

103D CONGRESS
1ST SESSION

S. 732

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, and Ms. MIKULSKI) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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”.

6 (b) REFERENCES.—Except as otherwise expressly
7 provided, whenever in this Act an amendment or repeal
8 is expressed in terms of an amendment to, or repeal of,
9 a section or other provision, the reference shall be consid-

1 ered to be made to a section or other provision of the Pub-
2 lic Health Service Act (42 U.S.C. 201 et seq.).

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

4 (a) FINDINGS.—

5 (1) CURRENT CIRCUMSTANCES.—Congress
6 finds the following:

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

9 (B) Although Federal support for child-
10 hood immunizations has been in existence since
11 1962, the full potential of immunizations re-
12 mains to be achieved. Enactment and enforce-
13 ment of school immunization requirements have
14 resulted in excellent immunization levels (96
15 percent or greater) in school children. However,
16 approximately 80 percent of vaccine doses
17 should be received before the second birthday in
18 order to protect children during their most vul-
19 nerable periods. Many children do not receive
20 their basic immunizations by that time, and in
21 some inner cities as few as 10 percent of 2-
22 year-olds have received a complete series. This
23 low level of immunizations has been reflected in
24 recent years by outbreaks of measles among in-
25 adequately immunized preschool children.

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

8 (D) Prices for privately purchased vaccines
9 exceed the prices paid for like vaccines in some
10 other industrialized nations by over 2500 per-
11 cent.

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

17 (F) Eleven States now have programs that
18 provide vaccines without charge to both public
19 and private health care providers. Other States
20 that have sought to establish such programs
21 have been denied additional discounted vaccines
22 by manufacturers.

23 (G) There is no evidence to suggest that a
24 negotiated price that takes into account the rea-
25 sonable cost of production, marketing, research

1 and development, and distribution will not fairly
2 compensate vaccine manufacturers. Indeed, a
3 recent report by the Congressional Office of
4 Technology Assessment supports the propo-
5 sition that negotiated rates can assure fair com-
6 pensation while holding down costs.

7 (H) The Secretary of Health and Human
8 Services has experience negotiating vaccine pur-
9 chase through the Federal contract system.

10 (I) The National Vaccine Injury Com-
11 pensation Program is an essential element in a
12 comprehensive immunization program and
13 should be strengthened and applied to addi-
14 tional vaccines recommended for universal use
15 in children.

16 (2) NEEDED ACTIONS.—With respect to actions
17 necessary to ensure the full immunization of children
18 at the earliest possible age, Congress finds the fol-
19 lowing:

20 (A) The Federal Government should pur-
21 chase and provide free of charge to health care
22 providers vaccines recommended for universal
23 use in children. This action will not only remove
24 financial barriers to immunization that impede
25 children from being vaccinated at the appro-

1 appropriate time, but will also facilitate the develop-
2 ment of an immunization tracking system.

3 (B) The Federal Government and the
4 States should develop linked registries to track
5 the immunization status of the Nation's chil-
6 dren. The registry system should have the capa-
7 bility to notify parents of inadequately immu-
8 nized children of the need to protect their chil-
9 dren with specific vaccines.

10 (C) The coordinated national information
11 and education outreach initiative operated
12 through the Department of Health and Human
13 Services should be sustained to bring needed in-
14 formation to parents and health care providers
15 and focus their attention on the importance of
16 achieving the full and timely immunization of
17 children at the earliest appropriate age.

18 (D) Private and public health insurers
19 should be encouraged to provide adequate reim-
20 bursement for the administration of childhood
21 vaccines.

22 (E) Volunteer community activities to pro-
23 mote the full immunization of children at the
24 earliest appropriate age should be encouraged.

1 (F) The National Vaccine Injury Com-
2 pensation Program should be extended and im-
3 proved. Vaccine information materials should be
4 simplified to ensure that parents can under-
5 stand the benefits and risks of vaccines.

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

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

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

14 **“Subtitle 3—Improved Immuniza-**
15 **tion and National Tracking Sys-**
16 **tem**

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

18 “Not later than October 1, 1994, (and periodically
19 thereafter as the Secretary determines appropriate in view
20 of advances in scientific understanding in the areas of im-
21 munization and disease control) the Secretary shall pro-
22 mulgate a list of vaccines that provide immunization
23 against naturally occurring infectious diseases and are
24 recommended for universal use in children. The Secretary
25 shall concurrently promulgate recommendations regarding

1 the appropriate dosage for each such vaccine, and the age
2 or ages of children at which each vaccine should be admin-
3 istered.

