

103RD CONGRESS
2^D SESSION

H. R. 2659

AMENDMENT

In the Senate of the United States,

March 24 (legislative day, February 22), 1994.

Resolved, That the bill from the House of Representatives (H.R. 2659) entitled “An Act to amend the Public Health Service Act to revise and extend programs relating to the transplantation of organs and of bone marrow”, do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

1 ***SECTION 1. SHORT TITLE.***

2 *This Act may be cited as the “Organ Transplant Pro-*
3 *gram Reauthorization Act of 1994”.*

4 ***SEC. 2. ORGAN PROCUREMENT ORGANIZATIONS.***

5 *(a) IN GENERAL.—Subsection (a) of section 371 of the*
6 *Public Health Service Act (42 U.S.C. 273(a)) is amended*
7 *to read as follows:*

8 *“(a)(1) The Secretary may make grants for the consoli-*
9 *ation and expansion of qualified organ procurement orga-*
10 *nizations described in subsection (b).*

1 “(2) The Secretary may make grants to, and enter into
2 cooperative agreements and contracts with, qualified organ
3 procurement organizations described in subsection (b) and
4 other public or nonprofit private entities for the purpose
5 of increasing organ donation through—

6 “(A) the planning and conducting of programs
7 to provide information and education to the public on
8 the need for organ donations;

9 “(B) the training of individuals in requesting
10 such donations; or

11 “(C) the provision of technical assistance to
12 organ procurement organizations and other entities
13 in the health care system.

14 “(3)(A) In making awards of grants, cooperative
15 agreements and contracts under subparagraphs (A) and (B)
16 of paragraph (2), the Secretary shall give priority to carry-
17 ing out the purpose described in such paragraph with re-
18 spect to minority or other populations for which there is
19 a greater degree of organ shortages relative to the general
20 population.

21 “(B) In making awards of grants, cooperative agree-
22 ments and contracts under paragraph (2)(C), the Secretary
23 shall give priority to carrying out the purpose described in
24 such paragraph with respect to organ procurement organi-

1 *zations and hospitals with lower rates of procurement rel-*
2 *ative to other such organizations or hospitals.”.*

3 (b) *QUALIFIED ORGAN PROCUREMENT ORGANIZA-*
4 *TIONS.—Section 371(b) of such Act (42 U.S.C. 273(b)) is*
5 *amended—*

6 (1) *in paragraph (1)—*

7 (A) *in the matter preceding subparagraph*
8 *(A), by striking “for which grants may be made*
9 *under subsection (a)” and inserting “described*
10 *in this section”;*

11 (B) *by realigning the margin of subpara-*
12 *graph (E) so as to align with the margin of sub-*
13 *paragraph (D); and*

14 (C) *in subparagraph (G)—*

15 (i) *in the matter preceding clause (i),*
16 *by striking “directors or an advisory*
17 *board” and inserting “directors (or an ad-*
18 *visory board, in the case of a hospital-based*
19 *organ procurement organization established*
20 *prior to September 1, 1993)”;* and

21 (ii) *in clause (i)—*

22 (I) *by striking “composed of” in*
23 *the matter preceding subclause (I) and*
24 *inserting “composed of a reasonable*
25 *balance of”;* and

1 (II) by inserting before the comma
2 in subclause (II) the following: “, in-
3 cluding individuals who have received
4 a transplant of an organ (or trans-
5 plant candidates), and individuals who
6 are part of the family of an individual
7 who has donated an organ”;

8 (2) by striking paragraph (2);

9 (3) by redesignating paragraph (3) as para-
10 graph (2);

11 (4) in paragraph (2) (as so redesignated)—

12 (A) by redesignating subparagraphs (B)
13 through (K) as subparagraphs (C) through (L),
14 respectively,

15 (B) by inserting after subparagraph (A) the
16 following new subparagraph:

17 “(B) conduct and participate in systematic ef-
18 forts, including public education, to increase the num-
19 ber of potential donors,”;

20 (C) by inserting before the comma in sub-
21 paragraph (F) (as so redesignated) the following:

22 “, which system shall, at a minimum, allocate
23 each type of organ on the basis of—

24 “(i) a single list encompassing the entire
25 service area;

1 “(ii) a list that encompasses at least an en-
2 tire State; or

3 “(iii) a list that encompasses an approved
4 alternative local unit (as defined in paragraph
5 (4)),

6 of individuals who have been medically referred to a
7 transplant center in the service area of the organiza-
8 tion in order to receive a transplant of the type of
9 organ with respect to which the list is maintained;”;

10 (D) by striking subparagraph (I) (as so re-
11 designated) and inserting the following new sub-
12 paragraph:

13 “(I) be a member of and abide by the rules and
14 requirements of the Organ Procurement and Trans-
15 plantation Network established under section 372,”;
16 and

17 (E) by striking subparagraph (K) (as so re-
18 designated) and inserting the following new sub-
19 paragraph:

20 “(K) evaluate annually, and report to the Organ
21 Procurement and Transplantation Network estab-
22 lished under section 372, on the effectiveness of the or-
23 ganization in acquiring potentially available organs,
24 particularly among minority populations, and the
25 variation of procurement across hospitals within the

1 *organ procurement organization region, and identify*
2 *a plan to increase procurement, particularly among*
3 *minority populations and other populations for which*
4 *there is a greater degree of organ shortages relative to*
5 *the general population, and at hospitals with low*
6 *rates of procurement, and”;* and

7 *(5) by adding at the end thereof the following*
8 *new paragraphs:*

9 *“(3)(A) The Office of Technology Assessment shall con-*
10 *duct a study for the purpose of defining—*

11 *“(i) the appropriate standards by which to judge*
12 *the quality of performance of organ procurement or-*
13 *ganizations; and*

14 *“(ii) the proper criteria for a determination of*
15 *inadequate service from an organ procurement orga-*
16 *nization.*

17 *“(B) Not later than 2 years after the date of enactment*
18 *of this paragraph, the Office of Technology Assessment shall*
19 *complete the study required under subparagraph (A) and*
20 *prepare and submit to the Committee on Labor and Human*
21 *Resources of the Senate, the Committee on Energy and*
22 *Commerce of the House of Representatives, and the Sec-*
23 *retary, a report describing the findings made as a result*
24 *of the study.*

1 “(C) For purposes of this paragraph the term ‘organ’
2 means a human kidney, liver, heart, lung, pancreas, and
3 any other human organ or tissue specified by the Secretary
4 for purposes of this paragraph.

