

103^D CONGRESS
1ST SESSION

S. 887

To amend the Public Health Service Act to improve immunization rates among children through the establishment of data registries and educational programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 4 (legislative day, APRIL 19), 1993

Mr. DANFORTH (for himself, Mrs. KASSEBAUM, Mr. DURENBERGER, Mr. GREGG, and Mr. BOND) introduced the following bill; which was read twice and referred to the Committee on Finance

MAY 18 (legislative day, APRIL 19), 1993

Committee discharged; ordered referred to the Committee on Labor and Human Resources

A BILL

To amend the Public Health Service Act to improve immunization rates among children through the establishment of data registries and educational programs, 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.**

4 This Act may be cited as the “National Immunization
5 Improvement Act of 1993”.

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

2 (a) FINDINGS.—Congress finds that—

3 (1) 90 percent of all children under the age of
4 2 receive at least one vaccination yet only 40 to 60
5 percent of these children receive a complete set of
6 vaccinations;

7 (2) the low immunization rate for children
8 stems from inadequate immunization delivery sys-
9 tems and a lack of public education concerning the
10 risks related to the nonimmunization of children;
11 and

12 (3) government health care programs must co-
13 ordinate their activities in order to increase immuni-
14 zation rates.

15 (b) PURPOSE.—It is the purpose of this Act to—

16 (1) assist the States in developing State sys-
17 tems to monitor the immunization status of children
18 in order to ensure that these children are provided
19 with the recommended number of vaccinations;

20 (2) in cooperation with the States, improve the
21 immunization delivery system and expand outreach
22 and awareness efforts to ensure that every child
23 under 2 years of age is properly immunized;

24 (3) provide for increased coordination among
25 Federal programs in order to improve immunization
26 rates;

1 (4) encourage increased coordination among
2 Federal, State and private programs to improve im-
3 munization rates; and

4 (5) make certain revisions with respect to the
5 Vaccine Injury Compensation Program.

6 **SEC. 3. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.**

7 (a) IMPROVED IMMUNIZATION.—Subtitle 2 of title
8 XXI of the Public Health Service Act (42 U.S.C. 300aa-
9 1 et seq.) is amended—

10 (1) by redesignating part D as part E;

11 (2) by redesignating sections 2131 through
12 2134 as sections 2151 through 2154, respectively;
13 and

14 (3) by inserting after part C, the following new
15 part:

16 **“Part D—Improved Immunization**
17 **Efforts**

18 **“SEC. 2131. VOLUNTARY STATE REGISTRY GRANT PRO-**
19 **GRAM.**

20 “(a) IN GENERAL.—Not later than 1 year after the
21 date of enactment of this part, the Secretary shall estab-
22 lish a program under which the Secretary may award
23 grants to States to enable such States to develop and oper-
24 ate computerized State registries to collect, track and

1 monitor immunization data with respect to children resid-
2 ing within such States as described in subsection (c).

3 “(b) APPLICATION.—To be eligible to receive a grant
4 under subsection (a), a State shall prepare and submit to
5 the Secretary an application at such time, in such manner,
6 and containing such information as the Secretary may re-
7 quire. Such application shall include a plan to ensure that
8 necessary immunization information is provided to the
9 State registry.

10 “(c) DATA.—

11 “(1) DATA SET AND STANDARDS.—The Sec-
12 retary shall develop a minimum uniform data set
13 and data standards applicable to State registries de-
14 veloped under this section, in order to allow compat-
15 ibility between States.

16 “(2) DESIGN.—A State immunization tracking
17 and surveillance registry established under sub-
18 section (a) shall be designed to collect immunization
19 information on each child residing within the State
20 from the time that each such child is born, and
21 track the immunization records of each such child as
22 they grow older. The registry shall contain at least
23 the following information with respect to each child
24 residing within the State:

1 “(A) The name, address and date of birth
2 of the child.

3 “(B) The complete immunization history of
4 the child.

5 “(C) The type and lot numbers of each
6 vaccine provided to the child.

