

Calendar No. 214

103D CONGRESS
1ST SESSION

S. 732

A BILL

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

SEPTEMBER 28 (legislative day, SEPTEMBER 27), 1993
Reported with an amendment

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

IN THE SENATE OF THE UNITED STATES

APRIL 1 (legislative day, MARCH 3), 1993

Mr. KENNEDY (for himself, Mr. RIEGLE, Mr. SIMON, Mr. WELLSTONE, Mr. METZENBAUM, Ms. MIKULSKI, Mr. PELL, Mr. DORGAN, Mr. BINGAMAN, Mr. HARKIN, Mr. WOFFORD, Mr. DODD, Mrs. KASSEBAUM, Mr. JEFFORDS, and Mr. CAMPBELL) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

SEPTEMBER 28 (legislative day, SEPTEMBER 27), 1993

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

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 AND REFERENCES.**

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 **SEC. 2. FINDINGS AND PURPOSE.**

8 (a) FINDINGS.—

9 (1) CURRENT CIRCUMSTANCES.—Congress
10 finds the following:

11 (A) Immunizations are among the most
12 cost-effective means of preventing disease.

13 (B) Although Federal support for child-
14 hood immunizations has been in existence since
15 1962, the full potential of immunizations re-
16 mains to be achieved. Enactment and enforce-
17 ment of school immunization requirements have
18 resulted in excellent immunization levels (96
19 percent or greater) in school children. However,
20 approximately 80 percent of vaccine doses
21 should be received before the second birthday in
22 order to protect children during their most vul-
23 nerable periods. Many children do not receive
24 their basic immunizations by that time, and in
25 some inner cities as few as 10 percent of 2-

1 year-olds have received a complete series. This
2 low level of immunizations has been reflected in
3 recent years by outbreaks of measles among in-
4 adequately immunized preschool children.

5 (C) The immunization services delivery in-
6 frastructure to immunize children is both public
7 and private. There is considerable evidence to
8 suggest that the private infrastructure has been
9 eroded over the past decade as a result of the
10 significantly increased cost of privately pur-
11 chased vaccines.

12 (D) Prices for privately purchased vaccines
13 exceed the prices paid for like vaccines in some
14 other industrialized nations by over 2500 per-
15 cent.

16 (E) High vaccine costs, coupled with the
17 growing number of uninsured and underinsured
18 families, has resulted in private physicians in-
19 creasingly referring their private-pay patients to
20 overburdened public clinics for vaccinations.

21 (F) Eleven States now have programs that
22 provide vaccines without charge to both public
23 and private health care providers. Other States
24 that have sought to establish such programs

1 have been denied additional discounted vaccines
2 by manufacturers.

3 (G) There is no evidence to suggest that a
4 negotiated price that takes into account the rea-
5 sonable cost of production, marketing, research
6 and development, and distribution will not fairly
7 compensate vaccine manufacturers. Indeed, a
8 recent report by the Congressional Office of
9 Technology Assessment supports the propo-
10 sition that negotiated rates can assure fair com-
11 pensation while holding down costs.

12 (H) The Secretary of Health and Human
13 Services has experience negotiating vaccine pur-
14 chase through the Federal contract system.

15 (I) The National Vaccine Injury Com-
16 pensation Program is an essential element in a
17 comprehensive immunization program and
18 should be strengthened and applied to addi-
19 tional vaccines recommended for universal use
20 in children.

21 (2) NEEDED ACTIONS.—With respect to actions
22 necessary to ensure the full immunization of children
23 at the earliest possible age, Congress finds the fol-
24 lowing:

1 (A) The Federal Government should purchase and provide free of charge to health care
2 providers vaccines recommended for universal
3 use in children. This action will not only remove
4 financial barriers to immunization that impede
5 children from being vaccinated at the appropriate
6 time, but will also facilitate the development
7 of an immunization tracking system.
8

9 (B) The Federal Government and the
10 States should develop linked registries to track
11 the immunization status of the Nation's children.
12 The registry system should have the capability
13 to notify parents of inadequately immunized
14 children of the need to protect their children
15 with specific vaccines.

16 (C) The coordinated national information
17 and education outreach initiative operated
18 through the Department of Health and Human
19 Services should be sustained to bring needed information
20 to parents and health care providers and focus
21 their attention on the importance of achieving
22 the full and timely immunization of children
23 at the earliest appropriate age.

24 (D) Private and public health insurers
25 should be encouraged to provide adequate reim-

1 bursement for the administration of childhood
2 vaccines.

3 (E) Volunteer community activities to pro-
4 mote the full immunization of children at the
5 earliest appropriate age should be encouraged.

6 (F) The National Vaccine Injury Com-
7 pensation Program should be extended and im-
8 proved. Vaccine information materials should be
9 simplified to ensure that parents can under-
10 stand the benefits and risks of vaccines.

11 (b) PURPOSE.—It is the purpose of this Act to ensure
12 that all children in the United States are fully immunized
13 against vaccine preventable infectious diseases at the earli-
14 est appropriate age.

15 **SEC. 3. NATIONAL IMMUNIZATION TRACKING SYSTEM.**

16 (a) IN GENERAL.—Title XXI of the Public Health
17 Service Act (42 U.S.C. 300aa–1 et seq.) is amended by
18 adding at the end thereof the following new subtitle:

19 **“Subtitle 3—Improved Immuniza-**
20 **tion and National Tracking Sys-**
21 **tem**

22 **“SEC. 2141. RECOMMENDED CHILDHOOD VACCINES.**

23 “Not later than October 1, 1994, (and periodically
24 thereafter as the Secretary determines appropriate in view
25 of advances in scientific understanding in the areas of im-

1 munization and disease control) the Secretary shall pro-
2 mulgate a list of vaccines that provide immunization
3 against naturally occurring infectious diseases and are
4 recommended for universal use in children. The Secretary
5 shall concurrently promulgate recommendations regarding
6 the appropriate dosage for each such vaccine, and the age
7 or ages of children at which each vaccine should be admin-
8 istered.

9 **“SEC. 2142. TRACKING OF CHILDHOOD IMMUNIZATIONS.**

10 “(a) NATIONAL TRACKING SYSTEM.—

11 “(1) ESTABLISHMENT.—The Secretary shall es-
12 tablish a national system to track the immunization
13 status of children.

14 “(2) SYSTEM DESIGN.—The system established
15 under paragraph (1) shall be designed to—

16 “(A) provide accurate and up to date sur-
17 veillance data regarding immunization rates at
18 the local and State levels;

19 “(B) assist in identifying localities with in-
20 adequate immunization rates to target for nec-
21 essary remedial actions;

22 “(C) be used to identify unvaccinated chil-
23 dren and trigger a notification system for the
24 parents or legal guardians and health care pro-
25 viders of such children;

1 ~~“(D)~~ be used to assist in the effective ad-
 2 ministration and management of immunization
 3 programs at State and local levels by providing
 4 data to guide immunization program efforts;

5 ~~“(E)~~ assist States and localities in tracking
 6 the immunization status of children who move
 7 across geographic boundaries that are covered
 8 by different State or local registries; and

9 ~~“(F)~~ monitor the safety and effectiveness
 10 of vaccines by linking vaccine dosage informa-
 11 tion with adverse events reporting under section
 12 2125(b) and disease outbreak patterns.

13 ~~“(3) NOTIFICATION OF PARENTS.—~~The Sec-
 14 retary is authorized, in the case of inadequately im-
 15 munized children in States not receiving grants
 16 under subsection (b), to notify the parents or guard-
 17 ians of those children receiving services through
 18 paragraphs (1), (2) or (3) of section 2143(a) of the
 19 need to protect their children with specific vaccine.

20 ~~“(b) STATE REGISTRY GRANTS.—~~

21 ~~“(1) IN GENERAL.—~~The Secretary may award
 22 grants to States to enable such States to establish
 23 and operate State immunization tracking registries.
 24 A State receiving a grant under this section shall

1 maintain a registry that includes the following infor-
2 mation for each child living within the State:

3 “(A) The type and lot number of each rec-
4 ommended childhood vaccine administered after
5 September 30, 1996.

6 “(B) An identification of the health care
7 provider administering such vaccine.