5 “(4)(A) As used in paragraph (2)(F), the term ‘alter-
6 native local unit’ means—

7 “(i) a unit composed of two or more contiguous
8 organ procurement organizations; or

9 “(ii) a subdivision of an organ procurement or-
10 ganization that operates as a distinct procurement
11 and distribution unit as a result of special geo-
12 graphic, rural, or minority population concerns but
13 that is not composed of any subunit of a metropolitan
14 statistical area.

15 “(B) The Organ Procurement and Transplantation
16 Network shall make recommendations to the Secretary con-
17 cerning the approval or denial of alternative local units.
18 The Network shall assess whether the alternative local units
19 will better promote organ donation and the equitable alloca-
20 tion of organs.

21 “(C) The Secretary shall approve or deny any alter-
22 native local unit principle or designation recommended by
23 the Network. If the Secretary does not provide otherwise
24 prior to the expiration of the 90-day period beginning on
25 the date on which the application is submitted, the rec-

1 *ommendations of the Network under subparagraph (B) with*
2 *respect to the application of the alternative local unit shall*
3 *go into effect.”.*

4 (c) *EFFECTIVE DATE.*—*The amendments made by sub-*
5 *section (b)(5) shall apply to organ procurement organiza-*
6 *tions beginning January 1, 1995.*

7 **SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION**
8 **NETWORK.**

9 *Section 372(b) of the Public Health Service Act (42*
10 *U.S.C. 274(b)) is amended—*

11 (1) *in paragraph (1)(B)—*

12 (A) *in clause (i)—*

13 (i) *by striking “(including organiza-*
14 *tions that have received grants under sec-*
15 *tion 371)”;* and

16 (ii) *by striking “; and” at the end*
17 *thereof and inserting “(including both indi-*
18 *viduals who have received a transplant of*
19 *an organ (or transplant candidates), and*
20 *individuals who are part of the family of*
21 *individuals who have donated an organ, the*
22 *number of whom shall make up not less*
23 *than 40 percent of the total number of*
24 *board members); and”;* and

1 (B) in clause (ii), by inserting “including
2 a patient affairs committee” after “committees,”;
3 and

4 (2) in paragraph (2)—

5 (A) in subparagraph (A), by striking clause
6 (i) and inserting the following new clause:

7 “(i) with respect to each type of transplant,
8 a national list of individuals who have been
9 medically referred to receive a transplant of the
10 type of organs with respect to which the list is
11 maintained (which list shall include the names
12 of all individuals included on lists in effect
13 under section 371(b)(2)(F), and”;

14 (B) in subparagraph (B), by inserting “,
15 including requirements under section 371(b),”
16 after “membership criteria”;

17 (C) by redesignating subparagraphs (E)
18 through (L), as subparagraphs (F) through (M),
19 respectively;

20 (D) by inserting after subparagraph (D),
21 the following new subparagraph:

22 “(E) assist organ procurement organizations in
23 the equitable distribution of organs among transplant
24 patients,”;

1 (E) in subparagraph (K) (as so redesignated), by striking “and” at the end thereof;

3 (F) in subparagraph (L) (as so redesignated), by striking the period and inserting “, including making recommendations to organ procurements organizations and the Secretary based on the annual reports required under section 371(b)(2)(K),”;

9 (G) in subparagraph (M) (as so redesignated), by striking the period and inserting a comma; and

12 (H) by adding at the end thereof the following new subparagraphs:

14 “(N) submit to the Secretary for review and approval any change in the amount of fees imposed by the Network for the registration of individuals on the lists maintained under subparagraph (A)(i), such change to be considered as approved if the Secretary does not provide otherwise prior to the expiration of the 90-day period beginning on the date on which the change is submitted to the Secretary,

22 “(O) make available to the Secretary such information, books, and records regarding the Network as the Secretary may require,

1 “(P) submit to the Secretary, on an annual
2 basis, a report on the clinical and scientific status of
3 the organ transplantations, and

4 “(Q) meet such other criteria regarding compli-
5 ance with this part as the Secretary may establish.”.

6 **SEC. 4. STUDY BY GENERAL ACCOUNTING OFFICE.**

7 Section 377 of the Public Health Service Act (42
8 U.S.C. 274f) is amended to read as follows:

9 **“SEC. 377. STUDY BY GENERAL ACCOUNTING OFFICE.**

10 “(a) *STUDY.*—

11 “(1) *IN GENERAL.*—The Comptroller General of
12 the United States shall conduct a study for the pur-
13 pose of determining and making recommendations
14 concerning—

15 “(A) the composition of the boards of direc-
16 tors of organ procurement organizations and of
17 the Organ Procurement and Transplantation
18 Network on the date of enactment of this section,
19 and the effect of the Organ Transplant Program
20 Reauthorization Act of 1994 on the composition
21 and functioning of such boards;

22 “(B)(i) the number and percentage of
23 cadaveric organ transplants for foreign nationals
24 and nonresident aliens categorized by organ pro-
25 curement organization and by transplant center

