who move

1 across geographic boundaries that are covered
2 by different State or local registries at the re-
3 quest of such States or localities; and

4 “(D) monitoring the safety and effective-
5 ness of vaccines by linking vaccine dosage infor-
6 mation with adverse events reporting under sec-
7 tion 2125(b) and disease outbreak patterns.

8 “(b) RULE OF CONSTRUCTION.—Nothing in this sub-
9 title shall be construed to authorize the release of person
10 specific information to the Secretary for the purpose of
11 immunization surveillance.

12 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated such sums as may be
14 necessary to carry out this section in each of the fiscal
15 years 1994 through 1999.

16 **“SEC. 2154. REPORT.**

17 “Not later than January 1, 1995, and biennially
18 thereafter, the Secretary shall prepare and submit to the
19 appropriate committees of Congress a report concerning
20 the planning, development, operation and effectiveness of
21 the national immunization surveillance program and the
22 State immunization registries.

1 **“Part C—Distribution of Vaccines, Public Outreach**
2 **and Education**

3 **“SEC. 2155. DISTRIBUTION OF VACCINES.**

4 “(a) IN GENERAL.—

5 “(1) HEALTH CARE PROVIDERS.—The Sec-
6 retary shall provide for the distribution, without
7 charge, of recommended pediatric vaccines (in ac-
8 cordance with section 2141) purchased by the Sec-
9 retary to health care providers who serve children
10 and who—

11 “(A) are members of a uniformed service,
12 or are officers or employees of the United
13 States;

14 “(B) are health centers (as defined in sec-
15 tion 2162(2)); or

16 “(C) provide services under section 503 of
17 the Indian Health Care Improvement Act or
18 pursuant to a contract under section 102 of the
19 Indian Self Determination Act.

20 “(2) STATES.—The Secretary shall provide for
21 the distribution, without charge, of those rec-
22 ommended pediatric vaccines that are purchased by
23 the Secretary and provided to States for the pur-
24 poses of immunizing medicaid-eligible children, and
25 additional vaccines that may be purchased by the
26 Secretary for children within those States.

1 “(b) DUTIES OF HEALTH CARE PROVIDERS.—

2 “(1) FREE PROVISION TO CHILDREN.—A health
3 care provider or entity receiving vaccine under this
4 section may use such vaccine only for administration
5 to children and may not impose a charge for such
6 vaccine. A provider or health care entity may impose
7 a fee that reflects actual regional costs as deter-
8 mined by the Secretary for the administration of
9 such vaccine, except that a provider may not deny
10 a child a vaccination due to the inability of the
11 child’s parent to pay an administration fee.

12 “(2) REPORTING REQUIREMENTS.—A health
13 care provider receiving vaccine under this section
14 shall report the information required under section
15 2147 to the applicable State registry operated pur-
16 suant to a grant under section 2146 if such State
17 registry exists. The provider shall additionally report
18 to such State registry any occurrence reported to the
19 Secretary pursuant to section 2125(b). The provider
20 shall also provide regular and periodic estimates to
21 the State of the provider’s future dosage needs for
22 recommended childhood vaccines distributed under
23 this section. All reports shall be made with such fre-
24 quency and in such detail as the Secretary, in con-

1 sultation with State public health officials, may pre-
2 scribe.

3 **“SEC. 2156. IMPROVED IMMUNIZATION DELIVERY, OUT-
4 REACH AND EDUCATION.**

5 “(a) FEDERAL EFFORTS.—The Secretary, acting
6 through the Centers for Disease Control and Prevention
7 and in conjunction with State health officials and other
8 appropriate public and private organizations, shall conduct
9 the following activities to improve Federal, State and local
10 vaccine delivery systems and immunization outreach and
11 education efforts:

12 “(1) NATIONAL PUBLIC AWARENESS CAM-
13 PAIGN.—

14 “(A) IN GENERAL.—The Secretary, in con-
15 junction with State health officials and other
16 appropriate public and private organizations,
17 shall develop and implement a National Immu-
18 nization Public Awareness Campaign to assist
19 families (through bilingual means if necessary)
20 of children under the age of 2 years, and ex-
21 pectant parents, in obtaining knowledge con-
22 cerning the importance of having their children
23 immunized and in identifying the vaccines,
24 schedules for immunization, and vaccine pro-

1 vider locations, appropriate with respect to their
2 children.