8 “(C) The address and other demographic
9 data needed to find the child.

10 “(D) Notations of any adverse events asso-
11 ciated with each immunization.

12 “(E) Special religious considerations or
13 medical conditions that are contraindications
14 for immunizations.

15 “(F) Such other information as the Sec-
16 retary may prescribe.

17 “(2) GRANT CONDITIONS.—A State, as a condi-
18 tion of receiving a grant under this subsection, shall
19 comply with the following requirements:

20 “(A) The State registry shall provide for
21 entry of the birth of each infant within the
22 state within six weeks following the birth, and
23 for timely entry thereafter of all information re-
24 ceived from health care providers pursuant to
25 section 2143(b)(2) or section 2125(b).

1 “(B) Subject to subsection (c), the State
2 shall provide for the sharing of appropriate in-
3 formation from the State’s registry, including
4 immunization status and reports of adverse re-
5 actions, with health care providers who offer
6 immunizations for the purpose of achieving the
7 full immunization of all children in accordance
8 with the recommendations of the Secretary
9 under section 2141.

10 “(C) The State shall provide for notifica-
11 tion to the parents or guardian of an inad-
12 equately immunized child of the need to protect
13 the child with specific vaccine, except as pro-
14 vided in paragraph (1)(E).

15 “(D) Subject to subsection (c), the State
16 shall provide for the coordination and exchange
17 of information with other State registries to
18 allow the tracking of the immunization status
19 of children changing State of residence.

20 “(E) The State shall periodically furnish to
21 the Secretary, at such times and in such form
22 as the Secretary may prescribe, information
23 contained in the State registry.

24 “(F) In designing its registry, the State
25 shall adhere to tracking models and systems

1 specifications prescribed by the Secretary for
2 the purpose of ensuring the mutual compatibil-
3 ity of the data systems and electronic informa-
4 tion technology utilized by the Secretary and
5 the various States in carrying out activities
6 under this subtitle.

7 “(G) The State shall monitor and enforce
8 compliance by health care providers with the re-
9 quirements of section 2143(b). The State shall
10 establish procedures satisfactory to the Sec-
11 retary for terminating from participation in the
12 recommended childhood vaccine distribution
13 program any health care provider who fails to
14 comply with the requirements of section
15 2143(b)(1) and for reinstating such provider to
16 program participation upon receiving from such
17 provider—

18 “(i) the reports necessary to make
19 current and complete the information that
20 would have been furnished to the State
21 registry between the dates of the provider’s
22 termination and reinstatement; and

23 “(ii) satisfactory assurances regarding
24 the provider’s future compliance.

1 “(H) If a State distributes recommended
2 childhood vaccines within the State on behalf of
3 the Secretary pursuant to section 2143(a), the
4 State shall compile data, including lot numbers,
5 on the vaccines distributed to each health care
6 provider and shall furnish such data to the Sec-
7 retary in such form and at such intervals as the
8 Secretary may prescribe.

9 “(3) APPLICATIONS.—A State shall prepare
10 and submit to the Secretary an application for a
11 grant under subsection (b) in such form and con-
12 taining such information as the Secretary may pre-
13 scribe. The application shall include—

14 “(A) a description of the methods by which
15 the State will comply with the requirements of
16 paragraph (2);

17 “(B) the assurances required by paragraph
18 (4); and

19 “(C) a description of the expenses that the
20 State will incur in connection with its respon-
21 sibilities under the grant.

22 “(4) ASSURANCES.—A State submitting an ap-
23 plication for a grant under this section shall provide
24 assurances satisfactory to the Secretary that—

1 “(A) the State’s tracking registry will be
2 fully operational not later than October 1,
3 1996;

4 “(B) the State’s tracking registry will ad-
5 here to any tracking models and systems speci-
6 fications prescribed by the Secretary pursuant
7 to paragraph (2)(F); and

8 “(C) as appropriate, the State is making
9 satisfactory and timely progress toward achiev-
10 ing the conditions described in subparagraphs
11 (A) and (B).

12 “(5) ALLOWABLE USES OF GRANT FUNDS.—A
13 State may use amounts from a grant awarded under
14 this subsection for reasonable costs associated with
15 the development and operation of its registry, includ-
16 ing computer needs, technical assistance and train-
17 ing, education of health care providers, personnel
18 costs, travel expenses, and other appropriate activi-
19 ties.

20 “(6) STATE REPORTS TO THE SECRETARY.—A
21 State shall prepare and submit annual reports to the
22 Secretary concerning the operation of the State’s
23 registry and other activities under this subtitle. Such
24 reports shall be in such form, contain such informa-

1 tion, and be submitted at such intervals as the Sec-
2 retary may prescribe.

3 ~~“(c) USE AND DISCLOSURE OF PERSONAL INFORMA-~~
4 ~~TION.—~~

5 ~~“(1) GENERAL RULE.—No personally identifi-~~
6 ~~able information relating to a child who receives rec-~~
7 ~~ommended childhood vaccine under this subtitle or~~
8 ~~to the parent or guardian of such a child that is col-~~
9 ~~lected or maintained by the National Tracking Sys-~~
10 ~~tem established under subsection (a), or a State im-~~
11 ~~munization tracking registry established under sub-~~
12 ~~section (b), may be used or disclosed by any holder~~
13 ~~of such information except as permitted by this sub-~~
14 ~~section.~~

15 ~~“(2) GENERAL PERMISSIBLE USES.—Informa-~~
16 ~~tion described in paragraph (1) may be used or dis-~~
17 ~~closed, without the consent of the individual to~~
18 ~~whom it refers, or of the parent or guardian of such~~
19 ~~individual, for—~~

20 ~~“(A) the tracking of children’s immuniza-~~
21 ~~tion status, and other purposes directly related~~
22 ~~to the health of the children being tracked and~~
23 ~~of their families;~~

24 ~~“(B) oversight, audit, and evaluation of~~
25 ~~the immunization delivery and tracking activi-~~

1 ties, and the enforcement of the provisions of
2 this title;

3 ~~“(C) activities relating to establishing and~~
4 ~~maintaining a safe and effective supply of rec-~~
5 ~~ommended childhood vaccine (including activi-~~
6 ~~ties to carry out part C of subtitle 2);~~

7 ~~“(D) processing of insurance claims for~~
8 ~~payment for vaccine administration (but only to~~
9 ~~the extent necessary to process a claim); or~~

10 ~~“(E) administration of the National Vac-~~
11 ~~eine Injury Compensation Program under sub-~~
12 ~~title 2.~~

13 ~~“(3) PERMISSIBLE USE WITH WRITTEN AU-~~
14 ~~THORIZATION.—Information described in paragraph~~
15 ~~(1) may be used or disclosed with the written au-~~
16 ~~thorization of the individual to whom it refers, or~~
17 ~~the parent or guardian of such individual, and must,~~
18 ~~upon the request of such individual, or parent or~~
19 ~~guardian, be provided in writing to the individual.~~

20 ~~“(4) REGULATIONS.—The Secretary is author-~~
21 ~~ized to issue regulations—~~

22 ~~“(A) governing the use, maintenance, and~~
23 ~~disclosure, by any holder of information de-~~
24 ~~scribed in paragraph (1), including appropriate~~
25 ~~administrative, technical and physical safe-~~

1 guards to ensure that only authorized persons
2 have access to the information; and

3 ~~“(B) establishing conditions for access by~~
4 ~~individuals, and their parents or guardians, to~~
5 ~~such information about themselves.~~

6 ~~“(5) VIOLATIONS.—Any person who know-~~
7 ~~ingly—~~

8 ~~“(A) uses or discloses information in viola-~~
9 ~~tion of this subsection; or~~

10 ~~“(B) requests or obtains any information~~
11 ~~in violation of this subsection, and offers or~~
12 ~~provides anything of value in exchange for the~~
13 ~~provision of the information;~~

14 shall be fined as prescribed by title 18, United
15 States Code, or imprisoned not more than 3 years,
16 or both.