1 *and information on any reciprocal agreements*
2 *between organ procurement organizations and*
3 *foreign countries or territories;*

4 “(ii) *the number and percent of the organi-*
5 *zations referred to in clause (i) above the organ*
6 *procurement transplant network guideline of 10*
7 *percent; and*

8 “(III) *any information on the current rate*
9 *of organ donation by individuals other than*
10 *United States citizens or legal residents;*

11 “(C) *organ donation rates and the impact*
12 *of various organ allocation systems on organ*
13 *procurement rates; and*

14 “(D) *the equitable allocation of organs na-*
15 *tionwide, including an analysis of the relative*
16 *probability of receiving an organ for patients*
17 *with similar characteristics for each category of*
18 *transplanted organ by organ procurement orga-*
19 *nization and recommendations for developing a*
20 *regional allocation system in order to ensure*
21 *that—*

22 “(i) *patients in one region have an*
23 *equivalent probability of receiving an organ*
24 *as do patients with similar characteristics*
25 *in another region; and*

1 “(ii) patients within a region have an
2 equivalent probability of receiving an organ
3 as do other patients with similar character-
4 istics in that region.

5 “(2) *EQUITABLE ALLOCATION*.—In carrying out
6 paragraph (1) with respect to subparagraph (D), the
7 Comptroller General shall—

8 “(A) recommend regions for allocating or-
9 gans to encompass as large a geographic area as
10 is practical, taking into account medical appro-
11 priateness, and the geographic proximity of pa-
12 tients with comparable priority for receiving an
13 organ;

14 “(B) take into account the impact on organ
15 donation and procurement rates; and

16 “(C) consult with experts in the area of organ al-
17 location and organ donations and consider their rec-
18 ommendations regarding the establishment of regions
19 in the country for the purpose of allocating organs.

20 “(b) *REPORT*.—Not later than 2 years after the date
21 of enactment of the Organ Transplant Program Reauthor-
22 ization Act of 1994, the Comptroller General of the United
23 States shall complete the study required under subsection
24 (a) and prepare and submit to the Committee on Energy
25 and Commerce of the House of Representatives, and to the

1 *Committee on Labor and Human Resources of the Senate,*
2 *a report describing the findings made as a result of the*
3 *study.”.*

4 **SEC. 5. GENERAL PROVISIONS.**

5 (a) *LIMITATION.*—*Section 374(b) of the Public Health*
6 *Service Act (42 U.S.C. 274b(b)) is amended—*

7 (1) *by striking paragraph (2);*

8 (2) *by redesignating paragraph (3) as para-*
9 *graph (2); and*

10 (3) *in paragraph (2) (as so redesignated), by*
11 *striking “371(a)(3)” and inserting “371(a)(2)”.*

12 (b) *REPEAL.*—*Section 376 of the Public Health Service*
13 *Act (42 U.S.C. 274d) is repealed.*

14 (c) *TRANSFER.*—*Section 378 of the Public Health*
15 *Service Act (42 U.S.C. 274g) is amended—*

16 (1) *by transferring such section to part H of title*
17 *III; and*

18 (2) *by inserting such section after section 377.*

19 (d) *AUTHORIZATION OF APPROPRIATIONS.*—*Section*
20 *378 of the Public Health Service Act (42 U.S.C. 274g) is*
21 *amended by striking “1991” and all that follows through*
22 *the period and inserting “1994, and such sums as may be*
23 *necessary for each of the fiscal years 1995 and 1996.”.*

24 **SEC. 6. COMPREHENSIVE CHILD IMMUNIZATION.**

25 (a) *SHORT TITLE; REFERENCES AND PURPOSE.*—

1 (1) *SHORT TITLE.*—*This section may be cited as*
2 *the “Comprehensive Child Immunization Act of*
3 *1994”.*

4 (2) *REFERENCES.*—*Except as otherwise expressly*
5 *provided, whenever in this section an amendment or*
6 *repeal is expressed in terms of an amendment to, or*
7 *repeal of, a section or other provision, the reference*
8 *shall be considered to be made to a section or other*
9 *provision of the Public Health Service Act (42 U.S.C.*
10 *201 et seq.).*

11 (3) *PURPOSE.*—*It is the purpose of this section*
12 *to ensure that children in the United States are ap-*
13 *propriately immunized against vaccine preventable*
14 *infectious diseases at the earliest appropriate age.*

15 (b) *MONITORING OF CHILDHOOD IMMUNIZATIONS.*—
16 *Title XXI of the Public Health Service Act (42 U.S.C.*
17 *300aa-1 et seq.) is amended by adding at the end thereof*
18 *the following new subtitle:*

19 **“Subtitle 3—Improved Immuniza-**
20 **tion Delivery and Monitoring**
21 **Systems**

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

23 **“SEC. 2141. LIST OF PEDIATRIC VACCINES; SCHEDULE FOR**
24 **ADMINISTRATION.**

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

1 “(1) *IN GENERAL.*—*The Secretary shall establish*
2 *a list of the vaccines that the Secretary recommends*
3 *for administration to all children for the purpose of*
4 *immunizing the children, subject to such contra-*
5 *indications for particular medical categories of chil-*
6 *dren as the Secretary may establish under subsection*
7 *(b)(1)(D). The Secretary shall periodically review the*
8 *list, and shall revise the list as appropriate.*

9 “(2) *RULE OF CONSTRUCTION.*—

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

13 “(B) *The list of vaccines specified in this*
14 *subparagraph is the list of vaccines that, for pur-*
15 *poses of paragraph (1), is established (and peri-*
16 *odically reviewed and as appropriate revised) by*
17 *the Advisory Committee on Immunization Prac-*
18 *tices, an advisory committee established by the*
19 *Secretary, acting through the Director of the*
20 *Centers for Disease Control and Prevention.*