3 “(B) IMPLEMENTATION.—In implementing
4 the Campaign under subparagraph (A), the
5 Secretary shall ensure that—

6 “(i) new and innovative methods are
7 developed and utilized to publicly advertise
8 the need to have children immunized in a
9 timely manner;

10 “(ii) print, radio and television media
11 are utilized to convey immunization infor-
12 mation to the public; and

13 “(iii) with respect to immunization in-
14 formation, efforts are made to target preg-
15 nant women and the parents of children
16 under the age of 2.

17 “(2) INTERAGENCY COMMITTEE ON IMMUNIZA-
18 TION.—The Secretary, in conjunction with the Sec-
19 retary of Agriculture, the Secretary of Housing and
20 Urban Development, and the Secretary of Edu-
21 cation, shall carry out activities through the Inter-
22 agency Committee on Immunization to incorporate
23 immunization status assessments and referral serv-
24 ices as an integral part of the process by which indi-
25 viduals apply for assistance under—

1 “(A) the food stamp program under the
2 Food Stamp Act of 1977;

3 “(B) section 17 of the Child Nutrition Act
4 of 1966;

5 “(C) the Head Start Act;

6 “(D) part A of title IV of the Social Secu-
7 rity Act;

8 “(E) title XIX of the Social Security Act;

9 “(F) any of the housing assistance laws of
10 the United States; and

11 “(G) other programs determined appro-
12 priate by any of the Secretaries described in
13 this paragraph.

14 “(3) EXPANDED OPPORTUNITY FOR NATIONAL
15 SERVICE.—The Secretary, in conjunction with the
16 Commission on National and Community Service
17 and other independent agencies, is encouraged to de-
18 velop opportunities for participants in national and
19 community service programs to contribute to local
20 initiatives for the improvement of immunization
21 services, including public outreach and education ef-
22 forts.

23 “(b) GRANTS TO STATES.—

24 “(1) IN GENERAL.—

1 “(A) The Secretary may award grants to
2 States to enable such State to develop, revise
3 and implement immunization improvement
4 plans as described in paragraph (2).

5 “(B) To be eligible to receive a grant
6 under subparagraph (A), a State shall prepare
7 and submit to the Secretary an application at
8 such time, in such manner, and containing such
9 information as the Secretary may require.

10 “(2) DESIGN.—A State immunization improve-
11 ment plan shall be designed to improve immuniza-
12 tion delivery, outreach, education and coordination
13 within the State. Such plan shall provide for the cre-
14 ation of—

15 “(A) a vaccine provider education cam-
16 paign and the distribution of any other mate-
17 rials determined to be appropriate by State
18 health officials—

19 “(i) to enable such providers to make
20 the best use of vaccination opportunities;
21 and

22 “(ii) to educate such providers con-
23 cerning their obligation to report immuni-
24 zation information with respect to their pa-
25 tients to State registries;

1 “(B) expanded capacity for the delivery of
2 immunizations through—

3 “(i) increasing the number or type of
4 facilities through which vaccines may be
5 made available and the capacity of such fa-
6 cilities to immunize more children;

7 “(ii) developing alternative methods of
8 delivering vaccines, such as mobile health
9 clinics;

10 “(iii) increasing the number of hours
11 during which vaccines are made available
12 by providers within the State; or

13 “(iv) coordinating with federally quali-
14 fied health centers to reach and immunize
15 underserved children through education,
16 outreach, tracking, and the provision of
17 services;

18 except that, the Secretary may waive any spe-
19 cific requirement of this subparagraph if the
20 Secretary determines that State immunization
21 delivery efforts are sufficient without the impo-
22 sition of such requirement;

23 “(C) population-based assessment criteria
24 through which the State is able to assess the ef-
25 fectiveness of immunization activities in the

1 State, which may be fulfilled through the imple-
2 mentation of a State immunization registry
3 under section 2146;

4 “(D) a public awareness campaign, in con-
5 junction with the National Campaign estab-
6 lished under subsection (a)(1), to provide par-
7 ents with information about the importance of
8 immunization, the types and schedules for the
9 administration of vaccines, and the locations of
10 vaccines providers;

11 “(E) coordinated community outreach ac-
12 tivities among public or private health pro-
13 grams, including local health departments and
14 health centers, and other public or private enti-
15 ties, to encourage and facilitate the ability of
16 parents to obtain immunization services for
17 their children; and

18 “(F) other activities that are not inconsis-
19 tent with the purposes of this subtitle, subject to
20 the approval of the Secretary.