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

5 “(a) NATIONAL TRACKING SYSTEM.—

6 “(1) ESTABLISHMENT.—The Secretary shall es-
7 tablish a national system to track the immunization
8 status of children.

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

11 “(A) provide accurate and up to date sur-
12 veillance data regarding immunization rates at
13 the local and State levels;

14 “(B) assist in identifying localities with in-
15 adequate immunization rates to target for nec-
16 essary remedial actions;

17 “(C) be used to identify unvaccinated chil-
18 dren and trigger a notification system for the
19 parents or legal guardians and health care pro-
20 viders of such children;

21 “(D) be used to assist in the effective ad-
22 ministration and management of immunization
23 programs at State and local levels by providing
24 data to guide immunization program efforts;

1 “(E) assist States and localities in tracking
2 the immunization status of children who move
3 across geographic boundaries that are covered
4 by different State or local registries; and

5 “(F) monitor the safety and effectiveness
6 of vaccines by linking vaccine dosage informa-
7 tion with adverse events reporting under section
8 2125(b) and disease outbreak patterns.

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

16 “(b) STATE REGISTRY GRANTS.—

17 “(1) IN GENERAL.—The Secretary may award
18 grants to States to enable such States to establish
19 and operate State immunization tracking registries.
20 A State receiving a grant under this section shall
21 maintain a registry that includes the following infor-
22 mation for each child living within the State:

23 “(A) The type and lot number of each rec-
24 ommended childhood vaccine administered after
25 September 30, 1996.

1 “(B) An identification of the health care
2 provider administering such vaccine.

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

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

7 “(E) Special religious considerations or
8 medical conditions that are contraindications
9 for immunizations.

10 “(F) Such other information as the Sec-
11 retary may prescribe.

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

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

21 “(B) Subject to subsection (c), the State
22 shall provide for the sharing of appropriate in-
23 formation from the State’s registry, including
24 immunization status and reports of adverse re-
25 actions, with health care providers who offer

1 immunizations for the purpose of achieving the
2 full immunization of all children in accordance
3 with the recommendations of the Secretary
4 under section 2141.

5 “(C) The State shall provide for notifica-
6 tion to the parents or guardian of an inad-
7 equately immunized child of the need to protect
8 the child with specific vaccine, except as pro-
9 vided in paragraph (1)(E).

10 “(D) Subject to subsection (c), the State
11 shall provide for the coordination and exchange
12 of information with other State registries to
13 allow the tracking of the immunization status
14 of children changing State of residence.

15 “(E) The State shall periodically furnish to
16 the Secretary, at such times and in such form
17 as the Secretary may prescribe, information
18 contained in the State registry.

19 “(F) In designing its registry, the State
20 shall adhere to tracking models and systems
21 specifications prescribed by the Secretary for
22 the purpose of ensuring the mutual compatibil-
23 ity of the data systems and electronic informa-
24 tion technology utilized by the Secretary and

1 the various States in carrying out activities
2 under this subtitle.

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

14 “(i) the reports necessary to make
15 current and complete the information that
16 would have been furnished to the State
17 registry between the dates of the provider’s
18 termination and reinstatement; and

19 “(ii) satisfactory assurances regarding
20 the provider’s future compliance.

21 “(H) If a State distributes recommended
22 childhood vaccines within the State on behalf of
23 the Secretary pursuant to section 2143(a), the
24 State shall compile data, including lot numbers,
25 on the vaccines distributed to each health care

1 provider and shall furnish such data to the Sec-
2 retary in such form and at such intervals as the
3 Secretary may prescribe.

4 “(3) APPLICATIONS.—A State shall prepare
5 and submit to the Secretary an application for a
6 grant under subsection (b) in such form and con-
7 taining such information as the Secretary may pre-
8 scribe. The application shall include—

9 “(A) a description of the methods by which
10 the State will comply with the requirements of
11 paragraph (2);

12 “(B) the assurances required by paragraph
13 (4); and

14 “(C) a description of the expenses that the
15 State will incur in connection with its respon-
16 sibilities under the grant.