21 “(b) *RECOMMENDED SCHEDULE FOR ADMINISTRA-*
22 *TION.*—

23 “(1) *IN GENERAL.*—*Subject to paragraph (2), in*
24 *the case of a pediatric vaccine, the Secretary shall es-*
25 *tablish (and periodically review and as appropriate*

1 *revise) a schedule of nonbinding recommendations for*
2 *the following:*

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

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

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

9 “(D) *Any contraindications regarding ad-*
10 *ministration of the vaccine.*

11 “(E) *Such other guidelines as the Secretary*
12 *determines to be appropriate with respect to ad-*
13 *ministering the vaccine to children.*

14 “(2) *VARIATIONS IN MEDICAL PRACTICE.—In es-*
15 *tablishing and revising a schedule under paragraph*
16 *(1), the Secretary shall ensure that, in the case of the*
17 *pediatric vaccine involved, the schedule provides for*
18 *the full range of variations in medical judgment re-*
19 *garding the administration of the vaccine, subject to*
20 *remaining within medical norms.*

21 “(3) *RULE OF CONSTRUCTION.—*

22 “(A) *The schedule specified in subparagraph*
23 *(B) is deemed to be the schedule maintained*
24 *under paragraph (1).*

1 *Centers for Disease Control and Prevention, shall make an*
2 *allotment each fiscal year for each State in an amount de-*
3 *termined in accordance with section 2151. The Secretary*
4 *shall make a grant to the State of the allotment made for*
5 *the State for the fiscal year if the State submits to the Sec-*
6 *retary an application in accordance with section 2150 on*
7 *behalf of the chief executive officer of such State.*

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

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

14 “(2) *assist in identifying localities with inad-*
15 *equiate immunization rates to target for necessary re-*
16 *medial assistance;*

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

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

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

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

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

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

13 “(3) utilizing the data to monitor the extent to
14 which children have received immunizations in ac-
15 cordance with the schedule established under section
16 2141;

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

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

24 “(6) such other activities as the Secretary may
25 authorize with respect to achieving the objectives es-

1 *tablished by the Secretary for the year 2000 for the*
2 *immunization status of children in the United States.*

3 *“(d) REQUIREMENT REGARDING STATE LAW.—*

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

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

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

17 *“(C) has in effect such laws and regulations*
18 *as may be necessary to ensure the following safe-*
19 *guards for the rights of parents:*

20 *“(i) An exemption for the parent, upon*
21 *the request of the parent, from the require-*
22 *ments established by the State, pursuant to*
23 *this part, for the collection of data described*
24 *in subsections (b) and (c) of section 2147, or*
25 *the collection of any other data regarding*

1 *any child of the parent that the State may*
2 *require for incorporation in the State im-*
3 *munization registry.*

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

14 “(2) *RULES OF CONSTRUCTION.—*

15 “(A) *With respect to the agreements made*
16 *by a State under this part, other than para-*
17 *graph (1)(B), the Secretary may require compli-*
18 *ance with the agreements only to the extent con-*
19 *sistent with such paragraph.*

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

1 *State pursuant to this part for the collection of*
2 *data regarding any child of the parent.*

3 ***“SEC. 2147. REGISTRY DATA.***

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

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

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

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

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

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

24 “(c) *DATA REGARDING INDIVIDUAL IMMUNIZA-*
25 *TIONS.—With respect to a child to whom a pediatric vac-*

1 *cine is administered in the State involved, the data de-*
2 *scribed in this subsection is as follows:*

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

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

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

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

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

14 “(6) *The type of vaccine.*

15 “(7) *The lot number or other information identi-*
16 *fying the particular manufacturing batch of the vac-*
17 *cine.*

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

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

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

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

8 “(d) *LIMITATION.—The Secretary may not establish*
9 *information reporting requirements in addition to those de-*
10 *scribed in subsection (c) if such requirements are unduly*
11 *burdensome.*

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

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

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

1 “(f) *UNIFORMITY IN METHODOLOGIES.*—The Secretary
2 shall, in consultation with State public health officials, es-
3 tablish standards regarding the methodologies used in estab-
4 lishing and operating registries under section 2146, and
5 may make a grant under such section only if the State
6 agrees to comply with the standards. The Secretary shall
7 provide maximum flexibility to the States while also retain-
8 ing a reasonable degree of uniformity among the States in
9 such methodologies for the purpose of ensuring the utility,
10 comparability, and exchange of the data maintained in
11 such registries.

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

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

20 “(a) *ESTABLISHMENT.*—

21 “(1) *IN GENERAL.*—The Secretary, in consulta-
22 tion with the States, shall by regulation establish
23 standards providing for maintaining the confidential-
24 ity of the identity of individuals with respect to
25 whom data are maintained in registries under section

1 2146. *Such standards shall, with respect to a State,*
2 *provide that the State is to have in effect laws or reg-*
3 *ulations regarding such confidentiality, including ap-*
4 *propriate penalties for violation of the laws. The Sec-*
5 *retary may make a grant under such section only if*
6 *the State involved agrees to comply with the stand-*
7 *ards.*

8 “(2) *USE OF DISCLOSURE.—*

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

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

17 “(ii) *oversight, audit, and evaluation*
18 *of the immunization delivery and registry*
19 *systems;*

20 “(iii) *activities relating to establishing*
21 *and maintaining a safe and effective supply*
22 *of recommended childhood vaccine;*

23 “(iv) *processing of insurance claims for*
24 *payment for vaccine administration (but*

1 *only to the extent necessary for processing*
2 *claims); and*

3 “(v) *administration of the National*
4 *Vaccine Injury Compensation Program*
5 *under subtitle 2.*