21 “(3) IMMUNIZATION IMPROVEMENT PLAN AP-
22 PROVAL.—

23 “(A) GOALS.—As part of the immunization
24 improvement plan of a State, the State shall es-

1 tablish immunization rate goals for children re-
2 siding within the State.

3 “(B) APPROVAL.—The immunization im-
4 provement plan developed by a State under this
5 subsection shall be submitted to the Secretary
6 for approval prior to the distribution of grant
7 funds to the States under this subsection. The
8 Secretary shall periodically review the progress
9 that the State has made under such plan in
10 achieving the goals established under subpara-
11 graph (A).

12 “(C) DISTRIBUTION OF GRANTS.—In
13 awarding grants under this section, the Sec-
14 retary shall ensure that grant awards will be
15 equitably distributed between rural and urban
16 areas. In determining such distribution, the
17 Secretary shall take into account the added
18 costs of supporting the health care delivery in-
19 frastructure in sparsely populated areas. The
20 Secretary shall give special consideration to
21 those States that have low childhood immuniza-
22 tion rates and that submit plans that dem-
23 onstrate the State’s substantial effort and com-
24 mitment to improving such rates.

1 “(D) REPORTING.—A State shall annually
2 prepare and submit to the Director of the Cen-
3 ters for Disease Control and Prevention a re-
4 port concerning the implementation of the State
5 immunization improvement plan.

6 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
7 are authorized to be appropriated to carry out this section,
8 \$250,000,000 for fiscal year 1994, and such sums as may
9 be necessary for each of the fiscal years 1995 through
10 1999.

11 **“SEC. 2157. PERFORMANCE BASED GRANT PROGRAM.**

12 “(a) ANNUAL REPORT.—Not later than July 1 of
13 each year, a State shall prepare and submit to the Direc-
14 tor of the Centers for Disease Control and Prevention a
15 report that contains an estimate (based on a base popu-
16 lation sample) of the percentage of 2 year old residents
17 of the State who have been fully immunized as described
18 in subsection (c).

19 “(b) PAYMENTS TO STATES.—

20 “(1) IN GENERAL.—Subject to the availability
21 of appropriations, the Secretary shall provide to a
22 State that has submitted an annual report under
23 subsection (a) that demonstrates that the State has
24 fully immunized at least 50 percent of the 2 year old
25 residents of that State, with respect to the year for

1 which the report was prepared, a payment in an
2 amount equal to—

3 “(A) with respect to a State that has dem-
4 onstrated the full immunization of at least 50
5 and less than 64 percent of all 2 year old resi-
6 dents of the State, \$50 multiplied by the num-
7 ber of fully immunized 2 year old resident chil-
8 dren in excess of the number of children equal-
9 ing such 50 percent amount;

10 “(B) with respect to a State that has dem-
11 onstrated the full immunization of at least 65
12 and less than 70 percent of all 2 year old resi-
13 dents of the State, \$75 multiplied by the num-
14 ber of fully immunized 2 year old resident chil-
15 dren in excess of the number of children equal-
16 ing such 65 percent amount; and

17 “(C) with respect to a State that has dem-
18 onstrated the full immunization of at least 70
19 and less than 91 percent of all 2 year old resi-
20 dents of the State, \$100 multiplied by the num-
21 ber of fully immunized 2 year old resident chil-
22 dren in excess of the number of children equal-
23 ing such 70 percent amount.

24 “(2) USE OF FUNDS.—

1 “(A) CONDITION.—As a condition of re-
2 ceiving amounts under this section a State that
3 uses a combination of Federal and State funds
4 in achieving the immunization goals described
5 in paragraph (1) shall agree to reinvest, in ac-
6 tivities related to improving immunization serv-
7 ices, that percentage of the payments to the
8 State under paragraph (1) that is equal to the
9 amount of Federal contributions to immuniza-
10 tion services in the State as compared to the
11 amount of the State contributions to such serv-
12 ices.