7 “(D) The name and address of each health
8 care provider providing a vaccination to the
9 child.

10 “(E) Identifying data that is sufficient to
11 enable the registry to locate the child for pur-
12 poses of conducting immunization notification
13 activities concerning the child.

14 “(F) Information designed to monitor the
15 safety and effectiveness of vaccines by linking
16 vaccine dosage information with adverse events
17 reporting and disease outbreak patterns, includ-
18 ing events reported by petitioners under parts A
19 or B.

20 “(d) TECHNICAL ASSISTANCE.—The Secretary shall
21 provide technical assistance to States for the development
22 of State registries under this section.

23 “(e) REPORTING.—Each State that receives a grant
24 under this section shall annually prepare and submit to

1 the Secretary a report concerning the progress made by
2 the State in operating a State registry under the grant.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to carry out this section,
5 \$150,000,000 for fiscal year 1995, and such sums as may
6 be necessary for each of the fiscal years 1995 through
7 1999.

8 **“SEC. 2132. IMPROVED IMMUNIZATION DELIVERY, OUT-
9 REACH AND EDUCATION.**

10 “(a) REQUIRED ACTIVITIES.—The Secretary, acting
11 through the Centers for Disease Control and Prevention
12 and in conjunction with State health officials and other
13 appropriate public and private organizations, shall conduct
14 the following activities to improve Federal, State and local
15 vaccines delivery systems and immunization outreach and
16 education efforts:

17 “(1) IMMUNIZATION EDUCATIONAL MATERIALS
18 FOR PROVIDERS.—Not later than 1 year after the
19 date of enactment of this part, the Secretary, in con-
20 junction with State health officials and other appro-
21 priate public and private organizations, shall develop
22 and disseminate standard immunization educational
23 materials for providers, including—

1 “(A) a list of basic recommended vaccines
2 and the schedules for immunizing children with
3 such vaccines;

4 “(B) recommended criteria for the admin-
5 istration of vaccines;

6 “(C) recommended criteria for determining
7 when vaccines should not be administered;

8 “(D) recommended criteria for the screen-
9 ing of children prior to immunization;

10 “(E) informed consent materials consistent
11 with those required under section 2126(c); and

12 “(F) any other information determined ap-
13 propriate by the Secretary.

14 “(2) NATIONAL PUBLIC AWARENESS CAM-
15 PAIGN.—

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

1 schedules for immunization, and vaccine pro-
2 vider locations, appropriate with respect to their
3 children.

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

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

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

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

18 “(3) INTERAGENCY COMMITTEE ON IMMUNIZA-
19 TION.—The Secretary, in conjunction with the Sec-
20 retary of Agriculture, the Secretary of Housing and
21 Urban Development, and the Secretary of Edu-
22 cation, shall carry out activities through the Inter-
23 agency Committee on Immunization to incorporate
24 immunization status assessments and referral serv-

1 ices as an integral part of the process by which indi-
2 viduals apply for assistance under—

3 “(A) the food stamp program under the
4 Food Stamp Act of 1977;

5 “(B) section 17 of the Child Nutrition Act
6 of 1966;

7 “(C) the Head Start Act;

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

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

11 “(F) any of the housing assistance laws of
12 the United States; and

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

16 “(4) OUTREACH ACTIVITIES.—The Secretary
17 shall conduct immunization outreach activities, in-
18 cluding—

19 “(A) conducting research concerning alter-
20 native delivery systems (such as mobile immuni-
21 zation clinics);

22 “(B) utilization of National Health Service
23 Corps members and other measures to conduct
24 immunization outreach activities in medically

1 underserved areas and for medically under-
2 served populations;

3 “(C) conducting research concerning the
4 implementation of innovative methods to—

5 “(i) contact parents or legal guardians
6 concerning their children’s immunization
7 status;

8 “(ii) refer such parents or legal
9 guardians to immunization providers; and

10 “(iii) conduct follow-up activities con-
11 cerning the immunization status of chil-
12 dren affected by the activities conducted
13 under this subparagraph;

14 “(D) the coordination of vaccine outreach
15 and education activities with other Federal,
16 State and local programs to encourage parents
17 to have their children immunized; and

18 “(E) any other activities determined ap-
19 propriate by the Secretary.

