Colorado Immunization Manual

SECTION 5

National Vaccine Injury Compensation Program (NVICP)

SECTION 5

National Vaccine Injury Compensation Program (NVICP)

CONTENTS

Commonly Asked Questions About
The National Vaccine Injury Compensation Program

1. What is the National Vaccine Injury Compensation Program (VICP)?

The National Childhood Vaccine Injury Act of 1986, as amended, (the Act) established the VICP. The VICP went into effect on October 1, 1988 and is a Federal "no-fault" system designed to compensate individuals or families of individuals, who have been injured by covered childhood vaccines, whether administered in the private or public sector.

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2. What vaccines are covered?

The following vaccines are covered by the VICP:

- Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, or TT)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Human Papillomavirus (HPV)
- Influenza (TIV, LAIV) [given each year during the flu season]
- Measles, mumps, rubella (MMR, MR, M, R)
- Meningococcal (MCV4, MPSV4)
- Polio (OPV or IPV)
- Pneumococcal conjugate (PCV)
- Rotavirus (Rota)
- Varicella (Var)
- Any combination of the vaccines above
- Additional vaccines may be added in the future

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3. How are new vaccines added for coverage under the VICP?

On March 24, 1997, a final rule was published which, in part, provided for the "automatic" addition of future vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. However, Congress will still need to set an appropriate excise tax on any new vaccines recommended by CDC before those vaccines are effectively covered under the Vaccine Injury Compensation Program. Under the current statutory language, 8 years' retroactive coverage will be provided for those claiming injury or death resulting from a vaccine or vaccine-related adverse event newly added to the VICP.

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4. Who may file a claim?

Any injured individual or a parent, legal guardian, or trustee of an injured child or an incapacitated person may file a claim. A claim may be made for any injury or death thought to be a result of a covered vaccine. These injuries may include, but are not limited to: **anaphylaxis, paralytic polio, and encephalopathy.**

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5. What is the time frame in which to file a claim?

To be eligible for compensation, claims must be filed:

- within 3 years after the first symptom of the vaccine injury; or
- within 2 years of the vaccine-related death and not more than 4 years after the start of the first symptom of the vaccine-related injury from which the death occurred; or
- 2 years from the date the vaccine is covered for injuries or deaths that occurred up to 8 years before the date the vaccine is covered. For example, hepatitis A was covered by the VICP as of December 1, 2004, and claims have to be filed by December 1, 2006 for injuries or deaths that occurred on or after December 1, 1996.

For individuals filing a claim, the appropriate filing deadline is the one above that provides them with the most time to file their injury or death claims.

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6. Whom can I contact to get more information about the VICP?

a. This Web site (http://www.hrsa.gov/osp/vicp)
b. The toll-free number for the National Vaccine Injury Compensation Program is **1-800-338-2382** to obtain an information packet detailing how to file a claim, criteria for eligibility, and the documentation required. For further information write to:

National Vaccine Injury Compensation Program
Parklawn Building, Room 11C-26
5600 Fishers Lane
Rockville, Maryland 20857

c. For information on the rules of the U.S. Court of Federal Claims, including requirements for filing a petition, go to http://www.uscfc.uscourts.gov/osmPage.htm, call **1-202-357-6400** or write to:

U.S. Court of Federal Claims
717 Madison Place, N.W.
Washington, D.C. 20005

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7. How is the VICP funded?

Funding of vaccine claims **depends on the date of vaccination:**

a. For vaccines administered **prior to October 1, 1988,** awards are compensated from Federal tax dollars allocated by Congress at $110 million per year.
b. For vaccines administered **on or after October 1, 1988,** awards are paid from the Vaccine Injury Compensation Trust Fund, funded from an excise tax of $.75 on every dose of covered vaccine that is purchased.

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8. How does the VICP work?

The VICP is administered jointly by the U.S. Court of Federal Claims (the Court), the Department of Health and Human Services (HHS), and the Department of Justice (DOJ). The process is as follows:

a. An individual claiming injury or death from a vaccine files a petition for compensation with the Court;
b. A physician at the Division of Vaccine Injury Compensation, HHS, reviews each petition to determine whether it meets the criteria for compensation. This recommendation is provided to the Court through a report filed by the DOJ, although it is not binding.
c. The HHS position is represented by an attorney from the DOJ in hearings before a "special master" who makes the initial decision for compensation under the VICP. A special master is an attorney appointed by the judges of the Court.
d. Decisions may be appealed to the Court and then to the Federal Circuit Court of Appeals.