13 “(B) DISCRETIONARY USE.—A State that
14 has demonstrated that the use of State-only
15 funds was responsible for the increase in the
16 immunization rate which qualified such State
17 for payments under paragraph (1), may use
18 amounts awarded under this section for other
19 purposes, at the discretion of the State.

20 “(3) VERIFICATION.—Prior to making a pay-
21 ment to a State under this subsection, the Secretary
22 shall, in collaboration with the Centers for Disease
23 Control and Prevention, verify the accuracy of the
24 State report involved.

1 “(c) DEFINITION.—For purposes of this section, the
2 term ‘fully immunized’ means a 2 year old child that has
3 received four doses of DTP vaccine (diphtheria, tetanus,
4 pertussis), three doses of polio vaccine, and one dose of
5 MMR (measles, mumps, rubella) vaccine.

6 **“Part D—General Provisions**

7 **“SEC. 2161. REPORT.**

8 “Not later than October 1, 1995, and biennially
9 thereafter, the Secretary shall prepare and submit to the
10 appropriate committees of Congress a report concerning
11 the costs, efficiency, and effectiveness of procedures estab-
12 lished to deliver vaccine to health care providers.

13 **“SEC. 2162. NATIONAL VACCINE PROGRAM.**

14 “The Secretary shall authorize a report to be pre-
15 pared by the National Academy of Sciences concerning the
16 role of the National Vaccine Program established under
17 this title in achieving progress towards the nationally es-
18 tablished immunization goals for the year 2000, and rec-
19 ommendations with respect to the changes in such Pro-
20 gram that would facilitate greater progress towards
21 achieving such goals.

22 **“SEC. 2163. DEFINITIONS.**

23 “For purposes of this subtitle—

24 “(1) HEALTH CARE PROVIDER.—The term
25 ‘health care provider’, with respect to the adminis-

1 tration of vaccines to children, means an entity that
2 is licensed or otherwise authorized for such adminis-
3 tration under the law of the State in which the en-
4 tity administers the vaccine, subject to section
5 333(e).

6 “(2) HEALTH CENTER.—The term ‘health cen-
7 ter’ means—

8 “(A) a federally qualified health center, as
9 defined in section 1905(l)(2) of the Social Secu-
10 rity Act; or

11 “(B) a public or nonprofit private entity
12 receiving Federal funds under—

13 “(i) section 329, 330 or 340;

14 “(ii) section 340A (relating to grants
15 for health services for residents of public
16 housing); or

17 “(iii) section 501(a)(2) of the Social
18 Security Act (relating to special projects of
19 regional and national significance).

20 “(3) IMMUNIZATION.—The term ‘immunization’
21 means an immunization against a vaccine-prevent-
22 able disease.

23 “(4) PARENT.—The term ‘parent’, with respect
24 to a child, means a legal guardian of the child.

1 “(5) PEDIATRIC VACCINE.—The term ‘pediatric
2 vaccine’ means a vaccine included on the list estab-
3 lished under section 2141.

4 “(6) STATE.—The term ‘State’ means the 50
5 States, the District of Columbia, the Commonwealth
6 of Puerto Rico, Guam, American Samoa, the U.S.
7 Virgin Islands, the Republic of the Marshall Islands,
8 Micronesia, the Northern Mariana Islands, and
9 Palau.”.

10 **SEC. 3. NATIONAL VACCINE INJURY COMPENSATION PRO-**
11 **GRAM AMENDMENTS.**

12 (a) AMENDMENT OF VACCINE INJURY TABLE.—

13 (1) ADDITION OF VACCINES.—Section 2114 (42
14 U.S.C. 300aa-14) is amended by adding at the end
15 thereof the following new subsection:

16 “(f) ADDITION OF VACCINES TO TABLE.—

17 “(1) IN GENERAL.—The Vaccine Injury table
18 contained in subsection (a) shall also include any
19 recommended childhood vaccine included in the list
20 promulgated by the Secretary under section 2141.