17 ~~“(d) AUTHORITY TO USE SOCIAL SECURITY NUM-~~
18 ~~BERS.—~~

19 ~~“(1) IN GENERAL.—Notwithstanding section~~
20 ~~205 of the Social Security Act or any other provision~~
21 ~~of law, the Secretary and States receiving grants~~
22 ~~under subsection (b) may utilize the social security~~
23 ~~number, or other means of identification, of a child~~
24 ~~or of a parent or guardian of the child for purposes~~
25 ~~of identification of a child in any registry established~~

1 under this section, and may require a child's parent
2 or guardian to furnish such number (in any case
3 where such a number has been assigned by the So-
4 cial Security Administration) as a condition of the
5 child receiving recommended childhood vaccine under
6 this subtitle.

7 “(2) AUTHORITY TO REDISCLOSE.—Notwith-
8 standing section 205(c)(2)(C)(vii)(I) of the Social
9 Security Act, a social security number obtained in
10 connection with activities under this subtitle may be
11 redisclosed if such redisclosure is otherwise in ac-
12 cordance with subsection (c) of this section.

13 “(c) REPORTS BY SECRETARY TO THE CONGRESS.—
14 Not later than January 1, 1995, and biennially thereafter,
15 the Secretary shall prepare and submit to the appropriate
16 committees of Congress a report concerning the planning,
17 development and operation of the national tracking system
18 and the State registries.

19 **“SEC. 2143. DISTRIBUTION OF VACCINES.**

20 “(a) IN GENERAL.—The Secretary shall provide for
21 the distribution without charge of recommended childhood
22 vaccines purchased by the Secretary under the Social Se-
23 curity Act to health care providers who serve children and
24 who—

1 “(1) are members of a uniformed service, or are
2 officers or employees of the United States;

3 “(2) are health centers (as defined in section
4 2144(2));

5 “(3) provide services under section 503 of the
6 Indian Health Care Improvement Act or pursuant to
7 a contract under section 102 of the Indian Self De-
8 termination Act; or

9 “(4) are located in a State receiving a grant
10 under section 2142(b).

11 The Secretary may provide for such distribution through
12 any State that receives a grant under section 2142(b).

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

14 “(1) FREE PROVISION TO CHILDREN.—A health
15 care provider receiving vaccine under this section
16 may use such vaccine only for administration to chil-
17 dren and may not impose a charge for such vaccine.
18 A provider may impose a fee for the administration
19 of such vaccine, except that a provider may not deny
20 a child a vaccination due to the inability of the
21 child’s parent or guardian to pay an administration
22 fee.

23 “(2) REPORTING REQUIREMENTS.—A health
24 care provider receiving vaccine under this section
25 shall report to the applicable State registry operated

1 pursuant to a grant under section 2142(b) (or to the
 2 Secretary if there is no such State registry) the data
 3 described in section 2142(b)(1) for each dose of vac-
 4 cine administered to a child. The provider shall addi-
 5 tionally report to such State registry any occurrence
 6 reported to the Secretary pursuant to section
 7 2125(b). The provider shall also provide regular and
 8 periodic estimates to the State of the provider's fu-
 9 ture dosage needs for recommended childhood vac-
 10 cine distributed under this section. All reports shall
 11 be made with such frequency and in such detail as
 12 the Secretary may prescribe.

13 **~~SEC. 2144. DEFINITIONS.~~**

14 ~~“For purposes of this subtitle—~~

15 ~~“(1) HEALTH CENTER.—The term ‘health cen-~~
 16 ~~ter’ means—~~

17 ~~“(A) a federally-qualified health center, as~~
 18 ~~defined in section 1905(l)(2) of the Social Secu-~~
 19 ~~rity Act; or~~

20 ~~“(B) a public or nonprofit private entity~~
 21 ~~receiving Federal funds under—~~

22 ~~“(i) section 340A (relating to grants~~
 23 ~~for health services for residents of public~~
 24 ~~housing); or~~

1 ~~“(ii) section 501(a)(2) of the Social~~
2 ~~Security Act (relating to special projects of~~
3 ~~regional and national significance).~~

4 ~~“(2) RECOMMENDED CHILDHOOD VACCINE.—~~

5 ~~The term ‘recommended childhood vaccine’ is a vac-~~
6 ~~cine on the list promulgated by the Secretary pursu-~~
7 ~~ant to section 2141.~~

8 ~~“SEC. 2145. AUTHORIZATION OF APPROPRIATIONS.~~

9 ~~“For the purpose of awarding grants under section~~
10 ~~2142 and for the operation of the tracking system author-~~
11 ~~ized by such section, there are authorized to be appro-~~
12 ~~priated \$152,000,000 for fiscal year 1995, \$125,000,000~~
13 ~~for fiscal year 1996, and \$35,000,000 for each of fiscal~~
14 ~~years 1997 through 1999.”.~~

15 ~~SEC. 4. GRANTS FOR IMMUNIZATION.~~

16 ~~Section 317(j)(1) (42 U.S.C. 247b(j)(1)) is amended~~
17 ~~by adding at the end thereof the following new subpara-~~
18 ~~graph:~~

19 ~~“(C)(i) Funds that are made available for the pur-~~
20 ~~pose of strengthening the public health infrastructure and~~
21 ~~used in the delivery of childhood immunization services~~
22 ~~shall be used for activities that are consistent with a stra-~~
23 ~~tegic plan that meets nationally established immunization~~
24 ~~goals and that was developed by the State in consultation~~
25 ~~with representatives of health care providers, health cen-~~

1 ters (as defined in clause (iii)), State agencies serving
 2 young children, and other entities involved in the preven-
 3 tion and control of vaccine-preventable illnesses.

4 “(ii) For purposes of clause (i), activities designed to
 5 strengthen the public health infrastructure and used in the
 6 delivery of childhood immunization services shall include
 7 public and provider education, community outreach initia-
 8 tives, improvements in the capacity of health centers and
 9 local health departments to provide immunization services
 10 (including expansion of the number of hours in which such
 11 services are provided), and activities to facilitate the devel-
 12 opment and operation of State immunization tracking reg-
 13 istries.

14 “(iii) For purposes of this paragraph, the term
 15 ‘health center’ means a public or nonprofit private entity
 16 receiving Federal funds under—

17 “(I) section 329 (relating to grants for migrant
 18 health centers);

19 “(II) section 330 (relating to grants for com-
 20 munity health centers);

21 “(III) section 340 (relating to grants for health
 22 services for the homeless); or

23 “(IV) section 340A (relating to grants for
 24 health services for residents of public housing).”.

1 **SEC. 5. NATIONAL VACCINE INJURY COMPENSATION PRO-**
2 **GRAM AMENDMENTS.**

3 (a) AMENDMENT OF VACCINE INJURY TABLE.—

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

7 “(f) ADDITION OF VACCINES TO TABLE.—The Vac-
8 cine Injury Table in subsection (a) shall also include any
9 recommended childhood vaccine included in the list pro-
10 mulgated by the Secretary under section 2141. The Sec-
11 retary may modify the Table with respect to any vaccine
12 added by operation of the preceding sentence only in ac-
13 cordance with subsection (c). For purposes of section
14 2116(b), the addition of a vaccine to the Table by oper-
15 ation of this subsection shall constitute a revision of this
16 Table.”.

17 (2) LIMITATION OF ACTIONS.—Section 2116(b) (42
18 U.S.C. 300aa-16(b)) is amended by striking “such person
19 may file” and inserting “or to significantly increase the
20 likelihood of obtaining compensation, such person may,
21 notwithstanding section 2111(b)(2), file”.

22 (b) EXTENSION OF TIME FOR DECISION.—Section
23 2112(d)(3)(D) (42 U.S.C. 300aa-12(d)(3)(D)) is amend-
24 ed by striking “540 days” and inserting “30 months (but
25 for not more than 6 months at a time)”.

1 (c) SIMPLIFICATION OF VACCINE INFORMATION MA-
2 TERIALS.—

3 (1) INFORMATION.—Section 2126(b) (42
4 U.S.C. 300aa-26(b)) is amended—

5 (A) by striking “by rule” in the matter
6 preceding paragraph (1);

7 (B) in paragraph (1), by striking “, oppor-
8 tunity for a public hearing, and 90” and insert-
9 ing “and 30”; and

10 (C) in paragraph (2), by striking “, appro-
11 priate health care providers and parent organi-
12 zations”.