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9. How is eligibility for compensation determined?

There are three means to qualify for compensation:

a. A petitioner must show that an injury found on the Vaccine Injury Table (the Table) occurred; or
b. A petitioner must prove that the vaccine caused the condition; or
c. A petitioner must prove that the vaccine significantly aggravated a pre-existing condition.

The Table lists specific injuries or conditions and the time frames in which they must occur after vaccine administration. The Table is a legal mechanism for defining complex medical conditions and allows a statutory "presumption of causation." It is much easier to demonstrate a "Table

Injury" than to prove that the vaccine caused the condition, and most claims allege that a Table Injury occurred. Compensation is not awarded, however, if the Court determines that the injury or death was due to a cause unrelated to the vaccine, even if it was a Table Injury.

In contrast to civil liability suits, hearings to determine eligibility under the VICP usually last only 1 or 2 days. A case found eligible for compensation is scheduled for a hearing to assess the amount of compensation. Most claims found to be noncompensable receive awards for attorney's fees and costs.

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10. What is the amount of an award under the VICP?

Awards to the estate in a vaccine-related death are limited to $250,000 plus attorney's fees and costs. Awards to individuals with an injury judged to be vaccine-related have averaged $1,022,699. There is no limitation on the amount of an **award** in a vaccine-related injury. However, the law does contain certain restrictions.

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11. How does the VICP protect vaccine administrators and vaccine manufacturers?

The Act requires that vaccine injury claims involving covered vaccines given on or after October 1, 1988 must first be filed with the VICP before civil litigation through the tort system can be pursued. If a petitioner accepts an award under the VICP, the claim cannot be brought subsequently to the tort system.

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12. Under what circumstances may a vaccine administrator or manufacturer be sued?

a. If the petition has been judged non-compensable or dismissed under the VICP; or
b. If the award granted by the VICP is otherwise rejected by the petitioner; or
c. If the vaccine is not covered under the VICP.

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13. Have there been changes to the Vaccine Injury Table?

On March 10, 1995, a modified Table (and the accompanying Qualifications and Aids to Interpretation) became effective for all claims filed on or after that date. Significant changes include the addition of chronic arthritis under vaccines containing rubella (e.g., MMR, MR, R vaccines), and the removal of Residual Seizure Disorder and Hypotonic-Hyporesponsive Episode (HHE) under the DTP vaccine. The definition of Encephalopathy was clarified in the Qualifications and Aids to Interpretation.

On March 24, 1997, further modifications to the Table took effect that include the addition of brachial neuritis and removal of encephalopathy for tetanus-containing vaccines, addition of thrombocytopenia and vaccine-strain measles virus infection, removal of residual seizure disorder for measles-containing vaccines, and addition of vaccine-strain poliovirus infection for live polio virus vaccine. Modifications also included the addition of three new vaccines: hepatitis B, *Haemophilus influenzae* type b, and varicella. Coverage for these three new vaccines went

into effect August 6, 1997. The Rule also provided for "automatic" addition of future vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children, although injuries for such vaccines will be specified only after additional rulemaking. All other Table changes became effective for all claims filed on or after March 24.

On October 22, 1998, rotavirus vaccine was added to the Table for coverage.

On August 26, 2002, a modified Table (and the accompanying Qualifications and Aids to Interpretation) became effective for all claims filed on or after that date. A second category of rotavirus (live, oral, rhesus-based) vaccine was added to the Table with intussusception listed as an injury with a time interval of onset of 0-30 days. A separate category was added for pneumococcal conjugate vaccines with no condition specified. Haemophilus influenzae type b (Hib) polysaccharide vaccines was removed from the Table; however, Haemophilus influenzae type b (Hib) conjugate vaccines remains on the Table with no condition specified. Under the Table's Qualifications and Aids to Interpretation, early-onset Hib disease and residual seizure disorder were removed.

On December 1, 2004, hepatitis A vaccine was added to the Table for coverage.

On July 1, 2005, trivalent influenza vaccines were added to the Table for coverage.