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

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

20 **“SEC. 2149. PROVIDER PARTICIPATION.**

21 “(a) *IN GENERAL.—The State shall monitor and en-*
22 *force compliance by health care providers with the require-*
23 *ments of sections 2147 and 2148 and section 2155(b) for*
24 *all doses of pediatric vaccine administered in the State. The*
25 *State shall establish procedures satisfactory to the Secretary*

1 *for discontinuing the distribution of federally purchased or*
2 *State purchased vaccine for any health care provider who*
3 *fails to comply with the requirements of section 2147 and*
4 *for reinstating such vaccine supply to such provider upon*
5 *receiving from such provider—*

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

10 “(2) *satisfactory assurances regarding the pro-*
11 *vider’s future compliance.*

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

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

18 “*An application by a State for a grant under section*
19 *2146 is in accordance with this section if the application—*

20 “(1) *is submitted not later than the date speci-*
21 *fied by the Secretary;*

22 “(2) *contains each agreement required in this*
23 *part;*

24 “(3) *contains any information required in this*
25 *part to be submitted to the Secretary; and*

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

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

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

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

13 *“For the purpose of carrying out this part, other than*
14 *section 2153, there are authorized to be appropriated*
15 *\$152,000,000 for fiscal year 1994, \$125,000,000 for fiscal*
16 *year 1995, and \$35,000,000 for each of the fiscal years 1996*
17 *through 1999.*

18 **“SEC. 2153. NATIONAL IMMUNIZATION SURVEILLANCE PRO-**

19 **GRAM.**

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

1 “(1) provide technical assistance to States for the
2 development of vaccination registries and monitoring
3 systems; and

4 “(2) receive aggregate epidemiologic data (that is
5 in a format that is not person specific) collected by
6 States as provided for in section 2147 at intervals de-
7 termined appropriate by the Secretary for the purpose
8 of—

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

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

19 “(C) providing technical assistance to
20 States and localities to facilitate monitoring the
21 immunization status of children who move across
22 geographic boundaries that are covered by dif-
23 ferent State or local registries at the request of
24 such States or localities; and

1 “(D) monitoring the safety and effectiveness
2 of vaccines by linking vaccine dosage informa-
3 tion with adverse events reporting under section
4 2125(b) and disease outbreak patterns.

5 “(b) *RULE OF CONSTRUCTION.*—Nothing in this sub-
6 title shall be construed to authorize the release of person
7 specific information to the Secretary for the purpose of im-
8 munization surveillance.

9 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—There are
10 authorized to be appropriated such sums as may be nec-
11 essary to carry out this section in each of the fiscal years
12 1994 through 1999.

13 “**SEC. 2154. REPORT.**

14 “Not later than January 1, 1995, and biennially there-
15 after, the Secretary shall prepare and submit to the appro-
16 priate committees of Congress a report concerning the plan-
17 ning, development, operation and effectiveness of the na-
18 tional immunization surveillance program and the State
19 immunization registries.

20 “**Part C—Distribution of Vaccines, Public Outreach**
21 **and Education**

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

23 “(a) *IN GENERAL.*—

24 “(1) *HEALTH CARE PROVIDERS.*—The Secretary
25 shall provide for the distribution, without charge, of

1 *recommended pediatric vaccines (in accordance with*
2 *section 2141) purchased by the Secretary to health*
3 *care providers who serve children and who—*

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

6 *“(B) are health centers (as defined in sec-*
7 *tion 2163); or*

8 *“(C) provide services under section 503 of*
9 *the Indian Health Care Improvement Act or*
10 *pursuant to a contract under section 102 of the*
11 *Indian Self Determination Act.*

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

19 *“(b) DUTIES OF HEALTH CARE PROVIDERS.—*

20 *“(1) FREE PROVISION TO CHILDREN.—A health*
21 *care provider or entity receiving vaccine under this*
22 *section may use such vaccine only for administration*
23 *to children and may not impose a charge for such*
24 *vaccine. A provider or health care entity may impose*
25 *a fee that reflects actual regional costs as determined*

1 *by the Secretary for the administration of such vac-*
2 *cine, except that a provider may not deny a child a*
3 *vaccination due to the inability of the child's parent*
4 *to pay an administration fee.*

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

19 **“SEC. 2156. IMPROVED IMMUNIZATION DELIVERY, OUT-**
20 **REACH AND EDUCATION.**

21 “(a) *FEDERAL EFFORTS.*—The Secretary, acting
22 *through the Centers for Disease Control and Prevention and*
23 *in conjunction with State health officials and other appro-*
24 *priate public and private organizations, shall conduct the*
25 *following activities to improve Federal, State and local vac-*

1 *cine delivery systems and immunization outreach and edu-*
2 *cation efforts:*

3 “(1) NATIONAL PUBLIC AWARENESS CAMPAIGN.—

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

16 “(B) IMPLEMENTATION.—In implementing
17 the Campaign under subparagraph (A), the Sec-
18 retary shall ensure that—

19 “(i) new and innovative methods are
20 developed and utilized to publicly advertise
21 the need to have children immunized in a
22 timely manner;

23 “(ii) print, radio and television media
24 are utilized to convey immunization infor-
25 mation to the public; and

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

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

14 “(A) the food stamp program under the
15 Food Stamp Act of 1977;

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

18 “(C) the Head Start Act;

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

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

22 “(F) any of the housing assistance laws of
23 the United States; and

1 “(G) other programs determined appro-
2 priate by any of the Secretaries described in this
3 paragraph.