20 “(b) IMMUNIZATION ACTION PLANS.—

21 “(1) GRANTS.—

22 “(A) IN GENERAL.—The Secretary may
23 award grants to States to enable such State to
24 develop, revise and implement immunization ac-
25 tion plans as described in paragraph (2).

1 “(B) APPLICATION.—To be eligible to re-
2 ceive a grant under subparagraph (A), a State
3 shall prepare and submit to the Secretary an
4 application at such time, in such manner, and
5 containing such information as the Secretary
6 may require.

7 “(2) DESIGN.—A State immunization action
8 plan shall be designed to improve immunization de-
9 livery, outreach, education and coordination within
10 the State. Such plan shall provide for the creation
11 of—

12 “(A) a vaccine provider education cam-
13 paign under which standard immunization cri-
14 teria developed under subsection (a)(1), and
15 any other materials determined to be appro-
16 priate by State health officials, will be distrib-
17 uted to immunization providers—

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

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

1 “(B) expanded immunization delivery
2 through—

3 “(i) increasing the number or type of
4 facilities through which vaccines may be
5 made available;

6 “(ii) developing alternative methods of
7 delivering vaccines, such as mobile health
8 clinics or through programs of the type de-
9 scribed in subsection (a)(5); or

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

13 except that, the Secretary may waive the re-
14 quirements of this subparagraph if the Sec-
15 retary determines that State immunization de-
16 livery efforts are sufficient;

17 “(C) population-based assessment criteria
18 through which the State is able to assess the ef-
19 fectiveness of immunization activities in the
20 State;

21 “(D) a public awareness campaign, in con-
22 junction with the National Campaign estab-
23 lished under subsection (a)(2), to provide par-
24 ents with information concerning the types and

1 schedules for the administration of vaccines,
2 and the locations of vaccines providers;

3 “(E) coordination of outreach activities
4 with other public or private health programs to
5 encourage parents to have their children immu-
6 nized; and

7 “(F) significant collaboration with private
8 entities in achieving the goals of the plan.

9 “(3) IMMUNIZATION ACTION PLAN APPROVAL.—

10 “(A) GOALS.—As part of the immunization
11 action plan of a State, the State shall establish
12 immunization rate goals for children residing
13 within the State.

14 “(B) APPROVAL.—The immunization ac-
15 tion plan developed by a State under this sub-
16 section shall be submitted to the Secretary for
17 approval prior to the distribution of grant funds
18 to the States under this subsection. The Sec-
19 retary shall periodically review the progress that
20 the State has made under such plan in achiev-
21 ing the goals established under subparagraph
22 (A).

23 “(C) REPORTING.—A State shall annually
24 prepare and submit to the Director of the Cen-
25 ters for Disease Control and Prevention a re-

1 port concerning the implementation of the State
2 immunization action plan. If the Director or the
3 Secretary, in reviewing the reports submitted
4 under this subparagraph determine that the
5 State has not made sufficient progress towards
6 achieving the goals established under subpara-
7 graph (A), the Secretary may reduce the State's
8 grant funds.

9 **“SEC. 2133. AUTHORIZATION OF APPROPRIATIONS.**

10 “There are authorized to be appropriated to carry out
11 2132(b), \$200,000,000 for fiscal year 1994, and such
12 sums as may be necessary for each of the fiscal years 1995
13 through 1999.”.

14 (b) SIMPLIFICATION OF INFORMED CONSENT MATE-
15 RIALS.—Section 2126(c) of the Public Health Service Act
16 (42 U.S.C. 300aa-26(c)) is amended—

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

20 (B) by striking out “include—” and all
21 that follows through the paragraph (10) and in-
22 serting in lieu thereof “include a concise de-
23 scription of the benefits and the risks of the
24 vaccines and a statement of the availability of

1 the National Vaccine Injury Compensation
2 Fund.”.

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