On February 1, 2007, meningococcal and human papillomavirus (HPV) vaccines were added to the Table for coverage.

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14. What documentation are vaccine administrators required to keep?

The National Childhood Vaccine Injury Act of 1986 (as amended) requires that the date of administration; vaccine manufacturer; lot number; and name, address, and title of the health care provider be recorded in the patient's permanent medical record.

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15. What adverse events are health care providers required to report?

The Vaccine Adverse Event Reporting System (VAERS), operated by the Food and Drug Administration (FDA) and the CDC, should be notified of any adverse event by completing a VAERS reporting form. The following events are required to be reported:

a. Any event set forth in the Vaccine Injury Table that occurs within the time period specified or within 7 days, if that is longer.
b. Any contraindicating event listed in the manufacturer's package insert.

In addition, VAERS accepts all reports by any interested party of real or suspected adverse events occurring after the administration of ***any*** vaccine.

The VAERS form may be obtained by calling **1-800-822-7967** or from the FDA Website at https://secure.vaers.org/VaersDataEntryintro.htm.

Please note: Submitting a reporting form to VAERS in ***not*** the same as filing a claim under the VICP as they are two separate programs.

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16. How many petitions have been filed under the VICP? Of those petitions filed, how many have been awarded compensation? How much money has been spent on compensation awards?

To obtain a copy of the most recent VICP "Monthly Statistics Report" please visit the VICP Website at www.hrsa.gov/osp/vicp/monthly.htm, telephone 1-800-338-2382, or write to the National Vaccine Injury Compensation Program, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857.

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17. If I believe that the thimerosal (mercury) in a vaccine caused an injury or death, can I file a claim with the VICP?

For vaccines covered under the VICP, individuals alleging that the thimerosal in a vaccine caused an injury or death must first file a claim with the VICP before any civil litigation can be pursued. According to section 2133 of the Public Health Service Act (42 U.S.C. 300aa-33(5)), a "vaccine-related injury or death" eligible for compensation under the VICP does not include an injury or death associated with an adulterant or contaminant intentionally added to a vaccine. Components, such as thimerosal, that are added to microorganisms to create vaccines cannot and should not be considered adulterants or contaminants. Instead, preservatives and components, such as thimerosal, should be considered one of several elements that comprise vaccines.

Because thimerosal is not an adulterant to or a contaminant in vaccines, individuals who have claims relating to thimerosal in vaccines covered under the VICP are not statutorily barred from filing claims with the VICP. As such, the Department of Health and Human Services (HHS) believes individuals interested in filing such a claim must first file the claim with the VICP before pursuing any other civil litigation.

On October 11, 2002, the U.S Court of Federal Claims (the Court) ruled that thimerosal-related injury claims are subject to the Court's jurisdiction pursuant to the National Childhood Vaccine Injury Act of 1986, as amended. Plaintiffs had filed a petition for compensation in the Court, but then filed a motion to challenge the jurisdiction of the Court for thimerosal-related injuries. The Court found the plaintiff's arguments to be without merit. As such, the Court's Chief Special Master accepted HHS's arguments and found that the Court's jurisdiction was mandated on all fronts. *Leroy v. Secretary of HHS* is the first definitive statement by the Court that thimerosal-related vaccine injury claims are subject to its jurisdiction.

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18. Where can I get information about anthrax or smallpox vaccines?

Currently, the anthrax and smallpox vaccines are not covered under the VICP. To obtain information about these vaccines, contact the National Immunization Program, Centers for Disease Control and Prevention (CDC) at 1600 Clifton Road, N.E., Mail Stop E-61, Atlanta, Georgia 30333. You may also contact them at 1-800-232-2522 or visit their Internet Website at: www.cdc.gov/vaccines.