13 (2) REQUIREMENTS.—Section 2126(c) (42
14 U.S.C. 300aa-26(c)) is amended—

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

18 (B) by striking out paragraphs (1) through
19 (10) and inserting in lieu thereof the following
20 new paragraphs:

21 “(1) a concise description of the benefits of the
22 vaccine;

23 “(2) a concise description of the risks associ-
24 ated with the vaccine; and

1 ~~“(3) a statement of the availability of the Na-~~
2 ~~tional Vaccine Injury Compensation Program.”.~~

3 ~~(3) OTHER INDIVIDUALS.—Subsections (a) and~~
4 ~~(d) of section 2126 (42 U.S.C. 300aa-26(a) and~~
5 ~~(d)) are amended by inserting “or to any other indi-~~
6 ~~vidual” immediately after “to the legal representa-~~
7 ~~tive of any child” each place that such occurs.~~

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

10 ~~(A) by striking all after “subsection (a),”~~
11 ~~the second place it appears in the first sentence~~
12 ~~and inserting “supplemented with visual presen-~~
13 ~~tations or oral explanations, in appropriate~~
14 ~~cases.”; and~~

15 ~~(B) by striking “or other information” in~~
16 ~~the last sentence.~~

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

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

20 ~~(b) REFERENCES.—Except as otherwise expressly pro-~~
21 ~~vided, whenever in this Act an amendment or repeal is ex-~~
22 ~~pressed in terms of an amendment to, or repeal of, a section~~
23 ~~or other provision, the reference shall be considered to be~~
24 ~~made to a section or other provision of the Public Health~~
25 ~~Service Act (42 U.S.C. 201 et seq.).~~

1 (c) *PURPOSE.*—It is the purpose of this Act to ensure
 2 that children in the United States are appropriately immu-
 3 nized against vaccine preventable infectious diseases at the
 4 earliest appropriate age.

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

6 Title XXI of the Public Health Service Act (42 U.S.C.
 7 300aa–1 et seq.) is amended by adding at the end thereof
 8 the following new subtitle:

9 **“Subtitle 3—Improved Immuniza-**
 10 **tion Delivery and Monitoring**
 11 **Systems**

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

13 **“SEC. 2141. LIST OF PEDIATRIC VACCINES; SCHEDULE FOR**
 14 **ADMINISTRATION.**

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

16 “(1) *IN GENERAL.*—The Secretary shall establish
 17 a list of the vaccines that the Secretary recommends
 18 for administration to all children for the purpose of
 19 immunizing the children, subject to such contra-
 20 indications for particular medical categories of chil-
 21 dren as the Secretary may establish under subsection
 22 (b)(1)(D). The Secretary shall periodically review the
 23 list, and shall revise the list as appropriate.

24 “(2) *RULE OF CONSTRUCTION.*—

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

4 “(B) *The list of vaccines specified in this*
5 *subparagraph is the list of vaccines that, for pur-*
6 *poses of paragraph (1), is established (and peri-*
7 *odically reviewed and as appropriate revised) by*
8 *the Advisory Committee on Immunization Prac-*
9 *tices, an advisory committee established by the*
10 *Secretary, acting through the Director of the*
11 *Centers for Disease Control and Prevention.*

12 “(b) *RECOMMENDED SCHEDULE FOR ADMINISTRA-*
13 *TION.—*

14 “(1) *IN GENERAL.—Subject to paragraph (2), in*
15 *the case of a pediatric vaccine, the Secretary shall es-*
16 *tablish (and periodically review and as appropriate*
17 *revise) a schedule of nonbinding recommendations for*
18 *the following:*

19 “(A) *The number of immunizations with*
20 *the vaccine that children should receive.*

21 “(B) *The ages at which children should re-*
22 *ceive the immunizations.*

23 “(C) *The dose of vaccine that should be ad-*
24 *ministered in the immunizations.*

1 “(D) Any contraindications regarding ad-
2 ministration of the vaccine.

3 “(E) Such other guidelines as the Secretary
4 determines to be appropriate with respect to ad-
5 ministering the vaccine to children.

6 “(2) VARIATIONS IN MEDICAL PRACTICE.—In es-
7 tablishing and revising a schedule under paragraph
8 (1), the Secretary shall ensure that, in the case of the
9 pediatric vaccine involved, the schedule provides for
10 the full range of variations in medical judgment re-
11 garding the administration of the vaccine, subject to
12 remaining within medical norms.

13 “(3) RULE OF CONSTRUCTION.—

14 “(A) The schedule specified in subpara-
15 graph (B) is deemed to be the schedule main-
16 tained under paragraph (1).

17 “(B) The schedule specified in this subpara-
18 graph is the schedule that, for purposes of para-
19 graph (1), is established (and periodically
20 reviewed and as appropriate revised) by the ad-
21 visory committee specified in subsection
22 (a)(2)(B).

23 “(c) GENERALLY APPLICABLE RULES OF CONSTRUC-
24 TION.—This section does not supersede any State law or
25 requirements with respect to receiving immunizations (in-

1 *cluding any such law relating to religious exemptions or*
2 *other exemptions under such State laws).*

3 *“(d) ISSUANCE OF LIST AND SCHEDULES.—Not later*
4 *than 180 days after the date of the enactment of this section,*
5 *the Secretary shall establish the initial list required in sub-*
6 *section (a) and the schedule required in subsection (b).*

7 **“Part B—State Registry System for Immunization**
8 **Information**

9 **“SEC. 2145. PURPOSE.**

10 *“It is the purpose of this part to authorize the Sec-*
11 *retary, in consultation with State public health officials,*
12 *to establish State registry systems to monitor the immuni-*
13 *zation status of all children.*

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

15 *“(a) IN GENERAL.—For the purpose described in sec-*
16 *tion 2145, the Secretary, acting through the Director of the*
17 *Centers for Disease Control and Prevention, shall make an*
18 *allotment each fiscal year for each State in an amount de-*
19 *termined in accordance with section 2151. The Secretary*
20 *shall make a grant to the State of the allotment made for*
21 *the State for the fiscal year if the State submits to the Sec-*
22 *retary an application in accordance with section 2150 on*
23 *behalf of the chief executive officer of such State.*

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

4 “(1) provide accurate and up to date surveil-
5 lance data regarding immunization rates at the State
6 and local levels;

7 “(2) assist in identifying localities with inad-
8 equate immunization rates to target for necessary re-
9 medial assistance;

10 “(3) assist in the effective administration and
11 management of immunization programs at State and
12 local levels by providing data to guide immunization
13 program efforts;

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

18 “(5) facilitate the linkage of vaccine dosage in-
19 formation to adverse events reported to the Centers for
20 Disease Control and Prevention under section 2125(b)
21 and disease outbreak patterns, for the purpose of mon-
22 itoring vaccine safety and effectiveness.

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

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

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

5 “(3) utilizing the data to monitor the extent to
6 which children have received immunizations in ac-
7 cordance with the schedule established under section
8 2141;

9 “(4) notifying parents, as appropriate, if chil-
10 dren have not received immunizations in accordance
11 with such schedule;

12 “(5) coordinating and exchanging information
13 with other State registries to allow the monitoring of
14 the immunization status of children changing State of
15 residence; and

16 “(6) such other activities as the Secretary may
17 authorize with respect to achieving the objectives es-
18 tablished by the Secretary for the year 2000 for the
19 immunization status of children in the United States.