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

12 “(b) GRANTS TO STATES.—

13 “(1) IN GENERAL.—

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

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

23 “(2) DESIGN.—A State immunization improve-
24 ment plan shall be designed to improve immunization
25 delivery, outreach, education and coordination within

1 *the State. Such plan shall provide for the creation*
2 *of—*

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

7 “(i) to enable such providers to make
8 *the best use of vaccination opportunities;*
9 *and*

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

14 “(B) expanded capacity for the delivery of
15 *immunizations through—*

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

20 “(ii) developing alternative methods of
21 *delivering vaccines, such as mobile health*
22 *clinics;*

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

1 “(iv) coordinating with federally quali-
2 fied health centers to reach and immunize
3 underserved children through education,
4 outreach, tracking, and the provision of
5 services;

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

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

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

24 “(E) coordinated community outreach ac-
25 tivities among public or private health pro-

1 grams, including local health departments and
2 health centers, and other public or private enti-
3 ties, to encourage and facilitate the ability of
4 parents to obtain immunization services for their
5 children; and

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

9 “(3) IMMUNIZATION IMPROVEMENT PLAN AP-
10 PROVAL.—

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

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

23 “(C) DISTRIBUTION OF GRANTS.—In
24 awarding grants under this section, the Sec-
25 retary shall ensure that grant awards will be eq-

1 *uitably distributed between rural and urban*
2 *areas. In determining such distribution, the Sec-*
3 *retary shall take into account the added costs of*
4 *supporting the health care delivery infrastruc-*
5 *ture in sparsely populated areas. The Secretary*
6 *shall give special consideration to those States*
7 *that have low childhood immunization rates and*
8 *that submit plans that demonstrate the State's*
9 *substantial effort and commitment to improving*
10 *such rates.*

11 “(D) *REPORTING.*—A State shall annually
12 prepare and submit to the Director of the Cen-
13 ters for Disease Control and Prevention a report
14 concerning the implementation of the State im-
15 munization improvement plan.

16 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—There are
17 authorized to be appropriated to carry out this section,
18 \$250,000,000 for fiscal year 1994, and such sums as may
19 be necessary for each of the fiscal years 1995 through 1999.

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

21 “(a) *ANNUAL REPORT.*—Not later than July 1 of each
22 year, a State shall prepare and submit to the Director of
23 the Centers for Disease Control and Prevention a report
24 that contains an estimate (based on a base population sam-
25 ple) of the percentage of 2 year old residents of the State

1 *who have been fully immunized as described in subsection*
2 *(c).*

3 *“(b) PAYMENTS TO STATES.—*

4 *“(1) IN GENERAL.—Subject to the availability of*
5 *appropriations, the Secretary shall provide to a State*
6 *that has submitted an annual report under subsection*
7 *(a) that demonstrates that the State has fully immu-*
8 *nized at least 50 percent of the 2 year old residents*
9 *of that State, with respect to the year for which the*
10 *report was prepared, a payment in an amount equal*
11 *to—*

12 *“(A) with respect to a State that has dem-*
13 *onstrated the full immunization of at least 50*
14 *and less than 64 percent of all 2 year old resi-*
15 *dents of the State, \$50 multiplied by the number*
16 *of fully immunized 2 year old resident children*
17 *in excess of the number of children equaling such*
18 *50 percent amount;*

19 *“(B) with respect to a State that has dem-*
20 *onstrated the full immunization of at least 65*
21 *and less than 70 percent of all 2 year old resi-*
22 *dents of the State, \$75 multiplied by the number*
23 *of fully immunized 2 year old resident children*
24 *in excess of the number of children equaling such*
25 *65 percent amount; and*

1 “(C) with respect to a State that has dem-
2 onstrated the full immunization of at least 70
3 and less than 91 percent of all 2 year old resi-
4 dents of the State, \$100 multiplied by the num-
5 ber of fully immunized 2 year old resident chil-
6 dren in excess of the number of children equaling
7 such 70 percent amount.

8 “(2) USE OF FUNDS.—

9 “(A) CONDITION.—As a condition of receiv-
10 ing amounts under this section a State that uses
11 a combination of Federal and State funds in
12 achieving the immunization goals described in
13 paragraph (1) shall agree to reinvest, in activi-
14 ties related to improving immunization services,
15 that percentage of the payments to the State
16 under paragraph (1) that is equal to the amount
17 of Federal contributions to immunization serv-
18 ices in the State as compared to the amount of
19 the State contributions to such services.

20 “(B) DISCRETIONARY USE.—A State that
21 has demonstrated that the use of State-only
22 funds was responsible for the increase in the im-
23 munization rate which qualified such State for
24 payments under paragraph (1), may use

1 *amounts awarded under this section for other*
2 *purposes, at the discretion of the State.*

3 “(3) *VERIFICATION.*—*Prior to making a pay-*
4 *ment to a State under this subsection, the Secretary*
5 *shall, in collaboration with the Centers for Disease*
6 *Control and Prevention, verify the accuracy of the*
7 *State report involved.*

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

13 **“Part D—General Provisions**

14 **“SEC. 2161. REPORT.**

15 *“Not later than October 1, 1995, and biennially there-*
16 *after, the Secretary shall prepare and submit to the appro-*
17 *priate committees of Congress a report concerning the costs,*
18 *efficiency, and effectiveness of procedures established to de-*
19 *liver vaccine to health care providers.*

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

21 *“The Secretary shall authorize a report to be prepared*
22 *by the National Academy of Sciences concerning the role*
23 *of the National Vaccine Program established under this title*
24 *in achieving progress towards the nationally established im-*
25 *munization goals for the year 2000, and recommendations*

1 *with respect to the changes in such Program that would*
2 *facilitate greater progress towards achieving such goals.*

3 ***“SEC. 2163. DEFINITIONS.***

4 *“For purposes of this subtitle—*

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

11 *“(2) HEALTH CENTER.—The term ‘health center’*
12 *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 329, 330 or 340;*

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

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

1 “(3) *IMMUNIZATION.*—The term ‘immunization’
2 means an immunization against a vaccine-prevent-
3 able disease.