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

20 “(A) the State’s tracking registry will be
21 fully operational not later than October 1,
22 1996;

23 “(B) the State’s tracking registry will ad-
24 here to any tracking models and systems speci-

1 fications prescribed by the Secretary pursuant
2 to paragraph (2)(F); and

3 “(C) as appropriate, the State is making
4 satisfactory and timely progress toward achiev-
5 ing the conditions described in subparagraphs
6 (A) and (B).

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

15 “(6) STATE REPORTS TO THE SECRETARY.—A
16 State shall prepare and submit annual reports to the
17 Secretary concerning the operation of the State’s
18 registry and other activities under this subtitle. Such
19 reports shall be in such form, contain such informa-
20 tion, and be submitted at such intervals as the Sec-
21 retary may prescribe.

22 “(c) USE AND DISCLOSURE OF PERSONAL INFORMA-
23 TION.—

24 “(1) GENERAL RULE.—No personally-identifi-
25 able information relating to a child who receives rec-

1 recommended childhood vaccine under this subtitle or
2 to the parent or guardian of such a child that is col-
3 lected or maintained by the National Tracking Sys-
4 tem established under subsection (a), or a State im-
5 munization tracking registry established under sub-
6 section (b), may be used or disclosed by any holder
7 of such information except as permitted by this sub-
8 section.

9 “(2) GENERAL PERMISSIBLE USES.—Informa-
10 tion described in paragraph (1) may be used or dis-
11 closed, without the consent of the individual to
12 whom it refers, or of the parent or guardian of such
13 individual, for—

14 “(A) the tracking of children’s immuniza-
15 tion status, and other purposes directly related
16 to the health of the children being tracked and
17 of their families;

18 “(B) oversight, audit, and evaluation of
19 the immunization delivery and tracking activi-
20 ties, and the enforcement of the provisions of
21 this title;

22 “(C) activities relating to establishing and
23 maintaining a safe and effective supply of rec-
24 ommended childhood vaccine (including activi-
25 ties to carry out part C of subtitle 2);

1 “(D) processing of insurance claims for
2 payment for vaccine administration (but only to
3 the extent necessary to process a claim); or

4 “(E) administration of the National Vac-
5 cine Injury Compensation Program under sub-
6 title 2.

7 “(3) PERMISSIBLE USE WITH WRITTEN AU-
8 THORIZATION.—Information described in paragraph
9 (1) may be used or disclosed with the written au-
10 thorization of the individual to whom it refers, or
11 the parent or guardian of such individual, and must,
12 upon the request of such individual, or parent or
13 guardian, be provided in writing to the individual.

14 “(4) REGULATIONS.—The Secretary is author-
15 ized to issue regulations—

16 “(A) governing the use, maintenance, and
17 disclosure, by any holder of information de-
18 scribed in paragraph (1), including appropriate
19 administrative, technical and physical safe-
20 guards to ensure that only authorized persons
21 have access to the information; and

22 “(B) establishing conditions for access by
23 individuals, and their parents or guardians, to
24 such information about themselves.

1 “(5) VIOLATIONS.—Any person who know-
2 ingly—

3 “(A) uses or discloses information in viola-
4 tion of this subsection; or

5 “(B) requests or obtains any information
6 in violation of this subsection, and offers or
7 provides anything of value in exchange for the
8 provision of the information;

9 shall be fined as prescribed by title 18, United
10 States Code, or imprisoned not more than 3 years,
11 or both.

12 “(d) AUTHORITY TO USE SOCIAL SECURITY NUM-
13 BERS.—

14 “(1) IN GENERAL.—Notwithstanding section
15 205 of the Social Security Act or any other provision
16 of law, the Secretary and States receiving grants
17 under subsection (b) may utilize the social security
18 number, or other means of identification, of a child
19 or of a parent or guardian of the child for purposes
20 of identification of a child in any registry established
21 under this section, and may require a child’s parent
22 or guardian to furnish such number (in any case
23 where such a number has been assigned by the So-
24 cial Security Administration) as a condition of the

1 child receiving recommended childhood vaccine under
2 this subtitle.