20 “(d) REQUIREMENT REGARDING STATE LAW.—

21 “(1) IN GENERAL.—The Secretary may make a
22 grant under subsection (a) only if the State in-
23 volved—

24 “(A) provides assurances satisfactory to the
25 Secretary that, not later than October 1, 1996,

1 *the State will be operating a registry in accord-*
2 *ance with this part, including having in effect*
3 *such laws and regulations as may be necessary*
4 *to so operate such a registry; and*

5 *“(B) agrees that, prior to such date, the*
6 *State will make such efforts to operate a registry*
7 *in accordance with this part as may be author-*
8 *ized in the law and regulations of the State.*

9 *“(2) RULES OF CONSTRUCTION.—*

10 *“(A) With respect to the agreements made*
11 *by a State under this part, other than para-*
12 *graph (1)(B), the Secretary may require compli-*
13 *ance with the agreements only to the extent con-*
14 *sistent with such paragraph.*

15 *“(B) The provisions of this part do not au-*
16 *thorize the Secretary, as a condition of the re-*
17 *ceipt of a grant under subsection (a) by a State,*
18 *to prohibit the State from providing any parent,*
19 *upon the request of the parent, with an exemp-*
20 *tion from the requirements established by the*
21 *State pursuant to this part for the collection of*
22 *data regarding any child of the parent.*

23 **“SEC. 2147. REGISTRY DATA.**

24 *“(a) IN GENERAL.—For purposes of section*
25 *2146(c)(1), the data described in this section are the data*

1 *described in subsection (b) and the data described in sub-*
2 *section (c).*

3 “(b) *DATA REGARDING BIRTH OF CHILD.*—With re-
4 *spect to the birth of a child, the data described in this sub-*
5 *section is as follows:*

6 “(1) *The name of each child born in the State*
7 *involved after the date of the implementation of the*
8 *registry (in no event shall such date be later than Oc-*
9 *tober 1, 1996).*

10 “(2) *Demographic data on the child.*

11 “(3) *The name of one or both of the parents of*
12 *the child. If the child has been given up for adoption,*
13 *any information regarding the identity of the birth*
14 *parent or parents of the child may not be entered into*
15 *the registry, or if entered, shall be deleted.*

16 “(4) *The address, as of the date of the birth of*
17 *the child, of each parent whose name is received in*
18 *the registry pursuant to paragraph (3).*

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

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

24 “(2) *The date on which the vaccine was adminis-*
25 *tered to the child.*

1 “(3) *The name and business address of the health*
2 *care provider that administered the vaccine.*

3 “(4) *The address of the facility at which the vac-*
4 *cine was administered.*

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

9 “(6) *The type of vaccine.*

10 “(7) *The lot number or other information identi-*
11 *fying the particular manufacturing batch of the vac-*
12 *cine.*

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

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

18 “(10) *The presence of contraindications noted by*
19 *the health care provider with respect to administra-*
20 *tion of the vaccine to the child.*

21 “(11) *Such other data regarding immunizations*
22 *for the child, including identifying data, as the Sec-*
23 *retary, in consultation with State public health offi-*
24 *cial, may require consistent with applicable law (in-*
25 *cluding social security account numbers furnished*

1 *pursuant to section 205(c)(2)(E) of the Social Secu-*
2 *rity Act).*

3 “(d) *LIMITATION.—The Secretary may not establish*
4 *information reporting requirements in addition to those de-*
5 *scribed in subsection (c) if such requirements are unduly*
6 *burdensome.*

7 “(e) *DATE CERTAIN FOR SUBMISSION TO REGISTRY.—*
8 *The Secretary may make a grant under section 2146 only*
9 *if the State involved agrees to ensure that, with respect to*
10 *a child—*

11 “(1) *the data described in subsection (b) are sub-*
12 *mitted to the registry under such section as soon as*
13 *possible but in no event later than 8 weeks after the*
14 *date on which the child is born; and*

15 “(2) *the data described in subsection (c) with re-*
16 *spect to a vaccine are submitted to such registry as*
17 *soon as possible but in no event later than 4 weeks*
18 *after the date on which the vaccine is administered to*
19 *the child.*

20 “(f) *UNIFORMITY IN METHODOLOGIES.—The Secretary*
21 *shall, in consultation with State public health officials, es-*
22 *tablish standards regarding the methodologies used in estab-*
23 *lishing and operating registries under section 2146, and*
24 *may make a grant under such section only if the State*
25 *agrees to comply with the standards. The Secretary shall*

1 *provide maximum flexibility to the States while also retain-*
2 *ing a reasonable degree of uniformity among the States in*
3 *such methodologies for the purpose of ensuring the utility,*
4 *comparability, and exchange of the data maintained in*
5 *such registries.*

6 “(g) *COORDINATION AMONG STATES.*—*The Secretary*
7 *may make a grant under section 2146 to a State only if,*
8 *with respect to the operation of the registry of the State*
9 *under such section, the State agrees to transfer that infor-*
10 *mation contained in the State registry pursuant to section*
11 *2146 to other States upon the request of such States for such*
12 *information.*

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

14 “(a) *ESTABLISHMENT.*—

15 “(1) *IN GENERAL.*—*The Secretary, in consulta-*
16 *tion with the States, shall by regulation establish*
17 *standards providing for maintaining the confidential-*
18 *ity of the identity of individuals with respect to*
19 *whom data are maintained in registries under section*
20 *2146. Such standards shall, with respect to a State,*
21 *provide that the State is to have in effect laws or reg-*
22 *ulations regarding such confidentiality, including ap-*
23 *propriate penalties for violation of the laws. The Sec-*
24 *retary may make a grant under such section only if*

1 *the State involved agrees to comply with the stand-*
2 *ards.*

3 *“(2) USE OF DISCLOSURE.—*

4 *“(A) No personally identifiable information*
5 *relating to a child or to the parent or guardian*
6 *of such child that is collected or maintained by*
7 *the State registry may be used or disclosed by*
8 *any holder of such information except as per-*
9 *mitted for—*

10 *“(i) the monitoring of a child’s immu-*
11 *nization status;*

12 *“(ii) oversight, audit, and evaluation*
13 *of the immunization delivery and registry*
14 *systems;*

15 *“(iii) activities relating to establishing*
16 *and maintaining a safe and effective supply*
17 *of recommended childhood vaccine;*

18 *“(iv) processing of insurance claims for*
19 *payment for vaccine administration (but*
20 *only to the extent necessary for processing*
21 *claims); and*

22 *“(v) administration of the National*
23 *Vaccine Injury Compensation Program*
24 *under subtitle 2.*

1 “(B) Information regarding immunizations
2 provided as described in subparagraph (A)(i)
3 may be used or disclosed only with the written
4 authorization of the individual to whom it refers
5 or to the parent with custody of such individual.

6 “(b) USE OF SOCIAL SECURITY ACCOUNT NUMBERS.—
7 Any usage or disclosure of data in registries under section
8 2146 that consists of social security account numbers and
9 related information which is otherwise permitted under this
10 part may be exercised only to the extent permitted under
11 section 205(c)(2)(E) of the Social Security Act. For pur-
12 poses of the preceding sentence, the term ‘related informa-
13 tion’ has the meaning given such term in clause (iv)(II)
14 of such section.

15 **“SEC. 2149. PROVIDER PARTICIPATION.**

16 “(a) IN GENERAL.—The State shall monitor and en-
17 force compliance by health care providers with the require-
18 ments of sections 2147 and 2148 and section 2155(b) for
19 all doses of pediatric vaccine administered in the State. The
20 State shall establish procedures satisfactory to the Secretary
21 for discontinuing the distribution of federally purchased or
22 State purchased vaccine for any health care provider who
23 fails to comply with the requirements of section 2147 and
24 for reinstating such vaccine supply to such provider upon
25 receiving from such provider—

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

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

7 “(b) *REPORTS TO SECRETARY.*—The Secretary may
8 make a grant under section 2146 only if the State involved
9 agrees to submit to the Secretary such reports as the Sec-
10 retary determines to be appropriate with respect to the ac-
11 tivities of the State under this part.

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

13 “An application by a State for a grant under section
14 2146 is in accordance with this section if the application—

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

17 “(2) contains each agreement required in this
18 part;

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

21 “(4) is in such form, is made in such manner,
22 and contains such agreements, assurances, and infor-
23 mation as the Secretary determines to be necessary to
24 carry out this part.