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

6 “(5) *PEDIATRIC VACCINE.*—The term ‘pediatric
7 vaccine’ means a vaccine included on the list estab-
8 lished under section 2141.

9 “(6) *STATE.*—The term ‘State’ means the 50
10 States, the District of Columbia, the Commonwealth
11 of Puerto Rico, Guam, American Samoa, the U.S.
12 Virgin Islands, the Republic of the Marshall Islands,
13 Micronesia, the Northern Mariana Islands, and
14 Palau.”.

15 (c) *NATIONAL VACCINE INJURY COMPENSATION PRO-*
16 *GRAM AMENDMENTS.*—

17 (1) *AMENDMENT OF VACCINE INJURY TABLE.*—

18 (A) *ADDITION OF VACCINES.*—Section 2114
19 (42 U.S.C. 300aa–14) is amended by adding at
20 the end thereof the following new subsection:

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

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

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

9 “(A) *revisions with respect to illnesses, dis-*
10 *abilities, injuries or conditions covered by such*
11 *table;*

12 “(B) *appropriate specifications of the time*
13 *period for the first symptom or manifestation of*
14 *onset or of significant aggravation of such ill-*
15 *nesses, disabilities, injuries or condition after*
16 *vaccine administration, for purposes of receiving*
17 *compensation under the Program; and*

18 “(C) *recommendations as to the amount of*
19 *tax that should be imposed under section 4131 of*
20 *the Internal Revenue Code of 1986 for each dose*
21 *of vaccine.*

22 “(3) *LIMITATION.*—*The Secretary may modify*
23 *the table contained in subsection (a) pursuant to*
24 *paragraphs (1) and (2) only in accordance with sub-*
25 *section (c).*

1 “(4) *REVISION.*—For purposes of section
2 2116(b), the addition of vaccine to the table contained
3 in subsection (a) by operation of this subsection shall
4 constitute a revision of the table.”.

5 (B) *ATTORNEYS FEES.*—Section 2115(e) (42
6 U.S.C. 300aa-15(e)) is amended by adding at the
7 end thereof the following new paragraph:

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

12 (C) *CONSENT FOR ANNUITY.*—Subpara-
13 graphs (A) and (B) of section 2115(f)(4) are
14 amended by striking “; with the consent of the
15 petitioner,” each place that such appears.

16 (C) *TIME PERIODS FOR FEES AND COSTS.*—

17 (i) *IN GENERAL.*—Section 2115(e) (42
18 U.S.C. 300aa-15(e)) (as amended by para-
19 graph (3)) is further amended by adding at
20 the end thereof the following new para-
21 graph:

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

24 “(A) if the respondent enters no objection to
25 such application within 21 days of the date on

1 *which the application was filed (unless such time*
2 *period is extended by the special master with the*
3 *consent of the petitioner) the special master shall*
4 *enter a decision on such application within 30*
5 *days of such filing;*

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

14 “(C) if the respondent files an objection to
15 such application and the petitioner moves to re-
16 duce costs and fees as provided for in the objec-
17 tion, the special master shall enter a decision
18 within 5 days after the receipt of the petitioner’s
19 motion.

20 *The chief special master, upon the request of a special*
21 *master, may waive the time limitations applicable to*
22 *the special master under this paragraph if the special*
23 *master demonstrates that complicating factors exist*
24 *with respect to the issues involved to which the time*
25 *limitation applies.”.*

1 (B) *APPLICATION.*—The amendment made
2 by subparagraph (A) shall apply to all petition-
3 ers’ applications for attorneys’ fees and costs
4 filed under section 2115(e) of the Public Health
5 Service Act which are pending on the date of en-
6 actment of this Act.

7 (E) *AUTHORIZATION OF APPROPRIA-*
8 *TIONS.*—Section 2115(j) (42 U.S.C. 300aa-15(j))
9 is amended by striking “\$80,000,000 for each
10 succeeding fiscal year” and inserting in lieu
11 thereof “\$110,000,000 for each succeeding fiscal
12 year”.

13 (F) *LIMITATION OF ACTIONS.*—Section
14 2116(b) (42 U.S.C. 300aa-16(b)) is amended by
15 striking “such person may file” and inserting
16 “or to significantly increase the likelihood of ob-
17 taining compensation, such person may, not-
18 withstanding section 2111(b)(2), file”.

19 (2) *EXTENSION OF TIME FOR DECISION.*—

20 (A) *JURISDICTION.*—Section 2112(d)(3)(D)
21 (42 U.S.C. 300aa-12(d)(3)(D)) is amended by
22 striking “540 days” and inserting “30 months
23 (but for not more than 6 months at a time)”.

24 (B) *REPORT ON COLLECTIONS.*—Section
25 2117 (42 U.S.C. 300aa-17) is amended by add-

1 *ing at the end thereof the following new sub-*
2 *section:*

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

7 (C) *INCREASED RESPONSIBILITIES OF COM-*
8 *MISSION.*—*Section 2119(f) (42 U.S.C. 300aa-*
9 *19(f)) is amended—*

10 (i) *by striking “and” at the end of*
11 *paragraph (4);*

12 (ii) *by striking the period at the end of*
13 *paragraph (5) and inserting “, and”; and*

14 (iii) *by adding at the end thereof the*
15 *following new paragraph:*

16 “(6) *monitor the balance of the Vaccine Injury*
17 *Trust Fund established by section 9510 of the Inter-*
18 *nal Revenue Code and, as appropriate, recommend*
19 *changes in the tax per dose of vaccine imposed under*
20 *section 4131 of such Code.”.*

21 (3) *SIMPLIFICATION OF VACCINE INFORMATION*
22 *MATERIALS.—*

23 (A) *INFORMATION.*—*Section 2126(b) (42*
24 *U.S.C. 300aa-26(b)) is amended—*

1 (i) by striking “by rule” in the matter
2 preceding paragraph (1);

3 (ii) in paragraph (1), by striking “90”
4 and inserting “30”; and

5 (iii) in paragraph (2), by striking “,
6 appropriate health care providers and par-
7 ent organizations”.