21 “(2) REVIEW OF INFORMATION AND REVI-
22 SION.—Not later than 2 years after the addition of
23 a new vaccine to the table contained in subsection
24 (a), and on a regular basis thereafter, the Secretary
25 shall review information obtained under sections

1 2125 and part B of subtitle 3, and based on such
2 review (and other relevant information) shall, as ap-
3 propriate, develop with respect to such new vac-
4 cine—

5 “(A) revisions with respect to illnesses, dis-
6 abilities, injuries or conditions covered by such
7 table;

8 “(B) appropriate specifications of the time
9 period for the first symptom or manifestation of
10 onset or of significant aggravation of such ill-
11 nesses, disabilities, injuries or condition after
12 vaccine administration, for purposes of receiv-
13 ing compensation under the Program; and

14 “(C) recommendations as to the amount of
15 tax that should be imposed under section 4131
16 of the Internal Revenue Code of 1986 for each
17 dose of vaccine.

18 “(3) LIMITATION.—The Secretary may modify
19 the table contained in subsection (a) pursuant to
20 paragraphs (1) and (2) only in accordance with sub-
21 section (c).

22 “(4) REVISION.—For purposes of section
23 2116(b), the addition of vaccine to the table con-
24 tained in subsection (a) by operation of this sub-
25 section shall constitute a revision of the table.”.

1 (2) ATTORNEYS' FEES.—Section 2115(e) (42
2 U.S.C. 300aa-15(e)) is amended by adding at the
3 end thereof the following new paragraph:

4 “(4) The special master may award reasonable
5 attorneys' fees whether or not an election has been
6 made under section 2121(a) to file a civil action con-
7 cerning such petition.”.

8 (3) CONSENT FOR ANNUITY.—Subparagraphs
9 (A) and (B) of section 2115(f)(4) are amended by
10 striking “, with the consent of the petitioner,” each
11 place that such appears.

12 (4) TIME PERIODS FOR FEES AND COSTS.—

13 (A) IN GENERAL.—Section 2115(e) (42
14 U.S.C. 300aa-15(e)) (as amended by paragraph
15 (3)) is further amended by adding at the end
16 thereof the following new paragraph:

17 “(5) With respect to a petitioners' application
18 for attorneys' fees and costs—

19 “(A) if the respondent enters no objection
20 to such application within 21 days of the date
21 on which the application was filed (unless such
22 time period is extended by the special master
23 with the consent of the petitioner) the special
24 master shall enter a decision on such applica-
25 tion within 30 days of such filing;

1 “(B) if the respondent files an objection to
2 such application and the special master does
3 not enter a decision with respect to the applica-
4 tion within 60 days after the date on which the
5 objection is filed, the special master involved
6 shall, upon the written request of the petitioner,
7 enter a decision within 15 days after the filing
8 of such request; and

9 “(C) if the respondent files an objection to
10 such application and the petitioner moves to re-
11 duce costs and fees as provided for in the objec-
12 tion, the special master shall enter a decision
13 within 5 days after the receipt of the petition-
14 er’s motion.

15 The chief special master, upon the request of a spe-
16 cial master, may waive the time limitations applica-
17 ble to the special master under this paragraph if the
18 special master demonstrates that complicating fac-
19 tors exist with respect to the issues involved to
20 which the time limitation applies.”.

21 (B) APPLICATION.—The amendment made
22 by subparagraph (A) shall apply to all petition-
23 ers’ applications for attorneys’ fees and costs
24 filed under section 2115(e) of the Public Health

1 Service Act which are pending on the date of
2 enactment of this Act.

3 (5) AUTHORIZATION OF APPROPRIATIONS.—
4 Section 2115(j) (42 U.S.C. 300aa-15(j)) is amended
5 by striking “\$80,000,000 for each succeeding fiscal
6 year” and inserting in lieu thereof “\$110,000,000
7 for each succeeding fiscal year”.

8 (6) LIMITATION OF ACTIONS.—Section 2116(b)
9 (42 U.S.C. 300aa-16(b)) is amended by striking
10 “such person may file” and inserting “or to signifi-
11 cantly increase the likelihood of obtaining compensa-
12 tion, such person may, notwithstanding section
13 2111(b)(2), file”.

14 (b) EXTENSION OF TIME FOR DECISION.—

15 (1) JURISDICTION.—Section 2112(d)(3)(D) (42
16 U.S.C. 300aa-12(d)(3)(D)) is amended by striking
17 “540 days” and inserting “30 months (but for not
18 more than 6 months at a time)”.

