

**SUBCHAPTER I—(RESERVED)  
SUBCHAPTER J—VACCINES**

**PART 100—VACCINE INJURY  
COMPENSATION**

Sec.

100.1 Applicability.

100.2 Average cost of a health insurance policy.

100.3 Vaccine injury table.

**AUTHORITY:** Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act, 100 Stat. 3767, as amended (42 U.S.C. 300aa-15); §100.3, the Vaccine Injury Table, issued under sec. 312 of Pub. L. 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and sec. 2114(c) of the PHS Act (42 U.S.C. 300aa-14(c)).

**§ 100.1 Applicability.**

This part applies to the National Vaccine Injury Compensation Program (VICP) under subtitle 2 of title XXI of the Public Health Service (PHS) Act.

[60 FR 7693, Feb. 8, 1995]

**§ 100.2 Average cost of a health insurance policy.**

For purposes of determining the amount of compensation under the VICP, section 2115(a)(3)(B) of the PHS Act, 42 U.S.C. 300aa.15(a)(3)(B), provides that certain individuals are entitled to receive an amount reflecting lost earnings, less certain deductions. One of the deductions is the average cost of a health insurance policy, as determined by the Secretary of Health and Human Services. The Secretary has determined that the average cost of a health

insurance policy is \$158.00 per month. This amount will be revised to reflect the changes in the medical care component of the Consumer Price Index (All Urban Consumers, U.S. City Average), published by the United States Bureau of Labor Statistics, plus 2 percent per year. The revised amounts will be effective upon their delivery by the Secretary to the United States Claims Court, and the amounts will be published in a notice in the FEDERAL REGISTER from time to time as determined by the Secretary.

[57 FR 28099, June 24, 1992, as amended at 60 FR 7693, Feb. 8, 1995]

**§ 100.3 Vaccine injury table.**

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub. L. 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa-14(c)), 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**

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. DTP; P; DT; Td; or Tetanus Toxoid; or in any combination with Polio; or any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Pertussis Bacteria, or Specific Pertussis Antigen(s): A. Anaphylaxis or anaphylactic shock ..... B. Encephalopathy (or encephalitis) ..... C. Any 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.	4 hours. 72 hours. Not applicable.
II. (a). Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component: A. Anaphylaxis or anaphylactic shock .....	4 hours.

VACCINE INJURY TABLE—Continued

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
B. Encephalopathy (or encephalitis) .....	5-15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component.
C. Residual seizure disorder in accordance with subsection (b)(3) .....	5-15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component.
D. Any 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. (b). In the case of measles, mumps, rubella (MMR), measles, rubella (MR) or rubella vaccines only:	
A. Chronic arthritis .....	42 days.
B. Any 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 Vaccine (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 .....	4 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 paragraph (a) of this section:

(1) *Anaphylaxis and anaphylactic shock.* For purposes of paragraph (a) of this section, Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction,

edema of the hypopharynx, epiglottitis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) *Encephalopathy.* For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization.

(A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting

for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(1)(A) and (b)(2)(1)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act 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.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) *Residual Seizure Disorder.* (1) A petitioner may be considered to have suffered a residual seizure disorder for purposes of paragraph (a) of this section, if the first seizure or convulsion occurred 5-15 days (not less than 5 days and not more than 15 days) after administration of the vaccine and 2 or more additional distinct seizure or convulsion episodes occurred within 1 year after the administration of the vaccine which were unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal to

or greater than 100.0 degrees Fahrenheit). A distinct seizure or convulsion episode is ordinarily defined as including all seizure or convulsive activity occurring within a 24-hour period, unless competent and qualified expert neurological testimony is presented to the contrary in a particular case.

(ii) For purposes of paragraph (a) of this section, a petitioner shall not be considered to have suffered a residual seizure disorder, if the petitioner suffered a seizure or convulsion unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal to or greater than 100.0 degrees Fahrenheit) before the fifth day after the administration of the vaccine involved.

(4) *Seizure and convulsion.* For purposes of paragraphs (b) (2) and (3) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(5) *Sequela.* The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(6) *Chronic Arthritis.* (i) For purposes of paragraph (a) of this section, chronic arthritis may be found in a person with no prior history of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred within 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continu-

ous arthritis for more than 6 months following vaccination.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

(iii) Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of paragraph (a) of this section.

(c) *Effective date provisions.* The Table of Injuries set forth in paragraph (a) of this section applies to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after March 10, 1995. The Qualifications and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions filed with the United States Court of Federal Claims on or after March 10, 1995. The petitions for compensation filed with the United States Court of Federal Claims before March 10, 1995 shall be governed by section 2114(a) (initial "Table") and section 2114(b) (initial "Qualification and Aids to Interpretation") of the Public Health Service Act as in effect on February 8, 1995.

[60 FR 7694, Feb. 8, 1995]

**PART 110—(RESERVED)**