8 (B) *REQUIREMENTS*.—Section 2126(c) (42
9 U.S.C. 300aa–26(c)) is amended—

10 (i) in the matter preceding paragraph
11 (1), by inserting “shall be based on avail-
12 able data and information,” after “such
13 materials”; and

14 (ii) by striking out paragraphs (1)
15 through (10) and inserting in lieu thereof
16 the following new paragraphs:

17 “(1) a concise description of the benefits of the
18 vaccine;

19 “(2) a concise description of the risks associated
20 with the vaccine;

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

23 “(4) a statement of the availability from the Sec-
24 retary of more detailed written information concern-
25 ing the information required under paragraphs (1),

1 (2), and (3), that shall be made available to the par-
2 ent, legal guardian, or other responsible person upon
3 request; and

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

6 (C) *OTHER INDIVIDUALS.*—Subsections (a)
7 and (d) of section 2126 (42 U.S.C. 300aa–26(a)
8 and (d)) are amended by inserting “or to any
9 other individual” immediately after “to the legal
10 representative of any child” each place that such
11 occurs.

12 (D) *PROVIDER DUTIES.*—Subsection (d) of
13 section 2126 (42 U.S.C. 300aa–26(d)) is amend-
14 ed—

15 (i) by striking all after “subsection
16 (a),” the second place it appears in the first
17 sentence and inserting “supplemented with
18 visual presentations or oral explanations, in
19 appropriate cases.”; and

20 (ii) by striking “or other information”
21 in the last sentence.

22 (4) *AUTHORIZATION OF APPROPRIATIONS.*—Part
23 A of subtitle 2 of title XXI (42 U.S.C. 300aa–10 et
24 seq.) is amended by adding at the end thereof the fol-
25 lowing new section:

1 “AUTHORIZATION OF APPROPRIATIONS

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

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

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

19 (d) MISCELLANEOUS PROVISIONS.—Section 317(k) (42
20 U.S.C. 247b(k)) is amended—

21 (1) by striking out paragraph (1); and
22 (2) by redesignating paragraphs (2) through (5)
23 as paragraphs (1) and (4), respectively.

24 (e) AMENDMENTS TO THE FEDERALLY SUPPORTED
25 HEALTH CENTERS ASSISTANCE ACT OF 1992.—

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

8 (2) *COVERAGE FOR SERVICES FURNISHED TO IN-*
9 *DIVIDUALS OTHER THAN PATIENTS OF CLINIC.*—*Sec-*
10 *tion 224(g) of such Act (42 U.S.C. 233(g)(1)), as*
11 *amended by paragraph (1), is further amended—*

12 (A) *in the first sentence of paragraph (1),*
13 *by inserting after “Service” the following: “with*
14 *respect to services provided to patients of the en-*
15 *tity and (subject to paragraph (7)) to certain*
16 *other individuals”;* and

17 (B) *by adding at the end the following new*
18 *paragraph:*

19 *“(7) For purposes of paragraph (1), an officer, em-*
20 *ployee, or contractor described in such paragraph may be*
21 *deemed to be an employee of the Public Health Service with*
22 *respect to services provided to individuals who are not pa-*
23 *tients of an entity described in paragraph (4) only if the*
24 *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 (3) DETERMINING COMPLIANCE OF ENTITY WITH
13 REQUIREMENTS FOR COVERAGE.—

14 (A) IN GENERAL.—Section 224(h) of such
15 Act (42 U.S.C. 233(h)), as added by section 2(b)
16 of the Federally Supported Health Centers As-
17 sistance Act of 1992, is amended by striking “the
18 entity—” and inserting the following: “the Sec-
19 retary, after receiving such assurances and con-
20 ducting such investigation as the Secretary con-
21 siders necessary, finds that the entity—”.

22 (B) FINDING.—Section 224 of such Act (42
23 U.S.C. 233) is amended by adding at the end
24 thereof 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 (4) *PAYMENT OF JUDGMENTS.*—Section
8 224(k)(2) of such Act (42 U.S.C. 233(k)(2)), as added
9 by section 4 of the Federally Supported Health Cen-
10 ters Assistance Act of 1992, is amended by adding at
11 the end thereof the following new sentence: “Appro-
12 priations for purposes of this paragraph shall be
13 made separate from appropriations made for pur-
14 poses of sections 329, 330, 340 and 340A.”.

15 (5) *EFFECTIVE DATE.*—The amendments made
16 by this section shall take effect as if included in the
17 enactment of the Federally Supported Health Centers
18 Assistance Act of 1992.

19 **SEC. 7. EFFECTIVE DATES.**

20 (a) *IN GENERAL.*—Except as provided in subsection
21 (b), the amendments made by this Act shall become effective
22 on the date of enactment of this Act.

23 (b) *EXCEPTION.*—The amendments made by section
24 2(b)(4)(C) shall become effective 9 months after the date of
25 enactment of this Act. Prior to such date, section

- 1 *371(b)(3)(E) of the Public Health Service Act, as in effect*
- 2 *on the day before the date of the enactment of this Act, shall*
- 3 *remain in effect.*

Attest:

Secretary.

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HR 2659 EAS—4

HR 2659 EAS—5