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

2 *“The Secretary shall determine the amount of the allot-*
3 *ments required in section 2146 for States for a fiscal year*
4 *in accordance with a formula established by the Secretary*
5 *that allots the amounts appropriated under section 2152*
6 *for the fiscal year on the basis of the costs of the States*
7 *in establishing and operating registries under section 2146.*

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

9 *“For the purpose of carrying out this part, other than*
10 *section 2153, there are authorized to be appropriated*
11 *\$152,000,000 for fiscal year 1994, \$125,000,000 for fiscal*
12 *year 1995, and \$35,000,000 for each of the fiscal years 1996*
13 *through 1999.*

14 **“SEC. 2153. NATIONAL IMMUNIZATION SURVEILLANCE PRO-**
15 **GRAM.**

16 *“(a) IN GENERAL.—The Secretary shall establish a na-*
17 *tional immunization surveillance program for the purpose*
18 *of assessing the effects of the programs and activities pro-*
19 *vided for in this subtitle towards appropriately immuniz-*
20 *ing children and facilitating State immunization registries.*
21 *The national immunization surveillance program shall—*

22 *“(1) provide technical assistance to States for the*
23 *development of vaccination registries and monitoring*
24 *systems; and*

25 *“(2) receive aggregate epidemiologic data (that is*
26 *in a format that is not person specific) collected by*

1 *States as provided for in section 2147 at intervals de-*
2 *termined appropriate by the Secretary for the purpose*
3 *of—*

4 *“(A) compiling accurate and up-to-date*
5 *surveillance data regarding immunization rates*
6 *at the State level in order to assess the progress*
7 *made towards achieving nationally established*
8 *immunization goals;*

9 *“(B) assisting in the effective administra-*
10 *tion and management of immunization pro-*
11 *grams at the State level by providing technical*
12 *assistance to guide immunization program ef-*
13 *forts at the request of the State;*

14 *“(C) providing technical assistance to*
15 *States and localities to facilitate monitoring the*
16 *immunization status of children who move across*
17 *geographic boundaries that are covered by dif-*
18 *ferent State or local registries at the request of*
19 *such States or localities; and*

20 *“(D) monitoring the safety and effectiveness*
21 *of vaccines by linking vaccine dosage informa-*
22 *tion with adverse events reporting under section*
23 *2125(b) and disease outbreak patterns.*

24 *“(b) RULE OF CONSTRUCTION.—Nothing in this sub-*
25 *title shall be construed to authorize the release of person*

1 *specific information to the Secretary for the purpose of im-*
2 *munization surveillance.*

3 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—*There are*
4 *authorized to be appropriated such sums as may be nec-*
5 *essary to carry out this section in each of the fiscal years*
6 *1994 through 1999.*

7 **“SEC. 2154. REPORT.**

8 “*Not later than January 1, 1995, and biennially there-*
9 *after, the Secretary shall prepare and submit to the appro-*
10 *priate committees of Congress a report concerning the plan-*
11 *ning, development, operation and effectiveness of the na-*
12 *tional immunization surveillance program and the State*
13 *immunization registries.*

14 **“Part C—Distribution of Vaccines, Public Outreach**
15 **and Education**

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

17 “(a) *IN GENERAL.*—

18 “(1) *HEALTH CARE PROVIDERS.*—*The Secretary*
19 *shall provide for the distribution, without charge, of*
20 *recommended pediatric vaccines (in accordance with*
21 *section 2141) purchased by the Secretary to health*
22 *care providers who serve children and who—*

23 “(A) *are members of a uniformed service, or*
24 *are officers or employees of the United States;*

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

3 “(C) provide services under section 503 of
4 the Indian Health Care Improvement Act or
5 pursuant to a contract under section 102 of the
6 Indian Self Determination Act.

7 “(2) STATES.—The Secretary shall provide for
8 the distribution, without charge, of those rec-
9 ommended pediatric vaccines that are purchased by
10 the Secretary and provided to States for the purposes
11 of immunizing medicaid-eligible children, and addi-
12 tional vaccines that may be purchased by the Sec-
13 retary for children within those States.

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

15 “(1) FREE PROVISION TO CHILDREN.—A health
16 care provider or entity receiving vaccine under this
17 section may use such vaccine only for administration
18 to children and may not impose a charge for such
19 vaccine. A provider or health care entity may impose
20 a fee that reflects actual regional costs as determined
21 by the Secretary for the administration of such vac-
22 cine, except that a provider may not deny a child a
23 vaccination due to the inability of the child’s parent
24 to pay an administration fee.

1 “(2) *REPORTING REQUIREMENTS.*—A health care
2 provider receiving vaccine under this section shall re-
3 port the information required under section 2147 to
4 the applicable State registry operated pursuant to a
5 grant under section 2146 if such State registry exists.
6 The provider shall additionally report to such State
7 registry any occurrence reported to the Secretary pur-
8 suant to section 2125(b). The provider shall also pro-
9 vide regular and periodic estimates to the State of the
10 provider’s future dosage needs for recommended child-
11 hood vaccines distributed under this section. All re-
12 ports shall be made with such frequency and in such
13 detail as the Secretary, in consultation with State
14 public health officials, may prescribe.

15 **“SEC. 2156. IMPROVED IMMUNIZATION DELIVERY, OUT-**
16 **REACH AND EDUCATION.**

17 “(a) *FEDERAL EFFORTS.*—The Secretary, acting
18 through the Centers for Disease Control and Prevention and
19 in conjunction with State health officials and other appro-
20 priate public and private organizations, shall conduct the
21 following activities to improve Federal, State and local vac-
22 cine delivery systems and immunization outreach and edu-
23 cation efforts:

24 “(1) *NATIONAL PUBLIC AWARENESS CAMPAIGN.*—

1 “(A) *IN GENERAL.*—*The Secretary, in con-*
2 *junction with State health officials and other ap-*
3 *propriate public and private organizations, shall*
4 *develop and implement a National Immuniza-*
5 *tion Public Awareness Campaign to assist fami-*
6 *lies (through bilingual means if necessary) of*
7 *children under the age of 2 years, and expectant*
8 *parents, in obtaining knowledge concerning the*
9 *importance of having their children immunized*
10 *and in identifying the vaccines, schedules for im-*
11 *munization, and vaccine provider locations, ap-*
12 *propriate with respect to their children.*

13 “(B) *IMPLEMENTATION.*—*In implementing*
14 *the Campaign under subparagraph (A), the Sec-*
15 *retary shall ensure that—*

16 “(i) *new and innovative methods are*
17 *developed and utilized to publicly advertise*
18 *the need to have children immunized in a*
19 *timely manner;*

20 “(ii) *print, radio and television media*
21 *are utilized to convey immunization infor-*
22 *mation to the public; and*

23 “(iii) *with respect to immunization in-*
24 *formation, efforts are made to target preg-*

1 *nant women and the parents of children*
2 *under the age of 2.*

3 *“(2) INTERAGENCY COMMITTEE ON IMMUNIZA-*
4 *TION.—The Secretary, in conjunction with the Sec-*
5 *retary of Agriculture, the Secretary of Housing and*
6 *Urban Development, and the Secretary of Education,*
7 *shall carry out activities through the Interagency*
8 *Committee on Immunization to incorporate immuni-*
9 *zation status assessments and referral services as an*
10 *integral part of the process by which individuals*
11 *apply for assistance under—*

12 *“(A) the food stamp program under the*
13 *Food Stamp Act of 1977;*

14 *“(B) section 17 of the Child Nutrition Act*
15 *of 1966;*

16 *“(C) the Head Start Act;*

17 *“(D) part A of title IV of the Social Secu-*
18 *rity Act;*

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

20 *“(F) any of the housing assistance laws of*
21 *the United States; and*

22 *“(G) other programs determined appro-*
23 *priate by any of the Secretaries described in this*
24 *paragraph.*

1 “(3) *EXPANDED OPPORTUNITY FOR NATIONAL*
2 *SERVICE.—The Secretary, in conjunction with the*
3 *Commission on National and Community Service*
4 *and other independent agencies, is encouraged to de-*
5 *velop opportunities for participants in national and*
6 *community service programs to contribute to local*
7 *initiatives for the improvement of immunization serv-*
8 *ices, including public outreach and education efforts.*

9 “(b) *GRANTS TO STATES.—*

10 “(1) *IN GENERAL.—*

11 “(A) *The Secretary may award grants to*
12 *States to enable such State to develop, revise and*
13 *implement immunization improvement plans as*
14 *described in paragraph (2).*

15 “(B) *To be eligible to receive a grant under*
16 *subparagraph (A), a State shall prepare and*
17 *submit to the Secretary an application at such*
18 *time, in such manner, and containing such in-*
19 *formation as the Secretary may require.*

20 “(2) *DESIGN.—A State immunization improve-*
21 *ment plan shall be designed to improve immunization*
22 *delivery, outreach, education and coordination within*
23 *the State. Such plan shall provide for the creation*
24 *of—*