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

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

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

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

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

23 “(2) are health centers (as defined in section
24 2144(2));

1 “(3) provide services under section 503 of the
2 Indian Health Care Improvement Act or pursuant to
3 a contract under section 102 of the Indian Self De-
4 termination Act; or

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

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

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

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

19 “(2) REPORTING REQUIREMENTS.—A health
20 care provider receiving vaccine under this section
21 shall report to the applicable State registry operated
22 pursuant to a grant under section 2142(b) (or to the
23 Secretary if there is no such State registry) the data
24 described in section 2142(b)(1) for each dose of vac-
25 cine administered to a child. The provider shall addi-

1 tionally report to such State registry any occurrence
2 reported to the Secretary pursuant to section
3 2125(b). The provider shall also provide regular and
4 periodic estimates to the State of the provider's fu-
5 ture dosage needs for recommended childhood vac-
6 cine distributed under this section. All reports shall
7 be made with such frequency and in such detail as
8 the Secretary may prescribe.

9 **“SEC. 2144. DEFINITIONS.**

10 “For purposes of this subtitle—

11 “(1) HEALTH CENTER.—The term ‘health cen-
12 ter’ means—

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

16 “(B) a public or nonprofit private entity
17 receiving Federal funds under—

18 “(i) section 340A (relating to grants
19 for health services for residents of public
20 housing); or

21 “(ii) section 501(a)(2) of the Social
22 Security Act (relating to special projects of
23 regional and national significance).

24 “(2) RECOMMENDED CHILDHOOD VACCINE.—
25 The term ‘recommended childhood vaccine’ is a vac-

1 cine on the list promulgated by the Secretary pursu-
2 ant to section 2141.

3 **“SEC. 2145. AUTHORIZATION OF APPROPRIATIONS.**

4 “For the purpose of awarding grants under section
5 2142 and for the operation of the tracking system author-
6 ized by such section, there are authorized to be appro-
7 priated \$152,000,000 for fiscal year 1995, \$125,000,000
8 for fiscal year 1996, and \$35,000,000 for each of fiscal
9 years 1997 through 1999.”.

10 **SEC. 4. GRANTS FOR IMMUNIZATION.**

11 Section 317(j)(1) (42 U.S.C. 247b(j)(1)) is amended
12 by adding at the end thereof the following new subpara-
13 graph:

14 “(C)(i) Funds that are made available for the pur-
15 pose of strengthening the public health infrastructure and
16 used in the delivery of childhood immunization services
17 shall be used for activities that are consistent with a stra-
18 tegic plan that meets nationally established immunization
19 goals and that was developed by the State in consultation
20 with representatives of health care providers, health cen-
21 ters (as defined in clause (iii)), State agencies serving
22 young children, and other entities involved in the preven-
23 tion and control of vaccine-preventable illnesses.

24 “(ii) For purposes of clause (i), activities designed to
25 strengthen the public health infrastructure and used in the

1 delivery of childhood immunization services shall include
 2 public and provider education, community outreach initia-
 3 tives, improvements in the capacity of health centers and
 4 local health departments to provide immunization services
 5 (including expansion of the number of hours in which such
 6 services are provided), and activities to facilitate the devel-
 7 opment and operation of State immunization tracking reg-
 8 istries.

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

12 “(I) section 329 (relating to grants for migrant
 13 health centers);

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

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

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

20 **SEC. 5. NATIONAL VACCINE INJURY COMPENSATION PRO-**
 21 **GRAM AMENDMENTS.**

22 (a) AMENDMENT OF VACCINE INJURY TABLE.—

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

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

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

16 (b) EXTENSION OF TIME FOR DECISION.—Section
17 2112(d)(3)(D) (42 U.S.C. 300aa-12(d)(3)(D)) is amend-
18 ed by striking “540 days” and inserting “30 months (but
19 for not more than 6 months at a time)”.

20 (c) SIMPLIFICATION OF VACCINE INFORMATION MA-
21 TERIALS.—

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

24 (A) by striking “by rule” in the matter
25 preceding paragraph (1);

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

4 (C) in paragraph (2), by striking “, appro-
5 priate health care providers and parent organi-
6 zations”.

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

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

12 (B) by striking out paragraphs (1) through
13 (10) and inserting in lieu thereof the following
14 new paragraphs:

15 “(1) a concise description of the benefits of the
16 vaccine;

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

19 “(3) a statement of the availability of the Na-
20 tional Vaccine Injury Compensation Program.”.

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

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

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

8 (B) by striking “or other information” in
9 the last sentence.

○