

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term “factors unrelated to the administration of the vaccine”—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner’s evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner’s illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) “Record” defined

For purposes of this section, the term “record” means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa-11 of this title.

(July 1, 1944, ch. 373, title XXI, §2113, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3763; amended Pub. L. 100-203, title IV, §4307(4), Dec. 22, 1987, 101 Stat. 1330-224; Pub. L. 101-239, title VI, §6601(j), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 101-502, §5(c), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102-572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

PRIOR PROVISIONS

A prior section 300aa-13, act July 1, 1944, §2114, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

A prior section 2113 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1992—Subsec. (c). Pub. L. 102-572 substituted “United States Court of Federal Claims” for “United States Claims Court”.

1990—Subsec. (c). Pub. L. 101-502 inserted “the” after “special masters of”.

1989—Subsecs. (a)(1), (b). Pub. L. 101-239, §6601(j)(1), substituted “special master or court” for “court” wherever appearing.

Subsec. (c). Pub. L. 101-239, §6601(j)(2), inserted “special masters of” after “established by the”.

1987—Subsec. (c). Pub. L. 100-203 substituted “the United States Claims Court” for “a district court of the United States”.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-572 effective Oct. 29, 1992, see section 911 of Pub. L. 102-572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101-502, set out as a note under section 300aa-11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101-239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101-239, set out as a note under section 300aa-10 of this title.

§ 300aa-14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	Illness, disability, injury, or condition covered:	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	
	—in a non-immunodeficient recipient	30 days
	—in an immunodeficient recipient	6 months
	—in a vaccine-associated community case	Not applicable
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term “encephalopathy” means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent inconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa-11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the

encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms “seizure” and “convulsion” include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(3) Vaccines recommended for use in pregnant women

The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.

(July 1, 1944, ch. 373, title XXI, §2114, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3764; amended Pub. L. 101-239, title VI, §6601(k), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 103-66, title XIII, §13632(a)(2), Aug. 10, 1993, 107 Stat. 645; Pub. L. 114-255, div. A, title III, §3093(c)(1), Dec. 13, 2016, 130 Stat. 1152.)

PRIOR PROVISIONS

A prior section 300aa-14, act July 1, 1944, §2115, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

A prior section 2114 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

AMENDMENTS

2016—Subsec. (e)(3). Pub. L. 114-255 added par. (3).

1993—Subsec. (e). Pub. L. 103-66 amended heading and text of subsec. (e) generally. Prior to amendment, text read as follows: “The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table.”

1989—Subsec. (a). Pub. L. 101-239, §6601(k)(1), substituted “(b)(2)” for “(c)(2)” in items I.D. and II.C. in table.

Subsec. (b)(3)(B). Pub. L. 101-239, §6601(k)(2), substituted “300aa-11 of this title” for “300aa-11(b) of this title”.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101-239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101-239, set out as a note under section 300aa-10 of this title.

REVISIONS OF VACCINE INJURY TABLE

The Vaccine Injury Table as modified by regulations promulgated by the Secretary of Health and Human Services is set out at 42 CFR 100.3.

Pub. L. 103-66, title XIII, §13632(a)(3), Aug. 10, 1993, 107 Stat. 646, provided that: "A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa-14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa-14(a))."

§ 300aa-15. Compensation**(a) General rule**

Compensation awarded under the Program to a petitioner under section 300aa-11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa-16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of \$250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed \$250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa-11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of \$30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e)).¹

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa-11 of this title the special master or court shall also award as part of such compensation an amount to cover—

¹ So in original. Probably should be preceded by another closing parenthesis.