1 “(A) a vaccine provider education cam-
2 paign and the distribution of any other mate-
3 rials determined to be appropriate by State
4 health officials—

5 “(i) to enable such providers to make
6 the best use of vaccination opportunities;
7 and

8 “(ii) to educate such providers concern-
9 ing their obligation to report immunization
10 information with respect to their patients to
11 State registries;

12 “(B) expanded capacity for the delivery of
13 immunizations through—

14 “(i) increasing the number or type of
15 facilities through which vaccines may be
16 made available and the capacity of such fa-
17 cilities to immunize more children;

18 “(ii) developing alternative methods of
19 delivering vaccines, such as mobile health
20 clinics;

21 “(iii) increasing the number of hours
22 during which vaccines are made available
23 by providers within the State; or

24 “(iv) coordinating with federally quali-
25 fied health centers to reach and immunize

1 *underserved children through education,*
2 *outreach, tracking, and the provision of*
3 *services;*

4 *except that, the Secretary may waive any spe-*
5 *cific requirement of this subparagraph if the Sec-*
6 *retary determines that State immunization de-*
7 *livery efforts are sufficient without the imposi-*
8 *tion of such requirement;*

9 *“(C) population-based assessment criteria*
10 *through which the State is able to assess the ef-*
11 *fectiveness of immunization activities in the*
12 *State, which may be fulfilled through the imple-*
13 *mentation of a State immunization registry*
14 *under section 2146;*

15 *“(D) a public awareness campaign, in con-*
16 *junction with the National Campaign established*
17 *under subsection (a)(1), to provide parents with*
18 *information about the importance of immuniza-*
19 *tion, the types and schedules for the administra-*
20 *tion of vaccines, and the locations of vaccines*
21 *providers;*

22 *“(E) coordinated community outreach ac-*
23 *tivities among public or private health pro-*
24 *grams, including local health departments and*
25 *health centers, and other public or private enti-*

1 *ties, to encourage and facilitate the ability of*
2 *parents to obtain immunization services for their*
3 *children; and*

4 *“(F) other activities that are not inconsis-*
5 *tent with the purposes of this subtitle, subject to*
6 *the approval of the Secretary.*

7 *“(3) IMMUNIZATION IMPROVEMENT PLAN AP-*
8 *PROVAL.—*

9 *“(A) GOALS.—As part of the immunization*
10 *improvement plan of a State, the State shall es-*
11 *tablish immunization rate goals for children re-*
12 *siding within the State.*

13 *“(B) APPROVAL.—The immunization im-*
14 *provement plan developed by a State under this*
15 *subsection shall be submitted to the Secretary for*
16 *approval prior to the distribution of grant funds*
17 *to the States under this subsection. The Secretary*
18 *shall periodically review the progress that the*
19 *State has made under such plan in achieving the*
20 *goals established under subparagraph (A).*

21 *“(C) DISTRIBUTION OF GRANTS.—In*
22 *awarding grants under this section, the Sec-*
23 *retary shall ensure that grant awards will be eq-*
24 *uitably distributed between rural and urban*
25 *areas. In determining such distribution, the Sec-*

1 *efficiency, and effectiveness of procedures established to de-*
2 *liver vaccine to health care providers.*

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

4 *“The Secretary shall authorize a report to be prepared*
5 *by the National Academy of Sciences concerning the role*
6 *of the National Vaccine Program established under this title*
7 *in achieving progress towards the nationally established im-*
8 *munization goals for the year 2000, and recommendations*
9 *with respect to the changes in such Program that would*
10 *facilitate greater progress towards achieving such goals.*

11 ***“SEC. 2163. DEFINITIONS.***

12 *“For purposes of this subtitle—*

13 *“(1) HEALTH CARE PROVIDER.—The term*
14 *‘health care provider’, with respect to the administra-*
15 *tion of vaccines to children, means an entity that is*
16 *licensed or otherwise authorized for such administra-*
17 *tion under the law of the State in which the entity*
18 *administers the vaccine, subject to section 333(e).*

19 *“(2) HEALTH CENTER.—The term ‘health center’*
20 *means—*

21 *“(A) a federally qualified health center, as*
22 *defined in section 1905(l)(2) of the Social Secu-*
23 *rity Act; or*

24 *“(B) a public or nonprofit private entity*
25 *receiving Federal funds under—*

1 “(i) section 329, 330 or 340;

2 “(ii) section 340A (relating to grants
3 for health services for residents of public
4 housing); or

5 “(iii) section 501(a)(2) of the Social
6 Security Act (relating to special projects of
7 regional and national significance).

8 “(3) IMMUNIZATION.—The term ‘immunization’
9 means an immunization against a vaccine-prevent-
10 able disease.

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

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

16 “(6) STATE.—The term ‘State’ means the 50
17 States, the District of Columbia, the Commonwealth
18 of Puerto Rico, Guam, American Samoa, the U.S.
19 Virgin Islands, the Republic of the Marshall Islands,
20 Micronesia, the Northern Mariana Islands, and
21 Palau.”.

22 **SEC. 3. NATIONAL VACCINE INJURY COMPENSATION PRO-**
23 **GRAM AMENDMENTS.**

24 (a) AMENDMENT OF VACCINE INJURY TABLE.—

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

4 “(f) *ADDITION OF VACCINES TO TABLE.*—

5 “(1) *IN GENERAL.*—The Vaccine Injury table
6 contained in subsection (a) shall also include any rec-
7 ommended childhood vaccine included in the list pro-
8 mulgated by the Secretary under section 2141.

9 “(2) *REVIEW OF INFORMATION AND REVISION.*—
10 Not later than 2 years after the addition of a new
11 vaccine to the table contained in subsection (a), and
12 on a regular basis thereafter, the Secretary shall re-
13 view information obtained under sections 2125 and
14 part B of subtitle 3, and based on such review (and
15 other relevant information) shall, as appropriate, de-
16 velop with respect to such new vaccine—

17 “(A) revisions with respect to illnesses, dis-
18 abilities, injuries or conditions covered by such
19 table;

20 “(B) appropriate specifications of the time
21 period for the first symptom or manifestation of
22 onset or of significant aggravation of such ill-
23 nesses, disabilities, injuries or condition after
24 vaccine administration, for purposes of receiving
25 compensation under the Program; and

1 “(C) recommendations as to the amount of
2 tax that should be imposed under section 4131 of
3 the Internal Revenue Code of 1986 for each dose
4 of vaccine.

5 “(3) LIMITATION.—The Secretary may modify
6 the table contained in subsection (a) pursuant to
7 paragraphs (1) and (2) only in accordance with sub-
8 section (c).

9 “(4) REVISION.—For purposes of section
10 2116(b), the addition of vaccine to the table contained
11 in subsection (a) by operation of this subsection shall
12 constitute a revision of the table.”.

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

16 “(4) The special master may award reasonable
17 attorneys’ fees whether or not an election has been
18 made under section 2121(a) to file a civil action con-
19 cerning such petition.”.