19 (2) REPORT ON COLLECTIONS.—Section 2117
20 (42 U.S.C. 300aa-17) is amended by adding at the
21 end thereof the following new subsection:

22 “(c) REPORT.—The Attorney General shall, on Janu-
23 ary 1 of each year, prepare and submit to the appropriate
24 committees of Congress a report concerning amounts col-
25 lected under this section.”.

1 (3) INCREASED RESPONSIBILITIES OF COMMIS-
2 SION.—Section 2119(f) (42 U.S.C. 300aa–19(f)) is
3 amended—

4 (A) by striking “and” at the end of para-
5 graph (4);

6 (B) by striking the period at the end of
7 paragraph (5) and inserting “, and”; and

8 (C) by adding at the end thereof the fol-
9 lowing new paragraph:

10 “(6) monitor the balance of the Vaccine Injury
11 Trust Fund established by section 9510 of the Inter-
12 nal Revenue Code and, as appropriate, recommend
13 changes in the tax per dose of vaccine imposed
14 under section 4131 of such Code.”.

15 (c) SIMPLIFICATION OF VACCINE INFORMATION MA-
16 TERIALS.—

17 (1) INFORMATION.—Section 2126(b) (42
18 U.S.C. 300aa–26(b)) is amended—

19 (A) by striking “by rule” in the matter
20 preceding paragraph (1);

21 (B) in paragraph (1), by striking “90” and
22 inserting “30”; and

23 (C) in paragraph (2), by striking “, appro-
24 priate health care providers and parent organi-
25 zations”.

1 (2) REQUIREMENTS.—Section 2126(c) (42
2 U.S.C. 300aa–26(c)) is amended—

3 (A) in the matter preceding paragraph (1),
4 by inserting “shall be based on available data
5 and information,” after “such materials”; and

6 (B) by striking out paragraphs (1) through
7 (10) and inserting in lieu thereof the following
8 new paragraphs:

9 “(1) a concise description of the benefits of the
10 vaccine;

11 “(2) a concise description of the risks associ-
12 ated with the vaccine;

13 “(3) a statement of the availability of the Na-
14 tional Vaccine Injury Compensation Program;

15 “(4) a statement of the availability from the
16 Secretary of more detailed written information con-
17 cerning the information required under paragraphs
18 (1), (2), and (3), that shall be made available to the
19 parent, legal guardian, or other responsible person
20 upon request; and

21 “(5) such other relevant information as deter-
22 mined appropriate by the Secretary.”.

23 (3) OTHER INDIVIDUALS.—Subsections (a) and
24 (d) of section 2126 (42 U.S.C. 300aa–26 (a) and
25 (d)) are amended by inserting “or to any other indi-

1 vidual” immediately after “to the legal representa-
2 tive of any child” each place that such occurs.

3 (4) PROVIDER DUTIES.—Subsection (d) of sec-
4 tion 2126 (42 U.S.C. 300aa–26(d)) is amended—

5 (A) by striking all after “subsection (a),”
6 the second place it appears in the first sentence
7 and inserting “supplemented with visual presen-
8 tations or oral explanations, in appropriate
9 cases.”; and

10 (B) by striking “or other information” in
11 the last sentence.

12 (d) AUTHORIZATION OF APPROPRIATIONS.—Part A
13 of subtitle 2 of title XXI (42 U.S.C. 300aa–10 et seq.)
14 is amended by adding at the end thereof the following new
15 section:

16 “AUTHORIZATION OF APPROPRIATIONS

17 “SEC. 2120. (a) SECRETARY.—For purposes of ad-
18 ministering this part, there are authorized to be appro-
19 priated from the Vaccine Injury Compensation Trust
20 Fund established under section 9510(c) of the Internal
21 Revenue Code of 1986, to the Secretary, \$3,000,000 for
22 each of the fiscal years 1994, 1995, and 1996.

23 “(b) ATTORNEY GENERAL.—For purposes of admin-
24 istering this part, there are authorized to be appropriated
25 from the Vaccine Injury Compensation Trust Fund de-
26 scribed in subsection (a), to the Attorney General,

1 \$3,000,000 for each of the fiscal years 1994, 1995, and
2 1996.