HRSA does have a **Smallpox** Vaccine Injury Compensation Program. For more information, see http://www.hrsa.gov/smallpoxinjury/

Source: http://www.hrsa.gov/vaccinecompensation/

National Childhood Vaccine Injury Act

Vaccine Injury Table[a]

Vaccine	Adverse Event	Time Interval
I. Tetanus toxoid-containing vaccines (e.g., DTaP, Tdap, DTP-Hib, DT, Td, TT)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Brachial neuritis	2-28 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, Tdap, DTP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Encephalopathy (or encephalitis)	0-72 hours
	C. Any acute complication or sequela (including death) of above events	Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Encephalopathy (or encephalitis)	5-15 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days
	B Any acute complication or sequela (including death) of above event	Not applicable
V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A Thrombocytopenic purpura	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	0-6 months
	C Any acute complication or sequela (including death) of above events	Not applicable
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio	
	--- in a non-immunodeficient recipient	0-30 days
	--- in an immunodeficient recipient	0-6 months
	--- in a vaccine assoc. community case	Not applicable
	B. Vaccine-strain polio viral infection	
	--- in a non-immunodeficient recipient	0-30 days
	--- in an immunodeficient recipient	0-6 months
	--- in a vaccine assoc. community case	Not applicable
	C. Any acute complication or sequela (including death) of above events	Not applicable
VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A Anaphylaxis or anaphylactic shock	0-4 hours
	B. Any acute complication or sequela (including death) of above event	Not applicable
VIII. Hepatitis B antigen- containing vaccines	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Any acute complication or sequela (including death) of above event	Not applicable
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines)	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage[bc]	A. No condition specified for compensation	Not applicable

[a]Effective date: November 10, 2008 [b]As of **December 1, 2004**, hepatitis A vaccines have been added to the Vaccine Injury Table (Table) under this Category. As of **July 1, 2005**, *trivalent* influenza vaccines have been added to the Table under this Category. Trivalent influenza vaccines are given annually during the flu season either by needle and syringe or in a nasal spray. All influenza vaccines routinely administered in the U.S. are trivalent vaccines covered under this Category. [c]As of **February 1, 2007**, meningococcal (conjugate and polysaccharide) and human papillomavirus (HPV) vaccines have been added to the Table under this Category. See *News* on the VICP website (www.hrsa.gov/vaccinecompensation).

Qualifications and Aids to Interpretation

(1) 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, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs ofrespiratory distress, there may not be significant pathologic findings.

(2) Encephalopathy. For purposes of the Vaccine Injury Table, 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 (whether or not hospitalization occurred).

(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" (see "D" below) 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 (2)(I)(A) and (2)(I)(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) Seizure and convulsion. For purposes of paragraphs (b)(2) 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.

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

(5) Chronic Arthritis. For purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination 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 between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination:

(C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, 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, fibromyalgia, 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.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(6) Brachial neuritis is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(7) Thrombocytopenic purpura is defined by a serum platelet count less than 50,000/mm^3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) Vaccine-strain measles viral infection is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(9)Vaccine-strain polio viral infection is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

"**Fold in thirds, tape & mail - DO NOT STAPLE FORM**"

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed)

GENERAL

Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)

Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.

Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility. These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine orthat person's legal representativewill not be made available tothe public, but may be available to the vaccinee or legal representative.

Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please

Item 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one priorvaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

VACCINE ADVERSE EVENT REPORTING SYSTEM

VAERS

24 Hour Toll Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name:

Last First M.I.

Address

City State Zip

Telephone no. (____) _____

Vaccine administered by (Name):

Responsible Physician _____

Facility Name/Address

City State Zip

Telephone no. (____) _____

Form completed by (Name):

Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other

Address *(if different from patient or provider)*

City State Zip

Telephone no. (____) _____

1. State	2. County where administered	3. Date of birth mm / dd / yy	4. Patient age	5. Sex ☐ M ☐ F	6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
- ☐ Patient died (date mm / dd / yy)
- ☐ Life threatening illness
- ☐ Required emergency room/doctor visit
- ☐ Required hospitalization (_____days)
- ☐ Resulted in prolongation of hospitalization
- ☐ Resulted in permanent disability
- ☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm / dd / yy
Time _____ AM PM

11. Adverse event onset mm / dd / yy
Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
- ☐ Private doctor's office/hospital
- ☐ Public health clinic/hospital
- ☐ Military clinic/hospital
- ☐ Other/unknown

16. Vaccine purchased with:
- ☐ Private funds
- ☐ Public funds
- ☐ Military funds
- ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medial conditions(specify)

20. Have you reported this adverse event previously?
☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under

22. Birth weight _____ lb. _____ oz.

23. No. of brother and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/Immunization project

24. Mfr./imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.