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

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

1 (A) *IN GENERAL.*—Section 2115(e) (42
2 U.S.C. 300aa–15(e)) (as amended by paragraph
3 (3)) is further amended by adding at the end
4 thereof the following new paragraph:

5 “(5) *With respect to a petitioners’ application*
6 *for attorneys’ fees and costs—*

7 “(A) *if the respondent enters no objection to*
8 *such application within 21 days of the date on*
9 *which the application was filed (unless such time*
10 *period is extended by the special master with the*
11 *consent of the petitioner) the special master shall*
12 *enter a decision on such application within 30*
13 *days of such filing;*

14 “(B) *if the respondent files an objection to*
15 *such application and the special master does not*
16 *enter a decision with respect to the application*
17 *within 60 days after the date on which the objec-*
18 *tion is filed, the special master involved shall,*
19 *upon the written request of the petitioner, enter*
20 *a decision within 15 days after the filing of such*
21 *request; and*

22 “(C) *if the respondent files an objection to*
23 *such application and the petitioner moves to re-*
24 *duce costs and fees as provided for in the objec-*
25 *tion, the special master shall enter a decision*

1 *within 5 days after the receipt of the petitioner's*
2 *motion.*

3 *The chief special master, upon the request of a special*
4 *master, may waive the time limitations applicable to*
5 *the special master under this paragraph if the special*
6 *master demonstrates that complicating factors exist*
7 *with respect to the issues involved to which the time*
8 *limitation applies.”.*

9 (B) *APPLICATION.*—*The amendment made*
10 *by subparagraph (A) shall apply to all petition-*
11 *ers' applications for attorneys' fees and costs*
12 *filed under section 2115(e) of the Public Health*
13 *Service Act which are pending on the date of en-*
14 *actment of this Act.*

15 (5) *AUTHORIZATION OF APPROPRIATIONS.*—*Sec-*
16 *tion 2115(j) (42 U.S.C. 300aa-15(j)) is amended by*
17 *striking “\$80,000,000 for each succeeding fiscal year”*
18 *and inserting in lieu thereof “\$110,000,000 for each*
19 *succeeding fiscal year”.*

20 (6) *LIMITATION OF ACTIONS.*—*Section 2116(b)*
21 *(42 U.S.C. 300aa-16(b)) is amended by striking*
22 *“such person may file” and inserting “or to signifi-*
23 *cantly increase the likelihood of obtaining compensa-*
24 *tion, such person may, notwithstanding section*
25 *2111(b)(2), file”.*

1 (b) *EXTENSION OF TIME FOR DECISION.*—

2 (1) *JURISDICTION.*—Section 2112(d)(3)(D) (42
3 U.S.C. 300aa-12(d)(3)(D)) is amended by striking
4 “540 days” and inserting “30 months (but for not
5 more than 6 months at a time)”.

6 (2) *REPORT ON COLLECTIONS.*—Section 2117
7 (42 U.S.C. 300aa-17) is amended by adding at the
8 end thereof the following new subsection:

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

13 (3) *INCREASED RESPONSIBILITIES OF COMMIS-*
14 *SION.*—Section 2119(f) (42 U.S.C. 300aa-19(f)) is
15 amended—

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

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

20 (C) by adding at the end thereof the follow-
21 ing new paragraph:

22 “(6) monitor the balance of the Vaccine Injury
23 Trust Fund established by section 9510 of the Inter-
24 nal Revenue Code and, as appropriate, recommend

1 *changes in the tax per dose of vaccine imposed under*
2 *section 4131 of such Code.”.*

3 *(c) SIMPLIFICATION OF VACCINE INFORMATION MATE-*
4 *RIALS.—*

5 *(1) INFORMATION.—Section 2126(b) (42 U.S.C.*
6 *300aa–26(b)) is amended—*

7 *(A) by striking “by rule” in the matter pre-*
8 *ceding paragraph (1);*

9 *(B) in paragraph (1), by striking “90” and*
10 *inserting “30”; and*

11 *(C) in paragraph (2), by striking “, appro-*
12 *priate health care providers and parent organi-*
13 *zations”.*

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

16 *(A) in the matter preceding paragraph (1),*
17 *by inserting “shall be based on available data*
18 *and information,” after “such materials”; and*

19 *(B) by striking out paragraphs (1) through*
20 *(10) and inserting in lieu thereof the following*
21 *new paragraphs:*

22 *“(1) a concise description of the benefits of the*
23 *vaccine;*

24 *“(2) a concise description of the risks associated*
25 *with the vaccine;*

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

3 “(4) a statement of the availability from the Sec-
4 retary of more detailed written information concern-
5 ing the information required under paragraphs (1),
6 (2), and (3), that shall be made available to the par-
7 ent, legal guardian, or other responsible person upon
8 request; and

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

11 (3) *OTHER INDIVIDUALS.*—Subsections (a) and
12 (d) of section 2126 (42 U.S.C. 300aa-26 (a) and (d))
13 are amended by inserting “or to any other individ-
14 ual” immediately after “to the legal representative of
15 any child” each place that such occurs.

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

18 (A) by striking all after “subsection (a),”
19 the second place it appears in the first sentence
20 and inserting “supplemented with visual presen-
21 tations or oral explanations, in appropriate
22 cases.”; and

23 (B) by striking “or other information” in
24 the last sentence.

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

5 “*AUTHORIZATION OF APPROPRIATIONS*

6 “*SEC. 2120. (a) SECRETARY.—For purposes of admin-*
7 *istering this part, there are authorized to be appropriated*
8 *from the Vaccine Injury Compensation Trust Fund estab-*
9 *lished under section 9510(c) of the Internal Revenue Code*
10 *of 1986, to the Secretary, \$3,000,000 for each of the fiscal*
11 *years 1994, 1995, and 1996.*

12 “*(b) ATTORNEY GENERAL.—For purposes of admin-*
13 *istering this part, there are authorized to be appropriated*
14 *from the Vaccine Injury Compensation Trust Fund de-*
15 *scribed in subsection (a), to the Attorney General,*
16 *\$3,000,000 for each of the fiscal years 1994, 1995, and 1996.*

17 “*(c) COURT OF FEDERAL CLAIMS.—For purposes of*
18 *administering this part, there are authorized to be appro-*
19 *priated from the Vaccine Injury Compensation Trust Fund*
20 *described in subsection (a), to the Court of Federal Claims,*
21 *\$3,000,000 for each of the fiscal years 1994, 1995, and*
22 *1996.”.*

23 **SEC. 4. MISCELLANEOUS PROVISIONS.**

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

25 *(1) by striking out paragraph (1); and*

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

3 **SEC. 5. FEDERAL TORT CLAIMS AMENDMENTS.**

4 (a) *CLARIFICATION OF COVERAGE OF OFFICERS AND*
5 *EMPLOYEES OF CLINICS.*—The first sentence of section
6 224(g)(1) of the Public Health Service Act (42 U.S.C.
7 233(g)(1)) is amended by striking “officer, employee, or
8 contractor” and inserting the following: “officer or employee
9 of such an entity, and any contractor”.

10 (b) *COVERAGE FOR SERVICES FURNISHED TO INDIVID-*
11 *UALS OTHER THAN PATIENTS OF CLINIC.*—Section 224(g)
12 of such Act (42 U.S.C. 233(g)(1)), as amended by para-
13 graph (1), is further amended—

14 (1) in the first sentence of paragraph (1), by in-
15 serting after “Service” the following: “with respect to
16 services provided to patients of the entity and (subject
17 to paragraph (7)) to certain other individuals”; and

18 (2) by adding at the end the following new para-
19 graph:

20 “(7) For purposes of paragraph (1), an officer, em-
21 ployee, or contractor described in such paragraph may be
22 deemed to be an employee of the Public Health Service with
23 respect to services provided to individuals who are not pa-
24 tients of an entity described in paragraph (4) only if the
25 Secretary determines—

1 “(A) that the provision of the services to such in-
2 dividuals benefits health center patients and general
3 populations that could be served by the health center
4 through community-wide intervention efforts within
5 the communities served by such health center, and fa-
6 cilitates the provision of services to health center pa-
7 tients; or

8 “(B) that such services are otherwise required to
9 be provided to such individuals under an employment
10 contract (or other similar arrangement) between the
11 individual and the entity.”.

12 (c) DETERMINING COMPLIANCE OF ENTITY WITH RE-
13 QUIREMENTS FOR COVERAGE.—

14 (1) IN GENERAL.—Section 224(h) of such Act (42
15 U.S.C. 233(h)), as added by section 2(b) of the Feder-
16 ally Supported Health Centers Assistance Act of 1992,
17 is amended by striking “the entity—” and inserting
18 the following: “the Secretary, after receiving such as-
19 surances and conducting such investigation as the
20 Secretary considers necessary, finds that the en-
21 tity—”.

22 (2) FINDING.—Section 224 of such Act (42
23 U.S.C. 233) is amended by adding at the end thereof
24 the following new subsection:

1 “(l) With respect to subsection (h), the finding of the
2 Secretary that an entity meets all of the requirements under
3 such subsection shall apply for the period specified by the
4 Secretary, and shall be binding for all parties unless the
5 Secretary reverses such finding for good cause shown at a
6 later date.”.

7 (d) *EFFECTIVE DATE.*—The amendments made by this
8 section shall take effect as if included in the enactment of
9 the Federally Supported Health Centers Assistance Act of
10 1992.

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