3 “(c) COURT OF FEDERAL CLAIMS.—For purposes of
4 administering this part, there are authorized to be appro-
5 priated from the Vaccine Injury Compensation Trust
6 Fund described in subsection (a), to the Court of Federal
7 Claims, \$3,000,000 for each of the fiscal years 1994,
8 1995, and 1996.”.

9 **SEC. 4. MISCELLANEOUS PROVISIONS.**

10 Section 317(k) (42 U.S.C. 247b(k)) is amended—

11 (1) by striking out paragraph (1); and

12 (2) by redesignating paragraphs (2) through
13 (5) as paragraphs (1) and (4), respectively.

14 **SEC. 5. AMENDMENTS TO THE FEDERALLY SUPPORTED**
15 **HEALTH CENTERS ASSISTANCE ACT OF 1992.**

16 (a) CLARIFICATION OF COVERAGE OF OFFICERS AND
17 EMPLOYEES OF CLINICS.—The first sentence of section
18 224(g)(1) of the Public Health Service Act (42 U.S.C.
19 233(g)(1)) is amended by striking “officer, employee, or
20 contractor” and inserting the following: “officer or em-
21 ployee of such an entity, and any contractor”.

22 (b) COVERAGE FOR SERVICES FURNISHED TO INDI-
23 VIDUALS OTHER THAN PATIENTS OF CLINIC.—Section
24 224(g) of such Act (42 U.S.C. 233(g)(1)), as amended
25 by paragraph (1), is further amended—

1 (1) in the first sentence of paragraph (1), by
2 inserting after “Service” the following: “with respect
3 to services provided to patients of the entity and
4 (subject to paragraph (7)) to certain other individ-
5 uals”; and

6 (2) by adding at the end the following new
7 paragraph:

8 “(7) For purposes of paragraph (1), an officer, em-
9 ployee, or contractor described in such paragraph may be
10 deemed to be an employee of the Public Health Service
11 with respect to services provided to individuals who are
12 not patients of an entity described in paragraph (4) only
13 if the Secretary determines—

14 “(A) that the provision of the services to such
15 individuals benefits health center patients and gen-
16 eral populations that could be served by the health
17 center through community-wide intervention efforts
18 within the communities served by such health center,
19 and facilitates the provision of services to health
20 center patients; or

21 “(B) that such services are otherwise required
22 to be provided to such individuals under an employ-
23 ment contract (or other similar arrangement) be-
24 tween the individual and the entity.”.

1 (c) DETERMINING COMPLIANCE OF ENTITY WITH
2 REQUIREMENTS FOR COVERAGE.—

3 (1) IN GENERAL.—Section 224(h) of such Act
4 (42 U.S.C. 233(h)), as added by section 2(b) of the
5 Federally Supported Health Centers Assistance Act
6 of 1992, is amended by striking “the entity—” and
7 inserting the following: “the Secretary, after receiv-
8 ing such assurances and conducting such investiga-
9 tion as the Secretary considers necessary, finds
10 that the entity—”.

11 (2) FINDING.—Section 224 of such Act (42
12 U.S.C. 233) is amended by adding at the end there-
13 of the following new subsection:

14 “(l) With respect to subsection (h), the finding of the
15 Secretary that an entity meets all of the requirements
16 under such subsection shall apply for the period specified
17 by the Secretary, and shall be binding for all parties unless
18 the Secretary reverses such finding for good cause shown
19 at a later date.”.

20 (d) PAYMENT OF JUDGMENTS.—Section 224(k)(2) of
21 such Act (42 U.S.C. 233(k)(2)), as added by section 4
22 of the Federally Supported Health Centers Assistance Act
23 of 1992, is amended by adding at the end thereof the fol-
24 lowing new sentence: “Appropriations for purposes of this

1 paragraph shall be made separate from appropriations
2 made for purposes of sections 329, 330, 340 and 340A.”.

3 (d) EFFECTIVE DATE.—The amendments made by
4 this section shall take effect as if included in the enact-
5 ment of the Federally Supported Health Centers Assist-
6 ance Act of 1992.

Passed the Senate November 4 (legislative day, No-
vember 2), 1993.

Attest:

Secretary.

S 732 ES—2

S 732 ES—3

S 732 ES—4

S 732 ES—5